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1 **THE PRESIDENT:** Good morning, ladies and 09:01

2 gentlemen. I open the hearing in the case of

3 Eli Lilly Company as Claimant versus the

4 Government of Canada as Respondent. You have in

5 front of you the Arbitral Tribunal. You know by now

6 Mr. Gary Born on my left-hand side and Sir Daniel

7 Bethlehem on my right-hand side and the Secretary of

8 the Tribunal, Ms. Lindsay Gastrell at the end of the

9 table. It is a good custom that each side

10 introduces his or her team. May I invite Ms. Cheek

11 for Claimant to introduce her team?

12 **MS. CHEEK:** Thank you very much. Good

13 morning, members of the Tribunal. I will go ahead

14 and go down our row. Next to me is Mr. Alex

15 Berengaut, Ms. Wendy Wagner, Mr. James Smith,

16 Mr. Rick Dearden. We then have three party

17 representatives from Eli Lilly and Company.

18 Steve Caltrider, Arvie Anderson and Arleen Palmberg.

19 We then have Mr. John Veroneau, Mr. Nikhil Gore,

20 Mr. Mike Chajon, Ms. Lauren Willard, Mr. Alex

21 Aronson and Ms. Gina Vetere. Our experts are also

22 in the room. I will go off my list. We have

23 Ms. Natalie Derzko, Ms. Tina Thomas. They actually

24 are part of our team here, as well as our expert,

25 Mr. Bruce Levin, Professor Robert Merges, Mr. Andy

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1 Reddon, Professor Norman Siebrasse and Philip 09:03

2 Thomas.

3 **THE PRESIDENT:** For the Respondent,

4 please.

5 **MR. SPELLISCY:** Good morning. Beside me I

6 have counsel Adrian Johnston, Mark Luz, the director

7 of the Trade Law Bureau, Ms. Sylvie Tabet. Krista

8 Zeman and Mariella Montplaisir. Then further down I

9 can see Ms. Shawna Lesaux and Marc-Andre Leveille,

10 who are our paralegals. Then from our clients we

11 have Mr. Sanjay Gupta. Mr. Denis Martel. We have

12 beside them one of our experts, Mr. Ron Dimock, Mr.

13 Ryan Evans, and at the very end we have another

14 representative from Industry Canada, Mr. Brad

15 Jenkins.

16 **THE PRESIDENT:** Thank you.

17 I also note that we have representatives

18 of the United States of Mexico. Could you please

19 tell us your name?

20 **MS. PONCE:** Linda Ortiz Ponce and Aristeo

21 Lopez.

22 **THE PRESIDENT:** For the United States?

23 **MS. ADKINS:** Jocelyn Adkins and Nicole

24 Thornton.

25 **THE PRESIDENT:** Welcome. Thank you.

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1 The hearing is being transmitted via a 09:05

2 videolink to another room in this building. There

3 is no video retention, no videos are being kept of

4 this hearing at the request of the Claimant. The

5 attendants, I understand, will see this, watch this

6 with an hour delay. The reason is purely technical.

7 There was no company to be available in the DC area

8 which could do it with the usual delay of ten

9 minutes, but so be it. But those who watch us are

10 welcome.

11 The next thing is we have the schedule.

12 There was a schedule from both sides on the

13 witnesses with the estimates. It turned out that

14 both sides had handed in their own estimates, but on

15 Friday we have sent you a combined version. Does

16 that give rise to any questions? Ms. Cheek, on your

17 side?

18 **MS. CHEEK:** That did not raise any

19 questions on our side.

20 **MR. SPELLISCY:** And not on our side.

21 **THE PRESIDENT:** So we will proceed on the

22 basis of that Excel sheet.

23 We also have asked you whether you agree

24 that the witnesses and the experts take pictures.

25 Both sides have agreed to that. Those pictures will

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09:06

1 be assembled by the Secretary of the Tribunal and
2 will be put in what we call a picture book. The
3 picture book is something which is for the parties
4 only and the Tribunal and need not to be published
5 on the website -- actually should not be published
6 on the website for privacy reasons.
7 I think that is all the Tribunal has to
8 mention. Are there any matters of an organizational
9 or administrative nature that you would like to
10 raise?
11 **MS. CHEEK:** Not from the Claimant.
12 **MR. SPELLISCY:** None from the Respondent
13 either.
14 **THE PRESIDENT:** I think then we can
15 commence with the opening statements, first by the
16 Claimants. Ms. Cheek, please proceed.
17 **MS. CHEEK:** You should have in front of
18 you a copy of the PowerPoint presentation that will
19 accompany our opening statement. We also have two
20 mini bundles. (Distributed)
21 **OPENING STATEMENT ON BEHALF OF CLAIMANT**
22 **MS. CHEEK:** Mr. President, members of the
23 Tribunal, good morning. Welcome to Washington, D.C.
24 We are here today because Eli Lilly
25 developed two groundbreaking medicines, Zyprexa for

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09:09

1 the treatment of schizophrenia, and Strattera for
2 the treatment of attention deficit/hyperactivity
3 disorder, or ADHD. Canada granted patents for
4 Zyprexa in 1998 and for Strattera in 2002.
5 The Zyprexa and Strattera patents are
6 protected investments under NAFTA Chapter 11 and,
7 just as with other forms of property, Canada may not
8 expropriate those patents without compensation or
9 deny those investments fair and equitable treatment.
10 Canada has breached these NAFTA
11 obligations. The law on utility, a patentability
12 requirement, has fundamentally changed in Canada.
13 When Lilly sought patent protection in the 1990s,
14 the utility requirement was simply whether an
15 invention was operable or had some industrial value.
16 A decade later, after Lilly relied upon its Canadian
17 patents and developed the market for Zyprexa and
18 Strattera in Canada and launched these drugs, the
19 Canadian courts revoked these patents, solely for
20 lacking utility or usefulness under Canada's novel
21 promise utility doctrine, even though Lilly's
22 competitors were selling these drugs and thousands
23 of Canadian patients were using these drugs.
24 I will provide you this morning with a
25 brief overview of Lilly's claims and I will walk you

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1 through the challenged measures in this case, which
2 are the Canadian courts' revocations of Zyprexa and
3 Strattera. Ms. Wagner will then explain Canada's
4 promise utility doctrine and its origins in greater
5 detail, and Mr. Smith will place Canada's doctrine
6 in context and explain its discriminatory effects on
7 the pharmaceutical sector. Mr. Berengaut and I will
8 then finish our presentation this morning with a
9 discussion of Lilly's legal claims for expropriation
10 and violation of fair and equitable treatment under
11 Chapter 11, and in the course of our presentation we
12 also will answer the Tribunal's questions that were
13 provided to us in advance.
14 Zyprexa and Strattera are both CNS drugs,
15 meaning they relate to the central nervous system.
16 Simply put, this is brain science. These drugs
17 affect receptor sites in the brain associated with
18 schizophrenia and ADHD. Zyprexa treats
19 schizophrenia and other mental disorders, as I
20 mentioned.
21 Schizophrenia is a devastating mental
22 illness. It causes hallucinations and delusions and
23 paranoia. Old treatments could address those
24 symptoms but at a cost. The cost was debilitating
25 side effects -- involuntary jerking, an inability to

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09:12

1 sit still -- and old treatments also failed to
2 address some of the symptoms of schizophrenia such
3 as apathy and withdrawal.
4 Zyprexa was one of a new class of
5 anti-psychotics that was able to effectively treat
6 the symptoms of schizophrenia with significantly
7 lower incidence of these debilitating side
8 effects. What did that mean for patients? In the
9 words of one mental health advocate with drugs like
10 Zyprexa: "The people who are most disabled in our
11 society... awaken after decades of being in a
12 semi-dazed state to become as smart, active, and
13 high functioning as they would have been." Zyprexa
14 was a new and revolutionary treatment for
15 schizophrenia.
16 Strattera is an ADHD medication. And
17 before Strattera, if you had a son who was diagnosed
18 with ADHD whose hyperactivity and impulsiveness and
19 inability to focus was preventing him from
20 succeeding in school and building relationships with
21 others, you faced a difficult choice as a parent.
22 Not all parents chose medication as a treatment
23 option for a son with ADHD, but for those who did,
24 the available treatment was a class of drugs such as
25 Ritalin, which is an addictive stimulant that's

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09:13

1 classified as a Schedule II narcotic, the same
2 classification as cocaine and amphetamines and
3 morphine due to their abuse potential.
4 These stimulant treatments, while they
5 were successful in treating ADHD, could cause
6 insomnia, anxiety and appetite suppression in
7 growing children and adolescents.
8 Strattera gave parents and prescribing
9 physicians a very meaningful choice, and that was a
10 new, non-stimulant treatment for ADHD. Now there
11 was an option to treat ADHD in children and adults
12 with a medicine that was not a Schedule II narcotic.
13 The economic reality is that these two
14 drugs represent rare instances where research in the
15 laboratory actually leads to a safe and effective
16 drug for human treatment. Lilly is a research-based
17 company. They spent 5.5 billion U.S. dollars in
18 research and development in 2013 alone. This
19 graphic depicts the reality for the industry that
20 only 1 in 5,000 tested compounds that are researched
21 in the laboratory ultimately become a safe and
22 effective clinical treatment for patients. Of the
23 many lines of research pursued by Lilly, few go on
24 to become safe and effective medicines, but in the
25 case of Zyprexa and Strattera, Lilly embarked upon

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1 and completed this journey.
2 After its research crystallized into a
3 patentable invention, Lilly applied for and received
4 patent protection from the Government of Canada. It
5 later developed the clinical dossier through
6 additional human clinical trial testing that was
7 necessary to prove that these drugs would be safe
8 and effective for human use, and they received
9 approval from Health Canada to sell these medicines
10 to Canadians. As described by Mr. Postlethwait and
11 Ms. Nobles, Lilly developed the market in Canada for
12 both of these drugs and provided these
13 groundbreaking treatments to Canadian patients who
14 had schizophrenia and other mental disorders and
15 ADHD. The patents for Strattera and Zyprexa were
16 critical to Lilly's decision to launch these
17 products in Canada.
18 And then Canada changed the patent rules.
19 Once the markets for these drugs were established,
20 Canadian generics, who wanted to sell these
21 successful drugs, challenged the patents, and in
22 those proceedings the Canadian courts applied a new
23 and additional utility requirement to the Zyprexa
24 and Strattera patents that did not exist when Lilly
25 applied for and was granted these patents more than

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1 a decade earlier. We call this new utility
2 requirement the promise utility doctrine, and the
3 Tribunal asked us at Question No. 4 whether the
4 promise utility is, in fact, a doctrine.
5 Canada's courts, in multiple decisions,
6 used "promise doctrine" as a shorthand for this
7 additional utility requirement in Canada. C-535 is
8 one example of a recent case. Lilly has used
9 promise utility doctrine rather than promise
10 doctrine in its memorials really simply for clarity,
11 since it's undisputed we're talking about Canada's
12 utility requirement. But whether you describe this
13 as a doctrine or a requirement or a test, the three
14 elements that Lilly has identified comprise a
15 unitary patent test that was applied by the courts
16 to invalidate these patents under the utility
17 requirement in Canada. This change in the rules,
18 this additional new utility requirement, the promise
19 utility doctrine, had dramatic consequences for
20 Lilly. The Zyprexa/Strattera patents met the old
21 utility requirement, the "mere scintilla" test, and
22 they were then revoked solely on the basis of this
23 additional utility requirement that was applied much
24 later.
25 Canada is the only country where the

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1 Strattera and Zyprexa patents have suffered this
2 fate. The only one. Zyprexa was patented in 81
3 jurisdictions around the world. It was challenged
4 by generic competitors in 24 of those jurisdictions.
5 The only jurisdiction where utility was challenged
6 at all, let alone there was a finding that these
7 patents lacked utility, is Canada. And the same can
8 be said for Strattera. Strattera was patented in 36
9 jurisdictions; it was challenged in 3 markets; and
10 the only jurisdiction where the utility of the
11 patent was even an issue was in Canada.
12 You'll hear from Professor Siebrasse,
13 Mr. Reddon and Mr. Wilson that the utility
14 requirement in Canada has dramatically changed, and
15 Ms. Wagner will walk you through that later this
16 morning. But Professor Siebrasse, Mr. Reddon and
17 Mr. Wilson are really three in a chorus of many who
18 have observed that a fundamentally new and unfair
19 utility requirement exists in Canada today. The
20 rules changed so dramatically that in the
21 contemporaneous internal communications of the
22 Canadian Intellectual Property Office that were
23 provided as part of the document production phase of
24 this case, Canada's own patent examiners at CIPO,
25 the Canadian IP Office, were asked to comment on the

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1 changes to their patent examination manual, the
2 MOPOP, in 2009 and 2010, the changes that
3 incorporated this new utility test. They were
4 confused at these new requirements.

5 Mr. Rymerson was confused. He noted that
6 the draft of Chapter 12, which is utility, contains
7 information that's not in our current examination
8 practice. Ms. Black was confused. She noted
9 "Pfizer v Apotex. This case is really new. Has the
10 office even completed a study of this case?"
11 Ms. Trus is another patent examiner who was
12 concerned about the changes. She noted "In biotech
13 the practice has always been that the applicant must
14 be able to show some result indicating that the
15 potential drug will be useful (i.e. affects cell
16 cultures or animal models or comparison to other
17 similar molecules) but actual proof of the ultimate
18 utility is an unrealistic request and potentially
19 unethical. As written it would appear that most
20 biotech applications directed to potential drugs,
21 vaccines, et cetera, would have to be rejected as
22 lacking utility based on the statements in these
23 paragraphs. This wording should be modified or
24 avoided."
25 There were others who were confused as

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1 well. Ms. Yurack was confused, so was Mr. Ohan, and
2 so was Mr. Candaliere. These exhibits are C-358,
3 C-357, C-361, C-362.

4 But the patent examiners were not the only
5 parties who were confused. Even Apotex, the generic
6 who is a party to many of these challenges and a
7 beneficiary of the promise utility doctrine,
8 describe the situation as a "free-for-all,"
9 described it as an arbitrary doctrine that creates
10 "intolerable confusion," and this is C-375 in
11 Apotex's submission to the Supreme Court of Canada
12 on this issue.

13 Apotex also has recognized that this law
14 is new. Here in litigation with Bristol-Myers
15 Squibb, it noted that the law changed following the
16 decision of the Supreme Court of Canada in December
17 of 2002; in Wellcome, that's the AZT case, and the
18 court itself accepted Apotex's characterization
19 noting at paragraph 31 that there was a change in
20 the law.

21 Before I discuss the revocation of the
22 Zyprexa and Strattera patents in greater detail --
23 and I'm going to walk through you the court cases
24 that revoked these patents -- let me pause here to
25 say that this case is properly before you. Canada

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1 made a belated attempt to say that Lilly's case is
2 time barred, but that should be summarily rejected
3 by the Tribunal.

4 The Tribunal asked at Question No. 2
5 whether Respondent's objection to jurisdiction was
6 timely. As we've said in our papers on this topic,
7 on which we'll largely rest, the applicable UNCITRAL
8 rule 21(3) is unambiguous. By not including a core
9 jurisdictional objection in its Statement of
10 Defense, Canada failed to comply with the rule.

11 Lilly's claims have remained consistent
12 throughout this proceeding, and Canada had no excuse
13 for its delay. The Tribunal should, therefore,
14 reject their jurisdictional objection as
15 inadmissible. But should the Tribunal consider it,
16 you also asked at Question No. 1 what the
17 significance was, if any, of the Raloxifene patent
18 in these proceedings. As you know, Canada's
19 findings of inutility with respect to Lilly's patent
20 for Raloxifene is not a challenged measure in this
21 case. The Raloxifene patent is not an investment
22 that's before you. That ruling is relevant as
23 background. It's a background fact because it was
24 the first time that a Canadian court rejected
25 evidence of a soundly predicted utility because the

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1 evidence was not disclosed in the patent application
2 itself, which is the third prong of the promise
3 utility doctrine that we discussed.

4 Raloxifene, which is a widely prescribed
5 osteoporosis medication, is also one of the 28
6 inutility decisions in the pharmaceutical sector
7 since 2005.

8 Canada has conjured up a number of other
9 specters in relation to Lilly's claims arguing that
10 they represent a novel attempt to usurp the
11 sovereignty of states and invade the jurisdiction of
12 other international Tribunals. Those charges are
13 unwarranted and without merit. Chapter 11 provides
14 an avenue for investors to pursue claims against a
15 NAFTA party for breaches of expropriation and fair
16 and equitable treatment. Canada consented to the
17 hearing of such cases before a neutral tribunal and
18 Lilly's claims, which are founded on violations of
19 international law and focused on Canada's
20 international responsibility for the acts of its
21 judiciary, are properly before you.

22 When Lilly applied for the Zyprexa and
23 Strattera patents in the 1990s Canada's utility
24 requirement was simple and straightforward. The
25 claimed invention needed to simply be operable or to

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1 have some industrial value, and that stands in sharp
2 contrast to the promise utility doctrine that was
3 applied to revoke these patents more than a decade
4 later. While Ms. Wagner will discuss the change in
5 the law in more detail, let me provide you an
6 overview here of Canada's simple, mere scintilla,
7 utility requirement that is a statutory test that
8 existed at the time these patents were granted and
9 continues to exist under Canadian law today, and the
10 promise utility doctrine, the additional extra
11 statutory requirement that was applied by the courts
12 to invalidated the Zyprexa and Strattera patents.
13 Under the mere scintilla requirement, the
14 utility inquiry is focused on operability of the
15 claimed invention, and a single utility is enough.
16 Under the promise utility doctrine the promise, or
17 multiple promises, are construed or implied from the
18 disclosure of the patent by the court. Under the
19 promise utility doctrine there's also a heightened
20 evidentiary burden. Post-filing evidence such as
21 commercial success cannot be considered and, prior
22 to the promise utility doctrine and particularly
23 prior to the AZT case, post-filing evidence was
24 permitted to show utility on the date of filing.
25 And for predicted utility -- utility is either

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1 demonstrated or predicted in Canada. For predicted
2 utility under the promise utility doctrine evidence
3 to support that predicted utility has to be in the
4 four corners of the patent application. Prior to
5 the promise utility doctrine, when post-filing
6 evidence was permitted, there was no real
7 distinction between demonstrated utility and soundly
8 predicted utility when it came to the evidence that
9 one could put forward to show operability or
10 usefulness of the patent. The additional disclosure
11 requirement just didn't come into play under mere
12 scintilla because it didn't exist.
13 Now, this change is well reflected in
14 Canada's Manual of Patent Office Practice. The
15 Tribunal asked in your Question No. 5 what are the
16 implications of the MOPOP for the determination of
17 Claimant's claims. So the MOPOP, the patent
18 examination manual of the Canadian IP office, is the
19 authoritative and comprehensive reference guide
20 that's used by patent office examiners. It's also
21 made available to the public as a compendium of
22 existing patentability requirements relied upon by
23 patent agents as a reference tool.
24 It does not have the force of law but the
25 MOPOP is a reliable restatement of Canada's patent

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1 law, and extensive revisions to the MOPOP in 2009
2 and 2010 are compelling evidence of the dramatic
3 shift in Canada's utility requirement. C-449, by
4 the way, is the MOPOP in the record.
5 You already saw that CIPO's patent
6 examiners were confused and concerned about the
7 change that took place in 2009 and 2010, so I'd like
8 to just walk you through that change. This is the
9 MOPOP from the 1990s and the utility requirement was
10 simple. Utility simply meant industrial value or
11 whether the subject matter is operable, and this
12 same focus on industrial value and operability
13 appears in the 1996 and 1998 MOPOPs as well. The
14 1990 MOPOP is C-54, the 1996 MOPOP is C-55, and the
15 1998 MOPOP is C-57.
16 **MR. BORN:** If I understand it correctly
17 from what you said previously, post-filing evidence
18 would be relevant and admissible with respect to
19 satisfying this standard?
20 **MS. CHEEK:** That is correct.
21 **THE PRESIDENT:** Also a further question.
22 On your previous slide 17 there you see the
23 difference, on the left-hand side the mere scintilla
24 and on the other side what you say is the new
25 approach about promise utility doctrine. The

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1 right-hand side applies only to those cases where
2 there is actually a promise expressed and you say
3 also they scour the patent to see whether there's
4 implied promise, but if they have not expressed or
5 implied promise, then still you have the mere
6 scintilla test on the left hand side. Is that
7 correct?
8 **MS. CHEEK:** That's correct.
9 **THE PRESIDENT:** I see Ms. Wagner can't
10 wait to make a presentation; she will tell us more
11 about this.
12 One further thing. You gave a reference
13 of C-449, that's the MOPOP you say is in the record,
14 but later on you gave references of C-54, C-55,
15 C-57.
16 **MS. CHEEK:** C-54, 55 and 57 are the
17 specific provisions. I believe C-449 actually is
18 perhaps the MOPOP website, so that would be in case
19 you wished to avail yourself of the entire MOPOP.
20 **THE PRESIDENT:** I see.
21 **MS. CHEEK:** But we've called out the
22 relevant provisions in C-54, C-55 and C-57.
23 **THE PRESIDENT:** Thank you.
24 **MS. CHEEK:** This now is the 2009 MOPOP
25 and, as you can see, in 2009 the utility standard is

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1 quite different. Now where the inventors "promise"
2 that their invention will provide particular
3 advantages, it will do something better or more
4 efficiently, or will be useful for a previously
5 unrecognized purpose, it is this utility that the
6 invention must have, and where several uses are
7 promised the applicant must be in a position to
8 establish each of them. So this is no longer about
9 a single utility and an operable invention.
10 The 2009 MOPOP also reflected that
11 post-filing evidence is now prohibited, thus
12 circumscribing the proof that may be put forward,
13 and AZT is cited after this proposition in the
14 MOPOP, and the 2010 revisions now require that
15 evidence supporting a predicted utility must be in
16 the patent itself. Here the cases cited are from
17 2005 onwards.
18 The 2009 MOPOP is at C-59, and the 2010
19 MOPOP is at C-60.
20 Now let's look at the Zyprexa patent. One
21 of the two bundles you've been provided is labeled
22 "Zyprexa and Strattera Patents" at the top and
23 behind tab 1 is the Zyprexa patent, which is C-132.
24 This is the patent for Zyprexa in Canada,
25 the '113 patent, and even the abstract on the very

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1 front informs the reader of the utility of the
2 invention. It notes that this compound is of
3 "particular use in the treatment of disorders of the
4 central nervous system".
5 Now, the claims that define the invention
6 are in the back of the patent, so if you turn
7 to page 27 of the patent, if you turn to the second
8 green tab, you'll see the claims. It's titled "The
9 embodiments of the invention in which an exclusive
10 property or privilege is claimed are defined as
11 follows."
12 Now, Professor Siebrasse explains at
13 paragraphs 10 and 11 of his first report that it's
14 these claims that define the invention, and it's an
15 invention as claimed that must meet the substantive
16 test for patentability, including the utility
17 requirement, and a person of ordinary skill in the
18 art can see from the claims that Lilly claimed the
19 chemical compound olanzapine. The claims also
20 mention the use of olanzapine for the treatment of
21 schizophrenia.
22 If you turn to the front of the patent,
23 which is the first green tab, there is a narrative.
24 It says "Thienobenzodiazepine Derivatives and Their
25 Use as Pharmaceuticals" and it tells the story or

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1 explains the invention. That's the disclosure.
2 The disclosure does not define the
3 invention for which you're granted exclusive rights.
4 It does not determine the scope of exclusivity. But
5 as Professor Siebrasse explains at Paragraph 11 of
6 his First Report the disclosure describes the
7 invention so that others may make and use the
8 invention at the end of the patent term. It permits
9 others to build upon the knowledge of the invention
10 during the patent term. So the claims and the
11 disclosures serve different functions.
12 When Zyprexa was examined, there were no
13 issues raised with respect to utility of the Zyprexa
14 patent during CIPO's examination. And this is not
15 surprising. The patent was for a newly synthesized
16 compound, olanzapine. That compound was a selection
17 from a broad class of compounds that had already
18 been determined to have patentable utility. So the
19 genus patent had been determined to have patentable
20 utility as antipsychotics, so the selective compound
21 from the genus that had utility would necessarily
22 also possess the utility required under the Patent
23 Act.
24 Second, it's apparent from the face of the
25 patent that the claim is that the compound had

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1 utility in the treatment of schizophrenia. That's
2 at the top of the claim. And if the patent examiner
3 had had questions about the utility of the invention
4 the examiner could request more information, and the
5 examiner did not ask any questions about utility and
6 the patent was granted in 1998.
7 So two decades after the Zyprexa patent
8 was granted, and well after Lilly launched Zyprexa
9 and developed the market for Zyprexa in Canada, the
10 Zyprexa patent was revoked solely on the basis that
11 the patent lacked utility under Canada's promise
12 utility doctrine, and this revocation of Zyprexa's
13 patent, as Mr. Berengaut and I will describe later
14 this morning, violates NAFTA Chapter 11.
15 Let's now look at the revocation of the
16 Zyprexa patent.
17 In the first instance the court construed
18 the heightened promise. The court did not identify
19 treatment of disorders of the central nervous system
20 or treatment of schizophrenia as the invention's
21 utility, despite the evident utility on the face of
22 the claims. And, as you can see on slide 23, the
23 claims and the stated utility in the claims --
24 that's claim 6 -- is at the top of the screen.
25 Instead, the court construed a broad promise from a

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1 general statement in the disclosure. I'm going to
2 be walking you through the decision to revoke this
3 patent. That decision is C-146.
4 The court construed the promise of the
5 '113 patent as follows. That "olanzapine is
6 substantially better ('marked superiority') in the
7 clinical treatment of schizophrenia (and related
8 conditions) than other known anti-psychotics, with a
9 better side effects profile, and a high level of
10 activity at low doses."
11 The Tribunal asked a question at No. 6:
12 In what way, if any, is this identification of the
13 promise subjective, as Lilly has submitted.
14 The process of construing the promise of
15 the patent is subjective in the sense that it
16 reflects a parsing of isolated statements that are
17 in the disclosure that are not intended to relate to
18 utility. The subjectivity is also reflected where
19 courts find multiple promises, despite the fact that
20 a single utility should suffice under the mere
21 scintilla standard, or the courts find implied
22 promises, as the courts did in this case. So unable
23 to rely on the patent's explicit claims of what the
24 claimed use of the invention is, patentees are left
25 to guess how promises of utility will be construed

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1 from the disclosure.
2 So having construed this heightened
3 promise the Canadian courts then considered the
4 evidence in view of it and, as Lilly has explained,
5 the promise and the heightened evidentiary burden
6 are linked. As the promise grows so does the
7 evidentiary burden needed to demonstrate or soundly
8 predict the promise.
9 In Zyprexa the court concluded that the
10 Zyprexa patent had a demonstrated utility but,
11 nevertheless, the court concluded that Lilly had not
12 demonstrated the promise as construed by the court.
13 This is Paragraph 209 of the court's decision.
14 The court says, "If the utility of the
15 invention in the '113 patent relates merely to a
16 compound with potential anti-psychotic properties
17 that might have relatively low EPS liability [those
18 are the side effects], that utility had been
19 demonstrated by the tests conducted prior to the
20 filing date."
21 So the court concluded that Lilly did, in
22 fact, demonstrate a utility, and that should have
23 been the end of the story. Indeed, the court
24 concluded not only that olanzapine had utility for
25 the treatment of schizophrenia, but the court

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1 concluded that Lilly had demonstrated an elevated
2 promise because it also found that it demonstrated
3 there was a low incidence of side effects. But that
4 was not enough. The court went on. "However, I
5 cannot accept that the 113's promise was so small."
6 As stated above the court went on to find
7 that "the promise of the patent is that olanzapine
8 treats schizophrenia patients in the clinic in a
9 markedly superior fashion with a better side-effects
10 profile than other known anti-psychotics."
11 So as the court considered whether Lilly
12 had demonstrated this promise, it actually ratcheted
13 up the bar even higher, and at Paragraph 210 the
14 court noted that utility would only be demonstrated
15 if the patent disclosed studies "showing that the
16 patented compound, when administered over a long
17 term, meets the promise", and the court found that
18 implied promise because, clearly, schizophrenia is a
19 chronic condition. So as the promise is ratcheted
20 up so, too, is the evidentiary burden.
21 Here there is now an implied additional
22 burden of long-term effectiveness because
23 schizophrenia is a chronic condition, and the word
24 "chronic" does not appear anywhere in the patent.
25 Also "It's not in the claims and it's not in the

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1 disclosure."
2 So the Canadian courts raised the bar by
3 construing a heightened promise for the olanzapine
4 patent, and the Canadian courts then circumscribed
5 the proof Lilly could put forward to meet the
6 heightened promise, and under the traditional
7 utility test that existed when Zyprexa patent was
8 granted, as we mentioned, the commercial success of
9 Zyprexa would have been sufficient to demonstrate
10 utility. Commercial success was considered good
11 evidence of utility on the theory that an invention,
12 and particularly a prescription drug, could not be
13 commercially successful unless it had a utility, and
14 Professor Siebrasse describes this in his First
15 Report, Paragraph 30.
16 Use of the drug by Novopharm, the generic
17 that was being sued for infringement, it was already
18 selling this drug when Lilly sued them for
19 infringement, that also would have been accepted as
20 evidence of the drug's usefulness because the
21 Respondent or the Defendant was making and using and
22 selling the drug. Further, other post-filing
23 evidence that might often be available, such as
24 further testing would be accepted as evidence of
25 utility. Since the laws of chemistry don't change,

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1 if a chemical process works today, then that is
2 evidence that it worked at the time of filing, and
3 Professor Siebrasse explains that at Paragraph 34 of
4 his expert report.
5 But under the new promise utility
6 doctrine, all of that post-filing evidence is
7 ignored.
8 Now, quite unusually there was a
9 significant amount of pre-filing evidence to
10 demonstrate the court's heightened promise. There
11 were in vitro lab tests that showed the compound had
12 anti-psychotic properties; there were in vivo animal
13 tests in mice and rats that showed results
14 predictive of anti-psychotic activity, along with a
15 toxicity study showing lesser side effects in dogs.
16 There were four studies on small groups of healthy
17 volunteers, and there was a completed open label
18 study of the compound's therapeutic effects on
19 olanzapine patients where six out of eight of the
20 patients who completed the treatment cycle showed a
21 66 to 87 percent improvement in their symptoms.
22 Nevertheless, the court concluded, "In my view,
23 Novopharm [the generic] has shown that the evidence
24 available to Lilly in 1991 was clearly insufficient
25 to demonstrate olanzapine's capacity to treat

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1 schizophrenia patients in the clinic in a superior
2 fashion with fewer side effects than other known
3 anti-psychotics."
4 That's Paragraph 213 of the decision and
5 in 212 it would appear the court believed that
6 nothing short of placebo controlled clinical trials
7 in sufficiently large groups of patients would have
8 sufficed to meet the court's heightened evidentiary
9 requirement linked to the heightened promise. Yet
10 such extensive clinical trials and extensive human
11 testing is typically developed well after the patent
12 protection is secured.
13 So having held that Lilly did not
14 demonstrate the promise, the court went on to
15 consider whether the promise was soundly predicted,
16 and there the court found -- and this is at
17 Paragraph 255 of the decision -- the court found
18 that the patent does set out a rational basis for
19 making a sound prediction that olanzapine would be
20 useful for the treatment of schizophrenia, but not
21 grounds for a sound prediction that the olanzapine
22 patent would treat schizophrenia in a markedly
23 superior fashion, with a better side-effects profile
24 than other known anti-psychotics.
25 So under the old utility test there was a

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1 rational basis for predicting olanzapine would be
2 useful for the treatment of schizophrenia, but with
3 the heightened promise the court concluded there was
4 no rational basis to predict the promise of the
5 patent.
6 As an aside, I'd note that Canada has made
7 much in this arbitration that the promise utility
8 doctrine is simply about holding patentees to their
9 promises that they made in the patent but, as
10 Professor Siebrasse will explain, there's a separate
11 provision in the Canadian Patent Act, Section 53,
12 that polices false statements in a patent, and
13 Section 53 was an issue in a prior Zyprexa case and
14 the court found there was no violation of
15 Section 53. There's no false statements in this
16 patent.
17 So let me conclude on Zyprexa. The
18 Zyprexa patent met the mere scintilla utility test
19 when Lilly applied for its patent in the 1990s. It
20 met the mere scintilla test when it was challenged
21 in the late 2000s, but rather than apply the mere
22 scintilla test the Canadian courts applied its new
23 additional utility requirement that didn't exist
24 when Canada applied for its patent. So under the
25 mere scintilla test, the claimed utility is simple

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1 and straightforward. Use of olanzapine for treating
2 schizophrenia. Does the invention work? The answer
3 is yes. But instead, under the promise utility
4 doctrine, the promise is that olanzapine is
5 substantially better with marked superiority in the
6 clinical treatment of schizophrenia than other known
7 anti-psychotics, with a better side effects profile
8 and a higher level of activity at low doses.
9 The courts also found an implied promise
10 of long-term treatment of a chronic condition. And
11 with the heightened promise came the heightened
12 evidentiary burden magnified by the fact that
13 commercial success is no longer permitted under the
14 promise utility doctrine. And the third element
15 actually, the disclosure requirement, was not at
16 issue in this case.
17 So how do we get from a straightforward
18 utility for Zyprexa, treatment of schizophrenia, to
19 the construed and implied promise of marked
20 superiority with a better side effect profile that
21 can treat schizophrenia in the long term? How do we
22 go from a utility test where commercial success is
23 proof that the invention had a utility to one where
24 the court puts blinders on and doesn't consider that
25 post-filing evidence? The answer is simple. The

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1 law fundamentally changed in Canada, and that change
2 had fatal consequences for the Zyprexa patent.
3 I'd now like to turn to the Strattera
4 patent.
5 **MR. BORN:** Before you do that, can I ask a
6 question about the promises that the court found,
7 the promise of marked superiority, the promise of a
8 better side effects profile and of long-term
9 efficacy? Were those promises relevant to other
10 aspects of patentability under Canadian law?
11 **MS. CHEEK:** In this case they were stated
12 advantages to explain what advantages the selection
13 had over the genus patent.
14 **MR. BORN:** Right, but did they go to the
15 other elements of non-obviousness invention and the
16 like under Canadian law for patentability?
17 **MS. CHEEK:** Yes, particularly for
18 non-obviousness they might go towards that
19 requirement.
20 **MR. BORN:** Thank you.
21 **MS. CHEEK:** So the Strattera patent is
22 Tab 2 in the mini bundle of the two patents. It's
23 also C-67 in the record. This is a Canadian patent
24 for Strattera. It's the '735 patent. Again on the
25 front of the patent it is clear in the abstract, it

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1 says Tomoxetine is a norepinephrine uptake inhibitor
2 used for the treatment of attention
3 deficit/hyperactivity disorder. The patent claims
4 in this patent are on page 8, it's the second tab
5 there in the back, and as you can see Claim No. 1 is
6 the use of tomoxetine for treating attention
7 deficit/hyperactivity disorder in a patient in need
8 thereof, and there are additional claims as well.
9 The front of this patent, at the first
10 tab, you'll see the disclosure on page 1, treatment
11 of attention deficit/hyperactivity disorder, and it
12 explains the background of the invention.
13 The Strattera patent is a method of use
14 patent, meaning it claims a particular clinical use
15 for a particular compound, and that use is treatment
16 of ADHD. As with Zyprexa, at the time the patent
17 was examined, Canada only had a mere scintilla
18 utility requirement. An invention would be
19 considered to have utility if it had industrial
20 value or it was operable. This is the 1998 MOPOP
21 which was the MOPOP that existed when this patent
22 was examined by CIPO. As you can see, it's the same
23 as the 1990 MOPOP. "Utility, as related to
24 inventions, means industrial value" or whether the
25 subject matter is operable.

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1 Again, with Strattera there were no issues
2 raised with respect to this patent's utility during
3 CIPO's examination and, again, that's not surprising
4 because the utility, use for the treatment of ADHD,
5 was apparent from the face of the patent and the
6 claims, and the Strattera patent was granted in
7 2002. So a decade later, after Lilly had launched
8 Strattera and developed the market for the drug in
9 Canada, the Strattera patent was revoked solely on
10 the basis that the patent lacked utility under
11 Canada's promise utility doctrine.
12 And how is the promise utility doctrine
13 applied to invalidate the Strattera patent? The
14 Canadian courts applied all three aspects of the
15 promise utility doctrine. They construed a promise.
16 The heightened utility requirement the ban
17 post-filing evidence and the disclosure rule for
18 sound prediction, and I'll walk through you that.
19 And the court then invalidated the Strattera patent
20 solely for lack of utility, despite the use of the
21 drug for thousands of Canadian patients.
22 First let's look at the promise. And on
23 slide 32 you'll see at the top is the stated utility
24 in the claims treating attention
25 deficit/hyperactivity disorder. The patent is C-67,

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1 and then the decision to revoke the patent is C-160.
2 This is Paragraph 112 in the decision. So the court
3 found an implicit promise. The court found that
4 "ADHD is a chronic disorder requiring sustained
5 treatment. Only where experimental results are
6 sufficiently compelling to independently support the
7 inventive promise (or to support a sound prediction)
8 is utility established. In the case of the '735
9 patent, the inventors claimed a new use for
10 atomoxetine to effectively treat humans with ADHD.
11 What is implicit in this promise is that atomoxetine
12 will work in the longer term." So this implicit
13 promise was apparently based on the patent's
14 disclosure which said that the drug is an effective
15 treatment for ADHD. The patent disclosure does not
16 use the word or mention "chronic" or "longer term",
17 and in fact this drug Strattera for ADHD is
18 prescribed for both long and short-term treatment of
19 ADHD. So with this heightened promise the
20 heightened evidentiary burden came into play and the
21 court required Lilly to demonstrate the promise
22 based only on pre-filing evidence, and given this
23 heightened promise even a human clinical trial, that
24 was conducted pre-filing, did not meet the
25 evidentiary burden.

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1 So the court, the Canadian court, accepted
2 that Strattera met the mere scintilla test. At
3 Paragraph 93 the court states "Lilly argues that it
4 need only show that atomoxetine had a 'mere
5 scintilla of utility'. If that phrase means only
6 that atomoxetine be shown to be somewhat useful to
7 treat ADHD I accept Lilly's point."
8 But having raised the bar by construing a
9 heightened promise for the atomoxetine patent, one
10 that implied effective long-term treatment in
11 humans, the evidentiary burden grew. And against
12 the court's construed promise of long-term
13 effectiveness, the Canadian court considered only
14 pre-filing evidence to determine whether the promise
15 of the patent was demonstrated. Strattera's
16 commercial success and the fact that it was being
17 used by thousands of Canadian patients to treat ADHD
18 was ignored.
19 Once again, although atypical, there was a
20 pre-filing clinical trial for the court to consider,
21 and that pre-filing clinical trial was quite
22 significant. The pre-filing evidence was a double
23 blind Massachusetts General Hospital study that
24 administered Strattera to 22 patients, and that MGH
25 study was conducted in early 1995. It was after the

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1 U.S. patent filing for Strattera which was in
2 January 1995. Lilly's scientists approached
3 Massachusetts General Hospital with a proposal for a
4 joint human clinical trial on the efficacy of
5 atomoxetine in treating ADHD. That trial was
6 conducted from January to April 1995 and, as I
7 mentioned, it was after the U.S. filing date, and as
8 an aside the U.S. patent issued and was found valid
9 by U.S. courts, even though this study was done
10 after the patent was filed. But in any case this
11 study was before the Canadian filing date, which is
12 January 4, 1996, and the study was eventually
13 published in a peer reviewed journal, the American
14 Journal of Psychiatry.
15 So in this MGH study 11 out of the 21
16 patients that were assessed showed a 30 percent or
17 better reduction in ADHD symptoms, and the
18 scientists concluded that atomoxetine "was
19 associated with clinically and statistically
20 significant improvement in individuals with ADHD
21 symptoms." The court, in its decision, discusses
22 the MGH study at Paragraph 98.
23 But with the heightened promise also came
24 heightened scrutiny. It was not enough that there
25 was a study conducted prior to the filing of the

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1 patent that showed that the drug worked. It was not
2 enough that the study showed that atomoxetine worked
3 in some patients and that the study's authors found
4 a positive result and an improvement in ADHD
5 symptoms. The court picks apart the study. It
6 finds it's too small, that it was too short. Even
7 the evidence of Novopharm's experts that the study
8 had promising results was disregarded, with the
9 court noting that the expert "opined that the
10 results of the MGH study were interesting and
11 promising but not sufficiently robust to establish
12 clinical efficacy." That's at Paragraph 95.
13 **THE PRESIDENT:** Ms. Cheek, the study is at
14 C-152, the MGH study? You referred now to it many
15 times, and it may be useful if you read the record
16 to understand the reference.
17 **MS. CHEEK:** All of the discussion I've
18 discussed is actually in the court's decision, but
19 let me also get you the exhibit number for the MGH
20 study itself.
21 So the court concluded that the study was
22 not enough to demonstrate a promise of long-term
23 clinical effectiveness. So having concluded that
24 Lilly failed to demonstrate utility -- excuse me,
25 Mr. President, I have a cite it is C-152. That will

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1 be the published version of the study, so that's the
2 American Journal of Psychiatry publication.
3 Having concluded that Lilly failed to
4 demonstrate utility, the court excluded the
5 pre-filing evidence, excluded consideration of the
6 MGH study from its sound prediction analysis. Even
7 though the court just considered it, the court
8 considered the MGH study to decide whether utility
9 had been demonstrated, but having found that it
10 wasn't enough because there was a heightened
11 evidentiary burden, shifting to see if there was a
12 soundly predicted utility, the court excluded its
13 consideration of the MGH study because it was not in
14 the four corners of the patent.
15 Now, the court commented -- this is slide
16 34, Paragraph 95, this is where the expert opined
17 that the results were promising but not sufficiently
18 robust to establish a clinical efficacy.
19 The court went on at Paragraph 113 and
20 noted that, "In some cases an initial study of this
21 sort" -- the MGH study -- "might provide a basis for
22 a sound prediction of utility" but, due to the
23 additional disclosure rule for sound prediction
24 cases whereby all evidence to support the prediction
25 of utility must be in the patent itself, the court

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1 simply refused to consider it. So Lilly couldn't
2 rely on the MGH study to predict utility.
3 With regards to the disclosure
4 requirement, the court says at Paragraph 116, "It
5 seems to me that it is beyond debate in Canada that
6 where a patentee asserts that the utility of its
7 invention has been demonstrated, it need not assert
8 its supporting evidence in the patent." But then it
9 notes in 117, "In a case involving a claimed sound
10 prediction of utility, it is equally beyond debate
11 that an additional disclosure obligation arises."
12 It cites to AZT for that proposition saying
13 "According to Justice Binnie in AZT, this obligation
14 is met by disclosing in the patent both the factual
15 data on which the prediction is based and the line
16 of reasoning followed to enable the prediction to be
17 made," although this particular finding, the
18 disclosure requirement, was only first applied by a
19 court in 2008 in the Raloxifene decision.
20 So the court appears to recognize that
21 there's some unfairness here in imposing the more
22 rigorous disclosure requirement. The court notes at
23 Paragraph 121 that "Lilly argues that the validity
24 of the '735 patent is now being assessed against the
25 backdrop of a more rigorous disclosure obligation

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1 than may have been apparent at the time of its
2 filing in 1998," but the court goes on to observe
3 that "The disclosure issue, however, has been
4 determined by earlier decisions that are binding
5 upon me and to the extent that it may be amenable to
6 reconsideration, it must be examined elsewhere."
7 So let me conclude on the Strattera
8 patent. The Strattera patent met the mere scintilla
9 utility test when Lilly applied for its patent in
10 the 1990s, and it met the mere scintilla test when
11 it was challenged in the 2000s. But the mere
12 scintilla test wasn't applied to Strattera's patent.
13 Under the mere scintilla test, the claimed utility
14 was simple, did the invention work, and there was no
15 question that when the Canadian courts revoked this
16 patent, that Strattera, which was being used by
17 thousands of Canadian patients, was useful in
18 treating ADHD.
19 Under the promise utility doctrine,
20 however, that was not the test. Instead, the court
21 construed its promise to effectively treat humans
22 with ADHD finding what's implicit in that promise is
23 that atomoxetine will work over the long term. But
24 with the heightened promise came a heightened
25 evidentiary burden, and post-filing evidence such as

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1 commercial success, once again, was excluded as
2 evidence to show the operability of the invention or
3 to show its usefulness. And under the promise
4 utility doctrine, even though there was a human
5 clinical trial, once the court was reviewing it
6 through the lens of soundly predicted utility, that
7 prefiled MGH study -- so a study conducted prior to
8 filing the patent for the invention -- was excluded
9 from consideration.
10 Once again the law fundamentally changed
11 in Canada, and that change had fatal consequences
12 for Lilly's Strattera patent.
13 Now, Canada claims that the law has not
14 fundamentally changed, that the promise utility
15 doctrine is not new, and Ms. Wagner will now rebut
16 that fallacy in greater detail.
17 **THE PRESIDENT:** Before we do that, you
18 pointed us to the court decisions which is at C-160
19 and Paragraph 121, slide 37. You see in 121, in the
20 penultimate line, it says -- let me read the full
21 sentence -- "The disclosure issue, however, has been
22 determined by earlier decisions that are binding
23 upon me and to the extent that it may be amenable to
24 reconsideration, it must be examined elsewhere."
25 Which are the earlier decisions which the

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1 judge says are "binding upon me"? You need not
2 answer now. You may wish to do that through your
3 expert testimony.
4 **MS. CHEEK:** That is not a specific
5 reference to the Strattera litigation itself; it's a
6 reference to the fact that there is earlier case law
7 that's been applying the disclosure rule that was
8 first articulated in Raloxifene in 2008, and then
9 courts have been applying that since then.
10 **THE PRESIDENT:** Those are the earlier
11 decisions?
12 **MS. CHEEK:** Yes.
13 **THE PRESIDENT:** They don't go back in time
14 prior to 2008?
15 **MS. CHEEK:** That's correct.
16 **THE PRESIDENT:** Thank you.
17 **MR. BORN:** It's AZT?
18 **MS. CHEEK:** For the disclosure rule it's
19 the 2008 Raloxifene decision.
20 **THE PRESIDENT:** AZT is 2002, wasn't it?
21 **MS. CHEEK:** It's 2002, and that's the
22 prohibition on post-filing evidence.
23 **MS. WAGNER:** Good morning, Mr. President,
24 members of the Tribunal. Just to pick up on that
25 last point you were asking about, AZT, I will get

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1 into this more in my presentation, but the AZT
2 decision basically stated an additional disclosure
3 rule, or what might have looked like an additional
4 disclosure rule, but didn't actually apply it in
5 that case because it wasn't at issue, and then
6 subsequent courts to that actually didn't read it as
7 an additional disclosure rule, and then it was in
8 2008 that it was actually applied in the first
9 Canadian decision to apply it, and upheld in 2009 by
10 the Federal Court of Appeal. We'll have the
11 citations to that as we go through.

