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

Case No. UNCT/14/2

ELI LILLY AND COMPANY

Claimant

vs.

GOVERNMENT OF CANADA

Respondent

MINUTES OF ARBITRATION

Washington, D.C.

Monday, 30 May 2016

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THE PRESIDENT: Good morning, ladies and gentlemen. I open the hearing in the case of Eli Lilly Company as Claimant versus the Government of Canada as Respondent. You have in front of you the Arbitral Tribunal. You know by now Mr. Gary Born on my left-hand side and Sir Daniel Bethlehem on my right-hand side and the Secretary of the Tribunal, Ms. Lindsay Gastrell at the end of the table. It is a good custom that each side introduces his or her team. May I invite Ms. Cheek for Claimant to introduce her team? 09:01

MS. CHEEK: Thank you very much. Good morning, members of the Tribunal. I will go ahead and go down our row. Next to me is Mr. Alex Berengaut, Ms. Wendy Wagner, Mr. James Smith, Mr. Rick Dearden. We then have three party representatives from Eli Lilly and Company. Steve Caltrider, Arvie Anderson and Arleen Palmberg. We then have Mr. John Veroneau, Mr. Nikhil Gore, Mr. Mike Chajon, Ms. Lauren Willard, Mr. Alex Aronson and Ms. Gina Vetere. Our experts are also in the room. I will go off my list. We have Ms. Natalie Derzko, Ms. Tina Thomas. They actually are part of our team here, as well as our expert, Mr. Bruce Levin, Professor Robert Merges, Mr. Andy

Reddon, Professor Norman Siebrasse and Philip Thomas. 09:03

THE PRESIDENT: For the Respondent, please.

MR. SPELLISCY: Good morning. Beside me I have counsel Adrian Johnston, Mark Luz, the director of the Trade Law Bureau, Ms. Sylvie Tabet. Krista Zeman and Mariella Montplaisir. Then further down I can see Ms. Shawna Lesaux and Marc-Andre Leveille, who are our paralegals. Then from our clients we have Mr. Sanjay Gupta. Mr. Denis Martel. We have beside them one of our experts, Mr. Ron Dimock, Mr. Ryan Evans, and at the very end we have another representative from Industry Canada, Mr. Brad Jenkins.

THE PRESIDENT: Thank you.

I also note that we have representatives of the United States of Mexico. Could you please tell us your name?

MS. PONCE: Linda Ortiz Ponce and Aristeo Lopez.

THE PRESIDENT: For the United States?

MS. ADKINS: Jocelyn Adkins and Nicole Thornton.

THE PRESIDENT: Welcome. Thank you.

The hearing is being transmitted via a videolink to another room in this building. There is no video retention, no videos are being kept of this hearing at the request of the Claimant. The attendants, I understand, will see this, watch this with an hour delay. The reason is purely technical. There was no company to be available in the DC area which could do it with the usual delay of ten minutes, but so be it. But those who watch us are welcome. 09:05

The next thing is we have the schedule. There was a schedule from both sides on the witnesses with the estimates. It turned out that both sides had handed in their own estimates, but on Friday we have sent you a combined version. Does that give rise to any questions? Ms. Cheek, on your side?

MS. CHEEK: That did not raise any questions on our side.

MR. SPELLISCY: And not on our side.

THE PRESIDENT: So we will proceed on the basis of that Excel sheet.

We also have asked you whether you agree that the witnesses and the experts take pictures. Both sides have agreed to that. Those pictures will

be assembled by the Secretary of the Tribunal and will be put in what we call a picture book. The picture book is something which is for the parties only and the Tribunal and need not to be published on the website -- actually should not be published on the website for privacy reasons. 09:06

I think that is all the Tribunal has to mention. Are there any matters of an organizational or administrative nature that you would like to raise?

MS. CHEEK: Not from the Claimant.

MR. SPELLISCY: None from the Respondent either.

THE PRESIDENT: I think then we can commence with the opening statements, first by the Claimants. Ms. Cheek, please proceed.

MS. CHEEK: You should have in front of you a copy of the PowerPoint presentation that will accompany our opening statement. We also have two mini bundles. (Distributed)

OPENING STATEMENT ON BEHALF OF CLAIMANT

MS. CHEEK: Mr. President, members of the Tribunal, good morning. Welcome to Washington, D.C.

We are here today because Eli Lilly developed two groundbreaking medicines, Zyprexa for

the treatment of schizophrenia, and Strattera for the treatment of attention deficit/hyperactivity disorder, or ADHD. Canada granted patents for Zyprexa in 1998 and for Strattera in 2002. 09:09

The Zyprexa and Strattera patents are protected investments under NAFTA Chapter 11 and, just as with other forms of property, Canada may not expropriate those patents without compensation or deny those investments fair and equitable treatment.

Canada has breached these NAFTA obligations. The law on utility, a patentability requirement, has fundamentally changed in Canada. When Lilly sought patent protection in the 1990s, the utility requirement was simply whether an invention was operable or had some industrial value. A decade later, after Lilly relied upon its Canadian patents and developed the market for Zyprexa and Strattera in Canada and launched these drugs, the Canadian courts revoked these patents, solely for lacking utility or usefulness under Canada's novel promise utility doctrine, even though Lilly's competitors were selling these drugs and thousands of Canadian patients were using these drugs.

I will provide you this morning with a brief overview of Lilly's claims and I will walk you

through the challenged measures in this case, which are the Canadian courts' revocations of Zyprexa and Strattera. Ms. Wagner will then explain Canada's promise utility doctrine and its origins in greater detail, and Mr. Smith will place Canada's doctrine in context and explain its discriminatory effects on the pharmaceutical sector. Mr. Berengaut and I will then finish our presentation this morning with a discussion of Lilly's legal claims for expropriation and violation of fair and equitable treatment under Chapter 11, and in the course of our presentation we also will answer the Tribunal's questions that were provided to us in advance. 09:10

Zyprexa and Strattera are both CNS drugs, meaning they relate to the central nervous system. Simply put, this is brain science. These drugs affect receptor sites in the brain associated with schizophrenia and ADHD. Zyprexa treats schizophrenia and other mental disorders, as I mentioned.

Schizophrenia is a devastating mental illness. It causes hallucinations and delusions and paranoia. Old treatments could address those symptoms but at a cost. The cost was dehabilitating side effects -- involuntary jerking, an inability to

sit still -- and old treatments also failed to address some of the symptoms of schizophrenia such as apathy and withdrawal. 09:12

Zyprexa was one of a new class of anti-psychotics that was able to effectively treat the symptoms of schizophrenia with significantly lower incidence of these dehabilitating side effects. What did that mean for patients? In the words of one mental health advocate with drugs like Zyprexa: "The people who are most disabled in our society... awaken after decades of being in a semi-dazed state to become as smart, active, and high functioning as they would have been." Zyprexa was a new and revolutionary treatment for schizophrenia.

Strattera is an ADHD medication. And before Strattera, if you had a son who was diagnosed with ADHD whose hyperactivity and impulsiveness and inability to focus was preventing him from succeeding in school and building relationships with others, you faced a difficult choice as a parent. Not all parents chose medication as a treatment option for a son with ADHD, but for those who did, the available treatment was a class of drugs such as Ritalin, which is an addictive stimulant that's

classified as a Schedule II narcotic, the same classification as cocaine and amphetamines and morphine due to their abuse potential. 09:13

These stimulant treatments, while they were successful in treating ADHD, could cause insomnia, anxiety and appetite suppression in growing children and adolescents.

Strattera gave parents and prescribing physicians a very meaningful choice, and that was a new, non-stimulant treatment for ADHD. Now there was an option to treat ADHD in children and adults with a medicine that was not a Schedule II narcotic.

The economic reality is that these two drugs represent rare instances where research in the laboratory actually leads to a safe and effective drug for human treatment. Lilly is a research-based company. They spent 5.5 billion U.S. dollars in research and development in 2013 alone. This graphic depicts the reality for the industry that only 1 in 5,000 tested compounds that are researched in the laboratory ultimately become a safe and effective clinical treatment for patients. Of the many lines of research pursued by Lilly, few go on to become safe and effective medicines, but in the case of Zyprexa and Strattera, Lilly embarked upon

and completed this journey. 09:15

After its research crystallized into a patentable invention, Lilly applied for and received patent protection from the Government of Canada. It later developed the clinical dossier through additional human clinical trial testing that was necessary to prove that these drugs would be safe and effective for human use, and they received approval from Health Canada to sell these medicines to Canadians. As described by Mr. Postlethwait and Ms. Nobles, Lilly developed the market in Canada for both of these drugs and provided these groundbreaking treatments to Canadian patients who had schizophrenia and other mental disorders and ADHD. The patents for Strattera and Zyprexa were critical to Lilly's decision to launch these products in Canada.

And then Canada changed the patent rules. Once the markets for these drugs were established, Canadian generics, who wanted to sell these successful drugs, challenged the patents, and in those proceedings the Canadian courts applied a new and additional utility requirement to the Zyprexa and Strattera patents that did not exist when Lilly applied for and was granted these patents more than

a decade earlier. We call this new utility requirement the promise utility doctrine, and the Tribunal asked us at Question No. 4 whether the promise utility is, in fact, a doctrine. 09:16

Canada's courts, in multiple decisions, used "promise doctrine" as a shorthand for this additional utility requirement in Canada. C-535 is one example of a recent case. Lilly has used promise utility doctrine rather than promise doctrine in its memorials really simply for clarity, since it's undisputed we're talking about Canada's utility requirement. But whether you describe this as a doctrine or a requirement or a test, the three elements that Lilly has identified comprise a unitary patent test that was applied by the courts to invalidate these patents under the utility requirement in Canada. This change in the rules, this additional new utility requirement, the promise utility doctrine, had dramatic consequences for Lilly. The Zyprexa/Strattera patents met the old utility requirement, the "mere scintilla" test, and they were then revoked solely on the basis of this additional utility requirement that was applied much later.

Canada is the only country where the

Strattera and Zyprexa patents have suffered this fate. The only one. Zyprexa was patented in 81 jurisdictions around the world. It was challenged by generic competitors in 24 of those jurisdictions. The only jurisdiction where utility was challenged at all, let alone there was a finding that these patents lacked utility, is Canada. And the same can be said for Strattera. Strattera was patented in 36 jurisdictions; it was challenged in 3 markets; and the only jurisdiction where the utility of the patent was even an issue was in Canada. 09:18

You'll hear from Professor Siebrasse, Mr. Reddon and Mr. Wilson that the utility requirement in Canada has dramatically changed , and Ms. Wagner will walk you through that later this morning. But Professor Siebrasse, Mr. Reddon and Mr. Wilson are really three in a chorus of many who have observed that a fundamentally new and unfair utility requirement exists in Canada today. The rules changed so dramatically that in the contemporaneous internal communications of the Canadian Intellectual Property Office that were provided as part of the document production phase of this case, Canada's own patent examiners at CIPO, the Canadian IP Office, were asked to comment on the

changes to their patent examination manual, the MOPOP, in 2009 and 2010, the changes that incorporated this new utility test. They were confused at these new requirements. 09:19

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

There were others who were confused as

well. Ms. Yurack was confused, so was Mr. Ohan, and so was Mr. Candaliere. These exhibits are C-358, C-357, C-361, C-362. 09:20

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

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

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

made a belated attempt to say that Lilly's case is time barred, but that should be summarily rejected by the Tribunal. 09:22

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

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

evidence was not disclosed in the patent application itself, which is the third prong of the promise utility doctrine that we discussed. 09:23

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

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

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

have some industrial value, and that stands in sharp contrast to the promise utility doctrine that was applied to revoke these patents more than a decade later. While Ms. Wagner will discuss the change in the law in more detail, let me provide you an overview here of Canada's simple, mere scintilla, utility requirement that is a statutory test that existed at the time these patents were granted and continues to exist under Canadian law today, and the promise utility doctrine, the additional extra statutory requirement that was applied by the courts to invalidated the Zyprexa and Strattera patents.

Under the mere scintilla requirement, the utility inquiry is focused on operability of the claimed invention, and a single utility is enough. Under the promise utility doctrine the promise, or multiple promises, are construed or implied from the disclosure of the patent by the court. Under the promise utility doctrine there's also a heightened evidentiary burden. Post-filing evidence such as commercial success cannot be considered and, prior to the promise utility doctrine and particularly prior to the AZT case, post-filing evidence was permitted to show utility on the date of filing. And for predicted utility -- utility is either

09:25

demonstrated or predicted in Canada. For predicted utility under the promise utility doctrine evidence to support that predicted utility has to be in the four corners of the patent application. Prior to the promise utility doctrine, when post-filing evidence was permitted, there was no real distinction between demonstrated utility and soundly predicted utility when it came to the evidence that one could put forward to show operability or usefulness of the patent. The additional disclosure requirement just didn't come into play under mere scintilla because it didn't exist.

Now, this change is well reflected in Canada's Manual of Patent Office Practice. The Tribunal asked in your Question No. 5 what are the implications of the MOPOP for the determination of Claimant's claims. So the MOPOP, the patent examination manual of the Canadian IP office, is the authoritative and comprehensive reference guide that's used by patent office examiners. It's also made available to the public as a compendium of existing patentability requirements relied upon by patent agents as a reference tool.

It does not have the force of law but the MOPOP is a reliable restatement of Canada's patent

09:26

law, and extensive revisions to the MOPOP in 2009 and 2010 are compelling evidence of the dramatic shift in Canada's utility requirement. C-449, by the way, is the MOPOP in the record.

You already saw that CIPO's patent examiners were confused and concerned about the change that took place in 2009 and 2010, so I'd like to just walk you through that change. This is the MOPOP from the 1990s and the utility requirement was simple. Utility simply meant industrial value or whether the subject matter is operable, and this same focus on industrial value and operability appears in the 1996 and 1998 MOPOPs as well. The 1990 MOPOP is C-54, the 1996 MOPOP is C-55, and the 1998 MOPOP is C-57.

MR. BORN: If I understand it correctly from what you said previously, post-filing evidence would be relevant and admissible with respect to satisfying this standard?

MS. CHEEK: That is correct.

THE PRESIDENT: Also a further question. On your previous slide 17 there you see the difference, on the left-hand side the mere scintilla and on the other side what you say is the new approach about promise utility doctrine. The

09:28

right-hand side applies only to those cases where there is actually a promise expressed and you say also they scour the patent to see whether there's implied promise, but if they have not expressed or implied promise, then still you have the mere scintilla test on the left hand side. Is that correct?

MS. CHEEK: That's correct.

THE PRESIDENT: I see Ms. Wagner can't wait to make a presentation; she will tell us more about this.

One further thing. You gave a reference of C-449, that's the MOPOP you say is in the record, but later on you gave references of C-54, C-55, C-57.

MS. CHEEK: C-54, 55 and 57 are the specific provisions. I believe C-449 actually is perhaps the MOPOP website, so that would be in case you wished to avail yourself of the entire MOPOP.

THE PRESIDENT: I see.

MS. CHEEK: But we've called out the relevant provisions in C-54, C-55 and C-57.

THE PRESIDENT: Thank you.

MS. CHEEK: This now is the 2009 MOPOP and, as you can see, in 2009 the utility standard is

09:29

quite different. Now where the inventors "promise" that their invention will provide particular advantages, it will do something better or more efficiently, or will be useful for a previously unrecognized purpose, it is this utility that the invention must have, and where several uses are promised the applicant must be in a position to establish each of them. So this is no longer about a single utility and an operable invention. 09:31

The 2009 MOPOP also reflected that post-filing evidence is now prohibited, thus circumscribing the proof that may be put forward, and AZT is cited after this proposition in the MOPOP, and the 2010 revisions now require that evidence supporting a predicted utility must be in the patent itself. Here the cases cited are from 2005 onwards.

The 2009 MOPOP is at C-59, and the 2010 MOPOP is at C-60.

Now let's look at the Zyprexa patent. One of the two bundles you've been provided is labeled "Zyprexa and Strattera Patents" at the top and behind tab 1 is the Zyprexa patent, which is C-132.

This is the patent for Zyprexa in Canada, the '113 patent, and even the abstract on the very

front informs the reader of the utility of the invention. It notes that this compound is of "particular use in the treatment of disorders of the central nervous system". 09:32

Now, the claims that define the invention are in the back of the patent, so if you turn to page 27 of the patent, if you turn to the second green tab, you'll see the claims. It's titled "The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows."

Now, Professor Siebrasse explains at paragraphs 10 and 11 of his first report that it's these claims that define the invention, and it's an invention as claimed that must meet the substantive test for patentability, including the utility requirement, and a person of ordinary skill in the art can see from the claims that Lilly claimed the chemical compound olanzapine. The claims also mention the use of olanzapine for the treatment of schizophrenia.

If you turn to the front of the patent, which is the first green tab, there is a narrative. It says "Thienobenzodiazepine Derivatives and Their Use as Pharmaceuticals" and it tells the story or

explains the invention. That's the disclosure. 09:34

The disclosure does not define the invention for which you're granted exclusive rights. It does not determine the scope of exclusivity. But as Professor Siebrasse explains at Paragraph 11 of his First Report the disclosure describes the invention so that others may make and use the invention at the end of the patent term. It permits others to build upon the knowledge of the invention during the patent term. So the claims and the disclosures serve different functions.

When Zyprexa was examined, there were no issues raised with respect to utility of the Zyprexa patent during CIPO's examination. And this is not surprising. The patent was for a newly synthesized compound, olanzapine. That compound was a selection from a broad class of compounds that had already been determined to have patentable utility. So the genus patent had been determined to have patentable utility as antipsychotics, so the selective compound from the genus that had utility would necessarily also possess the utility required under the Patent Act.

Second, it's apparent from the face of the patent that the claim is that the compound had

utility in the treatment of schizophrenia. That's at the top of the claim. And if the patent examiner had had questions about the utility of the invention the examiner could request more information, and the examiner did not ask any questions about utility and the patent was granted in 1998. 09:35

So two decades after the Zyprexa patent was granted, and well after Lilly launched Zyprexa and developed the market for Zyprexa in Canada, the Zyprexa patent was revoked solely on the basis that the patent lacked utility under Canada's promise utility doctrine, and this revocation of Zyprexa's patent, as Mr. Berengaut and I will describe later this morning, violates NAFTA Chapter 11.

Let's now look at the revocation of the Zyprexa patent.

In the first instance the court construed the heightened promise. The court did not identify treatment of disorders of the central nervous system or treatment of schizophrenia as the invention's utility, despite the evident utility on the face of the claims. And, as you can see on slide 23, the claims and the stated utility in the claims -- that's claim 6 -- is at the top of the screen. Instead, the court construed a broad promise from a

general statement in the disclosure. I'm going to be walking you through the decision to revoke this patent. That decision is C-146. 09:37

The court construed the promise of the '113 patent as follows. That "olanzapine is substantially better ('marked superiority') in the clinical treatment of schizophrenia (and related conditions) than other known anti-psychotics, with a better side effects profile, and a high level of activity at low doses."

The Tribunal asked a question at No. 6: In what way, if any, is this identification of the promise subjective, as Lilly has submitted.

The process of construing the promise of the patent is subjective in the sense that it reflects a parsing of isolated statements that are in the disclosure that are not intended to relate to utility. The subjectivity is also reflected where courts find multiple promises, despite the fact that a single utility should suffice under the mere scintilla standard, or the courts find implied promises, as the courts did in this case. So unable to rely on the patent's explicit claims of what the claimed use of the invention is, patentees are left to guess how promises of utility will be construed

from the disclosure. 09:38

So having construed this heightened promise the Canadian courts then considered the evidence in view of it and, as Lilly has explained, the promise and the heightened evidentiary burden are linked. As the promise grows so does the evidentiary burden needed to demonstrate or soundly predict the promise.

In Zyprexa the court concluded that the Zyprexa patent had a demonstrated utility but, nevertheless, the court concluded that Lilly had not demonstrated the promise as construed by the court. This is Paragraph 209 of the court's decision.

The court says, "If the utility of the invention in the '113 patent relates merely to a compound with potential anti-psychotic properties that might have relatively low EPS liability [those are the side effects], that utility had been demonstrated by the tests conducted prior to the filing date."

So the court concluded that Lilly did, in fact, demonstrate a utility, and that should have been the end of the story. Indeed, the court concluded not only that olanzapine had utility for the treatment of schizophrenia, but the court

concluded that Lilly had demonstrated an elevated promise because it also found that it demonstrated there was a low incidence of side effects. But that was not enough. The court went on. "However, I cannot accept that the 113's promise was so small." 09:39

As stated above the court went on to find that "the promise of the patent is that olanzapine treats schizophrenia patients in the clinic in a markedly superior fashion with a better side-effects profile than other known anti-psychotics."

So as the court considered whether Lilly had demonstrated this promise, it actually ratcheted up the bar even higher, and at Paragraph 210 the court noted that utility would only be demonstrated if the patent disclosed studies "showing that the patented compound, when administered over a long term, meets the promise", and the court found that implied promise because, clearly, schizophrenia is a chronic condition. So as the promise is ratcheted up so, too, is the evidentiary burden.

Here there is now an implied additional burden of long-term effectiveness because schizophrenia is a chronic condition, and the word "chronic" does not appear anywhere in the patent. Also "It's not in the claims and it's not in the

disclosure." 09:41

So the Canadian courts raised the bar by construing a heightened promise for the olanzapine patent, and the Canadian courts then circumscribed the proof Lilly could put forward to meet the heightened promise, and under the traditional utility test that existed when Zyprexa patent was granted, as we mentioned, the commercial success of Zyprexa would have been sufficient to demonstrate utility. Commercial success was considered good evidence of utility on the theory that an invention, and particularly a prescription drug, could not be commercially successful unless it had a utility, and Professor Siebrasse describes this in his First Report, Paragraph 30.

Use of the drug by Novopharm, the generic that was being sued for infringement, it was already selling this drug when Lilly sued them for infringement, that also would have been accepted as evidence of the drug's usefulness because the Respondent or the Defendant was making and using and selling the drug. Further, other post-filing evidence that might often be available, such as further testing would be accepted as evidence of utility. Since the laws of chemistry don't change,

09:42 if a chemical process works today, then that is evidence that it worked at the time of filing, and Professor Siebrasse explains that at Paragraph 34 of his expert report.

But under the new promise utility doctrine, all of that post-filing evidence is ignored.

Now, quite unusually there was a significant amount of pre-filing evidence to demonstrate the court's heightened promise. There were in vitro lab tests that showed the compound had anti-psychotic properties; there were in vivo animal tests in mice and rats that showed results predictive of anti-psychotic activity, along with a toxicity study showing lesser side effects in dogs. There were four studies on small groups of healthy volunteers, and there was a completed open label study of the compound's therapeutic effects on olanzapine patients where six out of eight of the patients who completed the treatment cycle showed a 66 to 87 percent improvement in their symptoms. Nevertheless, the court concluded, "In my view, Novopharm [the generic] has shown that the evidence available to Lilly in 1991 was clearly insufficient to demonstrate olanzapine's capacity to treat

09:43 schizophrenia patients in the clinic in a superior fashion with fewer side effects than other known anti-psychotics."

That's Paragraph 213 of the decision and in 212 it would appear the court believed that nothing short of placebo controlled clinical trials in sufficiently large groups of patients would have sufficed to meet the court's heightened evidentiary requirement linked to the heightened promise. Yet such extensive clinical trials and extensive human testing is typically developed well after the patent protection is secured.

So having held that Lilly did not demonstrate the promise, the court went on to consider whether the promise was soundly predicted, and there the court found -- and this is at Paragraph 255 of the decision -- the court found that the patent does set out a rational basis for making a sound prediction that olanzapine would be useful for the treatment of schizophrenia, but not grounds for a sound prediction that the olanzapine patent would treat schizophrenia in a markedly superior fashion, with a better side-effects profile than other known anti-psychotics.

So under the old utility test there was a

09:45 rational basis for predicting olanzapine would be useful for the treatment of schizophrenia, but with the heightened promise the court concluded there was no rational basis to predict the promise of the patent.

As an aside, I'd note that Canada has made much in this arbitration that the promise utility doctrine is simply about holding patentees to their promises that they made in the patent but, as Professor Siebrasse will explain, there's a separate provision in the Canadian Patent Act, Section 53, that polices false statements in a patent, and Section 53 was an issue in a prior Zyprexa case and the court found there was no violation of Section 53. There's no false statements in this patent.

So let me conclude on Zyprexa. The Zyprexa patent met the mere scintilla utility test when Lilly applied for its patent in the 1990s. It met the mere scintilla test when it was challenged in the late 2000s, but rather than apply the mere scintilla test the Canadian courts applied its new additional utility requirement that didn't exist when Canada applied for its patent. So under the mere scintilla test, the claimed utility is simple

09:46 and straightforward. Use of olanzapine for treating schizophrenia. Does the invention work? The answer is yes. But instead, under the promise utility doctrine, the promise is that olanzapine is substantially better with marked superiority in the clinical treatment of schizophrenia than other known anti-psychotics, with a better side effects profile and a higher level of activity at low doses.

The courts also found an implied promise of long-term treatment of a chronic condition. And with the heightened promise came the heightened evidentiary burden magnified by the fact that commercial success is no longer permitted under the promise utility doctrine. And the third element actually, the disclosure requirement, was not at issue in this case.

So how do we get from a straightforward utility for Zyprexa, treatment of schizophrenia, to the construed and implied promise of marked superiority with a better side effect profile that can treat schizophrenia in the long term? How do we go from a utility test where commercial success is proof that the invention had a utility to one where the court puts blinders on and doesn't consider that post-filing evidence? The answer is simple. The

law fundamentally changed in Canada, and that change had fatal consequences for the Zyprexa patent. 09:47

I'd now like to turn to the Strattera patent.

MR. BORN: Before you do that, can I ask a question about the promises that the court found, the promise of marked superiority, the promise of a better side effects profile and of long-term efficacy? Were those promises relevant to other aspects of patentability under Canadian law?

MS. CHEEK: In this case they were stated advantages to explain what advantages the selection had over the genus patent.

MR. BORN: Right, but did they go to the other elements of non-obviousness invention and the like under Canadian law for patentability?

MS. CHEEK: Yes, particularly for non-obviousness they might go towards that requirement.

MR. BORN: Thank you.

MS. CHEEK: So the Strattera patent is Tab 2 in the mini bundle of the two patents. It's also C-67 in the record. This is a Canadian patent for Strattera. It's the '735 patent. Again on the front of the patent it is clear in the abstract, it

says Tomoxetine is a norepinephrine uptake inhibitor used for the treatment of attention deficit/hyperactivity disorder. The patent claims in this patent are on page 8, it's the second tab there in the back, and as you can see Claim No. 1 is the use of tomoxetine for treating attention deficit/hyperactivity disorder in a patient in need thereof, and there are additional claims as well. 09:49

The front of this patent, at the first tab, you'll see the disclosure on page 1, treatment of attention deficit/hyperactivity disorder, and it explains the background of the invention.

The Strattera patent is a method of use patent, meaning it claims a particular clinical use for a particular compound, and that use is treatment of ADHD. As with Zyprexa, at the time the patent was examined, Canada only had a mere scintilla utility requirement. An invention would be considered to have utility if it had industrial value or it was operable. This is the 1998 MOPOP which was the MOPOP that existed when this patent was examined by CIPO. As you can see, it's the same as the 1990 MOPOP. "Utility, as related to inventions, means industrial value" or whether the subject matter is operable.

Again, with Strattera there were no issues raised with respect to this patent's utility during CIPO's examination and, again, that's not surprising because the utility, use for the treatment of ADHD, was apparent from the face of the patent and the claims, and the Strattera patent was granted in 2002. So a decade later, after Lilly had launched Strattera and developed the market for the drug in Canada, the Strattera patent was revoked solely on the basis that the patent lacked utility under Canada's promise utility doctrine. 09:51

And how is the promise utility doctrine applied to invalidate the Strattera patent? The Canadian courts applied all three aspects of the promise utility doctrine. They construed a promise. The heightened utility requirement the ban post-filing evidence and the disclosure rule for sound prediction, and I'll walk through you that. And the court then invalidated the Strattera patent solely for lack of utility, despite the use of the drug for thousands of Canadian patients.

First let's look at the promise. And on slide 32 you'll see at the top is the stated utility in the claims treating attention deficit/hyperactivity disorder. The patent is C-67,

and then the decision to revoke the patent is C-160. This is Paragraph 112 in the decision. So the court found an implicit promise. The court found that "ADHD is a chronic disorder requiring sustained treatment. Only where experimental results are sufficiently compelling to independently support the inventive promise (or to support a sound prediction) is utility established. In the case of the '735 patent, the inventors claimed a new use for atomoxetine to effectively treat humans with ADHD. What is implicit in this promise is that atomoxetine will work in the longer term." So this implicit promise was apparently based on the patent's disclosure which said that the drug is an effective treatment for ADHD. The patent disclosure does not use the word or mention "chronic" or "longer term", and in fact this drug Strattera for ADHD is prescribed for both long and short-term treatment of ADHD. So with this heightened promise the heightened evidentiary burden came into play and the court required Lilly to demonstrate the promise based only on pre-filing evidence, and given this heightened promise even a human clinical trial, that was conducted pre-filing, did not meet the evidentiary burden. 09:52

So the court, the Canadian court, accepted that Strattera met the mere scintilla test. At Paragraph 93 the court states "Lilly argues that it need only show that atomoxetine had a 'mere scintilla of utility'. If that phrase means only that atomoxetine be shown to be somewhat useful to treat ADHD I accept Lilly's point."

