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

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THE PRESIDENT: Good morning, ladies and gentlemen. I re-open the hearing on Day 6. As usual, are there any questions of an organizational, administrative or household nature?

MS. CHEEK: Mr. President, as you know, the Tribunal has ordered post hearing briefs in this proceeding, and you also intend to provide us some questions to address in closing on Monday evening. The parties have consulted, and to the extent that when we receive the Tribunal's questions you also have any views on the nature of post-hearing briefs -- for example, should they be a summary of the evidence, should we answer specific questions -- to the extent the Tribunal has any guidance, the parties would welcome that to factor it in as we discuss, ourselves, what proposal we'd like to put forward.

THE PRESIDENT: Same for Respondent?

MR. SPELLISCY: Yes. We had discussed this yesterday.

THE PRESIDENT: The Tribunal also has considered the question whether post-hearing briefs would be necessary having had closings of three and a half hours each and a rebuttal and we came to the conclusion yes, because it may well be that during

the closings we come up with a number of questions.

The Tribunal was also thinking that it might be useful after all to have post hearing briefs to see how -- and this is now the way we consider the post-hearing briefs -- how the evidence we have heard over the days of the hearing ties into your case, and then summaries for the positions of each of the parties on each of the main issues in this case, so that we will correctly capture them in the arbitral award.

MS. CHEEK: That's very helpful. Thank you.

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

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

THE PRESIDENT: We don't want to miss an issue. That's the point. Anything else?

MR. SPELLISCY: Not from Respondent.

THE PRESIDENT: Thank you.

JAY ERSTLING.

THE PRESIDENT: Mr. Erstling, good morning.

PROFESSOR ERSTLING: Good morning.

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

PROFESSOR ERSTLING: My name is Jay Erstling.

THE PRESIDENT: Professor Erstling, you are an expert testifying here for the Claimant.

PROFESSOR ERSTLING: Yes.

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

PROFESSOR ERSTLING: Thank you.

THE PRESIDENT: 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 statement, the text of which is in front of you.

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

THE PRESIDENT: Thank you. Could you

please go to your first Expert Report, which is dated September 27, 2014 and go to page 15, and confirm for the record that the signature appearing above your name is your signature?

PROFESSOR ERSTLING: Yes, it is.

THE PRESIDENT: Then could you go to your second Expert Report which is dated September 10, 2015 and go to page 12, and confirm for the record that the signature above your name is your signature?

PROFESSOR ERSTLING: Yes, it is.

THE PRESIDENT: In addition to the errata you find in tab 3 of your bundle, is there any other correction you wish to make to either report?

PROFESSOR ERSTLING: Not that I'm aware of, Mr. President.

THE PRESIDENT: Before we start direct examination I have one question, because I have been teaching at WIPO in the beginning of the '90s, so it is not a disclosure at all but I simply want to clarify one thing how I have to pronounce it. At the time when I was teaching I was also drafting the first set of Arbitration Rules, together with a number of others at WIPO, and at that time I was given to use what we believed was the politically

correct pronunciation of "Wipo". We said "Wipo". But they said no, no, the man on the 13th floor says you may not use Wipo, you have to use W-I-P-O, because he considered that Wipo was a detergent in the bathroom!

PROFESSOR ERSTLING: That's right.

THE PRESIDENT: I wonder, do we correct it also now amongst IP lawyers, so that we use the correct pronunciation? Which is it?

PROFESSOR ERSTLING: Now it's okay to say "Wipo".

THE PRESIDENT: Okay. Ms. Cheek?

MS. CHEEK: Ms. Wagner will direct the examination of Mr. Erstling.

MS. WAGNER: Good morning, Professor Erstling. We can begin by having you deliver your presentation, please.

PRESENTATION BY PROFESSOR ERSTLING

PROFESSOR ERSTLING: Thank you. My name is Jay Erstling and, as my background indicates, a major force in my life has been the Patent Cooperation Treaty, or PCT, as it's known, and the PCT continues to be a major factor in my teaching and practice. For that reason, Eli Lilly has asked me to serve as an expert witness in this matter on

the role of the PCT, on the PCT's industrial applicability standard, and on Canada's sound prediction requirement as it relates to the PCT's form and contents requirements, as that has bearing on this case in view of the invalidation of the Strattera patent, which was a PCT application.

The PCT is at the very heart of the international patent system, and since, Mr. President, you spent time in WIPO, you probably have an understanding of the role that the PCT plays in WIPO. The PCT is a multilateral treaty that was adopted in 1970 and came into effect in 1978 that establishes an international patent application filing system.

Among its many advantages, it allows a patent applicant to file a single international patent application that has effect in all PCT member countries instead of having to file an individual application in every country in which the applicant wants to have protection.

The PCT system is governed by the text of the Treaty as well as by a detailed set of regulations. Currently there are 148 contracting states. Canada has been a member of the Treaty since 1990. The Treaty is extremely widely used, including

in Canada.

The PCT is divided into two phases. There's an international phase and a national phase. During the international phase, an international application is processed. It's subject to an international search of the prior art and a preliminary examination as to its patentability, and the application is published.

Article 33 of the PCT, for the purposes of international preliminary examination, provides definitions of the substantive conditions of patentability, of novelty, of inventive step and of industrial applicability which, according to the PCT, as well as NAFTA and TRIPS and other international instruments, is synonymous with utility.

Article 33 defines industrial applicability by saying that an invention is industrially applicable if it can be made or used in a technological sense in any kind of industry with industry having the broadest definition. This is a longstanding, non-controversial and generally accepted definition of industrial applicability. It's actually a very low bar and, among the substantive conditions of patentability, it's the lowest bar.

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. PCT 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 its patentability 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.

The records of the Washington Diplomatic Conference, which was the diplomatic conference that adopted the PCT, provide that the sort of evidence that member states might want to include might be things like affidavits or laboratory notes in order to demonstrate that an invention is usable or operational.

This, in fact, is actually consistent with the right for an applicant to submit informal contents during the international phase, but what the PCT does do is to constrain member countries from requiring form and contents requirements that are different from or additional to those which are provided for in the Treaty and the regulations. In fact, Article 27(5), which I just mentioned, goes on to say that contracting states are free to apply criteria of national law in respect of conditions of patentability provided that those don't constitute conditions constituting requirements as to the form and contents of applications.

This, in my opinion, is an extremely important provision because it strikes a balance between the right of member countries to set the

substantive conditions of patentability where they would like and as they would like, even if they want to be an outlier. It at the same time balances that with the need of PCT applicants to be able to rely on the fact that if their international application is good as to form and contents in the international phase, it will be good as to form and contents in the national phase, and nothing more will be required in the international application itself.

The drafters of the PCT were fairly explicit in defining what they mean by form and contents. The post-conference documents which form an integral part of the records of the Diplomatic Conference provide that form and contents mean not only the physical requirements and the identification data, but also the form and manner of describing and claiming.

In addition, the records of the Diplomatic Conference make reference to the provisions of the PCT and the rules that relate -- excuse me. When I say "rules," there's a quirk in the PCT that the body of rules is referred to as "regulations," 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)(vi) 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 capable of exploitation in industry and the way in which it could be made and used or, if it can only be used, 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

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will be self-evident and nothing more will be required.

So, to put together what I've said, under the PCT, during the national phase, Canada can set the substantive test for utility wherever it chooses, but what Canada is constrained from doing and what the PCT constrains is as a matter of form and contents. Canada may not require an international application to include contents that go beyond what the PCT requires. It is constrained by the PCT as to what, as a matter of form and contents, a member country may require the international application to include for the substantive patentability requirement. If it wants more, it can ask for it, but it can't require that it be in the international application.

Canada's rule for evidence of sound prediction, as a result, is incompatible with the PCT. In Canada, evidence of soundly predicted utility will only be considered if it's in the application. It won't be considered if it's not. As a result, Canada's requirement to include evidence of sound prediction imposes a requirement on the contents of international applications that is, in fact, both different from and additional to what the

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PCT specifies, and I believe that is in contravention of Article 27(1).

The consequences of this are, in fact, quite grave, because failure to include evidence of soundly predicted utility in the international application can result in invalidation of the patent or denial of the patent application. The situation really puts applicants in a bind, and it requires applicants to make a choice that in most cases neither alternative is acceptable. Canada's additional contents requirements for evidence of sound prediction threaten an applicant's right of priority, which is not only a fundamental feature of the PCT and a fundamental right of the PCT but it is also really a foundational right of the international patent system as well. It requires applicants to make a choice.

If an applicant amends the application to meet the evidentiary requirement, it risks losing its priority date because it may have added new matter, which means that the applicant may not get a patent at all. But if the applicant chooses not to amend, then the applicant risks denial or invalidity for lack of utility. For all these reasons, it is my opinion that Canada's requirement to include evidence

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of sound prediction in the international application undermines a core objective of the PCT.

Thank you.

MS. WAGNER: Thank you. I have no questions for direct examination.

THE PRESIDENT: For cross-examination. Mr. Spelliscy, you will conduct the cross-examination?

CROSS-EXAMINATION ON BEHALF OF THE RESPONDENT

MR. SPELLISCY: Good morning, Professor Erstling. We appreciate you being here on a Saturday. My name is Shane Spelliscy. I'm senior counsel for the Government of Canada. I'm going to ask you a few questions and my goal today is just to understand a little bit more about the opinions you have submitted on behalf of the Claimant in this arbitration.

I don't expect that we're going to go for very long today, you'll be glad to know --

PROFESSOR ERSTLING: Thank you.

MR. SPELLISCY: -- but if we do need a break at any point let me know and I'll find a point to take one, but I don't think we'll be going very long.

As an initial matter, let me clarify

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the extent of your opinion. I think I understand from your presentation now, but let me turn to paragraph 1 of your Second Report. There you say in the fourth sentence, "The fundamental point of my initial report, apparently missed by Mr. Reed, is that Canada's new requirement to include proof or evidence of soundly predicted utility in the patent application is a matter of form and contents governed by the PCT and is at odds with the structure and purpose of the PCT." Do you see that?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: So you are offering here no opinion in your report or in your testimony this morning on the rule in Canadian law that utility will be judged against the promise of a patent, correct?

PROFESSOR ERSTLING: The extent of my opinion is that the heightened evidentiary requirement of sound prediction is at odds with the PCT.

MR. SPELLISCY: I'm not sure that was a direct answer. I understand that's the first part of what you said there. I'm trying to make sure, you've offered no opinion in your report on the rule in Canada that the utility will be judged against the

promise of the patent, correct?
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, 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,

in a contents informational sense, not in the strict submission of evidence in a trial court setting type of sense.
MR. SPELLISCY: Let me also just clarify a few things about your experience upon which your opinion is based, and I would actually like to come to your First Report and the disclosure you make about your relationship with the Claimant here.
Let's turn to page 3 of your First Report and paragraph 9. In this paragraph you disclose that in May 2009 you were retained by the Claimant, Eli Lilly, to review the Canadian Federal Court decisions relating to Raloxifene and to discuss your view of those decisions in the context of the PCT requirements for patent applications, correct?
PROFESSOR ERSTLING: Yes.
MR. SPELLISCY: When you say Federal Court decisions in that paragraph, you're talking about both the Federal Court and the Federal Court of Appeal, correct?
PROFESSOR ERSTLING: Yes. Although I believe my focus was on the Federal Court of Appeal.
MR. SPELLISCY: Right, because you were preparing an affidavit to be submitted by the Claimant, Eli Lilly, in the Supreme Court of Canada

in support of their application for leave to appeal, correct?

PROFESSOR ERSTLING: I did, yes.

MR. SPELLISCY: That request for leave to appeal was denied in October of 2009. Is that right?

PROFESSOR ERSTLING: I knew that it was denied. I was not aware of when.

MR. SPELLISCY: But you knew it was denied?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: Then you say after that, in January 2012, the Claimant requested you -- or your firm, you say, but I take it it was you -- to prepare a study on the utility requirements in Canada, correct?

PROFESSOR ERSTLING: That's correct.

MR. SPELLISCY: In fact, that was a study we looked at a few minutes ago at tab 1 of your binder, C-100, right?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: That was a study Eli Lilly requested you prepare?

PROFESSOR ERSTLING: Right. They requested the study which we then published -- "we"

being my co-authors and I.

MR. SPELLISCY: Right, your co-authors, who are partners at the firm where you are counsel, correct?

PROFESSOR ERSTLING: That's correct.

MR. SPELLISCY: Eli Lilly has also requested that you present this paper at at least two conferences that you disclosed in your report, one in Ottawa and one in Chicago. Is that right?