12 We're going to take you through the
13 current promise utility requirement in greater
14 detail, and in doing so I'm going to present the
15 following three arguments. The promise utility
16 doctrine has dramatically changed the utility
17 requirement in Canada, and when we're talking about
18 this we're talking about both the level of utility
19 that it sets, or the standard, which is a promise,
20 and also the proof that's required to meet it. The
21 two are inseparable and Canada has not shown that
22 that construct exists in any single case, any single
23 prior law case. And so, having failed to find
24 support for the prior law in that holistic sense,
25 Canada then tries to find support in prior law just

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1 for the individual aspects that we talked about, and
2 my point 2 is that this fall-back position also
3 fails because, even when considered on an
4 aspect-by-aspect basis, you don't see what we see
5 today in prior law.

6 My third argument is, having failed to
7 disprove that there is a dramatic change in the law,
8 what Canada then attempts to do is divert attention
9 away from the central issue and raise this
10 speculative patenting argument. But the patents in
11 issue here weren't speculative at all. They were
12 extraordinarily supported by human clinical trials
13 before the date of filing, as Ms. Cheek has
14 reviewed, and Canada also has no foundation for its
15 characterization of Lilly's broader patent filing
16 practices as speculative.

17 I'd also submit that this current utility
18 requirement is just incapable of deterring
19 speculation, because of the way it's so arbitrary
20 and subjective and unpredictable in its application.
21 A law that's like that just can't serve that policy
22 purpose.

23 As I noted, we've identified the various
24 aspects of the promise utility doctrine so that we
25 can trace their emergence and contrast them against

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1 what existed in prior law but, as I said, it's
2 important to recognize that they can't be considered
3 in isolation. They are all part of the current
4 utility requirement. The court construes a promise
5 or promises from the disclosure part of the patent;
6 it then looks to see whether each has been
7 demonstrated by only pre-filing evidence; and, if
8 the court finds that pre-filing evidence does not
9 demonstrate the promise, then it looks to see
10 whether there was a sound prediction of that
11 promised utility. But then in that case, as
12 Ms. Cheek has reviewed, any evidence that's not in
13 the patent itself is excluded. And you can see the
14 contrast between this new requirement and the prior
15 law by looking at one of the very cases that Canada
16 relies on in support of its position, and that's at
17 Exhibit C-118. That's the Supreme Court of Canada's
18 1981 decision in *Consolboard v MacMillan*. The
19 invention in that case was a type of building
20 material, a wafer board, and this highlighted
21 language on the screen is what's been discussed at
22 length in this proceeding: "not useful" in patent
23 law means "that the invention will not work, either
24 in the sense that it will not operate at all or,
25 more broadly, that it will not do what the

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1 specification promises that it will do'."

2 Canada has presented this as supporting
3 the existence of a bifurcated utility standard in
4 prior law, but the fact is that no Canadian court
5 interpreted this statement in this way for about
6 25 years, until this case was repurposed post 2005
7 by the courts and interpreted in a very different
8 way.

9 So what does the language mean within the
10 *Consolboard* decision?

11 It's the same standard that was reflected
12 in the patent office manuals that Ms. Cheek has
13 reviewed with you, and the same standard as when
14 Lilly's patents were filed and granted. The claimed
15 subject matter must be operable. It must work. And
16 a patent will be invalid if the desired result isn't
17 obtained when you follow the directions in the
18 specification, and that was a low standard, and what
19 was required is that the claimed invention actually
20 worked at challenge.

21 Additionally, the direct holding in
22 *Consolboard* was actually not about whether the
23 utility requirement was met. It was about
24 disclosure. And the holding in that case was that
25 the patent itself didn't actually have to disclose

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10:12

1 the utility, the utility was apparent, and so much
2 less having to disclose proof or evidence of utility
3 in the patent, which is what we see today, at least
4 under the sound prediction branch.
5 So, in summary, the standard expressed in
6 Consolboard focused on operability of the claimed
7 invention and post-filing evidence could be used and
8 there was no requirement to even disclose utility.
9 As I mentioned, this low bar utility
10 requirement was reflected in the few decisions that
11 had cited Consolboard in support of utility before
12 the Canadian courts reinterpreted starting in about
13 2005, and none of these prior cases involved a
14 search for promises of utility in the disclosure.
15 The focus was just on utility in fact, as of the
16 date of challenge. And this is a case called
17 Almecon Industries, and it involved bore hole plugs
18 used in commercial drilling. At Paragraph 46 of
19 this decision, this is the court citing from that
20 passage in Consolboard that we just reviewed, and
21 what the court has to say about utility based on
22 this passage in Consolboard is that the invention
23 was a commercial success so the court can conclude
24 it worked. There's no search for promises, and
25 there's no restriction on what can be used to prove

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1 that the invention works.
2 This was the old law, or the prior law,
3 and at base Canada's approach of trying to isolate
4 out the various aspects of the new doctrine and find
5 vestiges of it in prior law is a fallacy because, on
6 the one hand, we live in a common law system so new
7 law is not made out of whole cloth, so you're always
8 going to be able to find some antecedent aspects of
9 law such as in this case just the mere use of the
10 word "promise", and I'll discuss that further when
11 we get into discussing the standard.
12 More centrally, when you're considering
13 whether a law has changed, you have to consider both
14 the standard or the legal test and the required
15 proof to meet it. The two are not divorced from one
16 another. You can think of an example where all
17 citizens in a country are permitted to vote, but if
18 you change the law so that the proof of citizenship
19 requirements become very onerous and half the
20 population is disenfranchised, no one is going to
21 say that the law hasn't changed. It's changed
22 dramatically. You can't separate out the two. And
23 we have a visual that depicts this. It has the low
24 bar for utility, the mere scintilla, then we have
25 the elevated promise of utility as well.

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1 In this case, the patentee has enough
2 evidence so that they can both surpass the mere
3 scintilla and even enough evidence to meet the
4 elevated promise of utility. But then their ability
5 to rely on that evidence is taken away under the new
6 requirement.
7 First what comes off is any post-filing
8 evidence such as clinical trials or regulatory
9 approval or commercial success. But in this example
10 the applicant still might have enough, the patentee
11 still might have enough to surpass the elevated
12 promise of utility. Just based on the pre-filing
13 evidence that might be enough to predict utility,
14 such as was in the case of Strattera. But then what
15 happens is, if you're trying to rely on a prediction
16 of utility you have to show that your pre-filing
17 studies at least predicted utility. If that
18 evidence is not in the patent itself, that falls
19 away too. And that's basically a good depiction of
20 what occurred in the Strattera case.
21 Just to be clear, when you were reviewing
22 the slide 17, which showed the promise utility
23 doctrine on the one side and the mere scintilla on
24 the other, the mere scintilla is the standard, so if
25 we were looking at this from today's perspective,

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1 even if you're in the mere scintilla world from a
2 standard perspective, you'd still have to contend
3 with the fact that you can't rely on post-filing
4 evidence, and if you have to rely on a prediction of
5 utility because you didn't have enough pre-filing
6 evidence to demonstrate, that's still going to have
7 to be in the patent. So the standard is one
8 problem, but it's just a component of the problem.
9 Now let's consider that even if we take
10 Canada's argument at its best, it's also our
11 submission that Canada has failed to show that any
12 one single aspect of the current utility requirement
13 existed in prior law. And so we're going to deal
14 first with the standard, the promise aspect, and
15 it's important to understand what's happening today
16 so that we can contrast it against the standard in
17 prior law. So under prior law utility was assessed
18 by reference to the claimed invention and only a
19 mere scintilla was required.
20 Today -- so if the claimed invention, as
21 an example, was olanzapine for the treatment of
22 schizophrenia, then the standard for utility was
23 treatment of schizophrenia and very little would do.
24 A low bar. In contrast to prior law what's done
25 today is utility is assessed by reference to the

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1 promise of the patent found in the disclosure, or
 2 even promises and, if found, those impose elevated
 3 standards for utility. And what that means is, like
 4 the cases of the Zyprexa and Strattera, when there's
 5 a claimed utility, the courts might actually just
 6 disregard that claimed utility and they go to look
 7 to see what the promises are that were made in the
 8 disclosure. And whereas the mere scintilla standard
 9 still exists in theory, so it's possible that the
 10 court could conclude that there is no promise made
 11 in the disclosure, when the promise does apply or a
 12 promise is found, as can be seen from this citation,
 13 C-344 on the record, the 2014 case, the courts have
 14 acknowledged that the promise doctrine represents an
 15 exception to the above minimum statutory
 16 requirements, so it's an elevated or additional
 17 requirement existing above the statutory minimum,
 18 which is the mere scintilla.

19 **MR. BORN:** Just by way of background, to
 20 what extent, if you know, does the exception swallow
 21 the rule? How frequently?

22 **MS. WAGNER:** I was just about to say that
 23 in almost every single pharmaceutical case -- and
 24 the doctrine has primarily been applied to
 25 pharmaceutical products -- a promise is found.

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1 there may be one or two cases in which the court has
 2 looked at it from a mere scintilla perspective and
 3 said there was no promise in the disclosure, but
 4 it's almost overwhelmingly the case that a promise
 5 of utility is found. So the first thing the court
 6 does when it looks at utility now is what are the
 7 promises.

8 As my colleague, Ms. Cheek noted,
 9 disregarding the utility of the claimed invention
 10 and looking instead at promises in the disclosure
 11 essentially turns patent law on its head because
 12 it's the claims that stake out the scope of the
 13 exclusivity. It's the claims that define the
 14 invention. And so this elevated promise standard
 15 effectively jettisons one of the most basic tenets
 16 of patent law. Our experts Professor Siebrasse and
 17 Mr. Reddon have both testified about litigation
 18 involving a drug called latanoprost. What happened
 19 there is the trial court based the standard for
 20 utility on the claimed invention, and it was a
 21 pretty specific claim, "treatment of glaucoma or
 22 ocular hypertension without substantial ocular
 23 irritation". The trial court looked and concluded
 24 that testing that was done even before the patent
 25 was filed had demonstrated this utility. An unusual

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1 amount of pre-filing testing. And this decision was
 2 upheld by the appellate court, the Federal Court of
 3 Appeal.

4 Then a different generic company commenced
 5 litigation to invalidate the very same patent.
 6 Understandably the trial court, in fact it was the
 7 same judge, reached the same conclusion about the
 8 utility of the invention. However, this time, when
 9 it came to the Federal Court of Appeal -- and it was
 10 a different panel -- the Federal Court of Appeal
 11 overturned the decision because they accepted expert
 12 evidence of a different construction of the promised
 13 utility, and this is the construction "promise of
 14 the patent is chronic use of the compound for a
 15 chronic medical condition."

16 And so apart from showing the dramatic
 17 inconsistency, two vastly different interpretations
 18 of the same patent on a question of law, this also
 19 shows the different approaches. On the one hand,
 20 utility is assessed by reference to the claimed
 21 invention. On the other, by reference to, in this
 22 case, an implied promise of chronic use. And that
 23 utility was fatal to the patent. The pre-filing
 24 studies were not sufficient to show long-term use of
 25 the drug. And this latter approach of reading an

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1 implied chronic use was applied, as Ms. Cheek noted,
 2 in the Zyprexa and Strattera litigations and, in
 3 fact, those decisions had cited to the Federal Court
 4 of Appeal in latanoprost, both of them, and the
 5 exhibit is C-99 for the latanoprost decision, the
 6 one where the chronic use was implied.

7 As should be apparent from Ms. Cheek's
 8 review of the Zyprexa and Strattera litigation,
 9 there's no certainty on how promise will be
 10 ascertained in a given case, and sometimes the
 11 courts will consider statements in the patent
 12 disclosure to be merely a goal or object, and
 13 sometimes they'll see those as promises. In fact,
 14 they receive expert evidence on this very issue, and
 15 you can see this is an excerpt from a case, Exhibit
 16 C-48, where expert evidence is received on
 17 interpretation of the language in the patent and the
 18 expert is struggling to determine is that word
 19 "object" a goal, or is this something that would
 20 have to be demonstrated in order to find utility.
 21 Of course, the whole exercise is being applied after
 22 the fact to patents that were filed when this
 23 approach was not in existence and wouldn't have been
 24 conceived of.

25 So this elevated promise standard is

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1 contrary to basic patent law principles, and it's a
2 dramatic departure from prior law, and how do we
3 know it's a dramatic departure? Well, because
4 there's not one single case before 2005 where the
5 court identifies this elevated promise of utility
6 from the disclosure of the patent. Not one case.
7 So Canada hasn't conceded the law is new,
8 so what they do is try to find some antecedence in
9 prior law, even though there's no actual decision,
10 so, in the case of a promise, they look at
11 semantics. It's true that the use of the word
12 "promise" appears in prior law, but it appears as
13 shorthand for the promised results, what does the
14 invention do. It doesn't involve this exercise of
15 construing the disclosure of the patent to find an
16 elevated standard to which the patentee is held.
17 The second thing Canada attempts to do is
18 to conflate the utility requirement with other
19 patent law concepts, and to try to draw analogies to
20 these concepts or even to explain why we're seeing
21 this standard applied so frequently now when we
22 never saw it before.
23 Finally Canada also cites passages from
24 commentators, textbooks and materials, and none of
25 these established that the standard existed in prior

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1 law either.
2 Dealing first with the issue of semantics,
3 essentially Canada's expert Mr. Dimock maintains
4 that every time the word "promise" appears in prior
5 law this means the court applied the same elevated
6 standards as applied today. But this is a
7 simplistic approach and it's incorrect. You'll hear
8 from our expert Professor Siebrasse that, although
9 the word was used in these prior cases, the same
10 exercise was not applied. And, to the contrary, in
11 these cases how the utility standard was read was
12 consistent with prior law. Basically the claimed
13 invention has to work. And on this slide you can
14 see one of the cases, New Process Screw, that
15 Canada's relies on because this promise of the
16 patent is a phrase that's used in the decision, but
17 in that case the so-called promise was in the
18 claims. The claimed invention didn't actually work.
19 So that's why it didn't have utility.
20 So, in terms of conflating utility with
21 other patent law concepts, Canada's expert
22 Mr. Dimock has said that the promise approach was
23 applied in prior law cases that dealt with something
24 called overbreadth, and overbreadth is something
25 that overlaps with a bunch of patent law concepts so

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1 your claims can be overbroad because they encompass
2 something that's not new, or something that's
3 obvious, or because they do encompass something that
4 lacks utility. It's true that there's overlap.
5 But what there is not overlap between in
6 the prior law is overbreadth and the promise utility
7 analysis, so you just don't see any cases in prior
8 law where a claim was held to be overbroad because
9 it encompassed subject matter that didn't meet a
10 promise utility, because the courts weren't looking
11 for a promise utility. So although there's overlap
12 between the concepts, there's not overlap in the
13 prior law between utility as we see it today with
14 utility as we see it today.
15 Here on this slide is Exhibit R-172, the
16 Unilever case, where the court, when they were
17 considering a claim was overbroad because it
18 encompassed something that lacked utility, they
19 actually refused to consider statements in the
20 disclosure for this purpose. So they looked at what
21 the utility of the claimed invention was and whether
22 the claim was overbroad in light of that because it
23 encompassed things that didn't work, but they
24 refused to take a so-called promise utility from the
25 disclosure and apply that as the standard. So

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1 there's just no overlap.
2 Canada has also tried to deal with the
3 absence of promise standard cases by asserting that
4 this doctrine has always existed but we're just
5 seeing it now because certain types of patents are
6 more prevalent now, and Canada has referred to these
7 new types of inventions as secondary patents. They
8 really use this terminology to present these types
9 of patents as less worthy of protection.
10 In answer to Tribunal Question No. 7, you
11 had asked whether Canada's characterization of
12 Lilly's patents as secondary patents is relevant to
13 Lilly's claim. The response is no. There is
14 actually no Canadian case, no Canadian
15 jurisprudence, which uses the term "secondary
16 patent". In fact, Canada's expert, Mr. Dimock, does
17 not use the term "secondary patent" either.
18 But what Mr. Dimock does do is he appears
19 to maintain that this elevated promise standard is
20 particularly relevant to certain types of patents
21 that we are seeing more frequently now than before,
22 and he identifies new use patents and selection
23 patents and, in fact, Strattera was a new use patent
24 and Zyprexa was a selection patent.
25 But this argument doesn't stand up either

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1 and the first reason is that the elevated promise
2 standard applies to all pharmaceutical patents, and
3 this is conceded by Canada's expert, Mr. Dimock, and
4 it's apparent from the case law in any event.
5 The other thing is that new use patents in
6 particular aren't new, and Canada hasn't put forward
7 any evidence to support the proposition that the
8 vastly increased rate of invalidity that's based on
9 inutility coincides with the growth of certain types
10 of patents. The fact is that invalidations on
11 inutility grounds are happening more frequently
12 because the law has changed. That's the
13 explanation.
14 Then Canada has also raised a certain
15 analysis that's been applied by courts recently, and
16 you'll see it in the record. It's "reading up" and
17 "reading down." Basically according to this
18 analysis patentees will put certain statements --
19 this is the theory -- that patentees will put
20 certain statements in the disclosure of their patent
21 to meet other patentability criteria to show that
22 the invention is not obvious, or to show that it's
23 new. Then, having put those statements in the
24 patents for those purposes, the argument goes that
25 you can't read up the invention for that purpose and

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1 then read it down for utility. If you're going to
2 put statements in your patent you should be held to
3 them as a matter of utility. Mr. Born, I think you
4 were getting at that somewhat when you were asking
5 about the Zyprexa patent, but those statements are
6 put in patents for different purposes and there are
7 different rules that apply when considering, for
8 example, whether an invention is obvious or not, and
9 different evidentiary standards. For example, in
10 the case of obviousness, post-filing evidence is
11 admissible. So it's just not correct, it's not a
12 natural outcome of putting certain statements in
13 your patent that you're going to be held to them as
14 a matter of utility, because remember the utility
15 requirement is one requirement as well. Once those
16 statements are in there and they're read to be
17 promises, now you're in the promise world, you're in
18 the promise utility doctrine world, and you're going
19 to have to prove up all of that by evidence
20 available as the date of the filing of the patent,
21 which can be remarkably difficult if what you're
22 talking about is long-term clinical efficacy, at the
23 date of filing the patent. And so the reading up,
24 reading down is something -- and another point on
25 that is in the case of Zyprexa, it's not even true

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1 that the courts are taking that approach because, in
2 fact, the promise that they read was different from
3 what might be needed to support a patent to make it
4 non-obvious.
5 They required as a matter of the promise
6 marked superiority over all known other
7 anti-psychotics. You wouldn't need that to
8 establish that the invention was non-obvious in any
9 event, and the obviousness requirement was surpassed
10 in that case.
11 The thing with reading up and reading down
12 is that this is a concept that has only been applied
13 since the advent of the promise utility doctrine.
14 It's something that is a byproduct of that doctrine
15 because, before, the courts just didn't look to
16 statements in disclosure to create an elevated
17 standard for utility. We're only seeing reading
18 up/reading down in very recent law. It's not a
19 concept that existed in prior law; it's a concept
20 that exists because of the new approach that the
21 courts have taken.
22 Dealing with the third approach that
23 Canada takes to deal with the absence of the promise
24 standard in prior law, what they do is point to
25 various statements of commentators' text. But in

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1 most cases the commentators are just using promise
2 in that same innocuous way that they used it in
3 prior law, so speaking of the promise result. And,
4 most importantly, not one of the commentators
5 actually cites to Canadian cases that use this
6 analysis of looking to the disclosure and then
7 implying or finding an elevated promise. Of course,
8 if they did I'm sure Canada would have cited those
9 cases in support of an elevated promise standard.
10 I will turn now to the second aspect of
11 the promise utility doctrine, which is the bar on
12 post-filing evidence of utility. As Ms. Cheek had
13 explained, before the law changed with the Supreme
14 Court of Canada's decision in 2002 -- and this
15 requirement, the disregarding of post-filing
16 evidence, does absolutely date to AZT 2002. It's
17 the extra disclosure requirement that's uncertain
18 because the court alluded to it but then never
19 applied it, and then it wasn't until 2008 that it
20 actually was applied. So dealing with the bar on
21 post-filing evidence, as Ms. Cheek had explained,
22 before this change operable inventions essentially
23 couldn't be challenged -- successfully challenged --
24 on the basis that they lacked utility because
25 post-filing evidence could always be used to show

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1 that there is utility in fact. And it was often
2 commercial success that was used as that post-filing
3 evidence but, as Ms. Cheek noted, it could be other
4 forms of post-filing evidence as well. And the
5 change in the law is reflected in this passage from
6 the 2005 decision, and that's Exhibit C-209 in the
7 record, and the court observes, now 2005 -- so post
8 AZT -- "There is no question that the '206 patent
9 turned out to be a useful invention. However, this
10 sort of 'after the fact validation' was specifically
11 rejected by the Supreme Court of Canada in
12 Wellcome" -- that's the AZT case -- "Thus, the fact
13 that three compounds within the '206 patent later
14 turned out to have commercial value is of no
15 assistance."
16 Then you contrast this to a pre 2002 case
17 where post-filing evidence of commercial success of
18 the plaintiff's apparatus was proof of utility. The
19 law changed with AZT, and that's very clear, but
20 Canada doesn't concede even that.
21 Why do we say the law changed? Again,
22 there's numerous cases in the record showing that,
23 prior to AZT, post-filing evidence was admitted to
24 show utility, and its commercial success, but also
25 infringement, and that makes sense as a matter of

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1 equity because, if you're alleging invalidity based
2 on inutility just so you can turn around and sell a
3 copy of the same product, you know, there's a bit of
4 an equity issue there.
5 But in terms of all these cases that admit
6 post-filing evidence what Canada's expert Mr. Dimock
7 has said is that these cases were all about
8 operability. They were really about whether the
9 invention works as of the date of challenge. That's
10 what people were fighting about in these cases --
11 although that doesn't seem to make sense because why
12 would you even be infringing a product that you
13 didn't think had usefulness today?
14 It also shows the change in the law rather
15 than disproving it because the prior law cases were
16 all about whether the invention worked because
17 evidence was admissible (post-filing evidence) to
18 show that it worked, and so that was necessarily the
19 issue, was the product useful in fact.
20 There's no cases where the challenger
21 could make the argument that utility wasn't met
22 because it wasn't demonstrated or predicted as of
23 the date of filing. So yes, the cases are about
24 operability, but that proves the point rather than
25 disproving it, because post-filing evidence of

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1 operability was admissible.
2 We also know that the bar on post-filing
3 evidence is new with AZT because the Supreme Court
4 in Canada overturned prior jurisprudence that had
5 admitted post-filing evidence, and you can see they
6 overturned, it was discussed in the AZT case, and
7 Exhibit C-44 is the Ciba-Geigy case and post-filing
8 evidence was admitted in that case, and AZT also
9 overturned in the court below it, the Federal Court
10 of Appeal, and you can see what the Federal Court of
11 Appeal had decided in AZT, which is C-117. "In
12 other words, so long as an inventor can demonstrate
13 utility or a sound prediction at the time a patent
14 is attacked, the patent will not fail for lack of
15 utility." That finding was overturned by the
16 Supreme Court of Canada in AZT.
17 In fact, the very case that Canada can
18 point to that first required demonstrated or
19 predicted utility to be shown as of the date of
20 filing is the decision of the Supreme Court of
21 Canada in AZT, the very decision that changed the
22 law, and in not one case before 2002 does the court
23 exclude post-filing evidence in the context of a
24 challenge to utility.
25 So how does Canada attempt to deal with

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1 this? In this case they conflate it with the
2 distinct legal principle that used to apply in
3 Canadian law and is no longer applicable, and this
4 is the issue of who was the first inventor. It used
5 to apply in Canadian law because Canada used to have
6 a first-to-invent regime. So instead of a patent
7 going to the inventor who was the first to file the
8 patent, the court had to figure out if there were
9 competing claims, who was actually the first to
10 invent the patentable subject matter. So they
11 looked at the date on which the invention had
12 actually been made and who was the first to have
13 made it, and that usually far predated the actual
14 filing of the patent application, and to try and
15 draw an analogy to these cases and what was done in
16 AZT is just a false analogy.
17 The first reason why it's a false analogy
18 or why we can see it's a false analogy is because at
19 the same time as these cases were being decided,
20 there were challenges to utility. Yet, as we've
21 reviewed, post-filing evidence was admissible in
22 that context and there's no case which decided it.
23 So the fact that Canada's expert is trying to go to
24 a different patent law concept again just proves the
25 point rather than disproving it.

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1 But even if you can make some analogy
2 between these inventorship cases and challenges to
3 utility, the other thing is that it was simply not
4 true that in these cases you had to have
5 demonstrated or soundly predicted utility in order
6 to be found to be the first to have invented the
7 invention. To the contrary, you'll hear from our
8 expert, Professor Siebrasse, that all that was
9 required to have made the invention was a
10 description of the invention that would allow a
11 third party to put it into practice. That was what
12 determined who had first made the invention. It
13 wasn't testing to demonstrate or soundly predict
14 utility; it was who had afforded a description to
15 the public that would allow the invention to be
16 made. So, even if you can analogize, it doesn't
17 prove the point anyway.

18 Turning to the third aspect of the promise
19 utility doctrine, which is that evidence to support
20 predicted utility now has to be in the patent
21 application itself or it will be disregarded, our
22 Canadian law experts have testified -- and this is
23 in Professor Siebrasse's First Report at paragraphs
24 64 and 65 and Mr. Reddon's Report at paragraphs 9
25 and 10 -- they have testified that the first time

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1 this new requirement was applied was in 2008, and
2 that was actually in a decision involving Lilly's
3 compound Raloxifene.

4 As is apparent from this case excerpt,
5 which is Exhibit C-119 in the record, all the
6 decisions that apply this new rule actually tie the
7 origin of the rule back to the Supreme Court of
8 Canada decision in AZT, and they refer to the rule
9 as imposing a heightened obligation. "In sound
10 prediction cases there is a heightened obligation to
11 disclose the underlying facts and the line of
12 reasoning for inventions that comprise the
13 prediction."

14 But, as I noted, AZT didn't apply this
15 test. It alluded to it, and then it wasn't until
16 2008 that it was actually applied. And our expert
17 Professor Siebrasse has testified at Paragraph 67 of
18 his Report that apart from the requirement being
19 new -- and you probably already have this sense --
20 the rule is also internally inconsistent and it's
21 lacking in a rational basis. And it was quite
22 surprising for that reason. And you can see that in
23 the Strattera example, because what happened there
24 is the claimed utility was treatment for ADHD, but
25 the court read the elevated promise, so long-term or

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1 chronic, clinical effectiveness which was the
2 promise, and so Lilly had the MGH study available
3 pre-filing, but because there was that elevated
4 promise that was read Lilly had argued this study
5 demonstrates utility, we've got it, and the court
6 said well, no, it doesn't, it's not good enough.

7 They looked at the study and they examined
8 it and they concluded well, it's not for clinical
9 efficacy; this study doesn't show that. So then
10 Lilly wished to say well, at the very least it's
11 predictive of utility, in which circumstance the
12 court said well, it may be, and they didn't decide
13 the issue. They said it may be but now we can't
14 look at it because it's not in the patent
15 application itself.

16 As our experts have opined this is
17 unprincipled and it's unsound, because if the
18 disclosure in the patent is required for the
19 patentee to meet their end of the patent bargain,
20 then it would be required whether utility was
21 demonstrated or whether it was based on prediction.
22 In fact, you're not going to know whether that's the
23 case. There didn't used to be a line, a solid line,
24 between those two things because post-filing
25 evidence was admissible so it's normally the case

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1 that you demonstrated utility. Now sound
2 predictions become very important and, yet, this
3 evidence is excluded if it's not in the patent
4 itself.

5 Also as part of this case we say the new
6 additional rule is contrary to patentees' basic
7 expectations. Our expert, Professor Erstling, has
8 testified in this proceeding that patentees often
9 file their patents based on an international
10 application, and the Strattera patent was filed
11 under the Patent Cooperation Treaty -- PCT -- and
12 that's a standardized application that's used
13 globally and there's no requirement to disclose
14 proof of the utility within that patent application.
15 In fact, not only is there no requirement; it's not
16 permitted for member countries to impose that as an
17 additional form and contents requirement, so it's
18 contrary to the patentees' basic expectations when
19 they're relying on the PCT for their filing that you
20 would have this imposed; it's contrary to their
21 expectations even knowing that the rule now exists;
22 and, of course, not knowing that the rule existed
23 because the law changed, they would never have
24 expected that and don't have any way to deal with
25 it.

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1 So putting aside whether it's rational or
2 not, what is it that shows that the rule is new?
3 Well, there are several indications. One of these
4 is noted by Professor Siebrasse, our expert, in his
5 Second Report at Paragraph 74. He's explained that
6 there were cases that considered the issue of sound
7 prediction of utility post AZT, and, yet, they
8 considered evidence that was not in the patent in
9 that context because they didn't read the AZT
10 decision as having created this additional
11 disclosure requirement. So there is uncertainty
12 after AZT and prior to 2008 when the rule was
13 applied.

14 In addition, as you can see from this
15 citation on the slide which is from a 2014 case, at
16 Exhibit C-48 in the record, even today the courts
17 don't know the scope of the rule and continue to
18 debate its application. Justice Rennie in a case
19 wondered or opined that it should be limited to
20 certain types of patents, new use patents. That was
21 the type of patent that Strattera is. But other
22 judges have disagreed and continue to apply the rule
23 more broadly.

24 But, as in the other cases, the best
25 evidence to show that the rule is new is that in no

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1 case prior to 2008 did the court apply this
2 additional disclosure rule and hold that evidence to
3 support utility had to be in the patent itself.
4 There's no case. No case where they look and say
5 we're dealing with sound prediction so we've got to
6 exclude evidence that's not in the patent itself.

7 And so Canada relies on the same types of
8 arguments presented with respect to the other
9 aspects. First there is an issue of semantics so,
10 as I said, no case excluded evidence on this basis
11 but some decisions do contain a statement that
12 Canada has picked up on, and it's an uncontroversial
13 proposition that's made in patent law that a claim
14 will be valid if it does not go beyond the
15 consideration given by the disclosure. So Canada
16 says well, that means you had to have disclosed all
17 your proof that you're relying on in the disclosure
18 part of your patent. That's what that means.

19 But our expert, Professor Siebrasse, has
20 explained, at paragraphs 70 and 71 of his Second
21 Report he deals with this issue, that this statement
22 expresses nothing more than the basic patent law
23 principle that part of the consideration for
24 obtaining the patent is that you have to disclose to
25 the world how to make the invention. That's the

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1 basic consideration. In fact, in some of the older
2 cases that use this language, the Olin Mathieson
3 case you'll hear about in particular which was
4 received into Canadian law, it's clear that that
5 case considered all kinds of evidence from outside
6 of the patent when looking at whether utility was
7 predicted, but they use this same language because
8 it's a motherhood type of patent law statement.

9 Again, secondly, Canada points to certain
10 statements made by commentators, most of whom just
11 repeat this same type of language, consideration
12 given by the disclosure, which doesn't mean that you
13 had to include proof or evidence to support utility
14 within the patent itself.

15 So, third point of argument, speculation.
16 Having failed to show that the promise utility
17 doctrine or any aspect of it existed in prior law,
18 Canada attempts to justify the application of this
19 new utility requirement by saying that it exists to
20 deter speculation and was applied to Lilly's patents
21 for that reason. An overarching point is that, even
22 if this were true, it doesn't disprove that the law
23 was new and was applied retroactively to revoke
24 Lilly's patent rights, but it's also false on every
25 level.

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1 As evidenced by the presentation made to
2 you by Ms. Cheek, the patents in issue were not
3 speculative. They were extraordinarily supported by
4 human clinical studies at the date of filing. And
5 that's an unusually high amount of testing done pre
6 patent in the pharmaceutical context. So, if the
7 role was to deter speculative patenting, then the
8 rule shouldn't have been applied in this case.

9 Canada has also attempted to paint Lilly
10 as having engaged in more broad speculative
11 patenting practices, and that is not relevant, for
12 one, but it's also not supported. Canada has put in
13 the record patent applications relating to
14 olanzapine, which is the compound for Zyprexa, and
15 atomoxetine, which is the compound for Strattera, as
16 well as a third compound, Raloxifene, that relates
17 to drugs that are not at issue in this case.

18 They've put in the applications and they
19 are applications for a number of different uses of
20 these compounds, and the mere fact of the
21 applications is what they are relying on to say that
22 Lilly engaged in speculative patenting practices.

23 There's a couple of points on this, the
24 first being that, when Lilly filed these patents,
25 there was no obligation to include proof or evidence

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<p style="text-align: right;">81 10:53</p> <p>1 of utility in the patent itself, so there's nothing 2 to say that there isn't proof or evidence existing 3 outside the patents that supports those uses. More 4 fundamentally, it's simplistic to conclude that the 5 applications were speculative when filed based 6 solely on the fact that applications were filed for 7 multiple uses, because it's a basic principle in 8 patenting and it's a basic scientific principle that 9 a single molecule may support many different medical 10 uses based on its activities. So there's no 11 evidence at all that any of these applications were 12 speculative when filed, and so Canada says well, 13 they were abandoned so that shows that they were 14 speculative. But that doesn't show the patents were 15 speculative when filed prior to abandonment. 16 The Seven IP Scholars made submissions as 17 one of the amici in these proceedings, and they 18 noted that patenting of pharmaceutical inventions 19 necessarily occurs at an early stage of product 20 development because you need the patent in order to 21 make the research and development that's necessary 22 to bring the products to market. But very few 23 products actually make it to market. And if later 24 testing shows that the product won't be viable, or 25 if there's just no market for the product, then a</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">82 10:54</p> <p>1 patent may be abandoned, and in that case the 2 invention is disclosed. It's publicly available. 3 It's made available to the world. So abandonment 4 does not equate to speculation. 5 In fact, contrary to Canada's assertion 6 that the utility requirement today has a sound 7 policy basis, the Seven IP Scholars also confirmed 8 Lilly's submissions made in this proceeding that the 9 dramatically elevated standard that applies today 10 may actually make it impossible for patentees to 11 obtain or maintain pharmaceutical patents at all, 12 because if you're holding patentees to a requirement 13 to have large-scale clinical trials, that amount of 14 clinical evidence, those studies usually have to be 15 disclosed for ethical reasons. You can't conduct 16 the studies without disclosure. Yet that disclosure 17 gives rise to at least a risk that, when you go to 18 file your patent application, it may be found that 19 your invention has been anticipated. It won't meet 20 the requirements that the invention be new. So this 21 elevated utility standard puts patentees in a 22 catch-22 type of situation. So it doesn't create 23 the seamless garment of the law that Canada's 24 expert, Mr. Dimock, has referred to; it actually 25 does the opposite, or has the potential to,</p> <p style="text-align: center;">www.dianaburden.com</p>
<p style="text-align: right;">83 10:56</p> <p>1 depending on what kind of promise is read and how 2 elevated it is. 3 A final point is that the speculative 4 patenting justification put forth by Canada is also 5 undermined by the fact that this requirement today 6 is arbitrary and unpredictable and inconsistent in 7 its application, and I submit to you that that makes 8 it incapable of serving this kind of policy 9 justification. A standard that's based on what the 10 patentee is found to have promised about the 11 invention can't serve a rational policy-based 12 objective of trying to determine whether the 13 requisite utility actually exists. 14 Take this example. The law says that 15 you're eligible to obtain a driver's license if you 16 pass the standardized test so a young man goes to 17 take his driver's test and he says to the licensing 18 officer when I take this test I'm going to be as 19 good as a Formula 1 racer. So he takes the test and 20 the licensing officer thinks to himself, you know, 21 he really was not as good as a Formula 1 driver, 22 this guy is not a professional driver but he passed 23 the standardized test. If he passes the 24 standardized test he is entitled to a driver's 25 license, because that's what a standardized test</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">84 10:57</p> <p>1 does. It establishes the requirement that you have 2 to meet in order to obtain the license or do what it 3 is that the law requires you to do. And that's what 4 would be required to deter speculation. Not a 5 variable requirement that's based on what a court 6 finds to be promised in the patent disclosure or 7 even implies from the disclosure. 8 Equally as fundamental a law cannot be 9 considered to play a role in deterring speculation 10 when it doesn't give a patentee adequate notice of 11 what would be required before a patent is filed or 12 what would be required to maintain the patent once 13 granted due to the way that it is found to 14 arbitrarily and inconsistently apply from case to 15 case. 16 When such vastly different outcomes are 17 produced in similar cases, or even when dealing with 18 the same patent, it's just not possible to assert 19 that as a justification or to present this as having 20 a rational policy foundation. In any event, we say 21 that that argument is not relevant. 22 SIR DANIEL BETHLEHEM: I have a question. 23 THE PRESIDENT: Let's do it before the 24 break. 25</p> <p style="text-align: center;">www.dianaburden.com</p>

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1 QUESTIONS BY THE ARBITRAL TRIBUNAL
2 **SIR DANIEL BETHLEHEM:** This is really to
3 try and disentangle some things in my own mind.
4 You seem to be running three arguments
5 together. You can either tell me I've got it
6 completely wrong, or otherwise what I'd like you to
7 clarify is whether you are running three arguments
8 together or whether they are three separate
9 arguments.
10 The first line of argument you seem to be
11 presenting is that the new test is too onerous or
12 arbitrary or unprincipled or unsound -- you've used
13 a number of different words to describe. Possibly
14 the second line of argument is the evidential
15 shortcomings that the new test does not adequately
16 take account of historic information and does not
17 permit post-filing evidence, and then there's a
18 potentially a third line of argument which is simply
19 that the test is new and that it applies
20 retroactively.
21 I would just like you to clarify for me
22 whether this is a single line of argument or whether
23 there are three separate lines of argument in the
24 alternative.
25 **MS. WAGNER:** I think it's more of a single

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1 line of argument. Just dealing with the evidentiary
2 standard first, just in terms of imposing such a
3 high requirement that you can't meet it as a
4 patentee, we wouldn't phrase that as just an
5 evidentiary requirement, so it's the package that
6 makes it difficult to surpass the requirement.
7 Even today, even if you knew that this law
8 existed, that problem would still exist. So even if
9 you were filing a patent application today, that
10 problem would still exist because it's almost
11 impossible to know how the court is going to read a
12 promise in a given case. There's still
13 unpredictability. Even if you knew that the law
14 exists as it exists today, it would still be very
15 difficult for patentees I guess is the answer to
16 that. But I think an additional real unfairness
17 comes into play when it's applied retroactively, as
18 happened in this case, to patents that were filed at
19 a time when the law didn't exist. So then you had
20 no capability of dealing with any of the changes at
21 all.
22 I don't think that that erases the
23 difficulty that patentees filing today would have in
24 dealing with the law, but from Lilly's perspective
25 in this case the retroactivity made it exceedingly

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1 difficult.
2 Then the policy-based arguments I made
3 were essentially just to -- Canada uses those
4 policy-based arguments to sort of divert attention
5 away I think from what are the central issues in the
6 case, which is how difficult the law is to deal
7 with, whether you knew it existed or not, and how
8 impossible it is to deal with having been applied
9 retroactively. The policy-based arguments are
10 really Canada's arguments. They're really the gloss
11 that they put on it to try and say no, this always
12 existed and it always existed for this reason. I
13 think in that sense they're a bit subsidiary but
14 also play into the arguments we've made about
15 arbitrariness, and the fact that the law is applied
16 discriminatorily to pharmaceutical patents.
17 So I think all are very relevant but
18 probably to different aspects of our case, and maybe
19 when we get into the legal argument we'll try and
20 unpack that for you to a greater extent.
21 **SIR DANIEL BETHLEHEM:** Just to note that
22 I'd be grateful, when you do get into legal
23 argument, that you could unpack them because it
24 seems to me that different elements may be relevant
25 to different things but, because you're putting them

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1 all together in a single bundle, it's not quite
2 clear to me how you see them playing out into all
3 the legal arguments.
4 **THE PRESIDENT:** Thank you. Recess for
5 15 minutes, so at 11:20 we resume.
6 *(Recess taken)*
7 **THE PRESIDENT:** Let's resume.
8 Ms. Cheek, you have 77 minutes left,
9 according to the calculation of the Secretary of the
10 Tribunal.
11 **MS. CHEEK:** Very good. Thank you. We
12 will have Mr. Smith resume. He's going to discuss
13 how Canada is an outlier compared to the other NAFTA
14 parties, as well as the discriminatory effects of
15 the doctrine on the pharmaceutical sector, and then
16 Mr. Berengaut and I will do our legal argument.
17 **THE PRESIDENT:** Thank you. Mr. Smith,
18 please proceed.
19 **MR. SMITH:** Thank you. Canada's adoption
20 of this elevated utility test is a striking
21 departure not only from Canada's traditional utility
22 requirement, as my colleagues explained this
23 morning, but also from established practice in other
24 NAFTA countries.
25 In Question No. 10 the Tribunal asked