But having raised the bar by construing a heightened promise for the atomoxetine patent, one that implied effective long-term treatment in humans, the evidentiary burden grew. And against the court's construed promise of long-term effectiveness, the Canadian court considered only pre-filing evidence to determine whether the promise of the patent was demonstrated. Strattera's commercial success and the fact that it was being used by thousands of Canadian patients to treat ADHD was ignored.

Once again, although atypical, there was a prefiling clinical trial for the court to consider, and that prefiling clinical trial was quite significant. The pre-filing evidence was a double blind Massachusetts General Hospital study that administered Strattera to 22 patients, and that MGH study was conducted in early 1995. It was after the

U.S. patent filing for Strattera which was in January 1995. Lilly's scientists approached Massachusetts General Hospital with a proposal for a joint human clinical trial on the efficacy of atomoxetine in treating ADHD. That trial was conducted from January to April 1995 and, as I mentioned, it was after the U.S. filing date, and as an aside the U.S. patent issued and was found valid by U.S. courts, even though this study was done after the patent was filed. But in any case this study was before the Canadian filing date, which is January 4, 1996, and the study was eventually published in a peer reviewed journal, the American Journal of Psychiatry.

So in this MGH study 11 out of the 21 patients that were assessed showed a 30 percent or better reduction in ADHD symptoms, and the scientists concluded that atomoxetine "was associated with clinically and statistically significant improvement in individuals with ADHD symptoms." The court, in its decision, discusses the MGH study at Paragraph 98.

But with the heightened promise also came heightened scrutiny. It was not enough that there was a study conducted prior to the filing of the

patent that showed that the drug worked. It was not enough that the study showed that atomoxetine worked in some patients and that the study's authors found a positive result and an improvement in ADHD symptoms. The court picks apart the study. It finds it's too small, that it was too short. Even the evidence of Novopharm's experts that the study had promising results was disregarded, with the court noting that the expert "opined that the results of the MGH study were interesting and promising but not sufficiently robust to establish clinical efficacy." That's at Paragraph 95.

THE PRESIDENT: Ms. Cheek, the study is at C-152, the MGH study? You referred now to it many times, and it may be useful if you read the record to understand the reference.

MS. CHEEK: All of the discussion I've discussed is actually in the court's decision, but let me also get you the exhibit number for the MGH study itself.

So the court concluded that the study was not enough to demonstrate a promise of long-term clinical effectiveness. So having concluded that Lilly failed to demonstrate utility -- excuse me, Mr. President, I have a cite it is C-152. That will

be the published version of the study, so that's the American Journal of Psychiatry publication.

Having concluded that Lilly failed to demonstrate utility, the court excluded the pre-filing evidence, excluded consideration of the MGH study from its sound prediction analysis. Even though the court just considered it, the court considered the MGH study to decide whether utility had been demonstrated, but having found that it wasn't enough because there was a heightened evidentiary burden, shifting to see if there was a soundly predicted utility, the court excluded its consideration of the MGH study because it was not in the four corners of the patent.

Now, the court commented -- this is slide 34, Paragraph 95, this is where the expert opined that the results were promising but not sufficiently robust to establish a clinical efficacy.

The court went on at Paragraph 113 and noted that, "In some cases an initial study of this sort" -- the MGH study -- "might provide a basis for a sound prediction of utility" but, due to the additional disclosure rule for sound prediction cases whereby all evidence to support the prediction of utility must be in the patent itself, the court

simply refused to consider it. So Lilly couldn't rely on the MGH study to predict utility. 10:01

With regards to the disclosure requirement, the court says at Paragraph 116, "It seems to me that it is beyond debate in Canada that where a patentee asserts that the utility of its invention has been demonstrated, it need not assert its supporting evidence in the patent." But then it notes in 117, "In a case involving a claimed sound prediction of utility, it is equally beyond debate that an additional disclosure obligation arises." It cites to AZT for that proposition saying "According to Justice Binnie in AZT, this obligation is met by disclosing in the patent both the factual data on which the prediction is based and the line of reasoning followed to enable the prediction to be made," although this particular finding, the disclosure requirement, was only first applied by a court in 2008 in the Raloxifene decision.

So the court appears to recognize that there's some unfairness here in imposing the more rigorous disclosure requirement. The court notes at Paragraph 121 that "Lilly argues that the validity of the '735 patent is now being assessed against the backdrop of a more rigorous disclosure obligation

than may have been apparent at the time of its filing in 1998," but the court goes on to observe that "The disclosure issue, however, has been determined by earlier decisions that are binding upon me and to the extent that it may be amenable to reconsideration, it must be examined elsewhere." 10:02

So let me conclude on the Strattera patent. The Strattera patent met the mere scintilla utility test when Lilly applied for its patent in the 1990s, and it met the mere scintilla test when it was challenged in the 2000s. But the mere scintilla test wasn't applied to Strattera's patent. Under the mere scintilla test, the claimed utility was simple, did the invention work, and there was no question that when the Canadian courts revoked this patent, that Strattera, which was being used by thousands of Canadian patients, was useful in treating ADHD.

Under the promise utility doctrine, however, that was not the test. Instead, the court construed its promise to effectively treat humans with ADHD finding what's implicit in that promise is that atomoxetine will work over the long term. But with the heightened promise came a heightened evidentiary burden, and post-filing evidence such as

commercial success, once again, was excluded as evidence to show the operability of the invention or to show its usefulness. And under the promise utility doctrine, even though there was a human clinical trial, once the court was reviewing it through the lens of soundly predicted utility, that prefiled MGH study -- so a study conducted prior to filing the patent for the invention -- was excluded from consideration. 10:03

Once again the law fundamentally changed in Canada, and that change had fatal consequences for Lilly's Strattera patent.

Now, Canada claims that the law has not fundamentally changed, that the promise utility doctrine is not new, and Ms. Wagner will now rebut that fallacy in greater detail.

THE PRESIDENT: Before we do that, you pointed us to the court decisions which is at C-160 and Paragraph 121, slide 37. You see in 121, in the penultimate line, it says -- let me read the full sentence -- "The disclosure issue, however, has been determined by earlier decisions that are binding upon me and to the extent that it may be amenable to reconsideration, it must be examined elsewhere."

Which are the earlier decisions which the

judge says are "binding upon me"? You need not answer now. You may wish to do that through your expert testimony. 10:05

MS. CHEEK: That is not a specific reference to the Strattera litigation itself; it's a reference to the fact that there is earlier case law that's been applying the disclosure rule that was first articulated in Raloxifene in 2008, and then courts have been applying that since then.

THE PRESIDENT: Those are the earlier decisions?

MS. CHEEK: Yes.

THE PRESIDENT: They don't go back in time prior to 2008?

MS. CHEEK: That's correct.

THE PRESIDENT: Thank you.

MR. BORN: It's AZT?

MS. CHEEK: For the disclosure rule it's the 2008 Raloxifene decision.

THE PRESIDENT: AZT is 2002, wasn't it?

MS. CHEEK: It's 2002, and that's the prohibition on post-filing evidence.

MS. WAGNER: Good morning, Mr. President, members of the Tribunal. Just to pick up on that last point you were asking about, AZT, I will get

into this more in my presentation, but the AZT decision basically stated an additional disclosure rule, or what might have looked like an additional disclosure rule, but didn't actually apply it in that case because it wasn't at issue, and then subsequent courts to that actually didn't read it as an additional disclosure rule, and then it was in 2008 that it was actually applied in the first Canadian decision to apply it, and upheld in 2009 by the Federal Court of Appeal. We'll have the citations to that as we go through. 10:07

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

for the individual aspects that we talked about, and my point 2 is that this fall-back position also fails because, even when considered on an aspect-by-aspect basis, you don't see what we see today in prior law. 10:08

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

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

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

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

specification promises that it will do'." 10:11

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

So what does the language mean within the Consolboard decision?

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

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

the utility, the utility was apparent, and so much less having to disclose proof or evidence of utility in the patent, which is what we see today, at least under the sound prediction branch.

So, in summary, the standard expressed in Consolboard focused on operability of the claimed invention and post-filing evidence could be used and there was no requirement to even disclose utility.

As I mentioned, this low bar utility requirement was reflected in the few decisions that had cited Consolboard in support of utility before the Canadian courts reinterpreted starting in about 2005, and none of these prior cases involved a search for promises of utility in the disclosure. The focus was just on utility in fact, as of the date of challenge. And this is a case called Almecon Industries, and it involved bore hole plugs used in commercial drilling. At Paragraph 46 of this decision, this is the court citing from that passage in Consolboard that we just reviewed, and what the court has to say about utility based on this passage in Consolboard is that the invention was a commercial success so the court can conclude it worked. There's no search for promises, and there's no restriction on what can be used to prove

10:12

that the invention works.

This was the old law, or the prior law, and at base Canada's approach of trying to isolate out the various aspects of the new doctrine and find vestiges of it in prior law is a fallacy because, on the one hand, we live in a common law system so new law is not made out of whole cloth, so you're always going to be able to find some antecedent aspects of law such as in this case just the mere use of the word "promise", and I'll discuss that further when we get into discussing the standard.

More centrally, when you're considering whether a law has changed, you have to consider both the standard or the legal test and the required proof to meet it. The two are not divorced from one another. You can think of an example where all citizens in a country are permitted to vote, but if you change the law so that the proof of citizenship requirements become very onerous and half the population is disenfranchised, no one is going to say that the law hasn't changed. It's changed dramatically. You can't separate out the two. And we have a visual that depicts this. It has the low bar for utility, the mere scintilla, then we have the elevated promise of utility as well.

10:14

In this case, the patentee has enough evidence so that they can both surpass the mere scintilla and even enough evidence to meet the elevated promise of utility. But then their ability to rely on that evidence is taken away under the new requirement.

First what comes off is any post-filing evidence such as clinical trials or regulatory approval or commercial success. But in this example the applicant still might have enough, the patentee still might have enough to surpass the elevated promise of utility. Just based on the pre-filing evidence that might be enough to predict utility, such as was in the case of Strattera. But then what happens is, if you're trying to rely on a prediction of utility you have to show that your prefiling studies at least predicted utility. If that evidence is not in the patent itself, that falls away too. And that's basically a good depiction of what occurred in the Strattera case.

Just to be clear, when you were reviewing the slide 17, which showed the promise utility doctrine on the one side and the mere scintilla on the other, the mere scintilla is the standard, so if we were looking at this from today's perspective,

10:15

even if you're in the mere scintilla world from a standard perspective, you'd still have to contend with the fact that you can't rely on post-filing evidence, and if you have to rely on a prediction of utility because you didn't have enough pre-filing evidence to demonstrate, that's still going to have to be in the patent. So the standard is one problem, but it's just a component of the problem.

Now let's consider that even if we take Canada's argument at its best, it's also our submission that Canada has failed to show that any one single aspect of the current utility requirement existed in prior law. And so we're going to deal first with the standard, the promise aspect, and it's important to understand what's happening today so that we can contrast it against the standard in prior law. So under prior law utility was assessed by reference to the claimed invention and only a mere scintilla was required.

Today -- so if the claimed invention, as an example, was olanzapine for the treatment of schizophrenia, then the standard for utility was treatment of schizophrenia and very little would do. A low bar. In contrast to prior law what's done today is utility is assessed by reference to the

10:16

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

10:18

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

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

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

10:19

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

amount of prefiling testing. And this decision was upheld by the appellate court, the Federal Court of Appeal.

10:21

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

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

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

10:22

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

So this elevated promise standard is

contrary to basic patent law principles, and it's a dramatic departure from prior law, and how do we know it's a dramatic departure? Well, because there's not one single case before 2005 where the court identifies this elevated promise of utility from the disclosure of the patent. Not one case. 10:24

So Canada hasn't conceded the law is new, so what they do is try to find some antecedence in prior law, even though there's no actual decision, so, in the case of a promise, they look at semantics. It's true that the use of the word "promise" appears in prior law, but it appears as shorthand for the promised results, what does the invention do. It doesn't involve this exercise of construing the disclosure of the patent to find an elevated standard to which the patentee is held.

The second thing Canada attempts to do is to conflate the utility requirement with other patent law concepts, and to try to draw analogies to these concepts or even to explain why we're seeing this standard applied so frequently now when we never saw it before.

Finally Canada also cites passages from commentators, textbooks and materials, and none of these established that the standard existed in prior

law either. 10:25

Dealing first with the issue of semantics, essentially Canada's expert Mr. Dimock maintains that every time the word "promise" appears in prior law this means the court applied the same elevated standards as applied today. But this is a simplistic approach and it's incorrect. You'll hear from our expert Professor Siebrasse that, although the word was used in these prior cases, the same exercise was not applied. And, to the contrary, in these cases how the utility standard was read was consistent with prior law. Basically the claimed invention has to work. And on this slide you can see one of the cases, New Process Screw, that Canada's relies on because this promise of the patent is a phrase that's used in the decision, but in that case the so-called promise was in the claims. The claimed invention didn't actually work. So that's why it didn't have utility.

So, in terms of conflating utility with other patent law concepts, Canada's expert Mr. Dimock has said that the promise approach was applied in prior law cases that dealt with something called overbreadth, and overbreadth is something that overlaps with a bunch of patent law concepts so

your claims can be overbroad because they encompass something that's not new, or something that's obvious, or because they do encompass something that lacks utility. It's true that there's overlap. 10:27

But what there is not overlap between in the prior law is overbreadth and the promise utility analysis, so you just don't see any cases in prior law where a claim was held to be overbroad because it encompassed subject matter that didn't meet a promise utility, because the courts weren't looking for a promise utility. So although there's overlap between the concepts, there's not overlap in the prior law between utility as we see it today with utility as we see it today.

Here on this slide is Exhibit R-172, the Unilever case, where the court, when they were considering a claim was overbroad because it encompassed something that lacked utility, they actually refused to consider statements in the disclosure for this purpose. So they looked at what the utility of the claimed invention was and whether the claim was overbroad in light of that because it encompassed things that didn't work, but they refused to take a so-called promise utility from the disclosure and apply that as the standard. So

there's just no overlap. 10:28

Canada has also tried to deal with the absence of promise standard cases by asserting that this doctrine has always existed but we're just seeing it now because certain types of patents are more prevalent now, and Canada has referred to these new types of inventions as secondary patents. They really use this terminology to present these types of patents as less worthy of protection.

In answer to Tribunal Question No. 7, you had asked whether Canada's characterization of Lilly's patents as secondary patents is relevant to Lilly's claim. The response is no. There is actually no Canadian case, no Canadian jurisprudence, which uses the term "secondary patent". In fact, Canada's expert, Mr. Dimock, does not use the term "secondary patent" either.

But what Mr. Dimock does do is he appears to maintain that this elevated promise standard is particularly relevant to certain types of patents that we are seeing more frequently now than before, and he identifies new use patents and selection patents and, in fact, Strattera was a new use patent and Zyprexa was a selection patent.

But this argument doesn't stand up either

and the first reason is that the elevated promise standard applies to all pharmaceutical patents, and this is conceded by Canada's expert, Mr. Dimock, and it's apparent from the case law in any event. 10:30

The other thing is that new use patents in particular aren't new, and Canada hasn't put forward any evidence to support the proposition that the vastly increased rate of invalidity that's based on inutility coincides with the growth of certain types of patents. The fact is that invalidations on inutility grounds are happening more frequently because the law has changed. That's the explanation.

Then Canada has also raised a certain analysis that's been applied by courts recently, and you'll see it in the record. It's "reading up" and "reading down." Basically according to this analysis patentees will put certain statements -- this is the theory -- that patentees will put certain statements in the disclosure of their patent to meet other patentability criteria to show that the invention is not obvious, or to show that it's new. Then, having put those statements in the patents for those purposes, the argument goes that you can't read up the invention for that purpose and

then read it down for utility. If you're going to put statements in your patent you should be held to them as a matter of utility. Mr. Born, I think you were getting at that somewhat when you were asking about the Zyprexa patent, but those statements are put in patents for different purposes and there are different rules that apply when considering, for example, whether an invention is obvious or not, and different evidentiary standards. For example, in the case of obviousness, post-filing evidence is admissible. So it's just not correct, it's not a natural outcome of putting certain statements in your patent that you're going to be held to them as a matter of utility, because remember the utility requirement is one requirement as well. Once those statements are in there and they're read to be promises, now you're in the promise world, you're in the promise utility doctrine world, and you're going to have to prove up all of that by evidence available as the date of the filing of the patent, which can be remarkably difficult if what you're talking about is long-term clinical efficacy, at the date of filing the patent. And so the reading up, reading down is something -- and another point on that is in the case of Zyprexa, it's not even true 10:31

that the courts are taking that approach because, in fact, the promise that they read was different from what might be needed to support a patent to make it non-obvious. 10:32

They required as a matter of the promise marked superiority over all known other anti-psychotics. You wouldn't need that to establish that the invention was non-obvious in any event, and the obviousness requirement was surpassed in that case.

The thing with reading up and reading down is that this is a concept that has only been applied since the advent of the promise utility doctrine. It's something that is a byproduct of that doctrine because, before, the courts just didn't look to statements in disclosure to create an elevated standard for utility. We're only seeing reading up/reading down in very recent law. It's not a concept that existed in prior law; it's a concept that exists because of the new approach that the courts have taken.

Dealing with the third approach that Canada takes to deal with the absence of the promise standard in prior law, what they do is point to various statements of commentators' text. But in

most cases the commentators are just using promise in that same innocuous way that they used it in prior law, so speaking of the promise result. And, most importantly, not one of the commentators actually cites to Canadian cases that use this analysis of looking to the disclosure and then implying or finding an elevated promise. Of course, if they did I'm sure Canada would have cited those cases in support of an elevated promise standard. 10:34

I will turn now to the second aspect of the promise utility doctrine, which is the bar on post-filing evidence of utility. As Ms. Cheek had explained, before the law changed with the Supreme Court of Canada's decision in 2002 -- and this requirement, the disregarding of post-filing evidence, does absolutely date to AZT 2002. It's the extra disclosure requirement that's uncertain because the court alluded to it but then never applied it, and then it wasn't until 2008 that it actually was applied. So dealing with the bar on post-filing evidence, as Ms. Cheek had explained, before this change operable inventions essentially couldn't be challenged -- successfully challenged -- on the basis that they lacked utility because post-filing evidence could always be used to show

that there is utility in fact. And it was often commercial success that was used as that post-filing evidence but, as Ms. Cheek noted, it could be other forms of post-filing evidence as well. And the change in the law is reflected in this passage from the 2005 decision, and that's Exhibit C-209 in the record, and the court observes, now 2005 -- so post AZT -- "There is no question that the '206 patent turned out to be a useful invention. However, this sort of 'after the fact validation' was specifically rejected by the Supreme Court of Canada in Wellcome" -- that's the AZT case -- "Thus, the fact that three compounds within the '206 patent later turned out to have commercial value is of no assistance."

Then you contrast this to a pre 2002 case where post-filing evidence of commercial success of the plaintiff's apparatus was proof of utility. The law changed with AZT, and that's very clear, but Canada doesn't concede even that.

Why do we say the law changed? Again, there's numerous cases in the record showing that, prior to AZT, post-filing evidence was admitted to show utility, and its commercial success, but also infringement, and that makes sense as a matter of

equity because, if you're alleging invalidity based on inutility just so you can turn around and sell a copy of the same product, you know, there's a bit of an equity issue there.

But in terms of all these cases that admit post-filing evidence what Canada's expert Mr. Dimock has said is that these cases were all about operability. They were really about whether the invention works as of the date of challenge. That's what people were fighting about in these cases -- although that doesn't seem to make sense because why would you even be infringing a product that you didn't think had usefulness today?

It also shows the change in the law rather than disproving it because the prior law cases were all about whether the invention worked because evidence was admissible (post-filing evidence) to show that it worked, and so that was necessarily the issue, was the product useful in fact.

There's no cases where the challenger could make the argument that utility wasn't met because it wasn't demonstrated or predicted as of the date of filing. So yes, the cases are about operability, but that proves the point rather than disproving it, because post-filing evidence of

operability was admissible.

We also know that the bar on post-filing evidence is new with AZT because the Supreme Court in Canada overturned prior jurisprudence that had admitted post-filing evidence, and you can see they overturned, it was discussed in the AZT case, and Exhibit C-44 is the Ciba-Geigy case and post-filing evidence was admitted in that case, and AZT also overturned in the court below it, the Federal Court of Appeal, and you can see what the Federal Court of Appeal had decided in AZT, which is C-117. "In other words, so long as an inventor can demonstrate utility or a sound prediction at the time a patent is attacked, the patent will not fail for lack of utility." That finding was overturned by the Supreme Court of Canada in AZT.

In fact, the very case that Canada can point to that first required demonstrated or predicted utility to be shown as of the date of filing is the decision of the Supreme Court of Canada in AZT, the very decision that changed the law, and in not one case before 2002 does the court exclude post-filing evidence in the context of a challenge to utility.

So how does Canada attempt to deal with

this? In this case they conflate it with the distinct legal principle that used to apply in Canadian law and is no longer applicable, and this is the issue of who was the first inventor. It used to apply in Canadian law because Canada used to have a first-to-invent regime. So instead of a patent going to the inventor who was the first to file the patent, the court had to figure out if there were competing claims, who was actually the first to invent the patentable subject matter. So they looked at the date on which the invention had actually been made and who was the first to have made it, and that usually far predated the actual filing of the patent application, and to try and draw an analogy to these cases and what was done in AZT is just a false analogy.

The first reason why it's a false analogy or why we can see it's a false analogy is because at the same time as these cases were being decided, there were challenges to utility. Yet, as we've reviewed, post-filing evidence was admissible in that context and there's no case which decided it. So the fact that Canada's expert is trying to go to a different patent law concept again just proves the point rather than disproving it.

But even if you can make some analogy between these inventorship cases and challenges to utility, the other thing is that it was simply not true that in these cases you had to have demonstrated or soundly predicted utility in order to be found to be the first to have invented the invention. To the contrary, you'll hear from our expert, Professor Siebrasse, that all that was required to have made the invention was a description of the invention that would allow a third party to put it into practice. That was what determined who had first made the invention. It wasn't testing to demonstrate or soundly predict utility; it was who had afforded a description to the public that would allow the invention to be made. So, even if you can analogize, it doesn't prove the point anyway. 10:41

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

this new requirement was applied was in 2008, and that was actually in a decision involving Lilly's compound Raloxifene. 10:43

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

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

chronic, clinical effectiveness which was the promise, and so Lilly had the MGH study available prefiling, but because there was that elevated promise that was read Lilly had argued this study demonstrates utility, we've got it, and the court said well, no, it doesn't, it's not good enough. 10:44

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

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

that you demonstrated utility. Now sound predictions become very important and, yet, this evidence is excluded if it's not in the patent itself. 10:45

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

So putting aside whether it's rational or not, what is it that shows that the rule is new? Well, there are several indications. One of these is noted by Professor Siebrasse, our expert, in his Second Report at Paragraph 74. He's explained that there were cases that considered the issue of sound prediction of utility post AZT, and, yet, they considered evidence that was not in the patent in that context because they didn't read the AZT decision as having created this additional disclosure requirement. So there is uncertainty after AZT and prior to 2008 when the rule was applied. 10:47

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

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

case prior to 2008 did the court apply this additional disclosure rule and hold that evidence to support utility had to be in the patent itself. There's no case. No case where they look and say we're dealing with sound prediction so we've got to exclude evidence that's not in the patent itself. 10:48

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

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

basic consideration. In fact, in some of the older cases that use this language, the Olin Mathieson case you'll hear about in particular which was received into Canadian law, it's clear that that case considered all kinds of evidence from outside of the patent when looking at whether utility was predicted, but they use this same language because it's a motherhood type of patent law statement. 10:50

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

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

As evidenced by the presentation made to you by Ms. Cheek, the patents in issue were not speculative. They were extraordinarily supported by human clinical studies at the date of filing. And that's an unusually high amount of testing done pre patent in the pharmaceutical context. So, if the role was to deter speculative patenting, then the rule shouldn't have been applied in this case. 10:51

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

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

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

of utility in the patent itself, so there's nothing to say that there isn't proof or evidence existing outside the patents that supports those uses. More fundamentally, it's simplistic to conclude that the applications were speculative when filed based solely on the fact that applications were filed for multiple uses, because it's a basic principle in patenting and it's a basic scientific principle that a single molecule may support many different medical uses based on its activities. So there's no evidence at all that any of these applications were speculative when filed, and so Canada says well, they were abandoned so that shows that they were speculative. But that doesn't show the patents were speculative when filed prior to abandonment.

The Seven IP Scholars made submissions as one of the amici in these proceedings, and they noted that patenting of pharmaceutical inventions necessarily occurs at an early stage of product development because you need the patent in order to make the research and development that's necessary to bring the products to market. But very few products actually make it to market. And if later testing shows that the product won't be viable, or if there's just no market for the product, then a

10:53

patent may be abandoned, and in that case the invention is disclosed. It's publicly available. It's made available to the world. So abandonment does not equate to speculation.

In fact, contrary to Canada's assertion that the utility requirement today has a sound policy basis, the Seven IP Scholars also confirmed Lilly's submissions made in this proceeding that the dramatically elevated standard that applies today may actually make it impossible for patentees to obtain or maintain pharmaceutical patents at all, because if you're holding patentees to a requirement to have large-scale clinical trials, that amount of clinical evidence, those studies usually have to be disclosed for ethical reasons. You can't conduct the studies without disclosure. Yet that disclosure gives rise to at least a risk that, when you go to file your patent application, it may be found that your invention has been anticipated. It won't meet the requirements that the invention be new. So this elevated utility standard puts patentees in a catch-22 type of situation. So it doesn't create the seamless garment of the law that Canada's expert, Mr. Dimock, has referred to; it actually does the opposite, or has the potential to,

10:54

depending on what kind of promise is read and how elevated it is.

A final point is that the speculative patenting justification put forth by Canada is also undermined by the fact that this requirement today is arbitrary and unpredictable and inconsistent in its application, and I submit to you that that makes it incapable of serving this kind of policy justification. A standard that's based on what the patentee is found to have promised about the invention can't serve a rational policy-based objective of trying to determine whether the requisite utility actually exists.

Take this example. The law says that you're eligible to obtain a driver's license if you pass the standardized test so a young man goes to take his driver's test and he says to the licensing officer when I take this test I'm going to be as good as a Formula 1 racer. So he takes the test and the licensing officer thinks to himself, you know, he really was not as good as a Formula 1 driver, this guy is not a professional driver but he passed the standardized test. If he passes the standardized test he is entitled to a driver's license, because that's what a standardized test

10:56

does. It establishes the requirement that you have to meet in order to obtain the license or do what it is that the law requires you to do. And that's what would be required to deter speculation. Not a variable requirement that's based on what a court finds to be promised in the patent disclosure or even implies from the disclosure.

Equally as fundamental a law cannot be considered to play a role in deterring speculation when it doesn't give a patentee adequate notice of what would be required before a patent is filed or what would be required to maintain the patent once granted due to the way that it is found to arbitrarily and inconsistently apply from case to case.

When such vastly different outcomes are produced in similar cases, or even when dealing with the same patent, it's just not possible to assert that as a justification or to present this as having a rational policy foundation. In any event, we say that that argument is not relevant.

SIR DANIEL BETHLEHEM: I have a question.

THE PRESIDENT: Let's do it before the break.

10:57

QUESTIONS BY THE ARBITRAL TRIBUNAL 10:59

SIR DANIEL BETHLEHEM: This is really to try and disentangle some things in my own mind.

You seem to be running three arguments together. You can either tell me I've got it completely wrong, or otherwise what I'd like you to clarify is whether you are running three arguments together or whether they are three separate arguments.

The first line of argument you seem to be presenting is that the new test is too onerous or arbitrary or unprincipled or unsound -- you've used a number of different words to describe. Possibly the second line of argument is the evidential shortcomings that the new test does not adequately take account of historic information and does not permit post-filing evidence, and then there's a potentially a third line of argument which is simply that the test is new and that it applies retroactively.

I would just like you to clarify for me whether this is a single line of argument or whether there are three separate lines of argument in the alternative.