PROFESSOR ERSTLING: That's correct.

MR. SPELLISCY: And Eli Lilly has supported your attendance at these conferences? Did they pay for it?

PROFESSOR ERSTLING: I actually do not remember.

THE PRESIDENT: Excuse me, Mr. Spelliscy. What do you mean by "supported"? Paying the tickets and the hotel?

MR. SPELLISCY: Yes. They paid for it.

PROFESSOR ERSTLING: I don't recall.

MR. SPELLISCY: Let's turn to the paper again, tab 1, C-100. Let's look at page 14 this time. In the top paragraph -- I should say I think -- if you go back to page 13 for a second,

you'll see that you have a little C that says "Canada," so this is a section where you talk about Canada, is that correct, the Canadian law?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: If you come to page 14 in the top paragraph, you and your co-authors write, "In its interpretation of the statute, the Supreme Court of Canada has held that utility does not exist if 'the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises...'"

You see that?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: And you have a footnote 65 right at the end. That sentence does continue, but footnotes 55 and 56 actually refer to the same case. If you go down to footnote 65, the case you cite for that is the Consolboard decision in 1981, correct?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: That's the same case you actually cite in footnote 66, the Consolboard decision, 1981. Is that right?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: You also cite in footnote 66 the Unifloc decision from 1943, correct?

PROFESSOR ERSTLING: That's correct.

MR. SPELLISCY: So your research prepared at the request of the Claimant into the utility requirement in Canada led you to Consolboard for the doctrine of promise utility, correct?

PROFESSOR ERSTLING: Well, it did but in a backwards sort of way. Our focus was on the sound prediction requirement. We are not Canadian attorneys, I am certainly not a Canadian attorney, and I have no expertise in Canadian law, so we began by looking at sources like MOPOP, and MOPOP cited Consolboard and so we cited Consolboard. But it was really to establish, in our view, what the state of utility is in Canada so that we could at that point focus on sound prediction. It was really simply to place it in a very broad context; it was not to rely on it at all.

MR. SPELLISCY: But, in terms of placing the promise doctrine in the very broad context, in writing this article you felt that the Consolboard decision in 1981 provided you with all the context you need for the rule you cite here. Is that correct?

PROFESSOR ERSTLING: Well, actually it was MOPOP that probably led us to this that allowed us to rely on it. As you could tell from this article, this is not an in-depth exploration. This is really an attempt to present a very high level approach with the emphasis on sound prediction being at variance from or different from utility in the United States or industrial applicability in Europe.

MR. SPELLISCY: I understand the point of the article; I'm just not sure I've understood what you said there. When I look at footnote 65, I see the first reference is to Consolboard with a specific page cite, 525, and then I see it says "see also MOPOP", so your primary reference is to Consolboard there, is it not?

PROFESSOR ERSTLING: In terms of citation, in terms of our research, the research methodology that we used to get there, MOPOP came first.

MR. SPELLISCY: And, in fact, Consolboard and Unifloc are the only two Canadian law cases that you cite at all in those two footnotes, correct?

PROFESSOR ERSTLING: Yes, in those two footnotes.

MR. SPELLISCY: I'd like now to turn to tab 3 of your binder.

PROFESSOR ERSTLING: Of my binder?

MR. SPELLISCY: Not your binder, sorry. The red binder.

PROFESSOR ERSTLING: Okay.

MR. SPELLISCY: Tab 3 is Exhibit R-200, and it's the decision of Justice Hughes of the Federal Court in 2008 related to the Raloxifene decision. Do you see that?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: And this is the decision -- at least one of the decisions -- that you say you reviewed in preparing your affidavit in support of the Claimant's application for leave to appeal to the Supreme Court of Canada, correct?

PROFESSOR ERSTLING: This is the lower court decision, the decision upon which I really did not rely.

MR. SPELLISCY: In your witness statement you did say you read the Federal Court decisions, plural?

PROFESSOR ERSTLING: Yes. There's a difference between reading and reading.

MR. SPELLISCY: I just want to turn to

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

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: If you go down to paragraphs 167 and to 168 you will see that Eli Lilly argued in front of Justice Hughes in 2008 that article 27(1) means that the disclosure need only set out the invention and that no further disclosure can be required. Do you see that?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: This is the same argument that you made in the affidavit which you filed in support of Eli Lilly's application for leave to appeal to the Supreme Court a year later. Is that right?

PROFESSOR ERSTLING: Yes. That no further disclosure is required in the international application, and that further disclosure can be supplied subsequently in the international phase.

MR. SPELLISCY: If we look at paragraph 169 of the decision it says "Eli Lilly argues" -- in the first sentence -- "Eli Lilly argues

that the 'form and contents' provision at the end limits the necessity to make disclosure." Do you see that?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: This is the same argument you're making today in this Tribunal, right?

PROFESSOR ERSTLING: I assume that -- well, no, I actually shouldn't assume. Could you explain what "form and contents provision" at the end refers to?

MR. SPELLISCY: I think he's saying "...in the end limit the necessity to make the disclosure. I do not consider..." You would agree with me that Eli Lilly argued in this case, which you reviewed, that the form and contents provisions of the PCT limit the necessity to make disclosure, correct?

PROFESSOR ERSTLING: I would not argue that it limits the necessity to make disclosure. What I would argue is that it limits the requirement to make disclosure in the international application and to be penalized for not making that disclosure in the international application, as opposed to requiring that it be allowed to make it subsequently in the national phase, and the reason for that is

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that the very purpose and objective of the PCT is to allow the single application to be able to be relied upon in the national phase, and, where there is a need to meet additional substantive conditions of patentability requirements, to be able to make those subsequently, if every country were allowed to make form and contents requirements, then the purpose and objective of the PCT would be undermined completely. In fact, there would be no basis for having a PCT at all.

MR. SPELLISCY: You would agree with me, Mr. Erstling, that that was the argument that Eli Lilly was making in the Federal courts in Canada, correct?

PROFESSOR ERSTLING: Well, I can only base it on what I read in the decision. I was not privy to the argument that Eli Lilly actually made. Eli Lilly never spelled out that argument to me. Based on the decision here, I would assume that, on the basis of the decision, yes, that is the argument, but I have no personal knowledge of the argument that Eli Lilly made.

MR. SPELLISCY: But you were retained -- I don't understand, Mr. Erstling. You were retained by Eli Lilly to file an affidavit in

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support of their application for leave to appeal this issue to the Supreme Court. I assume you were retained not on Canadian law but on PCT issues, correct?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: So you understood, in making that affidavit, what Eli Lilly was arguing, correct?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: So you understood essentially that Eli Lilly started arguing -- or had made the arguments in 2008 in front of the Federal Court that you're making here now, and that you made in your affidavit in 2009 to the Supreme Court, correct?

PROFESSOR ERSTLING: What I can agree to is that my presentation here is consistent with my affidavit in 2009.

MR. SPELLISCY: You would agree with me, by reading on in 169 and by knowing the result in this case, that the Federal Court in the trial that Justice Hughes heard, provided reasons for but then disagreed with Eli Lilly's argument on the meaning of the PCT, correct?

PROFESSOR ERSTLING: I would agree

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that the court disagreed with Eli Lilly.

MR. SPELLISCY: You would agree that the judge provided reasons for doing so, too, correct? You can review, if you like, paragraphs 165 through 169.

PROFESSOR ERSTLING: With all due respect, I would disagree with the decision of the court.

MR. SPELLISCY: I understand you would disagree with the substance; my question is the court did provide reasons for its decision, correct?

PROFESSOR ERSTLING: It did.

MR. SPELLISCY: Thank you. We'll get to your disagreement with the substance in a second. If you could turn to tab 4 of your binder, this is Exhibit R-354, and this is the decision of the Federal Court of Appeal March 25, 2009. This was the one that you read in more detail, you said, in preparation for the submission of your affidavit, correct?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: And the Federal Court of Appeal also considered Eli Lilly's arguments on the PCT, correct?

PROFESSOR ERSTLING: If my

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recollection is correct, there was a summary dismissal of the argument, so I don't know to what extent the court considered it on the basis of this decision.

MR. SPELLISCY: Let's turn to page 6 and turn to paragraph 19. You would agree that the issue of compliance with the PCT was presented to the Federal Court of Appeal by the Appellant, Eli Lilly, correct?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: And they argued that requiring the complete disclosure of the factual basis underlying the sound prediction is inconsistent with the Patent Cooperation Treaty, correct?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: And that's the same argument you're presenting to this Tribunal here today, correct?

PROFESSOR ERSTLING: Basically, yes.

MR. SPELLISCY: The Federal Court of Appeal rejected this and said, "However, this treaty... contemplates the supremacy of national law in setting the rules for substantive conditions of patentability... We are concerned here with substantive conditions of patentability."

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You see that?
PROFESSOR ERSTLING: I do.
MR. SPELLISCY: I understand you 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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here, and I want you to go to the second excerpt, the third page in here, Article 59 on page 46 of the PCT titled "Disputes." Are you with me?
PROFESSOR ERSTLING: Yes.
MR. SPELLISCY: It says, "Subject to Article 64(5), any dispute between two or more Contracting States concerning the interpretation or application of this Treaty or the Regulations, not settled by negotiation, may, by any one of the States concerned, be brought before the International Court of Justice by application in conformity with the Statute of the Court, unless the States concerned agree on some other method of settlement."
See that?
PROFESSOR ERSTLING: I do.
MR. SPELLISCY: So the PCT only contemplates state-to-state dispute settlement over the interpretation and application of the PCT, correct?
PROFESSOR ERSTLING: Within the PCT itself, but it also says that it's subject to Article 64(5). Do you have reference to that? I have a recollection but it is a recollection only, as to what 64(5) provides.
THE PRESIDENT: Has such a declaration

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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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they declared that they are not bound.
MR. SPELLISCY: Unfortunately they decided not to join us on a Saturday so maybe we'll have to look it up ourselves. We can confirm, though, not a single one of Canada's Treaty partners under the PCT have ever brought a dispute against Canada concerning its interpretation application of the PCT, correct?
PROFESSOR ERSTLING: I don't think any state has ever brought an action against any other state on the basis of the PCT before the International Court of Justice.
MR. SPELLISCY: So the answer is no, none of Canada's Treaty partners under the PCT have brought a dispute complaining that Canada is violating the PCT, correct?
PROFESSOR ERSTLING: That is correct.
MR. SPELLISCY: Let's turn back to paragraph 1 of your Second Report.
PROFESSOR ERSTLING: That is in which binder?
MR. SPELLISCY: It would have been provided to you by your counsel in the large binder, at tabs 1 and 2. No. 2 is your Second Report. I'm looking at the sentence in paragraph 1 that starts

about halfway down the right side, the sentence that says, it was "the fundamental point of my initial report" and I want to understand the idea, you say that Canada's "new requirement to include proof or evidence of... utility...."

Let me understand a little bit about that. You earlier testified that you're certainly not an expert in Canadian law, correct?

PROFESSOR ERSTLING: That is correct.

MR. SPELLISCY: And, in terms of concluding to this Tribunal that this is a new requirement, you don't cite any authority there that I see. Is that right?

PROFESSOR ERSTLING: That's correct.

MR. SPELLISCY: So was this an instruction of Canadian counsel that this is a new requirement?

PROFESSOR ERSTLING: No. This was my understanding that it was a requirement brought into effect relatively recently. I may be getting the case wrong, but I believe it was in the AZT case.

MR. SPELLISCY: You said earlier today that the PCT has not harmonized substantive patent law but we were talking about disclosure. So I'd like now to understand a little bit more your

opinions on disclosure.

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.

What it does is reflect, really, prevailing standards, and that's, in my opinion, what allows the Treaty to be successful.

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 said was the -- the evidentiary requirement of the disclosure requirement 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?

PROFESSOR ERSTLING: Correct.

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

PROFESSOR ERSTLING: That's 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 to 5.1(a), it starts with --

PROFESSOR ERSTLING: Excuse me, I'm not...

MR. SPELLISCY: Are you in tab 7? You're there?

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

that are requirements that the description must contain, correct?

PROFESSOR ERSTLING: Correct.

MR. SPELLISCY: I want to look at No. (iii) on the next page. Page 29, No. (iii). The description must "disclose the invention, as claimed, in such terms that the technical problem (even if not expressly stated as such) and its solution can be understood, and state the advantageous effects, if any, of the invention with reference to the background art."

So the description must disclose the invention as claimed, right?

