**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.  

Saturday, 4 June 2016

(Pages 1562-1837)

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- Mr. Denis Martel
- Mr. Ryan Evans
- Mr. Brad Jenkins

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Thank you.

DANIEL GERVAIS
Presentation by Professor Gervais...............1741

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DANIEL GERVAIS
Presentation by Professor Gervais.................1741

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1  the closings we come up with a number of questions.
2  The Tribunal was also thinking that it
3  might be useful after all to have post hearing briefs
4  to see how -- and this is now the way we consider the
5  post-hearing briefs -- how the evidence we have heard
6  over the days of the hearing ties into your case, and
7  then summaries for the positions of each of the
8  parties on each of the main issues in this case, so
9  that we will correctly capture them in the arbitral
10  award.

MS. CHEEK: That's very helpful.

12 Thank you.

THE PRESIDENT: And you give the
14 reference to the main documents and transcripts in
15 those summaries of your case in the post-hearing
16 brief.

MS. CHEEK: Very good. We'll proceed
18 accordingly.

19 THE PRESIDENT: We don't want to miss
20 an issue. That's the point. Anything else?
21 MR. SPELLISCY: Not from Respondent.
22 THE PRESIDENT: Thank you.
23 JAY ERSTLING.
24 THE PRESIDENT: Mr. Erstling, good
25 morning.

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25 morning.

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1 the role of the PCT, on the PCT's industrial
2 applicability standard, and on Canada's sound
3 prediction requirement as it relates to the PCT's
4 form and contents requirements, as that has bearing
5 on this in case of view of the invalidation of the
6 Strattera patent, which was a PCT application.
7 The PCT is at the very heart of the
8 international patent system, and since,
9 Mr. President, you spent time in WIPO, you probably
10 have an understanding of the role that the PCT plays
11 in WIPO. The PCT is a multilateral treaty that was
12 adopted in 1970 and came into effect in 1978 that
13 establishes an international patent application
14 filing system.
15 Among its many advantages, it allows a
16 patent applicant to file a single international
17 patent application that has effect in all PCT member
18 countries instead of having to file an individual
19 application in every country in which the applicant
20 wants to have protection.
21 The PCT system is governed by the text
22 of the Treaty as well as by a detailed set of
23 regulations. Currently there are 148 contracting
24 states. Canada has been a member of the Treaty since
25 1990. The Treaty is extremely widely used, including

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1 correct pronunciation of "Wipo". We said "Wipo".
2 But they said no, no, the man on the 13th floor says
3 you may not use Wipo, you have to use W-I-P-O,
4 because he considered that Wipo was a detergent in
5 the bathroom!
6 PROFESSOR ERSTLING: That's right.
7 THE PRESIDENT: I wonder, do we
8 correct it also now amongst IP lawyers, so that we
9 use the correct pronunciation? Which is it?
10 PROFESSOR ERSTLING: Now it's okay to
11 say "Wipo".
12 THE PRESIDENT: Okay, Ms. Cheek?
13 NS. CHEEK: Ms. Wagner will direct the
14 examination of Mr. Erstling.
15 NS. WAGNER: Good morning,
16 Professor Erstling. We can begin by having you
17 deliver your presentation, please.
18 PRESENTATION BY PROFESSOR ERSTLING
19 PROFESSOR ERSTLING: Thank you. My
20 name is Jay Erstling and, as my background indicates,
21 a major force in my life has been the
22 Patent Cooperation Treaty, or PCT, as it's known, and
23 the PCT continues to be a major factor in my teaching
24 and practice. For that reason, Eli Lilly has asked
25 me to serve as an expert witness in this matter on

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Its purpose is to root out inventions that defy laws of nature, that are simply not operable, or workable, or inventions the use of which has not yet been determined.

In the second phase, the national phase of the PCT process, an international application is converted into national applications in all the countries in which the applicant actually wants to pursue patent protection, and from that point on national prosecution takes place.

To be clear, there is nothing in the PCT that is an effort to create substantive patent law. The PCT does not harmonize patent law, nor does it constrain Canada's substantive utility test that it can apply in the national phase.

Article 27(5) makes clear that nothing in the Treaty or the regulations is intended to be construed as prescribing anything that would limit the freedom of a contracting state to adopt the substantive conditions of patenability that it wishes.

In a similar vein, PCT Article 27(6) provides that national laws may require applicants to furnish evidence in respect of substantive conditions of patentability. There is nothing in the PCT to constrain a member country from requiring the submission of additional evidence in the national phase.

There is nothing in the PCT that the body of rules is referred to as "rules," but the individual regulations are referred to as rules, so I tend to use the two interchangeably, and if I confuse you please forgive me.

But the records refer to both the provisions of the Treaty and the provisions of the regulations that relate to form and contents, that are the form and contents requirements, and those include Article 5 of the Treaty which relates to the description, and rule 5.1 of the regulations, which relates to the manner of the description.

As I mentioned, rule 5.1 governs the manner of description, and it includes the description of a claimed invention's industrial applicability. It provides the form and contents requirements. And what rule 5.1(a)(v) provides is that, in order to meet the form and contents requirement, an applicant in the international application must indicate explicitly, when it's not obvious from the description or the nature of the invention, the way in which an invention is usable or operational.

This, in my opinion, is an extremely important provision because it strikes a balance between the right of member countries to set the terms of exploitation in industry and the way in which it is possible to operate, or workable, or inventions the use of which cannot be made and used or, if it can only be used, in the way in which it can be used. Nothing more is required, and nothing more may be required.

In fact, the international search and preliminary examination guidelines of the PCT make it clear that in most cases, industrial applicability
1 will be self-evident and nothing more will be
2 required.
3
4 So, to put together what I've said,
5 under the PCT, during the national phase, Canada can
6 set the substantive test for utility wherever it
7 chooses, but what Canada is constrained from doing
8 and what the PCT constrains is as a matter of form
9 and contents. Canada may not require an
10 international application to include contents that go
11 beyond what the PCT requires. It is constrained by
12 the PCT as to what, as a matter of form and contents,
13 a member country may require the international
14 application to include for the substantive
15 patentiability requirement. If it wants more, it can
16 ask for it, but it can't require that it be in the
17 international application.
18
19 Canada's rule for evidence of sound
20 prediction, as a result, is incompatible with the
21 PCT. In Canada, evidence of soundly predicted
22 utility will only be considered if it's in the
23 application. It won't be considered if it's not. As
24 a result, Canada's requirement to include evidence of
25 sound prediction imposes a requirement on the
26 contents of international applications that is, in
27 fact, both different from and additional to what the

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1 of sound prediction in the international application
2 undermines a core objective of the PCT.
3
4 Thank you.
5 MS. WAGNER: Thank you. I have no
6 questions for direct examination.
7 THE PRESIDENT: For cross-examination.
8
9 Mr. Spelliscy, you will conduct the
10 cross-examination?
11
12 CROSS-EXAMINATION ON BEHALF OF THE RESPONDENT
13
14 MR. SPELLISCY: Good morning.
15
16 Professor Erstling. We appreciate you being here on
17 a Saturday. My name is Shane Spelliscy. I'm senior
18 counsel for the Government of Canada. I'm going to
19 ask you a few questions and my goal today is just to
20 understand a little bit more about the opinions you
21 have submitted on behalf of the Claimant in this
22 arbitration.
23
24 I don't expect that we're going to go
25 for very long today, you'll be glad to know --
26
27 PROFESSOR ERSTLING: Thank you.
28
29 MR. SPELLISCY: -- but if we do need a
30 break at any point let me know and I'll find a point
31 to take one, but I don't think we'll be going very
32 long.
33
34 As an initial matter, let me clarify

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1 the extent of your opinion. I think I understand
2 from your presentation now, but let me turn to
3 paragraph 1 of your Second Report. There you say in
4 the fourth sentence, "The fundamental point of my
5 initial report, apparently missed by Mr. Reed, is
6 that Canada's new requirement to include proof of
7 evidence of soundly predicted utility in the patent
8 application is a matter of form and contents governed
9 by the PCT and is at odds with the structure and
10 purpose of the PCT." Do you see that?
11
12 PROFESSOR ERSTLING: Yes.
13
14 MR. SPELLISCY: So you are offering
15 here no opinion in your report or in your testimony
16 this morning on the rule in Canadian law that utility
17 will be judged against the promise of a patent,
18 correct?
19
20 PROFESSOR ERSTLING: The extent of my
21 opinion is that the heightened evidentiary
22 requirement of sound prediction is at odds with the
23 PCT.
24
25 MR. SPELLISCY: I'm not sure that was
26 a direct answer. I understand that's the first part
27 of what you said there. I'm trying to make sure,
28 you've offered no opinion in your report on the rule
29 in Canada that the utility will be judged against the

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PROFESSOR ERSTLING: That's right.

MR. SPELLISCY: And you've offered no opinion on the rule in Canadian law that utility must be soundly predicted or demonstrated at the time of filing, the rule regarding what we've called here post-filing evidence, correct?

PROFESSOR ERSTLING: Could you repeat that question? Because I'm not sure.

MR. SPELLISCY: Sure. You've offered no opinion on the rule in Canadian law that utility must be soundly predicted or demonstrated at the time of filing, correct?

PROFESSOR ERSTLING: That is correct, because my opinion goes to the ability to substantiate that that requirement has been met, under the PCT.

MR. SPELLISCY: Under the PCT, right. Great. You said today several times and emphasized that the PCT does not govern Canada's substantive utility requirement. And you say in paragraph 4 "on this point Mr. Reed and I agree."

So you would agree with me that under the PCT it is perfectly acceptable for Canada to say that, in order to establish the utility of an invention, the inventor must, if relying on a sound prediction, have a factual basis and a sound line of reasoning as of the filing date, correct?

PROFESSOR ERSTLING: Under the PCT, because it is not a substantive law treaty, makes no judgment about the substantive conditions of patentability that member countries prescribe. So under the PCT, a country can be unique, it could be an outlier, and in accordance with the PCT as a matter of substantive law, that could be okay.

MR. SPELLISCY: In paragraph 4 of your Second Report you do also say that "the PCT does govern what must (and need not) be disclosed in an international patent application regarding the utility of an invention." That's what I'd like to explore with you a little bit further now that we've got that clarified.

Let's turn to tab 1 in the much smaller red binder that you have in front of you there. This is Exhibit C-100. This is an article that you wrote in 2012, correct?

PROFESSOR ERSTLING: That I co-wrote.

MR. SPELLISCY: Right. I wanted to turn to page 29 of that article. I'm looking in the long paragraph here, the first sentence. You're writing about, in this article, the Canadian doctrine of sound prediction, correct?

PROFESSOR ERSTLING: Correct.

MR. SPELLISCY: Closer to the bottom of the page, say about two-thirds of the way down, you'll see a sentence that starts, midway through, "...Canadian law invokes" and you call it "the heightened evidentiary standard." I think that's what you were talking about a minute ago, that this was in your view a heightened evidentiary standard, talking about as a heightened evidentiary standard, the sound prediction rule, correct?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: To clarify, what we are discussing, then, in your view is an evidentiary requirement in Canadian law. Is that right?

PROFESSOR ERSTLING: It is the requirement that the international application contain in the application the evidence that demonstrates that sound prediction has been met.

MR. SPELLISCY: And that is, in your view, an evidentiary standard or an evidentiary requirement, correct?

PROFESSOR ERSTLING: Yes, with the term "evidentiary" being understood in a broad sense,
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Washington DC, USA

UNCT/14/2 Eli Lilly and Company v Government of Canada

Saturday, 4 June 2016

1 in support of their application for leave to appeal,
2 correct?
3 PROFESSOR ERSTLING: I did, yes.
4 MR. SPELLISCY: That request for leave
5 to appeal was denied in October of 2009. Is that
6 right?
7 PROFESSOR ERSTLING: I knew that it
8 was denied. I was not aware of when.
9 MR. SPELLISCY: But you knew it was
10 denied?
11 PROFESSOR ERSTLING: Yes.
12 MR. SPELLISCY: Then you say after
13 that, in January 2012, the Claimant requested you --
14 or your firm, you say, but I take it it was you -- to
15 prepare a study on the utility requirements in
16 Canada, correct?
17 PROFESSOR ERSTLING: That’s correct.
18 MR. SPELLISCY: In fact, that was a
19 study we looked at a few minutes ago at tab 1 of your
20 binder, C-100, right?
21 PROFESSOR ERSTLING: Yes.
22 MR. SPELLISCY: That was a study
23 Eli Lilly requested you prepare?
24 PROFESSOR ERSTLING: Right. They
25 requested the study which we then published "we"

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1 you’ll see that you have a little C that says
2 "Canada," so this is a section where you talk about
3 Canada, is that correct, the Canadian law?
4 PROFESSOR ERSTLING: Yes.
5 MR. SPELLISCY: If you come to page 14
6 in the top paragraph, you and your co-authors write,
7 "In its interpretation of the statute, the Supreme
8 Court of Canada has held that utility does not exist
9 if the invention will not work, either in the sense
10 that it will not operate at all or, more broadly,
11 that it will not do what the specification
12 promises…”
13 You see that?
14 PROFESSOR ERSTLING: Yes.
15 MR. SPELLISCY: And you have a
16 footnote 65 right at the end. That sentence does
17 continue, but footnotes 55 and 56 actually refer to
18 the same case. If you go down to footnote 65, the
19 case you cite for that is the Consolboard decision in
20 1981, correct?
21 PROFESSOR ERSTLING: Yes.
22 MR. SPELLISCY: That’s the same case
23 you actually cite in footnote 66, the Consolboard
24 decision, 1981. Is that right?
25 PROFESSOR ERSTLING: Yes.

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1. page 46 of this decision. Let's look to paragraph 165. You see here that Justice Hughes notes that the 2. Claimant, Eli Lilly, in 2008 makes an argument about 3. a disclosure requirement for sound prediction based 4. on the PCT, correct? 5. 

PROFESSOR ERLSTLING: Yes. 6. MR. SPELLISCY: Yes. 7. PROFESSOR ERLSTLING: If you go down to 8. paragraphs 167 and to 168 you will see that Eli Lilly 9. argued in front of Justice Hughes in 2008 that 10. article 27(1) means that the disclosure need only set 11. out the invention and that no further disclosure can 12. be required. Do you see that? 13. PROFESSOR ERLSTLING: Yes. 14. MR. SPELLISCY: This is the same 15. argument that you made in the affidavit which you 16. filed in support of Eli Lilly's application for leave 17. to appeal to the Supreme Court a year later. Is that 18. right? 19. PROFESSOR ERLSTLING: Yes. That no 20. further disclosure is required in the international 21. application, and that further disclosure can be 22. supplied subsequently in the international phase. 23. 

MR. SPELLISCY: If we look at 24. paragraph 169 of the decision it says "Eli Lilly 25. argues -- in the first sentence -- "Eli Lilly argues 26. that the 'form and contents' provision at the end 27. limits the necessity to make disclosure." Do you see 28. that? 29. PROFESSOR ERLSTLING: Yes. 30. MR. SPELLISCY: This is the same 31. argument you're making today in this Tribunal, right? 32. PROFESSOR ERLSTLING: I assume that -- 33. well, no, I actually shouldn't assume. Could you 34. explain what "form and contents provision" at the end 35. refers to? 36. MR. SPELLISCY: I think he's saying 37. "...in the end limit the necessity to make the 38. disclosure, I do not consider." You would agree 39. with me that Eli Lilly argued in this case, which you 40. reviewed, that the form and contents provisions of 41. the PCT limit the necessity to make disclosure, 42. correct? 43. PROFESSOR ERLSTLING: I would not argue 44. that it limits the necessity to make disclosure. 45. What I would argue is that it limits the requirement 46. to make disclosure in the international application 47. and to be penalized for not making that disclosure in 48. the international application, as opposed to 49. requiring that it be allowed to make it subsequently 50. in the national phase, and the reason for that is...
1 that the very purpose and objective of the PCT is to
2 allow the single application to be able to be relied
3 upon in the national phase, and, where there is a
4 need to meet additional substantive conditions of
5 patentability requirements, to be able to make those
6 subsequently, if every country were allowed to make
7 form and contents requirements, then the purpose and
8 objective of the PCT would be undermined completely.
9 In fact, there would be no basis for having a PCT at
10 all.
11 MR. SPELLISCY: You would agree with
12 me, Mr. Erstling, that that was the argument that Eli
13 Lilly was making in the Federal courts in Canada,
14 correct?
15 PROFESSOR ERSTLING: Well, I can only
16 base it on what I read in the decision. I was not
17 privy to the argument that Eli Lilly actually made.
18 Eli Lilly never spelled out that argument to me.
19 Based on the decision here, I would assume that, on
20 the basis of the decision, yes, that is the argument,
21 but I have no personal knowledge of the argument that
22 Eli Lilly made.
23 MR. SPELLISCY: But you were
24 retained -- I don't understand, Mr. Erstling. You
25 were retained by Eli Lilly to file an affidavit in

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1 that the court disagreed with Eli Lilly.
2 MR. SPELLISCY: You would agree that
3 the judge provided reasons for doing so, too,
4 correct? You can review, if you like, paragraphs 165
5 through 169.
6 PROFESSOR ERSTLING: With all due
7 respect, I would disagree with the decision of the
8 court.
9 MR. SPELLISCY: I understand you would
10 disagree with the substance; my question is the court
11 did provide reasons for its decision, correct?
12 PROFESSOR ERSTLING: It did.
13 MR. SPELLISCY: Thank you. We'll get
14 to your disagreement with the substance in a second.
15 If you could turn to tab 4 of your binder, this is
16 Exhibit R-354, and this is the decision of the
17 Federal Court of Appeal March 25, 2009. This was the
18 one that you read in more detail, you said, in
19 preparation for the submission of your affidavit,
20 correct?
21 PROFESSOR ERSTLING: Yes.
22 MR. SPELLISCY: And the Federal Court
23 of Appeal also considered Eli Lilly's arguments on
24 the PCT, correct?
25 PROFESSOR ERSTLING: If my

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1 You see that?
  PROFESSOR ERSTLING: I do.
  MR. SPELLISCY: I understand you

2 describe that as summary but you would agree that the
  issue was presented to the Federal Court of Appeal
  and the Federal Court of Appeal did issue a ruling on
  it, correct?
  PROFESSOR ERSTLING: It did, and
  again, with all due respect, I would disagree with
  the Federal Court's determination of what is a
  substantive condition of patentability.
  MR. SPELLISCY: That's what I
  understood. So you would now like this Chapter 11
  Tribunal to say that the Claimant, Eli Lilly, and
  you, rather than the Federal Canadian courts, were
  right about the meaning of the PCT, right?
  PROFESSOR ERSTLING: I would actually!
  MR. SPELLISCY: You would. Let's turn
  to tab 7 of your binder. This is -- it's not the
  whole patent -- sorry, I'm wrong. I'm at tab 5. It's
  not the whole Patent Cooperation Treaty -- I'm sure
  you know better than I -- for the record, this is
  from Exhibit C-106, an excerpt of the
  Patent Cooperation Treaty. As you flip it over,
  you'll see that there are a couple of excerpts in

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1 been made by Canada and the United States? Sorry,
  I'm already one question ahead.
  MR. SPELLISCY: Yes, Article 64(5)
  says, "Each State may declare that it does not
  consider itself bound by Article 59."
  PROFESSOR ERSTLING: I don't know the
  information offhand, but if I may -- and I really
  have no basis for this -- it is my understanding that
  the United States made such a declaration. But I am
  not sure.
  MR. SPELLISCY: But what this is
  really just saying is, unless you have declared that
  you don't want disputes resolved by the ICJ under
  64(5), unless you do not want to be bound on the
  dispute settlement provisions under 64(5), disputes
  may be taken to the International Court of Justice,
  correct?
  PROFESSOR ERSTLING: That is correct,
  but Article 59 is sort of standard language in
  international IP treaties and it does require
  state-to-state. It makes no provision for private
  parties. There is no private party dispute
  resolution procedure. Again, I'm speaking out of
  turn but it is my understanding or my belief that the
  United States routinely makes these sorts of -- that

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You're there?

PROFESSOR ERSTLING: May I just add a little bit more about that, about the harmonization part? What the PCT is, as I mentioned, it is not a substantive law treaty and it does not harmonize law, but it’s a treaty that is informed by and reflects international understandings and norms about patent law and particularly about the substantive conditions of patent law, so it never created its own law.

MR. SPELLISCY: I think we’ll hear from some experts later today more on that topic.

I’d like to focus more on the disclosure that you focused on in your report. Again, let’s go back to tab 5, which is the excerpts from the PCT. I want to look at Article 5, which is called “The Description,” correct?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: So all the PCT provides, you would agree with me, is that “The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.”

Correct?

MR. SPELLISCY: The text of the PCT itself provides no further information on what a “sufficiently clear and complete” disclosure is, correct?