MS. WAGNER: I think it's more of a single

line of argument. Just dealing with the evidentiary standard first, just in terms of imposing such a high requirement that you can't meet it as a patentee, we wouldn't phrase that as just an evidentiary requirement, so it's the package that makes it difficult to surpass the requirement. 11:00

Even today, even if you knew that this law existed, that problem would still exist. So even if you were filing a patent application today, that problem would still exist because it's almost impossible to know how the court is going to read a promise in a given case. There's still unpredictability. Even if you knew that the law exists as it exists today, it would still be very difficult for patentees I guess is the answer to that. But I think an additional real unfairness comes into play when it's applied retroactively, as happened in this case, to patents that were filed at a time when the law didn't exist. So then you had no capability of dealing with any of the changes at all.

I don't think that that erases the difficulty that patentees filing today would have in dealing with the law, but from Lilly's perspective in this case the retroactivity made it exceedingly

difficult. 11:01

Then the policy-based arguments I made were essentially just to -- Canada uses those policy-based arguments to sort of divert attention away I think from what are the central issues in the case, which is how difficult the law is to deal with, whether you knew it existed or not, and how impossible it is to deal with having been applied retroactively. The policy-based arguments are really Canada's arguments. They're really the gloss that they put on it to try and say no, this always existed and it always existed for this reason. I think in that sense they're a bit subsidiary but also play into the arguments we've made about arbitrariness, and the fact that the law is applied discriminatorily to pharmaceutical patents.

So I think all are very relevant but probably to different aspects of our case, and maybe when we get into the legal argument we'll try and unpack that for you to a greater extent.

SIR DANIEL BETHLEHEM: Just to note that I'd be grateful, when you do get into legal argument, that you could unpack them because it seems to me that different elements may be relevant to different things but, because you're putting them

all together in a single bundle, it's not quite clear to me how you see them playing out into all the legal arguments. 11:03

THE PRESIDENT: Thank you. Recess for 15 minutes, so at 11:20 we resume.

(Recess taken)

THE PRESIDENT: Let's resume.

Ms. Cheek, you have 77 minutes left, according to the calculation of the Secretary of the Tribunal.

MS. CHEEK: Very good. Thank you. We will have Mr. Smith resume. He's going to discuss how Canada is an outlier compared to the other NAFTA parties, as well as the discriminatory effects of the doctrine on the pharmaceutical sector, and then Mr. Berengaut and I will do our legal argument.

THE PRESIDENT: Thank you. Mr. Smith, please proceed.

MR. SMITH: Thank you. Canada's adoption of this elevated utility test is a striking departure not only from Canada's traditional utility requirement, as my colleagues explained this morning, but also from established practice in other NAFTA countries.

In Question No. 10 the Tribunal asked

about the relevance of the utility standards in the other NAFTA jurisdictions with respect to Claimant's claims. The utility standards in the United States and Mexico, which I will summarize, are relevant to our claims in two respects. Factually they demonstrate that the change in utility is unique to Canada, and legally they inform the interpretation of capable of industrial application consistent with Article 31 of the Vienna Convention, which provides for interpretation based on subsequent practice in the application of the treaty which establishes the agreement of the parties. 11:24

In both the United States and Mexico, the bar for utility was low when NAFTA entered into force. That was so in Canada as well with its traditional requirement. Unlike in Canada, however, utility in the United States and Mexico has remained a low bar consistent with widely shared international practice. Canada's new promise utility doctrine is a clear outlier.

Canada's sharp divergence from its NAFTA partners is evident from two sources: first, from the legal requirements for utility in the U.S. and Mexico, which on their face are nothing like Canada's promise utility doctrine, and, second, from

practice in the U.S. and Mexico, where utility is very rarely challenged and almost never the basis for denial or invalidation. 11:25

In the United States the legal test for utility, as Professor Robert Merges has explained, is a straightforward inquiry focused on operability. In multiple respects the U.S. test diverges from Canada's promise utility doctrine. First, utility is tested according to the claimed invention. The invention need only have one or "a" utility. An asserted utility is presumed to be true, and basic operability is all that is required, not proof of efficacy or of commercial viability.

The U.S. Patent Office's Manual Of Patenting Examining Procedure makes clear that the utility test for pharmaceutical inventions is this same low bar. For patents that assert a therapeutic use, mere identification of a pharmacological activity satisfies the utility requirement, and the manual also emphasizes that courts have found utility for therapeutic inventions, despite the fact that the applicant is at a very early stage in the development of the pharmaceutical product. Notably, U.S. courts have also rejected tests that resemble Canada's promise utility doctrine.

In Raytheon v Roper, for example, the court made clear that a failure to accomplish all requirements stated in the patent is not a basis to invalidate for lack of utility: "When a properly claimed invention meets at least one stated objective, utility is clearly shown." 11:27

Likewise, in In re Gottlieb, the court emphasized that "Having found that the antibiotic is useful for some purpose, it becomes unnecessary to decide whether it is in fact useful for other purposes 'indicated' in the specification as possibly useful."

In Mexico as well the bar is low as Professor Hilda Gonzalez has explained. Mexico's utility standard requires that an invention must be "susceptible" of industrial application. This means industrial application must be plausible, not certain or proven. Specifically, Mexico's industrial property law defines industrial application as "the possibility of an invention having a practical utility or being produced or used in any branch of economic activity". A "possibility" in Mexico is enough.

During examination at IMPI, the Mexican Institute of Industrial Property, there is no

requirement that applications include evidence to prove industrial applicability. So long as there is a basis to believe that the invention can possibly be produced or used in any branch of economic activity Mexico's test is met. Like the U.S., Mexico has also declined to raise the bar for utility; its Congress in 2010 rejected a proposal that would have changed this word "possibility" in the definition to "fact". 11:28

In sum, the legal tests for utility in the U.S. and Mexico are nothing like Canada's promise utility doctrine, but this divergence in law is reflected also in practice, as this graphic makes clear.

In the United States utility challenges are exceedingly rare. According to one study only five challenges on utility were decided in U.S. courts over an 8-year period when NAFTA entered into force. Overall, utility was therefore disputed in just 2 percent of the case sample, and only one patent fell for lack of utility in that set of 239 cases.

In Mexico there's no evidence of even a single patent application being denied for lack of industrial applicability, nor is there evidence of

even a single patent being declared invalid on that ground in a nullity proceeding. 11:29

In Canada, by contrast, utility is routinely challenged. A majority of all patent validity rulings since 2005 include a decision on utility, some 53 percent, and in the pharmaceutical sector at least no fewer than 28 such challenges have been successful.

Canada does not meaningfully dispute that its doctrine is an outlier in North America. Instead Canada makes two fallback points, neither of which withstand scrutiny. Its first offense is an attempt to widen the lens beyond utility to other distinct patent law doctrines. Canada argues that the U.S. and Mexico have similar requirements under different labels. For example, that enablement and written description in the United States play the same role as the promise utility doctrine in Canada. But enablement and written description are distinct requirements from utility. They serve different purposes. In no way do they resemble Canada's promise utility doctrine. That difference is clear not just in terms of doctrine but also in terms of outcomes.

If Canada were correct, patents found to

lack utility by Canadian courts would be falling on enablement or written description in the United States but, as you heard this morning, neither of the patents at issue in this case was invalidated in the United States. 11:30

Canada's second defense is to assert that each NAFTA party from the start had its own distinctive approach to utility and that the U.S. and Mexican tests have changed over time. As an initial matter we have not argued that NAFTA harmonized patent laws in North America. What we have argued is that NAFTA establishes a substantive baseline of protection that Canada has failed to respect, and Canada is simply wrong to suggest that utility standards differed across North America. At the time NAFTA entered into force the test was similar in all three countries, and a low bar. This basic understanding in North America reflects practice also in the rest of the world, where the core principle of the utility requirement that an invention have some practical use is widely shared.

But Canada's promise utility doctrine is not only an outlier. It also discriminates against pharmaceutical patents. The effects of the doctrine have been concentrated in the pharmaceutical sector,

exclusively so. Not a single patent in any other sector has been found invalid for lack of utility since 2005. This disparity across sectors is stark and also consistent, no matter how the numbers are presented. 11:31

This slide [68] presents an updated version of Figure 3 from our Memorial. It's based on data analyzed by Professor Bruce Levin. Since we filed the Memorial in September 2014 there have been 14 additional utility rulings, and the picture remains the same. There's been a dramatic shift in the pharmaceutical sector. In the early period utility was rarely challenged in that sector and never successfully but, since 2005, given the change in Canada's test, utility challenges have spiked and 28 cases (41 percent) have been successful.

Second, there's been no change across all other sectors. Both before and after 2005 there were relatively few challenges, and over more than three decades there have been only two judicial rulings in any other sector invalidating a patent for lack of utility, and none since 2005 after the advent of Canada's new test.

Canada has attempted to change this basic picture in various respects. It has argued that the

increase in overall pharmaceutical patent litigation is the real cause of these changes, and that a similar pattern of increased litigation in that sector is apparent in the United States. This is the graph that Canada put into its Rejoinder, for example. But the overall volume of patent litigation can't explain the dramatic change in the rate of successful utility challenges. That change has taken place only in Canada, not in the U.S., and only in the pharmaceutical sector. Again, the increase in the rate is specific to the pharmaceutical sector and to the recent period. 11:32

Canada has also taken the position that the vast majority of rulings in this chart, decisions and cases under the Patented Medicines (Notice of Compliance) Regulations, what we call PM(NOC) cases, should not be considered at all. But this is incorrect. There is no basis to exclude such cases where judges apply the same substantive law in precedential decisions that have significant effects in the marketplace. Canada has further attempted to muddy this picture by suggesting that we should have counted patents, not cases; that a few individual cases were coded inappropriately; and still other cases should be counted twice, both as

wins and as losses. But these various changes, as Lilly's witnesses will explain, either are of no consequence or are entirely unjustifiable. 11:33

At the end of the hearing this same clear picture will remain. Canada's promise utility doctrine has had a significant and disproportionate impact on pharmaceutical innovators.

This sharp contrast in terms of litigation outcomes is unambiguous but it's not the only evidence of discrimination. Two other indicia are significant.

First, well known features of the drug development process discussed by Ms. Wagner are driving the disproportionate impact of Canada's elevated test. Pharmaceutical innovators must seek patent protection early. To delay for additional testing creates the risk of a patent defeating disclosure. This is well known and therefore it is no surprise that the dramatic change in Canada's test has harmed innovators only in this sector.

Second, all of the innovative pharmaceutical companies whose patents have been challenged for lack of utility in Canada are foreign investors. Every pharmaceutical innovator in the cases represented on this chart is based outside of

Canada. By contrast the generic companies challenging those patents have major operations in Canada where many are based or were founded. 11:34

To conclude, in multiple respects Canada is out of line. Neither the United States nor Mexico has anything like the promise utility doctrine. Only Canada is revoking patents on plainly useful inventions, all of which are in the pharmaceutical sector. Thank you.

THE PRESIDENT: Thank you, Mr. Smith. Ms. Cheek, you will continue with the expropriation?

MS. CHEEK: Yes. Very good.

I will be discussing our expropriation claim, and Mr. Berengaut will discuss our fair and equitable treatment claim. The questions that were raised before the break related to the relevance of arbitrariness to our legal arguments, and the relevance of the change in the doctrine to our legal arguments will be addressed by Mr. Berengaut when he discusses our fair and equitable treatment claim.

Before we get to the specifics of the claims for expropriation and fair and equitable treatment, I did want to go back to Canada's arguments that Lilly's claims are novel. Canada is wrong about the merits of Lilly's claims and their

consequences, but they are right about one thing, and that is this case is novel but not in the way that Canada suggests. We are not asking you to usurp the sovereignty of states or invade the jurisdiction of other tribunals. 11:35

Rather, there are two novel issues that are really raised by Canada's defenses in this case. The first is should intellectual property rights, a protected investment under the Treaty, should intellectual property rights be subject to lesser protection than other protected investments. And the second novel issue raised by Canada's defenses is should this Tribunal grant special or new immunities for courts for measures that are otherwise inconsistent with the substantive rules of international law.

Canada's defense would require this Tribunal to reach an answer of yes on both of those questions, but as we will demonstrate at this hearing this Tribunal should decline both of those invitations. Rather than create special rules for intellectual property or special rules for the courts, this Tribunal should apply the same tried and true analysis that international law would require in any other case.

Of course, Article 1110 requires that there be an investment that is capable of being expropriated, and here Lilly has two, the Zyprexa and the Strattera patents. In response to Question No. 19 by the Tribunal about whether Lilly's patents constitute property that's capable of being expropriated -- and there was an additional question about whether Canada's argument to this effect is untimely -- in the first instance, as we said in our Reply at Paragraph 230, we do think that this was raised belatedly and therefore is not really before the Tribunal under UNCITRAL Rule 21(3), but in any event, setting aside the untimeliness of the issue, the fact that these courts found these patents to be void ab initio does not have the significance that Canada asserts. As a factual matter Lilly held valuable exclusive rights to this invention up until the moment that the Canadian courts revoked those patents. And as a legal matter, because the Canadian court decision revoking those patents is the very measure that Lilly is challenging in this proceeding, the fact that Lilly's patents were declared void ab initio by the courts is irrelevant. 11:37

Canada's second defense is that this Tribunal should grant a new immunity to national

courts for measures that are inconsistent with a substantive norm of international law. Yet, it is well established that Canada is responsible for the acts of its judiciary. 11:38

As Ian Brownlie observed, when it comes to the expropriation of foreign property "form should not take precedence over substance. The essence of the matter is the deprivation by state organs of a right to property." And that's CL-60.

Further, as the Tribunal observed in Rumeli Telekom v Kazakhstan (CL-58): "Whereas most cases of expropriation result from an action by the executive or legislative arm of a state, a taking by the judicial arm of a state may also amount to an expropriation". And that is the case we have here.

In a case such as this one where the judiciary has made substantive law, just like the Parliament or an executive branch agency might) and then apply that law, just like an agency might, this Tribunal should decline Canada's invitation to shield the acts of its third branch of government from scrutiny. So the starting point then for our analysis is whether or not there was a substantial deprivation under Article 1110.

Here Canada's measures plainly satisfy the

standard because the application of the promise utility doctrine to Lilly's patents resulted in a substantial deprivation of Lilly's property rights. And the Tribunal asked as your Question No. 21 related to the implications of Canada's argument that Lilly has not been substantially deprived of its investment because it continues to sell Zyprexa and Strattera. 11:40

The fact that Lilly can produce and sell Zyprexa and Strattera does not mean that the protected investments in this arbitration, the '113 and the '735 patents, have not been substantially, or really in this case completely, deprived of value. Because what patents are is a bundle of exclusive rights to make, sell and use the invention, and when Canada invalidated these patents it deprived Lilly of those exclusive rights and its ability to enforce those exclusive rights against others. So there was a complete deprivation of property rights in this case of the protected investment in this arbitration. So while a substantial deprivation is a necessary and sometimes sufficient criteria for an expropriation under the sole effects doctrine, we've acknowledged, in the case of a judicial expropriation, not every judicial

action resulting in a loss of an investment or a substantial deprivation of property is going to be an expropriation under Article 1110. In this case not every judicial patent revocation is an expropriation. Rather, Article 1110 is engaged by measures that substantially deprive an investment of value while violating a substantive rule of international law. 11:41

Saipam v Bangladesh (CL-62) exemplifies this rule. There the Tribunal explained that the most significant criteria to determine whether the disputed actions amount to an expropriation is the impact of the measure. Second, the Tribunal recognized that, since judicial revocation of property rights always results in a substantial deprivation of those rights, it's also necessary to demonstrate the unlawful character of the actions.

Third, that Tribunal went on to find that one of the ways in which those judicial measures at issue were unlawful is that they constituted a substantive violation of the New York Convention. So where Canada's courts have fundamentally changed their utility test, revoked Lilly's patents and in the process violated a substantive rule of international law, this Tribunal has the authority

and, indeed, the responsibility to award compensation to Lilly as an injured investor. 11:42

Now, Canada seeks to distinguish Saipem and the other cases such as ATA v Jordan that we cited for this proposition on the grounds that they involved property rights that were acknowledged to exist. Canada's Rejoinder at Paragraph 125 says Claimant relies upon cases in which courts interfered with or extinguished rights that were acknowledged to be valid in domestic law. But this is false. As you can see on slide 75, in Saipem, the Bangladesh court -- and here this is the Saipem decision at Paragraph 50 quoting the court -- the Bangladesh court held that as a legal matter there was no arbitration award to annul because the arbitration had been unlawful. Whether that award was a nullity was very much in dispute, just as whether or not the underlying patent here should be revoked or whether it was valid was similar in the underlying dispute.

And so in Saipem the Bangladeshi courts conclude that a non-existent award can neither be set aside nor enforced. In other words, it's precisely the opposite of what Canada claims. These cases are like Lilly's case which is before you in

that both there and here, there had been rights at issue in domestic courts that were declared void as a matter of domestic law but that did not preclude the Tribunal from looking to see if the court's actions violated international law. 11:44

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

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

case it is chapter 17, the intellectual property rights chapter of NAFTA. 11:45

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

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

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

Secondly, there is an alternative avenue to take, and that is through specifically the provision of 1110(7), which I'll also come to address in a moment. 11:47

THE PRESIDENT: Thank you.

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

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

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

Saipem route, as argued by the Claimant in this case, would you not import an entire universe of international law into potential violations leading to an expropriation? 11:48

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

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

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

basis because that is not within the scope of the expropriation provisions. But you are saying yes, it is. 11:50

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

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

MS. CHEEK: Right.

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

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

THE PRESIDENT: Okay. Please proceed.

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

the case that we've put before you. 11:51

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

MS. CHEEK: Yes, it could.

THE PRESIDENT: Thank you.

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

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

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

only a shield and not a sword, but this defies logic and the plain reading of Article 1110(7) particularly in light of the decision of the one NAFTA Tribunal that's addressed analogous language in 1110(8), and I'll get to that in a moment. 11:53

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

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

Now, Canada, at Paragraph 220 of its

rejoinder, likens this statement to if it is raining, the streets must be wet. 11:54

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

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

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

different. The point here in Waste Management v Mexico the Tribunal considered this provision and what this underlying provision, 1110(8), meant or signified about the breadth of the underlying obligations under Article 1110. The Tribunal concluded, CL-65, Paragraph 144, "It is true that Paragraph 8 is stated for greater certainty but if it was necessary, even for certainty's sake, to deal with such a case this suggests that the drafters entertained a broad view of what might be tantamount to expropriation." 11:56

So the Waste Management Tribunal correctly recognized that the language of 1110(8) is relevant to whether or not an expropriation, or measures tantamount thereto, had occurred. Similarly, Article 1110(7) is relevant to the circumstances in which the revocation of a patent constitutes an expropriation. When NAFTA's drafters carved out a category of measures from Article 1110 in only certain circumstances, they implied that such measures otherwise could fall within the scope of Article 1110.

The Tribunal submitted to us Question No. 20 regarding Article 1110(7) and whether, if one were to accept Canada's submissions that its actions

are consistent with chapter 17, what effect that would have on Lilly's claims under Article 1110. If the Tribunal finds that Canada is acting consistently with chapter 17, that its measures here, the revocation of the Zyprexa and Strattera patents are consistent with chapter 17, then by its plain terms of Article 1110(7), Article 1110 would not apply. It is a defense for Canada. But by the same token, if you find an inconsistency with chapter 17 and you find that a substantial deprivation has occurred, as in this case, then there is a substantial deprivation, there is a violation of a substantive rule of international law, and that leads to a violation of 1110. 11:58

I am now going to turn to the underlying violations of chapter 17. In the interests of time, I'm going to mostly respond to the Tribunal's questions that have been submitted. Let me make one more comment about the language of 1110(7) and whether or not every violation of Chapter 17, for example, would be a violation of Chapter 1110.

Like I said, one, you need a substantial deprivation. Frankly, that's accepted in this case. The patents were revoked. There was a substantial deprivation of the value of the investment. But you

could see, if there is just a limitation or a creation or some of these other issues that 1110(7) refers to, the Tribunal would have to do more work presumably to determine whether there had been a substantial deprivation in the value of the property that's at issue. 11:59

Second, this is a judicial expropriation, and so there needs to be some kind of finality to it.

Third, what you'll see in a moment when we get to Chapter 17, not every Chapter 17 violation would necessarily constitute a taking. But we believe that the four provisions that we've identified are violations of international law that, combined with the fact that the investment at issue was revoked, do constitute an expropriation under 1110.

So let me turn to Chapter 17 now.

THE PRESIDENT: Before you do that, simply to understand your argument under 1110(7), you rely basically on the final proviso "to the extent that", is that correct? What it says was this article does not apply to revocation of intellectual property rights, so that would take it out as the carve-out. Then you get it back in by "to the extent that" is

consistent with Chapter 17, and you say the first test you as a Tribunal have to do is to see whether it complies with the revocation, with the provisions of Chapter 17. 12:01

MS. CHEEK: Do you mind repeating?

THE PRESIDENT: I ask the question to find out where my reasoning is not following yours.

What it is is if you take this provision without the final proviso of "to the extent that" Chapter 17 would not be in, correct?

MS. CHEEK: That"'s correct. If this provision simply said "This article does not apply to the issuance of compulsory license or the revocation, creation or limitation of intellectual property rights", that's correct, it would not apply.

THE PRESIDENT: Now we go on, because you have to read the complete thing. It says "To the extent that revocation" -- and I skip a number of words which I think is not relevant for your case -- "revocation is consistent with Chapter 17", and since you have that in you say you, Tribunal, have first to figure out whether the revocations were consistent with Chapter 17.

MS. CHEEK: Exactly. That language tells

you that to the extent that the measures at hand are consistent or inconsistent with Chapter 17 is relevant to the inquiry that's before the Tribunal. 12:02

THE PRESIDENT: And when you find that they are not consistent, then the first part of this article doesn't apply, and you say for that reason 1110 applies to the inconsistent measures.

MS. CHEEK: Well, I do think you need to read 1110(7) as a whole, and you need to read it in the context of 1110. So I think --

THE PRESIDENT: I try simply to see whether I can follow your argument. It is no criticism on your side, it is criticism on my own side, maybe slow thinking in how this works out, what you have presented to us.

SIR DANIEL BETHLEHEM: So it's right that you are seeing 1110(7) both in terms of its substantive provisions but more importantly from your perspective, as I understand your argument, you are seeing it as a gateway. So if through 1110(7) you can get to Chapter 17, that means -- I think the language you used was it's not a one-way street, is that right?

MS. CHEEK: It's not a one-way street. I don't know that I would call it a gateway.

Obviously when you're looking at whether or not there's an expropriation, you're looking at the character of the measure, and one thing that is very relevant to the character of this measure is that it violates Chapter 17 and 1110(7) acknowledges that. But certainly that means it is a two-way street, because it's relevant both to the affirmative case and the defensive case. 12:03

Now I will talk about the underlying violations of Chapter 17. As I mentioned, in the interests of time I'm mainly going to respond to the Tribunal's questions that you've submitted, but of course I'm happy to pause at any time.

The first is Article 1709(1), which requires Canada to provide a baseline level of patent protection. And Article 1709(1) imposes a mandatory obligation to make patents available for inventions that meet the three core patentability requirements. Such inventions are new, result from an inventive step -- that's the non-obviousness test -- and are capable of industrial application.

The promise utility doctrine as applied to the Strattera and Zyprexa patents is an impermissible additional utility requirement that was applied to invalidate these patents up and above

the mere scintilla of utility test that we discussed. The Tribunal asked at Question No. 8 about the meaning of "shall make patents available" in this provision. "Shall make patents available" imposes a mandatory obligation to provide patents for inventions that satisfy the three core substantive patentability requirements -- new, non-obvious, and useful. Those are the three requirements of patentability of an invention. If those three substantive requirements are met, then the patent shall issue. 12:05

Now, you can put additional conditions on a patent grant. You can say you have to maintain fees, for example, or that you need to provide a disclosure. But those do not detract from the fact that if the substantive patentability requirements are met, then you are obligated to grant a patent, or make that patent available and provide that patent to the inventor.

MR. BORN: How do you deal with Canada's argument that enablement isn't included on this list?

MS. CHEEK: Enablement is not a question of patentability per se but has more to do with the disclosure part of patentability -- or not

patentability but requirements for a patent. For example, NAFTA doesn't have language to this effect, but TRIPS does. TRIPS categorizes enablement and disclosure as conditions for getting a patent, so there are other conditions you can place on awarding the patent grant, but these are the three substantive tests for whether an invention is a patentable invention. 12:06

MR. BORN: So enablement and disclosure are like fees or timing obligations?

MS. CHEEK: Right. I mean they are perhaps more hefty than a fees requirement, but they effectively are other conditions that you may place on a patentee as to whether the patent's ultimately granted. What's at issue here is the substantive patentability requirements. And particularly for these two patents, these kind of issues related to was there sufficient disclosure, these patents were found to have sufficient disclosure. So for our purposes all of those other issues in the context of these revocations ended up being off the table since they were struck down solely on the basis of not satisfying the utility requirement.

Because of that, because these are the three substantive requirements for patentability,

and this goes to the evidence that Mr. Smith presented about the utility requirement in Mexico and the United States and the relevance of that, when the NAFTA parties signed this agreement there was a common understanding that utility was a low bar and that it was the mere scintilla test, what it's called in Canada and, therefore, this language is meaningful. 12:07

Let me get to another question that was posed to us in advance and that was Question No. 9, which is as of what date was Respondent in breach of its Chapter 17 obligations. You also asked about the relevance of the 2002 AZT case in this context.

Canada has been in breach of its obligations under Chapter 17 since 2005, and those violations continue to this day. Now, the post-filing evidence rule in AZT is critically important, as we described earlier this morning, but it was not until that rule was married with the promise of the patent that Canada began denying patents to otherwise useful pharmaceutical inventions.

The Tribunal also asked at Question No. 11 about the implications for our claims if the Tribunal accepts Canada's submission that these are

several distinct patentability rules, all of which were part of Canadian law at the time we filed our patents. Now, I think as you probably took away from Ms. Wagner's presentation this morning, we strongly disagree that Canada has shown that any of these three aspects of the promise utility doctrine were part of Canadian law prior to 2002, and we don't think it's at all similar to what the courts are doing today. But even if all three aspects had existed in prior law, it was not until 2005 that they were married together in a way that resulted in the invalidation of pharmaceutical patents as well as invalidation of our patents. So we're looking at the utility test that was applied to our patents in 2010 and 2011, and the way in which they now work together, this utility requirement, is the utility test that we're looking at for purposes of whether Canada is in violation of its Chapter 17 obligations. 12:09

For the sake of completeness the Tribunal also asked a question related to the Patent Cooperation Treaty which I think I already answered at least in part, and that is for purposes of the case that we've put before you, the Patent Cooperation Treaty, also under the Vienna

Convention, should be considered a relevant rule of international law that's applicable to the relations between the parties, since the PCT applied among the NAFTA parties since 1995 and did include a definition of capable of industrial application or industrial applicability, even though there's not a definition in NAFTA itself. And the PCT, as I did already mention, is relevant to Lilly's expectations, particularly with regards to the PCT application it had filed and then transposed into the domestic process in Canada. 12:10

But Mr. Berengaut will discuss Lilly's legitimate expectations in a moment.

Let me now turn to the second underlying violation of Chapter 17, and that's 1709(7), which says that patents "shall be available and patent rights enjoyable without discrimination as to the field of technology."

Article 1709(7) bars de facto discrimination, measures that produce differentially disadvantageous effects irrespective of whether they're motivated by discriminatory intent. Throughout this case Canada has not disputed that 1709(7) is violated by measures that are de facto discriminatory. So that's common ground.

What it has strenuously tried to show is that there's not disproportionate effects on the pharmaceutical industry, but, as Mr. Smith explained, there are discriminatory effects here, and we will go through some of that evidence in more detail with the experts that will appear before you. 12:12

If Lilly can demonstrate disproportionate effects, that's sufficient to show a violation of 1709(7). But for the first time in Canada's comments on the Article 1128 submissions in this case, Canada suggested that there must also be discriminatory objectives, is what it said. That's Canada's submission at Paragraph 43.

Canada has not argued that previously. They also actually didn't argue it in the WTO proceeding against Canada, Canada Pharmaceuticals, which the U.S. Government relied on for this proposition. So our view is that actually the law here is you need not show discriminatory objectives, if you will.

But this does go to another question the Tribunal has asked us, Question No. 18, which asks Lilly to elaborate on Canada's discriminatory intent which Claimant says can be inferred from the objective characteristics of the promise utility

doctrine.

So, as I mentioned, the only case that's been relied on by the United States, and now belatedly Canada, for this notion is the WTO case that I mentioned. In that WTO case, Canada Pharmaceuticals, there was no evidence of discriminatory effects put forward. So without any evidence of discriminatory effects, in stark contrast to the case here, that Tribunal was trying to determine how else they might evaluate the claim and so they looked to the discriminatory objectives. In that context, what you look at is not animus or a subjective intent but you look at the objective characteristics of the challenged measure.