PROFESSOR ERSTLING: That's correct.

MR. SPELLISCY: In fact, if we further understand this -- now, I should say the PCT or the regulations don't provide any further detail as to what it means to disclose the invention as claimed in No. (iii), correct?

PROFESSOR ERSTLING: Because the disclosure requirement and the utility requirement are different things -- and if you would look at 5.1(a)(vi), that provides the description that is required for utility, for industrial applicability.

MR. SPELLISCY: That's a separate

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requirement. We're going to get to that requirement. 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?

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.

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 R-042, and you'll see at the top it's an excerpt from the PCT Applicant's Guide. The date at the bottom is July 24, 2014. Do you see that?

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

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?

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SIR DANIEL BETHLEHEM: Page 29?

MR. SPELLISCY: It is page 29.

PROFESSOR ERSTLING: Yes.

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."

Do you see that?

PROFESSOR ERSTLING: Yes.

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?

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

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

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in the international preliminary examination, correct?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: This is a guide directed to applicants on how to file their application, correct?

PROFESSOR ERSTLING: That's correct.

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?

PROFESSOR ERSTLING: Yes, that's correct.

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

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

MR. SPELLISCY: Sure.

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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that you cited necessarily puts applicants on warning that it needs to be aware of every distinct practice or substantive condition that may apply in all 148 member countries. Again, because the PCT is sort of rooted in common understandings, provisions that are unique or outlying provisions, I don't think there is in the PCT a sense that applicants need to be aware of national practice to the degree that I think your question may allude to, if that makes sense.

MR. SPELLISCY: Can you go back to tab 8, and let's look at the paragraph again.

PROFESSOR ERSTLING: Where in tab 8?

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?

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.

So I believe that what is underlying in this is that, if there is a need to amend the description, which applicants should try to minimize, the amendments that will be made during the national phase won't end up being penalties, or even resulting in the loss of a priority right, for example.

MR. SPELLISCY: Right. So if applicants -- what WIPO is telling applicants is that if applicants take due account of national practice when the description is drafted they may avoid the need to amend the description and avoid the priority problems that you are mentioning, correct?

PROFESSOR ERSTLING: Yes, that's correct.

MR. SPELLISCY: Let's turn to tab 9 again, R-043. These are excerpts from the practitioner's guide to the PCT authored by yourself, Mr. Helfgott and Mr. Reed?

PROFESSOR ERSTLING: That's correct.

MR. SPELLISCY: I want to turn to what's page 200 in this excerpt, in this exhibit -- page 200 in the book. There is a heading No. 2 that says "Different laws in Different Countries." Mr. Helfgott wrote this chapter, correct?

PROFESSOR ERSTLING: That's correct.

MR. SPELLISCY: He wrote "In order to be sure that your PCT application will be a viable application in foreign countries, care must be given to the various laws in foreign countries that may be different from those in the United States. In many cases the patent laws of many countries have been harmonized, but there are still differences, and these must be considered."

You would agree with Mr. Helfgott?

PROFESSOR ERSTLING: I would. He put this in a chapter that was suggestions and recommendations for solid drafting. The provision goes on to say, if I remember correctly, that what Mr. Helfgott was really -- was primarily referring to was the situation in the United States where we were at that point transitioning from a first-to-invent to a first-to-file system and that, as a result of that, being aware of needing to file applications early became more important and that we, in the United States, have a grace period that few countries have, and that the awareness that most countries do not have a grace period and a disclosure can immediately eliminate your right to seek a patent in a country needed to be taken into consideration.

It was really at that high level, not

that you needed to get into the weeds of the national laws of every PCT member country.

MR. SPELLISCY: I understand that's the example that he gives in the following paragraphs. What he says is the differences between the various laws in foreign countries must be considered. That's what he writes, right?

PROFESSOR ERSTLING: That's correct.

MR. SPELLISCY: And, as you indicated, you agree with that, correct?

PROFESSOR ERSTLING: I agree with that in the context in which it was stated.

MR. SPELLISCY: I want to now refer you and discuss with you your view that you raised earlier on the disclosure requirements. You mentioned earlier but if we come to paragraph 14 of your Second Report, I think this is what we just talked about in the last sentence in this paragraph. You say: "The PCT recognizes the need for adequate disclosure by expressly requiring that the claims in an international application shall be fully supported by the description." Then you write, "But the disclosure requirement is not at issue here." That's the last part that I want to focus on.

If you could turn to tab 3 of your

binder, which is Exhibit R-200, this is the Federal Court decision of Justice Hughes in the Raloxifene case.

PROFESSOR ERSTLING: I'm confused. In which binder am I now?

MR. SPELLISCY: I'm always taking you to the red binder. By referring to it as "your" binder doesn't mean you take ownership of it, but you're welcome to keep it, probably.

Tab 3, R-200, is the Justice Hughes decision in the trial court level in the Raloxifene case. I want to turn to page 20 now in this decision. Look at paragraph 68 and the last line in that paragraph. I'm going to go through a couple of examples here just to show you some text, and then I'll ask you some questions.

Justice Hughes writes, "We have reached the point of the 'bargain' theory in which a monopoly is exchanged for disclosure, a matter that is important in consideration of sound prediction and sufficiency." Do you see that? The last sentence?

PROFESSOR ERSTLING: Yes.

MR. SPELLISCY: If we keep going in this decision and turn to page 46 now and to paragraph 163, the very last sentence here which is

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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,

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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

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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 penalized, an application should not be denied or a patent invalidated because the disclosure which goes beyond that which the PCT requires was not

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in the international application.

MR. SPELLISCY: So as I understand 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?

PROFESSOR ERSTLING: That in order to meet the form and contents requirement there needs to be an explicit statement when an implicit understanding isn't just readily available, and that again reflecting the prevailing international norm.

MR. SPELLISCY: So we would agree that an implicit statement is less than an express statement?

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?

PROFESSOR ERSTLING: No, not in my view -- actually, not at all. The drafter of the application, in order to meet the form and contents requirement, needs to include, where it's not inherent, an explicit statement of the way in which the invention can be exploited industrially, or the way in which it can be made and used. It's then up to the examiner to determine whether that statement meets the substantive condition of patentability.

There's one thing that is what the law requires, and then there's the information that you provide in the application upon which that requirement will be judged.

MR. SPELLISCY: So it is up to the examiner to determine whether that statement meets the substantive condition of patentability. That's what you just said, correct? I'm reading from the transcript, if that helps -- which I have and you don't!

PROFESSOR ERSTLING: I know. That's unfair, you know!

Well, it is the role of the examiner to determine whether the conditions of patentability have been complied with or 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.

THE PRESIDENT: Thank you. Any questions for redirect?

MS. WAGNER: I do have one or two, if I can 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?

PROFESSOR ERSTLING: I don't think so. I think what they would assume is that, in accordance with standard practice, utility is something that's simply stated, and then it's evaluated on those grounds. To my knowledge, Canada is the only country that requires proof.

MS. WAGNER: Thank you. And where does Canada require that proof, to be clear?

PROFESSOR ERSTLING: Proof that the invention, the utility of the invention, has been soundly predicted.

MS. WAGNER: And where is it required in Canada?

PROFESSOR ERSTLING: Oh, in the application as filed.

MS. WAGNER: One other question. You had an exchange with Mr. Spelliscy at the end of the cross-examination there about specific, substantial and credible. If there was just an express statement of utility where one is required in the application, then how does the member country have an opportunity to evaluate whether that statement is specific, substantial or credible? How and what can they ask for, and in what context?

PROFESSOR ERSTLING: Well, in most

cases an examiner would look at what the claimed invention is and on that basis determine whether it is useful or, in an industrial applicability standard, whether it has an application in industry.

In general, if there is doubt, then the examiner would in some way reach out to the applicant. It may be raising an issue in an office action to which the applicant could respond, or it may be, depending upon national practice, in informal give-and-take with the examiner, but there generally would be an opportunity to, if there were doubt, to be able to overcome that doubt.

MS. WAGNER: And, putting Canada aside, would that material to be provided to overcome the doubt have to be in the application?

PROFESSOR ERSTLING: No. It would generally be supporting material that would be supplied post-filing.

MS. WAGNER: And is there a particular format that the supporting material would take, or...

PROFESSOR ERSTLING: No, not -- it could be in the form of affidavits. It could be in the form of supplying evidence or certificates of clinical data. It could be, where there is doubt, anything that would overcome that doubt.

MS. WAGNER: Thank you, Professor Erstling.

THE PRESIDENT: Any application for recross?

MR. SPELLISCY: None.

THE PRESIDENT: Thank you. Question by Sir Daniel.

QUESTIONS BY THE ARBITRAL TRIBUNAL

SIR DANIEL BETHLEHEM: Thank you very much, Professor Erstling. My questions, as usual, on these topics come with a caveat of my ignorance. Unlike our President I did not spend my formative years in the bowels -- or even the 13th floor -- of WIPO. I'm a little bit more familiar with some of the other Geneva organizations closer to the lake.

PROFESSOR ERSTLING: I know which one!

SIR DANIEL BETHLEHEM: I'd just like to try and situate some of your observations in that context. In your presentation -- and this was a theme that you came back to in the context of the cross-examination -- your testimony was that Canada's rule for evidence of sound prediction is in breach of Article 27(1) of the PCT. Counsel for Canada took you to Article 59 relating to the settlement of disputes in ICJ, and I'd note just as an aside that,

certainly as I see the PCT website, neither Canada nor the United States has made a declaration under Article 64 paragraph 5.

I'm less interested in that. What I'd like to try and explore is whether there are other mechanisms within the PCT Office, the one that you were the Director of, in which issues of compatibility or incompatibility would have been addressed, something akin to the way, for example, in which the World Trade Organisation may, through its trade policy review mechanism or something of that nature, focus on these issues.

My first question is just to ask you if you could describe or explain for me what a notification of incompatibility is under the PCT rules, and whether this would have any relevance to our discussion?

PROFESSOR ERSTLING: To be perfectly honest, I actually don't know what a notification of incompatibility would be or what form it would take. If you're speaking within Article 59, again --

SIR DANIEL BETHLEHEM: No. Let me clarify, excuse me. I'm not speaking within the context of Article 59, but I see across a number of the rules that there is an opportunity for

Intellectual Property Offices in States to make declarations of incompatibility.

PROFESSOR ERSTLING: Yes -- oh, so when the PCT rules are amended, which is a matter of general consensus and takes an enormously long time for consideration, in certain cases the adoption of the rule will be contrary to countries' national laws, and in those cases what often happens is the country doesn't want to block the adoption of the rule but it says that it cannot currently accept that rule because it is in contravention of its national law. So, in those cases, countries are free to file notices of incompatibility to let the world know that the rule will not apply to them until such time as they are able to amend their national law. And then they withdraw the notice of incompatibility.

SIR DANIEL BETHLEHEM: Are issues of incompatibility, whether or not the subject of a notification of incompatibility, are those issues discussed within the Office that you used to head?

PROFESSOR ERSTLING: Only on an informal basis. We would receive complaints. Sometimes they were complaints that particularly the legal division of the office would receive. It would always respond by saying that under the PCT, the

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 understand it, Article 59 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.

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?

MS. WAGNER: No questions, thank you.

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: Recess until 11:00.

(Recess taken)

THEODORE DAVID REED

THE PRESIDENT: Good morning, 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?

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. REED: 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.

THE PRESIDENT: Good. Mr. Reed, could you please go to your expert reports, and go first to the First Report which is dated 26 January 2015? Could you go to page 24?

MR. REED: Yes, I've found page 24.

THE PRESIDENT: Could you please confirm for the record that the signature appearing above your name is your signature?

MR. REED: The signature is mine, yes.

THE PRESIDENT: Could you please go to the Second Report dated December 7, 2015, and go to page 14 and confirm for the record that the signature appearing above your name is your signature?

MR. REED: Yes, that is my signature.

THE PRESIDENT: Mr. Reed, is there any correction you wish to make to either report?

MR. REED: No, not at this time.

THE PRESIDENT: Thank you. Mr. Spelliscy, you have the privilege of starting the direct examination.

MR. SPELLISCY: Good morning, Mr. Reed. I know you have a presentation to present, so please go ahead.

PRESENTATION BY MR. REED

MR. REED: Okay. Thank you.

A number of the things in my presentation were covered by Mr. Erstling and some of the things we just heard during his cross-examination, but I'll go ahead and start and give the same comments that I planned to give when I came in this morning.