MR. SPELLISCY: Let’s turn to tab 7 in your red binder, Exhibit R-040. As you know, these are the regulations which provide rules under the Patent Cooperation Treaty. I want to turn to Rule 5, which is the rule related to the description. If we look at 5.1(a), it starts with --

PROFESSOR ERSTLING: Excuse me, I’m not... You’re there?

MR. SPELLISCY: Are you in tab 7?

PROFESSOR ERSTLING: I am there, yes.

MR. SPELLISCY: Rule 5.1(a) under The Description, “The description shall first state the title of the invention as appearing in the request and shall...” then it contains a number of numerettes

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1. **PROFESSOR ERSTLING:** We're going to get to that requirement.

2. **MR. SPELLISCY:** You would agree with me that section (iii) has to disclose the invention as claimed. You just said that -- and I think you say in your report that -- disclosure is not at issue here, correct?

3. **PROFESSOR ERSTLING:** Disclosure in terms of meeting the sufficiency and enablement requirement is not at issue here because that is different from what is required for utility or industrial applicability.

4. **MR. SPELLISCY:** Let me try and understand that, because I'm not sure that I do. If we can turn to tab 8 in your binder, this is an excerpt from the PCT Applicant's Guide. The date at the bottom is July 24, 2014. Do you see that?

5. **PROFESSOR ERSTLING:** Yes, which I don't think is the most recent version, but the differences would be minor.

6. **MR. SPELLISCY:** I want to look at 5.094 first, how the description must be drafted. It says, "The description must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art," in the first sentence in 5.094. Do you see that?

7. **PROFESSOR ERSTLING:** Yes, that's right.

8. **MR. SPELLISCY:** So the WIPO Applicant Guide is warning applicants in the international phase to take account of national laws regarding what is required in the disclosure. Is that right?

9. **PROFESSOR ERSTLING:** It is. However, this is not the chapter of the search and examination guidelines that deals with meeting the utility requirement.

10. **MR. SPELLISCY:** Right, the search and examination guidelines are for the advisory opinion.

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1. **MR. SPELLISCY:** That's correct.

2. **PROFESSOR ERSTLING:** This is a guide directed to applicants on how to file their application, correct?

3. **PROFESSOR ERSTLING:** That's correct.

4. **MR. SPELLISCY:** So the PCT WIPO is warning applicants when they're drafting disclosure that due account be taken of national practice. We agree on that, right?

5. **PROFESSOR ERSTLING:** Yes, that's correct.

6. **MR. SPELLISCY:** Turn to tab 9 of your little red binder, which is an excerpt from R-043.

7. **PROFESSOR ERSTLING:** May I just add one thing more to the question?

8. **MR. SPELLISCY:** Sure.

9. **PROFESSOR ERSTLING:** The Applicant's Guide is -- you are absolutely correct -- telling applicants that they need to take due account of national practice, but it's national practice that is generally contemplated and anticipated in the PCT practice and in actual national practice throughout the world, and so what I don't think the paragraph

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1. **SIR DANIEL BETHLEHEM:** Page 29?

2. **MR. SPELLISCY:** It is page 29.

3. **PROFESSOR ERSTLING:** Yes.

4. **MR. SPELLISCY:** Next paragraph, 5.095, says on the same page, "The details required for the disclosure of the invention so that it can be carried out by a person skilled in the art depend on the practice of the national Offices. It is therefore recommended that due account be taken of national practice (for instance in Japan and the United States of America) when the description is drafted. The need to amend the description during the national phase may thus be avoided."

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1. **PROFESSOR ERSTLING:** Can you go back to tab 8, and let's look at the paragraph again.

2. **MR. SPELLISCY:** It's at page 29, R-042, paragraph 5.095. Can you point me to where it says what you just told me in that paragraph?

3. **PROFESSOR ERSTLING:** I can't point you exactly to that. I think that is implied. The paragraph also provides that the purpose of attempting to be aware of national practice is to avoid the need, or to minimize the need because there generally is usually a need, to amend the description during the national phase. And in Canada, because of the evidentiary rule of sound prediction, the ability to amend the description during the national phase is both limited and is accompanied by an increased risk.
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1  So I believe that what is underlying in this is that,
2  if there is a need to amend the description, which
3  applicants should try to minimize, the amendments
4  that will be made during the national phase won't end
5  up being penalties, or even resulting in the loss of
6  a priority right, for example.
7
8  **MR. SPELLISCY:** Right. So if
9  applicants -- what WIPO is telling applicants is that
10  if applicants take due account of national practice
11  when the description is drafted they may avoid the
12  need to amend the description and avoid the priority
13  problems that you are mentioning, correct?
14
15  **PROFESSOR ERSTLING:** Yes, that's
16  correct.
17
18  **MR. SPELLISCY:** Let's turn to tab 9
19  again, R-043. These are excerpts from the
20  practitioner's guide to the PCT authored by yourself,
21  Mr. Helfgott and Mr. Reed?
22
23  **PROFESSOR ERSTLING:** That's correct.
24  **MR. SPELLISCY:** I want to turn to
25  what's page 200 in this excerpt, in this exhibit --
26  page 200 in the book. There is a heading No. 2 that
27  says "Different laws in Different Countries."
28  Mr. Helfgott wrote this chapter, correct?
29
30  **PROFESSOR ERSTLING:** That's correct.

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1  **MR. SPELLISCY:** He wrote "In order to
2  be sure that your PCT application will be a viable
3  application in foreign countries, care must be given
4  to the various laws in foreign countries that may be
5  different from those in the United States. In many
6  cases the patent laws of many countries have been
7  harmonized, but there are still differences, and
8  these must be considered."
9
10  You would agree with Mr. Helfgott?
11  **PROFESSOR ERSTLING:** I would. He put
12  this in a chapter that was suggestions and
13  recommendations for solid drafting. The provision
14  goes on to say, if I remember correctly, that what
15  Mr. Helfgott was really -- was primarily referring to
16  was the situation in the United States where we were
17  at that point transitioning from a first-to-invent to
18  a first-to-file system and that, as a result of that,
19  being aware of needing to file applications early
20  became more important and that we, in the United
21  States, have a grace period that few countries have,
22  and that the awareness that most countries do not
23  have a grace period and a disclosure can immediately
24  eliminate your right to seek a patent in a country
25  needed to be taken into consideration.
26
27  It was really at that high level, not

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1  that you needed to get into the weeds of the national
2  laws of every PCT member country.
3
4  **MR. SPELLISCY:** I understand that's
5  the example that he gives in the following
6  paragraphs. What he says is the differences between
7  the various laws in foreign countries must be
8  considered. That's what he writes, right?
9
10  **PROFESSOR ERSTLING:** That's correct.
11  **MR. SPELLISCY:** And, as you indicated,
12  you agree with that, correct?
13
14  **PROFESSOR ERSTLING:** I agree with that
15  in the context in which it was stated.
16
17  **MR. SPELLISCY:** I want to now refer
18  you and discuss with you your view that you raised
19  earlier on the disclosure requirements. You
20  mentioned earlier but if we come to paragraph 14 of
21  your Second Report, I think this is what we just
22  talked about in the last sentence in this paragraph.
23  You say: "The PCT recognizes the need for adequate
24  disclosure by expressly requiring that the claims in
25  an international application shall be fully supported
26  by the description." Then you write, "But the
27  disclosure requirement is not at issue here." That's
28  the last part that I want to focus on.
29
30  If you could turn to tab 3 of your
the holding, "Thus, for lack of disclosure, there was no sound prediction." Correct? You see that?

PROFESSOR ERSTLING: Yes. I'm just reading the whole paragraph.

MR. SPELLISCY: Sure.

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: If we keep going in this decision to page 49, I guess it's paragraph 183 although it's really between 183 and 184, there is a section that says "In Summary," and if we look at the summary the Federal Court provided in the fourth bullet we see that it rules, "Apotex's allegation in respect of lack of sound prediction is justified because the '356 patent lacks adequate disclosure."

Correct?

PROFESSOR ERSTLING: That's what it says, yes.

MR. SPELLISCY: So you would agree with me that the Federal Court of Canada, the trial level, in making its decision saw this as a disclosure requirement, correct?

PROFESSOR ERSTLING: Yes, it did.

MR. SPELLISCY: Let's turn to tab 4, which is the Federal Court of Appeal decision again, R-354. Let's turn to page 4 in this decision, paragraph 3.

The Federal Court of Appeal says, "The Federal Court judge dismissed Eli Lilly's application on the basis that Apotex's allegation in respect of lack of sound prediction was justified because the '356 patent lacks adequate disclosure."

You see that?

PROFESSOR ERSTLING: Yes, I do.

MR. SPELLISCY: Turn to page 6 and paragraph 15. The Federal Court of Appeal concludes, "In my respectful view, the Federal Court judge proceeded on proper principle when he held, relying on AZT, that when a patent is based on a sound prediction, the disclosure must include the prediction. As the prediction was made sound by the Hong Kong study, this study had to be disclosed." Are you there with me on that?

PROFESSOR ERSTLING: Yes, I am.

MR. SPELLISCY: So you would agree with me that the Federal Court of Appeal also viewed it as disclosure that was at issue, correct?

PROFESSOR ERSTLING: Yes to a certain extent, which I -- so I think there are two issues here.

First of all, in accordance with the PCT, the PCT is not saying that there cannot be disclosure of utility. It's simply saying that the requirement, if it is beyond which the PCT requires, that additional disclosure, to use that term, needs to be allowed to be made by the applicant in the national phase. It's simply that it just can't be required in the application. It doesn't mean that it can't be required.

In addition there's disclosure of utility, which I would assume this is talking about, and disclosure of enablement and sufficiency, and that is where my report said there is a distinction.

There are the substantive conditions of patentability, and obviously they must be met. They are met through the written description and through the disclosure, but disclosure for the purpose of enablement and sufficiency and disclosure for the purpose of utility are not necessarily the same thing.

But the most important thing in all of this with respect to utility is, from a PCT perspective, that it's simply that an applicant should not be denied a patent invalidated because the disclosure which goes beyond that which the PCT requires was not in the international application.

But you would agree that in your presentation that the PCT requirements mean that there can be, at most, an express statement of utility required and nothing more, correct?

PROFESSOR ERSTLING: That in order to meet the form and contents requirement there needs to be an explicit statement when an implicit statement?

PROFESSOR ERSTLING: Yes. And then in your opinion, then, you're basing this on rule 5.1(a)(vi) of the regulations. I think you said even in your presentation that the PCT requirements mean that there can be, at most, an express statement of utility required and nothing more, correct?

MR. SPELLISCY: Yes.

PROFESSOR ERSTLING: Well, it could be inherent in the nature of the invention itself. As the search and examination guidelines state, in most cases the utility will be self-evident.

MR. SPELLISCY: And if it is not self-evident, the most that can be required is an express statement, is what you're saying, correct?

PROFESSOR ERSTLING: Yes. And then in the national phase, if a member country requires more, it can require more. It just can't penalize
The applicant for not having included that in the application.

MR. SPELLISCY: There's where I'm not sure I follow. Your opinion, then, is that, even if the expressly stated utility in an international application is not specific, substantial and credible, nothing more can be required as long as it's expressly stated. Is that your opinion?

PROFESSOR ERSTLING: No, because significant, substantive and credible is the substantive rule, condition, upon which that statement will be judged. There are two different things. There's the judging of the statement and the statement itself. In most cases, if it is not deemed to meet the substantive requirement of utility, the examiner will simply ask for more.

MR. SPELLISCY: But there's where I don't understand, Mr. Erstling, because you said that at most what can be required is an express statement of utility, but then you've just said that an express statement of utility is not all that's required; it has to be an express statement of utility that is specific, substantial, credible, because you said that's the substantive rule upon which the statement will be judged. Those two are in conflict, are they not?

MR. SPELLISCY: And the PCT has nothing to say on what those substantive conditions of patentability are, correct?

PROFESSOR ERSTLING: That's correct.

MR. SPELLISCY: Thank you, Mr. Erstling. I don't have any other questions this morning.

MS. WAGNER: I do have one or two, if you have two minutes to shuffle my notes.

THE PRESIDENT: Please go ahead.

RE-DIRECT EXAMINATION ON BEHALF OF THE CLAIMANT

MS. WAGNER: Good morning again, Professor Erstling. Can we go back to tab 8 in your binder, which is the cross-examination binder. The discussion was at page 29.

Mr. Spelliscy was asking you about section 5.094 and section 5.095, and the tenor of the question is related to 5.095 specifically and the need for applicants to take due account of national practice, which is what it states here.

Would applicants consider disclosure of proof of utility to be part of the requirements that they need to take account of here?
1 cases an examiner would look at what the claimed
2 invention is and on that basis determine whether it
3 is useful or, in an industrial applicability
4 standard, whether it has an application in industry.
5 In general, if there is doubt, then
6 the examiner would in some way reach out to the
7 applicant. It may be raising an issue in an office
8 action to which the applicant could respond, or it
9 may be, depending upon national practice, in informal
10 give-and-take with the examiner, but there generally
11 would be an opportunity to, if there were doubt, to
12 be able to overcome that doubt.
13 MS. WAGNER: And, putting Canada
14 aside, would that material to be provided to overcome
15 the doubt have to be in the application?
16 PROFESSOR ERSTLING: No. It would
17 generally be supporting material that would be
18 supplied post-filing.
19 MS. WAGNER: And is there a particular
20 format that the supporting material would take, or...
21 PROFESSOR ERSTLING: No, not -- it
22 could be in the form of affidavits. It could be in
23 the form of supplying evidence or certificates of
24 clinical data. It could be, where there is doubt, 25 anything that would overcome that doubt.

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1 certainly as I see the PCT website, neither Canada
2 nor the United States has made a declaration under
3 Article 64 paragraph 5.
4 I'm less interested in that. What I'd
5 like to try and explore is whether there are other
6 mechanisms within the PCT Office, the one that you
7 were the Director of, in which issues of
8 compatibility or incompatibility would have been
9 addressed, something akin to the way, for example, in
10 which the World Trade Organisation may, through its
11 trade policy review mechanism or something of that
12 nature, focus on these issues.
13 My first question is just to ask you
14 if you could describe or explain for me what a
15 notification of incompatibility is under the PCT
16 rules, and whether this would have any relevance to
17 our discussion?
18 PROFESSOR ERSTLING: To be perfectly
19 honest, I actually don't know what a notification of
20 incompatibility would be or what form it would take.
21 If you're speaking within Article 59, again --
22 SIR DANIEL BETHLEHEM: No. Let me
23 clarify, excuse me. I'm not speaking within the
24 context of Article 59, but I see across a number of
25 the rules that there is an opportunity for

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1 Office of the PCT, the International Bureau, didn't have authority to be able to either issue notices of violation or really take any effective measure, but it would occasionally attempt to exert informal influence or undertake discussions.

SIR DANIEL BETHLEHEM: So would complaints come to your office in the form of, as it were, informal comments, observations in the corridor, observations in the meetings of contracting parties? Would there be formal communications, a state saying "We are concerned about the law of a particular state"?

PROFESSOR ERSTLING: No. The comments would generally come from the applicants themselves who felt that they may have been aggrieved. In most cases it is when they have entered the national phase. Sometimes it's in the international phase.

Those are not a regular occurrence.

What the office of the PCT maintains is a helpline, and sometimes that's where these questions or problems arise. Sometimes it's in the form of letters.

SIR DANIEL BETHLEHEM: Your testimony that Canada's rule for evidence of sound prediction is in breach of Article 27(1) seems to go to a pretty fundamental aspect of the way in which the PCT operates. In the light of what you've just said, and given that you were the director of the Office between 2002 and 2007, which covers a very important part of the period that we're looking at, would you have expected to receive, or to your recollection did you receive, from applicants, from the United States, from other states, any complaints about Canada's sound prediction law?

PROFESSOR ERSTLING: I can't point to anything in particular that I recall, but when I was contacted by Eli Lilly in 2009 -- although I was really very, very ignorant of the situation -- it wasn't a surprise. It was not the first time that I had heard about this. But to put it in the exact context, I just can't recall.

SIR DANIEL BETHLEHEM: But there's nothing -- in case I've sort of missed it -- in your reports which puts a sort of finger on any communication or internal consideration or anything of that nature which would indicate that what you said in your report -- which is much more contemporaneous with this dispute -- had a reference back to concerns which were expressed at the time that you were the director of the Office?

PROFESSOR ERSTLING: Yes. That's correct. There's nothing in particular that I could point to.

If I may just add a little bit, because I think I gave you a very inadequate answer to your question about the way that consultations take place, there are often discussions country-to-country that the Office itself is not privy to. The way the Office is structured there are formal meetings where different offices could get together, so there is a group -- now I think it's 15 -- of international search and preliminary examination authorities, and both Canada and the United States are international search and preliminary examination authorities. That group of offices will get together generally in Geneva to look at some technical issues.

There's also a very large annual meeting of the Assembly of the PCT with all of the member states, and there are then also working group meetings that take place. In those the Office of the PCT plays obviously a very direct role, but then there are lots of -- as you would know from your experience -- discussions in the hallways as well.

SIR DANIEL BETHLEHEM: May we assume, in the light of what you've just said, though, that if you haven't referred to any documents, as it were, coming out of the Office of the PCT, that there is nothing, to your knowledge or recollection, that's relevant to this case that comes out of these types of meetings?

PROFESSOR ERSTLING: That is true, with the one exception of, particularly in the rules, when countries have a substantive condition of patentability that is somewhat different, the country has the opportunity in several meetings to bring that up and to make sure that that is explicitly included in the rules. For example, the explicit provision concerning best mode. There are not very many -- there are very few countries that require best mode, but the rule specifically says that you have to provide for best mode, or furnishing of nucleotide or amino acid sequence listings, so there would be the possibility, to the extent that a country would want its requirement to be embodied within the PCT rules, to bring those up and to have those added to the rules.

SIR DANIEL BETHLEHEM: Thank you very much.

THE PRESIDENT: A question by
Mr. Born.

MR. BORN: Just a very brief question, and I don't recall it being addressed in either of your two reports so it may take you outside of your zone of comfort.

Can we look at Article 59 of the PCT again? It's at tab 5 of the red binder. I suppose it's in the white binder, but look in tab 5. You can help me with this. If there are not Article 64(5) declarations, then, if I look at tab 5, I would provide a submission to ICJ jurisdiction for state-to-state disputes about the PCT. Is that right?

PROFESSOR ERSTLING: Yes, that's correct, unless the states agree on some other way of resolving.

MR. BORN: That was my question. It's not, so far as I understand it, an exclusive means of dispute resolution. It's mandatory if it hasn't been opted out of under Article 64(5), but it's not exclusive in the sense that any two states, any group of states, are free to agree to an alternative mechanism?

PROFESSOR ERSTLING: Yes, that's correct. That's my understanding.

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THEODORE DAVID REED

Mr. Reed.

MR. REED: Good morning.

THE PRESIDENT: Could you please state your full name for the record?

MR. REED: My name is Theodore David Reed. Go by David.

THE PRESIDENT: Mr. Reed, if any question is unclear to you, either because of language or for any other reason, please do seek a clarification because, if you don't do so, the Tribunal will assume that you've understood the question --

MR. REED: I think everything is fine as it currently stands.

THE PRESIDENT: -- and that your answer corresponds to the question.

MR. REED: I missed that.

THE PRESIDENT: Again, if you do not seek clarification for a question the Tribunal assumes that you understood the question and that your answer corresponds to the question.

MR. REED: Okay.

THE PRESIDENT: You understand that?

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MR. BORN: Does it apply to disputes about the PCT, questions of interpretation in the PCT, other than state-to-state disputes?

PROFESSOR ERSTLING: No. My understanding is that the provision of Article 59 is to deal with state-to-state disputes.

MR. BORN: You may not know the answer to this but, in the Raloxifene litigation in Canada, was there any suggestion the Canadian court couldn't interpret, look to the terms of the PCT, in that litigation?

PROFESSOR ERSTLING: You're right, I don't know the answer to that.

MR. BORN: Thank you. No further questions.

THE PRESIDENT: Any follow-up questions?

MR. SPELLISCY: None, thank you.

THE PRESIDENT: Mr. Erstling, thank you for testifying. You are now released as a witness and are excused.

PROFESSOR ERSTLING: Thank you.

THE PRESIDENT: Thank you. You will be assisted by the unlimitedly resourceful secretary of the Tribunal. Can you hear me?

MR. REED: Yes, I think so.

THE PRESIDENT: If you think so, that's not enough for me. You must be certain.

MR. REED: You will appreciate that testifying, be it before a court or an arbitral tribunal, is a very serious matter. In that connection, the Tribunal expects you to give the declaration, the text of which is in front of you.

Mr. Erstling, I solemnly declare upon my honor and conscience that my statements will be in accordance with my sincere belief.

Mr. Born.