Here, the way the courts have articulated and applied the utility requirement, the promise utility doctrine in Canada, the way that it requires heightened proof and human clinical trials, being able to demonstrate clinical efficacy at the time of patent filing, what we've shown is it would be extremely difficult -- if not impossible in many cases -- particularly if the promise is long-term clinical effectiveness in humans -- based on the way pharmaceuticals are developed and taken to market, you will never have that evidence at the time you

file for a patent. That explains why there's such a disproportionate effect on pharmaceuticals in this case. There's a reason why there's zero percent inutility decisions in any other field of technology, but it's a 41 percent inutility rate for pharmaceutical inventions.

Let me turn to 1709(8), that Canada's new utility requirement is retroactively applied to invalidate Lilly's Strattera and Zyprexa patents. Article 1709(8) says a party may revoke a patent only when grounds exist that would have justified a refusal to grant the patent. The provision here is violated because of Canada's new and additional test for utility that did not exist when these patents were granted.

Canada mentions in its comments on the Article 1128 submissions that Lilly said that this means the NAFTA parties must freeze their patent laws, but that's not what we have argued and that is not the case here. Here, Canada has two utility standards, where it used to have one. The one, the mere scintilla standard, was met by the Zyprexa and Strattera patents when those patents were granted. As I mentioned, no questions were even raised as to the utility of the patents when granted. It's the

second additional requirement that's new, the promise utility doctrine, that was then only later applied to revoke these patents.

The fourth underlying violation of chapter 17 is 1709(1) which provides that each party shall provide in its territory to the nationals of another party adequate and effective protection and enforcement of intellectual property rights. Here, the promise utility doctrine and using the promise utility doctrine to revoke these patents has made it so there is not adequate and effective protection of intellectual property rights, and in the interests of time I think we'll rest on our papers with regards to the rest of our arguments on the underlying violations of Chapter 17.

Before I pass the baton to Mr. Berengaut, the Tribunal did actually ask another question that I want to make sure I address, which is Question No 22, and that was about the criteria to establish direct expropriation in this case. To the extent you view this as a direct expropriation, we wanted to be clear that there's no requirement that Claimant -- that Lilly -- demonstrate that this investment was transferred to the state or transferred by the state to another third party.

And multiple cases have recognized that an expropriation, whether direct or indirect, may occur if an investment is destroyed, which is what happened here. And we address that further in our Reply at Paragraph 311.

So let me conclude on our Article 1110 claim. Canada insists that its court decisions cannot be scrutinized in the expropriation context. It insists that if you can scrutinize the actions of its courts, it can only be done in the context of denial of justice. It then insists that Article 1110(7) is only a shield but not a sword. It's irrelevant to your determination if there is an expropriation.

Further, if you reach Chapter 17, Canada says under Chapter 17 it has infinite flexibility to set its patentability requirements.

But what's the result of Canada's restrictive approach and its shrinking obligations in the case of intellectual property rights? Canada's restrictive approach would make intellectual property rights subject to lesser protections than other protected investments. Second, it would provide a new immunity to national courts for measures that are inconsistent with

substantive norms of international law in an expropriation context. 12:19

With that, I will hand it to my colleague, Mr. Berengaut, to talk about Lilly's 1105 fair and equitable treatment claim.

THE PRESIDENT: Thank you. Mr. Berengaut?

MR. BERENGAUT: Thank you. One preliminary before I get started on 1105, which is in response to your question, Mr. President, about the circumstances in which a Claimant can reach outside the Treaty to invoke a substantive rule of international law in relation to Saipem, I thought it would help the Tribunal to note that Bangladesh ran that exact argument in Saipem and the Tribunal addressed it in paragraphs 164 and 165, and that is CL-62.

Turning to Article 1105, this provision, as the Tribunal knows, requires states to afford fair and equitable treatment to the protected investments of foreign investors, and it is undisputed that, under the FTC note, the Tribunal should analyze the fair and equitable treatment standard by reference to the minimum standard of treatment under customary international law.

Now, what is also clear, however, is that

the minimum standard of treatment under customary international law has been shaped by the fair and equitable treatment standard embodied in the thousands of BITs that have been executed. This is language from Chemtura where the Tribunal noted that "In holding that Article 1105(1) refers to customary international law, the FTC interpretations incorporate current international law, whose content is shaped by the conclusion of more than 2,000 bilateral investment treaties and many treaties of friendship and commerce." 12:20

Given that these standards mutually influence each other it is not surprising that multiple tribunals have held that the two standards have effectively converged both inside and outside of the NAFTA context. This is the Merrill & Ring decision within the NAFTA context, where the Tribunal held that the fair and equitable treatment standard has "become sufficiently part of widespread and consistent practice so as to demonstrate that it is reflected today in customary international law as opinio juris. In the end, the name assigned to the standard does not really matter. What matters is that the standard protects against all such acts or behavior that might infringe a sense of fairness,

equity and reasonableness". 12:21

Outside the NAFTA context as well, this is from the Biwater case, the Tribunal accepted as found by a number of other arbitral tribunals and commentators, that the actual content of the fair and equitable treatment standard is not materially different from the content of the minimum standard under customary international law.

While the Tribunal would accordingly be on firm footing in relying on decisions involving treaty-based fair and equitable treatment standards, it is not necessary for it to do so in this case because each of the three components of Lilly's Article 1105 claim -- legitimate expectations, arbitrariness and discrimination -- are part of the minimum standard. Now, earlier during our presentation, Sir Daniel, you asked about the relevance of two factual propositions that Ms. Wagner discussed. One was the fact of change in the law, as I recall, and the other was arbitrariness of the promise utility doctrine.

The fact of change in the law is centrally relevant to Lilly's legitimate expectations claim because Lilly's legitimate expectations, as I'll discuss in a moment, were rooted in the Canadian law

at the time they filed their Zyprexa and Strattera patent applications, and the arbitrariness of the doctrine as it was applied in the Zyprexa and Strattera cases is also an independent basis under Article 1105 for concluding that Canada's measures are in breach of that article, and we'll discuss both of those headings in detail. 12:23

Before I do that, though, I'd like to respond to the Tribunal's Question No. 13 in regard to whether denial of justice is the only basis for liability for judgments of domestic courts interpreting domestic law as argued by the Respondent.

Ms. Cheek has addressed this point with regard to Article 1110, and it is worth noting at the outset that Canada's argument fails for the same reason under Article 1105. Denial of justice is one theory of liability for judicial measures but it is not the only theory, and a ruling to the contrary would create a broad immunity for national courts for measures that violate international law and would have the effect of treating some countries, i.e. those that articulate new legal rules more frequently through the courts, better than others, those that articulate new legal rules more

frequently through legislatures and executive branches. 12:24

As Judge Aréchaga has put it (Professor Paulsson's Denial of Justice treatise) "the obvious objection [to Canada's position] is that denial of justice and State responsibility are not co-extensive expressions, and that State responsibility for acts of the Judiciary does not exhaust itself in the concept of denial of justice."

In the specific context of Article 1105, Canada's argument is belied by the multiple tribunals, Limian Caspian, RL-27, White Industries CL-157, Frontier Petroleum, RL-67, which interpret both the fair and equitable treatment standard and the minimum standard of treatment, that considered not just whether a judicial measure represents a procedural denial of justice but also whether it is substantively discriminatory, arbitrary and in conflict with legitimate expectations.

Along the way, these tribunals have expressly rejected Canada's argument. This is from Limian Caspian. In that case the Tribunal noted that courts have a different function from other branches of government, yet it "still saw merit in Claimants' argument that the two standards are not

synonymous [that is fair and equitable treatment and denial of justice] with regard to acts of courts because this would introduce a distinction between acts of courts and acts of other State entities for which no support is provided" -- in that case by the ECT, but of course, NAFTA provides no support for drawing a distinction in this context either. 12:25

In the particular context of NAFTA the Mondev Tribunal, and this is CL-7, implicitly recognized that a judicial measure could violate Article 1105 irrespective of its procedural fairness. In Paragraph 134 the Tribunal discussed a rule articulated by the judiciary which could be interpreted as "affording governmental prerogative to violate investment contracts".

The Tribunal held that this substantive rule would appear to be inconsistent with the principles embodied in Article 1105 but ultimately held that it need not reach this question because the relevant rule had not clearly been adopted by the Massachusetts court and was not the basis for the Massachusetts court's decision.

Canada meanwhile lacked support for the proposition that denial of justice is the only theory of liability for judicial measures. In fact,

Canada really identifies only a single source that stands for the proposition that denial of justice is the only theory of liability, and that is an article by Professor Zachary Douglas, R-323. That article, however, does not identify any authority to support Professor Douglas' and Canada's preferred rule. In fact, the only authority discussed in the relevant portion of Professor Douglas' article is the Frontier Petroleum decision which Professor Douglas criticizes. The reason he criticizes it, of course, is because it contradicts him and adopts the view that denial of justice is not the exclusive theory of liability for judicial measures under the minimum standard. 12:26

In short, the Tribunal should apply the same tools of analysis to judicial measures as it would to a measure of legislative or executive branches. Any other approach would grant a special immunity to courts and have the effect of treating some countries better than others.

I will turn now to the three aspects of Lilly's article --

THE PRESIDENT: You say that you turn now to the three aspects but before you do that, may I ask you a question? Go back to slide 84. You

argued -- and please correct me if I'm wrong in my paraphrasing you -- look, the current standard of international law, of the customary international law on the FTC interpretation is the FTC said look, you have to do only the minimum standard, and you said no, that may be so, but these standards, the minimum standards, has converged basically to one standard, and you point to the Chemtura decision. 12:28

MR. BERENGAUT: Yes.

THE PRESIDENT: And you disagree with Glamis?

MR. BERENGAUT: We do.

THE PRESIDENT: I understand that. Can you help me? Has the note of 2001 actually become redundant to make this interpretation by the Commission? When you say actually, because of the convergence, there is only one standard?

MR. BERENGAUT: Yes, I would say that is our position, and we believe there is authority both inside the NAFTA context and outside of NAFTA that the two standards have converged. And, you're right, that as a logical matter, stating that Article 1105 refers to the MST would seem superfluous if the two standards had converged at the time of the FTC note.

We obviously don't think it was superfluous at the time but our view is the authorities have recognized since then that convergence has occurred. Of course, we don't rest on that point because we believe for each of the heads of argument under Article 1105 -- legitimate expectation, arbitrariness and discrimination -- there is ample legal basis for our position if you look solely at MST cases, but as a legal matter you're correct. We believe convergence has occurred. 12:29

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

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

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

become redundant. 12:30

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

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

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

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

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

which we focus because it's not a point on which we rely. 12:32

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

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

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

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

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

from the minimum standard? 12:33

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

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

MR. BERENGAUT: Yes, precisely so.

MR. BORN: Thank you.

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

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

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

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

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

you're saying. 12:34

MR. BERENGAUT: We are.

THE PRESIDENT: All right. You were at page 90 of your slides.

MR. BERENGAUT: Thank you.

I guess, just to be clear, on that proposition as well, the relevance of treaty practice for purposes of customary international law is only relevant to our case insofar as it supports the principle of convergence, which we advocate for but ultimately on which we don't need to rest because, even if you look at the narrower universe of cases interpreting the customary standard, there's ample support for each of the three components of our claim.

SIR DANIEL BETHLEHEM: It goes to the question, though, of the relevance of the 2001 statement, doesn't it, because that is presumably embodied by the states making the declaration a particular conception of what customary international law is and how it comes into being. You, I think, if I recall correctly, are relying on comments by Judge Schwebel, amongst others, to say that really you've got to look at customary international law through the prism of treaty

practice. This, as I understand it, is the 12:35
divergence between you and the Respondent.

MR. BERENGAUT: Yes, that's a fair description of the point of conflict there.

THE PRESIDENT: But when you talk about the Treaty practice and you refer to the 3,000 BITs or so, those are the first and the second generation bits, as you might call them, and we are now in the third generation BITs, for example CETA, and CETA you see under a further definition of FET. Is that what you ask us to look at, basically reflecting current customary international law, what is now the new Treaty design?

MR. BERENGAUT: That's a fair point. Just as there has been an evolution of the customary standard there has also been an evolution of the treaty standard, and I think, yes, in our position, we would want to look at the entire body of BITs because all of them reflect state practice which we believe is relevant to shaping the minimum standard norm.

THE PRESIDENT: Thank you.

MR. BERENGAUT: Legitimate expectations. On this point the Tribunal asked in Question 15 whether NAFTA protects investors' legitimate

expectations. Again, narrowing the focus of the 12:36
scrutiny to only those cases interpreting Article 1105 after the FTC note, many cases, including Bilcon, Waste Management, Grand River, Thunderbird, recognize that legitimate expectations play a role in the Article 1105 analysis. Rather than inflexibly revert back to state practice and opinio juris anew in each case, as Canada demands, these authorities consistently rely on earlier arbitral awards to understand and develop the governing standard.

As the Tribunal in Thunderbird explained, the concept of legitimate expectations relates within the context of the NAFTA framework to a situation where a contracting party's conduct creates reasonable and justifiable expectations on the part of an investor or investment to act in reliance on said conduct such that a failure by the NAFTA party to honor those expectations could cause the investor or investment to suffer damages.

Now, relatedly, the Tribunal has asked, Questions 16 and 17, regarding whether NAFTA should require that expectations be based in specific representations and, if so, whether Canada's grants of Claimant's patents constitute specific

representations for purposes of legitimate 12:38
expectations.

Now, here, as Thunderbird and Grand River recognize, reliance may be based in a state's overall conduct. Here, the relevant state conduct includes Canada's longstanding and well understood utility requirements at the time Lilly sought and received its Zyprexa and Strattera patents.

In any event, if the Tribunal is inclined to require a specific representation for purposes of Article 1105, as the Tribunal did, for example, in the Mobil Murphy case relatively recently, then the grant of the Zyprexa and Strattera patents plainly qualifies. A patent represents a specific commitment. Indeed, as Ms. Cheek discussed, it is a grant of legally enforceable rights to a patentee that it has the exclusive right to make, use and sell an invention until expiration. In other words, a patent is granted to be relied upon.

Now, Canada has repeatedly failed to answer this specific showing, and instead, has made the irrelevant assertion that courts cannot make representations to foreign investors and that's from Rejoinder Paragraph 265. Now, the specific representations here were not made by the courts.

They were made by Canada's patent office when it granted the Zyprexa and Strattera patents. 12:39

Now, here, Lilly had a legitimate expectation that its Zyprexa and Strattera patents would not be invalidated on the basis of a radically new utility requirement. Madam Secretary, the next slide has confidential information on it so I'd appreciate it if you could implement the procedure of Paragraph 8.

THE SECRETARY: Can we block the video feed, please? Can you note when you're finished with the confidential information?

MR. BERENGAUT: I will.

THE PRESIDENT: I grant you five more minutes on the condition you speak 50 percent slower. I'm concerned about the court reporters.

MR. BERENGAUT: I'd be pleased to accept that offer. Would you mind letting us know how much time we have remaining? I appreciate there have been a few questions but I don't want us to go over.

THE SECRETARY: As of now, you have 19 minutes left. That does not include the five extra minutes.

MR. BERENGAUT: As an initial matter, it is uncontroverted that Lilly, in fact, expected that

its patents complied with Canada's utility requirement. This is shown by the consistent recollections of Lilly's witnesses, Mr. Armitage, Postlethwait, Stringer and Ms. Nobles. 12:40

Lilly's expectations are also reflected in contemporaneous documents. With regard to Zyprexa, for example, Lilly's expectations are embodied in the status report from 1995, and this is confidential Exhibit C-130, which lists the many countries in which Lilly had filed for patent protection, including Canada, and notes that patents are issued or pending throughout the world with the expectations for issuance very good in all cases.

For Strattera, the contemporaneous documents present a similar account. Lilly developed a risk management plan relating to the global launch of Strattera and patent protection was not identified as a risk. And this is confidential Exhibit C-156.

When Canada invalidated the Zyprexa and Strattera patents under the promise utility doctrine, it contravened Lilly's legitimate expectations, irrespective of whether those expectations were grounded in Canada's utility requirement at the time the patents were filed, or

whether those expectations are grounded in the specific grants of the Zyprexa and Strattera patents. 12:41

Canada has three basic responses to Lilly's evidence of its legitimate expectations. First, Canada argues -- and this is at rejoinder Paragraph 281 -- that Lilly's expectations could not have been legitimate because the promise utility doctrine has always existed. And this goes to Sir Daniel's question about the relevance of the fact of change. Yet, if the Tribunal rejects this proposition, as it should, for the reasons that Ms. Cheek and Ms. Wagner have explained, then there is no denying the fact that Lilly experienced the invalidation of its patents based on a totally unexpected and radically new legal requirement in contravention of its legitimate expectations.

Second, Canada argues -- and this is Counter Memorial, Paragraph 293 -- that Lilly cannot rely on the recollections of its witnesses because "none of them offer evidence that they had any real understanding of Canadian patent law at the time", and none of them even testified in support of the atomoxetine and olanzapine patents before the Federal Court in Canada.

This answer misses the point in a few respects. It ignores the contemporaneous documentary evidence to which I have referred. It fails to appreciate that Lilly's witness testimony is relevant not because the witnesses themselves are experts in Canadian patent law but, rather, because they provide uncontroverted evidence of Lilly's robust processes for identifying patent-related risk. That no such risks were identified and escalated to the leadership of the Zyprexa and Strattera teams is probative of Lilly's expectations. 12:43

Lastly, the fact that none of these witnesses testified in Canadian court proceedings is irrelevant since, as we have repeatedly stressed, Lilly is not appealing those proceedings but, instead, is bringing separate claims with entirely distinct elements under NAFTA.

Third, Canada argues -- and this is rejoinder Paragraph 282 -- that sophisticated commercial parties do not predict specific litigation outcomes. Accordingly, Canada implies, Lilly should not have placed any reliance on the grant of the Zyprexa and Strattera patents because those patents could have been invalidated in

litigation. Yet, as Mr. Armitage explains, this is an overly simplistic portrayal of the commercial reality. 12:44

Madam Secretary, I can now confirm that we will no longer discuss confidential information.

THE SECRETARY: Excellent. Can you please restart the video feed?

MR. BERENGAUT: As Mr. Armitage explains, firms are certainly aware that validity litigation may be a risk, just as litigation over the validity of title is a risk when acquiring real property.

However, because most major markets offer stable and predictable patent regimes, the risks associated with validity challenges can generally be accounted for in advance.

It is these risks that firms assume. What firms do not expect and which risks they do not assume when they invest in a country like Canada, with a well-understood and longstanding utility requirement, is the creation of a radically new patentability requirement and the retroactive use of that requirement to invalidate a patent.

The next relevant aspect of Article 1105 relates to arbitrariness. Now, it is undisputed, I believe, that protection against some form of

arbitrariness is encompassed within Article 1105. 12:45 In Paragraph 224 of Canada's Counter Memorial, for example, it favorably cites Waste Management's articulation of the minimum standard noting that, "For there to be a breach of Article 1105, the impugned conduct must be, among other things, arbitrary." That's RL-14.

The disputed issue on the law here I believe is what does it take for a measure to be arbitrary. The concept of arbitrariness under customary international law has been described using several formulations. In this case the arbitrariness of Canada's measures is manifested through their incoherence and unpredictability.

To qualify as arbitrary under this standard it is not necessary that a measure be animated by animus or prejudice. It is enough that a government measure has the effect of creating a completely confused and unpredictable situation.

In Occidental v Ecuador, CL-97, the Tribunal held that the decisions taken by SRI, Ecuador's tax service, do not appear to have been founded on prejudice or preference rather than on reason or fact. In fact, the SRI was tasked with bringing "some resemblance of order" to the

confusing situation in Ecuador's administration of the VAT. 12:47

However, it is that very confusion and lack of clarity that resulted in some form of arbitrariness, even if not intended by the SRI.

Canada has strained to distinguish Occidental, arguing that the Occidental Tribunal specifically distinguished the autonomous fair and equitable treatment standard it was bound to apply as distinct from the customary international law minimum standard of treatment applicable in NAFTA.

In fact, the Occidental Tribunal found the exact opposite. There, as here, the issue arose whether the fair and equitable treatment standard mandated by the treaty is a more demanding standard than that prescribed by customary international law, and the Tribunal was of the opinion that in the instant case the treaty standard is not different.

Here there is no question that Canada's promise utility doctrine is arbitrary under this standard. You witnessed the incoherence and confusion of the doctrine in its application to Strattera and Zyprexa, as Ms. Cheek explained, but you do not need to take our word for it. This is the slide that Ms. Cheek showed earlier in our

presentation. Apotex, Lilly's competitor and Canada's largest generic company, has characterized the doctrine as a "free-for-all" in which the outcome of cases depends on a particular judge or panel hearing the dispute rather than on legal authority. "The outcome of such cases must not be determined so arbitrarily". This intolerable confusion should be resolved. 12:48

You also see it, as Ms. Cheek discussed, in how confused CIPO's own examiners were by the changes in Canadian law. You can also see it in the outcome of cases, for example, in the Latanoprost case, C-98 and 99, where two different Federal Court panels found different promises in identical patents with contradictory results. How can an inventor be expected to draft an application that meets Canada's utility requirement if two different courts look at the same patent and apply two different standards to it? As we have discussed, the promise utility doctrine is arbitrary in at least three critical respects.

First, the judges undertake the inherently unpredictable task of identifying the promises in the patent. As Ms. Cheek explained in the Zyprexa and Strattera cases, these promises were implied

based on the judge's subjective reading of the patent. Second, judges impose an unpredictable and incoherent heightened evidentiary burden which puts patentees in a Catch 22. Courts are all over the map in terms of the amount and type of human clinical trial data to require or even whether to require human clinical trial data at all. As part of this standard, the promise utility doctrine arbitrarily excludes post-filing evidence to support utility while allowing post-filing evidence to establish a lack of utility. 12:49

Third, the promise utility doctrine includes a disclosure rule for sound prediction but not to determine whether utility has been demonstrated. Under this rule, the court can only rely on evidence included in the patent application itself. But a patentee has no way of knowing whether the evidence it has will be enough to demonstrate utility or whether it will have to rely on sound prediction. Even the court in Lilly's case suggested that Lilly could not have known about the new disclosure obligation when it filed. C-160, Paragraph 121.

The third relevant aspect of Article 1105 is its protection against discrimination. The

customary norm against discrimination embodied in Article 1105 is not focused on any particular form of discrimination, but rather, as the Tribunal recently noted in Tenaris, provides that any differential treatment of a foreign investor must not be based on unreasonable distinctions and demands. 12:51

As discussed the statistical evidence establishes that the promise utility doctrine imposed on the Zyprexa and Strattera patents differential treatment by virtue of being pharmaceutical patents. There is also substantial evidence of discrimination on the basis of nationality. Every patent invalidated under the promise utility doctrine was owned by a foreign investor. Meanwhile, these invalidations worked to the advantage of the generic pharmaceutical industry, a prominent Canadian industry. In sum, the promise utility doctrine, as applied to Lilly's patents, violated Lilly's legitimate expectations, is arbitrary and is discriminatory. These are each independent bases for finding Canada in breach of Article 1105, but each of these grounds is also related.

As recognized in Waste Management II,

Article 1105 embraces a flexible standard which must be adapted to the circumstance of each case. This is Paragraph 99. A holistic examination of the promise utility doctrine as it has been applied to Lilly's patents unmistakably reveals that Canada has failed to respect the requirements of Article 1105. 12:52

Lastly, I will respond to the Tribunal's Question No. 14 regarding the implications of Paragraph B3 of the FTC notes. Paragraph B3 provides that a determination that there has been a breach of another provision of NAFTA, or of a separate international agreement, does not establish that there has been a breach of Article 1105(1). Here the Tribunal need not rely on another provision of NAFTA, or on another international agreement, to determine that Canada's measures violate Article 1105.

Rather, as I have discussed, the Tribunal can reach this conclusion on the basis of the violation of Lilly's legitimate expectations, and the promise utility doctrine's arbitrariness and discriminatory effects. In any event, Paragraph B3 does not prohibit tribunals from considering, in combination with other factors, other provisions of NAFTA. Rather, on its face, it only prohibits

Tribunals from determining that such breaches conclusively establish a violation of Article 1105. Thus, if the Tribunal concludes, as it should, that Canada's measures violate Chapter 17 for purposes of Lilly's Article 1110 claim, then that is an additional reason for concluding that they are arbitrary, in violation of Lilly's legitimate expectations, and discriminatory. But, again, it is not necessary for the Tribunal to consider Chapter 17 in the context of Article 1105 to reach these conclusions. 12:53

Thank you.

MS. CHEEK: I have concluding remarks, and then I will not keep everyone from their lunch.

Let me note that, for ease of presentation, when I talked about our Article 1110 claim, I focused on the relevance of Chapter 17, and Mr. Berengaut, when he talked about our Article 1105 claim, focused on legitimate expectations and arbitrariness and discrimination.

To be clear, as we have briefed it, we also would rest our Article 1110 claim on the violation of Lilly's legitimate expectations and also on the arbitrariness of the doctrine. So, from our perspective, the arbitrariness and the violation

of legitimate expectations are alternative, independent bases upon which you could find an expropriation in this case if you chose not to look to Chapter 17. 12:54

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

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

attention deficit/hyperactivity disorder, and that were being used by thousands of Canadian patients at the times that these patents were revoked solely on the basis that they lacked utility and were not useful. 12:56

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

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

THE PRESIDENT: That concludes the opening statement by the Claimant?

MS. CHEEK: Yes, it does.

THE PRESIDENT: Thank you, Ms. Cheek and your team, for making the presentations. I think we will have now our lunch, and resume at 2:00 sharp.

(Luncheon Recess)

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

OPENING STATEMENT ON BEHALF OF THE RESPONDENT

MR. SPELLISCY: Thank you very much. Good afternoon, members of the Tribunal.

Today in their opening statement, when we

got to the discussion of Article 1105 and 1110, the Claimant suggested there was nothing remarkable or unusual about what it is asking you to sit in judgment of in this case. The reality is to the contrary. The Claimant is asking you to do something truly remarkable. It is asking you to reconsider the decisions of the Canadian courts on the validity of its patents. Indeed, no matter how it wants to dress up and clothe its arguments today, to say that it is not trying to usurp the role of the domestic courts -- that is what it is asking you to do. 01:59

The Canadian courts determined that the Claimant's patents were invalid. The Claimant wants and needs you to disagree. In fact, this morning the Claimant walked you through the court decisions invalidating its patents, and the Claimant tried to show you how those decisions were wrong, that the drugs are useful and successful and that they were, to use their words, extraordinarily supported. Claimant wants you and needs to you find that its patents should have been found valid by Canadian law. Otherwise it has no claim for damages.

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

invalidity findings made by the Canadian judicial system. This is not the role of a NAFTA Chapter 11 Tribunal. There should be no doubt this is truly a remarkable claim. Indeed, in our view this is not a typical dispute where you must make significant factual determinations as to whether particular events happened or as to why particular decisions were made. The reason is simple. In our view the most relevant facts are not disputed. They are as follows. 02:01

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

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

ab initio. There was not a single dissent. The Claimant's request for leave to appeal to the Supreme Court of Canada were then denied. And now we find ourselves here in front of a Chapter 11 arbitration tribunal because the Claimant did not get the domestic law result that it wanted in the Canadian courts. 02:02

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

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

The expert evidence from Mr. Holbrook and

Ms. Lindner will show why the Claimant is wrong in its characterizations of U.S. and Mexican law, and the expert evidence of Mr. Gervais and Mr. Reed will show why the Claimant is wrong on Chapter 17 and why it is wrong on treaties like the PCT. 02:03

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

The Claimant answers this question by suggesting that you have exceptionally broad and wide-ranging authority to consider judicial measures. In fact, as I noted above, the Claimant is asking that this Tribunal do nothing less than sit as a supranational Court of Appeal to assess the legality of the judicial measures of the Canadian courts. It is our view and the view of the other

NAFTA parties that you cannot do so. 02:05

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

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

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

a breach of Chapter 17 of NAFTA. 02:06

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

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

And so we come back to answering the question I posed above. What is the role of a

Chapter 11 Tribunal when it is the acts of a state's domestic courts interpreting domestic laws that are alleged to be the source of a violation of articles 1105 and 1110 of NAFTA? 02:07

All three NAFTA parties agree that under the treaty that they negotiated and signed, the answer to this question is straightforward. When it is the acts of a neutral and independent judiciary that are being challenged, the Tribunal is limited to considering whether there has been a denial of justice. Nothing less. If there has been no denial of justice, then there is no need for you to consider any other issue in this case, because if there has been no denial of justice there has been no breach of Chapter 11. And any other considerations or other conclusions about obligations outside of Chapter 11 cannot change that answer.