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<p style="text-align: right;">89 11:24</p> <p>1 about the relevance of the utility standards in the 2 other NAFTA jurisdictions with respect to Claimant's 3 claims. The utility standards in the United States 4 and Mexico, which I will summarize, are relevant to 5 our claims in two respects. Factually they 6 demonstrate that the change in utility is unique to 7 Canada, and legally they inform the interpretation 8 of capable of industrial application consistent with 9 Article 31 of the Vienna Convention, which provides 10 for interpretation based on subsequent practice in 11 the application of the treaty which establishes the 12 agreement of the parties.</p> <p>13 In both the United States and Mexico, the 14 bar for utility was low when NAFTA entered into 15 force. That was so in Canada as well with its 16 traditional requirement. Unlike in Canada, however, 17 utility in the United States and Mexico has remained 18 a low bar consistent with widely shared 19 international practice. Canada's new promise 20 utility doctrine is a clear outlier.</p> <p>21 Canada's sharp divergence from its NAFTA 22 partners is evident from two sources: first, from 23 the legal requirements for utility in the U.S. and 24 Mexico, which on their face are nothing like 25 Canada's promise utility doctrine, and, second, from</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">90 11:25</p> <p>1 practice in the U.S. and Mexico, where utility is 2 very rarely challenged and almost never the basis 3 for denial or invalidation.</p> <p>4 In the United States the legal test for 5 utility, as Professor Robert Merges has explained, 6 is a straightforward inquiry focused on operability. 7 In multiple respects the U.S. test diverges from 8 Canada's promise utility doctrine. First, utility 9 is tested according to the claimed invention. The 10 invention need only have one or "a" utility. An 11 asserted utility is presumed to be true, and basic 12 operability is all that is required, not proof of 13 efficacy or of commercial viability.</p> <p>14 The U.S. Patent Office's Manual Of 15 Patenting Examining Procedure makes clear that the 16 utility test for pharmaceutical inventions is this 17 same low bar. For patents that assert a therapeutic 18 use, mere identification of a pharmacological 19 activity satisfies the utility requirement, and the 20 manual also emphasizes that courts have found 21 utility for therapeutic inventions, despite the fact 22 that the applicant is at a very early stage in the 23 development of the pharmaceutical product. Notably, 24 U.S. courts have also rejected tests that resemble 25 Canada's promise utility doctrine.</p> <p style="text-align: center;">www.dianaburden.com</p>
<p style="text-align: right;">91 11:27</p> <p>1 In Raytheon v Roper, for example, the 2 court made clear that a failure to accomplish all 3 requirements stated in the patent is not a basis to 4 invalidate for lack of utility: "When a properly 5 claimed invention meets at least one stated 6 objective, utility is clearly shown."</p> <p>7 Likewise, in In re Gottlieb, the court 8 emphasized that "Having found that the antibiotic is 9 useful for some purpose, it becomes unnecessary to 10 decide whether it is in fact useful for other 11 purposes 'indicated' in the specification as 12 possibly useful."</p> <p>13 In Mexico as well the bar is low as 14 Professor Hilda Gonzalez has explained. Mexico's 15 utility standard requires that an invention must be 16 "susceptible" of industrial application. This means 17 industrial application must be plausible, not 18 certain or proven. Specifically, Mexico's 19 industrial property law defines industrial 20 application as "the possibility of an invention 21 having a practical utility or being produced or used 22 in any branch of economic activity". A 23 "possibility" in Mexico is enough.</p> <p>24 During examination at IMPI, the Mexican 25 Institute of Industrial Property, there is no</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">92 11:28</p> <p>1 requirement that applications include evidence to 2 prove industrial applicability. So long as there is 3 a basis to believe that the invention can possibly 4 be produced or used in any branch of economic 5 activity Mexico's test is met. Like the U.S., 6 Mexico has also declined to raise the bar for 7 utility; its Congress in 2010 rejected a proposal 8 that would have changed this word "possibility" in 9 the definition to "fact".</p> <p>10 In sum, the legal tests for utility in the 11 U.S. and Mexico are nothing like Canada's promise 12 utility doctrine, but this divergence in law is 13 reflected also in practice, as this graphic makes 14 clear.</p> <p>15 In the United States utility challenges 16 are exceedingly rare. According to one study only 17 five challenges on utility were decided in U.S. 18 courts over an 8-year period when NAFTA entered into 19 force. Overall, utility was therefore disputed in 20 just 2 percent of the case sample, and only one 21 patent fell for lack of utility in that set of 239 22 cases.</p> <p>23 In Mexico there's no evidence of even a 24 single patent application being denied for lack of 25 industrial applicability, nor is there evidence of</p> <p style="text-align: center;">www.dianaburden.com</p>

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1 even a single patent being declared invalid on that
2 ground in a nullity proceeding.
3 In Canada, by contrast, utility is
4 routinely challenged. A majority of all patent
5 validity rulings since 2005 include a decision on
6 utility, some 53 percent, and in the pharmaceutical
7 sector at least no fewer than 28 such challenges
8 have been successful.
9 Canada does not meaningfully dispute that
10 its doctrine is an outlier in North America.
11 Instead Canada makes two fallback points, neither of
12 which withstand scrutiny. Its first offense is an
13 attempt to widen the lens beyond utility to other
14 distinct patent law doctrines. Canada argues that
15 the U.S. and Mexico have similar requirements under
16 different labels. For example, that enablement and
17 written description in the United States play the
18 same role as the promise utility doctrine in Canada.
19 But enablement and written description are distinct
20 requirements from utility. They serve different
21 purposes. In no way do they resemble Canada's
22 promise utility doctrine. That difference is clear
23 not just in terms of doctrine but also in terms of
24 outcomes.
25 If Canada were correct, patents found to

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1 lack utility by Canadian courts would be falling on
2 enablement or written description in the United
3 States but, as you heard this morning, neither of
4 the patents at issue in this case was invalidated in
5 the United States.
6 Canada's second defense is to assert that
7 each NAFTA party from the start had its own
8 distinctive approach to utility and that the U.S.
9 and Mexican tests have changed over time. As an
10 initial matter we have not argued that NAFTA
11 harmonized patent laws in North America. What we
12 have argued is that NAFTA establishes a substantive
13 baseline of protection that Canada has failed to
14 respect, and Canada is simply wrong to suggest that
15 utility standards differed across North America. At
16 the time NAFTA entered into force the test was
17 similar in all three countries, and a low bar. This
18 basic understanding in North America reflects
19 practice also in the rest of the world, where the
20 core principle of the utility requirement that an
21 invention have some practical use is widely shared.
22 But Canada's promise utility doctrine is
23 not only an outlier. It also discriminates against
24 pharmaceutical patents. The effects of the doctrine
25 have been concentrated in the pharmaceutical sector,

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1 exclusively so. Not a single patent in any other
2 sector has been found invalid for lack of utility
3 since 2005. This disparity across sectors is stark
4 and also consistent, no matter how the numbers are
5 presented.
6 This slide [68] presents an updated
7 version of Figure 3 from our Memorial. It's based
8 on data analyzed by Professor Bruce Levin. Since we
9 filed the Memorial in September 2014 there have been
10 14 additional utility rulings, and the picture
11 remains the same. There's been a dramatic shift in
12 the pharmaceutical sector. In the early period
13 utility was rarely challenged in that sector and
14 never successfully but, since 2005, given the change
15 in Canada's test, utility challenges have spiked and
16 28 cases (41 percent) have been successful.
17 Second, there's been no change across all
18 other sectors. Both before and after 2005 there
19 were relatively few challenges, and over more than
20 three decades there have been only two judicial
21 rulings in any other sector invalidating a patent
22 for lack of utility, and none since 2005 after the
23 advent of Canada's new test.
24 Canada has attempted to change this basic
25 picture in various respects. It has argued that the

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1 increase in overall pharmaceutical patent litigation
2 is the real cause of these changes, and that a
3 similar pattern of increased litigation in that
4 sector is apparent in the United States. This is
5 the graph that Canada put into its Rejoinder, for
6 example. But the overall volume of patent
7 litigation can't explain the dramatic change in the
8 rate of successful utility challenges. That change
9 has taken place only in Canada, not in the U.S., and
10 only in the pharmaceutical sector. Again, the
11 increase in the rate is specific to the
12 pharmaceutical sector and to the recent period.
13 Canada has also taken the position that
14 the vast majority of rulings in this chart,
15 decisions and cases under the Patented Medicines
16 (Notice of Compliance) Regulations, what we call
17 PM(NOC) cases, should not be considered at all. But
18 this is incorrect. There is no basis to exclude
19 such cases where judges apply the same substantive
20 law in precedential decisions that have significant
21 effects in the marketplace. Canada has further
22 attempted to muddy this picture by suggesting that
23 we should have counted patents, not cases; that a
24 few individual cases were coded inappropriately; and
25 still other cases should be counted twice, both as

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1 wins and as losses. But these various changes, as
2 Lilly's witnesses will explain, either are of no
3 consequence or are entirely unjustifiable.
4 At the end of the hearing this same clear
5 picture will remain. Canada's promise utility
6 doctrine has had a significant and disproportionate
7 impact on pharmaceutical innovators.
8 This sharp contrast in terms of litigation
9 outcomes is unambiguous but it's not the only
10 evidence of discrimination. Two other indicia are
11 significant.
12 First, well known features of the drug
13 development process discussed by Ms. Wagner are
14 driving the disproportionate impact of Canada's
15 elevated test. Pharmaceutical innovators must seek
16 patent protection early. To delay for additional
17 testing creates the risk of a patent defeating
18 disclosure. This is well known and therefore it is
19 no surprise that the dramatic change in Canada's
20 test has harmed innovators only in this sector.
21 Second, all of the innovative
22 pharmaceutical companies whose patents have been
23 challenged for lack of utility in Canada are foreign
24 investors. Every pharmaceutical innovator in the
25 cases represented on this chart is based outside of

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1 Canada. By contrast the generic companies
2 challenging those patents have major operations in
3 Canada where many are based or were founded.
4 To conclude, in multiple respects Canada
5 is out of line. Neither the United States nor
6 Mexico has anything like the promise utility
7 doctrine. Only Canada is revoking patents on
8 plainly useful inventions, all of which are in the
9 pharmaceutical sector. Thank you.
10 **THE PRESIDENT:** Thank you, Mr. Smith.
11 Ms. Cheek, you will continue with the expropriation?
12 **MS. CHEEK:** Yes. Very good.
13 I will be discussing our expropriation
14 claim, and Mr. Berengaut will discuss our fair and
15 equitable treatment claim. The questions that were
16 raised before the break related to the relevance of
17 arbitrariness to our legal arguments, and the
18 relevance of the change in the doctrine to our legal
19 arguments will be addressed by Mr. Berengaut when he
20 discusses our fair and equitable treatment claim.
21 Before we get to the specifics of the
22 claims for expropriation and fair and equitable
23 treatment, I did want to go back to Canada's
24 arguments that Lilly's claims are novel. Canada is
25 wrong about the merits of Lilly's claims and their

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1 consequences, but they are right about one thing,
2 and that is this case is novel but not in the way
3 that Canada suggests. We are not asking you to
4 usurp the sovereignty of states or invade the
5 jurisdiction of other tribunals.
6 Rather, there are two novel issues that
7 are really raised by Canada's defenses in this case.
8 The first is should intellectual property rights, a
9 protected investment under the Treaty, should
10 intellectual property rights be subject to lesser
11 protection than other protected investments. And
12 the second novel issue raised by Canada's defenses
13 is should this Tribunal grant special or new
14 immunities for courts for measures that are
15 otherwise inconsistent with the substantive rules of
16 international law.
17 Canada's defense would require this
18 Tribunal to reach an answer of yes on both of those
19 questions, but as we will demonstrate at this
20 hearing this Tribunal should decline both of those
21 invitations. Rather than create special rules for
22 intellectual property or special rules for the
23 courts, this Tribunal should apply the same tried
24 and true analysis that international law would
25 require in any other case.

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1 Of course, Article 1110 requires that
2 there be an investment that is capable of being
3 expropriated, and here Lilly has two, the Zyprexa
4 and the Strattera patents. In response to Question
5 No. 19 by the Tribunal about whether Lilly's patents
6 constitute property that's capable of being
7 expropriated -- and there was an additional question
8 about whether Canada's argument to this effect is
9 untimely -- in the first instance, as we said in our
10 Reply at Paragraph 230, we do think that this was
11 raised belatedly and therefore is not really before
12 the Tribunal under UNCITRAL Rule 21(3), but in any
13 event, setting aside the untimeliness of the issue,
14 the fact that these courts found these patents to be
15 void ab initio does not have the significance that
16 Canada asserts. As a factual matter Lilly held
17 valuable exclusive rights to this invention up until
18 the moment that the Canadian courts revoked those
19 patents. And as a legal matter, because the
20 Canadian court decision revoking those patents is
21 the very measure that Lilly is challenging in this
22 proceeding, the fact that Lilly's patents were
23 declared void ab initio by the courts is irrelevant.
24 Canada's second defense is that this
25 Tribunal should grant a new immunity to national

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<p style="text-align: right;">101 11:38</p> <p>1 courts for measures that are inconsistent with a 2 substantive norm of international law. Yet, it is 3 well established that Canada is responsible for the 4 acts of its judiciary. 5 As Ian Brownlie observed, when it comes to 6 the expropriation of foreign property "form should 7 not take precedence over substance. The essence of 8 the matter is the deprivation by state organs of a 9 right to property." And that's CL-60. 10 Further, as the Tribunal observed in 11 <i>Rumeli Telekom v Kazakhstan</i> (CL-58): "Whereas most 12 cases of expropriation result from an action by the 13 executive or legislative arm of a state, a taking by 14 the judicial arm of a state may also amount to an 15 expropriation". And that is the case we have here. 16 In a case such as this one where the 17 judiciary has made substantive law, just like the 18 Parliament or an executive branch agency might) and 19 then apply that law, just like an agency might, this 20 Tribunal should decline Canada's invitation to 21 shield the acts of its third branch of government 22 from scrutiny. So the starting point then for our 23 analysis is whether or not there was a substantial 24 deprivation under Article 1110. 25 Here Canada's measures plainly satisfy the</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">102 11:40</p> <p>1 standard because the application of the promise 2 utility doctrine to Lilly's patents resulted in a 3 substantial deprivation of Lilly's property rights. 4 And the Tribunal asked as your Question No. 21 5 related to the implications of Canada's argument 6 that Lilly has not been substantially deprived of 7 its investment because it continues to sell Zyprexa 8 and Strattera. 9 The fact that Lilly can produce and sell 10 Zyprexa and Strattera does not mean that the 11 protected investments in this arbitration, the '113 12 and the '735 patents, have not been substantially, 13 or really in this case completely, deprived of 14 value. Because what patents are is a bundle of 15 exclusive rights to make, sell and use the 16 invention, and when Canada invalidated these patents 17 it deprived Lilly of those exclusive rights and its 18 ability to enforce those exclusive rights against 19 others. So there was a complete deprivation of 20 property rights in this case of the protected 21 investment in this arbitration. So while a 22 substantial deprivation is a necessary and sometimes 23 sufficient criteria for an expropriation under the 24 sole effects doctrine, we've acknowledged, in the 25 case of a judicial expropriation, not every judicial</p> <p style="text-align: center;">www.dianaburden.com</p>
<p style="text-align: right;">103 11:41</p> <p>1 action resulting in a loss of an investment or a 2 substantial deprivation of property is going to be 3 an expropriation under Article 1110. In this case 4 not every judicial patent revocation is an 5 expropriation. Rather, Article 1110 is engaged by 6 measures that substantially deprive an investment of 7 value while violating a substantive rule of 8 international law. 9 <i>Saipam v Bangladesh</i> (CL-62) exemplifies 10 this rule. There the Tribunal explained that the 11 most significant criteria to determine whether the 12 disputed actions amount to an expropriation is the 13 impact of the measure. Second, the Tribunal 14 recognized that, since judicial revocation of 15 property rights always results in a substantial 16 deprivation of those rights, it's also necessary to 17 demonstrate the unlawful character of the actions. 18 Third, that Tribunal went on to find that 19 one of the ways in which those judicial measures at 20 issue were unlawful is that they constituted a 21 substantive violation of the New York Convention. 22 So where Canada's courts have fundamentally changed 23 their utility test, revoked Lilly's patents and in 24 the process violated a substantive rule of 25 international law, this Tribunal has the authority</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">104 11:42</p> <p>1 and, indeed, the responsibility to award 2 compensation to Lilly as an injured investor. 3 Now, Canada seeks to distinguish <i>Saipem</i> 4 and the other cases such as <i>ATA v Jordan</i> that we 5 cited for this proposition on the grounds that they 6 involved property rights that were acknowledged to 7 exist. Canada's Rejoinder at Paragraph 125 says 8 Claimant relies upon cases in which courts 9 interfered with or extinguished rights that were 10 acknowledged to be valid in domestic law. But this 11 is false. As you can see on slide 75, in <i>Saipem</i>, 12 the Bangladesh court -- and here this is the <i>Saipem</i> 13 decision at Paragraph 50 quoting the court -- the 14 Bangladesh court held that as a legal matter there 15 was no arbitration award to annul because the 16 arbitration had been unlawful. Whether that award 17 was a nullity was very much in dispute, just as 18 whether or not the underlying patent here should be 19 revoked or whether it was valid was similar in the 20 underlying dispute. 21 And so in <i>Saipem</i> the Bangladeshi courts 22 conclude that a non-existent award can neither be 23 set aside nor enforced. In other words, it's 24 precisely the opposite of what Canada claims. These 25 cases are like Lilly's case which is before you in</p> <p style="text-align: center;">www.dianaburden.com</p>

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1 that both there and here, there had been rights at
2 issue in domestic courts that were declared void as
3 a matter of domestic law but that did not preclude
4 the Tribunal from looking to see if the court's
5 actions violated international law.

6 Now, the Tribunal asked in Question 23
7 whether a denial of justice is a prerequisite for a
8 finding of expropriation based on a judicial
9 measure. And there the answer is no. Article 1110
10 does not create any special rules for judicial
11 measures and nor does customary international law.
12 And while Canada identifies cases where claims for
13 judicial expropriation were pled based on a denial
14 of justice, it identifies no authority for the
15 proposition that a denial of justice is the only
16 theory of liability. And again, the Saipem Tribunal
17 reached the same conclusion, noting that -- this is
18 at Paragraph 181 of the Saipem award -- while the
19 Tribunal concurs with the parties that expropriation
20 by the courts presupposes that the court's
21 intervention was illegal this does not mean that
22 expropriation by a court necessarily presupposes a
23 denial of justice."

24 So what is the substantive rule of
25 international law that Canada has breached? In this

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1 case it is chapter 17, the intellectual property
2 rights chapter of NAFTA.

3 **THE PRESIDENT:** May I ask a question on
4 that one before you continue? I try to connect now
5 the legal dots, not the factual dots. In order to
6 have an expropriation claim under 1110 of
7 Chapter 11, it is your position, your client's
8 position, that the expropriation occurred because of
9 violations of Section 1709, 1, 7 and 8, amongst
10 others, in the context of the expropriation.

11 How do you get legally 1709 into 1110, if
12 I may use these shorthands? I know your arguments
13 about 1110(7), interpretation of the revocation of a
14 patent, but is there also another way you argue that
15 it should be in under 1110? For example, Saipem?

16 **MS. CHEEK:** That's correct. We think
17 those are two alternative paths that the Tribunal
18 could follow, that you could follow the logic in the
19 Saipem case, whereas you could find that there is an
20 independent breach of international law where the
21 government measures at hand are directly related to
22 that international breach and there's a nexus, just
23 like there was in Saipem there's a nexus here, so
24 you can follow the independent logic that that
25 Tribunal did.

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1 Secondly, there is an alternative avenue
2 to take, and that is through specifically the
3 provision of 1110(7), which I'll also come to
4 address in a moment.

5 **THE PRESIDENT:** Thank you.

6 **MS. CHEEK:** I guess the one thing I would
7 say in follow-up, Mr. President, is that we don't
8 think it's strictly necessary, as in Saipem, that
9 the Treaty rule be found in the same arbitration
10 agreement. It happens to be found in the same
11 arbitration agreement in our case. It's chapter 17
12 of the NAFTA free trade agreement. But we would
13 argue that there is some limit. Like I said, the
14 rule needs to apply to the government measures at
15 issue and there needs to be some nexus.

16 For us perhaps it's simpler than in the
17 Saipem case because chapter 17 is part of the North
18 American Free Trade Agreement, and those
19 intellectual property rights provisions apply to
20 Canada and Canada has not objected to that notion,
21 so I think it's common ground that Canada has
22 obligations under these specific intellectual
23 property provisions related to patents.

24 **THE PRESIDENT:** Maybe you will address it
25 later. If you take that route and you take the

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1 Saipem route, as argued by the Claimant in this
2 case, would you not import an entire universe of
3 international law into potential violations leading
4 to an expropriation?

5 **MS. CHEEK:** No, I don't think that that's
6 the case. I think that there are limiting
7 principles. For example, in Saipem, in ATA v
8 Jordan, they look to the New York Convention. The
9 issue was an underlying arbitration award, and there
10 was relevance between the two in that the
11 international treaty at issue, the New York
12 Convention, specifically applied to the ICC Award,
13 the investment that was the subject matter of this
14 dispute.

15 So here you would have a similar nexus.
16 You could look to these IP obligations that directly
17 relate to obligations to grant and maintain patents,
18 but it wouldn't mean, for example, that you could
19 reach to international human rights conventions, for
20 example, and that would be beyond the scope. So I
21 do think that there's limits. This doesn't mean
22 that you can reach to any international treaty.

23 **THE PRESIDENT:** For example, the violation
24 of the Patent Cooperation Treaty. The Respondent
25 argues wait a moment, you cannot argue that in this

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1 basis because that is not within the scope of the
2 expropriation provisions. But you are saying yes,
3 it is.

4 **MS. CHEEK:** I was not referring to the
5 Patent Cooperation Treaty as much as I was referring
6 to chapter 17.

7 **THE PRESIDENT:** Sorry, assuming that it
8 contains substantive provisions, because that's also
9 not a contentious point between the parties.

10 **MS. CHEEK:** Right.

11 **THE PRESIDENT:** But you are specifically
12 now looking at the NAFTA provisions, at chapter 17?

13 **MS. CHEEK:** We are looking at the NAFTA
14 provisions. We are not basing our expropriation
15 claim on a violation specifically of the PCT. The
16 PCT we think is relevant to our expectations and
17 it's relevant to understanding Canada's utility
18 requirement, but we do not see Canada's violation of
19 the PCT as an independent basis on which to find an
20 expropriation in this case.

21 **THE PRESIDENT:** Okay. Please proceed.

22 **MS. CHEEK:** We have not asserted that.
23 Could we have asserted it because there is a clear
24 nexus between that treaty and the measures that are
25 challenged here? Perhaps we could. But that is not

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1 the case that we've put before you.

2 **THE PRESIDENT:** Could a violation of
3 chapter 17, in your submission, also have led to a
4 state-to-state under Chapter 20?

5 **MS. CHEEK:** Yes, it could.

6 **THE PRESIDENT:** Thank you.

7 **MS. CHEEK:** I think actually this now
8 takes me to 1110(7), and this is the additional
9 basis, if do you not purely follow Saipem, in which
10 we think you can look to chapter 17 to determine
11 whether Canada's measures are expropriatory.
12 Article 1110(7) establishes that judicial measures
13 that violate chapter 17 may engage Article 1110.
14 Slide 77 is on your screen. If you want to look at
15 it in paper in the mini bundle we provided you
16 selected treaty provisions and it's behind tab 1,
17 page 271.

18 It says, "This article does not apply to
19 the issuance of compulsory licenses granted in
20 relation to intellectual property rights or to the
21 revocation, limitation or creation of intellectual
22 property rights, to the extent that such issuance,
23 revocation, limitation or creation is consistent
24 with chapter 17."

25 As you know, Canada argues that 1110(7) is

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1 only a shield and not a sword, but this defies logic
2 and the plain reading of Article 1110(7)
3 particularly in light of the decision of the one
4 NAFTA Tribunal that's addressed analogous language
5 in 1110(8), and I'll get to that in a moment.

6 So the necessary implication of
7 Article 1110(7) is that patent revocations that
8 violate chapter 17 can be expropriatory. And having
9 granted this Tribunal competence to examine chapter
10 17 violations and acknowledging that chapter 17 is
11 relevant to intellectual property expropriation, as
12 Canada has, Canada would then force this Tribunal to
13 put blinders on and, when Lilly sets out its
14 affirmative case, you don't have jurisdiction to
15 look to chapter 17. But you take those blinders off
16 when Canada puts forward its defense of its
17 compliance with chapter 17. But there is nothing in
18 the language of the Treaty that supports that view.

19 Canada argues that this provision,
20 1110(7), says nothing about whether the measure is
21 expropriatory, and Canada states correctly that it's
22 an if/then statement. That if a measure is
23 consistent with chapter 17, it does not engage
24 Article 1110.

25 Now, Canada, at Paragraph 220 of its

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1 rejoinder, likens this statement to if it is
2 raining, the streets must be wet.

3 Canada claims that Lilly's position is the
4 inverse of this proposition, which is that if it's
5 not raining, the streets must not be wet, or if a
6 measure is inconsistent with chapter 17, then it
7 necessarily engages Article 1110. But our view is
8 not as categorical as Canada has put forward. Our
9 view is not that every violation of chapter 17 is
10 going to engage 1110.

11 What we're arguing is that the violation
12 of chapter 17 is highly relevant to your
13 determination as to whether or not there's been an
14 expropriation of intellectual property rights.
15 Knowing it's not raining is relevant to determining
16 whether the streets are wet. Canada, by contrast,
17 would have you believe that chapter 17 is totally
18 irrelevant to whether this measure is an
19 expropriation or not. Or, to use Canada's
20 hypothetical, Canada argues that knowing it's not
21 raining tells you nothing about whether the streets
22 might be wet or not. And that defies common sense.

23 Now the one Tribunal that's looked at
24 1110(8) had a consistent view. 1110(8) is also at
25 Tab 2 of your Treaty bundle. The language is a bit

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1 different. The point here in Waste Management v
2 Mexico the Tribunal considered this provision and
3 what this underlying provision, 1110(8), meant or
4 signified about the breadth of the underlying
5 obligations under Article 1110. The Tribunal
6 concluded, CL-65, Paragraph 144, "It is true that
7 Paragraph 8 is stated for greater certainty but if
8 it was necessary, even for certainty's sake, to deal
9 with such a case this suggests that the drafters
10 entertained a broad view of what might be tantamount
11 to expropriation."
12 So the Waste Management Tribunal correctly
13 recognized that the language of 1110(8) is relevant
14 to whether or not an expropriation, or measures
15 tantamount thereto, had occurred. Similarly,
16 Article 1110(7) is relevant to the circumstances in
17 which the revocation of a patent constitutes an
18 expropriation. When NAFTA's drafters carved out a
19 category of measures from Article 1110 in only
20 certain circumstances, they implied that such
21 measures otherwise could fall within the scope of
22 Article 1110.
23 The Tribunal submitted to us Question
24 No. 20 regarding Article 1110(7) and whether, if one
25 were to accept Canada's submissions that its actions

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1 are consistent with chapter 17, what effect that
2 would have on Lilly's claims under Article 1110. If
3 the Tribunal finds that Canada is acting
4 consistently with chapter 17, that its measures
5 here, the revocation of the Zyprexa and Strattera
6 patents are consistent with chapter 17, then by its
7 plain terms of Article 1110(7), Article 1110 would
8 not apply. It is a defense for Canada. But by the
9 same token, if you find an inconsistency with
10 chapter 17 and you find that a substantial
11 deprivation has occurred, as in this case, then
12 there is a substantial deprivation, there is a
13 violation of a substantive rule of international
14 law, and that leads to a violation of 1110.
15 I am now going to turn to the underlying
16 violations of chapter 17. In the interests of time,
17 I'm going to mostly respond to the Tribunal's
18 questions that have been submitted. Let me make one
19 more comment about the language of 1110(7) and
20 whether or not every violation of Chapter 17, for
21 example, would be a violation of Chapter 1110.
22 Like I said, one, you need a substantial
23 deprivation. Frankly, that's accepted in this case.
24 The patents were revoked. There was a substantial
25 deprivation of the value of the investment. But you

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1 could see, if there is just a limitation or a
2 creation or some of these other issues that 1110(7)
3 refers to, the Tribunal would have to do more work
4 presumably to determine whether there had been a
5 substantial deprivation in the value of the property
6 that's at issue.
7 Second, this is a judicial expropriation,
8 and so there needs to be some kind of finality to
9 it.
10 Third, what you'll see in a moment when we
11 get to Chapter 17, not every Chapter 17 violation
12 would necessarily constitute a taking. But we
13 believe that the four provisions that we've
14 identified are violations of international law that,
15 combined with the fact that the investment at issue
16 was revoked, do constitute an expropriation under
17 1110.
18 So let me turn to Chapter 17 now.
19 **THE PRESIDENT:** Before you do that, simply
20 to understand your argument under 1110(7), you rely
21 basically on the final proviso "to the extent that",
22 is that correct? What it says was this article does
23 not apply to revocation of intellectual property
24 rights, so that would take it out as the carve-out.
25 Then you get it back in by "to the extent that" is

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1 consistent with Chapter 17, and you say the first
2 test you as a Tribunal have to do is to see whether
3 it complies with the revocation, with the provisions
4 of Chapter 17.
5 **MS. CHEEK:** Do you mind repeating?
6 **THE PRESIDENT:** I ask the question to find
7 out where my reasoning is not following yours.
8 What it is is if you take this provision
9 without the final proviso of "to the extent that"
10 Chapter 17 would not be in, correct?
11 **MS. CHEEK:** That's correct. If this
12 provision simply said "This article does not apply
13 to the issuance of compulsory license or the
14 revocation, creation or limitation of intellectual
15 property rights", that's correct, it would not
16 apply.
17 **THE PRESIDENT:** Now we go on, because you
18 have to read the complete thing. It says "To the
19 extent that revocation" -- and I skip a number of
20 words which I think is not relevant for your case --
21 "revocation is consistent with Chapter 17", and
22 since you have that in you say you, Tribunal, have
23 first to figure out whether the revocations were
24 consistent with Chapter 17.
25 **MS. CHEEK:** Exactly. That language tells

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1 you that to the extent that the measures at hand are
2 consistent or inconsistent with Chapter 17 is
3 relevant to the inquiry that's before the Tribunal.
4 **THE PRESIDENT:** And when you find that
5 they are not consistent, then the first part of this
6 article doesn't apply, and you say for that reason
7 1110 applies to the inconsistent measures.
8 **MS. CHEEK:** Well, I do think you need to
9 read 1110(7) as a whole, and you need to read it in
10 the context of 1110. So I think --
11 **THE PRESIDENT:** I try simply to see
12 whether I can follow your argument. It is no
13 criticism on your side, it is criticism on my own
14 side, maybe slow thinking in how this works out,
15 what you have presented to us.
16 **SIR DANIEL BETHLEHEM:** So it's right that
17 you are seeing 1110(7) both in terms of its
18 substantive provisions but more importantly from
19 your perspective, as I understand your argument, you
20 are seeing it as a gateway. So if through 1110(7)
21 you can get to Chapter 17, that means -- I think the
22 language you used was it's not a one-way street, is
23 that right?
24 **MS. CHEEK:** It's not a one-way street. I
25 don't know that I would call it a gateway.

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1 Obviously when you're looking at whether or not
2 there's an expropriation, you're looking at the
3 character of the measure, and one thing that is very
4 relevant to the character of this measure is that it
5 violates Chapter 17 and 1110(7) acknowledges that.
6 But certainly that means it is a two-way street,
7 because it's relevant both to the affirmative case
8 and the defensive case.
9 Now I will talk about the underlying
10 violations of Chapter 17. As I mentioned, in the
11 interests of time I'm mainly going to respond to the
12 Tribunal's questions that you've submitted, but of
13 course I'm happy to pause at any time.
14 The first is Article 1709(1), which
15 requires Canada to provide a baseline level of
16 patent protection. And Article 1709(1) imposes a
17 mandatory obligation to make patents available for
18 inventions that meet the three core patentability
19 requirements. Such inventions are new, result from
20 an inventive step -- that's the non-obviousness
21 test -- and are capable of industrial application.
22 The promise utility doctrine as applied to
23 the Stratterra and Zyprexa patents is an
24 impermissible additional utility requirement that
25 was applied to invalidate these patents up and above

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1 the mere scintilla of utility test that we
2 discussed. The Tribunal asked at Question No. 8
3 about the meaning of "shall make patents available"
4 in this provision. "Shall make patents available"
5 imposes a mandatory obligation to provide patents
6 for inventions that satisfy the three core
7 substantive patentability requirements -- new,
8 non-obvious, and useful. Those are the three
9 requirements of patentability of an invention. If
10 those three substantive requirements are met, then
11 the patent shall issue.
12 Now, you can put additional conditions on
13 a patent grant. You can say you have to maintain
14 fees, for example, or that you need to provide a
15 disclosure. But those do not detract from the fact
16 that if the substantive patentability requirements
17 are met, then you are obligated to grant a patent,
18 or make that patent available and provide that
19 patent to the inventor.
20 **MR. BORN:** How do you deal with Canada's
21 argument that enablement isn't included on this
22 list?
23 **MS. CHEEK:** Enablement is not a question
24 of patentability per se but has more to do with the
25 disclosure part of patentability -- or not

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1 patentability but requirements for a patent. For
2 example, NAFTA doesn't have language to this effect,
3 but TRIPS does. TRIPS categorizes enablement and
4 disclosure as conditions for getting a patent, so
5 there are other conditions you can place on awarding
6 the patent grant, but these are the three
7 substantive tests for whether an invention is a
8 patentable invention.
9 **MR. BORN:** So enablement and disclosure
10 are like fees or timing obligations?
11 **MS. CHEEK:** Right. I mean they are
12 perhaps more hefty than a fees requirement, but they
13 effectively are other conditions that you may place
14 on a patentee as to whether the patent's ultimately
15 granted. What's at issue here is the substantive
16 patentability requirements. And particularly for
17 these two patents, these kind of issues related to
18 was there sufficient disclosure, these patents were
19 found to have sufficient disclosure. So for our
20 purposes all of those other issues in the context of
21 these revocations ended up being off the table since
22 they were struck down solely on the basis of not
23 satisfying the utility requirement.
24 Because of that, because these are the
25 three substantive requirements for patentability,

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<p style="text-align: right;">121 12:07</p> <p>1 and this goes to the evidence that Mr. Smith 2 presented about the utility requirement in Mexico 3 and the United States and the relevance of that, 4 when the NAFTA parties signed this agreement there 5 was a common understanding that utility was a low 6 bar and that it was the mere scintilla test, what 7 it's called in Canada and, therefore, this language 8 is meaningful.</p> <p>9 Let me get to another question that was 10 posed to us in advance and that was Question No. 9, 11 which is as of what date was Respondent in breach of 12 its Chapter 17 obligations. You also asked about 13 the relevance of the 2002 AZT case in this context.</p> <p>14 Canada has been in breach of its 15 obligations under Chapter 17 since 2005, and those 16 violations continue to this day. Now, the 17 post-filing evidence rule in AZT is critically 18 important, as we described earlier this morning, but 19 it was not until that rule was married with the 20 promise of the patent that Canada began denying 21 patents to otherwise useful pharmaceutical 22 inventions.</p> <p>23 The Tribunal also asked at Question No. 11 24 about the implications for our claims if the 25 Tribunal accepts Canada's submission that these are</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">122 12:09</p> <p>1 several distinct patentability rules, all of which 2 were part of Canadian law at the time we filed our 3 patents. Now, I think as you probably took away 4 from Ms. Wagner's presentation this morning, we 5 strongly disagree that Canada has shown that any of 6 these three aspects of the promise utility doctrine 7 were part of Canadian law prior to 2002, and we 8 don't think it's at all similar to what the courts 9 are doing today. But even if all three aspects had 10 existed in prior law, it was not until 2005 that 11 they were married together in a way that resulted in 12 the invalidation of pharmaceutical patents as well 13 as invalidation of our patents. So we're looking at 14 the utility test that was applied to our patents in 15 2010 and 2011, and the way in which they now work 16 together, this utility requirement, is the utility 17 test that we're looking at for purposes of whether 18 Canada is in violation of its Chapter 17 19 obligations.</p> <p>20 For the sake of completeness the Tribunal 21 also asked a question related to the Patent 22 Cooperation Treaty which I think I already answered 23 at least in part, and that is for purposes of the 24 case that we've put before you, the Patent 25 Cooperation Treaty, also under the Vienna</p> <p style="text-align: center;">www.dianaburden.com</p>
<p style="text-align: right;">123 12:10</p> <p>1 Convention, should be considered a relevant rule of 2 international law that's applicable to the relations 3 between the parties, since the PCT applied among the 4 NAFTA parties since 1995 and did include a 5 definition of capable of industrial application or 6 industrial applicability, even though there's not a 7 definition in NAFTA itself. And the PCT, as I did 8 already mention, is relevant to Lilly's 9 expectations, particularly with regards to the PCT 10 application it had filed and then transposed into 11 the domestic process in Canada.</p> <p>12 But Mr. Berengaut will discuss Lilly's 13 legitimate expectations in a moment.</p> <p>14 Let me now turn to the second underlying 15 violation of Chapter 17, and that's 1709(7), which 16 says that patents "shall be available and patent 17 rights enjoyable without discrimination as to the 18 field of technology."</p> <p>19 Article 1709(7) bars de facto 20 discrimination, measures that produce differentially 21 disadvantageous effects irrespective of whether 22 they're motivated by discriminatory intent. 23 Throughout this case Canada has not disputed that 24 1709(7) is violated by measures that are de facto 25 discriminatory. So that's common ground.</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">124 12:12</p> <p>1 What it has strenuously tried to show is 2 that there's not disproportionate effects on the 3 pharmaceutical industry, but, as Mr. Smith 4 explained, there are discriminatory effects here, 5 and we will go through some of that evidence in more 6 detail with the experts that will appear before you.</p> <p>7 If Lilly can demonstrate disproportionate 8 effects, that's sufficient to show a violation of 9 1709(7). But for the first time in Canada's 10 comments on the Article 1128 submissions in this 11 case, Canada suggested that there must also be 12 discriminatory objectives, is what it said. That's 13 Canada's submission at Paragraph 43.</p> <p>14 Canada has not argued that previously. 15 They also actually didn't argue it in the WTO 16 proceeding against Canada, Canada Pharmaceuticals, 17 which the U.S. Government relied on for this 18 proposition. So our view is that actually the law 19 here is you need not show discriminatory objectives, 20 if you will.</p> <p>21 But this does go to another question the 22 Tribunal has asked us, Question No. 18, which asks 23 Lilly to elaborate on Canada's discriminatory intent 24 which Claimant says can be inferred from the 25 objective characteristics of the promise utility</p> <p style="text-align: center;">www.dianaburden.com</p>

<p style="text-align: right;">125 12:13</p> <p>1 doctrine.</p> <p>2 So, as I mentioned, the only case that's</p> <p>3 been relied on by the United States, and now</p> <p>4 belatedly Canada, for this notion is the WTO case</p> <p>5 that I mentioned. In that WTO case, Canada</p> <p>6 Pharmaceuticals, there was no evidence of</p> <p>7 discriminatory effects put forward. So without any</p> <p>8 evidence of discriminatory effects, in stark</p> <p>9 contrast to the case here, that Tribunal was trying</p> <p>10 to determine how else they might evaluate the claim</p> <p>11 and so they looked to the discriminatory objectives.</p> <p>12 In that context, what you look at is not animus or a</p> <p>13 subjective intent but you look at the objective</p> <p>14 characteristics of the challenged measure.</p> <p>15 Here, the way the courts have articulated</p> <p>16 and applied the utility requirement, the promise</p> <p>17 utility doctrine in Canada, the way that it requires</p> <p>18 heightened proof and human clinical trials, being</p> <p>19 able to demonstrate clinical efficacy at the time of</p> <p>20 patent filing, what we've shown is it would be</p> <p>21 extremely difficult -- if not impossible in many</p> <p>22 cases -- particularly if the promise is long-term</p> <p>23 clinical effectiveness in humans -- based on the way</p> <p>24 pharmaceuticals are developed and taken to market,</p> <p>25 you will never have that evidence at the time you</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">126 12:15</p> <p>1 file for a patent. That explains why there's such a</p> <p>2 disproportionate effect on pharmaceuticals in this</p> <p>3 case. There's a reason why there's zero percent</p> <p>4 inutility decisions in any other field of</p> <p>5 technology, but it's a 41 percent inutility rate for</p> <p>6 pharmaceutical inventions.</p> <p>7 Let me turn to 1709(8), that Canada's new</p> <p>8 utility requirement is retroactively applied to</p> <p>9 invalidate Lilly's Strattera and Zyprexa patents.</p> <p>10 Article 1709(8) says a party may revoke a patent</p> <p>11 only when grounds exist that would have justified a</p> <p>12 refusal to grant the patent. The provision here is</p> <p>13 violated because of Canada's new and additional test</p> <p>14 for utility that did not exist when these patents</p> <p>15 were granted.</p> <p>16 Canada mentions in its comments on the</p> <p>17 Article 1128 submissions that Lilly said that this</p> <p>18 means the NAFTA parties must freeze their patent</p> <p>19 laws, but that's not what we have argued and that is</p> <p>20 not the case here. Here, Canada has two utility</p> <p>21 standards, where it used to have one. The one, the</p> <p>22 mere scintilla standard, was met by the Zyprexa and</p> <p>23 Strattera patents when those patents were granted.</p> <p>24 As I mentioned, no questions were even raised as to</p> <p>25 the utility of the patents when granted. It's the</p> <p style="text-align: center;">www.dianaburden.com</p>
<p style="text-align: right;">127 12:16</p> <p>1 second additional requirement that's new, the</p> <p>2 promise utility doctrine, that was then only later</p> <p>3 applied to revoke these patents.</p> <p>4 The fourth underlying violation of chapter</p> <p>5 17 is 1709(1) which provides that each party shall</p> <p>6 provide in its territory to the nationals of another</p> <p>7 party adequate and effective protection and</p> <p>8 enforcement of intellectual property rights. Here,</p> <p>9 the promise utility doctrine and using the promise</p> <p>10 utility doctrine to revoke these patents has made it</p> <p>11 so there is not adequate and effective protection of</p> <p>12 intellectual property rights, and in the interests</p> <p>13 of time I think we'll rest on our papers with</p> <p>14 regards to the rest of our arguments on the</p> <p>15 underlying violations of Chapter 17.</p> <p>16 Before I pass the baton to Mr. Berengaut,</p> <p>17 the Tribunal did actually ask another question that</p> <p>18 I want to make sure I address, which is Question No</p> <p>19 22, and that was about the criteria to establish</p> <p>20 direct expropriation in this case. To the extent</p> <p>21 you view this as a direct expropriation, we wanted</p> <p>22 to be clear that there's no requirement that</p> <p>23 Claimant -- that Lilly -- demonstrate that this</p> <p>24 investment was transferred to the state or</p> <p>25 transferred by the state to another third party.</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">128 12:18</p> <p>1 And multiple cases have recognized that an</p> <p>2 expropriation, whether direct or indirect, may occur</p> <p>3 if an investment is destroyed, which is what</p> <p>4 happened here. And we address that further in our</p> <p>5 Reply at Paragraph 311.</p> <p>6 So let me conclude on our Article 1110</p> <p>7 claim. Canada insists that its court decisions</p> <p>8 cannot be scrutinized in the expropriation context.</p> <p>9 It insists that if you can scrutinize the actions of</p> <p>10 its courts, it can only be done in the context of</p> <p>11 denial of justice. It then insists that</p> <p>12 Article 1110(7) is only a shield but not a sword.</p> <p>13 It's irrelevant to your determination if there is an</p> <p>14 expropriation.</p> <p>15 Further, if you reach Chapter 17, Canada</p> <p>16 says under Chapter 17 it has infinite flexibility to</p> <p>17 set its patentability requirements.</p> <p>18 But what's the result of Canada's</p> <p>19 restrictive approach and its shrinking obligations</p> <p>20 in the case of intellectual property rights?</p> <p>21 Canada's restrictive approach would make</p> <p>22 intellectual property rights subject to lesser</p> <p>23 protections than other protected investments.</p> <p>24 Second, it would provide a new immunity to national</p> <p>25 courts for measures that are inconsistent with</p> <p style="text-align: center;">www.dianaburden.com</p>

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1 substantive norms of international law in an
2 expropriation context.
3 With that, I will hand it to my colleague,
4 Mr. Berengaut, to talk about Lilly's 1105 fair and
5 equitable treatment claim.
6 **THE PRESIDENT:** Thank you. Mr. Berengaut?
7 **MR. BERENGAUT:** Thank you. One
8 preliminary before I get started on 1105, which is
9 in response to your question, Mr. President, about
10 the circumstances in which a Claimant can reach
11 outside the Treaty to invoke a substantive rule of
12 international law in relation to Saipem, I thought
13 it would help the Tribunal to note that Bangladesh
14 ran that exact argument in Saipem and the Tribunal
15 addressed it in paragraphs 164 and 165, and that is
16 CL-62.
17 Turning to Article 1105, this provision,
18 as the Tribunal knows, requires states to afford
19 fair and equitable treatment to the protected
20 investments of foreign investors, and it is
21 undisputed that, under the FTC note, the Tribunal
22 should analyze the fair and equitable treatment
23 standard by reference to the minimum standard of
24 treatment under customary international law.
25 Now, what is also clear, however, is that