MR. BORN: I solemnly declare upon my honor and conscience that my statements will be in accordance with my sincere belief.

THE PRESIDENT: Thank you. You will be assisted by the unlimitedly resourceful secretary of the Tribunal. Can you hear me?

MR. REED: Yes, much better.

THE PRESIDENT: One thing I must make clear because I don't think you understood everything I told you in the beginning.

If any question is unclear, either because of language or for any other reason, do seek a clarification because, if you don't do so, the Tribunal assumes you have understood the question and that your answer corresponds to the question?

MR. REED: Very well. I understood that completely.
1 In about 1980, I was taken off of my
2 product development duties and put onto a special
3 assignment to assist trial counsel in a number of
4 product liability lawsuits, and also to assist
5 Procter & Gamble's counsel in a number of patent
6 lawsuits. I became very interested in patent law and
7 in 1988 I took and passed the U.S. patent bar and
8 became a registered agent before the USPTO.
9 During my time at Procter & Gamble, 10
11 starting in 1990 in response to the needs of the
12 company, we converted our practice from a practice
13 under direct national practice under the Paris
14 Convention to a practice under the Patent Cooperation
15 Treaty. Since that conversion in late 1990, I have
16 either been the agent of record or have managed the
17 agents of record in over 9,000 PCT filings.
18 There was a time when P&G was the 19
20 largest single user of the PCT in the world. Long
21 since -- long ago we lost that title, but we had it
22 for a short period of time. But because of the wide
23 use we had of the PCT and the success we made in
24 utilizing the PCT, WIPO approached me in 1996 and
25 asked me if I would be available to go to countries
26 that were considering joining the PCT, or countries
27 that were just learning to use the PCT having joined

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1 around the United States giving PCT seminars,
2 teaching practitioners how to use the PCT to their
3 greatest advantage, and I did that full-time starting
4 in 2006 until 2014. At the end of 2014 I stopped
5 doing that, and am now looking forward to full
6 retirement.
7 We've been talking about the PCT.
8 Exactly what is the PCT? The Patent Cooperation
9 Treaty is an international patent filing system.
10 Please note, it just works for filing patent
11 applications; it does not grant applications.
12 In my opinion, the PCT is the
13 greatest single advancement in foreign patent
14 practice since the advent of the Paris Convention in
15 1883.
16 Under the PCT, the applicant will file
17 a single application in their home country, in
18 general; also in general in their home language; and
19 establish a filing date in all PCT contracting
20 states. There are currently 148 of them.
21 In the process of the PCT, the
22 applicant will receive some very valuable information
23 regarding the prior art that can be found through the
24 international search, possibly get information
25 regarding the comparison of their particular claimed

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1 for an explicit statement, if it's not obvious based
2 on the description or the nature of the invention, an
3 explicit statement as to how the invention can be
4 exploited or used in the industry. Think of that in
5 the context of this particular proceedings as having
6 utility. And also how it can be made and used.
7 The PCT process itself, once you have
8 the application, consists of two phases.
9 Mr. Erstling covered this to some
10 degree but the two phases are an international phase
11 in which the PCT is processed under the PCT
12 regulations. At the end of this international phase,
13 which is 30 months from the earliest claimed priority
14 date, the application if you're going to proceed to
15 seek patent protection then moves into the national
16 phase where the application is converted into a
17 national application for national processing.
18 During this international phase, as I
19 mentioned, you will get a search. The particular
20 application will be sent to an international
21 searching authority. The searching authority will
22 look to find any relevant prior art that might affect
23 the novelty or inventive step of the particular
24 application.
25 Since 2004, when there was a change in

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1 the PCT, post-2004 you will also get a written
2 opinion from the searching examiner where the
3 examiner will take the art found in the search report
4 and apply it against the novelty and inventive step
5 of your particular application. Prior to 2004 this
6 was not automatic and did not happen in the first
7 part of the international phase, but could be
8 obtained by applicants through payment of a fee and
9 making a request to go into what we would call
10 Chapter 2 examination, and Chapter 2 was a separate
11 process that an applicant can use or may choose not
12 to use, depending on what their particular needs are.
13 In the search of prior art and also of
14 the written opinion, the examiners will follow the
15 guidelines that are provided under the WIPO as to how
16 to go ahead and examine the application. In addition
17 to working with the examiner to come up with the
18 final report as to whether the invention appears to
19 be novel or appears to be inventive or have
20 industrial application or utility, these are judged
21 against the guidelines in the PCT in Article 33.
22 Please note that anything that comes
23 out of the PCT does not relate to the patentability
24 of the particular invention under any given national
25 law. Article 33 does give the standards that you can
I'd like to go ahead and correct that now. It says that the form and contents are not the criteria of patentability, et cetera. But the last sentence of that statement, Mr. Erstling in his report indicated, again based on Rule 5.1(vi), I believe it is, that the words 'form or contents' are used merely to see what they had to say about Article 27(1), the Canadian requirement that the factual basis leading to a sound prediction of utility be in the description or the nature of the invention.

Based on that he feels that the words 'form or contents' are used merely to see what the examiner is using to make the judgment as to whether a patent should be granted under Chapter 2 of the Treaty.

Additionally, the PCT standardizes formal requirements for all the contracting states, and that really kind of gets down to the guts of what we're going to be talking about today, the formality standardization that occurs under PCT versus the substantive requirements of patentability.

One thing we have to emphasize is that the PCT does not grant patents. Granting of patents is solely the responsibility and right of each contracting state, and a contracting state will make the judgment as to whether a patent should be granted or not under their own national laws. Second of all -- I believe Mr. Erstling and I agree on this -- the PCT does not standardize or harmonize national laws or the conditions required to determine patentability. Those are left to each of the individual countries to set as they see fit.

Mr. Erstling in his report indicated, again based on Rule 5.1(vi), I believe it is, that the Canadian requirement that the factual basis leading to a sound prediction of utility be in the description or the nature of the invention.

Based on that he feels that the words 'form or contents' are used merely to see what the examiner is using to make the judgment as to whether a patent should be granted.

What Article 27(1) has to do with is the form and contents from the standpoint of broad categories of material that are required to be covered in the application, and not in any way to get involved in restricting substantive criteria of patent law which are not meant by the word's "form and contents."

The standardization of formal requirements and just formal requirements is riddled throughout the PCT. If you look at the WIPO training material such as the PCT Applicant's Guide in section 4.011, if you look at material posted on the WIPO website, the material supplied to me by WIPO for teaching PCT, if you look at the Washington Conference papers, in many cases they all talk about the "standardization of formal requirements", so that if your application is in good shape from a formality standpoint, it will be accepted in each individual country.

So, again, the form and contents does not relate to substantive issues of patentability. Those are left to the individual countries. As a matter of fact, we looked at Article 27(5), which we'll take a look at again here in a minute, which...
indicates that national laws can have any substantive criterion that they want for determining patentability.  
4 27(5), as I mentioned, gives national law complete freedom to prescribe substantive conditions of patentability. Utility, like novelty and inventive step, is a substantive condition of patentability. 

I mentioned the examination that is put on by WIPO comes with every case after 2004 (it could be ordered pre-2004) where an international examiner will take a look at the application. Insofar as utility or industrial applicability is concerned, we have to go to the international search and examination guidelines, Chapter 14 and the annex to Chapter 14. 

In that, when we take a look at utility, utility has to be specific. It has to be substantial and it has to be credible. Those are the three things we heard yesterday as far as U.S. law, we can be required to be in the application, is an explicit statement of what the utility might be, where are we going to find out if that particular...
MR. REED: I see. And it would be identified as a priority application, yes.

MS. WAGNER: That would be information that could be used to assess credibility of the use of a drug. Dosing information?

MR. REED: Yes. I would say that's a part of the description that might include information such as information relating to dosing in a drug context.

MR. REED: I have the sequencing correct in all of this. It's a bit complicated.

MS. WAGNER: Thank you. I just want to start with some questions about the PCT process, which you did outline. I just want to make sure that I have the sequencing correct in all of this. It's a bit complicated.

MR. REED: In most circumstances what happens is that an applicant who wishes to obtain a patent will file an initial application somewhere in the world. Then, if the applicant wants to use the PCT system for filing their priority application globally, then within 12 months of that priority application they'll file their PCT application.

MR. REED: Again, I have no knowledge of the pharmaceutical industry, so whether dosing information has anything to do with the use of a drug. I realize that's the instructions on how to administer it but it has nothing to do with the effects or... 

MS. WAGNER: It might include things that an applicant who wishes to obtain a patent will file their PCT application globally, then within 12 months of that priority application they'll file their PCT application? 

MS. WAGNER: And the method of administration might be something you could use to assess credibility?

MR. REED: I can't see how the method of administering, whether you get a shot or take a pill or whatever, has anything to do with credibility regarding utility.

MS. WAGNER: But you don't actually know because you're not familiar with the pharmaceutical industry.

MR. REED: I am not familiar with the pharmaceutical industry.

MS. WAGNER: Thank you. I just want to start with some questions about the PCT process, which you did outline. I just want to make sure that I have the sequencing correct in all of this. It's a bit complicated.

In most circumstances what happens is that an applicant who wishes to obtain a patent will file an initial application somewhere in the world. Then, if the applicant wants to use the PCT system for filing their priority application globally, then within 12 months of that priority application they'll file their PCT application.

MR. REED: In a Paris Convention or WTO country.

MS. WAGNER: And that will be referred to as a "local" or "national" application?

MR. REED: That's what I would call it, yes.

MS. WAGNER: That would also be normally referred to as the "priority" application?

MR. REED: If a subsequent case is filed in other jurisdictions within 12 months, it

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of them do.

MS. WAGNER: So then the filing of
international application starts off the PCT
international phase?

MR. REED: Yes.

MS. WAGNER: And later on in that
process at some point, that's when the PCT will do
the international search?

MR. REED: Yes.

MS. WAGNER: And preliminary
examination?

MR. REED: After 2004, yes.

MS. WAGNER: And at that stage at some
point, again, the PCT will issue a non-binding
opinion as to whether the international application
meets patentability criteria?

MR. REED: Again, after 2004, they
will issue the written opinion that will express
based on the prior art whether it's novel, inventive
or industrially applicable. Prior to 2004, the
applicant would have had to pay a fee and submit a
demand for preliminary examination to start the
process and get the written opinion.

MS. WAGNER: I think I got it.

MR. REED: Okay.
So basically what you've said in that paragraph is all that's required for this is a title, request, claims, description of the invention, drawings, all formatted in accordance with the PCT requirements, and so, in your view, it's more of a cursory review, correct?

MR. REED: There are no technical examiners for applications at the time of filing.

MS. WAGNER: In fact, you said it's typically reviewed by clerks.

MR. REED: That is typically true.

MS. WAGNER: Can you turn to paragraph 27 as well of your First Report? Again, we're talking about acceptance of the international application under the PCT, and basically the same type of thing is said. You say in the second sentence, "Such standardization of formalities avoids the need for applicants to redraft an application merely to comply with national requirements concerning the general presentation of information."

MR. REED: Okay.

MS. WAGNER: So I take your point in these paragraphs to be that the PCT form and contents requirement really shouldn't be taken as establishing any significant requirements as to form and content other than the fact that there are headings required, because it seems apparent that the acceptance into the international phase is somewhat automatic. I guess it's not automatic, they're checking, but it's a matter of formalities and it's reviewed by clerks.

MR. REED: To my knowledge, it's a matter of formalities, yes. In order to get a PCT filing date, which is actually the entrance, then you need to have something that looks like a description. They don't get involved as to what's in there. Something that looks like a claim needs to be there -- I'm trying to remember -- there are three or four other little things that are strictly formalities of what one needs to get a filing date.

MS. WAGNER: The same types of comments are made I think again in paragraph 37 of your report.

MR. REED: I didn't realize I was so redundant. I've got 37. Actually the statements -- we don't need to read them out -- but similar statements are made at the end of paragraph 37.

MR. REED: Okay.

MS. WAGNER: I'm actually going to be referring you to tab 5. These are the records of the Washington Diplomatic Conference on the Patent Co-operation Treaty.

Regarding these records, at paragraph 13 of your Second Report you had discussed these records generally, and you've said that they comprise extensive written materials explaining the meaning of the Treaty and how it should be interpreted and applied, correct?

MR. REED: I don't know. I'd have to find my Second Report.

MS. WAGNER: It's at tab 2. I'm looking at paragraph 13.
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MS. WAGNER: Let's turn back to those
Washington Diplomatic Conference records. They were
at tab 5. I'm going to be looking at page 21.
MR. REED: Okay.
MS. WAGNER: And so this is
Article 11, and if I have it correct, what this
article does is address the filing date and effects
of the international application.
MR. REED: Hang on a second. It's
been a while since I've read 11.
NS. WAGNER: It's C-112 in the record
as well.
MR. REED: I've read Article 11.
MS. WAGNER: So this is what happens
when the receiving -- or this governs the receipt of
the international application by the receiving
office, correct? Accurate?
MR. REED: For purposes of obtaining
the filing date, yes.
NS. WAGNER: So one of the criteria
for obtaining the filing date is that the
international application contains some elements, and
those are listed in Article 11(1)(iii).
MR. REED: Okay.
NS. WAGNER: And I guess the one
Article 5 (clarity and completeness of the
description) and Rule 5 (manner of the description),
or if the claims do not comply with Article 6* -- I'm
skipping some here -- "and Rule 6."
Then if you go down just to the bottom
paragraph it says, "All the receiving Office
is allowed to do is check whether the application
contains passages which, on their face, appear to be
a description and a claim or claims."
And that's consistent with your
experience, I take it?
MR. REED: Yes.
NS. WAGNER: And this article, again,
governs what the receiving Office has to do when it
receives an application in terms of assigning the
filing date, correct?
MR. REED: I think so.
NS. WAGNER: Close? Accurate?
MR. REED: I'm just sitting here --
there is an initial examination that determines
whether the application has a filing date but then
there are further examinations down the road a little
bit. Maybe in the receiving Office, maybe in the
International Bureau. I'm not exactly sure if I
remember correctly.
NS. WAGNER: Understood. But the fact

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1 that's probably most pertinent to us is on the next
2 page, and it's item (d) at the top there. It has to
3 contain a part which on the face of it appears to be
4 a description.
5 MR. REED: Yes.
6 NS. WAGNER: And, if we look at the
7 notes below -- and they are in tiny writing, but if
8 you go back to page 21 and you look at the notes to
9 paragraph 1(iii) it says "the designation of at least
10 one Contracting State is indispensable, but otherwise
11 the international filing date will be accorded, even
12 if the other elements enumerated in this provision do
13 not comply with the requirements of form and contents
14 provided for in the Treaty and Regulations."
15 MR. REED: Accurately quoted.
16 NS. WAGNER: Accurately quoted, and,
17 if you look at the following page but again sticking
18 in the notes --
19 MR. REED: Oh, okay, in the notes.
20 NS. WAGNER: In the notes but on the
21 following page, sorry to take to you these teeny tiny
22 notes again, right at the top there it says "as to
23 (d) [which is the description] it will not matter, in
24 particular, if the description does not comply with
25 Article 5 (clarity and completeness of the


MS. WAGNER: First Report. And they are paragraph 11, 27 and 37.

MR. REED: Okay.

MS. WAGNER: So the fact that the receiving office does this cursory review has nothing to do with the actual meaning of form and contents in the PCT, correct?

MR. REED: It has nothing to do with the actual meaning of--

MS. WAGNER: Of form and contents, because it's just a cursory review. They are not determining whether form and contents requirements are met, correct?

MR. REED: They're following the PCT rules and regulations and we looked at what is it, Rule 11 or Article 11? I forget which.

MS. WAGNER: Article 11, the cursory review for receiving Office purposes, does not establish that the form and contents requirements are actually met, correct?

MR. REED: Not with the first--I'd have to go back and look at the receiving Office guidelines, and I have not done that.

MS. WAGNER: We've just read, sir, that it's a "facial review," as per these records--

MS. WAGNER: "the Guidelines require the IPEA examiner to look to the claimed invention and the guidelines to determine whether the claimed invention has utility." And you indicate further, "The Appendix prescribes a three-pronged test for this purpose of the IPEA advisory opinion. The examiner must determine if the claimed invention has utility that is, (a), specific, (b), substantial and (c), credible."

I want to look specifically at paragraph 33.

MR. REED: Of the Second Report?

MS. WAGNER: In the same place, just below 32--in fact, let's just go back to 32 for one brief moment. In the first sentence you said that the guidelines require "the IPEA examiner to look at the claimed invention and the Guidelines to determine whether the claimed invention has utility," correct?

That's the exercise--

MR. REED: Yes.

MS. WAGNER: --described?

In paragraph 33 you say that "The IPEA examiner may need to revert to the three-pronged test when an IA"--I take it that's an International Application--"claims a selection invention singling out specific members of a known generic group and asserting that the selected species have unexpected higher efficacy than other members of the genus and this discovery advances the state of the art sufficiently to warrant a separate additional term of exclusivity."

MR. REED: Okay.

MS. WAGNER: And you go on to say, "This is particularly relevant when the same applicant has already enjoyed patent protection for the selected species (compound) in a granted patent claiming the entire genus. In the absence of evidence in the application at the time of filing clearly showing that the selected species (compound) has superior efficacy compared to other members of the genus, it is highly unlikely a POSITA"--I take it that's a "person of ordinary skill in the art"--"could review the disclosure and conclude the claims covering the selected species (compounds) actually possess the utility (and the unexpectedly higher efficacy) necessary to justify a second term of exclusivity."

So your testimony here relates to a pretty specific area of patent law, and that relates to patentability criteria as they apply to a
1 particular type of invention and that's known as
2 "selection" patents?
3 MR. REED: Okay. That's what I called
4 it. I don't know whether it's a standard term or
5 not. I've heard somebody here use it yesterday.
6 MS. WAGNER: Do you have any
7 particular expertise in the law relating to selection
8 patents?
9 MR. REED: No.
10 MS. WAGNER: Did you prepare and file
11 applications for selection inventions when you were
12 at P&G, to your recollection?
13 MR. REED: You know I don't know
14 because I didn't write them.
15 MS. WAGNER: And you don't recall
16 having any involvement with those particular
17 applications?
18 MR. REED: No, other than the fact
19 that -- no, I don't, other than the fact that they
20 exist, and if looking for the patentability is based
21 on the superior performance or the superior benefit
22 that's unexpected, I have no particular expertise.
23 MS. WAGNER: So what is your authority
24 for asserting that the guidelines -- the
25 International Preliminary Guidelines, is that the

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MR. REED: No, I didn't see in the
1 guidelines about selection invention, but I haven't
2 read them for a few days.
3 MS. WAGNER: Are you aware that it's
4 only in Canada that the disclosed advantages of a
5 selection invention are treated as being the utility
6 of that invention?
7 MR. REED: I have no knowledge at all
8 of that.
9 MS. WAGNER: And are you aware that
10 Canadian law has only recently treated selection
11 inventions in this way?
12 MR. REED: I don't know anything about
13 Canadian law and how they operate up there.
14 MS. WAGNER: So your understanding in
15 paragraph 33 was simply based on a general
16 understanding that utility is related to selection
17 inventions?
18 MR. REED: Well, it was more for the
19 three-pronged test, which it happens to be for
20 utility, yes.
21 MS. WAGNER: And you don't have any
22 experience that that's how selection compounds have
23 been treated in the United States?
24 MR. REED: No, no knowledge at all.

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and an abstract. Correct?

MR. REED: Actually that's -- I believe that's in the Articles, but then we also get into some of the stuff under rule 5.1 in a little more detail, but... THE PRESIDENT: Please speak up.

MR. REED: I'm sorry. I said rule 5.1 gives a little more detail but yes, that's basically the first cut of the broad categories.

MS. WAGNER: If we turn back to paragraph 33, which is my reference point for this, if I understand you correctly, in your view the PCT places no constraints on the actual contents of the PCT application insofar as those contents relate to substantive patentability criteria?

MR. REED: That is my position, yes.

MS. WAGNER: One of those substantive patentability criteria is industrial applicability or, otherwise stated, utility, correct?

MR. REED: Okay.

MS. WAGNER: Agree?

MR. REED: I agree.

MS. WAGNER: If you go to paragraph 39 of your statement. I'm looking specifically at the last sentence. It's your opinion that disclosure of the PCT rightfully places the decision into some of the stuff under rule 5.1 in a little more detail, but yes, that's basically the first cut of the broad categories.

MS. WAGNER: One of those substantive patentability criteria is industrial applicability or, otherwise stated, utility, correct?

MR. REED: Okay.

MS. WAGNER: Agree?

MR. REED: I agree.

MS. WAGNER: If you go to paragraph 39 of your statement. I'm looking specifically at the last sentence. It's your opinion that disclosure of the PCT rightfully places the decision...
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MR. REED: I didn't know there was a question on the table.