As I say, my name is David Reed, and I'm here today to talk about the PCT and some of its features based on my experience as a long-time practitioner under PCT, as well as over nine years of teaching the PCT as an independent consultant for WIPO. My teaching was primarily limited to the United States and a few excursions into Canada teaching the basics of the PCT.

First of all, I'd like to give you a little background about myself. I have a Bachelor of Science degree in Chemical Engineering from Northwestern University, and I have also supplemented that with some postgraduate studies also in Chemical Engineering at the University of Cincinnati following my employment at Procter & Gamble. In 1966 following graduation I joined the Procter & Gamble company in Cincinnati, Ohio as a development engineer working on new products and new processes for the Procter & Gamble company.

In about 1980, I was taken off of my product development duties and put onto a special assignment to assist trial counsel in a number of product liability lawsuits, and also to assist Procter & Gamble's counsel in a number of patent lawsuits. I became very interested in patent law and in 1988 I took and passed the U.S. patent bar and became a registered agent before the USPTO.

During my time at Procter & Gamble, starting in 1990 in response to the needs of the company, we converted our practice from a practice under direct national practice under the Paris Convention to a practice under the Patent Cooperation Treaty. Since that conversion in late 1990, I have either been the agent of record or have managed the agents of record in over 9,000 PCT filings.

There was a time when P&G was the largest single user of the PCT in the world. Long since -- long ago we lost that title, but we had it for a short period of time. But because of the wide use we had of the PCT and the success we made in utilizing the PCT, WIPO approached me in 1996 and asked me if I would be available to go to countries that were considering joining the PCT, or countries that were just learning to use the PCT having joined

the PCT, and lecture on P&G's practice on PCT, how it worked, and the advantages we received.

THE PRESIDENT: Mr. Reed, on this point -- because you have heard, with Professor Erstling, that I have been also involved in WIPO -- that was a different involvement. You have been involved in teaching how the PCT works, I understand; I have been involved in, A, drafting the Arbitration Rules and B, in workshops on the WIPO arbitration schemes. That's a different type of instruction than what you have done.

So simply to be very clear for the parties, we have never met before, never worked together before, never taught together before. There was a whole other part of WIPO.

MR. REED: Not only that, I was not really invited to go to Geneva very often. We always just went to foreign countries, so we would never run into each other.

THE PRESIDENT: Okay. Good.

MR. REED: In 2006 I retired from P&G after 40 years of service and, as I retired, WIPO approached me and asked me if I would pass on my role of relating Procter & Gamble's practice under the PCT and take over operating a help desk as well as going

around the United States giving PCT seminars, teaching practitioners how to use the PCT to their greatest advantage, and I did that full-time starting in 2006 until 2014. At the end of 2014 I stopped doing that, and am now looking forward to full retirement.

We've been talking about the PCT. Exactly what is the PCT? The Patent Cooperation Treaty is an international patent filing system. Please note, it just works for filing patent applications; it does not grant applications.

In my personal opinion, the PCT is the greatest single advancement in foreign patent practice since the advent of the Paris Convention in 1883.

Under the PCT, the applicant will file a single application in their home country, in general; also in general in their home language; and establish a filing date in all PCT contracting states. There are currently 148 of them.

In the process of the PCT, the applicant will receive some very valuable information regarding the prior art that can be found through the international search, possibly get information regarding the comparison of their particular claimed

invention on novelty, inventive step, industrial applicability.

The PCT has also standardized some formalities. Those are listed in Articles 3 through 7 and further detailed in Rules 5 through 8. But primarily the PCT is set up to say that you need to have a description in your application, you need to have at least one claim; drawings if they're necessary -- in many applications they're not necessary; you want an abstract so that people can search and find the information in your particular case when it gets published, and finally a request form that's going to contain a request to process under the PCT, as well as bibliographic information related to the particular application.

We took a look at Rule 5.1. It was on the screen a little bit earlier. As far as the description is concerned, it was talking about such things as wanting a description of what the prior art is, the closest prior art, what the technical field is -- a number of formal categories of what WIPO or what the PCT says should be included in a PCT application.

In addition to those categories, we also took a look at Rule 5.1(a)(vi). 5.1(vi) calls

for an explicit statement, if it's not obvious based on the description or the nature of the invention, an explicit statement as to how the invention can be exploited or used in the industry. Think of that in the context of this particular proceedings as having utility. And also how it can be made and used.

The PCT process itself, once you have the application, consists of two phases.

Mr. Erstling covered this to some degree but the two phases are an international phase in which the PCT is processed under the PCT regulations. At the end of this international phase, which is 30 months from the earliest claimed priority date, the application if you're going to proceed to seek patent protection then moves into the national phase where the application is converted into a national application for national processing.

During this international phase, as I mentioned, you will get a search. The particular application will be sent to an international searching authority. The searching authority will look to find any relevant prior art that might affect the novelty or inventive step of the particular application.

Since 2004, when there was a change in

the PCT, post-2004 you will also get a written opinion from the searching examiner where the examiner will take the art found in the search report and apply it against the novelty and inventive step of your particular application. Prior to 2004 this was not automatic and did not happen in the first part of the international phase, but could be obtained by applicants through payment of a fee and making a request to go into what we would call Chapter 2 examination, and Chapter 2 was a separate process that an applicant can use or may choose not to use, depending on what their particular needs are.

In the search of prior art and also of the written opinion, the examiners will follow the guidelines that are provided under the WIPO as to how to go ahead and examine the application. In addition to working with the examiner to come up with the final report as to whether the invention appears to be novel or appears to be inventive or have industrial application or utility, these are judged against the guidelines in the PCT in Article 33.

Please note that anything that comes out of the PCT does not relate to the patentability of the particular invention under any given national law. Article 33 does give the standards that you can

go in and see what the examiner is using to make the judgments on that, but, again, any report or any final report coming out of the examination process under the PCT is merely advisory and does not have any bearing on whether the application is truly patentable or not patentable under any national law.

Also, if you go into preliminary examination under Chapter 2 of the PCT, you also have the opportunity to amend the application as well as work with the examiner. In today's world, if you have a written opinion that came with the search report and you choose to rebut that with the international examiner, you may go ahead and do that 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 unless it's obvious from the description and nature of the invention, the author should write into the application an explicit statement on the subject of industrial applicability, utility, how the particular invention can be used in industry, which is one of the pillars, if you will, of patentability, along with novelty or inventive step.

He then further goes on to take a look at Article 27(1) which states that no national office can have requirements that are in addition to or different from those that are set forth in the PCT, and that is based on looking at the form and contents, as is described in Article 27(1). Mr. Erstling then opines that Canada's requirement regarding a factual basis and reasoning for leading to a sound prediction is, in fact, a requirement of form and contents different from or additional to

what is called for in the PCT, because all the PCT says is that you need an explicit statement regarding utility if the utility is not, in fact, obvious from the description or the nature of the invention.

Based on that he feels that the Canadian requirement that the factual basis leading to a sound prediction of utility be in the application beginning at the date of filing is a requirement of form and contents, and is in violation of Article 27.

I disagree. Article 27(1) restricts the form and contents that national law can require in an international application. But what do we mean by form and contents? If we take a look at the notes from the Washington Conference on the PCT in 1970 and see what they had to say about Article 27(1), the first thing we see is something that Mr. Erstling put up in a slide earlier talking about the description, claims, et cetera. But the last sentence of that particular comment was not put onto that slide, and I'd like to go ahead and correct that now. It says "The words 'form or contents' are used merely to emphasize something that should go without saying, namely that the requirements of substantive patent law (criteria of patentability, et cetera) are not

meant."

What Article 27(1) has to do with is 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 words "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.

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 particular 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, the same three criteria for determining of utility. But if all we have in the application, if all that 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

application or invention has utility that is substantial, specific and credible? The PCT guidelines themselves send the people, send the examiners, to the description. There's got to be more in there in order to make a case for utility than just an explicit statement, even during the PCT. You can't send it in. The examination, at least in today's world, is going to be conducted on the application as it is filed. You can't add new matter. In fact, indeed in today's world, when this is put forth, there's not even an opportunity to amend the case to add anything that might be considered missing.

Also, form and contents does not encompass what is required for sufficient disclosure of the invention, including its utility under national law. Let's take a look at the PCT Applicant's Guide, and I think this was put up a little bit earlier. The Applicant's Guide informs the users and says "details required for the disclosure of the invention so that it can be carried out by a person skilled in the art depends on the practices of national Offices" and warns applicants "that due account be taken of national practice... when the description is drafted."

Based on everything I've seen in the PCT, the use I've done in my over 9,000 applications, et cetera, the PCT does not limit the right of a contracting states to require, at the time of filing, the disclosure of a factual basis and the reasoning leading to a sound prediction of utility. These are substantive conditions of patentability under Canadian law and do not fall under the restrictions of Article 27(1).

Thank you.

THE PRESIDENT: Thank you.

MR. SPELLISCY: We have no additional questions on direct examination.

THE PRESIDENT: Thank you. Cross-examination?

MS. CHEEK: Ms. Wagner will be conducting the examination of Mr. Reed.

THE PRESIDENT: Ms. Wagner, please proceed.

CROSS-EXAMINATION ON BEHALF OF THE CLAIMANT

MS. WAGNER: Good morning, Mr. Reed.

MR. REED: Good morning.

MS. WAGNER: I just want to pick up on something you've just dealt with in your presentation. We're just going to be on hold for a

moment while everyone has the appropriate materials.

(Distributed)

SIR DANIEL BETHLEHEM: Is this bundle the same just with the expert reports switched around?

MS. WAGNER: That is entirely possible, but I would actually have to check the table of contents. It is a different binder, so there may be --

THE PRESIDENT: The binder is different and the Expert Reports contained in it are different.

MS. WAGNER: That's right, yes.

THE PRESIDENT: I think tab 5 is the same, isn't it? It is again the Washington Conference, which makes it so voluminous.

MS. WAGNER: I regret the number of trees that have been killed in this process. The exhibits are all the same; they're just ordered differently.

SIR DANIEL BETHLEHEM: So, in fact, we can just refer to this one?

MS. WAGNER: We can. Because I've been working from the cross-examination binder it might take me a moment to cross-reference tabs as I'm

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going through.
THE PRESIDENT: Please proceed on the bundle you have just given to us.
MS. WAGNER: Thank you.
Mr. Reed, you were discussing in your presentation that -- actually I don't think your slides are numbered but it's the slide the title of which is "My opinion of Canada's rights (continued)"?
MR. REED: They are numbered.
MS. WAGNER: They are numbered. Slide 7. You're correct.
MR. REED: Slide 7. Okay.
MS. WAGNER: You have at point 3, "The PCT advisory examination process itself requires more than an explicit statement of utility under some circumstances", and you refer to the Search and Examination Guidelines.
Just to be clear on what that information might require, you'd agree that it might require things like prior art to be included in the application?
MR. REED: Chapter 14 has to do with utility or industrial applicability. I don't see where prior art has any relevance to that particular question.

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MS. WAGNER: It might include things about the technical field to which the invention relates?
MR. REED: I guess it could. That is a specific thing. That is part of the description.
MS. WAGNER: That's right, yes. And it might include information such as information relating to dosing in a drug context?
MR. REED: I really know little or nothing about the pharmaceutical industry, so I'm sure I'm even qualified to answer that.
MS. WAGNER: That would be information that could be used to assess credibility of the use of a drug? Dosing information?
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: 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

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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?
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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could be the priority application, yes.
MS. WAGNER: Then, if the applicant wants to use the PCT system for filing their application globally, then within 12 months of that priority application they'll file their PCT application?
MR. REED: In general, that's what they would do, yes.
MS. WAGNER: And they will do that either with the office of a PCT contracting state, or directly with the International Bureau of WIPO. Is that correct?
MR. REED: Yes. I would say they do it with the receiving office for the state in which they live. It's not with any -- they don't get to choose any receiving office. There are competent receiving offices, and the International Bureau is competent for residents and nationals of all PCT contracting states.
MS. WAGNER: So when it's filed with a particular country then you'd normally refer to that country as a receiving office as the correct terminology?
MR. REED: Right. Not every country that is in the PCT has a receiving office, but most

of them do.
MS. WAGNER: So then the filing of that 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.