Why have I spent so much time on this one point in my introductory remarks this afternoon, a point that I have just told you renders everything we are about to spend two weeks of your time on pretty much irrelevant? It is because if you agree that the only real question here is whether there is a denial of justice, then this case is over, and it

is over right now. The Claimant could have made such an allegation. It would have failed as a matter of merit, but it could have done so under Chapter 11. However, the Claimant has never alleged denial of justice. 02:08

In fact, quite to the contrary, the Claimant has been express that it is not making any such claim. In light of such an admission there is, as a matter of law, no valid claim here and this arbitration should be dismissed with Canada being awarded all of its costs.

As the Respondent, Canada is in a position where it does have to respond to the Claimant's allegations and address, in the alternative, why all of those allegations are beyond this Tribunal's jurisdiction, ratione temporis and without merit. Let me explain how we will organize the rest of our opening remarks today.

My colleague, Mr. Johnston, will speak next and he will spend roughly 45 minutes giving you some key background on Canadian patent law, in general and helping you understand as a matter of fact how the Claimant's patents and the decisions regarding them by the Canadian courts fit into decades of Canadian jurisprudence. My colleague

Mr. Luz will spend about 45 minutes addressing the law of Article 1105 and 1110. He will in particular explain why, as I have just introduced, the only possible cause of action under Article 1105 and 1110, where what has been challenged are judicial decisions or denial of justice. He will also address the other legal standards in Article 1105 and 1110 so that you have a complete picture of the applicable law. At that point we will have been going for roughly over an hour and a half and so I would suggest it would be a good time for our afternoon break. When we return, I will then spend roughly 60 minutes or so explaining why there has been no breach of Canada's obligations under NAFTA and, in particular, I will summarize today the reasons why Canada suggests that after you hear the argument and evidence in this claim over the next several days, you will have no choice but to conclude that the Claimant's claims must be dismissed. 02:10

In making my remarks I will cover four points. First I will briefly return to my main point that I have covered here and offer a little more detail on why, if you agree with Canada, the United States and Mexico that under Articles 1105

and 1110 of the Treaty they chose to sign, an allegation arising from the decision of a court must be based on a claim of denial of justice, then this claim must be dismissed. 02:11

I will then turn to our alternative arguments and everything that I cover after this point has to be understood expressly in that context. It is in the alternative.

I will explain that even if you find that the claim here is not limited to a claim for denial of justice, the Claimant's challenge to the judicial interpretation of Canada's Patent Act is time barred. The Claimant undoubtedly knew of the alleged breaching measure and loss by no later than October 22, 2009 when the Supreme Court of Canada denied its leave to appeal the decision with respect to its Raloxifene patent, but it did not bring its claim within the three-year limitation set by NAFTA.

We will then proceed further into the alternative. As my third point, I will discuss with you why this claim must fail because it necessarily depends upon a false factual predicate. In particular, the Claimant's whole claim, as we understand it, depends upon you concluding that there has been a substantial and unexpected change

in the judicial interpretation of Canada's Patent Act, beginning, at least as we understood it until today, in 2002. 02:12

I believe as a matter of fact, if you review the evidence presented so far and consider the evidence presented by experts like Dr. Gillen and Mr. Dimock this week you will be able to reach only one conclusion, that the principles in the judicial interpretations challenged by the Claimant are not new. They have existed in Canadian law for decades.

As my fourth point we will then proceed even further into the alternative and show why, even if you find that the claim here is not limited to a claim for denial of justice, and even if you find that the Claimant's challenge is not time barred, and even if you find that there has been a substantial change in the way Canadian courts have interpreted the Patent Act since 2002, there has still been no breach of either Article 1105 or 1110 of NAFTA.

In this part I will first discuss with you the reasons why you should conclude that the Claimant has failed to establish a breach of the customary international law minimum standard of

treatment contained in Article 1105. The interpretation given to Canada's Patent Act by the Canadian courts simply does not rise to the level that would breach that standard. 02:13

I will then discuss Article 1110 and I'll explain why there was no taking of property in this case and, hence, no expropriation. And that, even if there was, the claim should fail because such a taking was consistent with Canada's obligations in NAFTA. For all of these reasons, the Claimant's claims must be dismissed and Canada should be awarded all of the costs for defending against a case that, in our view, should never have been brought.

And with that general overview, let me now hand the floor to my colleague, Mr. Johnston.

MR. BORN: Can I ask you one question just to test your answer to the primary question?

Suppose that a Canadian court applied in a challenge to the validity of a patent the doctrine of public policy, and concluded without prior support in judicial authority that Canada's interests would be better served if there was no patent here, and thereby invalidated it.

Am I right in understanding that you say

that couldn't be either an expropriation or denial of fair and equitable treatment? 02:14

MR. SPELLISCY: I guess in that context it would depend on whether or not it could amount to an actual denial of justice. I would think it would be then a consideration for this Tribunal as to whether or not the circumstances of that decision by the Canadian courts, if we presume it's been appealed all the way up and it's been affirmed, whether the circumstances amounted to a denial of justice, and that standard is set out and the parties are agreed that denial of justice is covered by customary international law. Here, I don't think we have to even engage in that because the Claimant has made clear that that is not its allegation.

MR. BORN: Just staying on my hypothetical, though, suppose it was the most superlatively perfect procedure, both in the trial court and the losing patent holder appealed all the way up to the Supreme Court, again through the most superlatively perfect procedures. It's your position there could be no expropriation or fair and equitable treatment as long as there wasn't a denial of justice?

MR. SPELLISCY: I think here we're getting

into the question essentially of whether there is such a thing as a substantive denial of justice or whether it's limited to procedural due process, and without wanting to steal my colleague, Mark Luz's, thunder, I think he will address that question when we get there. 02:16

MR. BORN: Thank you.

MR. JOHNSTON: Good afternoon, President van den Berg, members of the Tribunal. My name is Adrian Johnston. I will be addressing the key Canadian patent law issues raised in this arbitration.

My submissions will be in three parts. First I will highlight important context about the patent system; second, I will address the historical record regarding the utility requirement in Canada; and, third, I will address the invalidation of Claimant's patents for atomoxetene and olanzapene.

Claimant ignores essential context about how the patent system works in Canada and around the world. The patent bargain involves the disclosure of an invention in exchange for a time limited monopoly -- that's 20 years in Canada -- and the costs to the public of a monopoly are significant. Not only does it block competition in the

marketplace; it also prevents other inventors from exploring the patented research turf. And for the public's freedom to be limited in these ways, the inventor must uphold its side of the patent bargain. 02:17

The patent bargain is not the exchange of a monopoly for the disclosure of a guess. You actually have to have invented something before you apply for a patent, and you must disclose that invention to the public. That disclosure is the *quid pro quo* at the heart of the patent bargain.

I want to draw your attention to three important aspects of how the patent bargain operates. The role of the courts, the interlocking nature of patent rules, and how private parties drive outcomes in the patent system.

Right at the outset it's important to focus on exactly what Claimant is challenging in this arbitration -- the interpretation and application of Canadian patent law by Canadian courts. Claimant is trying to interfere with three vital roles of the courts that they play in upholding the patent bargain.

First, courts are the ultimate arbiters of patent validity. When the patent office grants a patent it is not guaranteeing that the patent is

valid. The patents are presumed valid, but that is subject to challenge in court. And when a patent is declared invalid, it is void ab initio, meaning there was never a valid patent right. It is not surprising that a reviewing court might reach a different conclusion than the patent office. Patent trials are full adversarial proceedings with extensive evidence. There cannot be a full trial on each of the tens of thousands of patent applications that come before the patent office each year. The system would break down. But the inevitable consequence is that patents will be granted that should not have been. There must be some mechanism to make sure that the patent bargain was met, and that mechanism is the courts. That's why Claimant has warned its investors in annual reports for decades that there is no assurance that the patents we have been granted would be found valid if challenged. And this is not mere boilerplate for the purposes of an SEC filing. In fact in the United States roughly half of challenged patents are found invalid upon court review, including patents of great commercial value. Every experienced participant in the patent system knows that this is how the patent system works. 02:18

The second essential role of the courts is interpreting and applying the Patent Act. Claimant has singled out Canada's utility requirement as extra-statutory judge-made law. That is absurd. The word "useful" is in the Patent Act, but there is no definition provided. What this broad statutory term means has to be interpreted by the courts. 02:20

As the UK House of Lords explained in Synthon v SmithKline, "In the interpretation and application of patent statutes judge-made doctrine has over the years done much to clarify the abstract generalities of the statutes and to secure uniformity in their application."

And as the U.S. Supreme Court noted with respect to the word "useful" in U.S. patent law, "a simple everyday word can be pregnant with ambiguity when applied to the facts of life."

Patent law concepts like "useful" have been in Canada's Patent Act since 1869, but evolution in the jurisprudence is as inevitable as the changing technologies that come before the courts. It shouldn't be surprising that a patent claiming billions of chemical compounds for treating a new disease would raise different sorts of questions than a patent claiming an improved

mousetrap. 02:21

Third, and finally, court decisions on patent validity are grounded in findings of fact and determinations on the credibility of witnesses that come before the courts. Judges hear weeks of expert testimony and review thousands of pages of evidence. They deliberate and craft their reasons over months before reaching a determination of if the patent is valid. Their findings deserve and receive high deference from appellate courts. There must be a palpable and overriding error to overturn a trial judge's findings of fact on patent validity.

Another contextual factor that Claimant is keen to hide from the Tribunal's view is the interlocking nature of patentability requirements.

Claimant has framed this entire arbitration around a false presumption, that it is possible to extract one legal concept from a patent system and consider it in abstract isolation. And we heard this again in Claimant's opening remarks today. Claimant asks this Tribunal to place Canada's utility requirement under the microscope but not to consider how utility fits into the patent bargain as a whole.

Every country's legal system contains an

array of legal concepts that work together as checks and balances to ensure that the patent bargain is upheld, and utility is just one of them. Claimant presents these legal concepts as if they were water-tight compartments, and argues that this Tribunal should concern itself only with the compartment labeled utility. But that is not how patent law works. The better metaphor is the seamless garment of the law, and Claimant's water-tight compartments approach work several kinds of mischief in a case like this. 02:23

First of all, it creates a false picture of change in the law, because its myopic focus on the utility label ignores earlier jurisprudence where the same issues may have been resolved under different patentability requirements, different legal concept like overbreadth, for example.

Second, it leads to flawed comparisons among countries. Different countries pursue similar policy goals under different legal labels such as enablement in the United States.

Just in the weeks before Claimant's atomoxetine patent was invalidated in Canada a district court in New Jersey found that that patent failed the enablement requirement under a heading in

its reasons labeled "Utility/enablement". That finding was reversed on appeal, but the decision illustrates the way that similar issues have been addressed under different headings in different countries. 02:24

Third, Claimant overlooks how different patent rules work together in the context of particular types of inventions. Increased emphasis on utility is in part driven by the types of patents coming before the courts, and here I want to turn to a question that the Tribunal posed, that is, is the classification of Claimant's patents as secondary patents relevant to Claimant's claims? Canada's answer is yes, this is relevant context for this arbitration, because secondary patents can bring issues of utility to the fore.

I want to be clear, we are not suggesting that secondary patents is a legal term of art in Canadian patent law. It is not. We use it for descriptive purposes here and we have not invented it for this arbitration; it is a term used by practitioners and scholars to talk about these types of patents.

Secondary patents such as Claimant's patents for olanzapine and atomoxetine follow on

from and build upon existing patented inventions. That's the idea we're getting at with this term of secondary patents. 02:26

One example is a new use patent. This type of patent takes an old object or compound and discloses a new use for it. Another example is a selection patent, and a selection patent follows on from an earlier patent that claimed a group or genus of compounds. The selection identifies a subset of the previously patented compounds as having special advantages over the rest of the class. Discovering that advantage unique to the selected members is the invention in that context. These types of patents are allowed in Canadian law and can encourage very important innovations, we don't want to be misunderstood as suggesting otherwise, but they can also face validity problems because of what the earlier patent already disclosed.

To merit a further 20-year monopoly, the patentee must be offering something more to meet the requirements of novelty and non-obviousness, and often that something more is having discovered new and greater utility for the subject matter of the earlier patent. In these cases a particular utility is at the core of the invention. The greater the

distance between the newly discovered utility and what came before, the better the chance that the patent will meet the requirements of novelty and non-obviousness. Making strong assertions about utility in the patent can set a secondary patent apart from the earlier patent, and this puts utility front and center in what the patentee is offering the public in the context of the patent bargain as a whole. 02:27

This brings me to the third and final contextual element, which is how private parties drive the development and evolution of patent law. Utility issues are not gaining prominence on the whim of the patent office or the judiciary, but because utility is being placed front and center by patentees and patent challengers at every stage in the process, from the drafting of the patent to the patent office, to litigation before the courts. We see this in Claimant's own conduct. That's something that I'll return to later.

As discussed, some types of patents have to offer something more in terms of utility to clear other requirements of patentability, and it's no surprise, then, that when applicants are drafting such patents they are keen to emphasize the

advantages or heightened usefulness of their invention. The words used in the patent are not accidental. Patentees like the Claimant, guided by expert advice, choose them deliberately to maximize the chances of securing a patent. In patent examination, the patentee may again stress the advantages of the invention to overcome an examiner's objections and yet, again, if the patent is later challenged in court, a patentee may extol the particular utility of its invention to overcome other challenges. 02:28

When patent validity is litigated, it's important to remember that it's the parties and not the courts that are driving the process. One party argues that the patent is valid, the other argues that it is invalid, and contrary to Claimant's submissions, it is the parties that are scouring the patents, that are scrutinizing one another's evidence. It is not the courts. The court's role is simply to hear all of the evidence in argument and to apply the law in a way that is fair, just and principled. The court is a neutral arbiter of the case and the evidence that is put forward by the parties. Claimant ignores all of this context in its myopic and self-serving account of Canadian law.

I'm going to turn now to the second main part of my presentation, which is correcting Claimant's inaccurate historical account of Canada's utility requirement. It is nothing but a caricature of Canadian law that ignores the contrary evidence. 02:30

Claimant stakes its entire case on the claim that Canadian law changed dramatically in the mid 2000s with the creation of the alleged promise utility doctrine. This is false.

The Tribunal has asked whether promise utility is, in fact, a doctrine as submitted by the Claimant, and we had some discussion on that earlier today. What Claimant and its experts describe as the promise utility doctrine is not, as Claimant again suggests today, a unitary doctrine recognized in Canadian law. It has been invented by Claimant to serve its purposes in this arbitration. And what's quite telling of this is that the way Claimant has cast the doctrine over the course of this arbitration has shifted strategically.

In its notice of intent, Claimant described the doctrine as a departure from the Supreme Court of Canada's Apotex v Wellcome Foundation decision. That's the 2002 AZT decision.

Later Claimant decided that its litigation

interests were better served by considering the AZT decision as part of the doctrine instead. 02:31

Claimant's characterizations of Canadian law are nothing but opportunistic. When you remove all of the jargon of invented doctrines, Claimant is really saying that there has been three changes in Canadian law. First, that since 2005 inventions are held to their promised utility. Second, that since 2002 utility must be established before filing for a patent and cannot be proved after the fact with post-filing evidence, and, third, that since 2008, to rely on a prediction of utility, a sound prediction of utility, the factual basis and the line of reasoning must be disclosed in the patent.

As a preliminary matter, it's worth noting that only the first of these alleged changes actually concerns the threshold or the standard of utility that is required for a valid patent under Canadian law. The other two points relate, at most, to how that threshold is implemented. What is the admissible evidence and how and what must be disclosed. Canadian courts have used the term "promise doctrine" to be sure, but when they do they're only referring to No. 1 on that list of alleged changes by Claimant, to the notion that

patentees are held to promises of utility. They are not referring to the distinct rules requiring utility to be established at the filing date and requiring that the basis for sound prediction be disclosed. Because, as Claimant told you this morning in its opening statement, those rules apply whether or not there is a promise in the patent. Those rules equally apply if there is only a mere scintilla of utility, if that's the standard being applied. This is not a unitary doctrine. 02:33

There has been no dramatic change in any of these aspects of Canadian law. And as will be evident from my following submissions, the elements of Claimant's so-called promise utility doctrine all have a long history.

To be clear, Canada's position is not that there has been absolutely no change or evolution in Canadian law. That is inherent to common law adjudication and to the nature of patent law. But the notion that there has been a sea change in Canadian law is baseless.

Unable to deny the wealth of sources underpinning Canada's position, Claimant and its experts can only state that Canada's judiciary and the most prominent legal practitioners in Canada

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have repeatedly misread these sources and that Claimant's own reading of them should be preferred. Claimant attempts to rewrite or at least reinterpret legal history in Canada for the purposes of this proceeding, and that attempt lacks all credibility. 02:34

The central plank of Claimant's argument is that in 2005, Canadian courts began scouring patents and holding patentees to promises of utility found in the disclosure. This is contradicted by the historical record. But before I get to that, I want to focus on an important qualification within Claimant's own argument. And this requires pinning down some patent terminology.

There's two main parts to a patent, the claims and the disclosure, which is sometimes referred to as the description. Together they are called the patent specification, although specification is also sometimes used just to refer to the disclosure. The function of the disclosure is to describe the invention, and the claims define the monopoly claimed by the patent.

What's important is that Claimant's argument is not that it is new in Canadian law to hold patentees to statements of utility found just anywhere in the patent. Its argument is that since

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2005, courts have started finding promises in the disclosure. So what Claimant is acknowledging and what its experts acknowledge and they acknowledged this morning is that in cases where there is a promise of utility found in the claims, it has always been the case in Canadian law that that standard would have to be met in the claims of the patent. And this is how Claimant attempts to distinguish cases, early jurisprudence like the New Process Screw case, which I'm sure we will be discussing in the coming weeks. 02:36

We disagree with how to read that case, but even on Claimant's own reading, it is saying that the patent failed for not delivering the utility as claimed. The specific utility set out in the claims. So it focuses us on what Claimant is saying is new, it's finding promises in the disclosure portion of the patent, where courts are finding them, not whether patentees are being held to a statement of utility in the patent at all.

And the notion that this practice is new in 2005 is false. For decades Canadian law has been clear that patentees will be held to promises of utility in the patent specification, whether in the disclosure or in the claims. As the Supreme Court

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held in 1981 -- this is the Supreme Court of Canada's decision -- not useful in patent law means that the invention will not operate at all or, more broadly, that it will not do what the specification promises that it will do. This is the Supreme Court of Canada in 1981 saying what does "not useful" mean in Canadian patent law. Must do what the specification promises that it will do. 02:37

To avoid the reality of this historical record, Claimant has to stretch to convince this Tribunal that when the Supreme Court and other courts said "promise" in the past, they didn't really mean promise. They were just referring to whether the invention worked at all. Now, that is not only at odds with the bare words on the screen, but it is also at odds with how the word "promise" was being used and was understood by Canadian patent practitioners at the time.

The touchstone work, one of the most cited texts in the history of Canadian patent law is Dr. Harold Fox's Canadian Patent Law and Practice. In 1969 he wrote, "In those cases of patents that are based upon a promise of results contained in the specification it is not sufficient that the patent be useful for a part only of the result..."

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And in 1983, just two years after Consolboard was decided, William Hayhurst, an esteemed patent practitioner and lecturer at the University of Toronto, wrote "It is trite law that as long as that which is disclosed has some practical utility, the quantum of utility may be slight, unless the specification promises more." 02:38

The historical record is equally clear around the mid 1990s. This is, of course, when NAFTA was signed and Claimant was filing its patents. The Federal Court of Appeal in 1995 in the case of Wellcome versus Apotex, "Since the utility of a patent must ultimately be judged against its promise, the exercise requires that the specification be carefully construed to determine exactly what that promise is."

Carefully construe the specification to determine exactly what that promise is. It sounds a lot like what Claimant says is new in 2005. Once again, in the mid '90s, patent practitioners are on the same page as the courts about what this word "promise" means. "To avoid problems of false suggestion and inutility, the patent agent should be chary of promising results in the descriptive portion" -- not the claims; the descriptive

portion -- "where those results may not be achieved by things that arguably fall within the claims." 02:40

As Mr. Dimock's expert report shows, this is the tip of the iceberg of historical evidence that flatly contradicts Claimant's account of the origins of this central plank of its promise utility doctrine.

The Tribunal has asked "In what way, if any, is the identification of the promise of a patent by a judge subjective?" The answer is that it is not. The judge's interpretation is grounded in the words of the patent itself and the expert evidence submitted by the parties on how a person skilled in the art would understand the patent. Now, if this is subjective, so is every aspect of patent interpretation by the courts. Holding patentees to their promises is not an unfair or arbitrary rule. There is no obligation to make any promise of utility in a patent. A mere scintilla is still sufficient to get a patent under Canadian law. But if you make a promise, you're held to it. The patentee holds the pen when it drafts its application, and it secures the patent based on the strength of its representations. Representations of utility can enable a patentee to clear the other

hurdles of non-obviousness and utility and novelty. It is neither arbitrary nor unfair that patentees are held to the utility that they assert in their patent. 02:41

The second change that Claimant alleges is that Canada's Supreme Court, in the 2002 AZT decision, created a new rule preventing patentees from establishing utility based on post-filing evidence. This is false. To merit a patent, you actually have to have made an invention. And making an invention means establishing that what you have made is useful. If you have not done that when you file for a patent, then you have not made an invention. Deciding the point at which you can say that an invention has been made is a fraught question in any patent system. How sure do you have to be that the invention will work, how soon can you patent, at what point does speculation become invention?

Canada has, since the Supreme Court's 1979 decision in the Monsanto case, taken a permissive approach to this issue through the doctrine of sound prediction. There are two ways to establish utility in Canadian law, demonstration and sound prediction. Utility can be demonstrated by actually building and

practicing the invention, but under the doctrine of sound prediction inventors have been able to claim inventions that have not actually been built or fully tested before filing for a patent. Sound prediction lets you patent further upstream. 02:43

Patents can be obtained on those predictions so long as the prediction is sound, but this doctrine was never meant to permit patenting even further upstream at the stage of speculation or unsubstantiated predictions. Yet, Claimant argues that before 2002, this is exactly how Canadian patent law worked. On Claimant's view, it was permissible to file a patent on bare speculation or on inconclusive preliminary studies and then later conduct the research to prove that the invention actually works. This position is completely antithetical to longstanding principles of patent law. Courts have discussed this in different ways through the years, but the principle has always been there. You can't patent now and invent later.

As the Supreme Court of Canada held in its 1948 Wandscheer versus Sicard decision, "It isn't enough to obtain a patent for a man to say that an idea has floated through his brain. He must have reduced it to a definite and practical shape."

Or as the Manual of Patent Office Practice stated in 1990, "An invention may not be said to have been invented until the utility for it is known." And again in 2001, the Federal court held that "Proving actual utility at the claimed date of invention is not the only way of establishing it. Canadian patent law holds, in certain circumstances, sufficient that the inventor had soundly predicted the utility at that date." 02:44

All of these statements predate the Supreme Court of Canada's 2002 decision in AZT, which Claimant says radically changed Canadian law on this point. Claimant may prefer to live in a world where it can patent now and invent later, but this has never been allowed. The risk of abuse for speculative patenting is obvious, particularly when it comes to new use patents like Claimant's atomoxetine patent. If utility could be established using post-filing evidence, a patentee could simply file patents listing off lucrative uses for known compounds without doing any real research before filing. If a guess turned out to be correct, the patentee would have struck gold. And if it turned out to be wrong, well, it would have only lost a few hundred dollars in filing fees. And either way,

competitors would have been warded off the same research turf. 02:46

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

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

MOPOP cannot form the basis for any expectations about patent validity. It has always expressly stated that it is not an authoritative interpretation of Canadian law. It is a high-level summary, an operating manual for the patent office.

The fact that something was included in

MOPOP tells you that the patent office considered that statement relevant to its practice. It doesn't tell you definitively that it was the law. And the omission of something from MOPOP tells you absolutely nothing because of the high level and summary nature of that document. It is not a complete account of the content of Canadian patent law. 02:47

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

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

will have the promised utility. In the 1979 Monsanto case, the Supreme Court affirmed a sound prediction of utility for a group of compounds that was supported by three examples disclosed in the patent. The Supreme Court overturned the Patent Appeal Board's refusal to grant the patent holding that the Board had not provided any reason why three examples were inadequate to support a sound prediction. 02:49

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

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

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

invention is the *quid pro quo* of the patent bargain. But remember, in a case of sound prediction, this is a permissive rule for meeting the utility requirement. When you have actually demonstrated the utility of your invention, there is no dispute that you have actually done what you're claiming to have achieved to warrant a patent. But in the context of sound prediction, what you're claiming as your invention is more than you actually did before filing the patent. And in these circumstances, the patentee is not disclosing to the public an invention that is certain to work. To provide the public with a solid teaching, the patentee must at least give the skilled reader enough information so that they can recognize that the prediction is sound and is not mere speculation. And the skilled reader cannot know if the prediction is sound unless the skilled reader knows the factual basis and the line of reasoning supporting that prediction. 02:50

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

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were central to Claimant's attempts to further extend its monopoly over previously patented medicines. The story of Claimant's patents illustrates many of the over-arching themes that I've already discussed. The olanzapine and atomoxetine patents were filed by Claimant to extend existing monopolies. Claimant made and emphasized promises of utility to overcome other patentability requirements and justify further monopolies. When a generic company challenged the patents, the parties drove the litigation process, putting vast amounts of evidence before the courts. The court decisions on patent validity were grounded in findings of fact and credibility determinations. The courts were neutral arbiters of the dispute before them. There was no denial of justice.

I'll begin with olanzapine. The olanzapine patent at issue in this arbitration is known as the '113 patent. The claimant had enjoyed a monopoly over olanzapine under an earlier patent since 1980. That's the '687 patent. It covered a genus of compounds including olanzapine. As the term of the '687 patent wound down, Claimant looked to extend its monopoly. It filed the '113 patent in 1991 and 16 further patent applications for

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olanzapine in the following years.

The patent office granted Claimant's patent in July 1998. The '113 patent was a selection from the '687 patent. The '687 patent had already disclosed the compound olanzapine to the public. That invention was in the public domain since the '687 patent in 1980. And the '687 patent had already disclosed the potential for olanzapine to treat schizophrenia in the '687 patent. So that is a very important invention, and it is an invention that was made in 1980 and for which Claimant received a monopoly in 1980.

To warrant a further monopoly, Claimant had to have discovered surprising advantages of olanzapine over the rest of the genus. It's not surprising, then, that Claimant extolled the usefulness of olanzapine over the genus in its patent, stating that olanzapine shows marked superiority and a better side effects profile than prior known anti-psychotic agents and has a highly advantageous activity level.

Claimant did the same in its representations to the patent office in order to secure its patent. The olanzapine patent has come to be one of the most litigated patents in the

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history of Canadian patent law. There have been three separate proceedings challenging the validity of the patent on numerous interlocking grounds. The patent was at various points found by Canadian courts to be obvious, anticipated, insufficiently disclosed, an invalid selection patent and invalid for double patenting. In short, there were problems with the '113 patent that was at different stages addressed under different legal grounds.

In the infringement proceedings that ultimately led to the invalidation of the '113 patent, the trial judge heard evidence from 30 witnesses over 44 days. Now, earlier today Mr. Born asked whether it was -- whether the advantages stated in the patent were relevant to other patentability requirements. It is abundantly clear from the trial judgment that olanzapine lacked the special advantage over other compounds in the genus that is necessary for a valid selection patent. The trial judge found as a fact that there is no evidence that olanzapine was superior to any other compounds in the '687 class in respect of the characteristics described in the '113 patent.

So the whole point of the selection patent is to identify an advantage of this compound over

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the rest of the class. And this is the trial judge's finding of fact. There was no evidence that olanzapine was superior to any other compounds in that class. These findings led the trial judge to conclude that the '113 patent was not a valid selection patent. The Claimant appealed this decision and the Federal Court of Appeal reversed the trial judge on the basis that not being a valid selection patent was not a freestanding ground of invalidity in Canadian patent law. The requirements for valid selection have to be dealt with under the other patentability requirements. And specifically the Federal Court of Appeals said you should deal with the advantages necessary for a selection patent. Evidence of those advantages, you should deal with it under the utility requirement, and specifically through promised utility. The Federal Court of Appeal remanded the case to the trial judge instructing him to address evidence of the advantages necessary for a selection under the utility requirement. And here there's a twist in the litigation, because before the case was remanded, before it was sent back down to the trial court to be decided in accordance with utility, actually the generic challenger sought leave to

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appeal this decision to the Supreme Court of Canada. 02:57

And what did Claimant do when the generic sought leave to appeal? It opposed leave to appeal, and it said that the Federal Court of Appeal did nothing more than follow established principles of patent law and the jurisprudence of this court. This is Claimant's comments regarding the decision of the Federal Court of Appeal in which it specifically instructed the trial judge to deal with the advantages for a selection patent through promised utility. Claimant did not flag the slightest concern with the Federal Court of Appeal's instructions to the trial judge on this issue.