THE PRESIDENT: There was a reference to it. I think the question is still coming.

MR. REED: I see it.

MS. WAGNER: So you see it?

MR. REED: Yeah.

MS. WAGNER: Right below that it says that the final text of the Treaty and rules was signed at the close of the Conference on June 19, 1970.

MR. REED: Okay.

MS. WAGNER: See that there?

MR. REED: Yes.

MS. WAGNER: You weren't there?

MR. REED: I was not there.

MS. WAGNER: I didn't expect you to be. So these notes essentially reflect the minutes of the final negotiations of the text of the 20 Patent Cooperation Treaty. Is that a correct understanding?

MS. WAGNER: I think it does say that.

MR. REED: Is that what it says? I don't know that it reflects the minutes per se.

MS. WAGNER: I think it does say that.

MR. REED: It may. I've not read this.

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MS. WAGNER: Well, what I'm looking at is the second to last paragraph at the bottom. It refers to the "minutes of the Conference."

MR. REED: Okay. I see that.

MS. WAGNER: To provide you with the context, I am going to be referring to some material that is the minutes of the Main Committee, which start on page 591. We're not actually going to go to page 591, because that's just the start. We're going to go to page 635. These are, again, teeny, tiny little numbers at the top of the page there.

MR. REED: I found it.

MS. WAGNER: So, as it turns out, my hypothetical was not that hypothetical. Were you aware that, during the latter PCT negotiations, there were proposals to dispose of the requirement to explicitly state a utility if one were not apparent?

MR. REED: I was not aware of that.

MS. WAGNER: I was not either until very recently. If you look at page 635 --

MR. REED: You say there was a proposal to eliminate that, but they did not eliminate it?

MS. WAGNER: They did not eliminate it.

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It is there today, as we have seen.

MR. REED: Yes, it is.

MS. WAGNER: Right. So if you look down at the bottom of page 635, there's a paragraph 896.

MR. REED: Okay.

MS. WAGNER: All I'm doing here is just providing the frame of reference for these proposals to eliminate. So "Mr. Lips [Switzerland] moved the proposal of his Delegation concerning item (vi) contained in his documents PCT/DC/17. In most cases, the use or industrial manufacturer of an invention was obvious and required no special explanation such as that envisioned in item (vi) of the Draft. Consequently, item (vi) should read as follows: 'indicate the way in which the subject of the invention can be made and used in industry, if such indications cannot be implied from those indications mentioned in the preceding items of paragraph (a).' In 99 percent of the cases, the said implication would be possible and no specific statement would be necessary."

Then, 897, we have the proposal of France "referring to the proposal of his Delegation contained in document PCT/DC/21, said that item (vi)

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should be made entirely optional and should refer only to the general notion of 'industrial applications' without providing any exact and restricted definition. The industrial character or industrial application of the invention was in most cases so obvious from the general description of the invention that it required no special explanation.

Consequently, item (vi) could read as follows: 'possibly indicate the possibilities of industrial application of the invention.'"

So those were the proposals, but if you look at paragraph 901.1, which is just three paragraphs below that text that I just read out from France, 901.1, we have here -- and you can have a chance here to review it -- but we have here a Mr. McKie from the United States, and he felt that, as far as the United States of America was concerned, a statement on the utility of the invention was a minimum requirement. So I take it he's disagreeing with the proposal. Do you agree that he was disagreeing with the proposal?

MR. REED: I do. There wasn't a question on the table so...

MS. WAGNER: Then at 904, we also have Poland, Mr. Gierczak. He was also appearing to
1 oppose those proposals. I'll give you a chance to
2 read it and you can let me know if you agree.
3
4 MR. REED: Okay.
5
6 MS. WAGNER: Now, at 908.1, we have
7 Mr. Bogsch, the Secretary General --
8
9 MR. REED: Bogsh.
10
11 MS. WAGNER: Thank you. I notice you
12 didn't correct me on the Polish gentleman's name.
13 That's all right. I didn't know it either.
14 I'm going to read this out, and then
15 I'm going to characterize it and ask you a question.
16 if you agree. So he says, Mr. Bogsh, that "an
17 international application served not only the purpose
18 of international search but also the purpose of being
19 an application in each of the designated States.
20 Therefore, it was extremely important that the
21 international application should contain all the
22 elements which made it possible for the Contracting
23 States to regard it as an equivalent of a national
24 application. It was for that reason, and mainly for
25 that reason, that the PCT defined with precision the
26 formalities and the minimum contents of international
27 applications."
28 So I'm going to put it in my own
29 words, but in general do you agree that what the

---

1 saying is this: If the PCT does not require an
2 applicant to explicitly state a utility and the
3 United States does require the applicant to
4 explicitly state a utility, then there's a potential
5 problem because the applicant who uses the PCT system
6 might be in jeopardy when they go to file in the
7 United States?
8
9 MR. SPELLISCY: I've let this go on
10 for a while. We can all read it. I'm not sure that
11 Mr. Reed has any particular expertise to interpret
12 what the delegation of the United Kingdom or other
13 delegations were saying. I'm happy to have him
14 answer the question, but I really wonder, concerning
15 what other delegations and other people were saying,
16 whether he has any expertise that he can offer on
17 that.
18
19 MR. REED: Not only that, I've never
20 seen any of this stuff before, so I'm just reading it
21 for the first time myself.
22
23 MS. WAGNER: I am laying the
24 foundation for an ultimate question.
25
26 THE PRESIDENT: Overruled. Please
27 proceed.
28
29 MR. REED: Okay.
30
31 MS. WAGNER: So my question is this:

---

1 Secretary General is saying is that, if a PCT member
2 country is going to require an applicant to
3 explicitly state a utility, then we need to make sure
4 the PCT also requires the applicant to explicitly
5 state the utility, otherwise the application might
6 not have what it needs?
7
8 MR. REED: I think that's fair.
9
10 MS. WAGNER: You think that's fair?
11
12 Okay.
13
14 Now let's go to paragraph 910. Next
15 page. And we have Mr. Fergusson of the United
16 Kingdom. Again, I'm going to read out what he says,
17 and then let's see if we agree what he's saying.
18 He said that he "fully agreed with the
19 explanation given by the Secretary General of the
20 Conference. Since the delegation of the United
21 States of America had indicated that any broadening
22 of the provisions under discussion would put the
23 application in jeopardy in the United States of
24 America, it would be extremely difficult to accept
25 the proposals of the Delegations of Switzerland and
26 France. It would be best to leave the text as it
27 appeared in the Alternative Draft."
28
29 Again, to paraphrase, speaking
30 generally, do you agree that what the UK delegate is

---

1 The reason that a PCT applicant would be put in
2 jeopardy, if the PCT did not say you had to
3 explicitly state a utility but a member country's
4 laws required you to state a utility, that their
5 application would not have what it needed to satisfy
6 that member country, correct?
7
8 MR. REED: It was a little convoluted.
9
10 Try it one more time, please.
11
12 NS. WAGNER: Do you agree that a PCT
13 applicant will be put in jeopardy if the PCT does not
14 require an explicit statement of utility but a member
15 country does?
16
17 MR. REED: We're talking explicit
18 statement of utility which is basically the language
19 in 5.1(a)(vi).
20
21 NS. WAGNER: That's what I'm asking
22 you. If the PCT, as per this proposal, did not
23 require an explicit statement of utility but a member
24 country did require an explicit statement of utility,
25 then the PCT or the applicant would be put in
26 jeopardy when they go to file in the member country,
27 correct?
28
29 MR. REED: But the PCT does not
30 require an explicit statement of utility if it's
invention.

MS. WAGNER: That's correct, but the
proposal here was to get rid altogether of that
requirement to state an explicit statement of utility
if it were not apparent. That was the proposal.

MR. REED: But it didn't happen.

MS. WAGNER: It didn't happen but, if
it had happened and there were no requirement in the
PCT to state an explicit utility, if a member country
did require it, that would put the applicant in
jeopardy when they go to file in the member country,
correct?

MR. REED: As far as I'm concerned, if
they knew their national laws they would build it in
for that particular country anyway, and not rely on
the PCT.

MS. WAGNER: And, in your view, a
member country would not be constrained -- the fact
that the applicant might be put in jeopardy would not
constrain the member country from imposing that
obligation, correct?

MR. REED: The national law for
substantive material or criterion for patentability
is given totally to the national law, whether it's in
the PCT or not.

MS. WAGNER: If the PCT were silent as
to whether an applicant had to state a utility, so
there was nothing in there --

MR. REED: That's a hypothetical.

MS. WAGNER: It's a hypothetical --
then a member country could still require them to
state a utility. Is that your response?

MR. REED: Yes, again, in their
national law.

MS. WAGNER: Correct. Looking again
at 914.2, first column of page 637, it is in fact the
last passage I will read to you -- I stand corrected.
I have two passages to read to you and they will be
the last two passages I will read to you.

If you go to 636, previous page, and
it's right at the bottom in the second column and
it's 914.1, we have Mr. McKie of the United States
and he says: "Section 112 of the U.S. Patent Statute
required the specification to contain 'a written
description of the invention and of the manner and
process of making and using it, in such full, clear,
concise and exact terms as to enable any person

MS. WAGNER: So the member country
should not feel constrained about imposing that
requirement, even if the PCT does not, in your view?

MR. REED: As long as it's part of
their national law. Again, it cannot fall under the
definition of form and contents of the PCT. They
would have to take a look at that.

MS. WAGNER: And you have already --
we have already -- you have already answered that
question because you have already said that requiring
an explicit statement of utility, because it relates
to a substantive criteria of patentability, is not a
matter of form and contents under the PCT.

MR. REED: The material that -- the
explicit statement is part of the formality, is part
of the form and contents, and they can't require
more, but they can require more on utility to get
into the substantive aspects of patentability under
each national law.

MS. WAGNER: In your view, if the PCT
was silent about utility, member countries could not
ask them to make an explicit statement of utility?

MR. REED: Is that now your view? Because that's different then
the testimony you gave earlier.

MR. REED: That's not -- then I must

so I guess what he's saying here is
that you don't always have to explicitly state a
utility in the case of a chair; it would be obvious.

MR. REED: From the standpoint of rule
5.1(a)(vi), I think that would probably be obvious.

MS. WAGNER: Then one last passage.

1942. This is the United States saying, "It was in
view of Article 27(1) -- which provided that no
Contracting State had the right to require compliance
with requirements relating to the form or contents of
the international application different from or
additional to those which were provided for in the
PCT -- that it was essential that the Rules
concerning the description be such that they did not
Mr. Reed: Clearly the report is submitted to the people in Canada and must have been printed. I assume that was on the top of the page that I signed.

Ms. Wagner: So you didn't add that?

Mr. Reed: I guess they must have. I certainly didn't add it.

Ms. Wagner: Thank you.

The President: Any question for redirect, Mr. Spelliscy?

Mr. Spelliscy: Just one related to that last question.

DIRECT EXAMINATION ON BEHALF OF THE RESPONDENT

Mr. Spelliscy: Mr. Reed, did we help you with the formatting of your report?

Mr. Reed: Not at all.

Mr. Spelliscy: Thank you.

The President: Mr. Reed, thank you for testifying. You are now released and excused as an expert witness.

Mr. Reed: Thank you very much.

The President: We have lunch recess until 1:30.

(Recess taken)
Treaty, which took place in the 1980s and resulted in adoption of what was then called the Patent Law of negotiations which my report deals with.

The central tenet of this requirement was not controversial. I mention here the basic proposal, the central tenet of the requirement was not the point of controversy.

In practice, very few inventions are denied patentability on the basis of the utility requirement. Very rarely is an application rejected or a patent invalidated for want of utility. It is a very low bar to patentability. Different legislation uses different language in order to implement or elaborate this requirement, but the fact that there are those differences was not controversial. In particular, that central tenet of the requirement was not a point of controversy in either of the two sets of negotiations which my report deals with.

In the set of negotiations for adoption of what was then called the Patent Law Treaty, which took place in the 1980s and resulted in a Diplomatic Conference in 1991, in those discussions the central tenet of this requirement was not controversial. I mention here the basic proposal, that was the name given to the draft which was put to that Diplomatic Conference.

Then again, later, in the early 2000s, attempts were made within WIPO, within international discussions under the aegis of WIPO, to conclude a substantive patent law treaty. Once again, in those negotiations the utility requirement was not a point of controversy.
I say this as someone who worked in WIPO for nearly 20 years. One of my positions in WIPO was as director of the Patent Policy Department, and in that capacity I supervised staff whose responsibility was preparing draft texts of the SPLT -- the Substantive Patent Law Treaty, the draft Substantive Patent Law Treaty -- and I took part in all meetings of the WIPO body which considered those drafts, the Standing Committee on the law of patents, or SCP. Prior to that, I'd been in the Australian Patent Office, which I left as an assistant commissioner responsible for policy and legislation matters.

Well, I said at the outset that I don't believe that the utility requirement was the subject of controversy, but of those sets of negotiations concerning substantive patent law harmonization were indeed very controversial. What was the problem? Well, there were several but I think the two main ones were, in the case of the SPLT draft 2000 to 2004 -- the first of the issues which was a real sticking point was that a number of provisions in the draft depended on the perceived desire of many countries to see everyone operate under what was called a first-to-file patent system under which WIPO was as director of the Patent Policy Department, and in that capacity I supervised staff whose responsibility was preparing draft texts of the SPLT -- the Substantive Patent Law Treaty, the draft Substantive Patent Law Treaty -- and I took part in all meetings of the WIPO body which considered those drafts, the Standing Committee on the law of patents, or SCP. Prior to that, I'd been in the Australian Patent Office, which I left as an assistant commissioner responsible for policy and legislation matters.

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connection with one country's national law, and I
I think. There was a mention of promise in
central tenet of that requirement, the core principle
involved, has not attracted controversy in
international negotiations at WIPO concerning patent

The simple position is that the
central tenet of that requirement, the core principle
involved, has not attracted controversy in
international negotiations at WIPO concerning patent

Information from member states and produced a study
which summarized that information. In looking
particularly at the 2001 study, since
Professor Gervais mentions that expressly in his
Second Report, the word "promise" is most certainly
used, but to suggest that a promise approach is
discussed in that study would exaggerate the position
I think. There was a mention of promise in
connection with one country's national law, and I
think it becomes apparent from the 2001 study that
that country concerned was Canada, but there's no
elaboration of what the approach was on promise, and
there's nothing there which would suggest
that anything was taking place such as is currently
the subject of some contention in these proceedings.
So yes, promise is mentioned, but an
approach as to promise is most certainly not
described in that study or in its later embodiment.
The other point to make is that, in
referring to the matter of promise being acknowledged
by the Committee, well, the 2001 study was on the
available to members of the committee. The 2003
study was submitted as a formal document. But on
neither occasion did the committee acknowledge the
1 your report, you've got a heading, heading 2, that
2 says "Overview of Patent Law Harmonization in the
3 Context of WIPO." Do you see that?
4 MR. THOMAS: Yes, I do.
5 MR. SPELLISCY: I would just like to
6 confirm that you would agree with me today that there
7 has been no "patent law harmonization in the context
8 of WIPO," correct?
9 MR. THOMAS: Yes, in general, that is
10 true, yes.
11 MR. SPELLISCY: So your overview in
12 your statement here is about efforts to achieve
13 patent law harmonization, and not the actual
14 achievement of harmonization, correct?
15 MR. THOMAS: It's an overview of
16 really discussions or negotiations about patent law
17 harmonization, yes.
18 MR. SPELLISCY: And efforts to achieve
19 harmonization, correct?
20 MR. THOMAS: Yes.
21 MR. SPELLISCY: And those efforts have
22 all, as you've just noted in your presentation,
23 they've all failed, correct?
24 MR. THOMAS: That is substantially
25 correct, yes.

1 important to them that their applicants receive such
2 treatment in other countries, that the practical
3 outcome of filing applications and of obtaining
4 patents is substantially the same in other countries,
5 and the fact that different language may be used in
6 legislation is -- well, a subsidiary matter.
7 MR. SPELLISCY: Turn to paragraph 11
8 of your report. Here you're talking in the third
9 sentence, when you're talking about this different
10 terminology, "Different countries use different
11 terminology to implement the requirement" -- and
12 you're talking about industrial applicability or
13 utility -- "in their legislation. But the industrial
14 applicability (utility) standard is, as further
15 discussed below, applied in a manner that is
16 remarkably similar around the world. It is a low bar
17 that is rarely the basis for a rejection or
18 invalidation."
19 See that?
20 MR. THOMAS: Yes.
21 MR. SPELLISCY: In the next paragraph
22 you say in the first sentence that there is a
23 substantial consistency of practice with regard to
24 the core utility or industrial applicability
25 requirement. See that?
documents -- that there was consistency in the
application and the practice of the industrial
applicability and utility requirement, and a common
understanding of how it operated in practice, but you
would agree with me, would you not, that this
document from 2001, prepared by the International
Bureau from information received by members of the
standing patent committee, concludes otherwise. It
concludes there's wide -- or it says there is a wide
range of differences in how it is interpreted and the
practice relating to it, correct?

MR. THOMAS: Can I say that the word
"practice" is not used in an entirely consistent way
in all places. There are two notions associated with
the practice I think in this area. One would involve
the subsidiary legislation, regulations, guidelines
which were followed by examiners, for example, and
concern more definitional matters and more details of
exactly how a requirement was implemented.
On the other hand, there's a notion of
practice in terms of the practical outcome of the
consideration of applications and patents from the
point of view of compliance with this requirement,
and I think that second one is the kind of practice
which my report emphasizes, the practical outcomes of

handling applications. The fact that there was
difference in guidelines and in regulations in
different countries is something which is very
clearly the case, but there was consistent practice
in the practical outcomes in the sense that very few
applications at this stage were rejected on the basis
of the utility requirement. It was a low bar to
patentability, and I can't recall whether that
statement is made clearly in the 2001 version of this
study, but it most certainly is made clear in the
2003 version, which is somewhat more complete.

MR. SPELLISCY: We'll get to the 2003.
Come back to paragraph 11, the first one we looked at
in your report.

MR. THOMAS: Sorry, that was paragraph
11?

MR. SPELLISCY: 11, yes. You
concluded that it is applied in a manner that is
remarkably similar around the world. It is a low
bar, and I think that's what you were just saying.
But I'm looking at the first page of R-407, the first
paragraph. It seems to me that the standing
committee on patents requested the International
Bureau study the same thing, the application of the
industrial applicability requirement in various
1 countries. Would you not agree that comment on how
2 it is applied is the same as the study on
3 application?
4 MR. THOMAS: Well, it could be -- it's
5 a question of what it's focusing on. If one looks at
6 the wording of the legislation, not the wording of
7 the regulations, the wording of the practice
8 guidelines, yes, there are most certainly
9 differences. Absolutely.
10 If one looks at what happens as a
11 result, the outcome of applying those things, the
12 result's the same everywhere. The applications are
13 very seldom -- were very seldom rejected on the basis
14 of non-compliance with the utility requirement.
15 MR. SPELLISCY: Let's stay on the 2001
16 report. To be clear, you responded to this report
17 today. You didn't cite this report, or you didn't
18 review this report prior to preparing your Expert
19 Report?
20 MR. THOMAS: I'm sorry, I didn't catch
21 that, sir.
22 MR. SPELLISCY: It's a terrible
23 question.
24 You didn't review this 2001 report
25 prior to preparing your Expert Report in this

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1 and useful art, process, machine... and it goes on.
2 The second sentence says, "An invention lacks utility
3 if it is not operable or it will not do what the
4 specification promised it will do ('false promise')."
5 You see that?
6 MR. THOMAS: I see it.
7 MR. SPELLISCY: I think you said just
8 a few moments ago that you don't believe this
9 represents the promise doctrine in Canadian law. Is
10 that right?
11 MR. THOMAS: I don't think I said
12 that. I think I said that the references to the
13 promise doctrine are explained in a way which I would
14 think falls short of setting out what the promise
15 approach was. I think the word "approach" was used
16 in the quotation read to me.
17 MR. SPELL ISC Y: Right. Are you
18 familiar with Canadian law?
19 MR. THOMAS: No, I'm not, sir. I have
20 a passing familiarity but I am not an expert in
21 Canadian law, and nor is my report based on the
22 assumption that I am an expert in Canadian law.
23 MR. SPELL ISC Y: Let me understand how
24 these were put together. These were contributions
25 from members of the SCP, right? This was the

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1 secretariat summarizing the information it was told,
2 correct?
3 MR. THOMAS: Yes.
4 MR. SPELL ISC Y: So the information --
5 and I think you agreed earlier -- the law of another
6 country, the generic reference, this is a reference
7 to the law of Canada, correct?
8 MR. THOMAS: I think if you look at
9 the 2003 study, which is the more complete version of
10 this one, it becomes clear that what is contained
11 here in paragraph 13 does, indeed, relate to the law
12 in Canada, yes.
13 MR. SPELL ISC Y: So this would have
14 been, then, Canada informing the SCP of what its law
15 was, correct?
16 MR. THOMAS: Canada replied in
17 response to a survey saying what its law was. I
18 don't know that this was informing the SCP or that
19 the SCP -- there's no evidence -- there's no basis
20 for saying the SCP even took note of this report.
21 Indeed, I should perhaps just clarify
22 that the 2001 report was an informal document. It
23 would have been made available to member states but
24 it was not submitted as a formal document to the
25 Committee. Nonetheless, it certainly would have been

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MR. THOMAS: I want to talk about the statement you were discussing earlier in paragraph 11 in which you say industrial applicability... requirement...