MS. WAGNER: And when the PCT international phase ends, then the applicant enters the national phase?
MR. REED: Must do it within -- under the PCT the international phase ends at 30 months from priority. However, many countries will give you a little extra time, like Europe gives you 31 months. I think there's actually a country that gives you 33 months. And the most generous is Canada, for instance, because for a very small fee, 200 Canadian dollars, you can get a 12-month extension. But it's not really a late fee. The $200 is a late fee.
MS. WAGNER: Good on Canada.
And then they enter the national phase by converting the PCT international application into a national application in those Patent Offices in which they are seeking patent protection, correct?
MR. REED: Yes.
MS. WAGNER: So let's look at -- can you turn up tab 3, this is the Patent Cooperation Treaty itself, and I am looking at page 22.
MR. REED: Okay. I've got page 22 now.
MS. WAGNER: Article 27 is listed there, and it deals with national requirements.

MR. REED: Uh-huh.
MS. WAGNER: Correct? And Article 27 is basically meant to address what happens in what we had established was called the national phase.
MR. REED: Yes, it does. It has to do with what the national offices can and cannot require.
MS. WAGNER: And basically the national requirements concern, as you said, the requirements that may be imposed by PCT member countries in, I guess, the last stage of the process when the PCT member country files in a member country, correct?
MR. REED: I'm not sure I understood that. Try it again?
MS. WAGNER: The national requirements in Article 27 deal with the requirements that may be imposed by PCT member countries when an applicant enters the national phase?
MR. REED: Okay. I'll buy that.
MS. WAGNER: And one of the requirements we've been discussing today is Article 27(1), and that's the one that says "No national law shall require compliance with requirements relating to the form and contents of the

international application different from and additional to those which are provided in this Treaty or Regulations."
MR. REED: Accurately quoted.
MS. WAGNER: And you may not agree with me on what "form and contents" means, but you do agree that Article 27 is addressing what happens in the national phase?
MR. REED: Yes.
MS. WAGNER: In several paragraphs of your reports you made the observation -- and I'll take you to them, so no surprises -- you made the observation that a PCT application will be received into the international phase of the PCT if it complies with basic form and contents requirements.
MR. REED: I'd like to see the page. I'm not sure -- those don't sound like my words, but they might be.
MS. WAGNER: Let's go to your First Report. I'm at tab 1. We'll go to paragraph 11. You can feel free to read the whole paragraph but I'm going to be looking at the part that starts "So long" on the next page.
MR. REED: Okay.
MS. WAGNER: So the part that I'm

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reading, just so it's in the record, starts "So long" and it's on, again, page 6, not page 5, "So long as the international application complies with the basic 'form and contents' requirements of the PCT, (i.e. contains a title, request, claims, description of the invention and drawings (if required), formatted in accordance with PCT requirements), the application will be accepted into the international phase of the PCT and be eligible for continuation into the national phase. Fulfillment of the PCT's 'form and contents' requirements is typically reviewed by clerks."

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

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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

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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.

MS. WAGNER: 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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MR. REED: Okay.

MS. WAGNER: You've also said that these records serve as an annotated PCT text explaining what the contracting states intended by each article. Correct?

MR. REED: Are those the words I used?

MS. WAGNER: I hope so.

MR. REED: Hang on a second. Could you repeat the question?

MS. WAGNER: Sure. You've also said that these records serve as an annotated PCT text explaining what the contracting states intended by each article.

MR. REED: I'm trying to find those words about "contracting states" in paragraph 13 in my report, and for some reason I'm missing it.

THE PRESIDENT: It is the first line on page 5, of your second expert witness report.

MR. REED: I see that now, yes. Thank you so much.

MS. WAGNER: While you're there, you've also said that the Washington Conference papers provide important context in interpreting the PCT, correct?

MR. REED: Yes.

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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.
MS. 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.
MS. 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.
MS. WAGNER: And I guess the one

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

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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 of that 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.
MS. 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.
MS. 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.
MS. WAGNER: Understood. But the fact

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that the receiving Office only does the facial review of the application doesn't have anything to do with whether the PCT application actually meets the form and contents requirements, correct?
MR. REED: No, they just want something that looks like a description. Something that looks like a claim.
MS. WAGNER: And so the paragraphs in your report that we have discussed, which deal with the receiving Office and what they do, actually don't have anything to do with whether form and contents requirements are actually met?
MR. REED: I'd have to go back and read the report again to see what the context of that is.
MS. WAGNER: Well, we reviewed the three paragraphs where that was in your report.
MR. REED: You may remember them, but I don't.
MS. WAGNER: Do you want to go back and review those three paragraphs?
MR. REED: Yeah.
MS. WAGNER: I can point you to them.
MR. REED: We were in the Second Report?

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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 --

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MR. REED: It is.
MS. WAGNER: -- of the Washington Conference that you say are authoritative as to interpretation. It's a facial review, correct?
MR. REED: It's a facial review but you also have to look at the receiving Office. It's a big place. There may be multiple reviews. And there's also review by the International Bureau when it gets to Geneva.
MS. WAGNER: That's right, but that may be a different form of review, and the fact that it's a cursory review before the receiving Office is not the end of the story, correct?
MR. REED: Is not the end of the story.
MS. WAGNER: Can you turn to paragraph 32 of your Second Report, please? It's at tab 2.
What you say is that "If it is not obvious from the disclosure that the invention has utility, Chapter 14 requires the IPEA examiner" -- I take it that's the examiner in the international phase?
MR. REED: The International Preliminary Examining Authority. Yes, the international phase.

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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

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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

particular type of invention and that's known as "selection" patents?

MR. REED: Okay. That's what I called it. I don't know whether it's a standard term or not. I've heard somebody here use it yesterday.

MS. WAGNER: Do you have any particular expertise in the law relating to selection patents?

MR. REED: No.

MS. WAGNER: Did you prepare and file applications for selection inventions when you were at P&G, to your recollection?

MR. REED: You know I don't know because I didn't write them.

MS. WAGNER: And you don't recall having any involvement with those particular applications?

MR. REED: No, other than the fact that -- no, I don't, other than the fact that they exist, and if looking for the patentability is based on the superior performance or the superior benefit that's unexpected, I have no particular expertise.

MS. WAGNER: So what is your authority for asserting that the guidelines -- the International Preliminary Guidelines, is that the

correct term?

MR. REED: Go ahead.

MS. WAGNER: -- treat selection inventions in a particular way when it comes to utility? What's your authority for that?

MR. REED: I'm not sure that I said the guidelines treat things in a certain way. I said this was an example that I thought is a place where the examiner may -- and not "must" but "may" -- have to revert to the three-pronged test to make sure that the utility of the invention -- because without the improved benefit --

MS. WAGNER: So there's nothing --

MR. REED: -- the claims aren't novel.

THE PRESIDENT: Could you let the expert finish the answer?

MS. WAGNER: Apologies. Please go ahead.

MR. REED: Without the improved benefit for known material the claims aren't novel.

MS. WAGNER: So that was just based on your general understanding of selection inventions?

MR. REED: Yes, it was.

MS. WAGNER: And it wasn't based on anything in the guidelines?

MR. REED: No, I didn't see in the guidelines about selection invention, but I haven't read them for a few days.

MS. WAGNER: Are you aware that it's only in Canada that the disclosed advantages of a selection invention are treated as being the utility of that invention?

MR. REED: I have no knowledge at all of that.

MS. WAGNER: And are you aware that Canadian law has only recently treated selection inventions in this way?

MR. REED: I don't know anything about Canadian law and how they operate up there.

MS. WAGNER: So your understanding in paragraph 33 was simply based on a general understanding that utility is related to selection inventions?

MR. REED: Well, it was more for the three-pronged test, which it happens to be for utility, yes.

MS. WAGNER: And you don't have any experience that that's how selection compounds have been treated in the United States?

MR. REED: No, no knowledge at all.

MS. WAGNER: Or any other jurisdiction?

MR. REED: Nor any other jurisdiction.

MS. WAGNER: Thank you.

Let's go back to your First Report which is at tab 1.

I want to make sure that I understand your testimony as to the meaning of "form and contents" in the PCT system. Let's go to paragraph 35. What you say in paragraph 35 is that -- and I'm looking about midway through the second sentence -- "...the PCT itself, in confirming the meaning of 'form and contents', simply lists broad categories of information that must be included in the international application, and provides directions as to their order and format of presentation."

MR. REED: Okay.

MS. WAGNER: So, in general, in your view, "form and contents" in the PCT just refers to these broad categories of information?

MR. REED: That is correct.

MS. WAGNER: And in paragraph 36 you detail those broad categories and you indicate that they conclude a request and a description and one or more claims and one or more drawings (where required)

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

requirements related to industrial applicability, or utility, are a substantive condition of patentability?
MR. REED: Okay.
MS. WAGNER: So in that context you say that the PCT rightfully places the decision whether a given application has met those requirements, the disclosure requirements, on the national Patent Offices. Correct?
MR. REED: Yes.
MS. WAGNER: That's the framework of the PCT, in your opinion?
MR. REED: Yes.
MS. WAGNER: We have also heard this morning that PCT rule 5.1(a)(vi) essentially says that an applicant has to explicitly state the utility of an invention if it wouldn't be apparent. Accurate characterization?
MR. REED: It's a characterization, but it sounds proper.
MS. WAGNER: But it would be your opinion that the PCT does not constrain PCT members, member countries, from requiring that an applicant disclose something additional about utility in the application?

MR. REED: Say that again?
MS. WAGNER: It would be your opinion that the PCT doesn't restrain or constrain PCT member countries from requiring an applicant to disclose something additional about utility in the application?
MR. REED: Yes.
MS. WAGNER: Because utility is a substantive condition of patentability.
MR. REED: It certainly is.
MS. WAGNER: And, in your view, that's not governed by the PCT?
MR. REED: That is correct.
MS. WAGNER: I'm going to put a hypothetical to you. I think it's a simple one. My hypothetical is imagine that rule 5.1 didn't say anything about utility at all. Just silent. If that were the case, is it still your position that a PCT member country could, nonetheless, require an applicant to explicitly state a utility if that were part of its national law?
MR. REED: Yes.
MS. WAGNER: All right. And you think your view is widely shared?
MR. REED: I have no idea.

MS. WAGNER: Do you think that PCT member countries would subscribe to this view?
MR. REED: I don't know. I have no idea what they would subscribe to or not subscribe to.
MS. WAGNER: So it's your view based on your own interpretation of the Treaty?
MR. REED: My own interpretation, and all my experience, yes.
MS. WAGNER: Let's go to tab 5, which is Exhibit C-112. These are the records of the Washington Diplomatic Conference. Just to give us some context, if we go about three pages into the Editor's note --
MR. REED: I'm on page 13. Is that right?
MS. WAGNER: No, just three pages into the exhibit. We've got records of the Washington Diplomatic Conference and then the Editor's note, about three pages in.
MR. REED: I see it.
MS. WAGNER: It says this conference took place from May 25 to June 19, 1970?
THE PRESIDENT: The second paragraph, Mr. Reed, of the Editor's note.

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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 Patent Cooperation Treaty. Is that a correct understanding?
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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paragraph before.
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

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it. 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

oppose those proposals. I'll give you a chance to read it and you can let me know if you agree.

MR. REED: Okay.

MS. WAGNER: Now, at 908.1, we have Mr. Bogsch, the Secretary General --

MR. REED: Bogsch.

MS. WAGNER: Thank you. I notice you didn't correct me on the Polish gentleman's name. That's all right. I didn't know it either.

I'm going to read this out, and then I'm going to characterize it and ask you a question if you agree. So he says, Mr. Bogsch, that "an international application served not only the purpose of international search but also the purpose of being an application in each of the designated States. Therefore, it was extremely important that the international application should contain all the elements which made it possible for the Contracting States to regard it as an equivalent of a national application. It was for that reason, and mainly for that reason, that the PCT defined with precision the formalities and the minimum contents of international applications."

So I'm going to put it in my own words, but in general do you agree that what the

Secretary General is saying is that, if a PCT member country is going to require an applicant to explicitly state a utility, then we need to make sure the PCT also requires the applicant to explicitly state the utility, otherwise the application might not have what it needs?

MR. REED: I think that's fair.

MS. WAGNER: You think that's fair? Okay.

Now let's go to paragraph 910. Next page. And we have Mr. Fergusson of the United Kingdom. Again, I'm going to read out what he says, and then let's see if we agree what he's saying.

He said that he "fully agreed with the explanation given by the Secretary General of the Conference. Since the delegation of the United States of America had indicated that any broadening of the provision under discussion would put the applicant in jeopardy in the United States of America, it would be extremely difficult to accept the proposals of the Delegations of Switzerland and France. It would be best to leave the text as it appeared in the Alternative Draft."