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1 the minimum standard of treatment under customary
2 international law has been shaped by the fair and
3 equitable treatment standard embodied in the
4 thousands of BITs that have been executed. This is
5 language from Chemtura where the Tribunal noted that
6 "In holding that Article 1105(1) refers to customary
7 international law, the FTC interpretations
8 incorporate current international law, whose content
9 is shaped by the conclusion of more than 2,000
10 bilateral investment treaties and many treaties of
11 friendship and commerce."
12 Given that these standards mutually
13 influence each other it is not surprising that
14 multiple tribunals have held that the two standards
15 have effectively converged both inside and outside
16 of the NAFTA context. This is the Merrill & Ring
17 decision within the NAFTA context, where the
18 Tribunal held that the fair and equitable treatment
19 standard has "become sufficiently part of widespread
20 and consistent practice so as to demonstrate that it
21 is reflected today in customary international law as
22 opinio juris. In the end, the name assigned to the
23 standard does not really matter. What matters is
24 that the standard protects against all such acts or
25 behavior that might infringe a sense of fairness,

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1 equity and reasonableness".
2 Outside the NAFTA context as well, this is
3 from the Biwater case, the Tribunal accepted as
4 found by a number of other arbitral tribunals and
5 commentators, that the actual content of the fair
6 and equitable treatment standard is not materially
7 different from the content of the minimum standard
8 under customary international law.
9 While the Tribunal would accordingly be on
10 firm footing in relying on decisions involving
11 treaty-based fair and equitable treatment standards,
12 it is not necessary for it to do so in this case
13 because each of the three components of Lilly's
14 Article 1105 claim -- legitimate expectations,
15 arbitrariness and discrimination -- are part of the
16 minimum standard. Now, earlier during our
17 presentation, Sir Daniel, you asked about the
18 relevance of two factual propositions that
19 Ms. Wagner discussed. One was the fact of change in
20 the law, as I recall, and the other was
21 arbitrariness of the promise utility doctrine.
22 The fact of change in the law is centrally
23 relevant to Lilly's legitimate expectations claim
24 because Lilly's legitimate expectations, as I'll
25 discuss in a moment, were rooted in the Canadian law

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1 at the time they filed their Zyprexa and Strattera
2 patent applications, and the arbitrariness of the
3 doctrine as it was applied in the Zyprexa and
4 Strattera cases is also an independent basis under
5 Article 1105 for concluding that Canada's measures
6 are in breach of that article, and we'll discuss
7 both of those headings in detail.
8 Before I do that, though, I'd like to
9 respond to the Tribunal's Question No. 13 in regard
10 to whether denial of justice is the only basis for
11 liability for judgments of domestic courts
12 interpreting domestic law as argued by the
13 Respondent.
14 Ms. Cheek has addressed this point with
15 regard to Article 1110, and it is worth noting at
16 the outset that Canada's argument fails for the same
17 reason under Article 1105. Denial of justice is one
18 theory of liability for judicial measures but it is
19 not the only theory, and a ruling to the contrary
20 would create a broad immunity for national courts
21 for measures that violate international law and
22 would have the effect of treating some countries,
23 i.e. those that articulate new legal rules more
24 frequently through the courts, better than others,
25 those that articulate new legal rules more

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1 frequently through legislatures and executive
2 branches.
3 As Judge Aréchaga has put it (Professor
4 Paulsson's Denial of Justice treatise) "the obvious
5 objection [to Canada's position] is that denial of
6 justice and State responsibility are not
7 co-extensive expressions, and that State
8 responsibility for acts of the Judiciary does not
9 exhaust itself in the concept of denial of justice."
10 In the specific context of Article 1105,
11 Canada's argument is belied by the multiple
12 tribunals, Limian Caspian, RL-27, White Industries
13 CL-157, Frontier Petroleum, RL-67, which interpret
14 both the fair and equitable treatment standard and
15 the minimum standard of treatment, that considered
16 not just whether a judicial measure represents a
17 procedural denial of justice but also whether it is
18 substantively discriminatory, arbitrary and in
19 conflict with legitimate expectations.
20 Along the way, these tribunals have
21 expressly rejected Canada's argument. This is from
22 Limian Caspian. In that case the Tribunal noted
23 that courts have a different function from other
24 branches of government, yet it "still saw merit in
25 Claimants' argument that the two standards are not

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1 synonymous [that is fair and equitable treatment and
2 denial of justice] with regard to acts of courts
3 because this would introduce a distinction between
4 acts of courts and acts of other State entities for
5 which no support is provided" -- in that case by the
6 ECT, but of course, NAFTA provides no support for
7 drawing a distinction in this context either.
8 In the particular context of NAFTA the
9 Mondev Tribunal, and this is CL-7, implicitly
10 recognized that a judicial measure could violate
11 Article 1105 irrespective of its procedural
12 fairness. In Paragraph 134 the Tribunal discussed a
13 rule articulated by the judiciary which could be
14 interpreted as "affording governmental prerogative
15 to violate investment contracts".
16 The Tribunal held that this substantive
17 rule would appear to be inconsistent with the
18 principles embodied in Article 1105 but ultimately
19 held that it need not reach this question because
20 the relevant rule had not clearly been adopted by
21 the Massachusetts court and was not the basis for
22 the Massachusetts court's decision.
23 Canada meanwhile lacked support for the
24 proposition that denial of justice is the only
25 theory of liability for judicial measures. In fact,

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1 Canada really identifies only a single source that
2 stands for the proposition that denial of justice is
3 the only theory of liability, and that is an article
4 by Professor Zachary Douglas, R-323. That article,
5 however, does not identify any authority to support
6 Professor Douglas' and Canada's preferred rule. In
7 fact, the only authority discussed in the relevant
8 portion of Professor Douglas' article is the
9 Frontier Petroleum decision which Professor Douglas
10 criticizes. The reason he criticizes it, of course,
11 is because it contradicts him and adopts the view
12 that denial of justice is not the exclusive theory
13 of liability for judicial measures under the minimum
14 standard.
15 In short, the Tribunal should apply the
16 same tools of analysis to judicial measures as it
17 would to a measure of legislative or executive
18 branches. Any other approach would grant a special
19 immunity to courts and have the effect of treating
20 some countries better than others.
21 I will turn now to the three aspects of
22 Lilly's article --
23 **THE PRESIDENT:** You say that you turn now
24 to the three aspects but before you do that, may I
25 ask you a question? Go back to slide 84. You

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1 argued -- and please correct me if I'm wrong in my
2 paraphrasing you -- look, the current standard of
3 international law, of the customary international
4 law on the FTC interpretation is the FTC said look,
5 you have to do only the minimum standard, and you
6 said no, that may be so, but these standards, the
7 minimum standards, has converged basically to one
8 standard, and you point to the Chemtura decision.
9 **MR. BERENGAUT:** Yes.
10 **THE PRESIDENT:** And you disagree with
11 Glamis?
12 **MR. BERENGAUT:** We do.
13 **THE PRESIDENT:** I understand that. Can
14 you help me? Has the note of 2001 actually become
15 redundant to make this interpretation by the
16 Commission? When you say actually, because of the
17 convergence, there is only one standard?
18 **MR. BERENGAUT:** Yes, I would say that is
19 our position, and we believe there is authority both
20 inside the NAFTA context and outside of NAFTA that
21 the two standards have converged. And, you're
22 right, that as a logical matter, stating that
23 Article 1105 refers to the MST would seem
24 superfluous if the two standards had converged at
25 the time of the FTC note.

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1 We obviously don't think it was
2 superfluous at the time but our view is the
3 authorities have recognized since then that
4 convergence has occurred. Of course, we don't rest
5 on that point because we believe for each of the
6 heads of argument under Article 1105 -- legitimate
7 expectation, arbitrariness and discrimination --
8 there is ample legal basis for our position if you
9 look solely at MST cases, but as a legal matter
10 you're correct. We believe convergence has
11 occurred.

12 **THE PRESIDENT:** I am only asking; I don't
13 take a position on this one -- not yet.

14 The point is this. You say at the time
15 the FTC interpretation was issued in 2001 there was
16 a difference because what I understand is that the
17 FTC interpretation was prompted by decisions like
18 Pope & Talbot and a number of others at the time,
19 and the states got a little bit worried about
20 arbitral tribunals not going wild. Let me
21 paraphrase the situation at the time.

22 But you say since then the thing has
23 settled and tribunals have now issued
24 interpretations that converge the MST standard to
25 the effect that the interpretation of the FTC has

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1 become redundant.

2 **MR. BERENGAUT:** Yes, that's our position
3 now. Just to be clear, I don't know that I would
4 concede that at the time of the FTC note the two
5 standards had not converged. The FTC note may have
6 just been to reflect the parties' view on that but,
7 irrespective of that point, the Tribunals, since the
8 FTC note, which were for the first time forced to
9 confront this issue, have analyzed and recognized
10 the proposition of convergence.

11 **THE PRESIDENT:** I see. So is it then your
12 position that actually the FTC note is superfluous
13 on that point?

14 **MR. BERENGAUT:** I guess from our
15 perspective it's an academic question because,
16 whether or not it was superfluous at the time, it
17 has become superfluous by this point, in light of
18 the arbitral decision since that FTC note.

19 **THE PRESIDENT:** When three states sit
20 together and issue an interpretive note, it is not
21 an exercise in the sky -- we call it sky-cycling --
22 they have something in mind to do something
23 effective. Or am I wrong on that?

24 **MR. BERENGAUT:** No, we wouldn't dispute
25 that, but from our perspective it's not a point on

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1 which we focus because it's not a point on which we
2 rely.

3 **THE PRESIDENT:** But the other side
4 responds and says look, basically you have to apply
5 the Neer standard and Glamis, because that's the way
6 they read, as far as I understand it, the MST
7 interpretive note.

8 **MR. BERENGAUT:** Right. Well, the other
9 side has certainly advocated for that narrower
10 interpretation of Article 1105.

11 From my perspective that's a bit of a
12 different issue than the question how much of a
13 substantive change the FTC note affected at the time
14 it was enacted, because as decisions like Waste
15 Management and other more recent decisions have
16 recognized, even if you're looking solely at the
17 minimum standard, Neer and Glamis are unduly
18 restrictive.

19 **THE PRESIDENT:** I'm afraid I have stirred
20 a debate.

21 **MR. BORN:** You don't really mean that the
22 note is superfluous, I guess, in the sense that the
23 note makes clear that Tribunals should not derive a
24 separate and autonomous meaning from fair and
25 equitable treatment that could be entirely detached

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1 from the minimum standard?

2 **MR. BERENGAUT:** Yes, that's a fair
3 characterization.

4 **MR. BORN:** Instead what you say is that
5 the minimum standard, in fact, has converged to a
6 proper reading of fair and equitable treatment?

7 **MR. BERENGAUT:** Yes, precisely so.

8 **MR. BORN:** Thank you.

9 **SIR DANIEL BETHLEHEM:** You are saying, are
10 you not -- you haven't quite put it in these
11 terms -- that conduct in the performance of a treaty
12 is relevant for purposes of the formulation of
13 customary international law?

14 **MR. BERENGAUT:** Yes. I believe that's the
15 proposition that Chemtura embraced.

16 **SIR DANIEL BETHLEHEM:** Are you going to
17 come back and address this further, specifically the
18 question of whether you can rely on conduct in the
19 performance of a treaty for purposes of opinio juris
20 and state practice as a matter of custom?

21 **MR. BERENGAUT:** I had not planned on it
22 but I'm happy to further address it if you have
23 additional questions.

24 **SIR DANIEL BETHLEHEM:** We'll leave it at
25 that. I just wanted to clarify that that's what

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1 you're saying.

2 **MR. BERENGAUT:** We are.

3 **THE PRESIDENT:** All right. You were at

4 page 90 of your slides.

5 **MR. BERENGAUT:** Thank you.

6 I guess, just to be clear, on that

7 proposition as well, the relevance of treaty

8 practice for purposes of customary international law

9 is only relevant to our case insofar as it supports

10 the principle of convergence, which we advocate for

11 but ultimately on which we don't need to rest

12 because, even if you look at the narrower universe

13 of cases interpreting the customary standard,

14 there's ample support for each of the three

15 components of our claim.

16 **SIR DANIEL BETHLEHEM:** It goes to the

17 question, though, of the relevance of the 2001

18 statement, doesn't it, because that is presumably

19 embodied by the states making the declaration a

20 particular conception of what customary

21 international law is and how it comes into being.

22 You, I think, if I recall correctly, are relying on

23 comments by Judge Schwebel, amongst others, to say

24 that really you've got to look at customary

25 international law through the prism of treaty

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1 practice. This, as I understand it, is the

2 divergence between you and the Respondent.

3 **MR. BERENGAUT:** Yes, that's a fair

4 description of the point of conflict there.

5 **THE PRESIDENT:** But when you talk about

6 the Treaty practice and you refer to the 3,000 BITs

7 or so, those are the first and the second generation

8 bits, as you might call them, and we are now in the

9 third generation BITs, for example CETA, and CETA

10 you see under a further definition of FET. Is that

11 what you ask us to look at, basically reflecting

12 current customary international law, what is now the

13 new Treaty design?

14 **MR. BERENGAUT:** That's a fair point. Just

15 as there has been an evolution of the customary

16 standard there has also been an evolution of the

17 treaty standard, and I think, yes, in our position,

18 we would want to look at the entire body of BITs

19 because all of them reflect state practice which we

20 believe is relevant to shaping the minimum standard

21 norm.

22 **THE PRESIDENT:** Thank you.

23 **MR. BERENGAUT:** Legitimate expectations.

24 On this point the Tribunal asked in Question 15

25 whether NAFTA protects investors' legitimate

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1 expectations. Again, narrowing the focus of the

2 scrutiny to only those cases interpreting

3 Article 1105 after the FTC note, many cases,

4 including Bilcon, Waste Management, Grand River,

5 Thunderbird, recognize that legitimate expectations

6 play a role in the Article 1105 analysis. Rather

7 than inflexibly revert back to state practice and

8 opinio juris anew in each case, as Canada demands,

9 these authorities consistently rely on earlier

10 arbitral awards to understand and develop the

11 governing standard.

12 As the Tribunal in Thunderbird explained,

13 the concept of legitimate expectations relates

14 within the context of the NAFTA framework to a

15 situation where a contracting party's conduct

16 creates reasonable and justifiable expectations on

17 the part of an investor or investment to act in

18 reliance on said conduct such that a failure by the

19 NAFTA party to honor those expectations could cause

20 the investor or investment to suffer damages.

21 Now, relatedly, the Tribunal has asked,

22 Questions 16 and 17, regarding whether NAFTA should

23 require that expectations be based in specific

24 representations and, if so, whether Canada's grants

25 of Claimant's patents constitute specific

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1 representations for purposes of legitimate

2 expectations.

3 Now, here, as Thunderbird and Grand River

4 recognize, reliance may be based in a state's

5 overall conduct. Here, the relevant state conduct

6 includes Canada's longstanding and well understood

7 utility requirements at the time Lilly sought and

8 received its Zyprexa and Strattera patents.

9 In any event, if the Tribunal is inclined

10 to require a specific representation for purposes of

11 Article 1105, as the Tribunal did, for example, in

12 the Mobil Murphy case relatively recently, then the

13 grant of the Zyprexa and Strattera patents plainly

14 qualifies. A patent represents a specific

15 commitment. Indeed, as Ms. Cheek discussed, it is a

16 grant of legally enforceable rights to a patentee

17 that it has the exclusive right to make, use and

18 sell an invention until expiration. In other words,

19 a patent is granted to be relied upon.

20 Now, Canada has repeatedly failed to

21 answer this specific showing, and instead, has made

22 the irrelevant assertion that courts cannot make

23 representations to foreign investors and that's from

24 Rejoinder Paragraph 265. Now, the specific

25 representations here were not made by the courts.

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1 They were made by Canada's patent office when it
2 granted the Zyprexa and Strattera patents.
3 Now, here, Lilly had a legitimate
4 expectation that its Zyprexa and Strattera patents
5 would not be invalidated on the basis of a radically
6 new utility requirement. Madam Secretary, the next
7 slide has confidential information on it so I'd
8 appreciate it if you could implement the procedure
9 of Paragraph 8.
10 **THE SECRETARY:** Can we block the video
11 feed, please? Can you note when you're finished
12 with the confidential information?
13 **MR. BERENGAUT:** I will.
14 **THE PRESIDENT:** I grant you five more
15 minutes on the condition you speak 50 percent
16 slower. I'm concerned about the court reporters.
17 **MR. BERENGAUT:** I'd be pleased to accept
18 that offer. Would you mind letting us know how much
19 time we have remaining? I appreciate there have
20 been a few questions but I don't want us to go over.
21 **THE SECRETARY:** As of now, you have
22 19 minutes left. That does not include the five
23 extra minutes.
24 **MR. BERENGAUT:** As an initial matter, it
25 is uncontroverted that Lilly, in fact, expected that

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1 its patents complied with Canada's utility
2 requirement. This is shown by the consistent
3 recollections of Lilly's witnesses, Mr. Armitage,
4 Postlethwait, Stringer and Ms. Nobles.
5 Lilly's expectations are also reflected in
6 contemporaneous documents. With regard to Zyprexa,
7 for example, Lilly's expectations are embodied in
8 the status report from 1995, and this is
9 confidential Exhibit C-130, which lists the many
10 countries in which Lilly had filed for patent
11 protection, including Canada, and notes that patents
12 are issued or pending throughout the world with the
13 expectations for issuance very good in all cases.
14 For Strattera, the contemporaneous
15 documents present a similar account. Lilly
16 developed a risk management plan relating to the
17 global launch of Strattera and patent protection was
18 not identified as a risk. And this is confidential
19 Exhibit C-156.
20 When Canada invalidated the Zyprexa and
21 Strattera patents under the promise utility
22 doctrine, it contravened Lilly's legitimate
23 expectations, irrespective of whether those
24 expectations were grounded in Canada's utility
25 requirement at the time the patents were filed, or

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1 whether those expectations are grounded in the
2 specific grants of the Zyprexa and Strattera
3 patents.
4 Canada has three basic responses to
5 Lilly's evidence of its legitimate expectations.
6 First, Canada argues -- and this is at rejoinder
7 Paragraph 281 -- that Lilly's expectations could not
8 have been legitimate because the promise utility
9 doctrine has always existed. And this goes to
10 Sir Daniel's question about the relevance of the
11 fact of change. Yet, if the Tribunal rejects this
12 proposition, as it should, for the reasons that
13 Ms. Cheek and Ms. Wagner have explained, then there
14 is no denying the fact that Lilly experienced the
15 invalidation of its patents based on a totally
16 unexpected and radically new legal requirement in
17 contravention of its legitimate expectations.
18 Second, Canada argues -- and this is
19 Counter Memorial, Paragraph 293 -- that Lilly cannot
20 rely on the recollections of its witnesses because
21 "none of them offer evidence that they had any real
22 understanding of Canadian patent law at the time",
23 and none of them even testified in support of the
24 atomoxetine and olanzapine patents before the
25 Federal Court in Canada.

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1 This answer misses the point in a few
2 respects. It ignores the contemporaneous
3 documentary evidence to which I have referred. It
4 fails to appreciate that Lilly's witness testimony
5 is relevant not because the witnesses themselves are
6 experts in Canadian patent law but, rather, because
7 they provide uncontroverted evidence of Lilly's
8 robust processes for identifying patent-related
9 risk. That no such risks were identified and
10 escalated to the leadership of the Zyprexa and
11 Strattera teams is probative of Lilly's
12 expectations.
13 Lastly, the fact that none of these
14 witnesses testified in Canadian court proceedings is
15 irrelevant since, as we have repeatedly stressed,
16 Lilly is not appealing those proceedings but,
17 instead, is bringing separate claims with entirely
18 distinct elements under NAFTA.
19 Third, Canada argues -- and this is
20 rejoinder Paragraph 282 -- that sophisticated
21 commercial parties do not predict specific
22 litigation outcomes. Accordingly, Canada implies,
23 Lilly should not have placed any reliance on the
24 grant of the Zyprexa and Strattera patents because
25 those patents could have been invalidated in

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1 litigation. Yet, as Mr. Armitage explains, this is
2 an overly simplistic portrayal of the commercial
3 reality.
4 Madam Secretary, I can now confirm that we
5 will no longer discuss confidential information.
6 **THE SECRETARY:** Excellent. Can you please
7 restart the video feed?
8 **MR. BERENGAUT:** As Mr. Armitage explains,
9 firms are certainly aware that validity litigation
10 may be a risk, just as litigation over the validity
11 of title is a risk when acquiring real property.
12 However, because most major markets offer
13 stable and predictable patent regimes, the risks
14 associated with validity challenges can generally be
15 accounted for in advance.
16 It is these risks that firms assume. What
17 firms do not expect and which risks they do not
18 assume when they invest in a country like Canada,
19 with a well-understood and longstanding utility
20 requirement, is the creation of a radically new
21 patentability requirement and the retroactive use of
22 that requirement to invalidate a patent.
23 The next relevant aspect of Article 1105
24 relates to arbitrariness. Now, it is undisputed, I
25 believe, that protection against some form of

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1 arbitrariness is encompassed within Article 1105.
2 In Paragraph 224 of Canada's Counter Memorial, for
3 example, it favorably cites Waste Management's
4 articulation of the minimum standard noting that,
5 "For there to be a breach of Article 1105, the
6 impugned conduct must be, among other things,
7 arbitrary." That's RL-14.
8 The disputed issue on the law here I
9 believe is what does it take for a measure to be
10 arbitrary. The concept of arbitrariness under
11 customary international law has been described using
12 several formulations. In this case the
13 arbitrariness of Canada's measures is manifested
14 through their incoherence and unpredictability.
15 To qualify as arbitrary under this
16 standard it is not necessary that a measure be
17 animated by animus or prejudice. It is enough that
18 a government measure has the effect of creating a
19 completely confused and unpredictable situation.
20 In *Occidental v Ecuador*, CL-97, the
21 Tribunal held that the decisions taken by SRI,
22 Ecuador's tax service, do not appear to have been
23 founded on prejudice or preference rather than on
24 reason or fact. In fact, the SRI was tasked with
25 bringing "some resemblance of order" to the

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1 confusing situation in Ecuador's administration of
2 the VAT.
3 However, it is that very confusion and
4 lack of clarity that resulted in some form of
5 arbitrariness, even if not intended by the SRI.
6 Canada has strained to distinguish
7 *Occidental*, arguing that the *Occidental* Tribunal
8 specifically distinguished the autonomous fair and
9 equitable treatment standard it was bound to apply
10 as distinct from the customary international law
11 minimum standard of treatment applicable in NAFTA.
12 In fact, the *Occidental* Tribunal found the
13 exact opposite. There, as here, the issue arose
14 whether the fair and equitable treatment standard
15 mandated by the treaty is a more demanding standard
16 than that prescribed by customary international law,
17 and the Tribunal was of the opinion that in the
18 instant case the treaty standard is not different.
19 Here there is no question that Canada's
20 promise utility doctrine is arbitrary under this
21 standard. You witnessed the incoherence and
22 confusion of the doctrine in its application to
23 *Strattera* and *Zyprexa*, as Ms. Cheek explained, but
24 you do not need to take our word for it. This is
25 the slide that Ms. Cheek showed earlier in our

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1 presentation. Apotex, Lilly's competitor and
2 Canada's largest generic company, has characterized
3 the doctrine as a "free-for-all" in which the
4 outcome of cases depends on a particular judge or
5 panel hearing the dispute rather than on legal
6 authority. "The outcome of such cases must not be
7 determined so arbitrarily". This intolerable
8 confusion should be resolved.
9 You also see it, as Ms. Cheek discussed,
10 in how confused CIPO's own examiners were by the
11 changes in Canadian law. You can also see it in the
12 outcome of cases, for example, in the *Latanoprost*
13 case, C-98 and 99, where two different Federal Court
14 panels found different promises in identical patents
15 with contradictory results. How can an inventor be
16 expected to draft an application that meets Canada's
17 utility requirement if two different courts look at
18 the same patent and apply two different standards to
19 it? As we have discussed, the promise utility
20 doctrine is arbitrary in at least three critical
21 respects.
22 First, the judges undertake the inherently
23 unpredictable task of identifying the promises in
24 the patent. As Ms. Cheek explained in the *Zyprexa*
25 and *Strattera* cases, these promises were implied

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<p style="text-align: right;">153 12:49</p> <p>1 based on the judge's subjective reading of the 2 patent. Second, judges impose an unpredictable and 3 incoherent heightened evidentiary burden which puts 4 patentees in a Catch 22. Courts are all over the 5 map in terms of the amount and type of human 6 clinical trial data to require or even whether to 7 require human clinical trial data at all. As part 8 of this standard, the promise utility doctrine 9 arbitrarily excludes post-filing evidence to support 10 utility while allowing post-filing evidence to 11 establish a lack of utility.</p> <p>12 Third, the promise utility doctrine 13 includes a disclosure rule for sound prediction but 14 not to determine whether utility has been 15 demonstrated. Under this rule, the court can only 16 rely on evidence included in the patent application 17 itself. But a patentee has no way of knowing 18 whether the evidence it has will be enough to 19 demonstrate utility or whether it will have to rely 20 on sound prediction. Even the court in Lilly's case 21 suggested that Lilly could not have known about the 22 new disclosure obligation when it filed. C-160, 23 Paragraph 121.</p> <p>24 The third relevant aspect of Article 1105 25 is its protection against discrimination. The</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">154 12:51</p> <p>1 customary norm against discrimination embodied in 2 Article 1105 is not focused on any particular form 3 of discrimination, but rather, as the Tribunal 4 recently noted in Tenaris, provides that any 5 differential treatment of a foreign investor must 6 not be based on unreasonable distinctions and 7 demands.</p> <p>8 As discussed the statistical evidence 9 establishes that the promise utility doctrine 10 imposed on the Zyprexa and Strattera patents 11 differential treatment by virtue of being 12 pharmaceutical patents. There is also substantial 13 evidence of discrimination on the basis of 14 nationality. Every patent invalidated under the 15 promise utility doctrine was owned by a foreign 16 investor. Meanwhile, these invalidations worked to 17 the advantage of the generic pharmaceutical 18 industry, a prominent Canadian industry. In sum, 19 the promise utility doctrine, as applied to Lilly's 20 patents, violated Lilly's legitimate expectations, 21 is arbitrary and is discriminatory. These are each 22 independent bases for finding Canada in breach of 23 Article 1105, but each of these grounds is also 24 related.</p> <p>25 As recognized in Waste Management II,</p> <p style="text-align: center;">www.dianaburden.com</p>
<p style="text-align: right;">155 12:52</p> <p>1 Article 1105 embraces a flexible standard which must 2 be adapted to the circumstance of each case. This 3 is Paragraph 99. A holistic examination of the 4 promise utility doctrine as it has been applied to 5 Lilly's patents unmistakably reveals that Canada has 6 failed to respect the requirements of Article 1105.</p> <p>7 Lastly, I will respond to the Tribunal's 8 Question No. 14 regarding the implications of 9 Paragraph B3 of the FTC notes. Paragraph B3 10 provides that a determination that there has been a 11 breach of another provision of NAFTA, or of a 12 separate international agreement, does not establish 13 that there has been a breach of Article 1105(1). 14 Here the Tribunal need not rely on another provision 15 of NAFTA, or on another international agreement, to 16 determine that Canada's measures violate 17 Article 1105.</p> <p>18 Rather, as I have discussed, the Tribunal 19 can reach this conclusion on the basis of the 20 violation of Lilly's legitimate expectations, and 21 the promise utility doctrine's arbitrariness and 22 discriminatory effects. In any event, Paragraph B3 23 does not prohibit tribunals from considering, in 24 combination with other factors, other provisions of 25 NAFTA. Rather, on its face, it only prohibits</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">156 12:53</p> <p>1 Tribunals from determining that such breaches 2 conclusively establish a violation of Article 1105. 3 Thus, if the Tribunal concludes, as it should, that 4 Canada's measures violate Chapter 17 for purposes of 5 Lilly's Article 1110 claim, then that is an 6 additional reason for concluding that they are 7 arbitrary, in violation of Lilly's legitimate 8 expectations, and discriminatory. But, again, it is 9 not necessary for the Tribunal to consider 10 Chapter 17 in the context of Article 1105 to reach 11 these conclusions.</p> <p>12 Thank you.</p> <p>13 MS. CHEEK: I have concluding remarks, and 14 then I will not keep everyone from their lunch.</p> <p>15 Let me note that, for ease of 16 presentation, when I talked about our Article 1110 17 claim, I focused on the relevance of Chapter 17, and 18 Mr. Berengaut, when he talked about our Article 1105 19 claim, focused on legitimate expectations and 20 arbitrariness and discrimination.</p> <p>21 To be clear, as we have briefed it, we 22 also would rest our Article 1110 claim on the 23 violation of Lilly's legitimate expectations and 24 also on the arbitrariness of the doctrine. So, from 25 our perspective, the arbitrariness and the violation</p> <p style="text-align: center;">www.dianaburden.com</p>

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1 of legitimate expectations are alternative,
2 independent bases upon which you could find an
3 expropriation in this case if you chose not to look
4 to Chapter 17.

5 Independently, in response, Mr. President,
6 to the question that you had for Mr. Berengaut about
7 the evolution of the minimum standard of treatment
8 and whether or not it would be appropriate to look
9 to what I think you referred to as third generation
10 investment treaties, and specifically CETA, it would
11 not be appropriate to look specifically at CETA in
12 this case, as that treaty to the best of my
13 knowledge, although surely Canada can confirm, has
14 not even been ratified, let alone entered into
15 force. So I think it's premature to look at
16 practice under CETA when examining the minimum
17 standard of treatment, but I think the general
18 principle you are articulating still stands. So
19 that's just a CETA specific observation.

20 In conclusion, we've discussed this
21 morning how Canada has applied its promise utility
22 doctrine, this new and additional test, to revoke
23 Lilly's patents, the Zyprexa patent and the
24 Strattera patent, patents that were for
25 groundbreaking medicines to treat schizophrenia and

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1 attention deficit/hyperactivity disorder, and that
2 were being used by thousands of Canadian patients at
3 the times that these patents were revoked solely on
4 the basis that they lacked utility and were not
5 useful.

6 The revocation of these patents, as
7 Mr. Berengaut and I have discussed, constitutes both
8 a violation of expropriation and a violation of fair
9 and equitable treatment under NAFTA, for which Lilly
10 is entitled to compensation.

11 With that I hand over to you,
12 Mr. President.

13 **THE PRESIDENT:** That concludes the opening
14 statement by the Claimant?

15 **MS. CHEEK:** Yes, it does.

16 **THE PRESIDENT:** Thank you, Ms. Cheek and
17 your team, for making the presentations. I think we
18 will have now our lunch, and resume at 2:00 sharp.
19 *(Luncheon Recess)*

20 **THE PRESIDENT:** Please proceed with the
21 opening statement for Respondent.

22 **OPENING STATEMENT ON BEHALF OF THE RESPONDENT**

23 **MR. SPELLISCY:** Thank you very much. Good
24 afternoon, members of the Tribunal.
25 Today in their opening statement, when we

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1 got to the discussion of Article 1105 and 1110, the
2 Claimant suggested there was nothing remarkable or
3 unusual about what it is asking you to sit in
4 judgment of in this case. The reality is to the
5 contrary. The Claimant is asking you to do
6 something truly remarkable. It is asking you to
7 reconsider the decisions of the Canadian courts on
8 the validity of its patents. Indeed, no matter how
9 it wants to dress up and clothe its arguments today,
10 to say that it is not trying to usurp the role of
11 the domestic courts -- that is what it is asking you
12 to do.

13 The Canadian courts determined that the
14 Claimant's patents were invalid. The Claimant wants
15 and needs you to disagree. In fact, this morning
16 the Claimant walked you through the court decisions
17 invalidating its patents, and the Claimant tried to
18 show you how those decisions were wrong, that the
19 drugs are useful and successful and that they were,
20 to use their words, extraordinarily supported.

21 Claimant wants you and needs you to find that its
22 patents should have been found valid by Canadian
23 law. Otherwise it has no claim for damages.

24 In short, the Claimant is doing nothing
25 more than pursuing yet one more appeal of the

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1 invalidity findings made by the Canadian judicial
2 system. This is not the role of a NAFTA Chapter 11
3 Tribunal. There should be no doubt this is truly a
4 remarkable claim. Indeed, in our view this is not a
5 typical dispute where you must make significant
6 factual determinations as to whether particular
7 events happened or as to why particular decisions
8 were made. The reason is simple. In our view the
9 most relevant facts are not disputed. They are as
10 follows.

11 Pursuant to Canada's domestic Patent Act
12 the Claimant was granted patents by the Canadian
13 Patent Office with respect to its previously
14 patented compounds of olanzapine and atomoxetine.
15 In legal proceedings the Claimant's competitors
16 alleged that the Claimant never should have been
17 granted the patents for these alleged pharmaceutical
18 inventions because the Claimant had not met the
19 requirements set by Canada's Patent Act to merit the
20 patents.

21 After lengthy and comprehensive
22 proceedings, the Canadian courts agreed with the
23 Claimant's competitors, both at trial and at the
24 appellate level, and determined that, as a matter of
25 Canadian law, the Claimant's patents were invalid

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1 ab initio. There was not a single dissent. The
 2 Claimant's request for leave to appeal to the
 3 Supreme Court of Canada were then denied. And now
 4 we find ourselves here in front of a Chapter 11
 5 arbitration tribunal because the Claimant did not
 6 get the domestic law result that it wanted in the
 7 Canadian courts.

8 The Claimant alleges that these facts
 9 amount to a breach of Canada's obligations under
 10 Chapter 11 of NAFTA. They have offered you hundreds
 11 of pages of argument in support, argument that
 12 covers allegations concerning the content of
 13 Canadian law, the content of U.S. and Mexican law,
 14 the meaning of provisions not only of Chapter 11 but
 15 of NAFTA Chapter 17, and the meaning of provisions
 16 in treaties wholly unrelated to NAFTA, like the PCT,
 17 the Patent Cooperation Treaty.

18 The expert evidence from Mr. Dimock,
 19 Dr. Gillen and Dr. Brisebois that you will hear over
 20 the next two weeks will show why the Claimant is
 21 wrong in its description and characterization of
 22 Canadian law and its impacts, and why it is wrong in
 23 its claims about when the legal principles it
 24 challenges were first recognized.

25 The expert evidence from Mr. Holbrook and
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1 Ms. Lindner will show why the Claimant is wrong in
 2 its characterizations of U.S. and Mexican law, and
 3 the expert evidence of Mr. Gervais and Mr. Reed will
 4 show why the Claimant is wrong on Chapter 17 and why
 5 it is wrong on treaties like the PCT.

6 But as we go into this hearing today, and
 7 even as we proceed further through Canada's opening
 8 statement, I would suggest that you keep one point
 9 in mind. None of any of this is relevant to the
 10 primary question that you are called upon to answer
 11 in this dispute, a question that should be wholly
 12 determinative of this entire case. The primary
 13 question that you must adjudicate is the following.
 14 What is the role of a Chapter 11 Tribunal when it is
 15 the acts of a state's domestic courts interpreting
 16 domestic laws that are alleged to be the source of a
 17 violation of articles 1105 and 1110 of NAFTA?

18 The Claimant answers this question by
 19 suggesting that you have exceptionally broad and
 20 wide-ranging authority to consider judicial
 21 measures. In fact, as I noted above, the Claimant
 22 is asking that this Tribunal do nothing less than
 23 sit as a supranational Court of Appeal to assess the
 24 legality of the judicial measures of the Canadian
 25 courts. It is our view and the view of the other
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1 NAFTA parties that you cannot do so.

2 There should be no doubt in your minds, if
 3 you hold otherwise in this case, then every foreign
 4 patent holder in any NAFTA country who finds its
 5 patent invalidated at domestic law and who can turn
 6 to NAFTA Chapter 11 will do so. That is not all
 7 that the Claimant is actually asking you to do. It
 8 is also asking you to sit as a court of U.S. and
 9 Mexican law, making judgments about the content of
 10 those states' domestic laws. Again, it is our view
 11 and the view of the other NAFTA parties that you can
 12 not do so.

13 Notably the U.S. and Mexican governments
 14 both filed Article 1128 submissions here, and
 15 neither endorsed the Claimant's view of its own
 16 domestic international property law. In fact, the
 17 U.S. submission expressly refuses to endorse either
 18 party's view of U.S. law. Why?

19 Because determining what those laws are is
 20 an issue for the U.S. courts, not for a Chapter 11
 21 Tribunal. Sitting as a domestic court of each of
 22 the NAFTA parties is still not all that the Claimant
 23 is asking you to do here. It is also asking that
 24 you sit as a NAFTA Chapter 20 Tribunal,
 25 state-to-state dispute settlement tribunal, and find
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1 a breach of Chapter 17 of NAFTA.

2 Again, the NAFTA parties are all clear.
 3 You cannot do so. And at least until this morning I
 4 suggest it was even asking you to sit as a court of
 5 general international jurisdiction, and render a
 6 decision that the obligations of the PCT have been
 7 breached. That seems to perhaps now not be the
 8 case, and in that case I'm really not sure why we're
 9 talking about the PCT at all, but just in case it
 10 does come back later, to be clear, it is our view
 11 and the view of the other NAFTA parties, that you
 12 can not do so.

13 As a Chapter 11 Tribunal you only have the
 14 authority to determine whether there has been a
 15 breach of the provisions of Section A of Chapter 11
 16 of NAFTA. There are domestic courts with the sole
 17 authority to determine issues of domestic law.
 18 There are NAFTA Chapter 20 Tribunals empowered to
 19 decide disputes with respect to other chapters of
 20 NAFTA, and there are international tribunals like
 21 the International Court of Justice that may be
 22 called upon to decide disputes under other treaties
 23 like the PCT.

24 And so we come back to answering the
 25 question I posed above. What is the role of a
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1 Chapter 11 Tribunal when it is the acts of a state's
2 domestic courts interpreting domestic laws that are
3 alleged to be the source of a violation of articles
4 1105 and 1110 of NAFTA?
5 All three NAFTA parties agree that under
6 the treaty that they negotiated and signed, the
7 answer to this question is straightforward. When it
8 is the acts of a neutral and independent judiciary
9 that are being challenged, the Tribunal is limited
10 to considering whether there has been a denial of
11 justice. Nothing less. If there has been no denial
12 of justice, then there is no need for you to
13 consider any other issue in this case, because if
14 there has been no denial of justice there has been
15 no breach of Chapter 11. And any other
16 considerations or other conclusions about
17 obligations outside of Chapter 11 cannot change that
18 answer.
19 Why have I spent so much time on this one
20 point in my introductory remarks this afternoon, a
21 point that I have just told you renders everything
22 we are about to spend two weeks of your time on
23 pretty much irrelevant? It is because if you agree
24 that the only real question here is whether there is
25 a denial of justice, then this case is over, and it

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1 is over right now. The Claimant could have made
2 such an allegation. It would have failed as a
3 matter of merit, but it could have done so under
4 Chapter 11. However, the Claimant has never alleged
5 denial of justice.
6 In fact, quite to the contrary, the
7 Claimant has been express that it is not making any
8 such claim. In light of such an admission there is,
9 as a matter of law, no valid claim here and this
10 arbitration should be dismissed with Canada being
11 awarded all of its costs.
12 As the Respondent, Canada is in a position
13 where it does have to respond to the Claimant's
14 allegations and address, in the alternative, why all
15 of those allegations are beyond this Tribunal's
16 jurisdiction, *ratione temporis* and without merit.
17 Let me explain how we will organize the rest of our
18 opening remarks today.
19 My colleague, Mr. Johnston, will speak
20 next and he will spend roughly 45 minutes giving you
21 some key background on Canadian patent law, in
22 general and helping you understand as a matter of
23 fact how the Claimant's patents and the decisions
24 regarding them by the Canadian courts fit into
25 decades of Canadian jurisprudence. My colleague

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1 Mr. Luz will spend about 45 minutes addressing the
2 law of Article 1105 and 1110. He will in particular
3 explain why, as I have just introduced, the only
4 possible cause of action under Article 1105 and
5 1110, where what has been challenged are judicial
6 decisions or denial of justice. He will also
7 address the other legal standards in Article 1105
8 and 1110 so that you have a complete picture of the
9 applicable law. At that point we will have been
10 going for roughly over an hour and a half and so I
11 would suggest it would be a good time for our
12 afternoon break. When we return, I will then spend
13 roughly 60 minutes or so explaining why there has
14 been no breach of Canada's obligations under NAFTA
15 and, in particular, I will summarize today the
16 reasons why Canada suggests that after you hear the
17 argument and evidence in this claim over the next
18 several days, you will have no choice but to
19 conclude that the Claimant's claims must be
20 dismissed.
21 In making my remarks I will cover four
22 points. First I will briefly return to my main
23 point that I have covered here and offer a little
24 more detail on why, if you agree with Canada, the
25 United States and Mexico that under Articles 1105

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1 and 1110 of the Treaty they chose to sign, an
2 allegation arising from the decision of a court must
3 be based on a claim of denial of justice, then this
4 claim must be dismissed.
5 I will then turn to our alternative
6 arguments and everything that I cover after this
7 point has to be understood expressly in that
8 context. It is in the alternative.
9 I will explain that even if you find that
10 the claim here is not limited to a claim for denial
11 of justice, the Claimant's challenge to the judicial
12 interpretation of Canada's Patent Act is time
13 barred. The Claimant undoubtedly knew of the
14 alleged breaching measure and loss by no later than
15 October 22, 2009 when the Supreme Court of Canada
16 denied its leave to appeal the decision with respect
17 to its Raloxifene patent, but it did not bring its
18 claim within the three-year limitation set by NAFTA.
19 We will then proceed further into the
20 alternative. As my third point, I will discuss with
21 you why this claim must fail because it necessarily
22 depends upon a false factual predicate. In
23 particular, the Claimant's whole claim, as we
24 understand it, depends upon you concluding that
25 there has been a substantial and unexpected change

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1 in the judicial interpretation of Canada's
2 Patent Act, beginning, at least as we understood it
3 until today, in 2002.
4 I believe as a matter of fact, if you
5 review the evidence presented so far and consider
6 the evidence presented by experts like Dr. Gillen
7 and Mr. Dimock this week you will be able to reach
8 only one conclusion, that the principles in the
9 judicial interpretations challenged by the Claimant
10 are not new. They have existed in Canadian law for
11 decades.
12 As my fourth point we will then proceed
13 even further into the alternative and show why, even
14 if you find that the claim here is not limited to a
15 claim for denial of justice, and even if you find
16 that the Claimant's challenge is not time barred,
17 and even if you find that there has been a
18 substantial change in the way Canadian courts have
19 interpreted the Patent Act since 2002, there has
20 still been no breach of either Article 1105 or 1110
21 of NAFTA.
22 In this part I will first discuss with you
23 the reasons why you should conclude that the
24 Claimant has failed to establish a breach of the
25 customary international law minimum standard of

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1 treatment contained in Article 1105. The
2 interpretation given to Canada's Patent Act by the
3 Canadian courts simply does not rise to the level
4 that would breach that standard.
5 I will then discuss Article 1110 and I'll
6 explain why there was no taking of property in this
7 case and, hence, no expropriation. And that, even
8 if there was, the claim should fail because such a
9 taking was consistent with Canada's obligations in
10 NAFTA. For all of these reasons, the Claimant's
11 claims must be dismissed and Canada should be
12 awarded all of the costs for defending against a
13 case that, in our view, should never have been
14 brought.
15 And with that general overview, let me now
16 hand the floor to my colleague, Mr. Johnston.
17 **MR. BORN:** Can I ask you one question just
18 to test your answer to the primary question?
19 Suppose that a Canadian court applied in a
20 challenge to the validity of a patent the doctrine
21 of public policy, and concluded without prior
22 support in judicial authority that Canada's
23 interests would be better served if there was no
24 patent here, and thereby invalidated it.
25 Am I right in understanding that you say

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1 that couldn't be either an expropriation or denial
2 of fair and equitable treatment?
3 **MR. SPELLISCY:** I guess in that context it
4 would depend on whether or not it could amount to an
5 actual denial of justice. I would think it would be
6 then a consideration for this Tribunal as to whether
7 or not the circumstances of that decision by the
8 Canadian courts, if we presume it's been appealed
9 all the way up and it's been affirmed, whether the
10 circumstances amounted to a denial of justice, and
11 that standard is set out and the parties are agreed
12 that denial of justice is covered by customary
13 international law. Here, I don't think we have to
14 even engage in that because the Claimant has made
15 clear that that is not its allegation.
16 **MR. BORN:** Just staying on my
17 hypothetical, though, suppose it was the most
18 superlatively perfect procedure, both in the trial
19 court and the losing patent holder appealed all the
20 way up to the Supreme Court, again through the most
21 superlatively perfect procedures. It's your
22 position there could be no expropriation or fair and
23 equitable treatment as long as there wasn't a denial
24 of justice?
25 **MR. SPELLISCY:** I think here we're getting

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1 into the question essentially of whether there is
2 such a thing as a substantive denial of justice or
3 whether it's limited to procedural due process, and
4 without wanting to steal my colleague, Mark Luz's,
5 thunder, I think he will address that question when
6 we get there.
7 **MR. BORN:** Thank you.
8 **MR. JOHNSTON:** Good afternoon, President
9 van den Berg, members of the Tribunal. My name is
10 Adrian Johnston. I will be addressing the key
11 Canadian patent law issues raised in this
12 arbitration.
13 My submissions will be in three parts.
14 First I will highlight important context about the
15 patent system; second, I will address the historical
16 record regarding the utility requirement in Canada;
17 and, third, I will address the invalidation of
18 Claimant's patents for atomoxetine and olanzapine.
19 Claimant ignores essential context about
20 how the patent system works in Canada and around the
21 world. The patent bargain involves the disclosure
22 of an invention in exchange for a time limited
23 monopoly -- that's 20 years in Canada -- and the
24 costs to the public of a monopoly are significant.
25 Not only does it block competition in the

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1 marketplace; it also prevents other inventors from
2 exploring the patented research turf. And for the
3 public's freedom to be limited in these ways, the
4 inventor must uphold its side of the patent bargain.
5 The patent bargain is not the exchange of
6 a monopoly for the disclosure of a guess. You
7 actually have to have invented something before you
8 apply for a patent, and you must disclose that
9 invention to the public. That disclosure is the
10 *quid pro quo* at the heart of the patent bargain.
11 I want to draw your attention to three
12 important aspects of how the patent bargain
13 operates. The role of the courts, the interlocking
14 nature of patent rules, and how private parties
15 drive outcomes in the patent system.
16 Right at the outset it's important to
17 focus on exactly what Claimant is challenging in
18 this arbitration -- the interpretation and
19 application of Canadian patent law by Canadian
20 courts. Claimant is trying to interfere with three
21 vital roles of the courts that they play in
22 upholding the patent bargain.
23 First, courts are the ultimate arbiters of
24 patent validity. When the patent office grants a
25 patent it is not guaranteeing that the patent is

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1 valid. The patents are presumed valid, but that is
2 subject to challenge in court. And when a patent is
3 declared invalid, it is void ab initio, meaning
4 there was never a valid patent right. It is not
5 surprising that a reviewing court might reach a
6 different conclusion than the patent office. Patent
7 trials are full adversarial proceedings with
8 extensive evidence. There cannot be a full trial on
9 each of the tens of thousands of patent applications
10 that come before the patent office each year. The
11 system would break down. But the inevitable
12 consequence is that patents will be granted that
13 should not have been. There must be some mechanism
14 to make sure that the patent bargain was met, and
15 that mechanism is the courts. That's why Claimant
16 has warned its investors in annual reports for
17 decades that there is no assurance that the patents
18 we have been granted would be found valid if
19 challenged. And this is not mere boilerplate for
20 the purposes of an SEC filing. In fact in the
21 United States roughly half of challenged patents are
22 found invalid upon court review, including patents
23 of great commercial value. Every experienced
24 participant in the patent system knows that this is
25 how the patent system works.