MR. SPELLISCY: I want to talk about the statement you were discussing earlier in paragraph 11 in which you say industrial applicability... requirement...

MR. THOMAS: The content of this study?

MR. SPELLISCY: Yes.

MR. THOMAS: As long as the International Bureau was careful in what it did. It would certainly reflect accurately what the International Bureau did, and hopefully it would reflect accurately the responses that had been received at that date to the survey that was undertaken.

MR. SPELLISCY: This paper was dated April 2001, so you would agree with me, then, that this information must have been provided by Canada prior to that date, correct?

MR. THOMAS: Yes.

MR. SPELLISCY: And you said earlier this report was available to all members of the SCP, correct?

MR. THOMAS: Yes, it would have been made available. I can't say that I have any knowledge of exactly how it was made available, but it was certainly made available to all SCP members.

MR. SPELLISCY: According to the minutes of the meeting which was held and the later meeting considering the 2003 draft, there was no discussion of this document at all. It's not mentioned in the minutes of the 2001 meeting, and it's mentioned in the context of the 2003 meeting simply by virtue of the fact that it was available, but it's not noted or discussed by either the committee as a whole or by any delegation.

MR. SPELLISCY: So no concerns were raised then, correct?

MR. THOMAS: There were no concerns raised, nor was there any approval raised. It simply wasn't discussed.

MR. SPELLISCY: And no one raised any concerns to you on the secretariat, even outside of the plenary session, that wouldn't be reflected in the minutes, correct?
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<td>1</td>
<td>Bureau study reports that the reason member states are saying that utility is not often imposed is because it's covered in the same -- it's closely related to and achieves the same other things they were doing under other doctrines, like sufficient disclosure, definition of invention, obviousness.</td>
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<td>MR. THOMAS: It says that it's closely related to in the view of some countries, yes, and certainly the discussions of various matters come up under different heads.</td>
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<td>MR. SPELLISCY: It doesn't say &quot;some countries.&quot; It says &quot;many Offices,&quot; correct?</td>
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<td>MR. THOMAS: I'm sorry?</td>
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<td>MR. SPELLISCY: I think in your answer it says &quot;some countries&quot; say that, but it actually says &quot;some countries&quot; say that. You see that?</td>
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<td>MR. THOMAS: Yes, I see that. I don't have a count in my mind.</td>
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<td>THE PRESIDENT: Sorry, I think &quot;Many Offices indicated that&quot; -- if you quote from paragraph 20 -- and then &quot;several Offices.&quot;</td>
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<td>MR. SPELLISCY: I see. Fair enough.</td>
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<td>THE PRESIDENT: So what you should have been asked was &quot;several&quot; Offices, not &quot;some&quot;</td>
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<td>MR. SPELLISCY: Yes, your report, paragraph 12.</td>
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<td>MR. THOMAS: I'm sorry, could you repeat the question?</td>
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<td>MR. SPELLISCY: You said in the first line, &quot;Given the substantial consistency of practice... The issue was not considered to be a priority for harmonization&quot; about utility. I just wanted to understand that statement a little bit more.</td>
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<td>Let's look again at the 2001 study and turn to page 6 again, which is where we were in that paragraph 24. It says, &quot;It is apparent that the notions of 'industrial applicability' and 'utility' are broad and, at least in part, overlap. Further, they relate to other substantive requirements of patentability. Therefore, for the purposes of full harmonization of substantive patent law, the industrial applicability/utility requirement cannot be considered separately from other requirements. In this regard, the SCP may wish to consider the possibility of examining substantive patentability requirements as a whole, without giving too much focus on the terminology 'industrial applicability' or 'utility'.&quot;</td>
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<td>MR. THOMAS: I see it.</td>
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<td>MR. SPELLISCY: You would agree with me that far from saying utility and industrial applicability need not be addressed because there is a common agreement, this paper concludes that, in fact, they cannot be considered separately from other requirements and that the SCP should examine the patentability requirements as a whole, correct?</td>
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<td>MR. THOMAS: Yes, yes, I understand what you're asking, I understand what you're saying, but I'm not quite sure what you're asking me to say.</td>
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<td>MR. SPELLISCY: You would agree that the International Bureau here in 2001 is not concluding, as you did, that there is no reason to examine, or no reason to consider it a priority to harmonize utility. Its telling it's members that utility must be considered and it must be considered with other requirements, correct?</td>
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<td>MR. THOMAS: This suggestion by the International Bureau is that the SCP &quot;may&quot; wish to consider -- I wouldn't use the word &quot;must&quot; -- but it may wish to consider the possibility of doing these things, but in practice the SCP did not so proceed, and I think that is borne out in the statement made.</td>
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in paragraph 12 of my report. Priority was not given
back and discuss that in a second in terms of the
priority given to this matter. Maybe let's do it
right now. Let's come to tab 3 in your binder, which
is the 2003 report that you did cite, the WIPO
report, Exhibit R-230, titled "Industrial
applicability and 'utility' requirements."
This document is an official WIPO
report, correct?
MR. THOMAS: It's an official WIPO
document, yes, and it's a report in the sense that
it's a study based on responses given by member
states.
MR. SPELLISCY: And it was prepared
now during the middle of the SPLT negotiations,
correct?
MR. THOMAS: It was issued. It was
prepared, as pointed out in paragraph 2 of the
report, there's a reference there which, in fact, is
to the study at tab 1, but the preparation of this
would have taken place continuously over the period
from whenever the invitation to respond to the survey
was first issued, which would have been sometime in

There was no discussion on it.

There were two delegations which made a
suggestion that such a study be prepared, and then
the chair concluded -- there was no other remark --
the chair concluded that the International Bureau
should go ahead to prepare this study, so I don't
think the word "mandated" should be read in a very
exalted kind of way.

Why was it done? Because some
delegations requested it. The more important thing
is what happened to the study when it was prepared,
when the mandated study was prepared? The answer is
it was submitted to the committee with a request -- a
suggestion at the end, there's a paragraph right at
the end of the study -- which says "The SCP is
invited to note the contents of this document." When
one looks at the minutes of the meeting which
considered the document, the only reference to it is
the fact that it was on the table. There was no
noting, no acknowledging, no approval -- nothing.

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1. study on two separate occasions within a two-year period, correct?

MR. THOMAS: The International Bureau was certainly asked to prepare the study, yes. There were member states who -- I should say which, perhaps -- would wish to see a result of this study, and they may well have found it interesting, but they didn't say so in meetings of the SCP.

MR. SPELLISCY: And these studies were available to them, though, right?

MR. THOMAS: I'm sorry?

MR. SPELLISCY: Both of these studies. This study too. This 2003 study was made available to member states, correct?

MR. THOMAS: Both studies were available to member states, yes, although one was a formal document, one was an informal document. But yes, they were certainly both available.

MR. SPELLISCY: In your report, Mr. Thomas, in paragraph 30, in the second sentence, you say, talking about this 2003 study, that the study was "undertaken by the International Bureau in light of the differences in domestic nomenclature." You see that?

MR. THOMAS: Yes.

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1. 3.

MR. THOMAS: The last one we mentioned was my report, so I just want to clarify.

MR. SPELLISCY: Tab 3, page 7, paragraph 25. The WIPO study in the first line concludes that, "As described above, national and regional laws and practices concerning the industrial applicability requirement vary significantly,"
correct?

MR. THOMAS: Yes. Here I think we should be clear that the word "practices" almost certainly refers to regulations and guidelines rather than practical outcomes.

MR. SPELLISCY: I understand that, but what it's saying is there's significant variance in the standard, correct?

MR. THOMAS: There most certainly is.

MR. SPELLISCY: If we turn to page 13 in this report, paragraph 49, we get to the conclusion on utility. The conclusion is, "As in the case of the industrial applicability requirement, practices in the countries which require utility (or usefulness) vary." Then it goes on to say, "As a general rule, however, certain characteristics commonly applicable to the utility requirement can be identified."

Do you see that?

MR. THOMAS: Yes, I see that.

MR. SPELLISCY: So the report here is again noting that, even though there are certain characteristics commonly applicable, that there is, again, variation in the practices of countries, correct?

MR. THOMAS: Yes.

MR. SPELLISCY: I want to understand again what would have been known at the time this was submitted because this is, again -- you said it was available to all SCP members, so let's come back to page 11 and paragraph 40 of this report.

MR. THOMAS: I think just to clarify -- I'm not sure I heard you correctly, but did you say SCP members? It was available to all SCP members, yes. Indeed, it would be publicly available.

MR. SPELLISCY: It would have been published on the WIPO website?

MR. THOMAS: Yes, it would -- I can't speak as a matter of confirmed fact but I'm sure this would have been made available to anyone who wanted it.

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MR. SPELLISCY: So we're going to start on page 11 and paragraph 40, where it says "Under the law of Canada". Earlier we had talked about the 2001 report which had just mentioned the laws of another country.

MR. THOMAS: I apologize for interrupting, but I didn't catch the reference.

MR. SPELLISCY: Page 11, paragraph 40.

MR. THOMAS: Yes, thank you.

MR. SPELLISCY: First line, "Under the law of Canada..."

MR. THOMAS: Yes.

MR. SPELLISCY: As we discussed earlier this is the follow-on, and what makes you conclude here that the "another country" that is referred to in the informal paper is, in fact, the laws of Canada. That's the reference, right?

MR. THOMAS: That's right, and it follows in the next two paragraphs.

MR. SPELLISCY: If we come to the next paragraph, paragraph 41, we see that what Canada told in response to the report -- or in response to this study was that "A finding that the alleged invention is not useful may be expressed in a way 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 ('false promise')." See that?

MR. THOMAS: I see it.

MR. SPELLISCY: The same language from the 2001 report, correct?

MR. THOMAS: I think you'll find that the whole of this paragraph is not identical to the 2001 study, but it may well be that that sentence is.

MR. SPELLISCY: Again, as you said earlier, this is in 2003, and this document you said wasn't discussed by members of the SCP, correct?

MR. THOMAS: I didn't catch the --

MR. SPELLISCY: This was in 2003, and you said that this document was never discussed by members of the SCP?

MR. THOMAS: I think I said no discussion was reported in the minutes. I can't say what countries may have discussed among themselves but, as a matter of the committee discussions, no, it wasn't discussed.

MR. SPELLISCY: And no concerns, to your knowledge, as a member of the secretariat there attending every meeting, no concerns, to your knowledge, were ever raised about this Canadian

---

MR. THOMAS: That is correct.

THE PRESIDENT: One question, if I may. You see the reference in footnote 14 -- this is a question actually to Respondent, not to the expert -- and you see there the Canadian Patent Act annotated by Mr. Barrigar in 1999, and he quotes it, and when I see this quote it seems similar to the Halsbury 3rd Edition, if I recall it. I see the words "more broadly." Is this reference in the record?

MR. SPELLISCY: I don't think that reference is.

THE PRESIDENT: Can we make a mental note that this one will be a Tribunal question?

Sorry for interrupting.

MR. SPELLISCY: Let's turn to page 14, paragraph 52 of this report. Here the International Bureau has reported, "As in the case of the industrial applicability requirement, the utility requirement also relates to other patentability requirements, in particular, requirements concerning the disclosure of the claimed invention. Since the required utility could not be a speculative one, it is also related to a principle that the scope of the..."
Presentations by Professor Gervais

Professor Gervais: I solemnly declare upon my honor and conscience that my statement will be in accordance with my sincere belief.

The President: Thank you. Can you go to your First Report? This is dated January 23, 2015. Please go to page 27 and confirm that the signature appearing above your name is your signature?

Professor Gervais: It is.

The President: Can you please go to your Second Report dated December 7, 2015, page 16, and confirm also for the record that the signature appearing above your name is your signature?

Professor Gervais: It is.

The President: Thank you. Is there any correction you wish to make to either report?

Professor Gervais: No, sir.

The President: Mr. Spelliscy?

Mr. Spelliscy: Professor Gervais, I know you have a presentation to give, so I invite you to give it now.

Professor Gervais: Thank you.

PRESENTATION BY PROFESSOR GERVAIS

Professor Gervais: Thank you very much, Mr. President, members of the Tribunal, for giving me this opportunity to appear before you in this particularly important matter. I will be relatively brief, a very quick overview of my qualifications.

I am currently full professor of law at Vanderbilt University and director of the IP Program. I used to work at WIPO as head of section, and before that at what we now call the WTO (in those days it was called the GATT) during the TRIPS negotiations. I then authored a book reference text on the TRIPS Agreement which has been cited in several countries. I'm also a member of both the Academy of Europe and the American Law Institute. There are essentially three main points made in my two reports, and I've tried to summarize them in view of the Claimant's new line of argument on the baseline.

Essentially, the three major substantive patentability criteria, the ones that are named in both NAFTA and the TRIPS Agreement, are, in fact, named, defined and applied differently around the world, and this changes not just geographically
but also through time. These are, as the Claimant
now acknowledges, not harmonization.
There is no international treaty, and
this would include both NAFTA and TRIPS, that
establishes a legal obligation to use a specific or
particular definition or application of any of the
substantive patentability criteria in the examination
of domestic patent applications.
Third, states all apply other factors
or criteria before a patent will be granted, most
notably disclosure of an invention as of the date of
application.

Very simple examples of all three.
Novelty: Here, we have apparent agreement on naming
the criterion but, in fact, there are three versions
that have existed since NAFTA -- first-to-file,
first-to-invent, and now the new system which the
U.S. at least refers to as first-inventor-to-file.
There are differences in countries in terms of how
they measure novelty, whether novelty needs to be
absolute or relative, by which --

**MR. BERENGAUT:** I'm sorry to interrupt
but I don't see references in these slides to
Professor Gervais' reports, and I don't believe he
addressed these topics in his reports.

---

"beneficial utility," what one of the amicus briefs I
think refers to as "Jeffersonian utility."
The law has changed and continues to
change on this. U.S. law certainly changed, at least
as far as I'm concerned, after the Juicy Whip case.
Laws do and will continue to change.
The 2001 study that is referred to in
my report, that was highlighted in a previous
expert's testimony, makes very clear that this is not
just a matter of nomenclature but a matter of
practice. The word "practice" is there; it's quite
clear.
The overlap between utility and other
requirements is also noted, and I would draw the
Tribunal's attention to the fact that enablement is
specifically mentioned. The relationship between
utility and enablement, for example, in U.S. law is
particularly clear, and I would be happy to say more
about that later.
Promise utility is specifically
mentioned. I don't quite know what promise utility
is but I'm using the term because I've seen it used
in briefs. I think it means that if you promise
something in your patent application then you must
deliver on that promise, which first of all strikes
of new technologies evolve; how lawyers approach
these issues in courts, how courts make policy,
because most patent policy is made by courts, very
few patent laws are amended on the level of how to
define these criteria. So when the Claimant says --
and I really tried hard to understand their baseline
argument and perhaps in cross-examination I'll get a
better understanding, but I honestly do not know what
the difference is between saying there's a baseline,
which I think is better viewed here as a ceiling,
basically a very low level of utility, and saying
that's the international norm, not documented but
that's it, and saying there's no harmonization. So I
would suggest that that's a distinction without a
difference.  
NAFTA does not require the parties
adopt the PCT definition of industrial applicability.
The PCT and the Paris Convention were both well-known
at the time that NAFTA was signed and TRIPS. Neither
one of those agreements incorporated the PCT, but
they both incorporated the Paris Convention.
Therefore, not being in the "must comply" list of
treaties in NAFTA is, I think, relevant.  
More importantly I think the PCT as
I've always understood it, and I will plainly admit

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defined requirements that the NAFTA parties may exceed but not contravene."  
21 Do you see that?  
22 PROFESSOR GERVIAIS: I do.  
23 MR. BERENGAUT: I take it you disagree with that proposition?  
24 PROFESSOR GERVIAIS: No, I don't -- of

characterizing your understanding of a point made in the Reply Memorial, correct?  
3 PROFESSOR GERVIAIS: Correct.  
4 MR. BERENGAUT: My question to you is whether you agree or disagree with that point stated in the Reply Memorial, as you understand it.  
5 PROFESSOR GERVIAIS: Oh, I understand.  
8 You're not asking if I agree with my characterization but with the baseline argument. I don't agree with the baseline argument, correct. I apologize, I misunderstood the first time.  
12 MR. BERENGAUT: You would agree, Professor, that in your view the TRIPS Agreement is relevant to the interpretation of Chapter 17, correct?  
16 PROFESSOR GERVIAIS: Relevant, yes.  
17 MR. BERENGAUT: Let's turn to your first statement, which is in tab 1.  
19 PROFESSOR GERVIAIS: First Report?  
20 Yes.  
21 MR. BERENGAUT: If you could please turn to paragraph 25 of your First Report, which is on page 9.

1 my statement -- this is my characterization of your argument.  
3 MR. BERENGAUT: I take it you disagree with the proposition that you are characterizing in Claimant's Reply Memorial.  
6 PROFESSOR GERVIAIS: I'm sorry. Let me read this again. So you say, okay, there's a baseline that Chapter 17 creates a minimum set of defined requirements the NAFTA parties may exceed, but not contravene. What is it -- you're asking me if I stand by that statement?  
12 MR. BERENGAUT: In this sentence, Professor, you say that the Reply Memorial -- that's Professor Gervais, my name is Alex Berengaut.  
13 MR. BERENGAUT: That's right. If you could please look at paragraph 4, where you write, beginning in the second sentence, "In particular, itsReply Memorial argues that there is a baseline in that Chapter 17 of NAFTA creates a minimum set of defined requirements that the NAFTA parties may exceed but not contravene."  
21 Do you see that?  
22 PROFESSOR GERVIAIS: I do.  
23 MR. BERENGAUT: I take it you disagree with that proposition?  
24 PROFESSOR GERVIAIS: No, I don't -- of

WIPO report which states, "It is to be noted that the TRIPS Agreement provides for minimum requirements."  
Do you see that?  
4 PROFESSOR GERVIAIS: I do.  
5 MR. BERENGAUT: Do you agree with the statement in this report that the TRIPS Agreement provides for minimum requirements?  
8 PROFESSOR GERVIAIS: It provides for minimum requirements subject to being consistent with the agreement, yes, so you can go above without contradicting the agreement or the terms of Article 1 of TRIPS.  
13 MR. BERENGAUT: And when you say "go above," you mean provide additional intellectual property protection, correct?  
16 PROFESSOR GERVIAIS: In most cases that would be the case, yes.  
18 MR. BERENGAUT: In the next paragraph you quote a different WIPO report which states "WTO members have the flexibility to design their national intellectual property IP systems within the minimum standards set by the TRIPS Agreement." Do you see that?  
24 PROFESSOR GERVIAIS: I do.  
25 MR. BERENGAUT: I take it you would
1 agree here as well that the TRIPS Agreement introduces minimum standards?
2 PROFESSOR GERVais: It does, subject
3 to what I said before.
4 MR. BERENGAUT: Let's take a look at
5 your treatise which is in tab 6. This is C-336. If
6 you could please turn to page 174?
7 PROFESSOR GERVais: Yes.
8 MR. BERENGAUT: The first full
9 paragraph begins "Article 1.1" where you write
10 "Article 1.1 also indicates that Member countries may
11 go beyond TRIPS, which thus sets minimum standards."
12 PROFESSOR GERVais: Yes.
13 MR. BERENGAUT: My question is just:
14 I take it that's a reference to the same point you
15 just made in response to my previous questions about
16 the WIPO documents?
17 PROFESSOR GERVais: Correct. Of
18 course, you'd have to read the whole paragraph to see
19 what actually it says, but yes.
20 MR. BERENGAUT: On that point I note
21 in the final sentence of the paragraph you write,
22 "This is related to the" -- no, fair enough, you're
23 talking about other things, and if you want to read
24 additional aspects of the paragraph in context I
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1 PROFESSOR GERVais: I see it, yes.
2 The point I made previously is in 1702 on the
3 previous page, but okay, I'm on 1709 now.
4 MR. BERENGAUT: I'm happy to read 1702
5 into the record for context. Article 1702: More
6 Extensive Protection. "A party may implement in its
7 domestic law more extensive protection of
8 intellectual property rights than is required under
9 this Agreement, provided that such protection is not
10 inconsistent with this Agreement."
11 Now, your view -- and I think this is
12 a fair characterization but you'll correct me -- is
13 that countries have broad flexibilities in
14 implementing the patentability requirements
15 identified in Article 1709(1). Is that fair?
16 PROFESSOR GERVais: Yes, I think it's
17 fair.
18 MR. BERENGAUT: Let's explore that
19 concept with an example. You mentioned in your
20 opening presentation the concept of novelty, right?
21 PROFESSOR GERVais: I did.
22 MR. BERENGAUT: And that is also
23 sometimes referred to as the requirement that an
24 invention be new, correct?
25 PROFESSOR GERVais: Yes.