So Claimant has today made much of a submission for leave by a generic company calling the promise utility doctrine a free-for-all, but this is certainly not the way Claimant was referring to the doctrine in its submissions to the Supreme Court of Canada after the Federal Court of Appeal's first decision in olanzapine. The Supreme Court of Canada denied leave to appeal and it went back to the trial judge. The judge concluded that the patent promised olanzapine treats schizophrenia patients in the clinic in a markedly superior fashion with a better side effects profile than

other known anti-psychotics. This was not 02:59
subjective or arbitrary, as you can see. It essentially directly tracks the language of the patent itself. The court found as a fact that Claimant had neither demonstrated nor soundly predicted this promised utility for olanzapine when it filed for the patent. So the patent was invalid, and that holding was affirmed on appeal. There was not a single dissent. Claimant sought leave to appeal to the Supreme Court of Canada , and leave was denied.

Just as with olanzapine, Claimant had already enjoyed a decades-long monopoly over atomoxetine before it filed the patent at issue in this arbitration, the '735 patent. The Claimant first obtained a monopoly over the genus of compounds including atomoxetine in 1979. In 1985 Claimant filed for a second patent, claiming only atomoxetine for use as an antidepressant. As the term of these patents wound down, starting in the mid 1990s, Claimant filed the '735 patent and 11 other patent applications claiming to have invented new uses for atomoxetine. Some disclosed experimental data, and others disclosed nothing at all. Claimant ultimately abandoned every one of

these secondary patent applications except for the 03:00
'735 patent, which it filed in 1996 and which was granted in October 2002.

A generic drug company challenged the validity of the '735 patent in 1998 for obviousness, anticipation and lack of utility. The Federal court heard argument and evidence from six witness over the course of a 19-day trial. The '735 patent expressly claimed the use of atomoxetine for treatment of attention deficit/hyperactivity disorder. This language was in the claims of the patent, not in the disclosure. The trial judge had to interpret what treatment of ADHD meant in the claims. This was the claimed utility of the invention. The trial judge followed the longstanding method of interpreting the claims through the eyes of a skilled reader based on expert evidence. He found as a fact that in the context of a patent claiming treatment of ADHD, which is a chronic disorder, a skilled reader would understand treatment to require sustained treatment. It's on the basis of this inventive contribution that the trial judge found the '735 patent to clear the hurdles of obviousness and anticipation. That left the issue of utility.

To establish utility, Claimant relied 03:02
exclusively on the results of a small short-term study conducted in 1995 known as the MGH study. The parties introduced competing evidence, but Claimant chose not to call any witnesses with direct knowledge of the study. After carefully weighing the evidence, the trial judge made credibility findings in favor of the generic company's expert, whose opinion was that the MGH study was a pilot study with so many methodological limitations that its data were only preliminary and, at best, interesting. The court found as a fact that the MGH study was not sufficient to demonstrate the claimed utility. Nor did the patent disclose any factual basis to support a sound prediction of utility. The MGH study was not mentioned anywhere in the patent.

Claimant showed a slide this morning -- and I'm afraid I don't have the number, but you'll remember it had a stack of boxes. It was quite remarkable. And those boxes showed the effect -- what it says is the effect of the promise utility doctrine in the atomoxetine case. But the boxes aren't quite right because what they showed was that in the absence of the disclosure rule, there was enough proof to establish utility. In other words,

there was enough proof in the MGH study to show a sound prediction of utility. The trial judge made no finding of fact to that effect, no finding that the MGH study would have provided adequate support for a sound prediction had it been disclosed in the patent. And given the judge's views on the study's many flaws, it is entirely possible the patent would still have been invalid had the study been disclosed in the patent. 03:03

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

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

roots of the rules applied to invalidate its patents, Claimant is trying to rewrite the history of Canadian patent law to serve its current interests. Claimant's myopic and self-serving account should not be accepted by the Tribunal. 03:05

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

THE PRESIDENT: No questions at this stage.

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

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

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

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

Federal courts. Again, a description that Canada submits is far less biased and self-serving than what the Claimant has presented to this Tribunal. 03:08

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

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

That conclusion became inescapable once the Claimant conceded that it had no basis to argue that Canada's Federal courts and the judgments at issue here constituted a denial of justice. That concession was fatal to the Claimant's entire case. When a NAFTA party is faced with a customary international law minimum standard of treatment of aliens claim, or a claim that a NAFTA party has expropriated the property of an investor, and the impugned measure is a judgment of a domestic court applying domestic law, there is only one basis of legal responsibility under 1110 and 1105, and that's denial of justice.

This NAFTA Tribunal can only base its decision on the legal rules, the international legal rules that are encompassed by 1105 and 1110. Those rules are clear when it comes to the final judgments by an independent judiciary on a question of domestic law. If the foreign investor cannot demonstrate that after all efforts to appeal, it suffered from egregious treatment from the host state's courts or that the judgment was so astonishing that judicial propriety has to be in question, its expropriation and minimum standard of treatment claims must fail. 03:09

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

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

all of the authorities upon which Professor Douglas relies, but quickly looking through them I notice Mondev, Loewen, Jan Paulsson -- 03:10

THE PRESIDENT: I have to slow you down.

MR. LUZ: I'm sorry. I will go slower.

There are a lot of footnotes. There are a lot of authorities for this statement. It really just states what the customary international legal rule is that all previous NAFTA Tribunals have endorsed and the three NAFTA parties have endorsed.

So I will commence my argument today with the -- first on 1105, the legal standard that must be applied under 1105, and explain why in the circumstances of this case, there is no liability for Canada without a denial of justice. Then I will address expropriation under 1110. Because the challenged measures here deal only with domestic court judgments determining that a domestic property right was invalid, the legal threshold for finding a violation of 1110 is the same as it is under 1105. Denial of justice.

But I will address some of the particularities of expropriation in international law. Specifically I'll first address how the NAFTA and international law deals with the question of

whether property exists. That is a condition precedent to the second question as to whether or not expropriation of that property, as understood in international law, has actually occurred. 03:11

And the third issue I'll deal with is Article 1110(7), and that's the provision that Canada submits was intended by the NAFTA parties to prevent exactly the kind of claim that is before this Tribunal.

Throughout my presentation I'll respond to questions that the Tribunal has posed, and after my presentation I'll turn the podium back to my colleague, Mr. Spelliscy, who will address not only Canada's ratione temporis argument, but the substance, or lack thereof, in the Claimant's claim.

So first I'll deal with 1105, minimum standard of treatment. I have three arguments.

First, the legal standard is the customary international law minimum standard of treatment of aliens. Any argument as to the content of that law is a burden that the Claimant must fulfill. It must adduce evidence of uniform and consistent state practice and opinio juris to establish those rules.

Second, when it comes to domestic court judgments in litigation in domestic courts between

private parties, customary international law is definitive. Only a denial of justice will result in a breach of the minimum standard of treatment. 03:13

My third argument is that the Claimant's attempt to eliminate the distinction between acts of an independent judiciary and acts of other branches of government, that is to deny the very existence of the denial of justice doctrine, is not only legally untenable, but it would result in the same outcome anyway. And that's because the Claimant's arguments regarding discrimination, arbitrariness and legitimate expectations are legally incorrect and factually irrelevant.

So my first argument, the legal standard applicable under 1105, customary international law minimum standard of treatment. Now, we know what Article 1105 says. The text is well known. It's presented there. But what does Article 1105 mean? Well, in July 2001, the NAFTA Free Trade Commission issued a note of interpretation which clarified exactly what 1105(1) meant. It said -- and it's not in dispute that this is binding on the Tribunal pursuant to 1131. But the NAFTA FTC -- Free Trade Commission said that the concept of fair and equitable treatment does not require treatment in

addition to or beyond that which is required by the customary international law minimum standard of treatment of aliens. 03:14

A couple of critical points for the Tribunal, because it was an issue of interest for the Tribunal this morning. The first critical point is that customary international law is a true source of law. It's not simply dispensable or replaceable with whatever principles or rules that an investor, a state or a Tribunal feels that would be desirable or convenient under the circumstances. Rules of custom are established by substantial state practice and opinio juris. That is a feeling on the part of the state that it is binding -- that it is binding and they are obliged to follow a legal rule.

Now, Article 1105 has been the subject of many NAFTA claims. And I won't spend a lot of time discussing them. Cases like Cargill, Mobil, Glamis and others which have affirmed the minimum standard of treatment requires evidence of egregious treatment in order to violate the standard. The Cargill tribunal, there's a representative statement there as to how serious the kind of behavior we're talking about is in order to breach 1105.

The reason why I don't need to spend a lot

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

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

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

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

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

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

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

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

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

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

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

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

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

that now. And the position of the NAFTA parties has always been that there's no evidence of state practice to support the thesis that there's a convergence in the minimum standard of treatment and customary international law with the findings of autonomous fair and equitable treatment standards that some other Tribunals have done. That's always been the position. It's been the argument that many Claimants have made, including the Claimant in Mobil, trying to bring together the findings of Tribunals that have interpreted fair and equitable treatment clauses that have no reference to customary international law to say that this is the same thing.

And the NAFTA parties have always said that that is not the -- that is not sufficient evidence, that findings of Tribunals that are interpreting autonomous fair and equitable treatment clauses do not constitute evidence of state practice, and Tribunals like Cargill and others have acknowledged that there needs to be state practice in order to be able to establish what the Claimants are arguing.

MR. BORN: Isn't it Canada's position that the Neer standard is the only standard that is

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applicable as a matter of customary international law in addressing denial of justice?

MR. LUZ: Canada has never said that the Neer standard is -- it will be frozen in time from that.

MR. BORN: It says the opposite, the Neer standard has evolved since the 1920s?

MR. LUZ: Not on the question of denial of justice, which is the issue that is before this court today -- before the Tribunal today. There has been a recognition that customary international law can evolve, but it certainly has not evolved to the point where Claimants can simply make the bold assertion that fair and equitable treatment equals customary international law. Therefore, what one Tribunal in a different arbitration studying a different treaty says is fair and equitable treatment equals customary international law.

MR. BORN: Does Canada have a position on how much the Neer standard has evolved?

MR. LUZ: Again, on the key issue here for denial of justice, that has been -- it's not really necessarily something that was dealt with directly in the Neer case, from what I recall. But in terms of the standard that is applicable here for denial

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of justice, it hasn't evolved in a way that the Claimant has suggested, that it has evolved to a point where actions of a judiciary and the absence of a denial of justice can violate the minimum standard of treatment.

MR. BORN: And when you refer to denial of justice in this context, what you mean is your submission on the slide, that the only way that a domestic court ruling can violate the minimum standard is by a denial of justice, not by any other means?

MR. LUZ: That's right. Under customary international law, that is the standard. And there has been no evidence provided that that has changed .

MR. BORN: Not just the standard, if I can quibble. The only standard.

MR. LUZ: That is the only standard that Canada is aware of. It's difficult to come up with any kind of scenario and especially given the fact that all of the arbitral precedent that the Claimant has relied on really does not get to the issue that is before this Tribunal. The only ones that have are the ones that Canada relies on, Mondev, for example, Loewen, for example. Azinian. In fact, Azinian is actually coming in the next slide, so

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perhaps I can use that as a segue to a further answer as to what a denial of justice is.

This is where the Azinian Tribunal with Chairman Paulsson pointed out that it could be refusal to entertain a suit subjected to undue delay or to administer justice in a seriously inadequate way. Then the fourth type of denial of justice, namely the clear and malicious misapplication of the law in pretense of form and questioning the bone fides of the judgments. I believe, Mr. Born, you did ask that question sort of earlier on about is there a difference between substantive and procedural denial of justice. I don't suggest that we need to come to an arrival on that. Jan Paulsson would say that all denials of justice are procedural, that if there is a decision by a court that is so fundamentally baffling and no reasonable judge could ever come to that conclusion, that that really is a procedural failure of the entire legal system to find a correction for that. So while there -- you know, this question of clear and malicious misapplication of the law, that really is a denial of justice.

I'll come to some other quotes that really do emphasize that even if a domestic court got a

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decision wrong under domestic law or even if it was something that you could have a preferred or a better interpretation, that's not good enough. That will not violate international law. And I will come more to explain why that is the case. 03:26

SIR DANIEL BETHLEHEM: Are you hinting you'll get there but that's something like egregious irrationality? Are you grappling towards kind of a common law approach what might be unreasonableness amounting to a denial of justice?

MR. LUZ: That's right. I guess this goes back to the question as to why the denial of justice is the standard when it comes to the actions of the court. It comes down to state sovereignty and the special role that courts play as the neutral adjudicators of justice. I don't need to remind the Tribunal the importance an independent judiciary plays in upholding the rule of law and in resolving disputes. That's where why there are appellate mechanisms and safeguards in a judicial system to ensure that litigants are afforded due process, rules are applied impartially and properly as best they can within an imperfect system.

I have to say, the Tribunal knows that domestic courts face difficult questions of

substantive law, facts, procedural evidence on a daily basis. It's for those reasons that the acts of independent judiciaries are entitled to a presumption of regularity, and they are accorded great deference, especially when it comes to the interpretation of their own domestic law. 03:27

It seems to be lost on the Claimant, but it's to state the obvious that reasonable minds can disagree on findings of fact and findings of law. It's only when a judgment is so bereft of logic and foundation that international law might then question whether a denial of justice has occurred.

If I could go to the next slide, Judge Greenwood -- or Professor Greenwood at the time he filed this but now Judge Greenwood in the International Court of Justice said it, I think, very well. "The international Tribunal is not a Court of Appeal from national courts. It's not the task to review the findings of national courts. It's in the absence of clear evidence of bad faith on the part of the relevant court, the Claimant must demonstrate that it was either the victim of discrimination on account of its nationality or that the administration of justice was scandalously irregular.

The last sentence I think encapsulates what I've been trying to respond to the Tribunal's questions that defects in procedure or a judgment which is open to criticism on the basis of either rulings of law or findings of fact are not enough. 03:29

The Loewen Tribunal recognized that that was the customary standard, and again, as I mentioned earlier, the Mondev Tribunal also came to that question, and it stands out because of the striking similarities the Mondev case has to the case before you today. In that case the Claimant argued that the Massachusetts Supreme Judicial Court had engaged in a significant and serious departure from its previous jurisprudence and had rendered an arbitrary and profoundly unjust judgment. But Sir Steven and Judges Crawford and Schwebel, they were cognizant of their limited role as a Chapter 11 Tribunal and the legal rules it had to apply. They noted in the context of 1105 that it's denial of justice -- and you can see it right here. "The Tribunal is thus concerned only with that aspect of 1105 which is commonly called ...denial of justice. The standard... of treatment of aliens applicable to the decisions of the host state's courts or Tribunals."

It went on to say that, "It is one thing to deal with the unremedied acts of the local constabulary and another to second-guess the reasoned decisions of the highest courts of the state. Under NAFTA, parties have the option to seek local remedies. If they do so and [they] lose on the merits, it is not the function of NAFTA Tribunals to act as courts of appeal." 03:30

A key part of the Mondev ruling is they said that even if the courts had changed the rule and even if they had made a new rule, that was a normal part of common law adjudication. It was acceptable, and it was not at all shocking to judicial sensibility because that was the test.

MR. BORN: Just to try to pursue a little bit the hypothetical that I provided earlier to elaborate it a bit just for the sake of analysis, if Parliament adopted legislation that revoked all, I don't know, automotive parts patents on the basis that it was in the national interest to do so, that might be an expropriation. Might be. There could be defenses. But if a Canadian court reached exactly the same ruling using the doctrine of public policy for the purposes of the Patent Act, that couldn't be an expropriation because it's not a

denial of justice. Is that your position? 03:31

MR. LUZ: Mr. Born, I think I can answer that question by turning to the next slide. Mondev said, "The test is not whether a particular result is surprising, but whether the shock or surprise occasioned to an impartial Tribunal leads, on reflection, to justified concerns as to the judicial priority of the outcome."

So there is a very big difference obviously between the two scenarios that you've presented between Parliament doing something, revoking a patent. That was something that patent rights existed before and they don't exist later. What a court does when it does an invalidation in this case is that it examines whether or not the patent was valid to begin with. It's a very different kind of scenario. So in a scenario where a court comes up with a rule out of nowhere and applies it in a way that is so surprising or shocking and that no impartial Tribunal could think that was an appropriate way to deal with it, I think that would fall into what Jan Paulsson said is that that's a procedural denial of justice. It's something that represents a failure of the judicial system as a whole. So I think, again, it's

difficult to argue in the abstract, but the standards that the denial of justice, the customary international law denial of justice standard, covers those kinds of scenarios. We really are so far away from what happened in this case, I don't want to suggest at all that we're conceding that this is even in the realm of what's happening. But I appreciate the hypothetical. 03:33

MR. BORN: I'm just trying to push the envelope in terms of this step of the analysis.

MR. LUZ: Absolutely.

SIR DANIEL BETHLEHEM: Can I push it just a little bit further?

Were we to be with the Claimant on the issue of referability to Chapter 17 and were we to be against you on the question of what our competence is as a Tribunal and we come, then, to the point of 1709(8), a party may revoke a patent only when grounds exist that would have justified a refusal to grant the patent, and were we to be with the Claimant on the question that the refusal in this case was on new grounds, would that give rise to a denial of justice because it would not be within the contemplation of the -- I mean as the principle set out in Mondev here?

MR. LUZ: It would not. And international law is very clear on that. That might give rise to a question of Canada's international legal obligations vis-a-vis the United States. And that would be within the realm of a NAFTA Chapter 20 Tribunal. So there is a very big difference between the obligations that are owed to a state's counterparties and obligations that are owed under customary international law for 1105 and 1110. So that would not be, ipso facto, an expropriation. You would still need to reach the denial of justice standard. 03:34

And with respect to 1105, that is very clear from the FTC note. It says that finding of breach of another provision of the NAFTA is not a breach of Article 1105. And unless there is some other customary international rule that the Claimants can prove by substantial state practice and opinio juris, that is the rule that applies.

THE PRESIDENT: Sorry.

MR. LUZ: Please. I'm happy to answer questions as long as it's being counted towards someone else's time.

THE PRESIDENT: Can you go back to slide 67. It might tie in to the last question you had,

but in all the discussion I may have missed your answer on Tribunal question 14. If you have given it, would you be so kind to give it again? 03:35

MR. LUZ: Of course. A breach of another provision of the NAFTA or of another international treaty does not, ipso facto, result in a breach of 1105. And I gave the example of the Mobil case where there was a breach of 1106 that was found by a majority of the Tribunal; but, yet, the breach of 1105 was not found because they applied the customary international standard in that case and they were two separate issues.

MR. BORN: I was going to ask before but decided I wouldn't, but since you said it again, I can't resist. You said a breach of another obligation doesn't, ipso facto, result in a breach here. I suspect the Claimants would agree with you on that, but I think the real question is is the breach of Chapter 17 relevant and, if so, how, to a breach under 1105?

MR. LUZ: We would say that it is not. Again, because of the fact that the denial of justice standard applies to this scenario before the Tribunal. It is the decision of a court, an independent court after due consideration, that it

decided that under Canadian patent law the Claimant's patents were not valid. That cannot be, without something more, a violation of international law because at that point then the Tribunal does become automatically an appellate review for every single allegation that a Claimant might have. There has to be the egregious treatment. There has to be the level of offensiveness to judicial propriety that -- as I went to the Azinian case and other cases, and Mondev, that is what has to be reached. And I did say that there were other NAFTA cases.

If we could skip forward back to Waste Management. And I won't go through it too much, but Waste Management did the same thing. It acknowledged that the Tribunal is not a court of appeal, and it's not the role of a NAFTA Chapter 11 Tribunal to review the domestic decisions and that denial of justice is the standard. Grand River as well. They said that the Tribunal is loathe to address these delicate questions of U.S. constitutional and Indian law. Those belong in national courts, not international Tribunal.

I'd already mentioned that the United States is also onboard with Canada's position. Challenging judicial measures under 1105 is limited

to a claim of denial of justice. Mexico feels the exact same way. Mexico agrees with Canada that denial of justice is the only rule of custom that is part of the minimum standard treatment of aliens.

My third and final argument on 1105 responds to the Claimant's use of catch phrases like discrimination, arbitrariness and legitimate expectations. Labels are no substitute for analysis. Analysis confirms that the Claimant's allegations are void of merit. I'll just briefly discuss the legal standards because my colleague, Mr. Spelliscy, will talk about them in the context of actually what happened here.

Discrimination. Again, context is critical. In a domestic court proceeding, if the judge engages in local prejudice or animus against an investor because he or she is a foreigner, that's the kind of malicious discrimination that might support a denial of justice claim. But the minimum standard of treatment of aliens in custom has nothing to say about favoring one type of technology over another or domestic product or a foreign one. Customary international law allows for differential treatment. States do that all the time with respect to foreign goods and services, as the Grand River

Tribunal pointed out.

So there's been no allegation that the outcome of these trials had anything to do with Lilly's status as an American corporation, so the 1105 analysis really ends there.

Arbitrariness. Claimant doesn't say that the trials themselves were arbitrary, although depending on how you listen to what they said this morning, that might be the conclusion you come to. It's just that the Canadian court's interpretation of the word "useful" is arbitrary. This argument is less than paper thin, and I'll let my colleagues explain why, as Mr. Johnston has already said.

But the point is that even if the Claimant disagrees with the Canadian court's interpretation and even if they have some plausible or credible ideas as to why a different interpretation of utility might be preferable, a reasoned rationale based on a good-faith interpretation of the statute and jurisprudence and the assessment of facts of an Tribunal cannot be arbitrary in international law. The statement of arbitrariness, you can see from the LC decision before the International Court of Justice made it clear that arbitrariness is not something opposed to a rule of law. It's something

opposed to the rule of law.

The Cargill tribunal also went in and noted in its findings that you can't simply label something arbitrary because of inconsistency or you think there could have been or should have been a different outcome. The arbitrary label here that the Claimant uses really is just designed to second-guess the outcome of the domestic litigations and avoid the denial of justice rule.

Legitimate expectations.

SIR DANIEL BETHLEHEM: Sorry. You're setting the standard very high, aren't you? I mean if you're saying that a reasoned, rational decision based on good faith cannot be arbitrary, if it's a reasoned rational based on good faith but, for example, it doesn't take into account something which manifestly it should have because it was just not within the judge's contemplation, doesn't that change the equation? I mean I'm really just trying to put a finger on whether you're really meaning what you're saying here, whether you're stating this too highly.

MR. LUZ: I apologize if I left the words out, but a good-faith interpretation of the statute and the jurisprudence and the assessment of the

facts at trial, so something to be able to say that there was a rational and reasoned basis by a court that was not in the way that was described before in denial of justice, that had a result that was so surprising that propriety and competence had to be questioned. Obviously there is a limit to that, and we can't say that any kind of judgment by any court as long as it was written on a piece of paper that had no reasons fulfills the standard, no. Clearly not. 03:42

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

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

administrative agency changed the prior legal interpretation of certain mining rights and even though that new legal interpretation dramatically changed the regime, there was still no breach of Article 1105 without a gross denial of justice or complete lack of due process. 03:43

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

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

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

no awards or academic support whatsoever that graft the theory of legitimate expectations and then apply them to the outcome and rulings of a domestic court interpreting domestic law. It wouldn't even make sense in the domestic arena, let alone international. No court gives assurances on the outcome of a litigation. No court says that its view and interpretation of the law will not evolve or even change as new evidence, new facts, new circumstances are presented before it in trial. 03:44

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

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

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

and whether it is capable of being taken. It's universally recognized that property rights, be they patents or real estate, are defined and created by domestic law and it's exclusively a matter for a court to determine whether or not patents fulfill the criteria set out in the Patent Act. If it doesn't, there is no property that can be taken. 03:46

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

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

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

Now, let's go to NAFTA Article 1110 because that's the provision that says what expropriation is. It's well known, and I need not to get into too much of the text, but obviously it puts conditions on expropriation or nationalization of an investment of an investor if it's taken for public purpose, nondiscrimination, due process and with compensation. 03:47

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

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

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

value destroyed by discriminatory zoning laws. Here the property rights in question, the patents, were adjudicated by a competent court to be legally invalid under the legislation that establishes how those property rights are created. So unless there is an attack on the bona fides of the court, international law accepts that the claimant does not have their property taken or value destroyed. The property right was invalid to begin with. That's neither a direct nor an indirect expropriation. And the reasoning behind this really lies at the heart of the NAFTA and international law. I'll explain. 03:48

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

very well accepted in the academic literature, and I have four of them but I won't go through all of them, but just point out the first one where it says the relationship between domestic law and expropriation. 03:50

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

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

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

through that, but the NAFTA parties are all together on this. 03:51

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

There is no support for the Claimant's

contention that this scenario that is before the Tribunal that the validity of a property right that has been determined by a domestic court is invalid can constitute an expropriation. Mark Cantor here said there was a dearth of precedent which could end the analysis of international law after a mere paragraph, and that mere paragraph cites the Loewen case, and the Loewen Tribunal recognized exactly what Canada is submitting, that reliance on 1110 adds nothing to the claim based on 1105. 03:52

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

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

Under GEA v Ukraine, again, that was another case where there was a question as to whether or not the actions of the courts were being impugned. The Tribunal found that there was no evidence of egregious behavior, and that could not constitute an expropriation. 03:53

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

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

$3,000 of compensation for shares that were valued at $350 million before. The cases that they rely on are so completely inapposite to what happened here. They demonstrate the kind of egregious behavior that, even if the Tribunal doesn't call it a denial of justice, they all demonstrate that level of egregiousness that has to be reached. 03:55

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

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

discussion on this issue and I'll leave some of the more specific issues to my colleague, Mr. Spelliscy. But the NAFTA parties are in agreement that this is intended as a shield to expropriation claims. It's not intended as a jurisdictional hook for Claimants to somehow get into Chapter 17. The reason for that, as Meg Kinnear pointed out, is that this would cause incredible mischief on the domestic law patent regimes of the NAFTA parties (slide 107). 03:56

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

of the jurisdiction of this Tribunal to assume the role of a NAFTA Chapter 20 Tribunal or a WTO panel interpreting the TRIPS or anything else. 03:58

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

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

shouldn't say "there's no doubt" but there would be a question as to whether or not there has been an expropriation of otherwise valid property rights. Then in that case 1110(7) provides the defense or the safe harbor for a NAFTA party to say well, it was done in accordance with Chapter 17, ergo 1110 does not apply. A very different scenario of a court determining that a patent is invalid under the domestic law. So I think that really gets to the heart of it. 03:59

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

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

MR. LUZ: Only if the Tribunal finds that

there has been an expropriation, so the question becomes is there an expropriation and then, at that point, that would be a defense that Canada or a NAFTA party would put forward for consistency with Chapter 17. 04:01

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

MR. LUZ: I'm sorry?

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

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

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

point. It still has to be an expropriation before you get to the consistency test. 04:02

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

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

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

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

THE PRESIDENT: Could you please take the

text of 1110(7))? It's always a problem if there are double negatives in a legal text or otherwise. If you take out the two negatives, of course it is a bit of an undertaking but let's do it for sake of the argument, then it would read: This article applies to the revocation of intellectual property rights in the event that the revocation is inconsistent with Chapter 17."

Is that a permissible reading?

MR. LUZ: No, because again, the question for an expropriation still comes into play. You still have to determine -- and my colleague Mr. Spelliscy has a couple of examples of where you would have that. But, again, the first question is always is there an expropriation, and you won't get to that point if there isn't.

THE PRESIDENT: Maybe we can make another suggestion, because I'm looking at the court reporter. Shall we take a break?

MR. LUZ: I think so.

THE PRESIDENT: You are, of course, allowed to continue after the break.

MR. LUZ: No, I am done. I'm sure my colleague, Mr. Spelliscy, will address any other issues that are remaining.

SIR DANIEL BETHLEHEM: I'll put a question to him that I would have put to you.

THE PRESIDENT: Recess until 4:20.

(Recess taken)

THE PRESIDENT: Please continue opening statement for Respondent.

MR. SPELLISCY: Thank you, President van den Berg. Good afternoon again.

As I explained in my opening remarks this afternoon, I will now spend the remainder of Canada's opening statement explaining the four reasons why you should reach the conclusion that this claim must fail. Let's turn to the first.

As Mr. Luz has explained, Canada, the United States and Mexico agree as to the meaning and application of their treaty, NAFTA. When it is a judicial measure applying domestic law that is being challenged under 1105 or 1110, the only possible claim is that there has been a denial of justice. The Claimant has never alleged that it was denied justice in any way by the Canadian courts. To the contrary, it has expressly stated that it is not alleging that it was denied justice by the Canadian courts. And I think that it is helpful to take a look at some of these to see what it has said. In

its reply Memorial at Paragraph 17 it states, Lilly's claims do not rest on denial of justice. It further clarifies that it is not claiming it was not afforded procedural justice. In Paragraph 217 of its reply it states, "Canada emphasizes the procedural history of each case. Canada recites the number of witnesses each trial included and the number of days each trial spanned, maintaining that the judges carefully weighed and extensively analyzed the evidence through months of deliberation. Canada does this because it would prefer to litigate whether the proceedings in Canada were procedurally fair. But that is not Lilly's case."