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1 The second essential role of the courts is
2 interpreting and applying the Patent Act. Claimant
3 has singled out Canada's utility requirement as
4 extra-statutory judge-made law. That is absurd.
5 The word "useful" is in the Patent Act, but there is
6 no definition provided. What this broad statutory
7 term means has to be interpreted by the courts.
8 As the UK House of Lords explained in
9 *Synthon v SmithKline*, "In the interpretation and
10 application of patent statutes judge-made doctrine
11 has over the years done much to clarify the abstract
12 generalities of the statutes and to secure
13 uniformity in their application."
14 And as the U.S. Supreme Court noted with
15 respect to the word "useful" in U.S. patent law, "a
16 simple everyday word can be pregnant with ambiguity
17 when applied to the facts of life."
18 Patent law concepts like "useful" have
19 been in Canada's Patent Act since 1869, but
20 evolution in the jurisprudence is as inevitable as
21 the changing technologies that come before the
22 courts. It shouldn't be surprising that a patent
23 claiming billions of chemical compounds for treating
24 a new disease would raise different sorts of
25 questions than a patent claiming an improved

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1 mousetrap.
2 Third, and finally, court decisions on
3 patent validity are grounded in findings of fact and
4 determinations on the credibility of witnesses that
5 come before the courts. Judges hear weeks of expert
6 testimony and review thousands of pages of evidence.
7 They deliberate and craft their reasons over months
8 before reaching a determination of if the patent is
9 valid. Their findings deserve and receive high
10 deference from appellate courts. There must be a
11 palpable and overriding error to overturn a trial
12 judge's findings of fact on patent validity.
13 Another contextual factor that Claimant is
14 keen to hide from the Tribunal's view is the
15 interlocking nature of patentability requirements.
16 Claimant has framed this entire
17 arbitration around a false presumption, that it is
18 possible to extract one legal concept from a patent
19 system and consider it in abstract isolation. And
20 we heard this again in Claimant's opening remarks
21 today. Claimant asks this Tribunal to place
22 Canada's utility requirement under the microscope
23 but not to consider how utility fits into the patent
24 bargain as a whole.
25 Every country's legal system contains an

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<p style="text-align: right;">177 02:23</p> <p>1 array of legal concepts that work together as checks 2 and balances to ensure that the patent bargain is 3 upheld, and utility is just one of them. Claimant 4 presents these legal concepts as if they were 5 water-tight compartments, and argues that this 6 Tribunal should concern itself only with the 7 compartment labeled utility. But that is not how 8 patent law works. The better metaphor is the 9 seamless garment of the law, and Claimant's 10 water-tight compartments approach work several kinds 11 of mischief in a case like this.</p> <p>12 First of all, it creates a false picture 13 of change in the law, because its myopic focus on 14 the utility label ignores earlier jurisprudence 15 where the same issues may have been resolved under 16 different patentability requirements, different 17 legal concept like overbreadth, for example.</p> <p>18 Second, it leads to flawed comparisons 19 among countries. Different countries pursue similar 20 policy goals under different legal labels such as 21 enablement in the United States.</p> <p>22 Just in the weeks before Claimant's 23 atomoxetine patent was invalidated in Canada a 24 district court in New Jersey found that that patent 25 failed the enablement requirement under a heading in</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">178 02:24</p> <p>1 its reasons labeled "Utility/enablement". That 2 finding was reversed on appeal, but the decision 3 illustrates the way that similar issues have been 4 addressed under different headings in different 5 countries.</p> <p>6 Third, Claimant overlooks how different 7 patent rules work together in the context of 8 particular types of inventions. Increased emphasis 9 on utility is in part driven by the types of patents 10 coming before the courts, and here I want to turn to 11 a question that the Tribunal posed, that is, is the 12 classification of Claimant's patents as secondary 13 patents relevant to Claimant's claims? Canada's 14 answer is yes, this is relevant context for this 15 arbitration, because secondary patents can bring 16 issues of utility to the fore.</p> <p>17 I want to be clear, we are not suggesting 18 that secondary patents is a legal term of art in 19 Canadian patent law. It is not. We use it for 20 descriptive purposes here and we have not invented 21 it for this arbitration; it is a term used by 22 practitioners and scholars to talk about these types 23 of patents.</p> <p>24 Secondary patents such as Claimant's 25 patents for olanzapine and atomoxetine follow on</p> <p style="text-align: center;">www.dianaburden.com</p>
<p style="text-align: right;">179 02:26</p> <p>1 from and build upon existing patented inventions. 2 That's the idea we're getting at with this term of 3 secondary patents.</p> <p>4 One example is a new use patent. This 5 type of patent takes an old object or compound and 6 discloses a new use for it. Another example is a 7 selection patent, and a selection patent follows on 8 from an earlier patent that claimed a group or genus 9 of compounds. The selection identifies a subset of 10 the previously patented compounds as having special 11 advantages over the rest of the class. Discovering 12 that advantage unique to the selected members is the 13 invention in that context. These types of patents 14 are allowed in Canadian law and can encourage very 15 important innovations, we don't want to be 16 misunderstood as suggesting otherwise, but they can 17 also face validity problems because of what the 18 earlier patent already disclosed.</p> <p>19 To merit a further 20-year monopoly, the 20 patentee must be offering something more to meet the 21 requirements of novelty and non-obviousness, and 22 often that something more is having discovered new 23 and greater utility for the subject matter of the 24 earlier patent. In these cases a particular utility 25 is at the core of the invention. The greater the</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">180 02:27</p> <p>1 distance between the newly discovered utility and 2 what came before, the better the chance that the 3 patent will meet the requirements of novelty and 4 non-obviousness. Making strong assertions about 5 utility in the patent can set a secondary patent 6 apart from the earlier patent, and this puts utility 7 front and center in what the patentee is offering 8 the public in the context of the patent bargain as a 9 whole.</p> <p>10 This brings me to the third and final 11 contextual element, which is how private parties 12 drive the development and evolution of patent law. 13 Utility issues are not gaining prominence on the 14 whim of the patent office or the judiciary, but 15 because utility is being placed front and center by 16 patentees and patent challengers at every stage in 17 the process, from the drafting of the patent to the 18 patent office, to litigation before the courts. We 19 see this in Claimant's own conduct. That's 20 something that I'll return to later.</p> <p>21 As discussed, some types of patents have 22 to offer something more in terms of utility to clear 23 other requirements of patentability, and it's no 24 surprise, then, that when applicants are drafting 25 such patents they are keen to emphasize the</p> <p style="text-align: center;">www.dianaburden.com</p>

<p style="text-align: right;">181 02:28</p> <p>1 advantages or heightened usefulness of their 2 invention. The words used in the patent are not 3 accidental. Patentees like the Claimant, guided by 4 expert advice, choose them deliberately to maximize 5 the chances of securing a patent. In patent 6 examination, the patentee may again stress the 7 advantages of the invention to overcome an 8 examiner's objections and yet, again, if the patent 9 is later challenged in court, a patentee may extol 10 the particular utility of its invention to overcome 11 other challenges. 12 When patent validity is litigated, it's 13 important to remember that it's the parties and not 14 the courts that are driving the process. One party 15 argues that the patent is valid, the other argues 16 that it is invalid, and contrary to Claimant's 17 submissions, it is the parties that are scouring the 18 patents, that are scrutinizing one another's 19 evidence. It is not the courts. The court's role 20 is simply to hear all of the evidence in argument 21 and to apply the law in a way that is fair, just and 22 principled. The court is a neutral arbiter of the 23 case and the evidence that is put forward by the 24 parties. Claimant ignores all of this context in 25 its myopic and self-serving account of Canadian law.</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">182 02:30</p> <p>1 I'm going to turn now to the second main 2 part of my presentation, which is correcting 3 Claimant's inaccurate historical account of Canada's 4 utility requirement. It is nothing but a caricature 5 of Canadian law that ignores the contrary evidence. 6 Claimant stakes its entire case on the 7 claim that Canadian law changed dramatically in the 8 mid 2000s with the creation of the alleged promise 9 utility doctrine. This is false. 10 The Tribunal has asked whether promise 11 utility is, in fact, a doctrine as submitted by the 12 Claimant, and we had some discussion on that earlier 13 today. What Claimant and its experts describe as 14 the promise utility doctrine is not, as Claimant 15 again suggests today, a unitary doctrine recognized 16 in Canadian law. It has been invented by Claimant 17 to serve its purposes in this arbitration. And 18 what's quite telling of this is that the way 19 Claimant has cast the doctrine over the course of 20 this arbitration has shifted strategically. 21 In its notice of intent, Claimant 22 described the doctrine as a departure from the 23 Supreme Court of Canada's Apotex v Wellcome 24 Foundation decision. That's the 2002 AZT decision. 25 Later Claimant decided that its litigation</p> <p style="text-align: center;">www.dianaburden.com</p>
<p style="text-align: right;">183 02:31</p> <p>1 interests were better served by considering the AZT 2 decision as part of the doctrine instead. 3 Claimant's characterizations of Canadian law are 4 nothing but opportunistic. When you remove all of 5 the jargon of invented doctrines, Claimant is really 6 saying that there has been three changes in Canadian 7 law. First, that since 2005 inventions are held to 8 their promised utility. Second, that since 2002 9 utility must be established before filing for a 10 patent and cannot be proved after the fact with 11 post-filing evidence, and, third, that since 2008, 12 to rely on a prediction of utility, a sound 13 prediction of utility, the factual basis and the 14 line of reasoning must be disclosed in the patent. 15 As a preliminary matter, it's worth noting 16 that only the first of these alleged changes 17 actually concerns the threshold or the standard of 18 utility that is required for a valid patent under 19 Canadian law. The other two points relate, at most, 20 to how that threshold is implemented. What is the 21 admissible evidence and how and what must be 22 disclosed. Canadian courts have used the term 23 "promise doctrine" to be sure, but when they do 24 they're only referring to No. 1 on that list of 25 alleged changes by Claimant, to the notion that</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">184 02:33</p> <p>1 patentees are held to promises of utility. They are 2 not referring to the distinct rules requiring 3 utility to be established at the filing date and 4 requiring that the basis for sound prediction be 5 disclosed. Because, as Claimant told you this 6 morning in its opening statement, those rules apply 7 whether or not there is a promise in the patent. 8 Those rules equally apply if there is only a mere 9 scintilla of utility, if that's the standard being 10 applied. This is not a unitary doctrine. 11 There has been no dramatic change in any 12 of these aspects of Canadian law. And as will be 13 evident from my following submissions, the elements 14 of Claimant's so-called promise utility doctrine all 15 have a long history. 16 To be clear, Canada's position is not that 17 there has been absolutely no change or evolution in 18 Canadian law. That is inherent to common law 19 adjudication and to the nature of patent law. But 20 the notion that there has been a sea change in 21 Canadian law is baseless. 22 Unable to deny the wealth of sources 23 underpinning Canada's position, Claimant and its 24 experts can only state that Canada's judiciary and 25 the most prominent legal practitioners in Canada</p> <p style="text-align: center;">www.dianaburden.com</p>

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1 have repeatedly misread these sources and that
2 Claimant's own reading of them should be preferred.
3 Claimant attempts to rewrite or at least reinterpret
4 legal history in Canada for the purposes of this
5 proceeding, and that attempt lacks all credibility.
6 The central plank of Claimant's argument
7 is that in 2005, Canadian courts began scouring
8 patents and holding patentees to promises of utility
9 found in the disclosure. This is contradicted by
10 the historical record. But before I get to that, I
11 want to focus on an important qualification within
12 Claimant's own argument. And this requires pinning
13 down some patent terminology.
14 There's two main parts to a patent, the
15 claims and the disclosure, which is sometimes
16 referred to as the description. Together they are
17 called the patent specification, although
18 specification is also sometimes used just to refer
19 to the disclosure. The function of the disclosure
20 is to describe the invention, and the claims define
21 the monopoly claimed by the patent.
22 What's important is that Claimant's
23 argument is not that it is new in Canadian law to
24 hold patentees to statements of utility found just
25 anywhere in the patent. Its argument is that since

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1 2005, courts have started finding promises in the
2 disclosure. So what Claimant is acknowledging and
3 what its experts acknowledge and they acknowledged
4 this morning is that in cases where there is a
5 promise of utility found in the claims, it has
6 always been the case in Canadian law that that
7 standard would have to be met in the claims of the
8 patent. And this is how Claimant attempts to
9 distinguish cases, early jurisprudence like the New
10 Process Screw case, which I'm sure we will be
11 discussing in the coming weeks.
12 We disagree with how to read that case,
13 but even on Claimant's own reading, it is saying
14 that the patent failed for not delivering the
15 utility as claimed. The specific utility set out in
16 the claims. So it focuses us on what Claimant is
17 saying is new, it's finding promises in the
18 disclosure portion of the patent, where courts are
19 finding them, not whether patentees are being held
20 to a statement of utility in the patent at all.
21 And the notion that this practice is new
22 in 2005 is false. For decades Canadian law has been
23 clear that patentees will be held to promises of
24 utility in the patent specification, whether in the
25 disclosure or in the claims. As the Supreme Court

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1 held in 1981 -- this is the Supreme Court of
2 Canada's decision -- not useful in patent law means
3 that the invention will not operate at all or, more
4 broadly, that it will not do what the specification
5 promises that it will do. This is the Supreme Court
6 of Canada in 1981 saying what does "not useful" mean
7 in Canadian patent law. Must do what the
8 specification promises that it will do.
9 To avoid the reality of this historical
10 record, Claimant has to stretch to convince this
11 Tribunal that when the Supreme Court and other
12 courts said "promise" in the past, they didn't
13 really mean promise. They were just referring to
14 whether the invention worked at all. Now, that is
15 not only at odds with the bare words on the screen,
16 but it is also at odds with how the word "promise"
17 was being used and was understood by Canadian patent
18 practitioners at the time.
19 The touchstone work, one of the most cited
20 texts in the history of Canadian patent law is
21 Dr. Harold Fox's Canadian Patent Law and Practice.
22 In 1969 he wrote, "In those cases of patents that
23 are based upon a promise of results contained in the
24 specification it is not sufficient that the patent
25 be useful for a part only of the result..."

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1 And in 1983, just two years after
2 Consolboard was decided, William Hayhurst, an
3 esteemed patent practitioner and lecturer at the
4 University of Toronto, wrote "It is trite law that
5 as long as that which is disclosed has some
6 practical utility, the quantum of utility may be
7 slight, unless the specification promises more."
8 The historical record is equally clear
9 around the mid 1990s. This is, of course, when
10 NAFTA was signed and Claimant was filing its
11 patents. The Federal Court of Appeal in 1995 in the
12 case of Wellcome versus Apotex, "Since the utility
13 of a patent must ultimately be judged against its
14 promise, the exercise requires that the
15 specification be carefully construed to determine
16 exactly what that promise is."
17 Carefully construe the specification to
18 determine exactly what that promise is. It sounds a
19 lot like what Claimant says is new in 2005. Once
20 again, in the mid '90s, patent practitioners are on
21 the same page as the courts about what this word
22 "promise" means. "To avoid problems of false
23 suggestion and inutility, the patent agent should be
24 chary of promising results in the descriptive
25 portion" -- not the claims; the descriptive

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1 portion -- "where those results may not be achieved
2 by things that arguably fall within the claims."
3 As Mr. Dimock's expert report shows, this
4 is the tip of the iceberg of historical evidence
5 that flatly contradicts Claimant's account of the
6 origins of this central plank of its promise utility
7 doctrine.
8 The Tribunal has asked "In what way, if
9 any, is the identification of the promise of a
10 patent by a judge subjective?" The answer is that
11 it is not. The judge's interpretation is grounded
12 in the words of the patent itself and the expert
13 evidence submitted by the parties on how a person
14 skilled in the art would understand the patent.
15 Now, if this is subjective, so is every aspect of
16 patent interpretation by the courts. Holding
17 patentees to their promises is not an unfair or
18 arbitrary rule. There is no obligation to make any
19 promise of utility in a patent. A mere scintilla is
20 still sufficient to get a patent under Canadian law.
21 But if you make a promise, you're held to it. The
22 patentee holds the pen when it drafts its
23 application, and it secures the patent based on the
24 strength of its representations. Representations of
25 utility can enable a patentee to clear the other

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1 hurdles of non-obviousness and utility and novelty.
2 It is neither arbitrary nor unfair that patentees
3 are held to the utility that they assert in their
4 patent.
5 The second change that Claimant alleges is
6 that Canada's Supreme Court, in the 2002 AZT
7 decision, created a new rule preventing patentees
8 from establishing utility based on post-filing
9 evidence. This is false. To merit a patent, you
10 actually have to have made an invention. And making
11 an invention means establishing that what you have
12 made is useful. If you have not done that when you
13 file for a patent, then you have not made an
14 invention. Deciding the point at which you can say
15 that an invention has been made is a fraught
16 question in any patent system. How sure do you have
17 to be that the invention will work, how soon can you
18 patent, at what point does speculation become
19 invention?
20 Canada has, since the Supreme Court's 1979
21 decision in the Monsanto case, taken a permissive
22 approach to this issue through the doctrine of sound
23 prediction. There are two ways to establish utility
24 in Canadian law, demonstration and sound prediction.
25 Utility can be demonstrated by actually building and

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1 practicing the invention, but under the doctrine of
2 sound prediction inventors have been able to claim
3 inventions that have not actually been built or
4 fully tested before filing for a patent. Sound
5 prediction lets you patent further upstream.
6 Patents can be obtained on those
7 predictions so long as the prediction is sound, but
8 this doctrine was never meant to permit patenting
9 even further upstream at the stage of speculation or
10 unsubstantiated predictions. Yet, Claimant argues
11 that before 2002, this is exactly how Canadian
12 patent law worked. On Claimant's view, it was
13 permissible to file a patent on bare speculation or
14 on inconclusive preliminary studies and then later
15 conduct the research to prove that the invention
16 actually works. This position is completely
17 antithetical to longstanding principles of patent
18 law. Courts have discussed this in different ways
19 through the years, but the principle has always been
20 there. You can't patent now and invent later.
21 As the Supreme Court of Canada held in its
22 1948 Wandscheer versus Sicard decision, "It isn't
23 enough to obtain a patent for a man to say that an
24 idea has floated through his brain. He must have
25 reduced it to a definite and practical shape."

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1 Or as the Manual of Patent Office Practice
2 stated in 1990, "An invention may not be said to
3 have been invented until the utility for it is
4 known." And again in 2001, the Federal court held
5 that "Proving actual utility at the claimed date of
6 invention is not the only way of establishing it.
7 Canadian patent law holds, in certain circumstances,
8 sufficient that the inventor had soundly predicted
9 the utility at that date."
10 All of these statements predate the
11 Supreme Court of Canada's 2002 decision in AZT,
12 which Claimant says radically changed Canadian law
13 on this point. Claimant may prefer to live in a
14 world where it can patent now and invent later, but
15 this has never been allowed. The risk of abuse for
16 speculative patenting is obvious, particularly when
17 it comes to new use patents like Claimant's
18 atomoxetine patent. If utility could be established
19 using post-filing evidence, a patentee could simply
20 file patents listing off lucrative uses for known
21 compounds without doing any real research before
22 filing. If a guess turned out to be correct, the
23 patentee would have struck gold. And if it turned
24 out to be wrong, well, it would have only lost a few
25 hundred dollars in filing fees. And either way,

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1 competitors would have been warded off the same
2 research turf.

3 Claimant said this morning because the
4 laws of chemistry don't change, the fact that it
5 works today means that it worked yesterday. But you
6 can't conclude from that the fact that it works
7 today, that you knew it would work yesterday. And
8 that's really the issue here. It's about what was
9 established at the filing date. You can't prove
10 that with testing done after the filing date. As
11 Justice Binnie explained in AZT, "Such speculative
12 patenting is fundamentally inconsistent with
13 longstanding principles of patent law."

14 Several slides back I made reference to a
15 quote found in the 1990 version of MOPOP, so I'll
16 take this opportunity to address the Tribunal's
17 question "What are the implications, if any, of
18 Canada's Manual of Patent Office Practice for the
19 determination of Claimant's claims?"

20 MOPOP cannot form the basis for any
21 expectations about patent validity. It has always
22 expressly stated that it is not an authoritative
23 interpretation of Canadian law. It is a high-level
24 summary, an operating manual for the patent office.
25 The fact that something was included in

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1 MOPOP tells you that the patent office considered
2 that statement relevant to its practice. It doesn't
3 tell you definitively that it was the law. And the
4 omission of something from MOPOP tells you
5 absolutely nothing because of the high level and
6 summary nature of that document. It is not a
7 complete account of the content of Canadian patent
8 law.

9 The last way in which Claimant alleges
10 Canadian law changed is the disclosure requirement
11 for sound prediction. As discussed, there are two
12 ways that a patentee can satisfy the utility
13 requirement. Demonstration or sound prediction.
14 And when a patentee relies on sound prediction, they
15 have to disclose the factual basis and the line of
16 reasoning that supports that prediction. In other
17 words, the inventor has got to tell the public what
18 it is that makes its prediction a sound one.

19 Claimant argues that this rule was created
20 in 2008 in the Raloxifene case, but once again, the
21 historical record undermines Claimant's account. As
22 far back as 1970, practitioners like William
23 Hayhurst were warning, you must include sufficient
24 examples to justify a sound prediction that
25 everything falling within the scope of the claims

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1 will have the promised utility. In the 1979
2 Monsanto case, the Supreme Court affirmed a sound
3 prediction of utility for a group of compounds that
4 was supported by three examples disclosed in the
5 patent. The Supreme Court overturned the Patent
6 Appeal Board's refusal to grant the patent holding
7 that the Board had not provided any reason why three
8 examples were inadequate to support a sound
9 prediction.

10 In its 2002 AZT decision the Supreme Court
11 explained, "In this sort of case the sound
12 prediction is to some extent the *quid pro quo* the
13 applicant offers in exchange for the patent
14 monopoly. Precise disclosure requirements in this
15 regard do not arise for decision in this case
16 because both the underlying facts and the line of
17 reasoning were in fact disclosed."

18 Patent practitioners writing soon after
19 AZT, including the well-known Canadian lawyer Adrian
20 Zahl, recognized the continuity of the disclosure
21 requirement for sound prediction running from
22 Monsanto through to AZT.

23 It's fair and reasonable that Canadian law
24 requires the basis for a sound prediction of utility
25 to be disclosed in the patent. Disclosure of an

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1 invention is the *quid pro quo* of the patent bargain.
2 But remember, in a case of sound prediction, this is
3 a permissive rule for meeting the utility
4 requirement. When you have actually demonstrated
5 the utility of your invention, there is no dispute
6 that you have actually done what you're claiming to
7 have achieved to warrant a patent. But in the
8 context of sound prediction, what you're claiming as
9 your invention is more than you actually did before
10 filing the patent. And in these circumstances, the
11 patentee is not disclosing to the public an
12 invention that is certain to work. To provide the
13 public with a solid teaching, the patentee must at
14 least give the skilled reader enough information so
15 that they can recognize that the prediction is sound
16 and is not mere speculation. And the skilled reader
17 cannot know if the prediction is sound unless the
18 skilled reader knows the factual basis and the line
19 of reasoning supporting that prediction.

20 I'll move now to the third and final part
21 of my submissions. It's essential to understand why
22 utility came to feature prominently in the two
23 patent invalidations that gave rise to this
24 proceeding. Far from being objectively seized upon
25 by the court, promises of new and heightened utility

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<p style="text-align: right;">197 02:52</p> <p>1 were central to Claimant's attempts to further 2 extend its monopoly over previously patented 3 medicines. The story of Claimant's patents 4 illustrates many of the over-arching themes that 5 I've already discussed. The olanzapine and 6 atomoxetine patents were filed by Claimant to extend 7 existing monopolies. Claimant made and emphasized 8 promises of utility to overcome other patentability 9 requirements and justify further monopolies. When a 10 generic company challenged the patents, the parties 11 drove the litigation process, putting vast amounts 12 of evidence before the courts. The court decisions 13 on patent validity were grounded in findings of fact 14 and credibility determinations. The courts were 15 neutral arbiters of the dispute before them. There 16 was no denial of justice. 17 I'll begin with olanzapine. The 18 olanzapine patent at issue in this arbitration is 19 known as the '113 patent. The claimant had enjoyed 20 a monopoly over olanzapine under an earlier patent 21 since 1980. That's the '687 patent. It covered a 22 genus of compounds including olanzapine. As the 23 term of the '687 patent wound down, Claimant looked 24 to extend its monopoly. It filed the '113 patent in 25 1991 and 16 further patent applications for</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">198 02:53</p> <p>1 olanzapine in the following years. 2 The patent office granted Claimant's 3 patent in July 1998. The '113 patent was a 4 selection from the '687 patent. The '687 patent had 5 already disclosed the compound olanzapine to the 6 public. That invention was in the public domain 7 since the '687 patent in 1980. And the '687 patent 8 had already disclosed the potential for olanzapine 9 to treat schizophrenia in the '687 patent. So that 10 is a very important invention, and it is an 11 invention that was made in 1980 and for which 12 Claimant received a monopoly in 1980. 13 To warrant a further monopoly, Claimant 14 had to have discovered surprising advantages of 15 olanzapine over the rest of the genus. It's not 16 surprising, then, that Claimant extolled the 17 usefulness of olanzapine over the genus in its 18 patent, stating that olanzapine shows marked 19 superiority and a better side effects profile than 20 prior known anti-psychotic agents and has a highly 21 advantageous activity level. 22 Claimant did the same in its 23 representations to the patent office in order to 24 secure its patent. The olanzapine patent has come 25 to be one of the most litigated patents in the</p> <p style="text-align: center;">www.dianaburden.com</p>
<p style="text-align: right;">199 02:55</p> <p>1 history of Canadian patent law. There have been 2 three separate proceedings challenging the validity 3 of the patent on numerous interlocking grounds. The 4 patent was at various points found by Canadian 5 courts to be obvious, anticipated, insufficiently 6 disclosed, an invalid selection patent and invalid 7 for double patenting. In short, there were problems 8 with the '113 patent that was at different stages 9 addressed under different legal grounds. 10 In the infringement proceedings that 11 ultimately led to the invalidation of the '113 12 patent, the trial judge heard evidence from 30 13 witnesses over 44 days. Now, earlier today Mr. Born 14 asked whether it was -- whether the advantages 15 stated in the patent were relevant to other 16 patentability requirements. It is abundantly clear 17 from the trial judgment that olanzapine lacked the 18 special advantage over other compounds in the genus 19 that is necessary for a valid selection patent. The 20 trial judge found as a fact that there is no 21 evidence that olanzapine was superior to any other 22 compounds in the '687 class in respect of the 23 characteristics described in the '113 patent. 24 So the whole point of the selection patent 25 is to identify an advantage of this compound over</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">200 02:56</p> <p>1 the rest of the class. And this is the trial 2 judge's finding of fact. There was no evidence that 3 olanzapine was superior to any other compounds in 4 that class. These findings led the trial judge to 5 conclude that the '113 patent was not a valid 6 selection patent. The Claimant appealed this 7 decision and the Federal Court of Appeal reversed 8 the trial judge on the basis that not being a valid 9 selection patent was not a freestanding ground of 10 invalidity in Canadian patent law. The requirements 11 for valid selection have to be dealt with under the 12 other patentability requirements. And specifically 13 the Federal Court of Appeals said you should deal 14 with the advantages necessary for a selection 15 patent. Evidence of those advantages, you should 16 deal with it under the utility requirement, and 17 specifically through promised utility. The Federal 18 Court of Appeal remanded the case to the trial judge 19 instructing him to address evidence of the 20 advantages necessary for a selection under the 21 utility requirement. And here there's a twist in 22 the litigation, because before the case was 23 remanded, before it was sent back down to the trial 24 court to be decided in accordance with utility, 25 actually the generic challenger sought leave to</p> <p style="text-align: center;">www.dianaburden.com</p>

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1 appeal this decision to the Supreme Court of Canada.
2 And what did Claimant do when the generic
3 sought leave to appeal? It opposed leave to appeal,
4 and it said that the Federal Court of Appeal did
5 nothing more than follow established principles of
6 patent law and the jurisprudence of this court.
7 This is Claimant's comments regarding the decision
8 of the Federal Court of Appeal in which it
9 specifically instructed the trial judge to deal with
10 the advantages for a selection patent through
11 promised utility. Claimant did not flag the
12 slightest concern with the Federal Court of Appeal's
13 instructions to the trial judge on this issue.
14 So Claimant has today made much of a
15 submission for leave by a generic company calling
16 the promise utility doctrine a free-for-all, but
17 this is certainly not the way Claimant was referring
18 to the doctrine in its submissions to the Supreme
19 Court of Canada after the Federal Court of Appeal's
20 first decision in olanzapine. The Supreme Court of
21 Canada denied leave to appeal and it went back to
22 the trial judge. The judge concluded that the
23 patent promised olanzapine treats schizophrenia
24 patients in the clinic in a markedly superior
25 fashion with a better side effects profile than

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1 other known anti-psychotics. This was not
2 subjective or arbitrary, as you can see. It
3 essentially directly tracks the language of the
4 patent itself. The court found as a fact that
5 Claimant had neither demonstrated nor soundly
6 predicted this promised utility for olanzapine when
7 it filed for the patent. So the patent was invalid,
8 and that holding was affirmed on appeal. There was
9 not a single dissent. Claimant sought leave to
10 appeal to the Supreme Court of Canada, and leave was
11 denied.
12 Just as with olanzapine, Claimant had
13 already enjoyed a decades-long monopoly over
14 atomoxetine before it filed the patent at issue in
15 this arbitration, the '735 patent. The Claimant
16 first obtained a monopoly over the genus of
17 compounds including atomoxetine in 1979. In 1985
18 Claimant filed for a second patent, claiming only
19 atomoxetine for use as an antidepressant. As the
20 term of these patents wound down, starting in the
21 mid 1990s, Claimant filed the '735 patent and 11
22 other patent applications claiming to have invented
23 new uses for atomoxetine. Some disclosed
24 experimental data, and others disclosed nothing at
25 all. Claimant ultimately abandoned every one of

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1 these secondary patent applications except for the
2 '735 patent, which it filed in 1996 and which was
3 granted in October 2002.
4 A generic drug company challenged the
5 validity of the '735 patent in 1998 for obviousness,
6 anticipation and lack of utility. The Federal court
7 heard argument and evidence from six witness over
8 the course of a 19-day trial. The '735 patent
9 expressly claimed the use of atomoxetine for
10 treatment of attention deficit/hyperactivity
11 disorder. This language was in the claims of the
12 patent, not in the disclosure. The trial judge had
13 to interpret what treatment of ADHD meant in the
14 claims. This was the claimed utility of the
15 invention. The trial judge followed the
16 longstanding method of interpreting the claims
17 through the eyes of a skilled reader based on expert
18 evidence. He found as a fact that in the context of
19 a patent claiming treatment of ADHD, which is a
20 chronic disorder, a skilled reader would understand
21 treatment to require sustained treatment. It's on
22 the basis of this inventive contribution that the
23 trial judge found the '735 patent to clear the
24 hurdles of obviousness and anticipation. That left
25 the issue of utility.

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1 To establish utility, Claimant relied
2 exclusively on the results of a small short-term
3 study conducted in 1995 known as the MGH study. The
4 parties introduced competing evidence, but Claimant
5 chose not to call any witnesses with direct
6 knowledge of the study. After carefully weighing
7 the evidence, the trial judge made credibility
8 findings in favor of the generic company's expert,
9 whose opinion was that the MGH study was a pilot
10 study with so many methodological limitations that
11 its data were only preliminary and, at best,
12 interesting. The court found as a fact that the MGH
13 study was not sufficient to demonstrate the claimed
14 utility. Nor did the patent disclose any factual
15 basis to support a sound prediction of utility. The
16 MGH study was not mentioned anywhere in the patent.
17 Claimant showed a slide this morning --
18 and I'm afraid I don't have the number, but you'll
19 remember it had a stack of boxes. It was quite
20 remarkable. And those boxes showed the effect --
21 what it says is the effect of the promise utility
22 doctrine in the atomoxetine case. But the boxes
23 aren't quite right because what they showed was that
24 in the absence of the disclosure rule, there was
25 enough proof to establish utility. In other words,

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1 there was enough proof in the MGH study to show a
2 sound prediction of utility. The trial judge made
3 no finding of fact to that effect, no finding that
4 the MGH study would have provided adequate support
5 for a sound prediction had it been disclosed in the
6 patent. And given the judge's views on the study's
7 many flaws, it is entirely possible the patent would
8 still have been invalid had the study been disclosed
9 in the patent.

10 Claimant appealed to the Federal Court of
11 Appeal, which upheld the trial court decision and
12 described it as "careful and thorough." There was
13 not a single dissent. Claimant sought leave to
14 appeal to the Supreme Court of Canada, but leave was
15 denied. It's uncontested that in both the
16 atomoxetine and olanzapine proceedings, Claimant had
17 robust due process and appellate review. Claimant
18 does not and could not possibly allege a denial of
19 justice.

20 Claimant is asking this Tribunal to
21 overturn the decisions of Canada's courts on whether
22 it lived up to the patent bargain. It asks this
23 Tribunal to scrutinize Canada's utility requirement
24 in isolation from the broader context of the patent
25 bargain as a whole. It not only ignores the deep

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1 Federal courts. Again, a description that Canada
2 submits is far less biased and self-serving than
3 what the Claimant has presented to this Tribunal.

4 Canada is confident that the Tribunal will
5 come to agree with Canada's view of the facts and
6 Canada's interpretation of patent law, especially
7 once it hears the testimony over the next couple of
8 weeks.

9 But the Tribunal does not need to wait for
10 two weeks of interesting but ultimately irrelevant
11 testimony to reach the conclusion that Canada has
12 not breached NAFTA articles 1105 and 1110.

13 That conclusion became inescapable once
14 the Claimant conceded that it had no basis to argue
15 that Canada's Federal courts and the judgments at
16 issue here constituted a denial of justice. That
17 concession was fatal to the Claimant's entire case.

18 When a NAFTA party is faced with a customary
19 international law minimum standard of treatment of
20 aliens claim, or a claim that a NAFTA party has
21 expropriated the property of an investor, and the
22 impugned measure is a judgment of a domestic court
23 applying domestic law, there is only one basis of
24 legal responsibility under 1110 and 1105, and that's
25 denial of justice.

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1 roots of the rules applied to invalidate its
2 patents, Claimant is trying to rewrite the history
3 of Canadian patent law to serve its current
4 interests. Claimant's myopic and self-serving
5 account should not be accepted by the Tribunal.

6 That concludes my submissions. I'd be
7 happy to answer any questions that the Tribunal has.

8 **THE PRESIDENT:** No questions at this
9 stage.

10 **MR. JOHNSTON:** With that, let me now
11 introduce my colleague, Mr. Luz.

12 **MR. LUZ:** Good afternoon. My name is Mark
13 Luz. I'm senior counsel for the Government of
14 Canada. For the next 45 minutes I will set out
15 Canada's legal argument with respect to the
16 interpretations of NAFTA articles 1105 and 1110.

17 My colleague, Mr. Johnston, described for
18 you the rich and complex history of patent law in
19 Canada and its treatment of the utility requirement,
20 a description that Canada submits is more fulsome
21 and more accurate than what you heard from the
22 Claimants this morning.

23 Mr. Johnston also described the history of
24 the litigations in which the Claimant's atomoxetine
25 and olanzapine patents were invalidated by the

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1 This NAFTA Tribunal can only base its
2 decision on the legal rules, the international legal
3 rules that are encompassed by 1105 and 1110. Those
4 rules are clear when it comes to the final judgments
5 by an independent judiciary on a question of
6 domestic law. If the foreign investor cannot
7 demonstrate that after all efforts to appeal, it
8 suffered from egregious treatment from the host
9 state's courts or that the judgment was so
10 astonishing that judicial propriety has to be in
11 question, its expropriation and minimum standard of
12 treatment claims must fail.

13 Before I go on with the outline of my
14 argument, I do have to point out the quote from
15 Professor Douglas that is up here because it was
16 brought up this morning by the Claimants saying
17 there was no support and that Professor Douglas did
18 not cite anything to support the restatement of the
19 rule that denial of justice is the sole form of
20 international delictual responsibility for acts or
21 omissions within an adjudicative procedure for which
22 the state is responsible.

23 I would just encourage the Tribunal to
24 read the 118 footnotes upon which this statement is
25 made, including -- and I haven't had time to count

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1 all of the authorities upon which Professor Douglas
2 relies, but quickly looking through them I notice
3 Mondev, Loewen, Jan Paulsson --
4 **THE PRESIDENT:** I have to slow you down.
5 **MR. LUZ:** I'm sorry. I will go slower.
6 There are a lot of footnotes. There are a lot of
7 authorities for this statement. It really just
8 states what the customary international legal rule
9 is that all previous NAFTA Tribunals have endorsed
10 and the three NAFTA parties have endorsed.
11 So I will commence my argument today with
12 the -- first on 1105, the legal standard that must
13 be applied under 1105, and explain why in the
14 circumstances of this case, there is no liability
15 for Canada without a denial of justice. Then I will
16 address expropriation under 1110. Because the
17 challenged measures here deal only with domestic
18 court judgments determining that a domestic property
19 right was invalid, the legal threshold for finding a
20 violation of 1110 is the same as it is under 1105.
21 Denial of justice.
22 But I will address some of the
23 particularities of expropriation in international
24 law. Specifically I'll first address how the NAFTA
25 and international law deals with the question of

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1 whether property exists. That is a condition
2 precedent to the second question as to whether or
3 not expropriation of that property, as understood in
4 international law, has actually occurred.
5 And the third issue I'll deal with is
6 Article 1110(7), and that's the provision that
7 Canada submits was intended by the NAFTA parties to
8 prevent exactly the kind of claim that is before
9 this Tribunal.
10 Throughout my presentation I'll respond to
11 questions that the Tribunal has posed, and after my
12 presentation I'll turn the podium back to my
13 colleague, Mr. Spelliscy, who will address not only
14 Canada's *ratione temporis* argument, but the
15 substance, or lack thereof, in the Claimant's claim.
16 So first I'll deal with 1105, minimum
17 standard of treatment. I have three arguments.
18 First, the legal standard is the customary
19 international law minimum standard of treatment of
20 aliens. Any argument as to the content of that law
21 is a burden that the Claimant must fulfill. It must
22 adduce evidence of uniform and consistent state
23 practice and *opinio juris* to establish those rules.
24 Second, when it comes to domestic court
25 judgments in litigation in domestic courts between

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1 private parties, customary international law is
2 definitive. Only a denial of justice will result in
3 a breach of the minimum standard of treatment.
4 My third argument is that the Claimant's
5 attempt to eliminate the distinction between acts of
6 an independent judiciary and acts of other branches
7 of government, that is to deny the very existence of
8 the denial of justice doctrine, is not only legally
9 untenable, but it would result in the same outcome
10 anyway. And that's because the Claimant's arguments
11 regarding discrimination, arbitrariness and
12 legitimate expectations are legally incorrect and
13 factually irrelevant.
14 So my first argument, the legal standard
15 applicable under 1105, customary international law
16 minimum standard of treatment. Now, we know what
17 Article 1105 says. The text is well known. It's
18 presented there. But what does Article 1105 mean?
19 Well, in July 2001, the NAFTA Free Trade Commission
20 issued a note of interpretation which clarified
21 exactly what 1105(1) meant. It said -- and it's not
22 in dispute that this is binding on the Tribunal
23 pursuant to 1131. But the NAFTA FTC -- Free Trade
24 Commission said that the concept of fair and
25 equitable treatment does not require treatment in

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1 addition to or beyond that which is required by the
2 customary international law minimum standard of
3 treatment of aliens.
4 A couple of critical points for the
5 Tribunal, because it was an issue of interest for
6 the Tribunal this morning. The first critical point
7 is that customary international law is a true source
8 of law. It's not simply dispensable or replaceable
9 with whatever principles or rules that an investor,
10 a state or a Tribunal feels that would be desirable
11 or convenient under the circumstances. Rules of
12 custom are established by substantial state practice
13 and *opinio juris*. That is a feeling on the part of
14 the state that it is binding -- that it is binding
15 and they are obliged to follow a legal rule.
16 Now, Article 1105 has been the subject of
17 many NAFTA claims. And I won't spend a lot of time
18 discussing them. Cases like Cargill, Mobil, Glamis
19 and others which have affirmed the minimum standard
20 of treatment requires evidence of egregious
21 treatment in order to violate the standard. The
22 Cargill tribunal, there's a representative statement
23 there as to how serious the kind of behavior we're
24 talking about is in order to breach 1105.
25 The reason why I don't need to spend a lot

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1 of time talking about those cases is because what is
2 unanimous amongst all the NAFTA Tribunals that have
3 come before this Tribunal is that the doctrine of
4 denial of justice applies when it comes to the
5 judgments of domestic courts. I'll return to that
6 point in a moment, but I do have to emphasize,
7 because the Tribunal's questions were coming up, and
8 it was a question as to whether or not the FTC note
9 has become superfluous. It is definitely not
10 superfluous. It is the binding authority and the
11 binding will of the NAFTA parties pursuant to
12 1131(2) that the Tribunal must apply what customary
13 international law is.