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PROFESSOR GERVAS: Well, there are two answers I can give you to that question. One is three words and the other is five minutes. The three words is “I don’t know.” The five minutes is “I can explain why.”

MR. BERENGAUT: Please -- maybe not for five minutes because we don’t have all that much time.

PROFESSOR GERVAS: It’s probably one of the core questions, as I see it, in the case. So it’s how you interpret the terms of Article 1709.

Clearly, there would be interpretations of the terms that are contained in 1709 that would go outside of boundaries. This is a notion that is well known certainly in trade law.

I could quote, or maybe not quote from but certainly cite Appellate Body and other Panel Reports in the WTO on this issue which is you have, as a member of the WTO applying TRIPS, leeway but it’s finite, and the question is where does that limit find itself. So is the example that you give me beyond that limit? Possibly. I might even say probably, given that you’ve really pushed it really far, but do I know with certainty where the limit is?

No, I don’t.

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1 discuss that topic, in this section of your report?

2 PROFESSOR GERVAS: Yes, I do.

3 MR. BERENGAUT: Your conclusion with regard to your review of these WIPO documents -- and now I’m quoting from paragraph 28 of your report -- is that there was “no consensus” on utility and industrial applicability. Is that right?

4 PROFESSOR GERVAS: Yes, that’s right.

5 MR. BERENGAUT: Now, in a number of places in your report you quote from WIPO documents statements to the effect that there are differences between utility and industrial applicability. Is that right?

6 PROFESSOR GERVAS: And within each group of countries applying both or either doctrines there are differences within each group as well, yes.

7 MR. BERENGAUT: And the reason you do this, I take it, is because in your view, these statements of difference evidence the fact that there was not consensus. Is that fair?

8 PROFESSOR GERVAS: There was not consensus.

9 MR. BERENGAUT: And the statements of difference, in your view, are evidence of that.

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1. convention for drivers' licenses for driving tests.
2. In my country, you get a license if you are an
3. adequate driver and in your country you get a license
4. if you are an able driver, and we are trying to reach
5. agreement on the test.
6. If you wanted to include as part of
7. the test a mountain driving skill and I didn't, that
8. would be a point of difference, right?
9. PROFESSOR GERVAIS: For example, yes.
10. MR. BERENGAUT: But if we both agreed
11. that drivers who show up to take their tests and are
12. completely intoxicated would mean that the drivers
13. were neither an adequate driver nor an able driver,
14. and if we could reach agreement on that, wouldn't
15. that be a point on which we had consensus?
16. PROFESSOR GERVAIS: It depends. If
17. we're only trying to discuss whether the rule for
18. drivers' licenses is able or adequate and we decide
19. on some way to define "able" or "adequate," or we say
20. "able" may be deemed synonymous with "adequate," do
21. we have consensus on that particular point -- yes.
22. If we are trying to decide what are
23. the rules that apply to drivers in our two states and
24. that's paragraph 381 of this whole document, then
25. yes, you could say we have consensus on 381. But

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MR. BERENGAUT: Doesn't this sentence indicate that industrial applicability and utility are part of the same requirement of patentability?

PROFESSOR GERVAIS: Now I understand the question.

Well, yes, there are three widely recognized requirements of patentability in 1709 and 27(1), novelty, industrial applicability with the possible synonymy with utility, and then inventive step and possible synonymy with non-obviousness. I would add disclosure to that. But yes, absolutely, this is a widely recognized requirement.

MR. BERENGAUT: The only identified practical example of something which would fail the industrial applicability or utility standard in this paragraph is a perpetual motion machine, correct?

PROFESSOR GERVAIS: Yes, that's the classic example most people use.

MR. BERENGAUT: Perpetual motion machines are necessarily inoperable?

PROFESSOR GERVAIS: Well, as I understand it they kind of go against the laws of physics.

MR. BERENGAUT: And devices that go against the laws of physics are necessarily inoperable?

PROFESSOR GERVAIS: Other than the private purposes. Is that right?

PROFESSOR GERVAIS: I believe, if it cannot work, it's probably not very useful.

MR. BERENGAUT: There are no examples of inventions in this document that fail utility or industrial applicability because they do not live up to a self-described promise. Is that right?

PROFESSOR GERVAIS: In this document -- not in the paragraph I'm looking at. I'd have to look at the entire document. I don't know.

MR. BERENGAUT: You're not aware of any indication in this source that the differences between utility and industrial applicability have any practical consequences, are you?

PROFESSOR GERVAIS: Oh, if you look at those two definitions they could definitely have practical implications. If you look at the last line of what it says on utility, if you're going to start measuring social benefit you're definitely going to be somewhere probably a little different than industrial applicability.

MR. BERENGAUT: There are no examples that are identified which would satisfy one standard but not the other, correct?

PROFESSOR GERVAIS: Other than the private purposes.

I'm looking at. I did not re-read this entire document.

MR. BERENGAUT: Let's go back to your First Report, tab 1, paragraph 32. In paragraph 32 you note that following the report that we just discussed there were comments that were submitted from various countries, including Canada and the United States. Do you see that?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: You refer to paragraphs 84 and 85 from those comments, correct?

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: This is R-222. Let's look at the document. It's tab 9.

PROFESSOR GERVAIS: Okay.

MR. BERENGAUT: Paragraphs 84 and 85 are on page 15.

PROFESSOR GERVAIS: Yeah. They're the first two paragraphs after the opening by the Chair.

MR. BERENGAUT: These comments that you quote do not indicate the extent to which utility and industrial applicability differ, if at all, do they?

PROFESSOR GERVAIS: Well, then I need to re-read them entirely. So your question again is whether there's a difference between industrial applicability and utility?

MR. BERENGAUT: My question is that these comments which you quote do not indicate the extent to which utility and industrial applicability differ, if at all?

PROFESSOR GERVAIS: Actually I disagree with that. The last line of 84, the International Bureau, the secretariat, answering questions from both Canada and the United States, said that the private purpose phrase that is in the paragraph in my report that we just quoted from related to industrial applicability, not to utility, and therefore at least the person from the International Bureau thought that there was a difference.

Now, what was going through that person's mind, obviously I do not know.

MR. BERENGAUT: And that difference pertained to inventions "which may only be used for private purposes." Is that right?

PROFESSOR GERVAIS: Yes. There's a
similar debate concerning test equipment, lab
equipment, that can be useful without necessarily
being in industry, and there's a long debate that is
referred to in one of the amicus briefs on the
Claimant's side by a group of law professors to a
document that explains this in great detail. These
two notions are not identical, and that's one place
where they differ quite significantly.

MR. BERENGAUT: Apart from this
reference to inventions which may only be used for
private purposes, there is no indication in this
document about the extent to which the utility and
industrial applicability standards differ, is there?

PROFESSOR GERVAIS: I've answered the
question. I'm not sure what else to tell you.
Paragraph 84 makes a distinction. You're asking me
the entire document? Again, I would have to read the
document. I cannot tell you what's in the rest of
the document.

MR. BERENGAUT: You're not aware of
any other --

PROFESSOR GERVAIS: No, I'm not.

MR. BERENGAUT: -- section?

Again, setting aside inventions which
may be used for private purpose, there's nothing in

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PROFESSOR GERVAIS: A condition? I'm
sorry, I don't know what you mean.

MR. BERENGAUT: There is no indication
in this document that you're aware of that any
country thought that an invention which claimed to
treat a medical condition --

PROFESSOR GERVAIS: Oh, a medical --

MR. BERENGAUT: That actually treated
that medical condition, being found to lack utility,
is there?

PROFESSOR GERVAIS: Am I aware in
this document of a reference to that? No.

MR. BERENGAUT: Same question with
regard to industrial applicability.

PROFESSOR GERVAIS: Same question
being a medical condition being treated and a
reference in this document? No, I would have to read
the document. I'm only looking at a few paragraphs
in front of me now.

MR. BERENGAUT: Well, I assume you
read the whole document before you quoted it in your
report.

PROFESSOR GERVAIS: I did, but this
was several months ago, and I'm afraid my memory
isn't good enough to recall the entirety of this

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1. this document which suggests the extent to which any
differences between the industrial applicability and
utility requirements would have any practical, real
world consequences, is there?

5. PROFESSOR GERVAIS: Other than use
for private purposes in paragraph 84 there's nothing
else. In the rest of the document, I do not know.

8. MR. BERENGAUT: And, again, the only
example of an invention which would fail the
industrial applicability requirement -- this is
paragraph 87 -- is the perpetual motion machine
again. You see that?

13. PROFESSOR GERVAIS: In paragraph 87,
yes, and it actually says more examples should be
provided. I don't know if they are elsewhere in the
document or not.

18. MR. BERENGAUT: So there's no
indication in this document that you're aware of
suggesting that any country thought that an invention
which claimed to treat a condition and actually
treated that condition being found to lack utility,
is there?

23. PROFESSOR GERVAIS: I do not
understand the question. I'm sorry.

25. MR. BERENGAUT: Let me repeat it.

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<td>PROFESSOR GERVAI S: I do.</td>
<td>MR. BERENGAUT: Let's take a quick</td>
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<td>PROFESSOR GERVAI S: Okay.</td>
<td>PROFESSOR GERVAI S: Yes.</td>
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<td>MR. BERENGAUT: You refer to page 24</td>
<td>MR. BERENGAUT: These notes are</td>
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<td>9</td>
<td>a page --</td>
<td>and let me just read this paragraph: &quot;This paragraph</td>
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<td>PROFESSOR GERVAI S: 22 does not have</td>
<td>contains the condition of patentability of industrial</td>
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<td>The page numbers are</td>
<td>applicability/utility. In order to reflect the</td>
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<td>at the top of the document.</td>
<td>debate at the SCP, three alternatives are proposed in</td>
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<td>PROFESSOR GERVAI S: I mean in my</td>
<td>this provision: The second and third alternative</td>
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<td>reference to this document I don't think that I</td>
<td>reflect the standard contained in many</td>
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<td>referred to specific page -- oh, yes, I do. I'm</td>
<td>national/regional legislation concerning industrial</td>
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<td>sorry. I missed it. Yes. Okay. 24.</td>
<td>applicability and utility, respectively. The first</td>
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<td>MR. BERENGAUT: Just to confirm, this</td>
<td>alternative attempts to take into consideration the</td>
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<td>is the language you were quoting, the paragraph</td>
<td>essence of both requirements, including real</td>
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<td>beginning numbered 4, which has the bracketed</td>
<td>practices, and reflects a more global approach,</td>
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<td>definition of industrial applicability/utility?</td>
<td>whereby an invention would have to be able to made or</td>
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| 43 | PROFESSOR GERVAI S: Yeah, I believe | used in any field of commercial activity."
| 45 | it's underlined because it reappeared from the | Do you see that? |
| 47 | previous draft -- or appeared from the | PROFESSOR GERVAI S: Yes, I do. |
| 49 | 22 draft. | MR. BERENGAUT: These notes are |
| 51 | MR. BERENGAUT: Professor, were you | prepared by the International Bureau of WIPO. Is |
| 53 | aware that there were notes that accompanied this | that right? |
| 55 | proposal? | PROFESSOR GERVAI S: Typically, yes. |

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<td>MR. BERENGAUT: And you would agree</td>
<td>MR. BERENGAUT: The sentence</td>
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<td>that this language shows that the International</td>
<td>referencing the first alternative, which &quot;takes into</td>
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<td>applicability and utility shared a common essence?</td>
<td>including real practices&quot;, do you see that clause?</td>
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<td>PROFESSOR GERVAI S: No, it doesn't</td>
<td>PROFESSOR GERVAI S: Yes, I do.</td>
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<td>use those words at all. I'm sorry, I don’t see those</td>
<td>MR. BERENGAUT: Would you agree that</td>
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<td>words. Consideration of the essence -- it says “to</td>
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<td>take into consideration the essence of both</td>
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<td>requirements.” It's trying to take into account the</td>
<td>reflect real practices at the time?</td>
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<td>19</td>
<td>essence of both requirements. It doesn't actually</td>
<td>PROFESSOR GERVAI S: Well, here's my</td>
</tr>
<tr>
<td>21</td>
<td>say that the essence is the same but it's trying to</td>
<td>trouble in answering your question. This is a 2002</td>
</tr>
<tr>
<td>23</td>
<td>take into consideration the essence of both. If it</td>
<td>document, therefore prepared between the 2001 and</td>
</tr>
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<td>25</td>
<td>doesn't say the essence is identical, and their very</td>
<td>2003 reports that were discussed with the previous</td>
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<tr>
<td>27</td>
<td>documents prove that they're not.</td>
<td>expert, and he said the word “practice&quot; means</td>
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<td>29</td>
<td>MR. BERENGAUT: So you read this</td>
<td>legislation, in the International Bureau's mind. So</td>
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<td>31</td>
<td>clause as saying that there are two independent and</td>
<td>if he means that it would capture the essence of</td>
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<td>33</td>
<td>different essences of the two requirements?</td>
<td>requirements in rules and regulations, that's one</td>
</tr>
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<td>35</td>
<td>PROFESSOR GERVAI S: No, sir, no. I</td>
<td>thing. If it means practice like I think practice</td>
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<td>37</td>
<td>believe that they're very closely related; they</td>
<td>means practice, it's a very honorable proposal to try</td>
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<td>39</td>
<td>overlap to large degree but they're not identical.</td>
<td>to unify the standard. There are several people who</td>
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<td>41</td>
<td>The WIPO documents made that quite clear. They're</td>
<td><a href="http://www.dianaburden.com">www.dianaburden.com</a></td>
</tr>
<tr>
<td>43</td>
<td>not identical and within both families there are</td>
<td><a href="http://www.dianaburden.com">www.dianaburden.com</a></td>
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<tr>
<td>45</td>
<td>23 divergences as well. I don't know that this means</td>
<td><a href="http://www.dianaburden.com">www.dianaburden.com</a></td>
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</table>
1 would like to have a global patent standard. We
don't have one. And, as I tried to show in my
presentation, when the three proposals were put to
the member states, the majority did not support the
first alternative, which meant to unify. They went
with the second one. And then there was support for
the third amendment, so I'm not sure how to answer
your question.

**MR. BERENGAUT:** Just so we're clear,
when you say the second and third alternatives, those
are the alternatives referenced in this paragraph
which reflect the standards contained in national
regional legislation. Is that right?

**PROFESSOR GERVAIS:** No. I mean the
two. (Pause)

**MR. BERENGAUT:** The three in the following meeting, in SCP 8. This is
SCP 7. The following meeting. The ones that were on
my slide were from the following meeting.

**MR. BERENGAUT:** You would agree that
the second and third alternatives reflected in the
bracketed language we just looked at correspond to
this paragraph and its statement that they reflect
the standard contained in many national regional
legislation?

**PROFESSOR GERVAIS:** That's what the
document says.

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1 be for some reason, and I think that's one example.
I'm sure we could come up with more.

**MR. BERENGAUT:** I'm a little confused
by your answer because I think the example you gave
of a difference between the two drafts of the text
was a reference to the phrase "in any field of
commercial activity." Right?

**PROFESSOR GERVAIS:** Yes.
**MR. BERENGAUT:** But, as I read it,
that phrase appears in both your slide and the three
bracketed definitions in tab 10 that we've just been
looking at?

**PROFESSOR GERVAIS:** Yes. It's
alternative A in my slides, correct.

**MR. BERENGAUT:** And it also appears in
tab 10?

**PROFESSOR GERVAIS:** It appears in tab
10, yes, it does, which is the previous meeting of
the SCP.

**MR. BERENGAUT:** So I would again ask
you my question, whether you are aware of any
substantive differences between tab 10 and the
alternatives that you discussed in your slides in
your opening presentation.

**PROFESSOR GERVAIS:** If I understand
1 paragraph number?
2 MR. BERENGAUT: 47.
3 PROFESSOR GERVAIS: Yes.
4 MR. BERENGAUT: You say that this
5 document shows that "notions of utility and
6 industrial applicability vary significantly by
7 jurisdiction." Do you see that?
8 PROFESSOR GERVAIS: I do.
9 MR. BERENGAUT: And you quote
10 paragraphs 2-5 for that proposition.
11 PROFESSOR GERVAIS: Yes.
12 MR. BERENGAUT: Let's take a look at
13 the document. It's tab 12. Paragraphs 2-5 are in
14 the section "Definitions and examples of 'industrial
15 applicability,' is that right?
16 PROFESSOR GERVAIS: Yes.
17 MR. BERENGAUT: You mentioned that, in
18 your view, the document shows that notions of utility
19 and industrial applicability vary significantly by
20 jurisdiction, but you would also agree that this
21 document recognizes that there is an overlap between
22 the two standards. Is that right?
23 PROFESSOR GERVAIS: I do recognize
24 that, definitely, yes.
25 MR. BERENGAUT: And, following the

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1 ultraviolet ray absorbing plastic film. Do you see
that?
2 PROFESSOR GERVAIS: I do.
3 MR. BERENGAUT: Are you aware of an
4 operable device that does that?
5 PROFESSOR GERVAIS: I'm not.
6 MR. BERENGAUT: Again, no indication
7 in these examples of a pharmaceutical invention that
8 claimed to treat a medical condition and actually
9 treated that condition being found to lack industrial
10 applicability, is there?
11 PROFESSOR GERVAIS: In those
12 examples, no.
13 MR. BERENGAUT: Are you aware of any
14 other examples in this section that provide such an
15 indication?
16 PROFESSOR GERVAIS: I believe there's
17 something later on, a document, but it's been a few
18 months since I've re-read it. Paragraph 15 of the
19 document says, "Case law determining whether an
20 applicant identifies any specific utility for the
21 claimed invention or has not been developed, in
22 particular, in the field of chemistry and
23 pharmacology..." and then they talk about compounds
24 that treat unspecified disorders that has useful

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1 paragraphs that you quoted, there is a section about
2 examples, beginning with paragraph 7. Do you see
3 that?
4 PROFESSOR GERVAIS: Yes, I do.
5 MR. BERENGAUT: And in paragraph 7, it
6 lists several examples of inventions that fail the
7 industrial applicability standard in "more than one
8 country." Do you see that?
9 PROFESSOR GERVAIS: Paragraph 7, yes.
10 MR. BERENGAUT: The perpetual motion
11 machine is back?
12 PROFESSOR GERVAIS: It's the
13 classroom textbook example.
14 MR. BERENGAUT: There's a ghost
15 catcher?
16 PROFESSOR GERVAIS: Yes. That would
17 go well with your flying car.
18 MR. BERENGAUT: And you're not aware
19 that there is an operable ghost catcher, are you?
20 PROFESSOR GERVAIS: I don't know that
21 there is one, despite Hollywood.
22 MR. BERENGAUT: There's also a method
23 for preventing the increase in ultraviolet ray
24 associated with the destruction of ozone layer by
25 covering the whole surface of the earth with an

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1 properties that would not be specific to define a
2 specific utility. So to that extent I guess that's
3 an example that's at least close to what you were
4 asking.
5 MR. BERENGAUT: I'm glad you brought
6 us to 15 but, if we may, let's just go to 14 before
7 we get to 15. Now we've moved from the section of
8 the document about industrial applicability to the
9 section that begins "Definitions and examples of
10 'utility.'" Do you see that?
11 PROFESSOR GERVAIS: I do.
12 MR. BERENGAUT: Let's look at the
13 preceding paragraph, paragraph 14, where, again in
14 the example section, it begins, "Situation where an
15 invention is found to be inoperative, and therefore
16 lacking utility, seem to be very rare. Examples of
17 such cases include: An invention asserted to change
18 the taste of food using a magnetic field, a flying
19 machine operating on a 'flapping or flutter
20 function', and a method of controlling the aging
21 process.'" Do you see that?
22 PROFESSOR GERVAIS: I do.
23 MR. BERENGAUT: As far as you are
24 aware, none of these inventions were operable in 2001

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1 when this document was created?

2  PROFESSOR GERVAIS: To my knowledge,

3  no.

4  MR. BERENGAUT: Let's look at the next
5  paragraph, which you just mentioned, which states --
6  this is paragraph 15 on page 4 -- "Case law
7  determining whether an applicant identifies any
8  specific utility for the claimed invention or has not
9  been developed, in particular, in the field of
10  chemistry and pharmacology. For example, indicating
11  that the compound may be useful in treating
12  unspecified disorders, or that the compound has
13  useful biological properties, would not be sufficient
14  to define a specific utility for the compound."
15  Do you see that?
16  PROFESSOR GERVAIS: I did. I just
17  read it.