And it further clarifies that the Canadian courts correctly applied existing Canadian law in invalidating the Claimant's patents. Specifically in Paragraph 334 of its reply, it clarified, "Lilly has not alleged that the Federal court and Federal Court of Appeal misapplied Canadian law as it stood in 2010 and 2011." There has been no allegation of a procedural denial of justice. There's not even been an allegation that the Canadian courts got Canadian law wrong in some egregious way. As there has been no allegation of any type of denial of

justice, the Claimant has failed to state a claim as a matter of law, and this action should be dismissed promptly, with costs.

However, even if you do not agree with Canada, the United States and Mexico as to the proper interpretation of their own treaty, I will still walk through with you three other reasons why this claim must be dismissed.

Let's turn to our second point, that this claim is time barred. As an initial matter, let me start with the Claimant's complaint that Canada's objection is untimely. In its questions to the parties, the Tribunal asked "Is Respondent's objection to jurisdiction ratione temporis untimely, as Claimant submits, and if so, what are the implications?"

We have laid out clearly in our Rejoinder both why the Claimant's claim did not become clear until its reply and why Canada -- and how Canada constantly put the Claimant on notice of a jurisdictional objection should it be the doctrine that was being challenged.

Originally the Claimant challenged the specific court decisions. It called those decisions relating to its olanzapine and atomoxetine patents

shocking and unexpected. However, as the quotes we have just reviewed above from its Reply Memorial show, the Claimant has retreated from these allegations. It now challenges what it identifies as a judicial doctrine itself. As a result, Canada's raised this objection in its Rejoinder as soon as it could. 04:25

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

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

As the rules are drafted, there is the

presumption that there will be a Notice of Arbitration, a Statement of Claim and a Statement of Defense. If we look to Article 22, we see that there is no presumption in the rules that there will necessarily be further written statements. Article 22 provides that the Arbitral Tribunal shall decide which further written statements, in addition to the Statement of Claim and the Statement of Defense, shall be required from the parties or may be presented by them. 04:26

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

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

hearing, and the Claimant was given the opportunity to respond in writing. As there is no prejudice here, Canada's objection to the jurisdiction of the Tribunal must be considered. So with that, let's turn to the substantive question of the limits of the Tribunal's jurisdiction. And in particular, the rules in NAFTA Articles 1116 and 1117. In its questions to the parties the Tribunal asked "what is the significance, if any, of the patent for Raloxifene in this proceedings?" In the next several minutes I am going to answer this question. I will do so partly by asking the following question: Could the Claimant have brought the exact same allegations it brings here, specifically that the judicial interpretation by the Canadian courts of the utility requirement in Canada's Patent Act violates Canada's obligations in articles 1105 and 1110. Could it have brought these exact same allegations to NAFTA Chapter 11 arbitration after the Raloxifene decision in 2008 and 2009? The answer is yes, it could have, but it didn't. And it has never answered the question of why it didn't and it avoided that entirely today. 04:28

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

its decision not to bring that challenge, this claim and the challenge to what the Claimant has labeled the promise utility doctrine must be dismissed as beyond the jurisdiction, ratione temporis, of the Tribunal. Let me offer that explanation why. We'll go to Article 1116(2). 04:29

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

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

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

constructive knowledge of the measure or measures question. Second, there has to be knowledge or constructive knowledge that the measure has caused loss. Let's look at the first. 04:30

Now, to do this, I could call back to the slide that Mr. Johnston showed you outlining the components of the doctrine, but I also recall that the Claimant's presentation this morning had a similar slide. And what I found interesting about that slide was that it was slide 17 and what I found interesting about it was that it did not have dates on it. So let's put some dates on it.

In doing so, I'm just going to accept that the Claimant's descriptions as to when the relevant doctrines in Canadian law arose for the purpose of considering this objection.

According to the Claimant's description of the radical change in Canadian law, it began in 2002 with the decision of the Supreme Court in AZT that a patentee must establish the utility of its invention before filing for a patent. Then it continued with several court decisions beginning in September of 2005 when, according to the Claimant, Canadian courts began to scour the patents for promises beyond those in the claims.

Then according to the Claimant, it ended in 2008 or 2009 when the appeal was heard, when the Federal Court adopted what the Claimant itself has called the Raloxifene rule, and that judgment was affirmed. That rule is the one that requires a basis for a sound prediction of utility to be disclosed in the patent. This is what the Claimant calls the promise utility doctrine, as I understand it. 04:32

As I said, I want to leave aside the factual dispute between the parties as to whether these changes occurred and just accept that they did, and I want to leave aside the dispute about whether this is a single doctrine as alleged by the Claimant and accept that it is.

As Canada pointed out in its Rejoinder, all three aspects of the radical change that the Claimant alleges occurred in Canadian law were actually applied to the Claimant in a decision in 2008, and that's because the Raloxifene case was about the Claimant's patent.

The trial court applied all three aspects. The Claimant appealed. But the Federal Court affirmed the decision on March 25, 2009. The Claimant appealed again to the Supreme Court, but

the Supreme Court refused to hear their case on October 22, 2009. 04:33

In their response to Canada's Rejoinder, and this morning as well, the Claimant did not dispute that, by the time that its request for leave to appeal the Raloxifene rule was denied by the Supreme Court on October 22, 2009, it had knowledge of all the aspects of the alleged dramatic change in Canadian law that it hinges its allegation of a breach of NAFTA upon. But it says -- and it said this morning -- that this is merely factual context for its claim.

That is incorrect.

Remember, this is a dispute, as of the Reply at least, about the doctrine itself, not whether the doctrine was correctly applied in the two cases for atomoxetine and olanzapine. If this was a claim that the promise utility doctrine was somehow inappropriately applied at Canadian law to its patents for atomoxetine and olanzapine, then we could discuss the doctrine, its development as factual context. But it is not that claim. The Claimant is not alleging the misapplication of Canadian law to its atomoxetine and olanzapine patents.

So by October 22, 2009, at the very latest, the Claimant had knowledge of the existence of all of the aspects of Canadian law that it bundles together and labels the promise utility doctrine. By no later than that date it had knowledge of the measures that it alleges breaches NAFTA. 04:34

So let's come to the second aspect of Article 1116(2). The only question is whether the Claimant knew or should have known at that moment in October of 2009 that it had suffered a loss. I want to focus on the language here.

The language of Article 1116(2) is, in our submission, clear. It says "knowledge that the investor has incurred loss or damage". It does not require that the investor know of a specific loss or even how much of a loss has been suffered by its investments. As the Tribunal in Mondev stated, "A Claimant may know that it has suffered loss or damage even if the extent or quantification of the last or damage is still unclear."

In our submission there is one question. Did the investor know or should it have known that it incurred loss or damage because of the measures it alleges breaches NAFTA? There can be no dispute

that the Claimant knew of a loss. As Canada explained in its Rejoinder, after the proceedings with respect to the Raloxifene patent finished, a competitor was allowed to enter the market and the Claimant suffered loss as a result. 04:35

The Tribunal in its questions asked, "According to Respondent, what is the meaning of the United States' statement that the time limitations period in Articles 1116(2) and 1117(2)... relate to the particular investment for which the investor seeks a remedy for the breach and loss?"

Of course I'm not really in a position to explain what the United States meant, but I believe that the U.S. position means that if the investor did not know and could not have known that a breaching measure would be applied to a particular investment causing loss to that specific investment, the limitations period will not begin to run.

Put simply, I believe that the U.S. statement simply means that the investor must have knowledge, actual or constructive, in relation to a particular investment. This is not an issue in this case. Let's look beyond the Claimant's losses with respect to Raloxifene and consider instead, as it suggests we must, only its patents for atomoxetine

and olanzapine. The conclusion you should reach with respect to its knowledge of loss concerning those patents is no different. 04:37

Again, as we saw a few minutes ago, the Claimant has admitted that it is not alleging that the Canadian courts incorrectly applied Canadian law as it existed in 2010 and 2011 in invalidating its patents with respect to atomoxetine and olanzapine. So what does that mean?

It means that you must accept that the Canadian courts correctly applied Canadian law as it existed after that decision to the Claimant's patents, and it must be assumed that the Claimant was capable of correctly understanding Canadian law in 2009 and, therefore, that it would understand how, correctly applied, that law would affect all of its other patents.

Now, what happened after the Raloxifene decision? According to the Claimant, the Canadian courts have done nothing more than continue to apply the same interpretations of Canada's Patent Act. In fact, I think I heard the Claimant this morning confirm that, in their view, Canada has been in breach of its obligations under Chapter 17 since 2005 and that the breach was made more egregious by

the disclosure rule in Raloxifene. As we heard their claim for a breach of NAFTA Article 1110 is based on the claim of a breach of Chapter 17, the international law that they claim is a source of expropriation. 04:38

But whether it is with reference to 2002, 2005, 2008, 2009, it doesn't matter. As Tribunals have recognized, and all three NAFTA parties have confirmed, the statute of limitations period in NAFTA is not renewed simply by one of the parties engaging in a continuing course of conduct. As Canada explained in its submission, the use of the word "first" marks the beginning of the time when knowledge of a breach and a loss existed. Not the middle or end of a continuous event or series of events. In other words, once the investor first acquires knowledge of the alleged breach and that it has suffered damage, the limitations period for filing a claim commences and will end at the three-year mark regardless of whether the impugned measure continues thereafter.

As the United States explained in its Article 1128 submission, "under articles 1116(2) and 1117(2), knowledge is acquired as of a particular 'date'. Such knowledge cannot first be acquired at

multiple points in time or on a recurring basis. Once a Claimant first acquires or should have first acquired knowledge of a breach and loss, subsequent transgressions by the state party arising from a continuing course of conduct do not renew the limitations period under Articles 1116(2) or Article 1117(2)." (Slide 127). 04:39

As Mexico similarly commented, "Neither a continuing course of conduct nor occurrence of subsequent acts or omissions can renew or interrupt the three-year limitation period once it has started to run."

I think perhaps the best applicable summary of the reason for such a strict non-renewing limitations period comes again in the Grand River case. I think you will see there is no more of an apt description of why this claim is also time barred for the same reasons that the Tribunal in Grand River highlighted. In rejecting the idea that subsequent acts allowed the Claimant to evade the three-year deadline to file a claim, the Tribunal in that case explained, "... this analysis seems to render the limitations provisions ineffective in any situation involving a series of similar or related actions by a respondent state, since a claimant

would be free to base its claim on the most recent transgression, even if it had knowledge of earlier breaches and injuries." 04:40

As I have explained, the Claimant's claims here amount to nothing more than the exact same sort of improper attempt to base a claim on the most recent alleged transgressions in a series of similar actions by Canada, even though it was without question that it had knowledge of the earlier alleged breaches and injury. The Claimant cannot avoid the limitations period in NAFTA simply by pleading its case as only related to specific investments to which a known and understood law has yet to be specifically applied, especially not when it knew or should have known how that law would affect and cause loss to those investments.

The limitations period in NAFTA depends on knowledge, whether actual or constructive, not the strategic decisions made by counsel in how to plead the case.

MR. BORN: Would I be right in thinking that the consequence of that analysis is that the Claimant, and I guess also other companies, should bring NAFTA arbitrations before any invalidation litigation has been started, or I guess even

threatened? 04:42

MR. SPELLISCY: I think I said in our view this is an alternative argument. So when you are challenging the acts of a court, you can bring a denial of justice claim. A denial of justice claim would not be time barred. You can challenge the application, you can challenge the procedural fairness, but if what you are looking to challenge is the actual judicial doctrine and you are not disputing that judicial doctrine was wrong, then the three-year limitations period starts from the moment at which you knew of the measure, and you knew or should have known of the loss that would occur to your investments.

MR. BORN: But your colleague, Mr. Johnston, pointed out -- I thought very ably -- how the Canadian patent litigation process is party-driven, and it might well be the case, I assume, that many patents would never be challenged and it would seem from your answer that nonetheless, if what one is doing is challenging the judicial doctrine, one would need under that analysis to begin a NAFTA arbitration before there's been a judicial challenge from a competitor and perhaps in circumstances where there would never be one.

MR. SPELLISCY: You would be required to bring a judicial challenge under NAFTA to the judicial doctrine as soon as you were aware and you had adequate constructive knowledge of breach and loss. I think it's interesting because it does get back to whether or not on constructive knowledge and if you don't have an investment that's affected, when do you have adequate constructive knowledge. And I would suggest that that's what makes the patent in Raloxifene so important in our view in this case. This is not really a question of whether Lilly had constructive knowledge of the doctrines and the laws. It did. It was its patent in the Raloxifene decision. It was its patent that was invalidated under these same three doctrines, which is why I wanted to focus on the language in Article 1116(2), which is a loss. 04:43

SIR DANIEL BETHLEHEM: Can I follow up on that and the proposition from your colleagues that the courts are neutral and the revocation of a patent is not certain until it happens? How, then, do you address the issue of 1116(2) and knowledge of the loss if the revocation of a patent is entirely speculative until it happens?

MR. SPELLISCY: I would think that I would

come back to what the Tribunal in Mondev said which is that you don't need to know of the extent of the quantification of loss. What I would suggest is in a situation where you don't know on the outcome of the litigation but that you do know that this doctrine exists -- and we can take it back particularly to the atomoxetine patent, and I will pull up a slide later. The judge in that case essentially said it follows inevitably from the existing law that Raloxifene and all the way back to AZT that the patent is invalidated. It has to be understood that it really could have appropriately evaluated the loss or the potential harm to its patent. It may not have known of the specific effect on each individual patent, but it would be able to evaluate and assess and have knowledge of some loss or some diminution in the value of its patents even before they were challenged. 04:44

SIR DANIEL BETHLEHAM: That's not the issue that Mondev was addressing, though. Mondev was addressing the quantification of loss within the context of the same case, and it must surely be the case on the thesis that you put that in respect of the two patents at issue in this case, until they came before the court and were struck down, they

were speculative and therefore how could one even identify that there would be a loss whether or not it was quantifiable? 04:46

MR. SPELLISCY: Again, I think it comes down to the assumption that we can assume that Eli Lilly would understand how the law would be appropriately applied, and they have not alleged here that the law was inappropriately applied. They have alleged that the law was correctly applied. And so when we understand that the law was correctly applied, I think that answers the question. They would have been aware of some loss but not necessarily the exact quantification.

Let me try and approach the question --

THE PRESIDENT: Sorry, may I follow up on that point?

MR. SPELLISCY: Yes.

THE PRESIDENT: Is it one thing to be aware of the doctrine and another thing to be confronted with the application of the doctrine, and especially in the context of what you mentioned, the loss. Until you have an invalidation of your patent, you don't know whether it will be first invalidated with finality, and the second thing is you also don't know whether you will have a loss,

even quantified or not. So is it not more that you have to look at the application rather than the awareness of the doctrine itself? 04:47

MR. SPELLISCY: I think I would suggest -- I was going to say we approach this in a slightly different, in a hypothetical that had been raised, what if this was legislation. And if this was legislation that applied that said certain patents were going to be taken away. You don't wait, you can't wait until that legislation is applied against you in order to bring a challenge under NAFTA. In a sense, the NAFTA parties have a valued peace in terms of the litigation process with respect to their policies above some of the other aspects that might be challenged.

THE PRESIDENT: Are you sure about this? Because in my previous life as a litigator -- although I still am from time to time --

MR. SPELLISCY: I've seen!

THE PRESIDENT: -- clients always ask you how much percentage do we have a chance of succeeding or the other side losing, and you have to be very careful giving percentages, that I learned as a young lawyer. More recently you become slightly more confident and give some percentages

but never above 70 percent. How do you know that you will win or lose the case, now in the case of invalidation of a patent? 04:48

MR. SPELLISCY: I think the answer to this comes back to the point that we have made, that if the law is clear and the law is crystallized -- and what we've been talking about here are some of the rules that were applied, for example, in the atomoxetine case. The rule developed in Raloxifene is that you cannot rely upon a study that was not included in your patent. If we look, and we'll get to that, you will see in the decision it fails for that reason. The Claimant would have known that immediately after Raloxifene that, if it was challenged in court, it could not rely upon that decision.

SIR DANIEL BETHLEHAM: Yes, if it was challenged in court. What happens if it was not challenged in court? If Novopharm took the view that there was no economic reason for it to challenge it in court, for example?

MR. SPELLISCY: Yes, and I think this comes back to sort of the fundamental question on this argument, and what is the extent of the constructive knowledge that you need to have. Does

NAFTA worry about whether or not, in order to challenge a law or legislation, that law or legislation has to be applied to you? 04:49

Now I come back to what I said earlier, that if this is actually a case that the law was inappropriately applied to Lilly, there would be no issue of time bar. So we can consider the question of the court in terms of the application of the case, but in our view what we cannot go back and challenge and what we cannot go back and question is the judicial doctrines at play, because if we did that, that would mean that essentially the statute of limitations in NAFTA means nothing.

What's to stop, if the Canadian courts continue to apply this doctrine, what's to stop the next time it happens, an investor from bringing a claim ten years from now? 25 years from now? Right at the end of its patent life? There is nothing to stop that. That's why I come back to, when it's the judicial doctrine that is being challenged, that is the judicial doctrine that's the source of the alleged breach, that's when we bring the limitations defense. And it's why it wasn't raised earlier.

If we just want to talk about the application, whether the cases were shocking,

whether the application of the doctrine was unexpected, we can talk about that. It's in the context of the denial of justice. But if we do want to come back and address the law and we want to have Article 1116(2) mean something in terms of the law, then we have to look at when that law was known and when it could be evaluated as to how it might affect their patents. 04:50

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

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

patent, there should be no dispute at that point that the statute of limitations period began to run. 04:52

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

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

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

But what they're challenging is not those determinations. What they're challenging is simply the application of well settled law that had existed for, in their view, at least three years. In our view, decades. And if we don't have a rule that says you can't sit on your hands and wait until -- and choose which to bring them to, then I would suggest that we end up with the situation in Glamis, that we are just allowing Claimants to bring actions for the most recent alleged transgression in a series of continuing acts. And I think it's important. They have not alleged that the law changed after Raloxifene. And that's the key point from our perspective. 04:53

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

doctrine it must be dismissed. 04:54

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

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

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

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

dramatic change in the law? I think, related to what we were just discussing, the doctrine is a doctrine and if time bar is not an issue, if the Claimant is right and time bar is not an issue, then why should it matter when that doctrine came about? 04:55

In this regard I note in its questions to the parties the Tribunal asked, "If one were to accept Respondent's factual submission that the promise utility doctrine is 'several distinct patent law rules, all of which were part of Canadian law when the Claimant filed its patents', what implication would this have on Claimant's claims?"

As I will show you, the reason why the Claimant is so emphatic in its arguments that these interpretations that it challenges are new, is that if it cannot prove that, the claim would not be in the jurisdiction of the Tribunal.

As the Tribunal in Gami made clear, NAFTA arbitrators have no mandate to evaluate laws and regulations that predate the decisions of a foreign investor to invest. As a recent Tribunal in Mesa reiterated, "As a consequence investment arbitration tribunals have repeatedly found that they do not have jurisdiction ratione temporis unless the Claimant can establish that it had an investment at

the time that the challenged measure was adopted." 04:57

In this case the Claimant has identified the investment that it claims had been accorded treatment in violation of 1105 and 1110 as follows. Lilly's Zyprexa and Strattera patents, which each encompass a bundle of exclusive property rights and the ability to enforce those rights, qualify as investments under Article 1139. You heard them reiterate that again this morning. There is no other claim that any other investment of the Claimant was treated in a way that violates Canada's obligations under Article 1105 and 1110 of NAFTA, nor could there be because the patents here were not even held by the Claimant's Canadian enterprise and there is no evidence of the investment in research and development with respect to these patents in Canada.

Hence, the real cut-off date for this Tribunal's jurisdiction is when those patents in Canada existed. As Mr. Johnston has explained, the Claimant was granted a patent in Canada for olanzapine in July of 1998, for atomoxetine in October of 2002. So what does that mean? Again, the Claimant can't challenge the interpretation of Canada's Patent Act by, at least if we use the

atomoxetine date, under doctrines prior to 2002. 04:58

Now, I want to make something quite clear here. This is not a jurisdictional issue with the way the claim has been pled. That claim is that there was a dramatic change in Canadian law after the Claimant made its investments.

However, in answer to your question, if you agree as a matter of fact with Canada that the doctrines in question here have long existed in Canadian law, existed at least prior to 2002, then there is no claim. The Claimant's claim that there has been a dramatic change in Canadian law beginning in 2002, or potentially 2005 depending on how we interpret what they said this morning, is a necessary condition for the Claimant's claim to proceed. If you find they are wrong, as I suggest that you will after hearing the evidence of experts like Mr. Dimock this week, their whole claim fails and there is no need for you to even consider the application of Articles 1105 and 1110 on the merits.

I would like now to come to my fourth point as to why this claim must fail, and that is even if you were to consider Canada's obligations further under Articles 1105 and 1110, this claim must still be dismissed.

First I will explain how the Claimant has failed to establish a breach of the customary international law minimum standard of treatment of aliens. As a reminder, and as Mr. Luz has explained, the law with respect to the customary international law minimum standard of treatment as applied to the measures of the judiciary is clear. The only applicable rule is denial of justice. Any other sort of review would turn investor state arbitration tribunals into courts of appeal. But even if you disagree and decide to examine the challenged measures against the standards that the Claimant has alleged, but has not proven, are contained in Article 1105, there is no breach here. I will address three separate points on 1105. 04:59

Canada's law on utility is, first, not discriminatory. Second, not arbitrary. And, third, not inconsistent with the Claimant's legitimate expectations. In short, even if the Claimant is correct as to the legal content of the Article 1105 when it comes to assessing judicial conduct -- and it is not, but even if it was -- the interpretation given to Canada's Patent Act by the Canadian courts is nowhere near the sort of conduct required to breach Article 1105, and let's start with the first

allegation, discrimination. 05:00

I will not say overly much here for two reasons. First, my colleague Mr. Luz has covered it and I would reiterate what he said. The idea that customary international law prohibits discrimination on the basis of a field of technology is truly beyond the pale. The fact is that customary international law does not even prohibit discrimination on the basis of nationality generally. That is why NAFTA contains express nationality-based antidiscrimination provisions in Article 1102 and 1103.

You will recall I believe there was at some point an allegation of a breach which isn't here anymore. There is no allegation in this case about nationality-based discrimination under Articles 1102 and 1103.

Second, the Claimant's allegations of discrimination against the pharmaceutical sector are based on a flawed statistical analysis that I propose to discuss not here but actually later in the context of Article 1709(7). When we do so, we will see that the challenged doctrine does not discriminate by industrial sector. It applies to all sectors and has resulted in invalidations in

sectors outside of the heavily litigated pharmaceutical patent field. 05:02

As Canada has shown, when the correct data is analyzed none of the differences between the application in the different sectors are statistically significant. In short, there is no evidence of any sort of significant disparate impact of the judicial interpretation the Claimant challenges on the pharmaceutical sector.

Let's now turn to the second alleged way in which the judicial interpretation given to the utility requirement in Canada's Patent Act allegedly violates Article 1105. The Claimant alleges and came back to it again this morning that the judicial interpretations of Canada's utility requirement since 2002 are arbitrary.

As Mr. Luz has explained in his reference to the ELSI case, careful attention must be paid by the Tribunal in understanding what arbitrary means, even if it is part of the minimum standard of treatment, which has not been proven.

The Claimant argued this morning about decisions in the cases involving its atomoxetine and olanzapine patents. I recall slide 24 where the Claimant put up a quote from the decision in the

olanzapine case, I believe, and what I found interesting was what was not highlighted on the slide. The court in that case said that it did not find the promise of the patent so small as alleged by the Claimant. At the beginning of the next sentence, which was not highlighted, he stated that he was deciding that based upon the wording of the patent and the evidence before him. This was a decision of the trial judge on the facts and on the evidence presented to him. 05:03

The Claimant also referred at length this morning to the MGH study in the context of the atomoxetine patent, and suggested that the judge in that case inappropriately dismissed the quality and importance of this study. Again, that is a question of a decision on the specific evidence before the trial judge in his judgment.

The Claimant also referred to several cases not involving its patents, I think it was the Latanoprost decision, and claimed that the fact that different outcomes were reached proved the arbitrary nature of the doctrine. I am, to say the least, surprised at how the Claimant can put all of this to you and ask you to find that this means it is arbitrary. In asking you to reach the conclusion,

Claimant is essentially asking you to review the factual record of those cases, to examine how those cases were pled, and then to conclude that they should have been decided differently and that the conclusions of the trial judges on the extensive evidence before them were wrong, and the request that you consider this as part of an arbitrary analysis baffles me because in other parts of their arguments, and today as well, they have suggested that they are not asking you to act as a supranational Court of Appeal and, yet, reviewing the decisions of a lower court for errors of this sort is essentially one of the key functions of a domestic appellate system. And it is what the Claimant is suggesting you do in this arbitrariness analysis. 05:04

I think throughout the first several hours of their presentation this morning, what you saw was basically the same appeal that the Claimant has been making in the Canadian courts and the same appeal that has been rejected. I mentioned I would get to this.

You recall, Mr. President, that you referred to a part of the decision in the atomoxetine case on slide 37 of the Claimant's

presentation, where the court said that the disclosure rule was determined in an earlier decision and to the extent that it may be amenable to reconsideration it must be examined elsewhere. 05:05

The Claimant seems still to be suggesting that this Tribunal is the "elsewhere" where its arguments may be reexamined. The Claimant is wrong. The "elsewhere" is the appellate process available to the Claimant in the Canadian courts. It's not the role of a Chapter 11 Tribunal.

As Mr. Luz has explained, a truly arbitrary judicial interpretation of Canada's utility requirement would be one for which there is no plausible rationale or law or reason. And for the reasons that have been explained at length by Mr. Johnston, which I will not repeat in detail here, one simply cannot say that the way the Canadian judiciary interprets Canada's utility requirement in the Patent Act is arbitrary.

Let's briefly consider them. First let's consider the requirement that the Claimant alleges arose in AZT, specifically that a patentee must have established the utility of its invention by the time of the filing, and it cannot rely on evidence generated after its patent application. Is this

arbitrary? 05:06

As Mr. Johnston explained, a patent is a limited time monopoly given in exchange for the disclosure of an invention. It is not a limited time monopoly in exchange for the disclosure of a guess or a prediction, even if that guess or prediction leads to an effective or important medication.

If one were to allow the introduction of post-filing evidence to prove that the invention actually met the patentability criteria, the state would be encouraging guessing and speculation and prediction. A requirement to prove that you invented before you filed for a patent is not arbitrary.

Let's move to the second now, which is a requirement in Canada that your invention have the utility that it is actually promised to have in the patent. Remember, as Mr. Johnston explained, in Canada there is no requirement that your patent promise any particular utility. If it works, a mere scintilla will do. But if you make promises in order to get over problems with obviousness and novelty you will be held to them.

I would suggest to you that holding

someone to their promises, especially where they themselves want to hold on to those promises for other patentability criteria, is not arbitrary, and I would suggest we would not want to live in the legal world where it was. 05:08

Finally, let's turn to the last element of the doctrine here, the Raloxifene rule, as labeled by the Claimant. Again, that's the evidentiary rule that the basis for a sound prediction be disclosed in the patent itself.

As Mr. Johnston has explained, disclosure is at the heart of the patent bargain and it must be disclosure sufficient to teach a person of ordinary skill in the art how to understand the advancement represented by the invention. You cannot teach a sound prediction unless the factual basis and the line of reasoning are disclosed. As he's explained, there is nothing arbitrary about requiring such evidence to be in the patent if it is not common knowledge of people skilled in the art.

In sum, there is nothing arbitrary about the way that the Canadian courts have interpreted the utility requirement in Canadian law and it is not for this Tribunal to substitute its views as to what might be more appropriate for those of the

Canadian courts. 05:09

MR. BORN: Can you help me for just one moment? What do you say the rationale is for the rule that the patentee will be held to all of its promises in the patent? If we start from, if you will, a baseline that a mere scintilla of utility will do, what's the rationale for saying that if a patent fulfills three out of four of its promises, it will still be invalid if it doesn't fulfill the fourth?

MR. SPELLISCY: I think it comes back down to what we heard a little bit earlier today about reading up and reading down in the patents. To the extent that a patentee is relying upon these promises in order to get over problems of obviousness, over problems of novelty, courts are construing the patents to find out what the invention is, and if the invention involves a promise of heightened utility then, in fact, you will be held to that promise of heightened utility.

I come back to the atomoxetine patent which was the one that said it would be used to treat ADHD and there was some discussion by the Claimant and Mr. Johnston earlier about what that is. Again, the court had to understand what it

meant to treat ADHD so it looked to the description to understand what was the promise, what was the invention, what was being described. And that was a promise of long-term effectiveness. It's a determination he made on the facts and the evidence before him. 05:10

So to the extent that you are offering, you're describing in your disclosure, in your description, in your specification generally your invention as offering, as granting enhanced benefits, then you will be held to that.