14 So if there is something else other than
15 denial of justice that is applicable to the
16 decisions of domestic courts, it is a burden that
17 the Claimant must establish through substantial
18 state practice and opinio juris. Again, I'll come
19 to that in a little bit.

20 I'd like to address the second critical
21 point, and this responds to the Tribunal's question
22 14 as to what are the implications of the FTC's note
23 that a determination of a breach of another NAFTA
24 provision or another international treaty does not
25 establish a breach of 1105.

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1 The answer is straightforward. Even if
2 the Claimant could establish that there was a breach
3 of NAFTA Chapter 17 or if a WTO panel found Canada
4 in violation of TRIPS or the International Court of
5 Justice found Canada in violation of the PCT, that
6 still would not, ipso facto, result in a breach of
7 1105. Again, Article 1105 can only be found if
8 there is behavior that falls below the minimum
9 standard of treatment. I'll just have a quick
10 illustration from the Mobil Murphy arbitration
11 because in that case the Tribunal found a research
12 and development expenditure requirement violated
13 NAFTA Article 1106, which is a provision on
14 performance requirements. Then in a split decision,
15 the majority of the Tribunal found that Canada's
16 reservation for the legislation at issue did not
17 save the violation. But the Mobil Tribunal
18 recognized that whether or not there was a violation
19 of 1105 is a very different question. It recognized
20 that it had to be judged on the same exacting
21 customary international legal standard that I
22 described before. And they concluded that there was
23 no such violation.

24 So my second argument on 1105 really gets
25 to the heart of the matter because as I said before,

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1 putting aside all of the debate on 1105 generally,
2 there is no dispute that when it comes to the
3 decisions of domestic courts, interpreting domestic
4 law, denial of justice is the only basis of
5 violation. And this goes to the Tribunal's question
6 No. 13.

7 **SIR DANIEL BETHLEHEM:** Mr. Luz, can I just
8 stop you there. And tell me if you're going to come
9 to this.

10 Are you going to tell us where customary
11 international law comes from for these purposes?

12 **MR. LUZ:** On the denial of justice
13 standard specifically, yes, I will be addressing
14 that.

15 In fact, the answer to the Tribunal's
16 question 13 is 1105 and 1110. Now, customary
17 international law does have special rules for
18 actions taken by a state's judiciary, and that has
19 developed over centuries. And I will be addressing
20 it in a little bit more detail in my discussion of
21 expropriation, but there have been many decades of
22 state practice and recognition by the states that
23 when it comes to the organs of -- there's no dispute
24 that states are responsible for their organs. It's
25 just a question of what is the level of

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1 responsibility for actions taken by courts. And all
2 three of the NAFTA parties, as we have submitted in
3 1128s, have acknowledged that there's the denial of
4 justice standard when it comes to the actions of
5 courts. And that is supported by many years of
6 state practice and opinio juris. It goes back to
7 many of the judicial doctrines and academic writings
8 and so on that have been built up. Many of those
9 are cited in Canada's pleadings, and it does go back
10 a fair way.

11 **SIR DANIEL BETHLEHEM:** I don't at all want
12 to subvert you from your submissions. Let me just
13 put down a marker because otherwise I'll come back
14 on it a little bit later. I think in the Claimant's
15 submissions this morning and the engagement with the
16 Tribunal, there was some discussion about whether
17 for shorthand we're looking for customary
18 international law to Neer and its progeny or whether
19 we're looking to a kind of a BIT standard. And I
20 think we haven't quite got to the nub of the
21 difference between the parties and, as I say, I
22 don't invite you -- unless you want to address that
23 now, but I would like you or Canada at some point to
24 address that issue.

25 **MR. LUZ:** Sir Daniel, I'm happy to address

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1 that now. And the position of the NAFTA parties has
 2 always been that there's no evidence of state
 3 practice to support the thesis that there's a
 4 convergence in the minimum standard of treatment and
 5 customary international law with the findings of
 6 autonomous fair and equitable treatment standards
 7 that some other Tribunals have done. That's always
 8 been the position. It's been the argument that many
 9 Claimants have made, including the Claimant in
 10 Mobil, trying to bring together the findings of
 11 Tribunals that have interpreted fair and equitable
 12 treatment clauses that have no reference to
 13 customary international law to say that this is the
 14 same thing.
 15 And the NAFTA parties have always said
 16 that that is not the -- that is not sufficient
 17 evidence, that findings of Tribunals that are
 18 interpreting autonomous fair and equitable treatment
 19 clauses do not constitute evidence of state
 20 practice, and Tribunals like Cargill and others have
 21 acknowledged that there needs to be state practice
 22 in order to be able to establish what the Claimants
 23 are arguing.
 24 **MR. BORN:** Isn't it Canada's position that
 25 the Neer standard is the only standard that is

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1 applicable as a matter of customary international
 2 law in addressing denial of justice?
 3 **MR. LUZ:** Canada has never said that the
 4 Neer standard is -- it will be frozen in time from
 5 that.
 6 **MR. BORN:** It says the opposite, the Neer
 7 standard has evolved since the 1920s?
 8 **MR. LUZ:** Not on the question of denial of
 9 justice, which is the issue that is before this
 10 court today -- before the Tribunal today. There has
 11 been a recognition that customary international law
 12 can evolve, but it certainly has not evolved to the
 13 point where Claimants can simply make the bold
 14 assertion that fair and equitable treatment equals
 15 customary international law. Therefore, what one
 16 Tribunal in a different arbitration studying a
 17 different treaty says is fair and equitable
 18 treatment equals customary international law.
 19 **MR. BORN:** Does Canada have a position on
 20 how much the Neer standard has evolved?
 21 **MR. LUZ:** Again, on the key issue here for
 22 denial of justice, that has been -- it's not really
 23 necessarily something that was dealt with directly
 24 in the Neer case, from what I recall. But in terms
 25 of the standard that is applicable here for denial

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1 of justice, it hasn't evolved in a way that the
 2 Claimant has suggested, that it has evolved to a
 3 point where actions of a judiciary and the absence
 4 of a denial of justice can violate the minimum
 5 standard of treatment.
 6 **MR. BORN:** And when you refer to denial of
 7 justice in this context, what you mean is your
 8 submission on the slide, that the only way that a
 9 domestic court ruling can violate the minimum
 10 standard is by a denial of justice, not by any other
 11 means?
 12 **MR. LUZ:** That's right. Under customary
 13 international law, that is the standard. And there
 14 has been no evidence provided that that has changed.
 15 **MR. BORN:** Not just the standard, if I can
 16 quibble. The only standard.
 17 **MR. LUZ:** That is the only standard that
 18 Canada is aware of. It's difficult to come up with
 19 any kind of scenario and especially given the fact
 20 that all of the arbitral precedent that the Claimant
 21 has relied on really does not get to the issue that
 22 is before this Tribunal. The only ones that have
 23 are the ones that Canada relies on, Mondev, for
 24 example, Loewen, for example. Azinian. In fact,
 25 Azinian is actually coming in the next slide, so

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1 perhaps I can use that as a segue to a further
 2 answer as to what a denial of justice is.
 3 This is where the Azinian Tribunal with
 4 Chairman Paulsson pointed out that it could be
 5 refusal to entertain a suit subjected to undue delay
 6 or to administer justice in a seriously inadequate
 7 way. Then the fourth type of denial of justice,
 8 namely the clear and malicious misapplication of the
 9 law in pretense of form and questioning the bone
 10 fides of the judgments. I believe, Mr. Born, you
 11 did ask that question sort of earlier on about is
 12 there a difference between substantive and
 13 procedural denial of justice. I don't suggest that
 14 we need to come to an arrival on that. Jan Paulsson
 15 would say that all denials of justice are
 16 procedural, that if there is a decision by a court
 17 that is so fundamentally baffling and no reasonable
 18 judge could ever come to that conclusion, that that
 19 really is a procedural failure of the entire legal
 20 system to find a correction for that. So
 21 while there -- you know, this question of clear and
 22 malicious misapplication of the law, that really is
 23 a denial of justice.
 24 I'll come to some other quotes that really
 25 do emphasize that even if a domestic court got a

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1 decision wrong under domestic law or even if it was
2 something that you could have a preferred or a
3 better interpretation, that's not good enough. That
4 will not violate international law. And I will come
5 more to explain why that is the case.
6 **STR DANIEL BETHLEHEM:** Are you hinting
7 you'll get there but that's something like egregious
8 irrationality? Are you grappling towards kind of a
9 common law approach what might be unreasonableness
10 amounting to a denial of justice?
11 **MR. LUZ:** That's right. I guess this goes
12 back to the question as to why the denial of justice
13 is the standard when it comes to the actions of the
14 court. It comes down to state sovereignty and the
15 special role that courts play as the neutral
16 adjudicators of justice. I don't need to remind the
17 Tribunal the importance an independent judiciary
18 plays in upholding the rule of law and in resolving
19 disputes. That's where why there are appellate
20 mechanisms and safeguards in a judicial system to
21 ensure that litigants are afforded due process,
22 rules are applied impartially and properly as best
23 they can within an imperfect system.
24 I have to say, the Tribunal knows that
25 domestic courts face difficult questions of

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1 substantive law, facts, procedural evidence on a
2 daily basis. It's for those reasons that the acts
3 of independent judiciaries are entitled to a
4 presumption of regularity, and they are accorded
5 great deference, especially when it comes to the
6 interpretation of their own domestic law.
7 It seems to be lost on the Claimant, but
8 it's to state the obvious that reasonable minds can
9 disagree on findings of fact and findings of law.
10 It's only when a judgment is so bereft of logic and
11 foundation that international law might then
12 question whether a denial of justice has occurred.
13 If I could go to the next slide, Judge
14 Greenwood -- or Professor Greenwood at the time he
15 filed this but now Judge Greenwood in the
16 International Court of Justice said it, I think,
17 very well. "The international Tribunal is not a
18 Court of Appeal from national courts. It's not the
19 task to review the findings of national courts.
20 It's in the absence of clear evidence of bad faith
21 on the part of the relevant court, the Claimant must
22 demonstrate that it was either the victim of
23 discrimination on account of its nationality or that
24 the administration of justice was scandalously
25 irregular.

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1 The last sentence I think encapsulates
2 what I've been trying to respond to the Tribunal's
3 questions that defects in procedure or a judgment
4 which is open to criticism on the basis of either
5 rulings of law or findings of fact are not enough.
6 The Loewen Tribunal recognized that that
7 was the customary standard, and again, as I
8 mentioned earlier, the Mondev Tribunal also came to
9 that question, and it stands out because of the
10 striking similarities the Mondev case has to the
11 case before you today. In that case the Claimant
12 argued that the Massachusetts Supreme Judicial Court
13 had engaged in a significant and serious departure
14 from its previous jurisprudence and had rendered an
15 arbitrary and profoundly unjust judgment. But Sir
16 Steven and Judges Crawford and Schwebel, they were
17 cognizant of their limited role as a Chapter 11
18 Tribunal and the legal rules it had to apply. They
19 noted in the context of 1105 that it's denial of
20 justice -- and you can see it right here. "The
21 Tribunal is thus concerned only with that aspect of
22 1105 which is commonly called ...denial of justice.
23 The standard... of treatment of aliens applicable to
24 the decisions of the host state's courts or
25 Tribunals."

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1 It went on to say that, "It is one thing
2 to deal with the unremedied acts of the local
3 constabulary and another to second-guess the
4 reasoned decisions of the highest courts of the
5 state. Under NAFTA, parties have the option to seek
6 local remedies. If they do so and [they] lose on
7 the merits, it is not the function of NAFTA
8 Tribunals to act as courts of appeal."
9 A key part of the Mondev ruling is they
10 said that even if the courts had changed the rule
11 and even if they had made a new rule, that was a
12 normal part of common law adjudication. It was
13 acceptable, and it was not at all shocking to
14 judicial sensibility because that was the test.
15 **MR. BORN:** Just to try to pursue a little
16 bit the hypothetical that I provided earlier to
17 elaborate it a bit just for the sake of analysis, if
18 Parliament adopted legislation that revoked all, I
19 don't know, automotive parts patents on the basis
20 that it was in the national interest to do so, that
21 might be an expropriation. Might be. There could
22 be defenses. But if a Canadian court reached
23 exactly the same ruling using the doctrine of public
24 policy for the purposes of the Patent Act, that
25 couldn't be an expropriation because it's not a

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1 denial of justice. Is that your position?
 2 **MR. LUZ:** Mr. Born, I think I can answer
 3 that question by turning to the next slide. Mondeve
 4 said, "The test is not whether a particular result
 5 is surprising, but whether the shock or surprise
 6 occasioned to an impartial Tribunal leads, on
 7 reflection, to justified concerns as to the judicial
 8 priority of the outcome."
 9 So there is a very big difference
 10 obviously between the two scenarios that you've
 11 presented between Parliament doing something,
 12 revoking a patent. That was something that patent
 13 rights existed before and they don't exist later.
 14 What a court does when it does an invalidation in
 15 this case is that it examines whether or not the
 16 patent was valid to begin with. It's a very
 17 different kind of scenario. So in a scenario where
 18 a court comes up with a rule out of nowhere and
 19 applies it in a way that is so surprising or
 20 shocking and that no impartial Tribunal could think
 21 that was an appropriate way to deal with it, I think
 22 that would fall into what Jan Paulsson said is that
 23 that's a procedural denial of justice. It's
 24 something that represents a failure of the judicial
 25 system as a whole. So I think, again, it's

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1 difficult to argue in the abstract, but the
 2 standards that the denial of justice, the customary
 3 international law denial of justice standard, covers
 4 those kinds of scenarios. We really are so far away
 5 from what happened in this case, I don't want to
 6 suggest at all that we're conceding that this is
 7 even in the realm of what's happening. But I
 8 appreciate the hypothetical.
 9 **MR. BORN:** I'm just trying to push the
 10 envelope in terms of this step of the analysis.
 11 **MR. LUZ:** Absolutely.
 12 **SIR DANIEL BETHLEHEM:** Can I push it just
 13 a little bit further?
 14 Were we to be with the Claimant on the
 15 issue of referability to Chapter 17 and were we to
 16 be against you on the question of what our
 17 competence is as a Tribunal and we come, then, to
 18 the point of 1709(8), a party may revoke a patent
 19 only when grounds exist that would have justified a
 20 refusal to grant the patent, and were we to be with
 21 the Claimant on the question that the refusal in
 22 this case was on new grounds, would that give rise
 23 to a denial of justice because it would not be
 24 within the contemplation of the -- I mean as the
 25 principle set out in Mondeve here?

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1 **MR. LUZ:** It would not. And international
 2 law is very clear on that. That might give rise to
 3 a question of Canada's international legal
 4 obligations vis-a-vis the United States. And that
 5 would be within the realm of a NAFTA Chapter 20
 6 Tribunal. So there is a very big difference between
 7 the obligations that are owed to a state's
 8 counterparties and obligations that are owed under
 9 customary international law for 1105 and 1110. So
 10 that would not be, ipso facto, an expropriation.
 11 You would still need to reach the denial of justice
 12 standard.
 13 And with respect to 1105, that is very
 14 clear from the FTC note. It says that finding of
 15 breach of another provision of the NAFTA is not a
 16 breach of Article 1105. And unless there is some
 17 other customary international rule that the
 18 Claimants can prove by substantial state practice
 19 and opinio juris, that is the rule that applies.
 20 **THE PRESIDENT:** Sorry.
 21 **MR. LUZ:** Please. I'm happy to answer
 22 questions as long as it's being counted towards
 23 someone else's time.
 24 **THE PRESIDENT:** Can you go back to slide
 25 67. It might tie in to the last question you had,

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1 but in all the discussion I may have missed your
 2 answer on Tribunal question 14. If you have given
 3 it, would you be so kind to give it again?
 4 **MR. LUZ:** Of course. A breach of another
 5 provision of the NAFTA or of another international
 6 treaty does not, ipso facto, result in a breach of
 7 1105. And I gave the example of the Mobil case
 8 where there was a breach of 1106 that was found by a
 9 majority of the Tribunal; but, yet, the breach of
 10 1105 was not found because they applied the
 11 customary international standard in that case and
 12 they were two separate issues.
 13 **MR. BORN:** I was going to ask before but
 14 decided I wouldn't, but since you said it again, I
 15 can't resist. You said a breach of another
 16 obligation doesn't, ipso facto, result in a breach
 17 here. I suspect the Claimants would agree with you
 18 on that, but I think the real question is is the
 19 breach of Chapter 17 relevant and, if so, how, to a
 20 breach under 1105?
 21 **MR. LUZ:** We would say that it is not.
 22 Again, because of the fact that the denial of
 23 justice standard applies to this scenario before the
 24 Tribunal. It is the decision of a court, an
 25 independent court after due consideration, that it

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1 decided that under Canadian patent law the
2 Claimant's patents were not valid. That cannot be,
3 without something more, a violation of international
4 law because at that point then the Tribunal does
5 become automatically an appellate review for every
6 single allegation that a Claimant might have. There
7 has to be the egregious treatment. There has to be
8 the level of offensiveness to judicial propriety
9 that -- as I went to the Azinian case and other
10 cases, and Mondev, that is what has to be reached.
11 And I did say that there were other NAFTA cases.
12 If we could skip forward back to Waste
13 Management. And I won't go through it too much, but
14 Waste Management did the same thing. It
15 acknowledged that the Tribunal is not a court of
16 appeal, and it's not the role of a NAFTA Chapter 11
17 Tribunal to review the domestic decisions and that
18 denial of justice is the standard. Grand River as
19 well. They said that the Tribunal is loathe to
20 address these delicate questions of U.S.
21 constitutional and Indian law. Those belong in
22 national courts, not international Tribunal.
23 I'd already mentioned that the United
24 States is also onboard with Canada's position.
25 Challenging judicial measures under 1105 is limited

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1 to a claim of denial of justice. Mexico feels the
2 exact same way. Mexico agrees with Canada that
3 denial of justice is the only rule of custom that is
4 part of the minimum standard treatment of aliens.
5 My third and final argument on 1105
6 responds to the Claimant's use of catch phrases like
7 discrimination, arbitrariness and legitimate
8 expectations. Labels are no substitute for
9 analysis. Analysis confirms that the Claimant's
10 allegations are void of merit. I'll just briefly
11 discuss the legal standards because my colleague,
12 Mr. Spelliscy, will talk about them in the context
13 of actually what happened here.
14 Discrimination. Again, context is
15 critical. In a domestic court proceeding, if the
16 judge engages in local prejudice or animus against
17 an investor because he or she is a foreigner, that's
18 the kind of malicious discrimination that might
19 support a denial of justice claim. But the minimum
20 standard of treatment of aliens in custom has
21 nothing to say about favoring one type of technology
22 over another or domestic product or a foreign one.
23 Customary international law allows for differential
24 treatment. States do that all the time with respect
25 to foreign goods and services, as the Grand River

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1 Tribunal pointed out.
2 So there's been no allegation that the
3 outcome of these trials had anything to do with
4 Lilly's status as an American corporation, so the
5 1105 analysis really ends there.
6 Arbitrariness. Claimant doesn't say that
7 the trials themselves were arbitrary, although
8 depending on how you listen to what they said this
9 morning, that might be the conclusion you come to.
10 It's just that the Canadian court's interpretation
11 of the word "useful" is arbitrary. This argument is
12 less than paper thin, and I'll let my colleagues
13 explain why, as Mr. Johnston has already said.
14 But the point is that even if the Claimant
15 disagrees with the Canadian court's interpretation
16 and even if they have some plausible or credible
17 ideas as to why a different interpretation of
18 utility might be preferable, a reasoned rationale
19 based on a good-faith interpretation of the statute
20 and jurisprudence and the assessment of facts of an
21 Tribunal cannot be arbitrary in international law.
22 The statement of arbitrariness, you can see from the
23 LC decision before the International Court of
24 Justice made it clear that arbitrariness is not
25 something opposed to a rule of law. It's something

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1 opposed to the rule of law.
2 The Cargill tribunal also went in and
3 noted in its findings that you can't simply label
4 something arbitrary because of inconsistency or you
5 think there could have been or should have been a
6 different outcome. The arbitrary label here that
7 the Claimant uses really is just designed to
8 second-guess the outcome of the domestic litigations
9 and avoid the denial of justice rule.
10 Legitimate expectations.
11 **SIR DANIEL BETHLEHEM:** Sorry. You're
12 setting the standard very high, aren't you? I mean
13 if you're saying that a reasoned, rational decision
14 based on good faith cannot be arbitrary, if it's a
15 reasoned rational based on good faith but, for
16 example, it doesn't take into account something
17 which manifestly it should have because it was just
18 not within the judge's contemplation, doesn't that
19 change the equation? I mean I'm really just trying
20 to put a finger on whether you're really meaning
21 what you're saying here, whether you're stating this
22 too highly.
23 **MR. LUZ:** I apologize if I left the words
24 out, but a good-faith interpretation of the statute
25 and the jurisprudence and the assessment of the

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1 facts at trial, so something to be able to say that
2 there was a rational and reasoned basis by a court
3 that was not in the way that was described before in
4 denial of justice, that had a result that was so
5 surprising that propriety and competence had to be
6 questioned. Obviously there is a limit to that, and
7 we can't say that any kind of judgment by any court
8 as long as it was written on a piece of paper that
9 had no reasons fulfills the standard, no. Clearly
10 not.

11 I do want to get to the Tribunal's
12 questions on legitimate expectations, questions 15
13 and 16. I don't want to spend too much time on them
14 because Canada would submit that the Tribunal
15 doesn't need to resolve this debate about legitimate
16 expectations. But we're pleased to respond, and
17 question 15, protecting investors legitimate
18 expectations, well, the NAFTA parties have always
19 said the protection of legitimate expectations is
20 not a rule of customary international law. It's the
21 longstanding position of the NAFTA parties. The
22 Claimant has submitted no evidence of opinio juris
23 and state practice to show otherwise.

24 I'll point the Tribunal to the Glamis
25 award, where it said that even when a state

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1 administrative agency changed the prior legal
2 interpretation of certain mining rights and even
3 though that new legal interpretation dramatically
4 changed the regime, there was still no breach of
5 Article 1105 without a gross denial of justice or
6 complete lack of due process.

7 Now, when the Tribunal asked about
8 specific representations in question 16, the Mobil
9 Murphy Tribunal, they talked about that. If you
10 were to take that into account as a factor as to
11 whether or not there has been egregious conduct,
12 there has to be clear and explicit representations
13 to the investor upon which it reasonably relied in
14 order to induce the investment, and then it was
15 subsequently repudiated with no justification.

16 The Mobil Tribunal did point out that 1105
17 is not intended to prevent new rules and new burdens
18 from emerging over the course of the life of an
19 investment. It's just that it's intended to make
20 sure that things are done in a way that comports
21 with the minimum standard of treatment.

22 But, again, we don't need to resolve this
23 debate because the one thing that is beyond doubt is
24 that the doctrine of legitimate expectations has no
25 application whatsoever to the judiciary. There are

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1 no awards or academic support whatsoever that graft
2 the theory of legitimate expectations and then apply
3 them to the outcome and rulings of a domestic court
4 interpreting domestic law. It wouldn't even make
5 sense in the domestic arena, let alone
6 international. No court gives assurances on the
7 outcome of a litigation. No court says that its
8 view and interpretation of the law will not evolve
9 or even change as new evidence, new facts, new
10 circumstances are presented before it in trial.

11 So really, again, because the denial of
12 justice standard is really all that is relevant
13 here, the debate of legitimate expectations, while
14 interesting, is a little superfluous. I think I'll
15 end on 1105 there and move on to expropriation.

16 I think I will be covering some of the
17 themes as well because, as I said earlier, the
18 standard for a violation of 1110 is the same as that
19 with respect to decisions of domestic courts. There
20 has to be denial of justice in order for there to be
21 an expropriation. I'll make three arguments on
22 1110.

23 First, before considering whether an
24 expropriation has occurred, the Tribunal has to
25 consider the nature of the property right at issue

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1 and whether it is capable of being taken. It's
2 universally recognized that property rights, be they
3 patents or real estate, are defined and created by
4 domestic law and it's exclusively a matter for a
5 court to determine whether or not patents fulfill
6 the criteria set out in the Patent Act. If it
7 doesn't, there is no property that can be taken.

8 Second argument. If a court has
9 determined that under domestic law the property
10 right in question is invalid, then again the only
11 basis to argue an expropriation is denial of
12 justice, and that is the longstanding customary rule
13 and the Claimant has not shown any evidence of state
14 practice nor opinio juris to show that that has
15 changed.

16 Third, with respect to 1110(7). That
17 provision is clearly designed to provide the
18 Respondent NAFTA party with a shield to an
19 expropriation claim. That is consistent with
20 Chapter 17. It's not a sword to be wielded by
21 Claimants to appeal and re-argue the merits of a
22 domestic court judgment on patent invalidity.

23 So I'll go to my first argument. Property
24 rights. They're protected by NAFTA, but they're
25 defined and created by the law of the host state.

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1 Now, let's go to NAFTA Article 1110 because that's
2 the provision that says what expropriation is. It's
3 well known, and I need not to get into too much of
4 the text, but obviously it puts conditions on
5 expropriation or nationalization of an investment of
6 an investor if it's taken for public purpose,
7 nondiscrimination, due process and with
8 compensation.

9 Before I get to the most salient issue,
10 I'd like to address the Tribunal's Question 22 with
11 respect to direct and indirect expropriation.

12 So in a direct expropriation property
13 rights are transferred to a third party or a state.
14 And that's not what happened here. In an indirect
15 expropriation, if a discriminatory measure with no
16 public purpose indirectly renders an investment
17 completely worthless, then an expropriation analysis
18 might be warranted to determine whether or not it
19 was unlawful or not. You recall that states have
20 the right in international law to nationalize or
21 expropriate property it just has to be done in
22 accordance with the conditions that are set out in
23 1110.

24 But that's not what happened here. There
25 was no factory that was physically seized or its

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1 value destroyed by discriminatory zoning laws. Here
2 the property rights in question, the patents, were
3 adjudicated by a competent court to be legally
4 invalid under the legislation that establishes how
5 those property rights are created. So unless there
6 is an attack on the bona fides of the court,
7 international law accepts that the claimant does not
8 have their property taken or value destroyed. The
9 property right was invalid to begin with. That's
10 neither a direct nor an indirect expropriation. And
11 the reasoning behind this really lies at the heart
12 of the NAFTA and international law. I'll explain.

13 Article 1110 says you can't expropriate an
14 investment of an investor. Well, what's an
15 investment? If you look to NAFTA Article 1139, that
16 includes subparagraph (g), real estate or other
17 property. Tangible or intangible. Now, the NAFTA
18 doesn't define property, nor does NAFTA confer
19 property rights to anybody. Instead, property
20 rights are created and defined by the domestic law
21 of the host state. It's really important to
22 reiterate. NAFTA protects property; it does not
23 create property. In other words, the first step in
24 an expropriation analysis always has to be whether
25 or not the property right validly exists. This is

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1 very well accepted in the academic literature, and I
2 have four of them but I won't go through all of
3 them, but just point out the first one where it says
4 the relationship between domestic law and
5 expropriation.

6 The rights associated with any investment
7 are normally determined by local law. Thus, the
8 nature and scope of property rights are determined
9 by the law of the state in which the property is
10 located, the lex situs. There are four other. I
11 won't go through them all but they are provided for
12 the Tribunal's reference.

13 In *Emmis v Hungary* which cited the *EnCana*
14 Tribunal, public international law does not create
15 property rights. Rather, it accords certain
16 protections to property rights created according to
17 municipal law. Again, for there to have been an
18 expropriation of an investment or return, the rights
19 affected must exist under the law which creates
20 them.

21 This is, again, accepted not only in the
22 literature, in the arbitral awards, but all three
23 NAFTA parties are in complete agreement on this, and
24 I put the U.S. submission here and the Mexico
25 submission following up. I don't want to have to go

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1 through that, but the NAFTA parties are all together
2 on this.

3 My second argument is the concept of a
4 judicial expropriation has no basis in international
5 law. This gets back to some of the issues that
6 Arbitrator Bethlehem, you were asking about some of
7 these and how the rules on expropriation have
8 evolved over centuries on the premise that
9 executives and legislatures sometimes with the
10 assistance of armies and police can seize property
11 or take property or nationalize the property of
12 foreign investors. But courts, however, don't have
13 independent power of eminent domain. They have
14 neither sword nor purse. They are simply expositors
15 of what the law is, and neutral adjudicators of how
16 it applies. So because property is created and
17 defined in domestic law and because courts of
18 charged with interpreting domestic law, it's
19 illogical to argue that a judgment defining a
20 property right simultaneously takes that same
21 property. It's for that reason, in answer to the
22 Tribunal's Question 23, this is why denial of
23 justice is a prerequisite for a finding of an
24 expropriation based on a judicial measure.

25 There is no support for the Claimant's

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1 contention that this scenario that is before the
2 Tribunal that the validity of a property right that
3 has been determined by a domestic court is invalid
4 can constitute an expropriation. Mark Cantor here
5 said there was a dearth of precedent which could end
6 the analysis of international law after a mere
7 paragraph, and that mere paragraph cites the Loewen
8 case, and the Loewen Tribunal recognized exactly
9 what Canada is submitting, that reliance on 1110
10 adds nothing to the claim based on 1105.

11 A claim alleging an expropriation in
12 violation of 1110 can succeed only if Loewen
13 establishes a denial of justice. In Azinian it was
14 the same outcome. The Tribunal pointed out that if
15 the Claimant didn't have a denial of justice claim,
16 then there could be no expropriation. It was fatal
17 to their claim. If there's no complaint against the
18 determination by a competent court that a contract
19 governed by Mexican law was invalid under Mexican
20 law, there is by definition no contract to be
21 expropriated.

22 In Liman v Kazakhstan they said the same
23 thing. A declaration that legal rights were invalid
24 cannot be expropriation unless you really hit the
25 denial of justice standard.

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1 Under GEA v Ukraine, again, that was
2 another case where there was a question as to
3 whether or not the actions of the courts were being
4 impugned. The Tribunal found that there was no
5 evidence of egregious behavior, and that could not
6 constitute an expropriation.

7 I should note the Saipem case was referred
8 to here and that's really the only one Claimants
9 have relied on extensively to argue that there is a
10 notion of judicial expropriation. I don't know if
11 we have the slide but I did have opportunity at one
12 point to point out how inapposite that case is for
13 the argument that a judicial expropriation can exist
14 in the absence of what is the standard of denial of
15 justice.

16 In that case the Tribunal just said it was
17 a grossly unfair ruling and that the Bangladesh
18 courts engaged in an abuse of rights and that they
19 could not have reached the kind of decision that
20 they did without some kind of egregious behavior.
21 And that was really what was at issue in the Saipem
22 case. Again, they rely on other cases. Rumeli v
23 Kazakhstan, their one case that involved collusion
24 between the state and the competitor that was
25 manifested in a court decision that gave, I believe,

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1 \$3,000 of compensation for shares that were valued
2 at \$350 million before. The cases that they rely on
3 are so completely inapposite to what happened here.
4 They demonstrate the kind of egregious behavior
5 that, even if the Tribunal doesn't call it a denial
6 of justice, they all demonstrate that level of
7 egregiousness that has to be reached.

8 Again, I have to emphasize, the rule is
9 acknowledged in customary international law for
10 denial of justice when it comes to the decisions of
11 domestic courts. The Claimant would have to adduce
12 evidence, state practice, of -- they have done none.
13 At one point they made allusions to the still
14 unsettled debate in U.S. law as to whether or not a
15 judicial taking can occur under certain
16 circumstances. Not only is that not a settled issue
17 in U.S. law, but they made no effort to show that
18 judicial expropriation is recognized in Canada,
19 Mexico, United States, United Kingdom, Russia, South
20 Africa -- any country in the world that suggests
21 that there is evidence for a rule that they propose.

22 I'm going to make my final argument with
23 respect to 1110 because I think I've spoken enough
24 and I will turn over to Mr. Spelliscy, but it's
25 really to deal with 1110(7). We've already had the

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1 discussion on this issue and I'll leave some of the
2 more specific issues to my colleague, Mr. Spelliscy.
3 But the NAFTA parties are in agreement that this is
4 intended as a shield to expropriation claims. It's
5 not intended as a jurisdictional hook for Claimants
6 to somehow get into Chapter 17. The reason for
7 that, as Meg Kinnear pointed out, is that this would
8 cause incredible mischief on the domestic law patent
9 regimes of the NAFTA parties (slide 107).

10 This answers Tribunal Question 24, is it
11 significant that the alleged violation is found in
12 Chapter 17, or would it be the same as if it was
13 found in a different treaty? Well, it's not
14 significant because whether the alleged violation
15 from NAFTA Chapter 17, the TRIPS, the PCT or any
16 other treaty, it doesn't change the expropriation
17 analysis, it first has to be a question of whether
18 or not an expropriation has occurred. And if the
19 Claimant's position is accepted, this not only
20 reverses the denial of justice rule but it does open
21 up any patent invalidation in any of the NAFTA
22 parties to an argument of expropriation. That is
23 exactly the kind of appellate review that NAFTA
24 Chapter 11 Tribunals have been warned against by
25 international law. It would be a radical expansion

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1 of the jurisdiction of this Tribunal to assume the
2 role of a NAFTA Chapter 20 Tribunal or a WTO panel
3 interpreting the TRIPS or anything else.

4 **SIR DANIEL BETHLEHEM:** May I just ask you
5 to help me with some issue which may be relevant to
6 this? Article 1101(3) says this chapter does not
7 apply to measures adopted or maintained by a party
8 to the extent that they are covered by Chapter 14
9 dealing with financial services, so here we have in
10 1101(3) a specific exclusion, does not apply to
11 Chapter 14. Why would one not expect to see
12 something similar in relation to Chapter 17 if your
13 thesis was accurate?

14 **MR. LUZ:** I'll give your question some
15 more consideration over the course of the next -- I
16 can give an initial suggestion that there are
17 certain aspects of the NAFTA that have been excluded
18 from the scope, and in this case the intention of
19 1110(7) was to ensure that if there was a measure
20 that constituted an expropriation, for example,
21 arguably compulsory license or perhaps -- and I
22 don't want to reinvent the example that Arbitrator
23 Born gave as Parliament created a brand-new law that
24 revoked all automobile patents, I think was the
25 scenario. In that case there's no doubt as to -- I

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1 shouldn't say "there's no doubt" but there would be
2 a question as to whether or not there has been an
3 expropriation of otherwise valid property rights.

4 Then in that case 1110(7) provides the defense or
5 the safe harbor for a NAFTA party to say well, it
6 was done in accordance with Chapter 17, ergo 1110
7 does not apply. A very different scenario of a
8 court determining that a patent is invalid under the
9 domestic law. So I think that really gets to the
10 heart of it.

11 It is not something that has direct
12 parallels with 1101 or the other exemptions from
13 taxation measures and so on, but I will think about
14 your question a little bit more to see if there is a
15 nuance that we can provide further clarity on.

16 **THE PRESIDENT:** Let me add food for
17 thought. Let me ask you, you remember this morning
18 I asked also the Claimant the question, maybe I will
19 ask you the question as well, in Paragraph 7 of 1110
20 how do you interpret the final proviso to the extent
21 that such revocation is consistent with Chapter 17,
22 in the sense that is this Tribunal required to look
23 into whether the measures were consistent with
24 Chapter 17?

25 **MR. LUZ:** Only if the Tribunal finds that

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1 there has been an expropriation, so the question
2 becomes is there an expropriation and then, at that
3 point, that would be a defense that Canada or a
4 NAFTA party would put forward for consistency with
5 Chapter 17.

6 **THE PRESIDENT:** If it is alleged that a
7 revocation is an expropriation, what does the
8 Tribunal have to do, in your submission?

9 **MR. LUZ:** I'm sorry?

10 **THE PRESIDENT:** If the allegation is that
11 the expropriation consists of a revocation of an
12 intellectual property right, what is this Tribunal
13 expected to do, in your submission?

14 **MR. LUZ:** Well, again, if there is an
15 expropriation, then that is where the NAFTA party
16 invokes Article 1110(7) to say that it does not
17 apply, because it is consistent with Chapter 17. So
18 that's where the consistency with Chapter 17 comes
19 in. In this case there has been no determination by
20 a NAFTA Chapter 20 Tribunal that Canada is in
21 violation of Chapter 17, which would be really where
22 Chapter 17 comes into play, as to whether or not a
23 Chapter 20 Tribunal goes into it.

24 Here, as my colleague Mr. Spelliscy will
25 address in further detail, we need not get to that

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1 point. It still has to be an expropriation before
2 you get to the consistency test.

3 **MR. BORN:** For purposes of deciding, to
4 use your words, whether Chapter 17 is a shield, is
5 it we or a Chapter 20 Tribunal that is supposed to
6 look at consistency with Chapter 17?

7 **MR. LUZ:** A Chapter 20 Tribunal is the
8 only Tribunal that would have competence to
9 adjudicate a breach of Chapter 17. That is a
10 chapter that is subject to the state-to-state
11 arbitration provisions of the NAFTA for Chapter 17.

12 **MR. BORN:** I understand that. So you're
13 saying that we, as a Chapter 11 Tribunal, could not,
14 for purposes of Chapter 1110(7), decide whether an
15 expropriation was consistent with Chapter 17?

16 **MR. LUZ:** The Tribunal does not have the
17 jurisdiction to decide that there was a breach of
18 Chapter 17. Again, we have to sort of go down the
19 line of all of the different steps to get there. If
20 there was an expropriation of a patent right, that
21 is when the NAFTA party would invoke 1110(7) as a
22 defense to say no, this expropriation provision
23 doesn't apply. It's a defense. Because it is
24 consistent with Chapter 17.

25 **THE PRESIDENT:** Could you please take the

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1 text of 1110(7))? It's always a problem if there
2 are double negatives in a legal text or otherwise.
3 If you take out the two negatives, of course it is a
4 bit of an undertaking but let's do it for sake of
5 the argument, then it would read: This article
6 applies to the revocation of intellectual property
7 rights in the event that the revocation is
8 inconsistent with Chapter 17."
9 Is that a permissible reading?
10 **MR. LUZ:** No, because again, the question
11 for an expropriation still comes into play. You
12 still have to determine -- and my colleague
13 Mr. Spelliscy has a couple of examples of where you
14 would have that. But, again, the first question is
15 always is there an expropriation, and you won't get
16 to that point if there isn't.
17 **THE PRESIDENT:** Maybe we can make another
18 suggestion, because I'm looking at the court
19 reporter. Shall we take a break?
20 **MR. LUZ:** I think so.
21 **THE PRESIDENT:** You are, of course,
22 allowed to continue after the break.
23 **MR. LUZ:** No, I am done. I'm sure my
24 colleague, Mr. Spelliscy, will address any other
25 issues that are remaining.

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1 its reply Memorial at Paragraph 17 it states,
2 Lilly's claims do not rest on denial of justice. It
3 further clarifies that it is not claiming it was not
4 afforded procedural justice. In Paragraph 217 of
5 its reply it states, "Canada emphasizes the
6 procedural history of each case. Canada recites the
7 number of witnesses each trial included and the
8 number of days each trial spanned, maintaining that
9 the judges carefully weighed and extensively
10 analyzed the evidence through months of
11 deliberation. Canada does this because it would
12 prefer to litigate whether the proceedings in Canada
13 were procedurally fair. But that is not Lilly's
14 case."
15 And it further clarifies that the Canadian
16 courts correctly applied existing Canadian law in
17 invalidating the Claimant's patents. Specifically
18 in Paragraph 334 of its reply, it clarified, "Lilly
19 has not alleged that the Federal court and Federal
20 Court of Appeal misapplied Canadian law as it stood
21 in 2010 and 2011." There has been no allegation of
22 a procedural denial of justice. There's not even
23 been an allegation that the Canadian courts got
24 Canadian law wrong in some egregious way. As there
25 has been no allegation of any type of denial of

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1 **SIR DANIEL BETHLEHEM:** I'll put a question
2 to him that I would have put to you.
3 **THE PRESIDENT:** Recess until 4:20.
4 *(Recess taken)*
5 **THE PRESIDENT:** Please continue opening
6 statement for Respondent.
7 **MR. SPELLISCY:** Thank you, President
8 van den Berg. Good afternoon again.
9 As I explained in my opening remarks this
10 afternoon, I will now spend the remainder of
11 Canada's opening statement explaining the four
12 reasons why you should reach the conclusion that
13 this claim must fail. Let's turn to the first.
14 As Mr. Luz has explained, Canada, the
15 United States and Mexico agree as to the meaning and
16 application of their treaty, NAFTA. When it is a
17 judicial measure applying domestic law that is being
18 challenged under 1105 or 1110, the only possible
19 claim is that there has been a denial of justice.
20 The Claimant has never alleged that it was denied
21 justice in any way by the Canadian courts. To the
22 contrary, it has expressly stated that it is not
23 alleging that it was denied justice by the Canadian
24 courts. And I think that it is helpful to take a
25 look at some of these to see what it has said. In

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1 justice, the Claimant has failed to state a claim as
2 a matter of law, and this action should be dismissed
3 promptly, with costs.
4 However, even if you do not agree with
5 Canada, the United States and Mexico as to the
6 proper interpretation of their own treaty, I will
7 still walk through with you three other reasons why
8 this claim must be dismissed.
9 Let's turn to our second point, that this
10 claim is time barred. As an initial matter, let me
11 start with the Claimant's complaint that Canada's
12 objection is untimely. In its questions to the
13 parties, the Tribunal asked "Is Respondent's
14 objection to jurisdiction *ratione temporis* untimely,
15 as Claimant submits, and if so, what are the
16 implications?"
17 We have laid out clearly in our Rejoinder
18 both why the Claimant's claim did not become clear
19 until its reply and why Canada -- and how Canada
20 constantly put the Claimant on notice of a
21 jurisdictional objection should it be the doctrine
22 that was being challenged.
23 Originally the Claimant challenged the
24 specific court decisions. It called those decisions
25 relating to its olanzapine and atomoxetine patents

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1 shocking and unexpected. However, as the quotes we
2 have just reviewed above from its Reply Memorial
3 show, the Claimant has retreated from these
4 allegations. It now challenges what it identifies
5 as a judicial doctrine itself. As a result,
6 Canada's raised this objection in its Rejoinder as
7 soon as it could.

8 Let me also come to the second part of the
9 question that you have asked, what are the
10 implications even if this was a late-raised
11 objection. I would suggest that in these
12 circumstances, there are none. The Claimant places
13 a lot of weight on Article 21(3) of the UNCITRAL
14 Arbitration Rules in its written submissions and,
15 again, it's really the only point it addressed on
16 this jurisdictional objection earlier today.

17 That article requires that a
18 jurisdictional objection be raised no later than the
19 Statement of Defense. I think we need to spend a
20 few minutes to understand that. After all, there is
21 no magic inherent in the Statement of Defense. But
22 in looking at the structure of the UNCITRAL rules, I
23 think it is clear that there was a reason why that
24 date was selected.

25 As the rules are drafted, there is the

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1 presumption that there will be a Notice of
2 Arbitration, a Statement of Claim and a Statement of
3 Defense. If we look to Article 22, we see that
4 there is no presumption in the rules that there will
5 necessarily be further written statements.
6 Article 22 provides that the Arbitral Tribunal shall
7 decide which further written statements, in addition
8 to the Statement of Claim and the Statement of
9 Defense, shall be required from the parties or may
10 be presented by them.

11 So the way the 1976 UNCITRAL Rules
12 envisaged the process is that it is possible that
13 the Statement of Defense will be the only written
14 submission from the Respondent prior to the oral
15 submissions at the hearing. And, of course, the
16 Claimant would have the opportunity to respond at
17 the hearing itself. The rule is about making sure
18 that the Claimant and the Tribunal have knowledge of
19 an objection and have time to prepare a response,
20 whether it is in writing or at the hearing.

21 Now, there should be no dispute. Canada
22 agrees jurisdictional objections are to be raised as
23 early in the process as possible. But not only was
24 Canada's jurisdictional objection raised as soon as
25 it was possible, it was raised six months before the

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1 hearing, and the Claimant was given the opportunity
2 to respond in writing. As there is no prejudice
3 here, Canada's objection to the jurisdiction of the
4 Tribunal must be considered. So with that, let's
5 turn to the substantive question of the limits of
6 the Tribunal's jurisdiction. And in particular, the
7 rules in NAFTA Articles 1116 and 1117. In its
8 questions to the parties the Tribunal asked "what is
9 the significance, if any, of the patent for
10 Raloxifene in this proceedings?" In the next
11 several minutes I am going to answer this question.
12 I will do so partly by asking the following
13 question: Could the Claimant have brought the exact
14 same allegations it brings here, specifically that
15 the judicial interpretation by the Canadian courts
16 of the utility requirement in Canada's Patent Act
17 violates Canada's obligations in articles 1105 and
18 1110. Could it have brought these exact same
19 allegations to NAFTA Chapter 11 arbitration after
20 the Raloxifene decision in 2008 and 2009? The
21 answer is yes, it could have, but it didn't. And it
22 has never answered the question of why it didn't and
23 it avoided that entirely today.