18  MR. BERENGAUT: So I would again ask
19  the question whether, even in light of this
20  paragraph, there is any indication in any of these
21  examples given in this paragraph about how this
22  invention would reduce heat generation in the
23  discharge lamps. The specification indicated that
24  invention related to control circuits for gas
25  utility.

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1  PROFESSOR GERVAIS: Yes, I believe it
2  was on the slides that were used for the examination
3  of the previous expert.

4  MR. BERENGAUT: And there are no
5  examples given in this paragraph about how this
6  standard was being employed in practice, are there?
7  PROFESSOR GERVAIS: Examples? No.
8  MR. BERENGAUT: Now let's look at
9  paragraph 19, which is the other paragraph you cited.
10  PROFESSOR GERVAIS: Yes.
11  MR. BERENGAUT: Paragraph 19 does have
12  two examples. "In addition, the following inventions
13  are considered not meeting the requirement that an
14  invention be 'useful'." The first one is "An
15  invention related to control circuits for gas
16  discharge lamps. The specification indicated that
17  the invention would reduce heat generation in the
18  ballast. However, the evidence was that some
19  circuits falling within the scope of the claims
20  failed to work and caused lamp failure because of
21  excessive heat generation. Consequently, the promise
22  of the invention was not fulfilled." Do you see
23  that?
24  PROFESSOR GERVAIS: I do.
25  MR. BERENGAUT: In this example, the

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that right?

PROFESSOR GERVAIS: I make many points about both reports.

MR. BERENGAUT: Okay, that's fine. We can go back to your First Report. Let's take a look at paragraph 39 of your First Report on page 12.

Here in the first sentence, the sentence reads "First, it" -- and by "It" it means this 2003 report, right -- "First, it" confirmed that the practice of the parties regarding 'industrial applicability' and 'utility' can 'differ substantially.' Do you see that?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: And in footnote 27 -- PROFESSOR GERVAIS: It's actually a quote. There are quotation marks around the words.

MR. BERENGAUT: right, it is a quote, and you quote the phrase "differ substantially." In footnote 27 you reference paragraph 56 of the document for that quote. Do you see that?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: This isn't a "gotcha" question but I don't think that's the right paragraph for that quote so let's take a look at paragraph 56...

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remains that they differ substantially in some respects and they overlap in others. That point remains true, independent of which paragraph it's from. I certainly apologize for the wrong paragraph quote.

MR. BERENGAUT: I guess where I'm getting stuck is that in your report you quote the language about them differing substantially, but you don't quote the language about the substantial overlap of practices, and I guess my question is whether, in your view, the language about the two overlaps was not relevant or whether there was a different reason you didn't include it.

PROFESSOR GERVAIS: No. It's relevant. Honestly I would have to go back to this report and find where these words appear in the report elsewhere and where I would have taken them from, but I completely stand by the point on substance, that the two differ substantially in some respects and overlap in others, as I said earlier.

MR. BERENGAUT: Okay. So the commonalities are discussed in paragraphs 54 and 55 of SCP 9/5 in tab 13.

PROFESSOR GERVAIS: I see that.

MR. BERENGAUT: And the first sentence of paragraph 54 reads, "Focusing on the general common characteristics of the two requirements, an invention that is inoperative, for example, an invention which is clearly non-operative in view of well-established laws of nature, would not comply with both the industrial applicability and utility requirements." Do you see that?

PROFESSOR GERVAIS: Yes, and I agree with that statement.

MR. BERENGAUT: Then let's look at the areas of difference, and this is paragraph 56, which is the paragraph you referenced in your report. The example here of differences is the same one that you mentioned earlier in our discussion, which is to say that some countries exclude inventions which "could apply solely to the private or personal sphere of one's own needs." Do you see that?

PROFESSOR GERVAIS: Or "could be applied solely in association with a particular person" -- yes, that's what it says.

MR. BERENGAUT: In fact, this paragraph says that there were -- and I'm now about halfway into the paragraph -- not many examples of inventions falling under this category were suggested by the SCP members?
frequency of utility invalidations or industrial
applicability invalidations varied across countries,
right?

professor: No indication that the

Mr. Berengaut: There's no indication
in this paragraph that countries were divided in how
exacting the utility requirement or industrial
applicability requirement should be as a general
matter, correct?

Professor Gervais: How exacting it
should be as a general matter? No, it only refers to
Australia and Canada, which are talking about utility
and benefits to the public, and then they say that
private use and utility, because this isn't a matter
of industry at that point, can exclude them under a
different doctrine. The doctrinal mix is different
country-by-country, and here we see a new doctrine,
de minimis, that was not mentioned before, to exclude
certain inventions.

Mr. Berengaut: No indication that the

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MR. BERENGAUT: You add in the next paragraph, "If utility, industrial applicability or both had been an easy target for negotiators and an easy 'win' for WIPO and negotiators, it would have been on the list or at the very least been mentioned as such."

PROFESSOR GERVais: I did write that, yes.

MR. BERENGAUT: Now, you were not involved in the preparation of the joint proposal, correct?

PROFESSOR GERVais: No.

MR. BERENGAUT: And nothing in the document, R-235, which is behind tab 14, says why utility was left off the agenda, does it?

PROFESSOR GERVais: Well, I don't remember seeing anything but, again, I can't exclude it without re-reading the document entirely. Off the top of my head I can't recall.

MR. BERENGAUT: Well, this one's only three pages, so if you want to take a moment to refresh your recollection, please go ahead.

PROFESSOR GERVais: I just did. So the first paragraph actually says there's a list of issues, and it does mention industrial applicability.
not think it was a priority to harmonize those
definitions?

PROFESSOR GERVAS: It's possible.

MR. BERENGAUT: And isn't it possible
that the reason they did not think it was a priority
to harmonize those definitions was because at the
time there was little variation in practical outcomes
among countries regarding utility?

PROFESSOR GERVAS: It's possible,
but I don't think that was the case. I disagree with
the premise of the question. I think that the 2001
and 2003 reports, which predate this proposal by just
a few months, show wide variations (I'm quoting from
those documents) and so the much more likely
conclusion to draw is that they didn't think they
could get there. If you look at what happened at
SCP/8 they tried three alternatives, the chairman
floated them and there was no agreement, and they
decided let's leave this one off the table, for
whatever reason.

MR. BERENGAUT: You make a similar
point about the Tegernsee Group. Let's go back to
your First Report, paragraph 53.

This was, as you quote, "a new
dialogue on the state of affairs concerning

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is the same. You have not cited to any language in
this report explaining why utility or industrial
applicability was left out, do you?

PROFESSOR GERVAS: Correct, I don't
recall seeing that language in there. I'm not saying
it's not, but I do not recall seeing it when I read
it.

MR. BERENGAUT: So, Professor, isn't
it possible that here again, the reason that utility
and industrial applicability were not included was
because it was not important for parties to harmonize
their utility/industrial applicability requirements
because they were not causing any problems in
practice?

PROFESSOR GERVAS: Theoretically,
yes, but I don't know that -- I shouldn't believe
empirically that's not supported. I think where I
might agree with you is that, if you were to look at
empirical data, utility is typically less difficult
for most patent applicants, certainly outside the
pharmaceutical field, and so if you were to look at
the number of patent applications that get in trouble
for utility compared to the other requirements, is
that why they decided not to discuss industrial
applicability and utility? I don't know. They don't
1. differences in utility/industrial applicability
2. requirements across jurisdictions?
3. PROFESSOR GERVIAUX: I don't see any,
4. no.
5. MR. BERENGAUT: No indication why
6. utility or industrial applicability were left off the
7. agenda for the session?
8. PROFESSOR GERVIAUX: Well, the words
9. mean what they mean. It says "issues most suitable
10. for further progress." This one is not most suitable
11. for further progress. It doesn't tell us why.
12. MR. BERENGAUT: Were you aware,
13. Professor, that other countries also responded to the
14. requests for feedback from the Tegernsee Group?
15. PROFESSOR GERVIAUX: I haven't read
16. those submissions.
17. MR. BERENGAUT: Let's take a look at a
18. few examples. Tab 17 of your binder, the next page,
19. C-340, is the Japanese report. If you could turn,
20. please, to the last page, page 21?
21. PROFESSOR GERVIAUX: Yes.
22. MR. BERENGAUT: Where it said "At the
23. last part of the questionnaire survey based on
24. questionnaires made by the Tegernsee Expert Group,
25. there was a question. "Other than these four issues,

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1. it's not an issue. As I said, utility, typically for
2. many types of inventions, is not an issue outside of
3. the pharmaceutical field. So I'm not particularly
4. surprised by this but I'm reading this for the first
5. time. Why it's not a main issue, was it an issue at
6. all, I don't know.
7. MR. BERENGAUT: Let's take a look at
8. another example. Tab 18. This is from Germany.
9. Let's take a look at page 2 which lists responses
10. regarding several patent law topics. Do you see
11. that?
12. PROFESSOR GERVIAUX: I do.
13. MR. BERENGAUT: B), c), d), e) and f).
14. Now, industrial applicability/utility does not appear
15. on this list, correct?
16. PROFESSOR GERVIAUX: Would you be able
17. to -- obviously -- oh, I see a) is there. Okay.
18. Well, again, they refer to main results of the
19. evaluation and, you're absolutely correct, industrial
20. applicability is not in the list of these main
21. results.
22. MR. BERENGAUT: And in the final
23. section, f), it states "Other areas requiring
24. harmonization." It states, "While the need for
25. harmonization is deemed to be constantly high for the

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1. is there any issue that has caused problems due to
2. differences in laws practiced in each country? For
3. this question, the JPO received many responses. The
4. main issues that the respondents raised are as
5. follows: Standards used to determine inventive step;
6. standards used to determine novelty; descriptive
7. requirements for specifications; description of
8. claims (for example, multiple dependent form claims,
9. product-by-process claims); limitations to
10. amendments, et cetera."
11. Do you see that?
12. PROFESSOR GERVIAUX: I do.
13. MR. BERENGAUT: Now, industrial
14. applicability or utility is not on this list,
15. correct?
16. PROFESSOR GERVIAUX: It is not
17. identified as a main issue, that's right.
18. MR. BERENGAUT: So, from the Japanese
19. perspective, you would agree there is no indication
20. that industrial applicability/utility "caused
21. problems due to differences in laws practiced in each
22. jurisdiction." Right?
23. PROFESSOR GERVIAUX: Well, it's not
24. identified as a main issue. We can draw whatever
25. inference we want from that. It doesn't mean that

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1. four aforementioned fields of law... there are no
2. other obvious topics deemed to be similarly important
3. by the applicants." Do you see that?
4. PROFESSOR GERVIAUX: I do.
5. MR. BERENGAUT: Doesn't this suggest
6. that, from Germany's perspective as well, industrial
7. applicability/utility was not an important topic to
8. put on the table for harmonization?
9. PROFESSOR GERVIAUX: That's a
10. reasonable inference.
11. MR. BERENGAUT: Let's go back to your
13. PROFESSOR GERVIAUX: But do you know
14. by any chance how many countries have replied to
15. this? Because we have two. I wondered if others
16. did. Anyway, tab 2, yes.
17. MR. BERENGAUT: Back to your First
18. Report, please, tab 1, paragraph 31. In paragraph 31
19. of your first statement you quote a discussion of
20. utility in a WIPO document, and we looked at this
21. document earlier.
22. PROFESSOR GERVIAUX: Yes.
23. MR. BERENGAUT: And I believe we
24. agreed, but just to confirm, that the reason you
25. thought this language regarding differences was
1 relevant is because it showed from your perspective a lack of consensus regarding those concepts.
2 PROFESSOR GERVAIS: Back to that word again. I am trying very hard in this report to explain that there are two notions, that they're not identical, and that within each family of notions there are variations. With all due respect, I'm not sure -- I'm not trying to show that there is or isn't a consensus. That's not my point.
3 MR. BERENGAUT: Paragraph 50 and 51, this is a reference to a joint report of the WTO, WIPO and WHO.
4 PROFESSOR GERVAIS: Yes. The first time these three published a joint report, I believe. And the report notes, and you quote a paragraph of the report and you quote paragraph 57. Do you see that?
5 MR. BERENGAUT: I do. That's at R-220 behind tab 5.
6 PROFESSOR GERVAIS: Yes.
7 MR. BERENGAUT: You quoted paragraph 57 of the report.
8 PROFESSOR GERVAIS: Page or paragraph?
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1 MR. BERENGAUT: Right. I will take you there next. I'm not trying to...
2 PROFESSOR GERVAIS: Well, you decide.
3 MR. BERENGAUT: I'm not trying to only show part of the exchange here. So then you go back to this report in your Second -- go back to this document in your Second Report?
4 PROFESSOR GERVAIS: I do.
5 MR. BERENGAUT: Paragraphs 39-44, where you take issue with Claimant stating that you omitted the paragraph from page 59 from your report.
6 PROFESSOR GERVAIS: Uh-huh.
7 MR. BERENGAUT: What I'm interested in is the sentence at the beginning of paragraph 44 that is the sentence at the beginning of paragraph 44 that the additional paragraph 149, "changes nothing on substance to [your] conclusion," and I'm having a hard time with that statement because if, in your view, statements to the effect that there were differences between industrial applicability and utility detract from the proposition that there was consensus, surely this statement on page 59, which provides a single definition of both concepts, reflects consensus at least in the content of page 59?
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1 PROFESSOR GERVAIS: No, I'm sorry, I have to disagree with both the premise and the question. First of all, paragraph 59 does not give a unique definition. There is one definition followed by "or" in the second. And, second, what I said was in general, it is true -- however you define utility and industrial applicability, and it doesn't mean there's consensus on what it means, what it means is, in general, most inventions, certainly outside of biotech and pharma, will easily surpass whatever definition a country adopts, or meet the test. Therefore, there are fewer problems --
2 MR. BERENGAUT: Professor, in your answer just now, you said what it means is in general, most inventions, certainly outside of biotech and pharma, will easily surpass whatever definition a country adopts.
3 PROFESSOR GERVAIS: Which I reformulated as "meet the criteria", if you keep reading.
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1  MR. BERENGUT: Or meet the criteria.
2  Now, in this paragraph, there is no discussion of
3  difficulties faced by the pharmaceutical industry, is
4  there?
5  PROFESSOR GERVAS: Well, it says --
6  it mentions biotech, which I believe is not that far
7  from pharma, but what I take issue with is saying
8  this report by these three organizations says there's
9  only issue with biotech. It doesn't. It says,
10  however, in this area there are considerations; there
11  might well be other areas, we don't know, but it
12  certainly uses biotech as an example.
13  MR. BERENGUT: The sentence that
14  you're referring to regarding biotechnology reads,
15  "However, in the area of biotechnology it needs some
16  consideration given concerns that patent applications
17  claiming gene-related inventions would block the use
18  of the claimed gene sequence for uses that were not
19  yet known by the applicant and therefore would not
20  justify the grant of a patent in respect of a
21  function which the applicant was not even aware of."
22  Do you see that?
23  PROFESSOR GERVAS: I do. That is
24  the example given.
25  MR. BERENGUT: There's no indication

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1  in this paragraph, apart from this one area of
2  biotechnology, in the broader context of
3  pharmaceutical inventions, utility "needs some
4  consideration," is there?
5  PROFESSOR GERVAS: Not in this
6  paragraph, but it is certainly my opinion that a
7  chair and a new chemical molecule will not
8  necessarily be looked at in the same fashion by an
9  examiner in terms of utility. Professor Holbrook has
10  a significant discussion of that, I believe, in his
11  report.
12  MR. BERENGUT: If I may have one
13  moment to confer with my colleagues, Mr. President.
14  Thank you, Mr. President. We have no
15  further questions.
16  THE PRESIDENT: Thank you.
17  MR. SPELLISCY: May I have one or two
18  minutes, or maybe five minutes, for a quick
19  discussion? If I have any redirect, it would be very
20  short.
21  THE PRESIDENT: A five-minute recess.
22  Professor Gervais, you are under testimony. You are
23  not allowed to discuss the case with anyone.
24  (Recess taken)
25  THE PRESIDENT: Please.

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1  REDIRECT EXAMINATION ON BEHALF OF THE RESPONDENT
2  MR. SPELLISCY: Good afternoon,
3  Mr. Gervais, I just have one simple question on
4  clarification.
5  A couple of times you mentioned a
6  study cited by one of the amici in this case. I
7  won't ask you questions about it because I don't know
8  if it is yet in the record, but can you give us the
9  author or the title of that study?
10  PROFESSOR GERVAS: Yes. It's a
11  study by the London School of Economics by
12  Dr. Thambisetty. I would strongly, if I may, suggest
13  that it's worth reading. It's very, very relevant to
14  this case. It's produced by the law professors who
15  produced an amicus brief on Claimant's behalf.
16  MR. SPELLISCY: Pursuant to the
17  Tribunal's procedure, we'll make sure to get a copy
18  of it onto the record, give it an R number and
19  produce it to the Claimant.
20  NS. CHEEK: I think, given the
21  procedural rules on documents, the parties will need
22  to confer as to whether or not that document can be
23  admitted to the record.
24  THE PRESIDENT: The document is not
25  yet in the record?

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1  MR. SPELLISCY: It's a document
2  referred to in one of the amicus submissions. In the
3  Tribunal's Order, right before the hearing, on
4  24 hours' notice before using it or referring to it,
5  we can put it in the record.
6  THE PRESIDENT: First to confer.
7  NS. CHEEK: But I just got notice.
8  MR. SPELLISCY: And I haven't put it
9  into the record yet but, 24 hours from now, it will
10  be there.
11  THE PRESIDENT: Okay. Sir Daniel has
12  a question or two.
13  QUESTIONS BY THE ARBITRAL TRIBUNAL
14  SIR DANIEL BETHLEHEM: Just a couple
15  of technical questions, if I may, and they may not be
16  relevant at all but I just want to clarify.
17  At the start of your cross-examination
18  you said -- and I think the language was at 15:05:11,
19  "TRIPS is relevant to the interpretation of NAFTA
20  Chapter 17," and in your First Report you've got
21  quite a lot of information about the origins of NAFTA
22  Chapter 17 being the Dunkel draft in 1991 and so on.
23  So my question is, and although I'm putting it in
24  terms of NAFTA and TRIPS it may have a bearing on the
25  relationship between NAFTA and other intellectual
property agreements as well -- the question is really
what is the formal relationship between NAFTA and
TRIPS?
You've put it in terms of relevance to
interpretation, but I have in mind when asking the
question Article 103 of NAFTA, which says in 103(1),
"The parties affirm their existing rights and
obligations with respect to each other under the
GATT", and then 103(2), "In the event of any
inconsistency between this Agreement and any such
other agreements, this Agreement shall prevail to the
degree of the inconsistency," so I just like to get
a sense from you what the formal relationship is
between them? Is it 31(3)(c) other relevant rules of
international law; is it subsequent agreement?
As a subset of that, without asking
you to either repeat everything that you've said or
for a long excursus, is your sense that there is
consistency, or are there important elements of
inconsistency which you think are relevant to these
proceedings?
That's a great question.
This is an unusual situation,
Sir Daniel, because we have a number of countries,

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1 to, and so I think that's what they were trying to do
with that safeguard clause. But the text of 27 and
1709(1) really has the same parentage, the same
origin.
What happened to this initial
submission by the private consortium was basically
that each government amended it to a certain degree
and then the European Union in March 1990 and then
the Americans and the Japanese and the Australians
and a few others submitted their own versions, and
this got consolidated in July of 2001 into one draft,
which then became the clay from which both NAFTA and
TRIPS are molded.
So your technical question is an
extremely interesting one under 31. This is an
unusual situation where two treaties emerge more or
less at the same time with more or less the same
object and purpose, and with the same language. So I
would suggest that it's wise to read them in
parallel.
Whether I can say formally you have to
read one the way you would read the other one, or you
would interpret one, under 31 that's not obvious. I
don't think the subsequent agreement quite works but
technically, it's true, GATT happened a few months

---

1 specifically an initial draft prepared by a
Washington economist on behalf of the pharmaceutical,
entertainment and part of the software industry was
circulated informally to governments in the U.S.,
Europe and Japan, and this unofficial draft became --
that's why I used the expression "molded from the
same clay" in my report. It's a really unusual
situation where two treaties are molded pretty much
by the same parties at the same time. It is not a
square 31 application or 32 for that matter, but
clearly the point I make is that when the same
different, the words are almost identical in
that section.
Sir Daniel, because we have a number of countries,

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1 later -- not GATT but WTO.
Am I answering your question
sufficiently?
SIR DANIEL BETHLEHEM: You are indeed
and that's exactly what I was getting at. Let me put
just a brief follow-up to you, in light of your
answer.
Would it be a fair understanding to
say that leaving aside any, as it were, technical
interpretation of 31(iii)(c) and other relevant rules
of international law, what you seem to be saying is
that there may be a useful and important relationship
between the two because it may be that the parties
intended special meanings of terms and that one could
derive that. So it may be that there is something in
Article 31(4), "A special meaning shall be given to
terms if it is established that the parties so
intended." Would that be a fair summation, broadly,
of what you're saying?
PROFESSOR GERVais: Yes, you would
have to show the intent to create the special meaning
on 31(4). That's right. Absolutely.
SIR DANIEL BETHLEHEM: The second
question that I've got, and this is not part of your
evidence but it goes to your expertise and, in
PROFESSOR GERVAIS: The book is back there, but otherwise, I will try.