Again, to paraphrase, speaking generally, do you agree that what the UK delegate is

saying is this: If the PCT does not require an applicant to explicitly state a utility and the United States does require the applicant to explicitly state a utility, then there's a potential problem because the applicant who uses the PCT system might be in jeopardy when they go to file in the United States?

MR. SPELLISCY: I've let this go on for a while. We can all read it. I'm not sure that Mr. Reed has any particular expertise to interpret what the delegation of the United Kingdom or other delegations were saying. I'm happy to have him answer the question, but I really wonder, concerning what other delegations and other people were saying , whether he has any expertise that he can offer on that.

MR. REED: Not only that, I've never seen any of this stuff before, so I'm just reading it for the first time myself.

MS. WAGNER: I am laying the foundation for an ultimate question.

THE PRESIDENT: Overruled. Please proceed.

MR. REED: Okay.

MS. WAGNER: So my question is this:

The reason that a PCT applicant would be put in jeopardy, if the PCT did not say you had to explicitly state a utility but a member country's laws required you to state a utility, that their application would not have what it needed to satisfy that member country, correct?

MR. REED: It was a little convoluted. Try it one more time, please.

MS. WAGNER: Do you agree that a PCT applicant will be put in jeopardy if the PCT does not require an explicit statement of utility but a member country does?

MR. REED: We're talking explicit statement of utility which is basically the language in 5.1(a)(vi).

MS. WAGNER: That's what I'm asking you. If the PCT, as per this proposal, did not require an explicit statement of utility but a member country did require an explicit statement of utility, then the PCT or the applicant would be put in jeopardy when they go to file in the member country, correct?

MR. REED: But the PCT does not require an explicit statement of utility if it's obvious from the description or nature of the

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: 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? Is that now your view? Because that's different than the testimony you gave earlier.
MR. REED: That's not -- then I must

have misunderstood my testimony because -- say that one again because I'm not going to -- I'm trying to go back and reconstruct what we talked about.
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

skilled in the art to which it pertains or with which it is most nearly connected to make and use the same'. Naturally, in the case of a chair, both the method of making it and the purpose for which it was used were so obvious, particularly to a person skilled in the art, that a statement on neither point would be required. However, the verb 'indicate' in the Alternative Draft took care of the problem since the indication could take many forms; for example, in the case of a chair, it could take the form of merely showing the chair."
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. 914.2. 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

require a change in the U.S. patent law which the United States of America could not effectuate."

So, as I understood your testimony --

THE PRESIDENT: So what was the question?

MS. WAGNER: I'm now asking the question.

If I understood your testimony, if the PCT did not require an explicit statement of utility, as was considered here, and the United States did require this under national law or any other member country did require this, it would simply be up to the applicant to make sure that they had complied with that requirement before they filed their PCT application.

MR. REED: That's certainly what I would do in the practice.

MS. WAGNER: But you'll agree with me that the delegate from the United States did not share your view?

MR. REED: I'm not sure -- I never compared what was in here with what my view was. Let me take a look. Apparently he didn't if he's talking about a requirement to change U.S. patent law, which wasn't going to happen.

MS. WAGNER: Thank you. Those are all my questions.

THE PRESIDENT: Thank you. Mr. Spelliscy, are there any questions for redirect?

MR. SPELLISCY: If you'll give me a minute or two, there may be one or two. I'm conscious of the time. I don't think redirect would take too long. We could probably, if there's any, get it in before lunch. (Pause)

We have no questions for Mr. Reed.

MS. WAGNER: Mr. President, I would beg your indulgence to ask one further question because it actually just came to my attention at this moment. I promise it does not involve reading any passages from anything whatever.

THE PRESIDENT: I will allow the question.

FURTHER CROSS-EXAMINATION ON BEHALF OF THE CLAIMANT

MS. WAGNER: Can you just turn to your Second Report? I'm just looking at the header of the report, so not actually in the text, and it's labeled "Rejoinder of Canada". Also on the front page you have address information that's from the Trade Law Bureau. I'm just wondering why those indications appear on your report?

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? Canada added 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)

PHILIP MORTIMER THOMAS

THE PRESIDENT: Good afternoon, Mr. Thomas.

MR. THOMAS: Good afternoon.

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

MR. THOMAS: My name is Philip Mortimer Thomas.

THE PRESIDENT: Mr. Thomas, you appear as an expert witness for the Claimant?

MR. THOMAS: Yes.

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

Mr. Thomas, 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 statement which is in front of you.

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

THE PRESIDENT: Mr. Thomas, could you please go to your Expert Report?
MR. THOMAS: Yes, sir.
THE PRESIDENT: And go to page 13. The Expert Report is dated September 7, 2015?
MR. THOMAS: Yes.
THE PRESIDENT: Could you confirm for the record that the signature appearing above your name is your signature?
MR. THOMAS: Yes, it is.
THE PRESIDENT: Is there any correction you wish to make to your report?
MR. THOMAS: Yes, sir, there's one typographical error which I'd like to correct, just for the sake of completeness on page 8, paragraph 24. There's an incorrect date in the third last line of that paragraph, a reference to the study on industrial applicability utility prepared by the WIPO Secretariat. The reference should be in 2003.
THE PRESIDENT: Thank you. Ms. Cheek?
MS. CHEEK: Mr. Berengaut will handle the examination of Mr. Thomas.
THE PRESIDENT: Please proceed with direct examination.
MR. BERENGAUT: Mr. Thomas, please

proceed with your presentation.

PRESENTATION BY MR. THOMAS

MR. THOMAS: Thank you, Mr. President, and members of the Tribunal, for this opportunity to present a summary of my Expert Report. It concerns some negotiations which took place at the World Intellectual Property Organization, or WIPO, over a period of -- well, in total a couple of decades, two sets of negotiations concerning substantive patent law and in particular, attempts to achieve some harmonization of substantive patent law, and my report is directed particularly to one question which arose in those negotiations, namely the question of a requirement that an invention have utility in order to be patentable.

The fundamental point I'd like to make at the outset is that the central tenet or the core principle of the utility requirement was not the subject of controversy during any negotiations which I took part in in my career, so I mention the central tenet or core principle which I describe as being that an invention must have some practical use. That is to say, it must have some practical use in order to qualify for the grant of a patent, but there are some things to bear in mind with this requirement.

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.

Now, I mentioned that the implementation in legislation in different jurisdictions is most certainly different from one jurisdiction to another. There is no agreement on the language in which this requirement should be implemented, but the thing my report focuses on is the practical results of the application of the requirement and, in essence, the practical results of implementing that requirement were the same everywhere and, in fact, very few applications were rejected on the basis of non-utility.

What was important for negotiating countries? Well, they wanted the inventors and their enterprises to be able to obtain patents in other countries in a consistent way based on similar principles which would apply in their own country. Of course, they also had an interest in the way in which their Patent Offices worked in implementing the requirements.

There was no agreed wording, no agreed definition included in various legislation but, since the practical outcomes were the same, there was simply no need for an agreed wording. It wasn't a vital issue in negotiations; it was not controversial.

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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 in 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

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rights to a patent are determined by who is the first to file an application.

On the other hand, the United States operated a first-to-invent system under which the rights to a patent would in general go to the first person to invent the application, as distinct from the first to file an application. The United States was unable to undertake to make that change and other countries said, without first-to-file we're not going to go ahead, so the SPLT didn't go ahead.

Then there were other issues which related to negotiations in other fora, outside WIPO as well as within WIPO, concerning patents related to genetic resources, the patenting of living things and requirements of patent applications -- sorry, of patents on genetic material and patents where genetic material was involved.

The first-to-file argument had contributed to the failure, first, of the basic proposal in 1991. There was a Diplomatic Conference held. No treaty was concluded. And in 2004, a decision was made that no Diplomatic Conference would be held so the draft SPLT was never concluded as a treaty.

Professor Gervais in his Expert Report

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emphasizes what he sees as the importance of the utility requirement as an issue of controversy which contributed to the failure of the negotiations over the draft SPLT. I do not agree with that assessment. There was controversy. Some controversy spilled over from other issues but the central tenet of the industrial applicability or utility requirement was not controversial.

The bottom line is that, yes, there are differences in implementation of the utility requirement in legislation. Very big differences, in fact. Many countries have similar laws, many countries have very different laws, but when it comes to the filing of applications and the assessment of the validity of granted patents, there's really no difference in the practical outcomes that arise. Very few applications are rejected on the basis of utility requirement. Very few.

Now, I'm speaking partly from the point of view of my experience in negotiations in international discussions, but there's a documentary record of those discussions, and in that documentary record one does not find controversy in connection with the core principle of the utility requirement. There was simply no such controversy. There was

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controversy in the negotiations, some of that flowed over from other issues, but it wasn't concerning the core of the utility requirement. The controversy was not concerning the core of the requirement.

So what do the documents say? Well, first of all, that there was a very limited discussion of utility. There was no controversy, however, over the core principle involved, the central tenet involved. At one stage a WIPO study on utility was prepared at the request of member states. It's referred to both in my Report and by Professor Gervais in his reports. That WIPO study on utility highlighted commonalities, highlighted differences, but when it came to the crunch it wasn't even discussed within the standing committee on the law of patents. It was just there, but it attracted no interest. There's certainly no basis for saying there was any controversial discussion on the basis of it. Indeed, there was no discussion of that study.

Another point raised is in connection with various draft provisions of the SPLT over a period of years in which there are alternative texts set out. But those texts aren't there because there's a great controversial discussion about which

ones are the best; they're simply there because they reflect the standard contained in existing legislation, in existing definitions, and from time to time an attempt at a wording which might bridge the differences and be acceptable to everyone. Well, those differences were never resolved. There are differences in legislative language but, in terms of the practical outcome, the patents are very, very seldom found invalid, and applications are very, very seldom rejected on the basis of utility requirements, at least at the time when these negotiations took place.

In summary, yes, there was controversy over patent law harmonization discussions. The basic proposal in 1991 was the subject of a failed Diplomatic Conference. No treaty was adopted. In 2004, a planned Diplomatic Conference never went ahead because the controversy was such that countries felt that a diplomatic conference was pointless. But on neither occasion was the utility requirement a reason for either failure.

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

law, namely that an invention have some practical use, and that is not a controversial point.

The fact that there was some controversy spilling over from other matters doesn't mean that the core notion of the utility requirement was a source of controversy in itself.

Thank you, sir.

MR. BERENGAUT: Thank you, Mr. Thomas.

DIRECT EXAMINATION ON BEHALF OF THE CLAIMANT

MR. BERENGAUT: You mentioned a 2003 study on utility. In his Second Report Professor Gervais discusses a 2001 study on utility, which he says -- and I quote from paragraph 47 of his Second Report -- shows that the "promise of the patent approach was acknowledged internationally at least as early as 2001, not just without any critical commentary but as an example of utility."

Are you familiar with the 2001 study on utility, and how would you respond to Professor Gervais' characterization of it?

MR. THOMAS: Yes, well, there are a couple of points to be made, I think.

I am familiar with the studies in 2001 and 2003. In fact, they both related to the same exercise. The International Bureau asked for

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 certainly 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 table. It was an informal document, but it was made available to members of the committee. The 2003 study was submitted as a formal document. But on neither occasion did the committee acknowledge the

report. It was not mentioned by any delegation in the reported minutes -- in the minutes reporting the results of the Committee's deliberations. It was not noted or discussed by the Committee. So I think to say that the promise approach was acknowledged as a result of that study would not be a correct statement.

MR. BERENGAUT: Thank you, Mr. Thomas. I have no further direct examination questions.

THE PRESIDENT: Thank you. Mr. Spelliscy, you will be conducting the cross-examination for the Respondent?

CROSS-EXAMINATION ON BEHALF OF THE RESPONDENT

MR. SPELLISCY: Good afternoon, Mr. Thomas. My name is Shane Spelliscy, senior counsel for Canada. I'm going to ask you a few questions with the goal of understanding some of what is in your Expert Report. If you don't understand me, do ask. I'll try and speak loudly and clearly. I also don't think we'll go for very long today, but if you do need a break, just let me know and we can deal with it.

I'd like to start just by clarifying something in your opinion which I think you just covered there. When I turn to your report, page 3 of

your report, you've got a heading, heading 2, that says "Overview of Patent Law Harmonization in the Context of WIPO." Do you see that?

MR. THOMAS: Yes, I do.

MR. SPELLISCY: I would just like to confirm that you would agree with me today that there has been no "patent law harmonization in the context of WIPO," correct?

MR. THOMAS: Yes, in general, that is true, yes.