24 As a result -- and I'm going to explain in
25 more detail why in a minute -- but as a result of

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1 its decision not to bring that challenge, this claim
2 and the challenge to what the Claimant has labeled
3 the promise utility doctrine must be dismissed as
4 beyond the jurisdiction, *ratione temporis*, of the
5 Tribunal. Let me offer that explanation why. We'll
6 go to Article 1116(2).

7 That article says, "An investor may not
8 make a claim if more than three years have elapsed
9 from the date on which the investor first acquired,
10 or should have first acquired, knowledge of the
11 alleged breach and knowledge that the investor has
12 incurred loss or damage."

13 The NAFTA parties are in agreement that
14 this clause imposes a strict three-year statute of
15 limitations for an investor to bring a claim
16 alleging that there has been a breach of NAFTA. For
17 example, all three NAFTA parties have endorsed the
18 description of the clause by the Tribunal in the
19 Grand River case, where that Tribunal held that
20 Article 1116(2) and 1117(2) impose a "clear and
21 rigid limitation defense not subject to any
22 suspension, prolongation or other qualification."

23 Let's pull Article 1116(2) up here again
24 and examine it carefully. We can see there are two
25 aspects to it. First, there has to be knowledge or

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1 constructive knowledge of the measure or measures
2 question. Second, there has to be knowledge or
3 constructive knowledge that the measure has caused
4 loss. Let's look at the first.
5 Now, to do this, I could call back to the
6 slide that Mr. Johnston showed you outlining the
7 components of the doctrine, but I also recall that
8 the Claimant's presentation this morning had a
9 similar slide. And what I found interesting about
10 that slide was that it was slide 17 and what I found
11 interesting about it was that it did not have dates
12 on it. So let's put some dates on it.
13 In doing so, I'm just going to accept that
14 the Claimant's descriptions as to when the relevant
15 doctrines in Canadian law arose for the purpose of
16 considering this objection.
17 According to the Claimant's description of
18 the radical change in Canadian law, it began in 2002
19 with the decision of the Supreme Court in AZT that a
20 patentee must establish the utility of its invention
21 before filing for a patent. Then it continued with
22 several court decisions beginning in September of
23 2005 when, according to the Claimant, Canadian
24 courts began to scour the patents for promises
25 beyond those in the claims.

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1 Then according to the Claimant, it ended
2 in 2008 or 2009 when the appeal was heard, when the
3 Federal Court adopted what the Claimant itself has
4 called the Raloxifene rule, and that judgment was
5 affirmed. That rule is the one that requires a
6 basis for a sound prediction of utility to be
7 disclosed in the patent. This is what the Claimant
8 calls the promise utility doctrine, as I understand
9 it.
10 As I said, I want to leave aside the
11 factual dispute between the parties as to whether
12 these changes occurred and just accept that they
13 did, and I want to leave aside the dispute about
14 whether this is a single doctrine as alleged by the
15 Claimant and accept that it is.
16 As Canada pointed out in its Rejoinder,
17 all three aspects of the radical change that the
18 Claimant alleges occurred in Canadian law were
19 actually applied to the Claimant in a decision in
20 2008, and that's because the Raloxifene case was
21 about the Claimant's patent.
22 The trial court applied all three aspects.
23 The Claimant appealed. But the Federal Court
24 affirmed the decision on March 25, 2009. The
25 Claimant appealed again to the Supreme Court, but

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1 the Supreme Court refused to hear their case on
2 October 22, 2009.
3 In their response to Canada's Rejoinder,
4 and this morning as well, the Claimant did not
5 dispute that, by the time that its request for leave
6 to appeal the Raloxifene rule was denied by the
7 Supreme Court on October 22, 2009, it had knowledge
8 of all the aspects of the alleged dramatic change in
9 Canadian law that it hinges its allegation of a
10 breach of NAFTA upon. But it says -- and it said
11 this morning -- that this is merely factual context
12 for its claim.
13 That is incorrect.
14 Remember, this is a dispute, as of the
15 Reply at least, about the doctrine itself, not
16 whether the doctrine was correctly applied in the
17 two cases for atomoxetine and olanzapine. If this
18 was a claim that the promise utility doctrine was
19 somehow inappropriately applied at Canadian law to
20 its patents for atomoxetine and olanzapine, then we
21 could discuss the doctrine, its development as
22 factual context. But it is not that claim. The
23 Claimant is not alleging the misapplication of
24 Canadian law to its atomoxetine and olanzapine
25 patents.

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1 So by October 22, 2009, at the very
2 latest, the Claimant had knowledge of the existence
3 of all of the aspects of Canadian law that it
4 bundles together and labels the promise utility
5 doctrine. By no later than that date it had
6 knowledge of the measures that it alleges breaches
7 NAFTA.
8 So let's come to the second aspect of
9 Article 1116(2). The only question is whether the
10 Claimant knew or should have known at that moment in
11 October of 2009 that it had suffered a loss. I want
12 to focus on the language here.
13 The language of Article 1116(2) is, in our
14 submission, clear. It says "knowledge that the
15 investor has incurred loss or damage". It does not
16 require that the investor know of a specific loss or
17 even how much of a loss has been suffered by its
18 investments. As the Tribunal in Mondev stated, "A
19 Claimant may know that it has suffered loss or
20 damage even if the extent or quantification of the
21 last or damage is still unclear."
22 In our submission there is one question.
23 Did the investor know or should it have known that
24 it incurred loss or damage because of the measures
25 it alleges breaches NAFTA? There can be no dispute

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1 that the Claimant knew of a loss. As Canada
2 explained in its Rejoinder, after the proceedings
3 with respect to the Raloxifene patent finished, a
4 competitor was allowed to enter the market and the
5 Claimant suffered loss as a result.
6 The Tribunal in its questions asked,
7 "According to Respondent, what is the meaning of the
8 United States' statement that the time limitations
9 period in Articles 1116(2) and 1117(2)... relate to
10 the particular investment for which the investor
11 seeks a remedy for the breach and loss?"
12 Of course I'm not really in a position to
13 explain what the United States meant, but I believe
14 that the U.S. position means that if the investor
15 did not know and could not have known that a
16 breaching measure would be applied to a particular
17 investment causing loss to that specific investment,
18 the limitations period will not begin to run.
19 Put simply, I believe that the U.S.
20 statement simply means that the investor must have
21 knowledge, actual or constructive, in relation to a
22 particular investment. This is not an issue in this
23 case. Let's look beyond the Claimant's losses with
24 respect to Raloxifene and consider instead, as it
25 suggests we must, only its patents for atomoxetine

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1 and olanzapine. The conclusion you should reach
2 with respect to its knowledge of loss concerning
3 those patents is no different.
4 Again, as we saw a few minutes ago, the
5 Claimant has admitted that it is not alleging that
6 the Canadian courts incorrectly applied Canadian law
7 as it existed in 2010 and 2011 in invalidating its
8 patents with respect to atomoxetine and olanzapine.
9 So what does that mean?
10 It means that you must accept that the
11 Canadian courts correctly applied Canadian law as it
12 existed after that decision to the Claimant's
13 patents, and it must be assumed that the Claimant
14 was capable of correctly understanding Canadian law
15 in 2009 and, therefore, that it would understand
16 how, correctly applied, that law would affect all of
17 its other patents.
18 Now, what happened after the Raloxifene
19 decision? According to the Claimant, the Canadian
20 courts have done nothing more than continue to apply
21 the same interpretations of Canada's Patent Act. In
22 fact, I think I heard the Claimant this morning
23 confirm that, in their view, Canada has been in
24 breach of its obligations under Chapter 17 since
25 2005 and that the breach was made more egregious by

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1 the disclosure rule in Raloxifene. As we heard
2 their claim for a breach of NAFTA Article 1110 is
3 based on the claim of a breach of Chapter 17, the
4 international law that they claim is a source of
5 expropriation.
6 But whether it is with reference to 2002,
7 2005, 2008, 2009, it doesn't matter. As Tribunals
8 have recognized, and all three NAFTA parties have
9 confirmed, the statute of limitations period in
10 NAFTA is not renewed simply by one of the parties
11 engaging in a continuing course of conduct. As
12 Canada explained in its submission, the use of the
13 word "first" marks the beginning of the time when
14 knowledge of a breach and a loss existed. Not the
15 middle or end of a continuous event or series of
16 events. In other words, once the investor first
17 acquires knowledge of the alleged breach and that it
18 has suffered damage, the limitations period for
19 filing a claim commences and will end at the
20 three-year mark regardless of whether the impugned
21 measure continues thereafter.
22 As the United States explained in its
23 Article 1128 submission, "under articles 1116(2) and
24 1117(2), knowledge is acquired as of a particular
25 'date'. Such knowledge cannot first be acquired at

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1 multiple points in time or on a recurring basis.
2 Once a Claimant first acquires or should have first
3 acquired knowledge of a breach and loss, subsequent
4 transgressions by the state party arising from a
5 continuing course of conduct do not renew the
6 limitations period under Articles 1116(2) or
7 Article 1117(2)." (Slide 127).
8 As Mexico similarly commented, "Neither a
9 continuing course of conduct nor occurrence of
10 subsequent acts or omissions can renew or interrupt
11 the three-year limitation period once it has started
12 to run."
13 I think perhaps the best applicable
14 summary of the reason for such a strict non-renewing
15 limitations period comes again in the Grand River
16 case. I think you will see there is no more of an
17 apt description of why this claim is also time
18 barred for the same reasons that the Tribunal in
19 Grand River highlighted. In rejecting the idea that
20 subsequent acts allowed the Claimant to evade the
21 three-year deadline to file a claim, the Tribunal in
22 that case explained, "... this analysis seems to
23 render the limitations provisions ineffective in any
24 situation involving a series of similar or related
25 actions by a respondent state, since a claimant

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1 would be free to base its claim on the most recent
2 transgression, even if it had knowledge of earlier
3 breaches and injuries."
4 As I have explained, the Claimant's claims
5 here amount to nothing more than the exact same sort
6 of improper attempt to base a claim on the most
7 recent alleged transgressions in a series of similar
8 actions by Canada, even though it was without
9 question that it had knowledge of the earlier
10 alleged breaches and injury. The Claimant cannot
11 avoid the limitations period in NAFTA simply by
12 pleading its case as only related to specific
13 investments to which a known and understood law has
14 yet to be specifically applied, especially not when
15 it knew or should have known how that law would
16 affect and cause loss to those investments.
17 The limitations period in NAFTA depends on
18 knowledge, whether actual or constructive, not the
19 strategic decisions made by counsel in how to plead
20 the case.
21 **MR. BORN:** Would I be right in thinking
22 that the consequence of that analysis is that the
23 Claimant, and I guess also other companies, should
24 bring NAFTA arbitrations before any invalidation
25 litigation has been started, or I guess even

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1 threatened?
2 **MR. SPELLISCY:** I think I said in our view
3 this is an alternative argument. So when you are
4 challenging the acts of a court, you can bring a
5 denial of justice claim. A denial of justice claim
6 would not be time barred. You can challenge the
7 application, you can challenge the procedural
8 fairness, but if what you are looking to challenge
9 is the actual judicial doctrine and you are not
10 disputing that judicial doctrine was wrong, then the
11 three-year limitations period starts from the moment
12 at which you knew of the measure, and you knew or
13 should have known of the loss that would occur to
14 your investments.
15 **MR. BORN:** But your colleague,
16 Mr. Johnston, pointed out -- I thought very ably --
17 how the Canadian patent litigation process is
18 party-driven, and it might well be the case, I
19 assume, that many patents would never be challenged
20 and it would seem from your answer that nonetheless,
21 if what one is doing is challenging the judicial
22 doctrine, one would need under that analysis to
23 begin a NAFTA arbitration before there's been a
24 judicial challenge from a competitor and perhaps in
25 circumstances where there would never be one.

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1 **MR. SPELLISCY:** You would be required to
2 bring a judicial challenge under NAFTA to the
3 judicial doctrine as soon as you were aware and you
4 had adequate constructive knowledge of breach and
5 loss. I think it's interesting because it does get
6 back to whether or not on constructive knowledge and
7 if you don't have an investment that's affected,
8 when do you have adequate constructive knowledge.
9 And I would suggest that that's what makes the
10 patent in Raloxifene so important in our view in
11 this case. This is not really a question of whether
12 Lilly had constructive knowledge of the doctrines
13 and the laws. It did. It was its patent in the
14 Raloxifene decision. It was its patent that was
15 invalidated under these same three doctrines, which
16 is why I wanted to focus on the language in
17 Article 1116(2), which is a loss.
18 **SIR DANIEL BETHLEHEM:** Can I follow up on
19 that and the proposition from your colleagues that
20 the courts are neutral and the revocation of a
21 patent is not certain until it happens? How, then,
22 do you address the issue of 1116(2) and knowledge of
23 the loss if the revocation of a patent is entirely
24 speculative until it happens?
25 **MR. SPELLISCY:** I would think that I would

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1 come back to what the Tribunal in Mondev said which
2 is that you don't need to know of the extent of the
3 quantification of loss. What I would suggest is in
4 a situation where you don't know on the outcome of
5 the litigation but that you do know that this
6 doctrine exists -- and we can take it back
7 particularly to the atomoxetine patent, and I will
8 pull up a slide later. The judge in that case
9 essentially said it follows inevitably from the
10 existing law that Raloxifene and all the way back to
11 AZT that the patent is invalidated. It has to be
12 understood that it really could have appropriately
13 evaluated the loss or the potential harm to its
14 patent. It may not have known of the specific
15 effect on each individual patent, but it would be
16 able to evaluate and assess and have knowledge of
17 some loss or some diminution in the value of its
18 patents even before they were challenged.
19 **SIR DANIEL BETHLEHAM:** That's not the
20 issue that Mondev was addressing, though. Mondev
21 was addressing the quantification of loss within the
22 context of the same case, and it must surely be the
23 case on the thesis that you put that in respect of
24 the two patents at issue in this case, until they
25 came before the court and were struck down, they

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1 were speculative and therefore how could one even
2 identify that there would be a loss whether or not
3 it was quantifiable?
4 **MR. SPELLISCY:** Again, I think it comes
5 down to the assumption that we can assume that
6 Eli Lilly would understand how the law would be
7 appropriately applied, and they have not alleged
8 here that the law was inappropriately applied. They
9 have alleged that the law was correctly applied.
10 And so when we understand that the law was correctly
11 applied, I think that answers the question. They
12 would have been aware of some loss but not
13 necessarily the exact quantification.
14 Let me try and approach the question --
15 **THE PRESIDENT:** Sorry, may I follow up on
16 that point?
17 **MR. SPELLISCY:** Yes.
18 **THE PRESIDENT:** Is it one thing to be
19 aware of the doctrine and another thing to be
20 confronted with the application of the doctrine, and
21 especially in the context of what you mentioned, the
22 loss. Until you have an invalidation of your
23 patent, you don't know whether it will be first
24 invalidated with finality, and the second thing is
25 you also don't know whether you will have a loss,

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1 even quantified or not. So is it not more that you
2 have to look at the application rather than the
3 awareness of the doctrine itself?
4 **MR. SPELLISCY:** I think I would suggest --
5 I was going to say we approach this in a slightly
6 different, in a hypothetical that had been raised,
7 what if this was legislation. And if this was
8 legislation that applied that said certain patents
9 were going to be taken away. You don't wait, you
10 can't wait until that legislation is applied against
11 you in order to bring a challenge under NAFTA. In a
12 sense, the NAFTA parties have a valued peace in
13 terms of the litigation process with respect to
14 their policies above some of the other aspects that
15 might be challenged.
16 **THE PRESIDENT:** Are you sure about this?
17 Because in my previous life as a litigator --
18 although I still am from time to time --
19 **MR. SPELLISCY:** I've seen!
20 **THE PRESIDENT:** -- clients always ask you
21 how much percentage do we have a chance of
22 succeeding or the other side losing, and you have to
23 be very careful giving percentages, that I learned
24 as a young lawyer. More recently you become
25 slightly more confident and give some percentages

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1 but never above 70 percent. How do you know that
2 you will win or lose the case, now in the case of
3 invalidation of a patent?
4 **MR. SPELLISCY:** I think the answer to this
5 comes back to the point that we have made, that if
6 the law is clear and the law is crystallized -- and
7 what we've been talking about here are some of the
8 rules that were applied, for example, in the
9 atomoxetine case. The rule developed in Raloxifene
10 is that you cannot rely upon a study that was not
11 included in your patent. If we look, and we'll get
12 to that, you will see in the decision it fails for
13 that reason. The Claimant would have known that
14 immediately after Raloxifene that, if it was
15 challenged in court, it could not rely upon that
16 decision.
17 **STR DANIEL BETHLEHAM:** Yes, if it was
18 challenged in court. What happens if it was not
19 challenged in court? If Novopharm took the view
20 that there was no economic reason for it to
21 challenge it in court, for example?
22 **MR. SPELLISCY:** Yes, and I think this
23 comes back to sort of the fundamental question on
24 this argument, and what is the extent of the
25 constructive knowledge that you need to have. Does

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1 NAFTA worry about whether or not, in order to
2 challenge a law or legislation, that law or
3 legislation has to be applied to you?
4 Now I come back to what I said earlier,
5 that if this is actually a case that the law was
6 inappropriately applied to Lilly, there would be no
7 issue of time bar. So we can consider the question
8 of the court in terms of the application of the
9 case, but in our view what we cannot go back and
10 challenge and what we cannot go back and question is
11 the judicial doctrines at play, because if we did
12 that, that would mean that essentially the statute
13 of limitations in NAFTA means nothing.
14 What's to stop, if the Canadian courts
15 continue to apply this doctrine, what's to stop the
16 next time it happens, an investor from bringing a
17 claim ten years from now? 25 years from now? Right
18 at the end of its patent life? There is nothing to
19 stop that. That's why I come back to, when it's the
20 judicial doctrine that is being challenged, that is
21 the judicial doctrine that's the source of the
22 alleged breach, that's when we bring the limitations
23 defense. And it's why it wasn't raised earlier.
24 If we just want to talk about the
25 application, whether the cases were shocking,

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1 whether the application of the doctrine was
2 unexpected, we can talk about that. It's in the
3 context of the denial of justice. But if we do want
4 to come back and address the law and we want to have
5 Article 1116(2) mean something in terms of the law,
6 then we have to look at when that law was known and
7 when it could be evaluated as to how it might affect
8 their patents.

9 **MR. BORN:** One of the rules, and certainly
10 one of the policies of investment protection law is
11 that through the doctrine of exhaustion of local
12 remedies you ought to give national courts an
13 opportunity to address complaints. Would it be a
14 good idea for us to adopt an interpretation of the
15 statute of limitations that encouraged investors not
16 to do that? Actually required them not to do that?

17 **MR. SPELLISCY:** So this is why I come
18 back, and I said our primary argument here is that
19 that's not an issue in this case. Because, in fact,
20 you have a case -- and I've only used October 22,
21 2009. That's the date on which the Supreme Court of
22 Canada denied Eli Lilly leave to appeal the
23 Raloxifene decision. That's the day on which the
24 Claimant did know. In our view, once Eli Lilly
25 suffered a loss with respect to its Raloxifene

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1 patent, there should be no dispute at that point
2 that the statute of limitations period began to run.

3 **MR. BORN:** But weren't there a whole host
4 of other arguments that they could make with regard
5 to the other two patents? They could make arguments
6 about what the promises were and weren't, whether
7 the law ought to be reconsidered, and wouldn't you,
8 had they just jumped into an arbitration without
9 doing that, be saying that's what they should have
10 done?

11 **MR. SPELLISCY:** I think that in the case
12 where they had brought this again with Raloxifene,
13 the answer would be simple. It wouldn't be barred
14 by the statute of limitations.

15 If the answer is that they had other
16 arguments that they could make, again I think we
17 have to look down to what is the alleged breaching
18 measure here. The alleged breaching measure is not
19 the other arguments that they made or not that the
20 promise should have been found to be something else.
21 If that's the argument, then that claim would not be
22 time barred. It would be an appeal of domestic law,
23 and unless there was a denial of justice, there
24 would be no claim, but that claim would not be time
25 barred.

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1 But what they're challenging is not those
2 determinations. What they're challenging is simply
3 the application of well settled law that had existed
4 for, in their view, at least three years. In our
5 view, decades. And if we don't have a rule that
6 says you can't sit on your hands and wait until --
7 and choose which to bring them to, then I would
8 suggest that we end up with the situation in Glamis,
9 that we are just allowing Claimants to bring actions
10 for the most recent alleged transgression in a
11 series of continuing acts. And I think it's
12 important. They have not alleged that the law
13 changed after Raloxifene. And that's the key point
14 from our perspective.

15 Let me put up the last two slides on this
16 quickly so we can see. If we come back to the
17 timeline slide, if we accept that it was October 22,
18 2009 as the date that they were required to bring
19 their claim, or that the Supreme Court, in fact,
20 denied their leave to appeal, that means they had
21 until October 22, 2012. The Claimant submitted its
22 Notice of Arbitration on September 12, 2013, a year
23 after it, a year after that limitations period had
24 expired. And that, we would submit, means this
25 claim is time barred on the doctrine. On the

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1 doctrine it must be dismissed.

2 However, even if you disagree that this
3 claim is time barred, I'd still like to kind of show
4 you two other reasons why this claim must be
5 dismissed in the alternative. Let's turn to the
6 third ground, which is that the necessary factual
7 predicate for this claim is false.

8 If we turn to Paragraph 334 of the
9 Claimant's Reply, the Claimant clarifies the nature
10 of its allegation in this case asserting that the
11 dramatic change in Canada's domestic laws as
12 reflected in the promise utility doctrine renders
13 them fundamentally at odds with its international
14 commitments.

15 As is clear from this language the
16 Claimant's claim is premised on there having been a
17 dramatic change. Now, that dramatic change that is
18 being alleged is not a change in the Patent Act
19 itself. That Patent Act has existed for long, long
20 before the Claimant obtained its patents. But it is
21 in the way that the Canadian courts have interpreted
22 the relevant sections of the Patent Act, and in
23 particular the utility requirement.

24 Now, why does the Claimant so expressly
25 pin its hopes on arguing that there has been a

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1 dramatic change in the law? I think, related to
2 what we were just discussing, the doctrine is a
3 doctrine and if time bar is not an issue, if the
4 Claimant is right and time bar is not an issue, then
5 why should it matter when that doctrine came about?
6 In this regard I note in its questions to
7 the parties the Tribunal asked, "If one were to
8 accept Respondent's factual submission that the
9 promise utility doctrine is 'several distinct patent
10 law rules, all of which were part of Canadian law
11 when the Claimant filed its patents', what
12 implication would this have on Claimant's claims?"
13 As I will show you, the reason why the
14 Claimant is so emphatic in its arguments that these
15 interpretations that it challenges are new, is that
16 if it cannot prove that, the claim would not be in
17 the jurisdiction of the Tribunal.
18 As the Tribunal in Gami made clear, NAFTA
19 arbitrators have no mandate to evaluate laws and
20 regulations that predate the decisions of a foreign
21 investor to invest. As a recent Tribunal in Mesa
22 reiterated, "As a consequence investment arbitration
23 tribunals have repeatedly found that they do not
24 have jurisdiction *ratione temporis* unless the
25 Claimant can establish that it had an investment at

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1 the time that the challenged measure was adopted."
2 In this case the Claimant has identified
3 the investment that it claims had been accorded
4 treatment in violation of 1105 and 1110 as follows.
5 Lilly's Zyprexa and Strattera patents, which each
6 encompass a bundle of exclusive property rights and
7 the ability to enforce those rights, qualify as
8 investments under Article 1139. You heard them
9 reiterate that again this morning. There is no
10 other claim that any other investment of the
11 Claimant was treated in a way that violates Canada's
12 obligations under Article 1105 and 1110 of NAFTA,
13 nor could there be because the patents here were not
14 even held by the Claimant's Canadian enterprise and
15 there is no evidence of the investment in research
16 and development with respect to these patents in
17 Canada.
18 Hence, the real cut-off date for this
19 Tribunal's jurisdiction is when those patents in
20 Canada existed. As Mr. Johnston has explained, the
21 Claimant was granted a patent in Canada for
22 olanzapine in July of 1998, for atomoxetine in
23 October of 2002. So what does that mean? Again,
24 the Claimant can't challenge the interpretation of
25 Canada's Patent Act by, at least if we use the

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1 atomoxetine date, under doctrines prior to 2002.
2 Now, I want to make something quite clear
3 here. This is not a jurisdictional issue with the
4 way the claim has been pled. That claim is that
5 there was a dramatic change in Canadian law after
6 the Claimant made its investments.
7 However, in answer to your question, if
8 you agree as a matter of fact with Canada that the
9 doctrines in question here have long existed in
10 Canadian law, existed at least prior to 2002, then
11 there is no claim. The Claimant's claim that there
12 has been a dramatic change in Canadian law beginning
13 in 2002, or potentially 2005 depending on how we
14 interpret what they said this morning, is a
15 necessary condition for the Claimant's claim to
16 proceed. If you find they are wrong, as I suggest
17 that you will after hearing the evidence of experts
18 like Mr. Dimock this week, their whole claim fails
19 and there is no need for you to even consider the
20 application of Articles 1105 and 1110 on the merits.
21 I would like now to come to my fourth
22 point as to why this claim must fail, and that is
23 even if you were to consider Canada's obligations
24 further under Articles 1105 and 1110, this claim
25 must still be dismissed.

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1 First I will explain how the Claimant has
2 failed to establish a breach of the customary
3 international law minimum standard of treatment of
4 aliens. As a reminder, and as Mr. Luz has
5 explained, the law with respect to the customary
6 international law minimum standard of treatment as
7 applied to the measures of the judiciary is clear.
8 The only applicable rule is denial of justice. Any
9 other sort of review would turn investor state
10 arbitration tribunals into courts of appeal. But
11 even if you disagree and decide to examine the
12 challenged measures against the standards that the
13 Claimant has alleged, but has not proven, are
14 contained in Article 1105, there is no breach here.
15 I will address three separate points on 1105.
16 Canada's law on utility is, first, not
17 discriminatory. Second, not arbitrary. And, third,
18 not inconsistent with the Claimant's legitimate
19 expectations. In short, even if the Claimant is
20 correct as to the legal content of the Article 1105
21 when it comes to assessing judicial conduct -- and
22 it is not, but even if it was -- the interpretation
23 given to Canada's Patent Act by the Canadian courts
24 is nowhere near the sort of conduct required to
25 breach Article 1105, and let's start with the first

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1 allegation, discrimination.
 2 I will not say overly much here for two
 3 reasons. First, my colleague Mr. Luz has covered it
 4 and I would reiterate what he said. The idea that
 5 customary international law prohibits discrimination
 6 on the basis of a field of technology is truly
 7 beyond the pale. The fact is that customary
 8 international law does not even prohibit
 9 discrimination on the basis of nationality
 10 generally. That is why NAFTA contains express
 11 nationality-based antidiscrimination provisions in
 12 Article 1102 and 1103.
 13 You will recall I believe there was at
 14 some point an allegation of a breach which isn't
 15 here anymore. There is no allegation in this case
 16 about nationality-based discrimination under
 17 Articles 1102 and 1103.
 18 Second, the Claimant's allegations of
 19 discrimination against the pharmaceutical sector are
 20 based on a flawed statistical analysis that I
 21 propose to discuss not here but actually later in
 22 the context of Article 1709(7). When we do so, we
 23 will see that the challenged doctrine does not
 24 discriminate by industrial sector. It applies to
 25 all sectors and has resulted in invalidations in

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1 sectors outside of the heavily litigated
 2 pharmaceutical patent field.
 3 As Canada has shown, when the correct data
 4 is analyzed none of the differences between the
 5 application in the different sectors are
 6 statistically significant. In short, there is no
 7 evidence of any sort of significant disparate impact
 8 of the judicial interpretation the Claimant
 9 challenges on the pharmaceutical sector.
 10 Let's now turn to the second alleged way
 11 in which the judicial interpretation given to the
 12 utility requirement in Canada's Patent Act allegedly
 13 violates Article 1105. The Claimant alleges and
 14 came back to it again this morning that the judicial
 15 interpretations of Canada's utility requirement
 16 since 2002 are arbitrary.
 17 As Mr. Luz has explained in his reference
 18 to the ELSI case, careful attention must be paid by
 19 the Tribunal in understanding what arbitrary means,
 20 even if it is part of the minimum standard of
 21 treatment, which has not been proven.
 22 The Claimant argued this morning about
 23 decisions in the cases involving its atomoxetine and
 24 olanzapine patents. I recall slide 24 where the
 25 Claimant put up a quote from the decision in the

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1 olanzapine case, I believe, and what I found
 2 interesting was what was not highlighted on the
 3 slide. The court in that case said that it did not
 4 find the promise of the patent so small as alleged
 5 by the Claimant. At the beginning of the next
 6 sentence, which was not highlighted, he stated that
 7 he was deciding that based upon the wording of the
 8 patent and the evidence before him. This was a
 9 decision of the trial judge on the facts and on the
 10 evidence presented to him.
 11 The Claimant also referred at length this
 12 morning to the MGH study in the context of the
 13 atomoxetine patent, and suggested that the judge in
 14 that case inappropriately dismissed the quality and
 15 importance of this study. Again, that is a question
 16 of a decision on the specific evidence before the
 17 trial judge in his judgment.
 18 The Claimant also referred to several
 19 cases not involving its patents, I think it was the
 20 Latanoprost decision, and claimed that the fact that
 21 different outcomes were reached proved the arbitrary
 22 nature of the doctrine. I am, to say the least,
 23 surprised at how the Claimant can put all of this to
 24 you and ask you to find that this means it is
 25 arbitrary. In asking you to reach the conclusion,

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1 Claimant is essentially asking you to review the
 2 factual record of those cases, to examine how those
 3 cases were pled, and then to conclude that they
 4 should have been decided differently and that the
 5 conclusions of the trial judges on the extensive
 6 evidence before them were wrong, and the request
 7 that you consider this as part of an arbitrary
 8 analysis baffles me because in other parts of their
 9 arguments, and today as well, they have suggested
 10 that they are not asking you to act as a
 11 supranational Court of Appeal and, yet, reviewing
 12 the decisions of a lower court for errors of this
 13 sort is essentially one of the key functions of a
 14 domestic appellate system. And it is what the
 15 Claimant is suggesting you do in this arbitrariness
 16 analysis.
 17 I think throughout the first several hours
 18 of their presentation this morning, what you saw was
 19 basically the same appeal that the Claimant has been
 20 making in the Canadian courts and the same appeal
 21 that has been rejected. I mentioned I would get to
 22 this.
 23 You recall, Mr. President, that you
 24 referred to a part of the decision in the
 25 atomoxetine case on slide 37 of the Claimant's

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<p style="text-align: right;">285 05:05</p> <p>1 presentation, where the court said that the 2 disclosure rule was determined in an earlier 3 decision and to the extent that it may be amenable 4 to reconsideration it must be examined elsewhere. 5 The Claimant seems still to be suggesting 6 that this Tribunal is the "elsewhere" where its 7 arguments may be reexamined. The Claimant is wrong. 8 The "elsewhere" is the appellate process available 9 to the Claimant in the Canadian courts. It's not 10 the role of a Chapter 11 Tribunal. 11 As Mr. Luz has explained, a truly 12 arbitrary judicial interpretation of Canada's 13 utility requirement would be one for which there is 14 no plausible rationale or law or reason. And for 15 the reasons that have been explained at length by 16 Mr. Johnston, which I will not repeat in detail 17 here, one simply cannot say that the way the 18 Canadian judiciary interprets Canada's utility 19 requirement in the Patent Act is arbitrary. 20 Let's briefly consider them. First let's 21 consider the requirement that the Claimant alleges 22 arose in AZT, specifically that a patentee must have 23 established the utility of its invention by the time 24 of the filing, and it cannot rely on evidence 25 generated after its patent application. Is this</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">286 05:06</p> <p>1 arbitrary? 2 As Mr. Johnston explained, a patent is a 3 limited time monopoly given in exchange for the 4 disclosure of an invention. It is not a limited 5 time monopoly in exchange for the disclosure of a 6 guess or a prediction, even if that guess or 7 prediction leads to an effective or important 8 medication. 9 If one were to allow the introduction of 10 post-filing evidence to prove that the invention 11 actually met the patentability criteria, the state 12 would be encouraging guessing and speculation and 13 prediction. A requirement to prove that you 14 invented before you filed for a patent is not 15 arbitrary. 16 Let's move to the second now, which is a 17 requirement in Canada that your invention have the 18 utility that it is actually promised to have in the 19 patent. Remember, as Mr. Johnston explained, in 20 Canada there is no requirement that your patent 21 promise any particular utility. If it works, a mere 22 scintilla will do. But if you make promises in 23 order to get over problems with obviousness and 24 novelty you will be held to them. 25 I would suggest to you that holding</p> <p style="text-align: center;">www.dianaburden.com</p>
<p style="text-align: right;">287 05:08</p> <p>1 someone to their promises, especially where they 2 themselves want to hold on to those promises for 3 other patentability criteria, is not arbitrary, and 4 I would suggest we would not want to live in the 5 legal world where it was. 6 Finally, let's turn to the last element of 7 the doctrine here, the Raloxifene rule, as labeled 8 by the Claimant. Again, that's the evidentiary rule 9 that the basis for a sound prediction be disclosed 10 in the patent itself. 11 As Mr. Johnston has explained, disclosure 12 is at the heart of the patent bargain and it must be 13 disclosure sufficient to teach a person of ordinary 14 skill in the art how to understand the advancement 15 represented by the invention. You cannot teach a 16 sound prediction unless the factual basis and the 17 line of reasoning are disclosed. As he's explained, 18 there is nothing arbitrary about requiring such 19 evidence to be in the patent if it is not common 20 knowledge of people skilled in the art. 21 In sum, there is nothing arbitrary about 22 the way that the Canadian courts have interpreted 23 the utility requirement in Canadian law and it is 24 not for this Tribunal to substitute its views as to 25 what might be more appropriate for those of the</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">288 05:09</p> <p>1 Canadian courts. 2 MR. BORN: Can you help me for just one 3 moment? What do you say the rationale is for the 4 rule that the patentee will be held to all of its 5 promises in the patent? If we start from, if you 6 will, a baseline that a mere scintilla of utility 7 will do, what's the rationale for saying that if a 8 patent fulfills three out of four of its promises, 9 it will still be invalid if it doesn't fulfill the 10 fourth? 11 MR. SPELLISCY: I think it comes back down 12 to what we heard a little bit earlier today about 13 reading up and reading down in the patents. To the 14 extent that a patentee is relying upon these 15 promises in order to get over problems of 16 obviousness, over problems of novelty, courts are 17 construing the patents to find out what the 18 invention is, and if the invention involves a 19 promise of heightened utility then, in fact, you 20 will be held to that promise of heightened utility. 21 I come back to the atomoxetine patent 22 which was the one that said it would be used to 23 treat ADHD and there was some discussion by the 24 Claimant and Mr. Johnston earlier about what that 25 is. Again, the court had to understand what it</p> <p style="text-align: center;">www.dianaburden.com</p>

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1 meant to treat ADHD so it looked to the description
2 to understand what was the promise, what was the
3 invention, what was being described. And that was a
4 promise of long-term effectiveness. It's a
5 determination he made on the facts and the evidence
6 before him.
7 So to the extent that you are offering,
8 you're describing in your disclosure, in your
9 description, in your specification generally your
10 invention as offering, as granting enhanced
11 benefits, then you will be held to that.
12 **MR. BORN:** Thank you.
13 **MR. SPELLISCY:** Let me turn, finally, to
14 the last aspect of the Claimant's allegation of a
15 breach of Article 1105, that the judicial
16 interpretation by the Canadian courts of the
17 Patent Act is contrary to what they say are their
18 legitimate expectations.
19 This is an allegation that entirely
20 depends on the Claimant's assertion that there's
21 been a dramatic change in Canadian law since it
22 obtained its patents. I believe we have already
23 shown you and will show you through the evidence
24 this week that there has been no such dramatic
25 change. Moreover, even if there has been a change

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1 in how the utility requirement of Canadian law has
2 been interpreted by the Canadian courts, this cannot
3 be relevant to a claim regarding the expectations of
4 a patentee. In its questions to the party the
5 Tribunal asked: Do Respondent's grants of
6 Claimant's patents constitute specific
7 representations to Claimant in the context of
8 determining Claimant's legitimate expectations?
9 They do not. The Claimant suggested this
10 morning that the grant of a patent does create some
11 sort of expectation about validity. Patent grants
12 do not create an expectation that such patents will
13 withstand validity challenges in the courts. This
14 fact is among the core principles of the patent
15 system, and we saw an acknowledgment of this fact by
16 the Claimant itself in its regulatory filings in the
17 United States. The granting of a patent by a state
18 is not a specific representation made by the state
19 about the validity of the granted patent. That is
20 an issue for the courts. In fact, patent offices
21 grant patents based on the specific representations
22 made by the patentee in its application.
23 But even taking a step further back and
24 looking at this more systematically, the Claimant
25 today discussed how in its view the Supreme Court of

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1 Canada overturned decisions in making its findings
2 in AZT, and later they explained that their
3 legitimate expectations claim in terms of an alleged
4 radical change in Canadian law. In our view to
5 suggest that a court decision interpreting the law,
6 even if it does so in an unexpected way, to suggest
7 that that can ever violate customary international
8 law would be to attack the very heart of the common
9 law.
10 In systems governed by judicial precedent,
11 like those of the United States, Canada, and the UK
12 for that matter, it will and does happen that the
13 courts will overrule longstanding, binding
14 precedent. Indeed, some of the most important legal
15 decisions in our systems involve the overruling of
16 longstanding, binding legal precedent. It simply
17 cannot be correct to conclude that every time a
18 domestic court does so -- not just offer new
19 interpretation but actually overrule precedent -- it
20 simply cannot be correct to suggest that that state
21 violates customary international law every time.
22 For these reasons, even if legitimate
23 expectations could be considered relevant to
24 Article 1105 generally, they do not apply in the
25 context of judicial decisions interpreting domestic

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1 laws.
2 Let me now, finally, turn to our
3 explanation of why there has been no breach of
4 Canada's obligations under Article 1110 of NAFTA.
5 **THE PRESIDENT:** Before you do that, may I
6 ask a question on the last point?
7 If you look to Article 1709(8), I will
8 read it to you, "A Party may revoke a patent only
9 when: (a) grounds exist that would have justified a
10 refusal to grant the patent", so, asking the other
11 way around, do you read this provision to mean that
12 you may only revoke a patent on grounds on which you
13 would have refused to grant the patent?
14 **MR. SPELLISCY:** This is going to steal my
15 thunder a little bit when we come to 1709(8) in the
16 context of expropriation but let me offer this. The
17 answer is no. This does not lock Canada, the United
18 States or Mexico into any ground that existed or any
19 standard of utility that existed at the time that a
20 patent was considered and granted. The parties in
21 the United States and Mexico -- the United States
22 has made clear, for example, in their Article 1128
23 submission, and we'll see this later, that 1709(8)
24 did not require the NAFTA parties to freeze their
25 intellectual property laws from the date of review

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1 of patent. 1709(8) allows for the evolvement of
2 patent law.

3 To suggest that in NAFTA two common law
4 jurisdictions would have sought to lock themselves
5 in in such a way through 1709(8) to what was
6 reviewed or to what grounds existed at the time of a
7 patent being granted I think would be contrary to
8 what the parties would have expected. They weren't
9 trying to do anything revolutionary with 1709(8) in
10 terms of how or restrict how their courts could
11 evolve their patent laws as they had done for
12 hundreds of years.

13 So what I would suggest is that what this
14 is talking about is a ground that would have
15 justified -- and I think the U.S. has explained it
16 well in their Article 1128 submission -- that if the
17 grounds exist at the time when the validity is
18 questioned, then that is consistent with Article
19 1709(8). It doesn't go back and lock us in to what
20 grounds existed at the time of the actual grant of
21 patent.

22 **THE PRESIDENT:** Can you repeat that?
23 **MR. SPELLISCY:** I think if we pull up -- I
24 don't have a slide for it unfortunately but I think
25 the way to think about this is that what the parties

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1 are trying to do in 1709(8) is to ensure that the
2 grounds exist that would have justified a refusal to
3 grant the patent. The grounds are not the grounds
4 that would have existed when the patent was granted.
5 There's not a limitation in that sense. There's not
6 an attempt to restrict the parties' right to evolve
7 their patent laws. If that was the case then I
8 think that, in fact, all of the NAFTA parties would
9 be in breach, because in fact, they have all evolved
10 their patent laws, as we will hear over the course
11 of the next several weeks. The U.S. doctrine
12 enablement and written description, which didn't
13 exist before. They may have their traces, they may
14 find, but these all come into, in the same way that
15 Canada's law has evolved, the laws of the United
16 States, Mexico -- they have all evolved since the
17 time that NAFTA was signed.

18 **THE PRESIDENT:** Could it be that this does
19 not prohibit the evolution of the law but it may
20 prohibit to apply to a particular patent grounds for
21 invalidation that are different for refusing to
22 grant the patent, to this specific patent?
23 **MR. SPELLISCY:** I think what would happen
24 in that case is you would have different law
25 applicable to every single patent that was out

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1 there. You would have to constantly be looking at
2 what was the grounds that existed at the time that
3 this particular patent was granted, and worry about
4 that with every patent, if I'm understanding your
5 question. I certainly don't think that that was the
6 intent.

7 Again, the idea here was to come back and
8 to create the check that a party may revoke a patent
9 when the grounds exist at law that would have
10 justified the refusal. But it is not a harkening
11 back to the time the patent was granted.

12 **THE PRESIDENT:** What you're saying is that
13 this applies to the moment that you revoke a patent,
14 at that moment in time that ground should also exist
15 to refuse in the first place the patent?
16 **MR. SPELLISCY:** Yes.
17 **THE PRESIDENT:** Okay. Thank you.
18 **MR. SPELLISCY:** We may be able to skip
19 that when we come to 1709(8) later.
20 **MR. BORN:** I'm struggling to reconcile
21 that interpretation with the language "would have
22 justified", which seems to be pretty
23 backward-looking. Not "would justify".
24 **MR. SPELLISCY:** Yes. I think that when we
25 look at this language, that a party may revoke a

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1 patent when the grounds exist that would have
2 justified a refusal, meaning would this have
3 justified a refusal to grant the patent but on the
4 grounds that exist now. Otherwise, I would suggest
5 that any other interpretation would lead to a
6 situation where you would have to be evaluating the
7 patent laws that existed, whenever a patent came up
8 for challenge a invalidity in the courts, the court
9 would have to look back and say when was this patent
10 granted, what was our law at that time.

11 But I would suggest again the courts --
12 and, again, this isn't a particular issue in our
13 case because in our view these laws and these
14 patents here in fact would have failed or could have
15 failed at any point in the last 25 years. You could
16 have brought this back. When we go to Sound
17 Prediction -- we find this in Monsanto. We go back
18 to Fox for the promise utility doctrine in 1969. In
19 our view this isn't primarily an issue that you need
20 to decide. These are longstanding doctrines and, in
21 fact, the patents would have the same laws that are
22 being used to revoke these patents or to invalidate
23 these patents in domestic courts existed at the
24 time. But I think that when we consider this, the
25 alternative interpretation of that language would

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1 have courts looking back and trying to parse which
2 authority was out at which individual time. And
3 that's something that, again, is antithetical to the
4 common law judicial system and would create a morass
5 in which to assess these patents. The law has to be
6 applied as it exists at the time that a case comes
7 before the court.

8 Let's come to Article 1110.

9 As I explained at the beginning of my
10 opening remarks this afternoon, I will explain with
11 respect to Article 10 why there's been no unlawful
12 expropriation for a number of reasons. Three.

13 First, I will explain that a court invalidation of a
14 patent is a determination that property does not
15 exist. It cannot amount to an expropriation.

16 Second, I will explain that even if there
17 was property, the invalidation of the Claimant's
18 patents was consistent with Canada's obligations
19 under Chapter 17. Here we will deal with Article
20 1110(7).