SIR DANIEL BETHLEHEM: It's simply a question to know whether the transparency requirements of TRIPS in Article 63, which require states to notify inter alia other judicial decisions and whatever in the TRIPS field, whether in your experience and knowledge, states actually do notify notable judicial decisions.

I see as well paragraph 63(3) says that each member shall be prepared to supply to other members on written request, so not associated with this case. We can put that to the parties as a later question if needs be. If you could tell us whether, in your experience, parties generally do notify significant judicial decisions, and whether there are follow-up questions from other parties in the context of TRIPS?

PROFESSOR GERVAIS: The short answer is no. 63 is implemented mostly through the WIPO-WTO Cooperation Agreement by which WIPO publishes the laws of its member states on its website, a service called WIPO Lex, which works reasonably well for laws and regulations but not court cases.

There was some discussion of publishing, for example, invalidation decisions in one jurisdiction so that other jurisdictions would have them and, for reasons that may or may not be obvious, there was some resistance to the idea. So that was dropped, and I'd never heard of another project to start a database of judicial decisions.

So I think 63 is read as if one government writes to another government and says we would like a copy of this decision, then they would send that to them. But this was -- this is 1993 thinking. I think today we would go on-line for most countries and just find it, but perhaps for some jurisdiction that does not so provide on-line, then you would be able to use 63 formally and request a copy.

SIR DANIEL BETHLEHEM: From what I understand from what you just said, there is nothing to your knowledge and experience, either in a WIPO context or a WTO TRIPS context, in which, for example, an invalidation decision by a national court would be circulated, published internationally on one of those websites?

PROFESSOR GERVAIS: There is no formal mechanisms at WIPO/WTO for that to happen that I'm aware of, no.

SIR DANIEL BETHLEHEM: Thank you very much.

THE PRESIDENT: Mr. Born has a few questions.

MR. BORN: Good evening.

PROFESSOR GERVAIS: Good evening.

MR. BORN: Can you look in tab 7 of the binder? It's Chapter 17 of NAFTA.

PROFESSOR GERVAIS: Yes. And in particular at Article 1709(1).

PROFESSOR GERVAIS: Yes, I'm quite familiar with that.

MR. BORN: That's why I'm asking the questions. I take it from your testimony that your view is that paragraph 1 imposes substantive limits of some sort on states but that, in your view, states have -- the NAFTA parties have substantial flexibility with operating within those limits.

PROFESSOR GERVAIS: This is a very important point, if I can just give you a slightly more detailed answer. The short answer is yes, but it may not fully satisfy.
PROFESSOR GERV AIS: Theoretically, yes.

MR. BORN: Can you help me? Can you give me -- and I know you recoiled from hypotheticals previously. So rather than try to give you one, can I ask you for one? Can you give me an example of a definition of hypothetically useful that would be outside 1709(1)?

PROFESSOR GERV AIS: Well, if I preface it with "arguably" because this is always so hard.

MR. BORN: Sure.

PROFESSOR GERV AIS: If a country said

...
1 maximize innovation in the right amount of
2 important -- or inventions that matter, I guess to
3 use as simple as possible term, and disclosure, and
4 some countries would add access to this. The bargain
5 is implemented a little differently, but it's not
6 that different.
7
8 What is different is the fact that
9 very often the patent statute doesn't say very much,
10 and so then it's left to courts to apply it. And
11 then they see this technology and hear new arguments
12 and they see, well, yes or no, and then it goes to
13 Supreme Court. That's the process. That's the way
14 these things work. But you asked me for a
15 hypothetical. That's the best I can come up with.
16 MR. BORN: And if I can just push you
17 on your answer on items A and B that I gave you, why
18 wouldn't it be relevant in deciding whether a
19 definition went beyond 1709(1) to see what states
20 generally had done and were doing?
21 I'm so sorry, I did not understand -- your question
22 was about surprising. Is that what you meant?
23 MR. BORN: Yes.
24 PROFEssor Gervais: I don't quite
25 understand -- it's not a word I'm familiar with,
1. field is an interesting question to begin with. So
2. you have terms that over time have evolved in two
3. different systems to be used and have been defined by
4. courts in those systems because most statutes do not
5. define utility and industrial applicability very
6. clearly, so you leave it up to a large degree to
7. courts. So you're already looking at a moving target
8. in terms of ordinary meaning on the domestic front,
9. and so if you look at dictionaries here, I don't
10. think they would help you very much. So the text
11. doesn't give you very much.
12. The context is all these doctrinal
13. tools, the three major criteria that are mentioned
14. here, the disclosure requirement, are all part of a
15. doctrinal mix. The United States is a little unique
16. because it adds written description and enablement.
17. Most countries do not have those notions. Certainly
18. not in the same way. So it achieves the doctrinal
19. mix differently. But as I said earlier, you try to
20. get to the same place as a court or as a legislator,
21. you try to get to an implementation of the patent
22. bargain that you think is the best policy. I'm
23. probably not answering your 31 question in terms
24. of --
25. THE PRESIDENT: You're back to the

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1. answer you gave to Mr. Born about policies. My
2. question is how do you get to policy here in the
3. legal analysis?
4. PROFESSOR GERVAIS: Well, I don't
5. know that the text tells you very much. The context
6. of 27 or 1709(1) does. It says there are three
7. criteria, and it says if you meet those, then patents
8. should be available. It doesn't say they should be
9. granted. Actually, it's important to note that in
10. the negotiation, that word was actually there,
11. granted, and it was removed. It's, in my book, very
12. clear. They're removed. They didn't want it. They
13. wanted available. So we have a context. The context
14. is availability for patents based on three criteria.
15. It doesn't say these are the only three. So that you
16. have the context that basically the context
17. provides -- the immediate context provides the fact
18. that there's a doctrinal mix there. Then you have
19. the whole patent section which provides the context
20. that you have -- you're dealing with some sort of
21. innovation but not just, because you have this
22. section of -- especially in TRIPS that deals with
23. compulsory licensing and so on.
24. So you have kind of that -- and
25. Article 7 of TRIPS, which deals with the objectives

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1. and principles of the agreement, emphasizes both the
2. need for innovation and benefits to user and all
3. that. So you're dealing with a context that already
4. provides a little bit more complexity. Then you look
5. at the object and purpose of this agreement and it's,
6. again, about protection of IP and enforcement of IP
7. up to a point. That's where it says, you know, you
8. can do more up to a point unless you're contravening
9. that agreement. It also says that there are a number
10. of areas where countries have flexibility. And
11. again, I go back to Article 1. I go back to the
12. preamble, Article 41. There's several places in this
13. agreement that have significant flexibility. It's
14. meant not to be defining but confining up to a point
15. what countries can and cannot do.
16. THE PRESIDENT: Thank you.
17. PROFESSOR GERVAIS: Is that helping?
18. THE PRESIDENT: Useful.
19. PROFESSOR GERVAIS: The best word to
20. end the day. Or maybe it's not the end of the day.
21. THE PRESIDENT: All right. Any
22. follow-up questions by, first, I think Respondent
23. because it's your expert.
24. MR. SPELLISCY: No follow-up questions
25. for us.

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|            | 1627/8          | 1716/9      | 1757/18      | 1757/18     | 1757/18| 1656/6      |         |            |            |
|            | 1643/22         | 1716/18     | 1757/21      | 1757/21     | 1757/21| 1680/18     |         |            |            |
|            | 1650/8          | 1716/21     | 1795/12      | 1783/17     |        | 1687/5      |         |            |            |
|            | 1581/14         | 1735/25     | 1783/20      | 1718/10     |        | 1724/19     |         |            |            |
|            | 1582/4          | 1736/6      | 1770/18      | 1737/24     |        | 1725/7      |         |            |            |
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| Discovery     | 1811/4  | 1825/21 | 1825/23 | 1826/7  | 1584/15 | 1650/5  | 1656/22 | 1720/6  | 1764/3  | 1799/9  |
| Discretion    | 1567/16 | 1585/13 | 1612/14 | 1726/4  | 1737/13 | 1759/13 | 1759/13 | 1759/17 | 1760/1  | 1762/17 | 1773/4  | 1781/24 | 1803/3  | 1804/24 | 1811/20 | 1815/23 | 1567/19 |
| Discuss       | 1820/17 | 1624/17 | 1683/18 | 1701/7  | 1701/18 | 1701/19 | 1701/25 | 1719/10 | 1729/1  | 1735/18 | 1737/19 | 1745/8  | 1746/25 |
| Discusses     | 1799/22 | 1799/22 | 1799/22 | 1799/22 | 1799/22 | 1799/22 | 1799/22 | 1799/22 | 1799/22 | 1799/22 | 1799/22 | 1799/22 | 1799/22 |
| Discussion    | 1585/13 | 1612/14 | 1726/4  | 1737/13 | 1759/13 | 1759/13 | 1759/17 | 1760/1  | 1762/17 | 1773/4  | 1781/24 | 1803/3  | 1804/24 | 1811/20 | 1815/23 | 1567/19 |</p>
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- 1697/11
- 1714/14
- 1743/8
- 1766/10
- 1793/4

**Non-Compliance**

- [1] 1714/14

**Non-Controversial**

- [1] 1573/21

**Non-Obviousness**

- [2] 1743/8
- 1766/10

**Non-Operative**

- [1] 1793/4

**Non-Utility**

- [1] 1697/11

**None**

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**Cooperation [9]**

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| Prior [18]          | 1610/11 | 1640/13 | 1652/23 | 1654/6
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|                    | 16720/14 | 16723/18 | 16724/8  | 16725/16
|                    | 16726/1 | 16726/5  | 1802/1  | 1802/5
|                    | 1805/2  |          |          |
| Private [10]       | 1600/21 | 1600/22  | 1769/14 | 1769/24
|                    | 1770/11 | 1770/25  | 1771/6  |
|                    | 1793/16 | 1794/19  | 1820/6  |
| Priority [18]      | 1579/13 | 1579/20  | 1610/6  |
| Probably [12]      | 1572/9  | 1590/2  | 1613/9  | 1663/1
|                   | 1689/16 |          | 1691/8  | 1758/9
<p>|                   | 1758/23 |          | 1767/3  |
|                   | 1767/20 |          | 1833/18 |
|                   | 1834/23 |          |          |
| Problem [4]        | 1605/7  | 1684/5  | 1689/8  |
|                   | 1698/19 |          |          |
| Problems [7]       | 1610/12 | 1626/21 | 1804/13 |
|                   | 1807/1  | 1807/21 |          |
| <strong>P</strong> | <strong>problems... [2]</strong> | <strong>1704/15</strong>&lt;br&gt;<strong>1818/21</strong>&lt;br&gt;<strong>process [20]</strong>&lt;br&gt;<strong>1574/6</strong>&lt;br&gt;<strong>1638/21</strong>&lt;br&gt;<strong>1639/13</strong>&lt;br&gt;<strong>1640/7</strong>&lt;br&gt;<strong>1641/11</strong>&lt;br&gt;<strong>1642/3</strong>&lt;br&gt;<strong>1649/18</strong>&lt;br&gt;<strong>1650/14</strong>&lt;br&gt;<strong>1652/9</strong>&lt;br&gt;<strong>1654/7</strong>&lt;br&gt;<strong>1654/23</strong>&lt;br&gt;<strong>1656/11</strong>&lt;br&gt;<strong>1658/2</strong>&lt;br&gt;<strong>1684/23</strong>&lt;br&gt;<strong>1694/23</strong>&lt;br&gt;<strong>1695/1</strong>&lt;br&gt;<strong>1725/24</strong>&lt;br&gt;<strong>1743/5</strong>&lt;br&gt;<strong>1750/6</strong>&lt;br&gt;<strong>proceeded [1]</strong>&lt;br&gt;<strong>1615/12</strong>&lt;br&gt;<strong>proceeding [1]</strong>&lt;br&gt;<strong>1567/7</strong>&lt;br&gt;<strong>proceedings [3]</strong>&lt;br&gt;<strong>1640/5</strong>&lt;br&gt;<strong>processed [2]</strong>&lt;br&gt;<strong>1573/5</strong>&lt;br&gt;<strong>1640/11</strong>&lt;br&gt;<strong>processes [1]</strong>&lt;br&gt;<strong>1635/24</strong>&lt;br&gt;<strong>processing [1]</strong>&lt;br&gt;<strong>1640/17</strong>&lt;br&gt;<strong>Procter [6]</strong>&lt;br&gt;<strong>1635/21</strong>&lt;br&gt;<strong>1635/22</strong>&lt;br&gt;<strong>1635/25</strong>&lt;br&gt;<strong>1636/5</strong>&lt;br&gt;<strong>1636/9</strong>&lt;br&gt;<strong>1637/24</strong>&lt;br&gt;<strong>produce [1]</strong>&lt;br&gt;<strong>1816/19</strong>&lt;br&gt;<strong>produced [3]</strong>&lt;br&gt;<strong>1704/1</strong>&lt;br&gt;<strong>1816/14</strong>&lt;br&gt;<strong>1816/15</strong>&lt;br&gt;<strong>producing [1]</strong>&lt;br&gt;<strong>1710/19</strong>&lt;br&gt;<strong>product [5]</strong>&lt;br&gt;<strong>1636/2</strong>&lt;br&gt;<strong>1636/4</strong>&lt;br&gt;<strong>1807/9</strong>&lt;br&gt;<strong>1828/4</strong>&lt;br&gt;<strong>1828/17</strong> |</p>
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**Putting** [4]
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**Notes:**
- The table shows the frequency of certain words and phrases in the text, with page numbers indicating where they appear.
- The words listed include sequence, sequencing, series, serious, serve, sessions, set, served, serves, service, sets, session, setting, settled, settlement, several.
- The page numbers range from 1569/18 to 1822/25, with some pages being referenced multiple times.

**Source:**
- UNCT/14/2 Eli Lilly v Govt of Canada

**Website:**
- www.dianaburden.com
| several... [16] | 1822/14 | should [34] | 1567/12  
| 1722/25 | 1565/5  
| 1723/8  | 1580/12  
| 1723/11 | 1705/15  
| 1741/15 | shape [1]  
| 1745/24 | 1645/18  
| 1757/7  | share [1]  
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| 1794/3  | SHAWNA [1]  
| 1795/13 | 1565/7  
| 1798/25 | she [1]  
| 1808/10 | 1757/21  
| 1827/2  | short [5]  
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<p>| they...... [47] | 1766/22 | 1767/6 | 1767/16 | 1769/1 1770/8 | 1771/15 | 1776/19 | 1778/5 | 1778/21 | 1779/11 | 1779/23 | 1784/24 | 1792/1 1792/2 | 1794/18 | 1798/13 | 1801/3 | 1801/12 | 1801/14 | 1802/5 | 1802/15 | 1802/15 | 1802/17 | 1802/18 |
| 1767/16 | 1769/1 1770/8 | 1771/15 | 1776/19 | 1778/5 | 1778/21 | 1779/11 | 1779/23 | 1784/24 | 1792/1 1792/2 | 1794/18 | 1798/13 | 1801/3 | 1801/12 | 1801/14 | 1802/5 | 1802/15 | 1802/15 | 1802/17 | 1802/18 |
| 1804/13 | 1804/24 | 1804/25 | 1806/9 | 1808/18 | 1817/15 | 1819/15 | 1819/24 | 1819/25 | 1820/1 | 1823/12 | 1825/8 | 1826/19 | 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1804/24 | 1804/25 | 1806/9 | 1808/18 | 1817/15 | 1819/15 | 1819/24 | 1819/25 | 1820/1 | 1823/12 | 1825/8 | 1826/19 | 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1804/25 | 1806/9 | 1808/18 | 1817/15 | 1819/15 | 1819/24 | 1819/25 | 1820/1 | 1823/12 | 1825/8 | 1826/19 | 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1806/9 | 1808/18 | 1817/15 | 1819/15 | 1819/24 | 1819/25 | 1820/1 | 1823/12 | 1825/8 | 1826/19 | 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1808/18 | 1817/15 | 1819/15 | 1819/24 | 1819/25 | 1820/1 | 1823/12 | 1825/8 | 1826/19 | 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1817/15 | 1819/15 | 1819/24 | 1819/25 | 1820/1 | 1823/12 | 1825/8 | 1826/19 | 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1819/15 | 1819/24 | 1819/25 | 1820/1 | 1823/12 | 1825/8 | 1826/19 | 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1819/24 | 1819/25 | 1820/1 | 1823/12 | 1825/8 | 1826/19 | 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1819/25 | 1820/1 | 1823/12 | 1825/8 | 1826/19 | 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1820/1 | 1823/12 | 1825/8 | 1826/19 | 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1823/12 | 1825/8 | 1826/19 | 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1825/8 | 1826/19 | 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1826/19 | 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1829/25 | 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1829/25 | 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1830/10 | 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
| 1830/11 | 1831/19 | 1832/14 | 1834/10 | 1835/8 |
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| 1653/5 | 1608/9 1639/8 | 1639/9 | 1649/19 | 1659/16 | 1666/14 | 1702/1 1731/9 | 1747/12 | 1759/4 | 1761/15 | 1768/20 | 1776/14 | 1776/19 | 1776/20 | 1776/21 | 1779/10 | 1799/10 | 1810/5 | 1825/19 | 1835/12 | 1706/23 | 1738/6 |
| Thing [20]          | 1618/13 | 1635/1 | 1635/3 | 1639/19 | 1646/20 | 1650/20 | 1651/1 | 1659/25 | 1671/7 | 1695/25 | 1699/14 | 1709/11 | 1714/11 | 1722/4 | 1725/24 | 1738/8 | 1754/24 | 1825/7 | 1830/13 | 1833/2 | 1601/9 | 1603/13 | 1606/4 | 1606/18 | 1608/25 | 1609/6 | 1609/8 | 1609/17 | 1612/17 | 1615/23 | 1617/4 | 1621/1 | 1621/2 | 1628/5 | 1628/11 | 1632/15 | 1633/1 | 1633/2 | 1633/17 | 1640/4 | 1647/18 | 1649/14 | 1650/6 | 1654/24 | 1655/8 | 1660/3 | 1664/16 | 1676/15 | 1676/23 |
|---------------------|---------|--------|--------|---------|---------|---------|--------|---------|--------|---------|---------|---------|---------|--------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| 1570/21             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1585/5              |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1608/17             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1616/19             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1616/20             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1619/11             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1633/16             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1642/21             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1644/17             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1651/5 1659/3       |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1697/6              |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1707/24             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1713/24             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1728/15             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1777/23             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1779/20             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1779/23             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1825/5              |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1826/25             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1829/25             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| Things [23]          |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1575/7 1585/5       |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 1605/22             |         |        |        |         |         |         |        |         |        |         |         |         |         |        |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |</p>
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| though... [2]                       | 1745/13 | 1826/25 |
| thought [11]                        | 1671/8  | 1728/1 |
|                                     | 1749/2  |
|                                     | 1769/18 |
|                                     | 1771/19 |
|                                     | 1772/5  |
|                                     | 1773/4  |
|                                     | 1776/3  |
|                                     | 1777/12 |
|                                     | 1809/25 |
|                                     | 1811/24 |
| threaten [1]                        | 1579/12 |
| three [41]                          | 1567/23 |
|                                     | 1646/20 |
|                                     | 1646/21 |
|                                     | 1659/24 |
|                                     | 1665/17 |
|                                     | 1665/21 |
|                                     | 1668/5  |
|                                     | 1668/23 |
|                                     | 1671/10 |
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|                                     | 1766/6  |
|                                     | 1775/10 |
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|                                     | 1778/15 |
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|                                     | 1779/4  |
|                                     | 1780/10 |
|                                     | 1800/21 |
| threshold [1]                       | 1828/23 |
| through [17]                        | 1584/6  |
|                                     | 1596/5  |
|                                     | 1613/14 |
|                                     | 1616/15 |
|                                     | 1616/15 |
|                                     | 1624/10 |
|                                     | 1638/23 |
|                                     | 1639/4  |
|                                     | 1639/5  |
|                                     | 1641/8  |
|                                     | 1650/1  |
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