MR. SPELLISCY: So your overview in your statement here is about efforts to achieve patent law harmonization, and not the actual achievement of harmonization, correct?

MR. THOMAS: It's an overview of really discussions or negotiations about patent law harmonization, yes.

MR. SPELLISCY: And efforts to achieve harmonization, correct?

MR. THOMAS: Yes.

MR. SPELLISCY: And those efforts have all, as you've just noted in your presentation, they've all failed, correct?

MR. THOMAS: That is substantially correct, yes.

MR. SPELLISCY: Let's stay on page 3 of your opinion. Go to the bullet right above that heading, so it's a bullet in paragraph 5, the third bullet, where you say, "As suggested by the double-barreled term by which it has come to be known, the industrial applicability (utility) requirement is given effect using somewhat varying language under different national legal systems. It is, however, understood to achieve the same practical results."

And I think you addressed this again in your presentation this morning. So that I understand, in terms of patent law your opinion is that the language used to describe a requirement in the national regime is not as important as the results that the requirement seeks to achieve. Is that right?

MR. THOMAS: I didn't say that it was -- that I don't think that it was not as important. I said that when it comes to what countries want in negotiations, they want to see consistent treatment for their applicants in other countries, and to that extent, it's not so -- the important thing to them -- yes, I can use the word "important" in a clear way, I think -- it is

important to them that their applicants receive such treatment in other countries, that the practical outcome of filing applications and of obtaining patents is substantially the same in other countries, and the fact that different language may be used in legislation is -- well, a subsidiary matter.

MR. SPELLISCY: Turn to paragraph 11 of your report. Here you're talking in the third sentence, when you're talking about this different terminology, "Different countries use different terminology to implement the requirement" -- and you're talking about industrial applicability or utility -- "in their legislation. But the industrial applicability (utility) standard is, as further discussed below, applied in a manner that is remarkably similar around the world. It is a low bar that is rarely the basis for a rejection or invalidation."

See that?

MR. THOMAS: Yes.

MR. SPELLISCY: In the next paragraph you say in the first sentence that there is a substantial consistency of practice with regard to the core utility or industrial applicability requirement. See that?

MR. THOMAS: Yes.

MR. SPELLISCY: One more. In paragraph 24 you state in the third sentence, "Nevertheless, the documentary record reflects the common understanding among WIPO member states of how the industrial applicability (utility) requirement operated in practice."

You see that?

MR. THOMAS: Yes, I see it.

MR. SPELLISCY: So we've got three things here. We've got in your view that it is applied in a manner that is remarkably similar, that there is consistency of practice, and that there was a common understanding of operation in practice, correct?

MR. THOMAS: Yes, I think that's correct.

MR. SPELLISCY: Let's turn to tab 1 in the red binder you were given, Exhibit R-407, the April 2001 paper, the informal paper that you were just referring to in your direct testimony.

MR. THOMAS: Yes.

MR. SPELLISCY: You were at WIPO when this document was prepared, correct?

MR. THOMAS: Yes.

MR. SPELLISCY: You were on the secretariat for the Standing Committee on patents when it was prepared?

MR. THOMAS: Yeah, I was a member of the secretariat participating at all the meetings that considered draft SPLT meetings. There were earlier meetings with the SCP which I would not have been present at.

MR. SPELLISCY: But you were on the secretariat at the time this paper was prepared, correct?

MR. THOMAS: Yes.

MR. SPELLISCY: In fact, this paper was being prepared, it says on the right above the summary box, April of 2001. You see that?

MR. THOMAS: Yes.

MR. SPELLISCY: So this paper was actually being prepared at the same time that the secretariat was producing the first proposed draft of the SPLT, correct?

MR. THOMAS: I can't say from immediate recollection whether it was the first draft but yes, they were certainly being prepared at about the same time.

MR. SPELLISCY: At around an early

draft.

Let's look at the first numbered paragraph in this document. It notes in the first sentence that, "At the fourth session of the SCP (in November of 2000) it was suggested that the International Bureau further study the application of the 'industrial applicability/utility' requirement in various countries."

You see that?

MR. THOMAS: I do.

MR. SPELLISCY: Stay on page 1 and look at the summary in the little box that was prepared by the International Bureau of the results of its further study of how the requirement was applied in countries around the world. It says in the first sentence, "The present paper, based on information received by SCP members, reveals that there is a wide range of differences among SCP members concerning the interpretation and practice relating to the 'industrial applicability... requirement'." You see that?

MR. THOMAS: I see it.

MR. SPELLISCY: So, in the three paragraphs in your report that we looked at, you concluded -- and you didn't reference any

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

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countries. Would you not agree that comment on how it is applied is the same as the study on application?

MR. THOMAS: Well, it could be -- it's a question of what it's focusing on. If one looks at the wording of the legislation, not the wording of the regulations, the wording of the practice guidelines, yes, there are most certainly differences. Absolutely.

If one looks at what happens as a result, the outcome of applying those things, the result's the same everywhere. The applications are very seldom -- were very seldom rejected on the basis of non-compliance with the utility requirement.

MR. SPELLISCY: Let's stay on the 2001 report. To be clear, you responded to this report today. You didn't cite this report, or you didn't review this report prior to preparing your Expert Report?

MR. THOMAS: I'm sorry, I didn't catch that, sir.

MR. SPELLISCY: It's a terrible question.

You didn't review this 2001 report prior to preparing your Expert Report in this

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arbitration. Is that right?

MR. THOMAS: I think if you look at the 2003 report it explains -- I would rather use the word "study" because it wasn't really reporting on anything, it was summarizing a lot of results, but if you look at the 2003 study, it refers expressly to this earlier study as being a preliminary version -- I can't remember the exact words, I'd have to refresh my memory, but it is this is a preliminary version of a more complete study issued in 2003, which I most certainly did refer to in my report, yes.

I was aware from that report that this study was there, yes.

MR. SPELLISCY: My question was did you go back actually and look at this study prior to submitting your Expert Report?

MR. THOMAS: Did I go back and look at the 2001 study? I don't believe so, no.

MR. SPELLISCY: Let's come to a paragraph that you briefly talked about I think in your direct examination in response to the question of my colleague, Mr. Berengaut. Turn to paragraph 13 on page 4.

Paragraph 13 says, "Under the law of another country, the term 'invention' means any new

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and useful art, process, machine..." and it goes on. The second sentence says, "An invention lacks utility if it is not operable or it will not do what the specification promised it will do ('false promise')." You see that?

MR. THOMAS: I see it.

MR. SPELLISCY: I think you said just a few moments ago that you don't believe this represents the promise doctrine in Canadian law. Is that right?

MR. THOMAS: I don't think I said that. I think I said that the references to the promise doctrine are explained in a way which I would think falls short of setting out what the promise approach was. I think the word "approach" was used in the quotation read to me.

MR. SPELLISCY: Right. Are you familiar with Canadian law?

MR. THOMAS: No, I'm not, sir. I have a passing familiarity but I am not an expert in Canadian law, and nor is my report based on the assumption that I am an expert in Canadian law.

MR. SPELLISCY: Let me understand how these were put together. These were contributions from members of the SCP, right? This was the

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secretariat summarizing the information it was told, correct?

MR. THOMAS: Yes.

MR. SPELLISCY: So the information -- and I think you agreed earlier -- the law of another country, the generic reference, this is a reference to the law of Canada, correct?

MR. THOMAS: I think if you look at the 2003 study, which is the more complete version of this one, it becomes clear that what is contained here in paragraph 13 does, indeed, relate to the law in Canada, yes.

MR. SPELLISCY: So this would have been, then, Canada informing the SCP of what its law was, correct?

MR. THOMAS: Canada replied in response to a survey saying what its law was. I don't know that this was informing the SCP or that the SCP -- there's no evidence -- there's no basis for saying the SCP even took note of this report.

Indeed, I should perhaps just clarify that the 2001 report was an informal document. It would have been made available to member states but it was not submitted as a formal document to the Committee. Nonetheless, it certainly would have been

present in the meeting room and available to the member states.

MR. SPELLISCY: And it would accurately reflect what the International Bureau was told, correct?

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: And, as you've said today -- and in your report as well -- you can recall no other state raising any concerns about the consistency of this statement with the core utility requirement, correct?

MR. THOMAS: 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?

MR. THOMAS: No one said anything to me, to my recollection, at all about this study. I would venture to say it would have been of passing interest.

MR. SPELLISCY: I want to talk about the statement you were discussing earlier in paragraph 11 in which you say industrial applicability is a low bar on which few patents are refused. I want to understand that a little bit better. I want to understand that in the context of paragraph 12. You seem to be saying "Given the substantial consistency of practice with regard to the core industrial applicability... requirement... the issue was not considered to be a priority for harmonization."

Am I correct to understand, then, that your view is that it is a low bar that is rarely the basis for rejection, and that's because there is some sort of core agreement on utility?

MR. THOMAS: I don't think there's a core agreement on utility, if that means that there's a core agreement on how it should be defined or elaborated in national legislation. In that respect there's no core agreement. But what negotiating countries wanted to see was their applicants, their

inventors, their enterprises, getting patents in other countries, and in this particular case for useful inventions, and, by and large, patents were granted in all countries for useful inventions with much the same result. So there didn't have to be agreement on any definition of utility.

MR. SPELLISCY: Let me come, then, to tab 1 in your binder again, Exhibit R-407. Turn to page 6, so we can see what the members were telling WIPO or the International Bureau about that. I want to look at paragraph 20.

Here it states, "Many Offices indicated that, in practice, the requirement concerning industrial applicability/utility was not often imposed. As several Offices mentioned, the main reason for that is that the requirement concerning industrial applicability/utility is closely related to other requirements, such as sufficient disclosure... requirement, the definition of 'invention', exclusions from patentable subject matter and the requirement concerning inventive step."

Do you see that?

MR. THOMAS: Yes, I see it.

MR. SPELLISCY: So this International

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. Correct?

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.

MR. SPELLISCY: It doesn't say "some countries." It says "many Offices," correct?

MR. THOMAS: I'm sorry?

MR. SPELLISCY: I think in your answer it says "some countries" say that, but it actually says "many Offices" indicated that. You see that?

MR. THOMAS: Yes, I see that. I don't have a count in my mind.

THE PRESIDENT: Sorry, I think "Many Offices indicated that" -- if you quote from paragraph 20 -- and then "several Offices."

MR. SPELLISCY: I see. Fair enough.

THE PRESIDENT: So what you should have been asked was "several" Offices, not "some"

offices.

MR. THOMAS: I focused on only one part of the question and not the other, but I'm indebted to you, sir.

THE PRESIDENT: You were asked that "many" offices did it because you had earlier testified it was "some" Offices, but now it turns out to be "several Offices," if you read the second sentence.

MR. THOMAS: The first sentence refers to "many Offices" and the second sentence to "several Offices". Personally I find no embarrassment in the fact that my report said "some" in the circumstances.

MR. SPELLISCY: I want to understand a little bit why you say utility was not being discussed. In paragraph 12 in that sentence it says, "Given the substantial consistency of practice, the issue was not considered to be a priority for harmonization," in the first sentence of paragraph 12.

MR. THOMAS: I'm sorry, we're now back in my report?

MR. SPELLISCY: Yes, your report.

MR. THOMAS: Were you asking a question about my report now?

MR. SPELLISCY: Yes, your report, paragraph 12.

MR. THOMAS: I'm sorry, could you repeat the question?

MR. SPELLISCY: You said in the first line, "Given the substantial consistency of practice... The issue was not considered to be a priority for harmonization" about utility. I just wanted to understand that statement a little bit more.

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, "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'."

Do you see that?

MR. THOMAS: I see it.

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?

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.

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?

MR. THOMAS: This suggestion by the International Bureau is that the SCP "may" wish to consider -- I wouldn't use the word "must" -- 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

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in paragraph 12 of my report. Priority was not given to this matter.

MR. SPELLISCY: We're going to come 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

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2001. So yes, this study was prepared in 2003 after a period of some two years when responses to the survey had been received.

MR. SPELLISCY: So that I understand, then, when work is being done on one of the early drafts in 2001 of the SPLT, the International Bureau has been requested to prepare an informal paper. Upon receipt of that informal paper, as we see in this at paragraph 1 --

MR. THOMAS: I was just going to ask if you could clarify where you're quoting from?

MR. SPELLISCY: We're talking about what we saw in 2001 on the request to prepare the informal paper. We can go back and look at it if you want. But then it gets to 2002 and in the first line of the first paragraph it says "At the 8th session of the Standing Committee... held in Geneva... the International Bureau was mandated to prepare a study regarding commonalities and differences between the 'industrial applicability' and the 'utility' standards."