MR. BORN: Thank you.

MR. SPELLISCY: Let me turn, finally, to the last aspect of the Claimant's allegation of a breach of Article 1105, that the judicial interpretation by the Canadian courts of the Patent Act is contrary to what they say are their legitimate expectations.

This is an allegation that entirely depends on the Claimant's assertion that there's been a dramatic change in Canadian law since it obtained its patents. I believe we have already shown you and will show you through the evidence this week that there has been no such dramatic change. Moreover, even if there has been a change

in how the utility requirement of Canadian law has been interpreted by the Canadian courts, this cannot be relevant to a claim regarding the expectations of a patentee. In its questions to the party the Tribunal asked: Do Respondent's grants of Claimant's patents constitute specific representations to Claimant in the context of determining Claimant's legitimate expectations? 05:11

They do not. The Claimant suggested this morning that the grant of a patent does create some sort of expectation about validity. Patent grants do not create an expectation that such patents will withstand validity challenges in the courts. This fact is among the core principles of the patent system, and we saw an acknowledgment of this fact by the Claimant itself in its regulatory filings in the United States. The granting of a patent by a state is not a specific representation made by the state about the validity of the granted patent. That is an issue for the courts. In fact, patent offices grant patents based on the specific representations made by the patentee in its application.

But even taking a step further back and looking at this more systematically, the Claimant today discussed how in its view the Supreme Court of

Canada overturned decisions in making its findings in AZT, and later they explained that their legitimate expectations claim in terms of an alleged radical change in Canadian law. In our view to suggest that a court decision interpreting the law, even if it does so in an unexpected way, to suggest that that can ever violate customary international law would be to attack the very heart of the common law. 05:12

In systems governed by judicial precedent, like those of the United States, Canada, and the UK for that matter, it will and does happen that the courts will overrule longstanding, binding precedent. Indeed, some of the most important legal decisions in our systems involve the overruling of longstanding, binding legal precedent. It simply cannot be correct to conclude that every time a domestic court does so -- not just offer new interpretation but actually overrule precedent -- it simply cannot be correct to suggest that that state violates customary international law every time.

For these reasons, even if legitimate expectations could be considered relevant to Article 1105 generally, they do not apply in the context of judicial decisions interpreting domestic

laws. 05:14

Let me now, finally, turn to our explanation of why there has been no breach of Canada's obligations under Article 1110 of NAFTA.

THE PRESIDENT: Before you do that, may I ask a question on the last point?

If you look to Article 1709(8), I will read it to you, "A Party may revoke a patent only when: (a) grounds exist that would have justified a refusal to grant the patent", so, asking the other way around, do you read this provision to mean that you may only revoke a patent on grounds on which you would have refused to grant the patent?

MR. SPELLISCY: This is going to steal my thunder a little bit when we come to 1709(8) in the context of expropriation but let me offer this. The answer is no. This does not lock Canada, the United States or Mexico into any ground that existed or any standard of utility that existed at the time that a patent was considered and granted. The parties in the United States and Mexico -- the United States has made clear, for example, in their Article 1128 submission, and we'll see this later, that 1709(8) did not require the NAFTA parties to freeze their intellectual property laws from the date of review

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

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

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

THE PRESIDENT: Can you repeat that?

MR. SPELLISCY: I think if we pull up -- I don't have a slide for it unfortunately but I think the way to think about this is that what the parties

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

THE PRESIDENT: Could it be that this does not prohibit the evolution of the law but it may prohibit to apply to a particular patent grounds for invalidation that are different for refusing to grant the patent, to this specific patent?

MR. SPELLISCY: I think what would happen in that case is you would have different law applicable to every single patent that was out

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

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

THE PRESIDENT: What you're saying is that this applies to the moment that you revoke a patent, at that moment in time that ground should also exist to refuse in the first place the patent?

MR. SPELLISCY: Yes.

THE PRESIDENT: Okay. Thank you.

MR. SPELLISCY: We may be able to skip that when we come to 1709(8) later.

MR. BORN: I'm struggling to reconcile that interpretation with the language "would have justified", which seems to be pretty backward-looking. Not "would justify".

MR. SPELLISCY: Yes. I think that when we look at this language, that a party may revoke a

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

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

have courts looking back and trying to parse which authority was out at which individual time. And that's something that, again, is antithetical to the common law judicial system and would create a morass in which to assess these patents. The law has to be applied as it exists at the time that a case comes before the court. 05:20

Let's come to Article 1110.

As I explained at the beginning of my opening remarks this afternoon, I will explain with respect to Article 10 why there's been no unlawful expropriation for a number of reasons. Three. First, I will explain that a court invalidation of a patent is a determination that property does not exist. It cannot amount to an expropriation.

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

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

unlawful expropriation. 05:21

Let's start with our first point. As Mr. Luz explained this afternoon, this is a point that all three NAFTA parties agree on. For there to have been an expropriation, there must have existed property at the domestic law of the NAFTA party that could be taken by the state. Let's recall again that the property that the Claimant said was expropriated is its two patents for olanzapine and atomoxetine. In its questions to the parties the Tribunal has asked: "Do Claimant's patents constitute property capable of expropriation within the meaning of Article 11101 of NAFTA?" I think this also provides some answer to our struggles and our questions on Article 1110(7). There are circumstances in which patents can be taken or expropriated by the state. Some of those circumstances would represent legitimate state actions consistent with Chapter 17. For example, under the law of all the NAFTA parties, if a patentee abuses its patent rights, the patent can be taken away. If we look to Section 66 of the Patent Act, we see that in Canada the Commissioner of Patents may order a patent to be revoked if compulsory licensing is inadequate to remedy an

abuse of patent rights. Such a revocation would amount to an executive action, taking a property right that existed at the time. 05:22

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

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

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

at all that could be taken. And when a domestic court makes a determination that the property did not exist, as the Federal courts did with respect to Claimant's atomoxetine and olanzapine patents, it is not an expropriation or taking that can give rise to a claim under Article 1110. 05:24

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

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

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

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Articles 1105 and 1110. The Tribunal would have jurisdiction to hear such a claim. 05:25

As became clear for the first time in their Reply the Claimant has made no such claim here, so as a result it cannot bring a claim under 1110.

This leads to my second point on the application of Article 1110, which will allow us to get perhaps into these questions, which is on the application of Article 1110(7).

The Tribunal has asked the parties "What are the implications of Article 1110(7) for Claimant's claims?" Let me spend a few minutes answering that question. We'll come back to the language of Article 1110(7) because it provides, "This article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter 17."

As Mr. Luz has explained, Article 1110(7) is a further shield or safe harbor for the NAFTA parties in the instance where they do, in fact, take

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intellectual property rights. For example, where we have the Commissioner of Patents taking a patent right for abuse. But they do so in a manner consistent with the obligations in Chapter 17. Again, this I think responds a little bit to Sir Daniel's question earlier about Chapter 14 and the exclusion in Article 1101(3). The exclusion Article 1101(3) is doing something very different. It is saying it is not covered at all -- matters covered by 14 are not covered at all. They're not within the scope of Chapter 11. 05:26

Article 1110(7) is doing something different. It is saying that if it is consistent with Chapter 17 it is not under this article. Article 1110. That doesn't mean that there might not be a claim under other articles; it is just applied to this article. And to come back to, I think, what Professor van den Berg has asked, this doesn't mean that there is no situation in which Article 1110(7) -- or Chapter 17 could not be analyzed by this Tribunal.

There may be a question about whether an act is consistent with Chapter 17. You may be called upon to decide whether or not the defense of consistency with Chapter 17 is a valid defense under

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Article 1110(7). There is a slight variation. You should not find a breach of our Chapter 17. That is for a Chapter 20 Tribunal. But if you find that an act is not consistent with Chapter 17, then you are permitted to consider whether there has been an expropriation under Article 1110. But at that point Chapter 17 no longer has anything to do with it. It becomes a question of whether there is an expropriation under Article 1110. Chapter 17 is a shield, but it is not a sword. A breach of Chapter 17 doesn't tell you anything about whether there has been a breach of Article 1110 of NAFTA. 05:27

MR. BORN: What's the difference between finding something isn't consistent with Chapter 17 and finding there's been a breach?

MR. SPELLISCY: I think it gets down to a question of jurisdiction really. In effect, it would just simply mean that you can consider Article 1110. But whether or not you could actually find a breach of the obligation as a matter of jurisdiction, you are limited to Section A of Chapter 11 of NAFTA. So in practical reality, I think that the determination you would make is the same, is the measure consistent with. But in terms of the formulation of what your finding would be I

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would suggest that you would say either it has not been proven that it is consistent with Chapter 17 and therefore we consider Article 1110. But, again, this is a last resort. A safe harbor. A shield for the NAFTA parties. It is not something that you should wade into, and Article 1110(7), as all the NAFTA parties have made clear, is not a gateway to Chapter 17 determinations. 05:29

What it was designed for was an extra caution or an extra shield so that the NAFTA parties who knew that there could be a revocation of a patent -- and we saw Section 66 of the Act. Revocation of a patent under Section 66 of Canada's Act would be potentially -- it would depend upon the factual evidence but it could be a substantial deprivation of the rights of that patent. In that case you might have an expropriation claim.

What the NAFTA parties wanted to make clear was that, if that act was consistent, if that taking was consistent with Chapter 17, you don't even engage in the 1110 analysis.

THE PRESIDENT: Basically what you're saying is -- please correct me if I'm wrong -- it is an entry ticket where you may not see the show?

MR. SPELLISCY: What I would suggest is

that it is -- I wouldn't describe it as an entry ticket but using that, if it is an entry ticket, you still have to determine whether the obligations have been complied with in order to see if the defense is valid. But actually finding a breach of the provisions of that chapter as opposed to simply that it is not consistent with, it may seem like a small distinction but a distinction that is important in the limits of the jurisdiction of this Tribunal. 05:30

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

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

intellectual property rights, and we saw one on Section 66 of the Act. 05:31

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

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

SIR DANIEL BETHLEHAM: So, just to be clear, you're not saying to us we are not competent to look at Chapter 17. You're just making the causation point? 05:32

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

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

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

Chapter 10 or 11 to become a sword for the Claimant. So in fact at that point what you then need to do is analyze whether there has, in fact, been expropriation, and this is where we get to the questions of whether there is actually been a substantial deprivation, the standard of legal expropriation under denial of justice. 05:34

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

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

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

What are the applicable rules of international law there? 05:35

MR. SPELLISCY: Typically when we come down to it really the Vienna Convention on the Law of Interpretation, how do you interpret the obligations, you're in customary rules of international law.

SIR DANIEL BETHLEHAM: So you're saying they're only procedural rules, not substantive rules? Because I forget whether it was you or the Claimant was invoking Article 31(3)(c), other relevant rules of international law of the Vienna Convention on the Law of Treaties. So you're saying that applicable rules of international law in 1131(1) does not refer to substantive obligations?

MR. SPELLISCY: What I would say is that it certainly does not allow you to sit in judgment of substantive obligations in other treaties, and I think I heard the Claimant say today, or resile against the idea that they were opening up the jurisdiction by introducing the idea that there has to be a breach of some other rule of international law. I think I also heard them earlier today talk about Chapter 17 as being part of the arbitration agreement that it's in the same treaty and maybe

they just misspoke, but in fact, Chapter 17 is not part of the agreement to arbitrate. Chapter 11 is. There's no reference to Chapter 17. Chapter 17 is subject to state to state dispute resolution, so I don't think that you can at all incorporate obligations such as those in Chapter 17 through Article 31(1). That is not what that is trying to do. 05:36

THE PRESIDENT: At a later moment you may need to explain it again, 1110(7). I think I'm not entirely with you on the point. I understand what you're saying is one way is indeed, when it is not consistent, then you may consider it, the revocation under the angle of expropriation, but you may not go further than that and go into Chapter 17 to see whether there is a breach of the obligations.

I find conceptually for me it is a difficult thing, but maybe it's late in the day. Maybe you can explain it tomorrow or on one of the other days.

MR. SPELLISCY: Let me take another shot at it now. I agree with Mr. Born that the distinction we're drawing here between consistency with Chapter 17 as a defense and a breach of Chapter 17 is a fine line to be drawn. But I don't

think that it's the overly relevant question here when you come to consider whether there's a breach of Article 1110. And that's the point that I want to be clear on because we're going to spend some time here talking about Chapter 17. Because even though I don't propose to spend a lot of time on it today, because in our view this is a shield we do not need in this case, because there are so many reasons that the Tribunal in our view should refrain from involving itself in Chapter 17, it's not necessary, and the meaning could be left to the state parties, to NAFTA and Chapter 20 dispute tribunals. 05:37

THE PRESIDENT: You remember the question I asked the Claimant this morning as well, how do you connect the legal dots, how do you get Chapter 17 into 1110? Maybe it's the same theme I'm playing here.

MR. SPELLISCY: And I would suggest to you that the answer is that the only reason you consider Chapter 17 is to understand whether Article 1110 might apply at all to the taking of intellectual property right. That is the only relevance it has. If you determine that it is not a shield, you must then find an expropriation. And Chapter 17 tells

you nothing about that. The Claimant's theory that they can prove an expropriation by referring to a breach of the principles of Chapter 17 is fundamentally wrong. 05:39

As Arbitrator Bethlehem said, this is an issue that a breach of Chapter 17 does not cause a breach of Chapter 11. A breach of Chapter 17 is not a sword, it is a shield. The only relevance it has to you is whether Canada can hold that shield. If you determine that the measures are not consistent with Chapter 17, it means Canada does not have that shield and you proceed with an 1110 analysis.

SIR DANIEL BETHLEHAM: But it may conceivably be useful -- sorry, I'm just trying to clarify -- it may conceivably be useful for purposes of, for example, making an assessment as to whether the public purpose requirement in 1110 has been satisfied evidentially, if you like?

MR. SPELLISCY: Right. I think if you are consistent with Chapter 17 one of the things that would be recognized is that there was a public purpose for it. Chapter 17 outlines a number of the things that the NAFTA parties are agreed are acceptable. But it does come back, and why I say it's not a sword -- or why I say Article 1110(7)

exists, why it was drafted, is because that wouldn't be enough to save a question on Article 1110. You would still need to pay compensation if Article 1110 applied. 05:40

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

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

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

Article 1701(1), Article 1709(1), Article 1709(7) and Article 1709(8). Each of their allegations of a breach is without merit. 05:42

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

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

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

perspective beyond the myopic one suggested by the Claimant. 05:43

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

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

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

industrial application' to be synonymous with the terms 'non-obvious' and 'useful', respectively." 05:44

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

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

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

patents to any invention that happens to be new, non-obvious and useful. In French, the relevant language is -- and I apologize to my French colleagues -- "... (French language spoken) ...".

So in French the language is "can grant" or "will be able to grant." It is not a mandate to grant. It does not say "shall" grant.

In Spanish the relevant language is ... (Spanish language spoken)...

So in Spanish again the language would be closer to the parties "will determine the grant of patents". It is not a mandate to grant a patent even if the invention is new, non-obvious and useful. Why? And let's turn back to the English version to examine the question further. I think that the explanation is relatively simple.

While the three patentability criteria listed are core criteria, they are not the only conditions that any of the NAFTA parties required at the time they concluded NAFTA or require now in order to obtain a patent. In fact, as Mr. Johnston explained, the core of the patent bargain is actually disclosure. One can manufacture an invention that is new, non-obvious and useful, but the inventor will not be entitled to a patent for

that invention unless he or she adequately discloses it to the public, and you can scan all of Article 1709. Disclosure is not mentioned a single time. Not once.

The NAFTA parties adopted no text at all that referenced, yet alone regulated, what they could require in terms of the most important obligation on the patentee and the patent bargain disclosure.

Mr. Born asked earlier today about other requirements. I'd point out that nowhere in 1709 do the NAFTA parties limit themselves in terms of the other requirements for a patent that they may have in their national laws. The reference was to enablement, or written description. In short, the introductory text Article 79(1) makes clear that it is not imposing an obligation on when a NAFTA party must grant a patent. It is establishing a number of necessary conditions that an invention must have to be considered for the grant of patents, but it is not outlining which conditions are sufficient.

What is sufficient for each of the parties to grant a patent with respect to both the core criteria themselves and other criteria is clearly and unequivocally left to their own domestic laws.

I think that even looking at the first three paragraphs of Article 1709(1) as a group shows this.

Article 1709(1) starts off with the proviso "Subject to paragraphs 2 and 3". Let's look at paragraphs 2 and 3. They are again about what is patentable, not about when a patent must be granted. I would suggest that if you read 1709(1) closely you will see that it is also truly about what types of inventions will be patentable in the NAFTA parties. It does not create an obligation on the NAFTA parties to grant patents even if an invention is new, non-obvious and useful.

I suggest to you that this fact should heavily influence how we then consider the meaning of what some of those necessary conditions are in the latter half of the sentence. Let's turn to the latter half and look at the necessary conditions --

SIR DANIEL BETHLEHAM: Before you get there may I just ask you, 1709(3), the second paragraph of that, notwithstanding subparagraph (b), 1709(3): "Notwithstanding subparagraph (b), each party shall provide for the protection of plant varieties through patents". That's requiring.

MR. SPELLISCY: This would be shall provide for the protection through patents meaning

that the patents -- I think that doesn't set the condition on when they shall be granted, but it is saying that patents must be available for plant varieties.

SIR DANIEL BETHLEHAM: I see. Thank you.

MR. BORN: Isn't the basic assumption of 1709(2) and (3) that there are some obligations with respect to patentability? There wouldn't be exceptions if there wasn't an obligation.

MR. SPELLISCY: I think that the answer is -- that yes, the idea is that there will be things that can be considered for things that are patentable, and I would suggest that that is what actually 1709(1) means. But to be patentable doesn't mean you are entitled to a patent. You still must meet other conditions. It just means you qualify for consideration for a patent. And that was a big thing at the time that NAFTA was being drafted, because there weren't the same rules on all inventions that were patentable among the parties, and I think if you look at the protection of plant varieties through patents again is an example, where the NAFTA parties were expressly saying you shall provide for the protection of plant varieties. Let's go to the next slide and turn to the latter

half and talk about "useful" in Article 1709(1). 05:51

The Claimant alleges that the term "useful" in 1709(1) must mean something, and on this, the parties are agreed. Of course it must have meaning. But the Claimant's suggestion as to how the Tribunal should understand the meaning of the phrase "useful" suffers from numerous flaws.

As Mr. Johnston explained earlier today, it focuses solely on utility, ignoring the interaction of that criteria with the other patentability criteria, particularly in the case of secondary patents and criteria like disclosure or enablement. It also importantly confuses the standard of utility with how a NAFTA party implements that standard.

In fact, as you will recall from Mr. Johnston's presentation, and the Claimant's as well, of the components of what the Claimant alleges is Canada's promise utility doctrine, only one is about the promise standard itself. It is the first, and that is the only one about what utility means. The rest are about how utility is implemented and the evidence that Canadian courts require to prove utility. And, as we have just gone through, Chapter 17 says absolutely nothing about the

evidence that the NAFTA parties can or cannot require in order for a patentee to prove that its invention is useful, or to prove that it should obtain a patent even if its invention is patentable. 05:52

Things such as disclosure and evidentiary rules are entirely outside of the scope of coverage because they relate to what will be sufficient to obtain a patent. As such, for the purposes of Chapter 17, the only relevant aspect of the Canadian doctrine that the Claimant is challenging is a requirement that, in order for it to be deemed useful, the invention must be useful for what it says it will be useful for rather than only for some use somewhere at some point.

The Claimant suggests that such a requirement is in breach of Article 1709(1). However, a proper Vienna Convention analysis shows its claim is without merit. As Canada explained in its written submissions, a proper analysis of the meaning of Article 1709(1) considers, 1, the ordinary meaning of the terms "useful" and "capable of industrial application" as understood in the patent laws of the NAFTA parties; 2, the context of 1709(1); 3, the subsequent practice of the NAFTA parties; 4, other relevant rules of international

law; and 5, to the extent necessary to eliminate ambiguity, any relevant supplemental means of interpretation. 05:53

Canada has laid this Vienna Convention analysis extensively out in its written submissions and I don't intend to repeat it here, especially given the limited relevance of these provisions in our view to what you must truly decide in this case.

As Mr. Johnston laid out earlier, Canada's law required that an invention must be useful for what it says it will be useful for for decades before NAFTA was signed. All of the NAFTA parties would have understood and accepted this. In this regard I note that in its questions to the parties the Tribunal has asked "What is the relevance, if any, of the utility standards in other NAFTA jurisdictions with respect to Claimant's claims?"

I think the answer to this is that the only relevance would be in the context of a Vienna Convention analysis, where it would be considered as relevant to both the ordinary meaning of the term when the parties agreed to NAFTA, to the context of that provision, and the subsequent practice of the NAFTA parties. I believe that the evidence this week from the various experts will show you two

things, both that the NAFTA parties all seek to achieve the same policy goals with their patent laws, though sometimes using different doctrines, and that there has never been a time when the definition that the Claimant seeks to ascribe to the term "utility" has been accepted by all of the NAFTA parties or by the rest of the international community. 05:55

There has always been variation how "utility" is understood and Article 1709(1) was certainly not meant to resolve that debate. If the NAFTA parties had meant to adopt the very specific definition of "utility" the Claimant now advocates must be read into 1709(1), they certainly could have done so. They would have had no reason to resort to subtlety and to interpretation of the word "utility."

When you look to the ordinary meaning of the term "useful" as the NAFTA parties would have understood it, and when you consider it appropriately in the context of the provision in light of the subsequent practice of the parties and other relevant rules of international law, there can be only one conclusion. Article 1709(1) does not have the specific and restrictive meaning that the

Claimant would like it to have. In fact, I would suggest that it is particularly telling that you have the submissions of the three NAFTA parties in front of you in this arbitration and not one has agreed that the Claimant has appropriately described the meaning of the term utility in Article 1709(1). 05:56

In sum, as fully set forth in our written submissions, even if you accept that the Claimant's assertion that the judicial interpretation of Canada's utility requirement has changed since 2005 -- and you should not, but even if you do -- there's still been no breach of the flexible standard contained in Article 1709(1).

Let's finish our look at Article 1709 quickly for the rest of this, because the hour does get late.

Let's turn to Article 1709(7) which provides in relevant part: "Subject to paragraphs 2 and 3, patents shall be available and patent rights enjoyable without discrimination as to the field of technology..."

As I noted a few minutes ago, since 2005 alone Canada has issued more than 13,000 pharmaceutical patents. The Claimant nevertheless claims a breach of this article because it alleges

that Canada's purported promise utility doctrine discriminates in fact against pharmaceutical inventions. This argument is ill-founded. 05:57

The Claimant relies on the expert report of Dr. Levin in order to ground its claim of discrimination. Certainly as far as I can tell Dr. Levin has done his math right. The problem is in the dataset that was provided to him to analyze.

As Canada has explained and as is extensively detailed in the witness statements of Dr. Brisebois, the issue is that the Claimant has provided a biased and inaccurate dataset to Dr. Levin. When appropriate corrections are applied and corrected to reflect reality, there has not been a statistically significant difference in utility based invalidation rates between pharmaceutical and non-pharmaceutical patents since 2005.

To come back to something that was raised earlier, even if the Claimant's statistics were accurate, as the United States noted in its Article 1128 submission, differential effects of a measure on a particular sector, even if shown, do not necessarily prove discrimination as to field of technology within the meaning of Article 1709(7).

In sum, the Claimant has adduced no

evidence of discrimination in law or in fact with respect to pharmaceutical inventions. Canada has acted consistently with its obligations in Article 1709(7). 05:58

Now we come to Article 1709(8), and we'll do this very quickly because we did talk about it earlier. As explained, Article 1709(8) was in no way intended to curtail the power of the courts to continue their role in interpreting the broad requirements of patent law. I mentioned this, and we can pull it up now. As the U.S. has pointed out in their 1128 submission, "Nor can Article 1709(8) mean that the NAFTA parties are required to freeze their intellectual property laws indefinitely from the date of review of a given patent. Article 1709(8) allows for evolvement of patent law."

In short, even if there has been a substantial change in the judicial interpretation of Canada's utility requirement, such a change does not violate the rules in 1709(8).

Let me turn very briefly to the third and last point I want to make on 1110 before I get to some concluding remarks. The Tribunal asked according to the Respondent if one were to accept the Claimant's allegation that Respondent's actions

were inconsistent with chapter 17, what effect would this have on Claimant's claim under Article 1110. I hope that we have answered this question sufficiently this afternoon. 05:59

The Tribunal also asked the parties, "What is the relevance, if any, of the Patent Cooperation Treaty, for the purposes of determining Claimant's claims?" The answer to this question is that there is none.

Now, I would suggest that contrary to what the Claimant told you this morning, the Patent Cooperation Treaty, like Chapter 17 and their arguments thereon, could only be relevant if you determine that the Claimant was right that you could sit in judgment of a PCT member's obligations in the context of deciding whether there has been an expropriation under 1110.

As I mentioned earlier in my remarks today, you cannot do so. The PCT is not incorporated in any other way into NAFTA but, as my colleague Mr. Luz explained, the same reason that makes Chapter 17 irrelevant is the same reason that makes the PCT irrelevant for the causation question of whether there has been a breach of Article 1110.

I would note that even if you could

consider the PCT, the evidence of Mr. Gervais and Mr. Reed will show that the Claimant has failed to establish a breach of any of Canada's other international obligations, and we'll get to that. 06:01

But the real question here is whether there has been a taking of the Claimant's property that amounts to a substantial deprivation of the Claimant's investment in violation of Article 1110. As I've explained, that is a question that neither the PCT nor Chapter 17 give you any answers to.

The Tribunal also asked the parties what are the implications, if any, of the Respondent's argument that the Claimant has not been substantially deprived of its investment.

Let me say this. The Claimant bears the burden of proving that the measures in question have resulted in the substantial deprivation of the value of its investments. Earlier the Claimant said that it was agreed that there has been a substantial deprivation simply because the patents were revoked. It's not been agreed. The Claimant bears the burden of showing that the value of its investments, its patents, was, in fact, substantially deprived even though it can continue to produce and sell its products in Canada. As Canada has explained in its

written submissions, it has not met this evidentiary burden of proof and, thus, it has failed to prove a violation of Article 1110 of NAFTA. 06:02

Now, let me offer you some concluding thoughts, and I will try to do this by summarizing these thoughts into a decision tree that I think will represent exactly how farfetched the Claimant's claim is.

As I said at the beginning, if you agree with Canada, the United States and Mexico as to the meaning of the Treaty they signed, then the only possible cause of action that can be brought with respect to the judicial decisions of a neutral independent court is a claim for denial of justice. There is no allegation of a denial of justice in this case and, hence, there is no claim here. This case should be dismissed as a result.

However, even if you consider the Claimant's challenge to the judicial interpretation of Canada's Patent Act justiciable in the absence of a denial of justice, it has been brought too late. NAFTA does not allow an investor to bide its time, sit on its hands, and bring a challenge to the most recent application of an older doctrine or law. The Claimant knew of the measures in question and the

losses it would suffer as a result by no later than 2009. It waited four years to bring a claim. As such its claim is time barred and should be dismissed. 06:03

Even if you disagree, however, this case must still be dismissed before you consider the legal merits of the claims, and that is because the necessary factual predicate for this claim is not present. As I explained earlier, the Claimant has grounded its claim on the idea that there has been a change in Canadian law, a dramatic change. It cannot do otherwise because if it is wrong and no such dramatic change occurred, then the doctrines and interpretations it wishes to challenge existed prior to its making its investments and cannot be challenged by it.

As Mr. Johnston has shown you earlier today and, as will be made clear in the testimony of the experts you will hear, there has been no dramatic change in Canadian law. Therefore, this claim fails for that reason as well.

It is over before there is any need to even consider the merits of the Claimant's allegations, but even if you did move on to consider the substantive protections offered by Article 1105

and 1110, and even if you accepted some of the standards that the Claimant has argued, the claim would still fail. There has been no conduct which breaches the standards of customary international law that are applicable under Article 1105. There has been no taking of property at all, let alone an expropriation in violation of Canada's obligations under Article 1110, so this claim of breach must be dismissed for that reason as well. And it should be dismissed with a full award of costs to Canada so that future claimants will be appropriately dissuaded from a similar misuse of Chapter 11 dispute resolution. 06:04

Thank you.

THE PRESIDENT: Thank you, Mr. Spelliscy. That concludes the opening statement by Respondent?

MR. SPELLISCY: Yes, unless there are questions?

THE PRESIDENT: I think you have heard already a sufficient number of questions.

Thank you. I think we can close the hearing for today and resume tomorrow morning at 9:00. I think the first witness is Mr. Armitage, as I understand it, for the Claimant?

MS. CHEEK: Yes. Mr. Armitage, that's

correct. 06:05

(The hearing closed at 6.05 pm)

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