21 Third, and finally, I will explain why
22 even if Article 1110 could be applied to the
23 judicial invalidation of the Claimant's patents,
24 Canada has not breached any of its obligations
25 because the Claimant has failed to establish an

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1 abuse of patent rights. Such a revocation would
2 amount to an executive action, taking a property
3 right that existed at the time.

4 So certainly patents are, in general,
5 property capable of being expropriated. But in its
6 questions the Tribunal also asked: "What, if any,
7 are the implications of the invalidation of
8 Claimant's patents ab initio for the purposes of
9 determining whether an expropriation has taken place
10 under Article 1110(1)?"

11 A declaration that a patent is void
12 ab initio means there has been no revocation or
13 taking of a property right that is acknowledged to
14 validly exist in Canadian law. As Mr. Dimock
15 explained in his second expert report, "Validity,
16 which is at issue in most patent cases, is not a
17 question of title but rather a question of the very
18 existence of the rights. To my knowledge, this is
19 very different than most other forms of property
20 where the existence of the property is not an
21 issue."

22 In short, in deciding whether or not a
23 patent was validly granted, a court is not
24 considering whether to take property. It is
25 considering whether there is, in fact, any property

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1 unlawful expropriation.

2 Let's start with our first point. As
3 Mr. Luz explained this afternoon, this is a point
4 that all three NAFTA parties agree on. For there to
5 have been an expropriation, there must have existed
6 property at the domestic law of the NAFTA party that
7 could be taken by the state. Let's recall again
8 that the property that the Claimant said was
9 expropriated is its two patents for olanzapine and
10 atomoxetine. In its questions to the parties the
11 Tribunal has asked: "Do Claimant's patents
12 constitute property capable of expropriation within
13 the meaning of Article 1110(1) of NAFTA?" I think
14 this also provides some answer to our struggles and
15 our questions on Article 1110(7). There are
16 circumstances in which patents can be taken or
17 expropriated by the state. Some of those
18 circumstances would represent legitimate state
19 actions consistent with Chapter 17. For example,
20 under the law of all the NAFTA parties, if a
21 patentee abuses its patent rights, the patent can be
22 taken away. If we look to Section 66 of the
23 Patent Act, we see that in Canada the Commissioner
24 of Patents may order a patent to be revoked if
25 compulsory licensing is inadequate to remedy an

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1 at all that could be taken. And when a domestic
2 court makes a determination that the property did
3 not exist, as the Federal courts did with respect to
4 Claimant's atomoxetine and olanzapine patents, it is
5 not an expropriation or taking that can give rise to
6 a claim under Article 1110.

7 This is not to say that a patentee has no
8 recourse if a state's courts declare its patents to
9 be invalid. It does. In its questions the Tribunal
10 asked the parties, "Is the Respondent's argument
11 that the property interests alleged to have been
12 taken were not valid property interests under
13 domestic law an untimely jurisdictional objection as
14 submitted by Claimant?"

15 The answer is it is not because the
16 Claimant would be able to bring a claim under
17 Chapter 11 within the jurisdiction of the Tribunal,
18 and I think that this also answers Sir Daniel's
19 question a little bit earlier about the difference
20 between expropriation and Chapter 14.

21 As Canada said again and again today, if a
22 patent was declared invalid at Canadian law, the
23 Claimant could bring a claim that, in determining
24 that there was no property right, the domestic
25 courts denied the Claimant justice in violation of

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1 Articles 1105 and 1110. The Tribunal would have
2 jurisdiction to hear such a claim.
3 As became clear for the first time in
4 their Reply the Claimant has made no such claim
5 here, so as a result it cannot bring a claim under
6 1110.
7 This leads to my second point on the
8 application of Article 1110, which will allow us to
9 get perhaps into these questions, which is on the
10 application of Article 1110(7).
11 The Tribunal has asked the parties "What
12 are the implications of Article 1110(7) for
13 Claimant's claims?" Let me spend a few minutes
14 answering that question. We'll come back to the
15 language of Article 1110(7) because it provides,
16 "This article does not apply to the issuance of
17 compulsory licenses granted in relation to
18 intellectual property rights, or to the revocation,
19 limitation or creation of intellectual property
20 rights, to the extent that such issuance,
21 revocation, limitation or creation is consistent
22 with Chapter 17."
23 As Mr. Luz has explained, Article 1110(7)
24 is a further shield or safe harbor for the NAFTA
25 parties in the instance where they do, in fact, take

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1 intellectual property rights. For example, where we
2 have the Commissioner of Patents taking a patent
3 right for abuse. But they do so in a manner
4 consistent with the obligations in Chapter 17.
5 Again, this I think responds a little bit to
6 Sir Daniel's question earlier about Chapter 14 and
7 the exclusion in Article 1101(3). The exclusion
8 Article 1101(3) is doing something very different.
9 It is saying it is not covered at all -- matters
10 covered by 14 are not covered at all. They're not
11 within the scope of Chapter 11.
12 Article 1110(7) is doing something
13 different. It is saying that if it is consistent
14 with Chapter 17 it is not under this article.
15 Article 1110. That doesn't mean that there might
16 not be a claim under other articles; it is just
17 applied to this article. And to come back to, I
18 think, what Professor van den Berg has asked, this
19 doesn't mean that there is no situation in which
20 Article 1110(7) -- or Chapter 17 could not be
21 analyzed by this Tribunal.
22 There may be a question about whether an
23 act is consistent with Chapter 17. You may be
24 called upon to decide whether or not the defense of
25 consistency with Chapter 17 is a valid defense under

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1 Article 1110(7). There is a slight variation. You
2 should not find a breach of our Chapter 17. That is
3 for a Chapter 20 Tribunal. But if you find that an
4 act is not consistent with Chapter 17, then you are
5 permitted to consider whether there has been an
6 expropriation under Article 1110. But at that point
7 Chapter 17 no longer has anything to do with it. It
8 becomes a question of whether there is an
9 expropriation under Article 1110. Chapter 17 is a
10 shield, but it is not a sword. A breach of
11 Chapter 17 doesn't tell you anything about whether
12 there has been a breach of Article 1110 of NAFTA.
13 **MR. BORN:** What's the difference between
14 finding something isn't consistent with Chapter 17
15 and finding there's been a breach?
16 **MR. SPELLISCY:** I think it gets down to a
17 question of jurisdiction really. In effect, it
18 would just simply mean that you can consider
19 Article 1110. But whether or not you could actually
20 find a breach of the obligation as a matter of
21 jurisdiction, you are limited to Section A of
22 Chapter 11 of NAFTA. So in practical reality, I
23 think that the determination you would make is the
24 same, is the measure consistent with. But in terms
25 of the formulation of what your finding would be I

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1 would suggest that you would say either it has not
2 been proven that it is consistent with Chapter 17
3 and therefore we consider Article 1110. But, again,
4 this is a last resort. A safe harbor. A shield for
5 the NAFTA parties. It is not something that you
6 should wade into, and Article 1110(7), as all the
7 NAFTA parties have made clear, is not a gateway to
8 Chapter 17 determinations.
9 What it was designed for was an extra
10 caution or an extra shield so that the NAFTA parties
11 who knew that there could be a revocation of a
12 patent -- and we saw Section 66 of the Act.
13 Revocation of a patent under Section 66 of Canada's
14 Act would be potentially -- it would depend upon the
15 factual evidence but it could be a substantial
16 deprivation of the rights of that patent. In that
17 case you might have an expropriation claim.
18 What the NAFTA parties wanted to make
19 clear was that, if that act was consistent, if that
20 taking was consistent with Chapter 17, you don't
21 even engage in the 1110 analysis.
22 **THE PRESIDENT:** Basically what you're
23 saying is -- please correct me if I'm wrong -- it is
24 an entry ticket where you may not see the show?
25 **MR. SPELLISCY:** What I would suggest is

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1 that it is -- I wouldn't describe it as an entry
2 ticket but using that, if it is an entry ticket, you
3 still have to determine whether the obligations have
4 been complied with in order to see if the defense is
5 valid. But actually finding a breach of the
6 provisions of that chapter as opposed to simply that
7 it is not consistent with, it may seem like a small
8 distinction but a distinction that is important in
9 the limits of the jurisdiction of this Tribunal.

10 **THE PRESIDENT:** But if the allegation is
11 you have expropriated my property because of a
12 violation of Chapter 17, that, you say, you are not
13 allowed to consider?

14 **MR. SPELLISCY:** The question is if you
15 have -- well, I would say that the "because" there
16 doesn't follow. You can't expropriate because of a
17 violation of Chapter 17. The question of whether or
18 not you have expropriated the property is a separate
19 question. An expropriation, as Mr. Luz explained,
20 requires a substantial deprivation or direct taking
21 of the property. That is a separate question that
22 you have to analyze. But I think you need to be
23 aware and cognizant of the fact that, certainly
24 under the law of all the NAFTA parties, there are
25 laws on the books in which every time you can take

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1 intellectual property rights, and we saw one on
2 Section 66 of the Act.

3 If I come back to that and suggest if that
4 was analyzed under Article 1110, if there was -- if
5 it could be factually proven that there was an
6 actual expropriation, a substantial deprivation
7 because of the taking of that property, even though
8 it might be for a valid public policy purpose --
9 remember that's one of the points to make it a
10 lawful expropriation. But you'd still have to have
11 an obligation arguably to pay compensation. That's
12 (d). And what the NAFTA parties want to make clear
13 is when they are engaged in acts of taking
14 intellectual property rights, which they all
15 recognize in Chapter 17 that they have the right to
16 do, that there is no obligation of that sort to pay
17 compensation, that Article 1110 does not apply.

18 So the question I think when you answer is
19 if, in fact, it is consistent with Chapter 17, as we
20 will discuss momentarily, then, in fact, you do not
21 get into the 1110 analysis, but merely being
22 inconsistent with does not lead you to the question
23 that there has been an expropriation. That is a
24 separate question. It is not a "because" between
25 Article 1110 and Chapter 17.

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1 **SIR DANIEL BETHLEHAM:** So, just to be
2 clear, you're not saying to us we are not competent
3 to look at Chapter 17. You're just making the
4 causation point?

5 **MR. SPELLISCY:** I'm certainly not saying
6 there is no situation in which you would be
7 competent to look at Chapter 17. I think that would
8 be inconsistent with 1110(7). You do obviously in
9 certain situations have competence to look and
10 assess, if a state raises a defense of Chapter 17,
11 whether or not, in fact, it is consistent with the
12 obligations in Chapter 17.

13 **SIR DANIEL BETHLEHAM:** But, as I think I'm
14 understanding what you're saying, if we were to look
15 at Chapter 17 and we were to conclude that there is
16 a sustainable allegation of breach of Chapter 17,
17 that would not flow into Chapter 11. That's the
18 point you're making?

19 **MR. SPELLISCY:** Yes, that is exactly the
20 point that I'm making. What Chapter 17 does, the
21 link between 1110(7) provides that shield. But
22 simply because when you take that away, or when you
23 find that it is not consistent with, that just means
24 a NAFTA party does not have that shield. It does
25 not flow into Chapter 17 to become a sword, or

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1 Chapter 10 or 11 to become a sword for the Claimant.
2 So in fact at that point what you then need to do is
3 analyze whether there has, in fact, been
4 expropriation, and this is where we get to the
5 questions of whether there is actually been a
6 substantial deprivation, the standard of legal
7 expropriation under denial of justice.

8 **MR. BORN:** And when you say in considering
9 whether there's an expropriation we shouldn't
10 consider consistency with Chapter 17, is that
11 because, A, we're incompetent to do it or, B,
12 because substantively an inconsistency with
13 Chapter 17 simply isn't relevant to whether there's
14 been an expropriation?

15 **MR. SPELLISCY:** Again, I think it falls
16 more to B. The question is that it is not relevant
17 to whether there is an expropriation. It simply
18 means there's no shield.

19 **SIR DANIEL BETHLEHAM:** May I just ask one
20 small follow-up question, and I apologize if this is
21 not relevant, but 1131(1), governing law: "A
22 tribunal established under this section shall decide
23 the issues in dispute in accordance with this
24 agreement and applicable rules of international
25 law."

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1 What are the applicable rules of
2 international law there?
3 **MR. SPELLISCY:** Typically when we come
4 down to it really the Vienna Convention on the Law
5 of Interpretation, how do you interpret the
6 obligations, you're in customary rules of
7 international law.
8 **SIR DANIEL BETHLEHAM:** So you're saying
9 they're only procedural rules, not substantive
10 rules? Because I forget whether it was you or the
11 Claimant was invoking Article 31(3)(c), other
12 relevant rules of international law of the Vienna
13 Convention on the Law of Treaties. So you're saying
14 that applicable rules of international law in
15 1131(1) does not refer to substantive obligations?
16 **MR. SPELLISCY:** What I would say is that
17 it certainly does not allow you to sit in judgment
18 of substantive obligations in other treaties, and I
19 think I heard the Claimant say today, or resile
20 against the idea that they were opening up the
21 jurisdiction by introducing the idea that there has
22 to be a breach of some other rule of international
23 law. I think I also heard them earlier today talk
24 about Chapter 17 as being part of the arbitration
25 agreement that it's in the same treaty and maybe

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1 they just misspoke, but in fact, Chapter 17 is not
2 part of the agreement to arbitrate. Chapter 11 is.
3 There's no reference to Chapter 17. Chapter 17 is
4 subject to state to state dispute resolution, so I
5 don't think that you can at all incorporate
6 obligations such as those in Chapter 17 through
7 Article 31(1). That is not what that is trying to
8 do.
9 **THE PRESIDENT:** At a later moment you may
10 need to explain it again, 1110(7). I think I'm not
11 entirely with you on the point. I understand what
12 you're saying is one way is indeed, when it is not
13 consistent, then you may consider it, the revocation
14 under the angle of expropriation, but you may not go
15 further than that and go into Chapter 17 to see
16 whether there is a breach of the obligations.
17 I find conceptually for me it is a
18 difficult thing, but maybe it's late in the day.
19 Maybe you can explain it tomorrow or on one of the
20 other days.
21 **MR. SPELLISCY:** Let me take another shot
22 at it now. I agree with Mr. Born that the
23 distinction we're drawing here between consistency
24 with Chapter 17 as a defense and a breach of
25 Chapter 17 is a fine line to be drawn. But I don't

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1 think that it's the overly relevant question here
2 when you come to consider whether there's a breach
3 of Article 1110. And that's the point that I want
4 to be clear on because we're going to spend some
5 time here talking about Chapter 17. Because even
6 though I don't propose to spend a lot of time on it
7 today, because in our view this is a shield we do
8 not need in this case, because there are so many
9 reasons that the Tribunal in our view should refrain
10 from involving itself in Chapter 17, it's not
11 necessary, and the meaning could be left to the
12 state parties, to NAFTA and Chapter 20 dispute
13 tribunals.
14 **THE PRESIDENT:** You remember the question
15 I asked the Claimant this morning as well, how do
16 you connect the legal dots, how do you get
17 Chapter 17 into 1110? Maybe it's the same theme I'm
18 playing here.
19 **MR. SPELLISCY:** And I would suggest to you
20 that the answer is that the only reason you consider
21 Chapter 17 is to understand whether Article 1110
22 might apply at all to the taking of intellectual
23 property right. That is the only relevance it has.
24 If you determine that it is not a shield, you must
25 then find an expropriation. And Chapter 17 tells

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1 you nothing about that. The Claimant's theory that
2 they can prove an expropriation by referring to a
3 breach of the principles of Chapter 17 is
4 fundamentally wrong.
5 As Arbitrator Bethlehem said, this is an
6 issue that a breach of Chapter 17 does not cause a
7 breach of Chapter 11. A breach of Chapter 17 is not
8 a sword, it is a shield. The only relevance it has
9 to you is whether Canada can hold that shield. If
10 you determine that the measures are not consistent
11 with Chapter 17, it means Canada does not have that
12 shield and you proceed with an 1110 analysis.
13 **SIR DANIEL BETHLEHAM:** But it may
14 conceivably be useful -- sorry, I'm just trying to
15 clarify -- it may conceivably be useful for purposes
16 of, for example, making an assessment as to whether
17 the public purpose requirement in 1110 has been
18 satisfied evidentially, if you like?
19 **MR. SPELLISCY:** Right. I think if you are
20 consistent with Chapter 17 one of the things that
21 would be recognized is that there was a public
22 purpose for it. Chapter 17 outlines a number of the
23 things that the NAFTA parties are agreed are
24 acceptable. But it does come back, and why I say
25 it's not a sword -- or why I say Article 1110(7)

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1 exists, why it was drafted, is because that wouldn't
2 be enough to save a question on Article 1110. You
3 would still need to pay compensation if Article 1110
4 applied.

5 So what the NAFTA parties wanted to make
6 very clear by Article 1110(7)), as we referred to in
7 a quote from Ms. Kinnear in her book, is to avoid
8 the mischief that that would cause about having what
9 all the parties recognize was legitimate reasons to
10 take intellectual property and not wanting to get
11 into an 1110 analysis as to whether or not
12 appropriate compensation or anything of that sort
13 was paid.

14 Let me offer you some brief thoughts on
15 why on Chapter 17 you should conclude that it is, in
16 fact, a shield for Canada in this arbitration.
17 Again, in our position it is a shield that Canada
18 does not need and that, in fact, you should not
19 address because it is better left for other
20 Tribunals. But if you disagreed and wanted to look
21 and thought that there was a taking here, I want to
22 walk through Chapter 17 and show why we are
23 consistent with it.

24 There are four separate obligations in
25 Chapter 17 that the Claimant has raised,

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1 Article 1701(1), Article 1709(1), Article 1709(7)
2 and Article 1709(8). Each of their allegations of a
3 breach is without merit.

4 I can start quickly with Article 1701(1)
5 which provides in relevant part that "Each party
6 shall provide in its territory to the nationals of
7 another party adequate and effective protection and
8 enforcement of intellectual property rights." This
9 obligation is further clarified in Article 1701(2)
10 which states that, "In order to provide adequate and
11 effective protection and enforcement of intellectual
12 property rights, each party shall, at a minimum,
13 give effect to this chapter" and the provisions of
14 several other international treaties.

15 As such, and as Canada has explained, this
16 is a general obligation about ensuring that there
17 exists an effective system to enforce and protect IP
18 rights.

19 The Claimant asserts that the dramatic
20 change in Canada's patent law that it alleges
21 occurred subsequent to 2002 has resulted in Canada
22 failing to meet its obligations under
23 Article 1701(1). There is no merit to this claim.
24 I think that the problem with the Claimant's
25 argument is rendered clear by just having a

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1 perspective beyond the myopic one suggested by the
2 Claimant.

3 For example, since 2005 Canada has granted
4 over 13,000 pharmaceutical patents. Even if you
5 wanted to use what we will show is an inappropriate
6 counting methodology employed by the Claimant, even
7 if you use their methodology, less than 30 have been
8 adversely affected by the alleged change in the
9 judicial doctrine that the Claimant says means that
10 Canada does not have a system that adequately and
11 effectively protects IP rights. That is absurd.
12 These alleged significant changes affect less than
13 one half of one percent of pharmaceutical patents in
14 Canada.

15 Canada's laws are consistent with
16 Article 1701(1).

17 Let's move on and spend more time on
18 Article 1709(1). Article 1709(1) provides:
19 "Subject to paragraphs 2 and 3, each party shall
20 make patents available for any inventions, whether
21 products or processes, in all fields of technology,
22 provided that such inventions are new, result from
23 an inventive step, and are capable of industrial
24 application. For purposes of this article, a party
25 may deem the terms 'inventive step' and 'capable of

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1 industrial application' to be synonymous with the
2 terms 'non-obvious' and 'useful', respectively."

3 The Claimant alleges that Canada is in
4 violation of the obligations under this article
5 because its approach to utility results in patents
6 not being made available even though the inventions
7 are, the Claimant alleges, new, non-obvious and
8 useful.

9 First let's look to the introductory
10 language of the article, and it says: "Subject to
11 paragraphs 2 and 3, each party shall make patents
12 available for any inventions". In its questions to
13 the parties the Tribunal asked, "What is the meaning
14 of 'shall make patents available' in Article 1709(1)
15 of NAFTA?"

16 Now, this is relatively complex language
17 in terms of language structure, and I think one
18 thing is clear. It doesn't mean what the Claimant
19 said this morning it means. It doesn't mean "shall
20 issue". If the parties had wanted to write "shall
21 issue" or "shall grant", that certainly would have
22 been much easier to do. The French and the Spanish
23 text of NAFTA make it equally clear that Article
24 1709(1) is not a mandate or an obligation, as the
25 Claimant said, for the NAFTA parties to grant

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1 patents to any invention that happens to be new,
2 non-obvious and useful. In French, the relevant
3 language is -- and I apologize to my French
4 colleagues -- "... (French language spoken) ...".
5 So in French the language is "can grant"
6 or "will be able to grant." It is not a mandate to
7 grant. It does not say "shall" grant.
8 In Spanish the relevant language is ...
9 (Spanish language spoken)...
10 So in Spanish again the language would be
11 closer to the parties "will determine the grant of
12 patents". It is not a mandate to grant a patent
13 even if the invention is new, non-obvious and
14 useful. Why? And let's turn back to the English
15 version to examine the question further. I think
16 that the explanation is relatively simple.
17 While the three patentability criteria
18 listed are core criteria, they are not the only
19 conditions that any of the NAFTA parties required at
20 the time they concluded NAFTA or require now in
21 order to obtain a patent. In fact, as Mr. Johnston
22 explained, the core of the patent bargain is
23 actually disclosure. One can manufacture an
24 invention that is new, non-obvious and useful, but
25 the inventor will not be entitled to a patent for

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1 that invention unless he or she adequately discloses
2 it to the public, and you can scan all of
3 Article 1709. Disclosure is not mentioned a single
4 time. Not once.
5 The NAFTA parties adopted no text at all
6 that referenced, yet alone regulated, what they
7 could require in terms of the most important
8 obligation on the patentee and the patent bargain
9 disclosure.
10 Mr. Born asked earlier today about other
11 requirements. I'd point out that nowhere in 1709 do
12 the NAFTA parties limit themselves in terms of the
13 other requirements for a patent that they may have
14 in their national laws. The reference was to
15 enablement, or written description. In short, the
16 introductory text Article 79(1) makes clear that it
17 is not imposing an obligation on when a NAFTA party
18 must grant a patent. It is establishing a number of
19 necessary conditions that an invention must have to
20 be considered for the grant of patents, but it is
21 not outlining which conditions are sufficient.
22 What is sufficient for each of the parties
23 to grant a patent with respect to both the core
24 criteria themselves and other criteria is clearly
25 and unequivocally left to their own domestic laws.

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1 I think that even looking at the first three
2 paragraphs of Article 1709(1) as a group shows this.
3 Article 1709(1) starts off with the
4 proviso "Subject to paragraphs 2 and 3". Let's look
5 at paragraphs 2 and 3. They are again about what is
6 patentable, not about when a patent must be granted.
7 I would suggest that if you read 1709(1) closely you
8 will see that it is also truly about what types of
9 inventions will be patentable in the NAFTA parties.
10 It does not create an obligation on the NAFTA
11 parties to grant patents even if an invention is
12 new, non-obvious and useful.
13 I suggest to you that this fact should
14 heavily influence how we then consider the meaning
15 of what some of those necessary conditions are in
16 the latter half of the sentence. Let's turn to the
17 latter half and look at the necessary conditions --
18 **SIR DANIEL BETHLEHAM:** Before you get
19 there may I just ask you, 1709(3), the second
20 paragraph of that, notwithstanding subparagraph (b),
21 1709(3): "Notwithstanding subparagraph (b), each
22 party shall provide for the protection of plant
23 varieties through patents". That's requiring.
24 **MR. SPELLISCY:** This would be shall
25 provide for the protection through patents meaning

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1 that the patents -- I think that doesn't set the
2 condition on when they shall be granted, but it is
3 saying that patents must be available for plant
4 varieties.
5 **SIR DANIEL BETHLEHAM:** I see. Thank you.
6 **MR. BORN:** Isn't the basic assumption of
7 1709(2) and (3) that there are some obligations with
8 respect to patentability? There wouldn't be
9 exceptions if there wasn't an obligation.
10 **MR. SPELLISCY:** I think that the answer
11 is -- that yes, the idea is that there will be
12 things that can be considered for things that are
13 patentable, and I would suggest that that is what
14 actually 1709(1) means. But to be patentable
15 doesn't mean you are entitled to a patent. You
16 still must meet other conditions. It just means you
17 qualify for consideration for a patent. And that
18 was a big thing at the time that NAFTA was being
19 drafted, because there weren't the same rules on all
20 inventions that were patentable among the parties,
21 and I think if you look at the protection of plant
22 varieties through patents again is an example, where
23 the NAFTA parties were expressly saying you shall
24 provide for the protection of plant varieties.
25 Let's go to the next slide and turn to the latter

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1 half and talk about "useful" in Article 1709(1).
2 The Claimant alleges that the term
3 "useful" in 1709(1) must mean something, and on
4 this, the parties are agreed. Of course it must
5 have meaning. But the Claimant's suggestion as to
6 how the Tribunal should understand the meaning of
7 the phrase "useful" suffers from numerous flaws.
8 As Mr. Johnston explained earlier today,
9 it focuses solely on utility, ignoring the
10 interaction of that criteria with the other
11 patentability criteria, particularly in the case of
12 secondary patents and criteria like disclosure or
13 enablement. It also importantly confuses the
14 standard of utility with how a NAFTA party
15 implements that standard.
16 In fact, as you will recall from
17 Mr. Johnston's presentation, and the Claimant's as
18 well, of the components of what the Claimant alleges
19 is Canada's promise utility doctrine, only one is
20 about the promise standard itself. It is the first,
21 and that is the only one about what utility means.
22 The rest are about how utility is implemented and
23 the evidence that Canadian courts require to prove
24 utility. And, as we have just gone through,
25 Chapter 17 says absolutely nothing about the

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1 evidence that the NAFTA parties can or cannot
2 require in order for a patentee to prove that its
3 invention is useful, or to prove that it should
4 obtain a patent even if its invention is patentable.
5 Things such as disclosure and evidentiary
6 rules are entirely outside of the scope of coverage
7 because they relate to what will be sufficient to
8 obtain a patent. As such, for the purposes of
9 Chapter 17, the only relevant aspect of the Canadian
10 doctrine that the Claimant is challenging is a
11 requirement that, in order for it to be deemed
12 useful, the invention must be useful for what it
13 says it will be useful for rather than only for some
14 use somewhere at some point.
15 The Claimant suggests that such a
16 requirement is in breach of Article 1709(1).
17 However, a proper Vienna Convention analysis shows
18 its claim is without merit. As Canada explained in
19 its written submissions, a proper analysis of the
20 meaning of Article 1709(1) considers, 1, the
21 ordinary meaning of the terms "useful" and "capable
22 of industrial application" as understood in the
23 patent laws of the NAFTA parties; 2, the context of
24 1709(1); 3, the subsequent practice of the NAFTA
25 parties; 4, other relevant rules of international

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1 law; and 5, to the extent necessary to eliminate
2 ambiguity, any relevant supplemental means of
3 interpretation.
4 Canada has laid this Vienna Convention
5 analysis extensively out in its written submissions
6 and I don't intend to repeat it here, especially
7 given the limited relevance of these provisions in
8 our view to what you must truly decide in this case.
9 As Mr. Johnston laid out earlier, Canada's
10 law required that an invention must be useful for
11 what it says it will be useful for for decades
12 before NAFTA was signed. All of the NAFTA parties
13 would have understood and accepted this. In this
14 regard I note that in its questions to the parties
15 the Tribunal has asked "What is the relevance, if
16 any, of the utility standards in other NAFTA
17 jurisdictions with respect to Claimant's claims?"
18 I think the answer to this is that the
19 only relevance would be in the context of a Vienna
20 Convention analysis, where it would be considered as
21 relevant to both the ordinary meaning of the term
22 when the parties agreed to NAFTA, to the context of
23 that provision, and the subsequent practice of the
24 NAFTA parties. I believe that the evidence this
25 week from the various experts will show you two

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1 things, both that the NAFTA parties all seek to
2 achieve the same policy goals with their patent
3 laws, though sometimes using different doctrines,
4 and that there has never been a time when the
5 definition that the Claimant seeks to ascribe to the
6 term "utility" has been accepted by all of the NAFTA
7 parties or by the rest of the international
8 community.
9 There has always been variation how
10 "utility" is understood and Article 1709(1) was
11 certainly not meant to resolve that debate. If the
12 NAFTA parties had meant to adopt the very specific
13 definition of "utility" the Claimant now advocates
14 must be read into 1709(1), they certainly could have
15 done so. They would have had no reason to resort to
16 subtlety and to interpretation of the word
17 "utility."
18 When you look to the ordinary meaning of
19 the term "useful" as the NAFTA parties would have
20 understood it, and when you consider it
21 appropriately in the context of the provision in
22 light of the subsequent practice of the parties and
23 other relevant rules of international law, there can
24 be only one conclusion. Article 1709(1) does not
25 have the specific and restrictive meaning that the

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1 Claimant would like it to have. In fact, I would
2 suggest that it is particularly telling that you
3 have the submissions of the three NAFTA parties in
4 front of you in this arbitration and not one has
5 agreed that the Claimant has appropriately described
6 the meaning of the term utility in Article 1709(1).
7 In sum, as fully set forth in our written
8 submissions, even if you accept that the Claimant's
9 assertion that the judicial interpretation of
10 Canada's utility requirement has changed since
11 2005 -- and you should not, but even if you do --
12 there's still been no breach of the flexible
13 standard contained in Article 1709(1).
14 Let's finish our look at Article 1709
15 quickly for the rest of this, because the hour does
16 get late.
17 Let's turn to Article 1709(7) which
18 provides in relevant part: "Subject to paragraphs 2
19 and 3, patents shall be available and patent rights
20 enjoyable without discrimination as to the field of
21 technology..."
22 As I noted a few minutes ago, since 2005
23 alone Canada has issued more than 13,000
24 pharmaceutical patents. The Claimant nevertheless
25 claims a breach of this article because it alleges

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1 evidence of discrimination in law or in fact with
2 respect to pharmaceutical inventions. Canada has
3 acted consistently with its obligations in
4 Article 1709(7).
5 Now we come to Article 1709(8), and we'll
6 do this very quickly because we did talk about it
7 earlier. As explained, Article 1709(8) was in no
8 way intended to curtail the power of the courts to
9 continue their role in interpreting the broad
10 requirements of patent law. I mentioned this, and
11 we can pull it up now. As the U.S. has pointed out
12 in their 1128 submission, "Nor can Article 1709(8)
13 mean that the NAFTA parties are required to freeze
14 their intellectual property laws indefinitely from
15 the date of review of a given patent. Article
16 1709(8) allows for evolvement of patent law."
17 In short, even if there has been a
18 substantial change in the judicial interpretation of
19 Canada's utility requirement, such a change does not
20 violate the rules in 1709(8).
21 Let me turn very briefly to the third and
22 last point I want to make on 1110 before I get to
23 some concluding remarks. The Tribunal asked
24 according to the Respondent if one were to accept
25 the Claimant's allegation that Respondent's actions

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1 that Canada's purported promise utility doctrine
2 discriminates in fact against pharmaceutical
3 inventions. This argument is ill-founded.
4 The Claimant relies on the expert report
5 of Dr. Levin in order to ground its claim of
6 discrimination. Certainly as far as I can tell
7 Dr. Levin has done his math right. The problem is
8 in the dataset that was provided to him to analyze.
9 As Canada has explained and as is
10 extensively detailed in the witness statements of
11 Dr. Brisebois, the issue is that the Claimant has
12 provided a biased and inaccurate dataset to
13 Dr. Levin. When appropriate corrections are applied
14 and corrected to reflect reality, there has not been
15 a statistically significant difference in utility
16 based invalidation rates between pharmaceutical and
17 non-pharmaceutical patents since 2005.
18 To come back to something that was raised
19 earlier, even if the Claimant's statistics were
20 accurate, as the United States noted in its
21 Article 1128 submission, differential effects of a
22 measure on a particular sector, even if shown, do
23 not necessarily prove discrimination as to field of
24 technology within the meaning of Article 1709(7).
25 In sum, the Claimant has adduced no

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1 were inconsistent with chapter 17, what effect would
2 this have on Claimant's claim under Article 1110. I
3 hope that we have answered this question
4 sufficiently this afternoon.
5 The Tribunal also asked the parties, "What
6 is the relevance, if any, of the Patent Cooperation
7 Treaty, for the purposes of determining Claimant's
8 claims?" The answer to this question is that there
9 is none.
10 Now, I would suggest that contrary to what
11 the Claimant told you this morning, the
12 Patent Cooperation Treaty, like Chapter 17 and their
13 arguments thereon, could only be relevant if you
14 determine that the Claimant was right that you could
15 sit in judgment of a PCT member's obligations in the
16 context of deciding whether there has been an
17 expropriation under 1110.
18 As I mentioned earlier in my remarks
19 today, you cannot do so. The PCT is not
20 incorporated in any other way into NAFTA but, as my
21 colleague Mr. Luz explained, the same reason that
22 makes Chapter 17 irrelevant is the same reason that
23 makes the PCT irrelevant for the causation question
24 of whether there has been a breach of Article 1110.
25 I would note that even if you could

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<p style="text-align: right;">329 06:01</p> <p>1 consider the PCT, the evidence of Mr. Gervais and 2 Mr. Reed will show that the Claimant has failed to 3 establish a breach of any of Canada's other 4 international obligations, and we'll get to that. 5 But the real question here is whether 6 there has been a taking of the Claimant's property 7 that amounts to a substantial deprivation of the 8 Claimant's investment in violation of Article 1110. 9 As I've explained, that is a question that neither 10 the PCT nor Chapter 17 give you any answers to. 11 The Tribunal also asked the parties what 12 are the implications, if any, of the Respondent's 13 argument that the Claimant has not been 14 substantially deprived of its investment. 15 Let me say this. The Claimant bears the 16 burden of proving that the measures in question have 17 resulted in the substantial deprivation of the value 18 of its investments. Earlier the Claimant said that 19 it was agreed that there has been a substantial 20 deprivation simply because the patents were revoked. 21 It's not been agreed. The Claimant bears the burden 22 of showing that the value of its investments, its 23 patents, was, in fact, substantially deprived even 24 though it can continue to produce and sell its 25 products in Canada. As Canada has explained in its</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">330 06:02</p> <p>1 written submissions, it has not met this evidentiary 2 burden of proof and, thus, it has failed to prove a 3 violation of Article 1110 of NAFTA. 4 Now, let me offer you some concluding 5 thoughts, and I will try to do this by summarizing 6 these thoughts into a decision tree that I think 7 will represent exactly how farfetched the Claimant's 8 claim is. 9 As I said at the beginning, if you agree 10 with Canada, the United States and Mexico as to the 11 meaning of the Treaty they signed, then the only 12 possible cause of action that can be brought with 13 respect to the judicial decisions of a neutral 14 independent court is a claim for denial of justice. 15 There is no allegation of a denial of justice in 16 this case and, hence, there is no claim here. This 17 case should be dismissed as a result. 18 However, even if you consider the 19 Claimant's challenge to the judicial interpretation 20 of Canada's Patent Act justiciable in the absence of 21 a denial of justice, it has been brought too late. 22 NAFTA does not allow an investor to bide its time, 23 sit on its hands, and bring a challenge to the most 24 recent application of an older doctrine or law. The 25 Claimant knew of the measures in question and the</p> <p style="text-align: center;">www.dianaburden.com</p>
<p style="text-align: right;">331 06:03</p> <p>1 losses it would suffer as a result by no later than 2 2009. It waited four years to bring a claim. As 3 such its claim is time barred and should be 4 dismissed. 5 Even if you disagree, however, this case 6 must still be dismissed before you consider the 7 legal merits of the claims, and that is because the 8 necessary factual predicate for this claim is not 9 present. As I explained earlier, the Claimant has 10 grounded its claim on the idea that there has been a 11 change in Canadian law, a dramatic change. It 12 cannot do otherwise because if it is wrong and no 13 such dramatic change occurred, then the doctrines 14 and interpretations it wishes to challenge existed 15 prior to its making its investments and cannot be 16 challenged by it. 17 As Mr. Johnston has shown you earlier 18 today and, as will be made clear in the testimony of 19 the experts you will hear, there has been no 20 dramatic change in Canadian law. Therefore, this 21 claim fails for that reason as well. 22 It is over before there is any need to 23 even consider the merits of the Claimant's 24 allegations, but even if you did move on to consider 25 the substantive protections offered by Article 1105</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">332 06:04</p> <p>1 and 1110, and even if you accepted some of the 2 standards that the Claimant has argued, the claim 3 would still fail. There has been no conduct which 4 breaches the standards of customary international 5 law that are applicable under Article 1105. There 6 has been no taking of property at all, let alone an 7 expropriation in violation of Canada's obligations 8 under Article 1110, so this claim of breach must be 9 dismissed for that reason as well. And it should be 10 dismissed with a full award of costs to Canada so 11 that future claimants will be appropriately 12 dissuaded from a similar misuse of Chapter 11 13 dispute resolution. 14 Thank you. 15 THE PRESIDENT: Thank you, Mr. Spelliscy. 16 That concludes the opening statement by Respondent? 17 MR. SPELLISCY: Yes, unless there are 18 questions? 19 THE PRESIDENT: I think you have heard 20 already a sufficient number of questions. 21 Thank you. I think we can close the 22 hearing for today and resume tomorrow morning at 23 9:00. I think the first witness is Mr. Armitage, as 24 I understand it, for the Claimant? 25 MS. CHEEK: Yes. Mr. Armitage, that's</p> <p style="text-align: center;">www.dianaburden.com</p>

1 correct.

2 (The hearing closed at 6.05 pm)

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<p>MR. BERENGAUT: [21] 129/6 136/8 136/11 136/17 138/1 138/13 138/23 139/7 140/1 140/6 140/13 140/20 141/1 141/4 142/2 142/13 142/22 145/12 145/16 145/23 149/7</p> <p>MR. BORN: [34] 23/15 37/4 37/13 37/19 48/16 57/18 119/19 120/8 139/20 140/3 140/7 170/16 171/15 172/6 217/23 218/5 218/18</p>	<p>219/5 219/14 224/14 226/8 228/12 248/2 248/11 265/20 266/14 273/8 274/2 288/1 289/11 295/19 303/12 308/7 320/5</p> <p>MR. JOHNSTON: [2] 172/7 206/9</p> <p>MR. LUZ: [26] 206/11 209/4 215/11 216/24 218/2 218/7 218/20 219/11 219/16 221/10 225/1 226/10 226/25 227/20 228/3 228/20 232/22 245/13 246/24 247/8</p>	<p>247/13 248/6 248/15 249/9 249/19 249/22</p> <p>MR. SMITH: [1] 88/18</p> <p>MR. SPELLISCY: [40] 7/4 8/19 9/11 158/22 171/2 171/24 250/6 266/1 266/25 267/24 269/3 269/16 270/3 270/18 271/3 271/21 273/16 274/10 288/10 289/12 292/13 293/22 294/22 295/15 295/17 295/23 303/15 304/24 305/13 307/4 307/18 308/14 309/2 309/15</p>
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<p>THE PRESIDENT:.... [46] 116/16 117/3 117/10 129/5 135/22 136/9 136/12 137/11 138/10 138/18 139/2 139/18 141/2 142/4 142/21 145/13 158/12 158/15 158/19 206/7 209/3 227/19 227/23 246/15 247/5 247/9 248/24 249/16 249/20 250/2 250/4 269/14 269/17 270/15 270/19 292/4 293/21 294/17 295/11 295/16 304/21</p>	<p>305/9 310/8 311/13 332/14 332/18 THE SECRETARY: [3] 145/9 145/20 149/5</p> <hr/> <p>\$</p> <hr/> <p>\$3,000 [1] 243/1</p> <p>\$350 [1] 243/2</p> <p>\$350 million [1] 243/2</p> <hr/> <p>'</p> <hr/> <p>'113 [11] 25/25 29/5 30/15 102/11 197/19 197/24 198/3 199/8 199/11 199/23 200/5</p> <p>'113 patent [2] 29/5 199/23</p> <p>'206 [2] 69/8</p>	<p>69/13 '687 [8] 197/21 197/23 198/4 198/4 198/7 198/7 198/9 199/22 '735 [10] 37/24 40/8 45/24 102/12 202/15 202/21 203/2 203/5 203/8 203/23 '90s [1] 188/20 'after [1] 69/10 'capable [1] 315/25 'date' [1] 263/25 'indicated' [1] 91/11 'inventive [1] 315/25 'marked [1] 29/6</p>
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one... [7]	92/20 94/23	208/1 209/17
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321/19 321/21	96/10 97/9	211/8 214/7
324/24 325/4	97/20 98/7	215/4 217/25
327/24	105/15 111/1	219/8 219/16
one-way [2]	113/19 125/2	219/17 219/22
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onerous [2]	128/10 128/12	226/19 230/3
54/19 85/11	132/10 132/19	236/10 239/21
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41/4 41/5	183/16 183/24	311/20 311/23
41/13 45/18	184/8 184/24	312/8 317/18
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139/1 141/2	226/17 226/20	275/17 275/24
141/10 141/11	228/21 229/12	276/8 277/2
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158/17 158/25	249/19 252/17	293/23 294/10
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168/19 168/23	263/1 268/6	298/22 298/23
169/2 169/12	269/5 269/10	302/1 304/3
171/8 171/13	270/5 270/21	304/12 306/1
172/6 174/18	271/5 271/11	306/19 307/2
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158/2 158/3	272/25 274/6	50/4 50/8 51/1
158/4 159/14	275/18 277/2	51/25 52/9
159/18 159/19	277/7 277/10	52/18 53/3
160/8 160/25	278/13 279/23	53/21 53/25
161/3 161/24	283/21 284/3	55/7 55/14
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187/13 194/23	300/12 307/14	57/7 57/20
195/8 195/17	307/15 309/20	58/6 58/18
197/1 197/6	320/20 320/23	61/8 61/13
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94/11 96/16	186/3 186/16	237/24 240/15
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113/3 113/10	188/18 188/19	247/7 247/12
114/1 115/10	188/21 189/8	250/25 252/15
115/22 116/8	190/11 190/18	253/4 253/9
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142/11 142/12	213/12 213/22	270/7 271/7
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283/1 283/2	319/5 319/8	32/18 35/19
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287/25 288/3	321/18 321/21	38/21 46/9
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288/24 288/25	323/8 323/11	49/17 50/3
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293/5 293/6	329/11	55/21 57/4
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293/25 294/23	56/15 56/24	61/21 63/16
295/2 295/12	120/15 128/18	66/4 66/7
296/10 299/6	182/18 185/22	76/18 77/12
301/11 302/18	226/7 238/14	79/6 80/24
303/25 304/9	272/14 272/15	81/5 81/12
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101/5 102/16	201/2 202/6	296/16 296/24
111/13 111/16	207/18 208/4	300/1 306/13
113/18 115/10	210/24 213/4	306/18 307/22
117/4 118/1	215/2 215/23	307/22 308/8
121/4 126/11	216/4 219/6	309/3 310/12
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167/12 168/15	272/22 273/6	24/1 25/1 25/6
172/5 173/24	273/7 277/5	29/18 33/19
174/2 175/17	277/11 278/19	36/22 36/23
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61/4 63/8	285/6 287/1	77/1 79/6
63/16 69/17	287/5 296/6	83/12 85/7
70/20 78/4	299/20 301/25	85/8 85/22
90/1 94/19	302/1 304/24	85/22 87/7
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189/1 192/14	15/3 15/12	115/4 116/2
215/10 218/13	19/5 23/11	116/23 117/12
219/3 220/3	24/3 31/11	118/1 120/7
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228/8 233/25	41/14 44/8	123/21 128/2
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171/6 171/9	267/6 267/11	26/9 26/23
172/1 172/3	269/2 269/23	27/3 38/21
182/10 184/7	269/25 272/1	40/14 42/1
186/19 186/24	272/25 273/1	42/11 45/15
187/14 199/14	274/6 299/9	46/16 47/18
199/14 205/21	299/22 299/24	47/25 47/25
210/1 210/2	299/25 302/22	49/19 53/3
213/8 214/18	302/24 303/5	55/22 57/18
216/16 216/18	303/8 303/11	58/1 61/16
222/12 225/4	303/19 305/3	64/15 66/21
225/5 225/15	305/17 307/11	68/11 71/11
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121/11 122/1	208/24 209/1	301/9 302/19
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