What I am trying to understand, Mr. Thomas, is why the standing committee would mandate the International Bureau to continue work on the informal paper and devote resources to that, when

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I thought it was your testimony that the 2001 paper wouldn't even have gotten much notice?

MR. THOMAS: Well, the first point to make is you've got to understand what was meant by the word "mandated." I would have to refresh my memory, but I think I'm confident enough to suggest that 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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There was no discussion on it.

MR. SPELLISCY: Let me understand, though, Mr. Thomas. So in November of 2000 -- and then again in November of 2002 -- the International Bureau of WIPO was first requested and then mandated by the chair, you said, to prepare studies on the commonalities and differences between industrial applicability and utility, correct?

MR. THOMAS: Yes.

MR. SPELLISCY: And you would agree with me, would you not, that, being requested to devote secretariat resources to the preparation of two separate reports within two years is not consistent with your view that the members were not concerned with the differences in commonalities in these two requirements, correct?

MR. THOMAS: Well, the fact that the study wasn't discussed or raised in discussions by the Committee doesn't really bear out the suggestion that it was regarded as having high importance, I don't think.

MR. SPELLISCY: You would agree with me certainly that it had high enough importance that the member states requested that the secretariat and the International Bureau devote its resources to this

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.

MR. SPELLISCY: Let's look at the study in tab 3 again. We just read the sentence, but I want to read it again, at least the last part of it. The first sentence in tab 3, first page in the introduction in the first paragraph.

"...the International Bureau was mandated to prepare a study regarding the commonalities and differences between the 'industrial applicability' and the 'utility' standards." They're not being mandated here to prepare a study on differences in nomenclature only, are they, Mr. Thomas?

MR. THOMAS: No, it doesn't -- it's not restrictive at all.

MR. SPELLISCY: In fact, do you know if the word "nomenclature" is mentioned a single time in this study?

MR. THOMAS: Well, the word "nomenclature" I think is referring to -- maybe I could have used a better word in my report, but I'm talking about the wording used in legislation or other formal regulations or other formal documents setting out the requirement.

MR. SPELLISCY: Let's turn to page 7 of this report, this report we're in right now, tab

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 I think 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

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will not operate at all or, more broadly, that it will not do what the specification promised it would 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 was not 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

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standard, correct?
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

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claims is commensurate with the invention as disclosed. Under national practices, this aspect is found, in particular, in relation to expressions such as 'credible utility', 'sound prediction' and 'false suggestion'." See that?
MR. THOMAS: Yes.
MR. SPELLISCY: So you would agree with me that, in fact, in 2003, the members of the SCP were at least all informed that utility and disclosure were related, correct?
MR. THOMAS: The members of the SCP were informed of everything that's in this study, and equally didn't discuss it.
MR. SPELLISCY: You would also see the reference to "sound prediction" there in the last line, correct?
MR. THOMAS: Yes, I can see that.
MR. SPELLISCY: And if you come back to paragraph 41 in the discussion of Canada you see there again that the Canadian delegate, I guess, has made reference to the sound prediction doctrine in Canada, correct? The very end of the paragraph?
MR. THOMAS: I think one does have to be careful about saying "Canadian delegate" because that implies it was a statement made in the meeting,

which there's no record of at all. But this, I feel sure, would have been based on information supplied by the Canadian Government in response to the survey.

MR. SPELLISCY: Right, so the Canadian Government is referencing the doctrine of sound prediction, and then WIPO is reporting that they've been told that, under national practices, utility is found in relation with things like disclosure and including sound prediction, correct? That it relates to those patentability requirements?

MR. THOMAS: The information here was related by the International Bureau based on information from the Canadian Government included in the study, which was presented to the Committee, yes. Yes, that's certainly the case.

MR. SPELLISCY: Thank you, Mr. Thomas. I have nothing further.

MR. BERENGAUT: Nothing for redirect, Mr. President.

THE PRESIDENT: Mr. Thomas, thank you for testifying. You are now released as an expert witness and excused.

MR. THOMAS: Thank you, sir.

THE PRESIDENT: Recess for ten minutes.

(Recess taken)

DANIEL GERVAIS

THE PRESIDENT: Good afternoon, Professor Gervais.

PROFESSOR GERVAIS: Good afternoon, Professor van den Berg.

THE PRESIDENT: Could you please state your full name?

PROFESSOR GERVAIS: Daniel Gervais.

THE PRESIDENT: You appear as an expert witness for the Respondent?

PROFESSOR GERVAIS: Yes, sir.

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

PROFESSOR GERVAIS: I understand.

THE PRESIDENT: Professor Gervais, you will appreciate that testifying, be it before a court or an arbitral tribunal, is a very serious matter.

PROFESSOR GERVAIS: Very much so.

THE PRESIDENT: In that connection, the Tribunal expects you to give the statement which

is in front of you.

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.

MR. SPELLISCY: The patentability criteria were addressed in all of his reports and yes, there are no references to slides.

THE PRESIDENT: Overruled. Please proceed.

PROFESSOR GERVAIS: Thank you, sir.

When it comes to inventiveness and non-obviousness the same difference is applied but there is that additional difference in terminology. If you were to look around the world you would see differences in the necessary height of the inventive step, to use the metaphor of the step, but also the way that courts have developed tests to assess obviousness or inventive step. And I believe Professor Holbrook has a very good explanation of the major change in U.S. law following the KSR case on that issue.

On utility and industrial applicability, again we have two different words. Some national laws, as the previous expert acknowledged, define them quite differently. Adjectives are used very often in conjunction with utility, words like "credible," "substantial," "practical," "specific," and in previous literature there was also reference made to "operable utility,"

"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

me as entirely consistent with the contract or bargain approach to patent law. You promise something and then you have to deliver, as you would in that context. But also, it has a specific history in patent law, and this is reflected in this WIPO report.

Now, Mr. Thomas reads the fact that there was no discussion as perhaps a lack of controversy. I beg to differ. I think that you could also see it differently, and I will show you what I mean in just two minutes, if you'll bear with me.

I do want to say first, though, that there have been a series of efforts to harmonize all patentability criteria and they have, as we've seen before, all failed. The lack of agreement is there. The reason for lack of agreement is partly because countries want to keep the ability to define these criteria. They know that their courts will continue to change the way that these criteria are applied and defined.

Mr. Thomas' conclusion on some sort of common understanding of the core strikes me as not entirely convincing. I noted that he refers several times to his beliefs in his report. The reports from

his own organization and my former organization, for that matter, that I cite do seem to go the other way. But, in fact, he does cite one document -- and I feel I have to show this -- he cites one document which is the SCP/8-2 document which is also mentioned in SCP/8-9, which is R-229. This is paragraph 28 of his report. This is the part that he cites. He says: Look, there is a proposal here. It proves that it would have been possible to reconcile all of these definitions.

Unfortunately, it doesn't mention in the quote that this was alternative A, that there were two other alternatives put to the member states. And, perhaps more importantly, the report of that meeting says this: "The chair summarized the discussions on this paragraph, the one I just quoted from, as follows: Three delegations supported alternative A, while a majority... expressed their preference for B." One delegation (the United States if you read the report) supported alternative C -- not surprisingly, it's the US language -- and then a suggestion by one delegation that alternative C be retained, and then some members proposed to modify A and B.

So to say that there was no discussion

of utility ever at WIPO or that there was no controversy strikes me as a slight oversimplification.

NAFTA, like TRIPS, does not require one way of defining these criteria. 1709(1), which corresponds to TRIPS 27.1, is not harmonizing this terminology. There is, as I say, in my report a negotiation. Some countries wanted industrial applicability; others wanted utility. They could not agree. They could not agree to state that these were synonymous terms for, I believe, the simple reason that they're not.

So some convoluted language was found in the end to find an agreement in the footnote to TRIPS, and in the case of NAFTA it's in the paragraph itself, using this interesting English expression that the terms "may be deemed" to be synonymous.

This is not a nomenclature issue only. It is, as the WIPO documents show, because there were significant differences not just in terminology but in actual practice.

These differences existed at the time. They have continued to exist. In fact, to me this is nothing surprising. Utility will continue to vary as either new types of inventions or new understandings

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

I'm not a PCT expert but I have read the PCT many times and I always thought that it meant what it says, which, as you see on this slide, strikes me as fairly clear.

Finally my last point is this. I think other criteria always apply, and I'd be happy to spend some time explaining how the language in both NAFTA and TRIPS evolved, but basically there was a clear understanding that the three patentability criteria were not the entire list of conditions that an applicant must comply with to obtain a patent.

In the case of TRIPS, we see this explicitly in Article 29, which in part resembles Article 5 PCT, and in Professor Holbrook's report we also see quite clearly that the U.S. has specific requirements in terms of written description and enablement.

How the patent bargain, therefore, is applied will change and evolve from jurisdiction to jurisdiction, and over time I would submit that this is the nature of the common law process, when the policy is mostly made in and by courts, and I would also stress that the disclosure and enablement obligations that are not mentioned in 27 or 1709(1) are core in implementing the bargain.

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With that, I very much look forward to the discussion. Thank you very much.

MR. SPELLISCY: There are no questions on direct.

THE PRESIDENT: Thank you. Please proceed, Mr. Berengaut.

CROSS-EXAMINATION ON BEHALF OF THE CLAIMANT

MR. BERENGAUT: Good afternoon, Professor Gervais, my name is Alex Berengaut.

If you could please turn to tab 2 of your binder?

PROFESSOR GERVAIS: Yes. That would be my Second Report.

MR. BERENGAUT: That's right. If you could please look at paragraph 4, where you write, beginning in the second sentence, "In particular, its Reply 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."

Do you see that?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: I take it you disagree with that proposition?

PROFESSOR GERVAIS: No, I don't -- of

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my statement -- this is my characterization of your argument.

MR. BERENGAUT: I take it you disagree with the proposition that you are characterizing in Claimant's Reply Memorial.

PROFESSOR GERVAIS: 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?

MR. BERENGAUT: In this sentence, Professor, you say that the Reply Memorial -- that's Claimant's Reply Memorial, correct?

PROFESSOR GERVAIS: I believe so.

MR. BERENGAUT: Were you referring to a different Reply Memorial?

PROFESSOR GERVAIS: No. I'm only aware of one.

MR. BERENGAUT: Claimant's Reply 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."

In that sentence you are

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characterizing your understanding of a point made in the Reply Memorial, correct?

PROFESSOR GERVAIS: Correct.

MR. BERENGAUT: My question to you is whether you agree or disagree with that point stated in the Reply Memorial, as you understand it.

PROFESSOR GERVAIS: Oh, I understand. 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.

MR. BERENGAUT: You would agree, Professor, that in your view the TRIPS Agreement is relevant to the interpretation of Chapter 17, correct?

PROFESSOR GERVAIS: Relevant, yes.

MR. BERENGAUT: Let's turn to your first statement, which is in tab 1.

PROFESSOR GERVAIS: First Report? Yes.

MR. BERENGAUT: If you could please turn to paragraph 25 of your First Report, which is on page 9.

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: There you excerpt a

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WIPO report which states, "It is to be noted that the TRIPS Agreement provides for minimum requirements." Do you see that?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: Do you agree with the statement in this report that the TRIPS Agreement provides for minimum requirements?

PROFESSOR GERVAIS: 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.

MR. BERENGAUT: And when you say "go above," you mean provide additional intellectual property protection, correct?

PROFESSOR GERVAIS: In most cases that would be the case, yes.

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?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: I take it you would

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agree here as well that the TRIPS Agreement incorporates minimum standards?

PROFESSOR GERVAIS: It does, subject to what I said before.

MR. BERENGAUT: Let's take a look at your treatise which is in tab 6. This is C-336. If you could please turn to page 174?

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: The first full paragraph begins "Article 1.1" where you write "Article 1.1 also indicates that Member countries may go beyond TRIPS, which thus sets minimum standards."

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: My question is just: I take it that's a reference to the same point you just made in response to my previous questions about the WIPO documents?

PROFESSOR GERVAIS: Correct. Of course, you'd have to read the whole paragraph to see what actually it says, but yes.

MR. BERENGAUT: On that point I note in the final sentence of the paragraph you write, "This is related to the" -- no, fair enough, you're talking about other things, and if you want to read additional aspects of the paragraph in context I

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totally understand, but my question is related to one clause in this sentence. This final sentence reads, "This is related to the idea (or theory) that TRIPS contains not just minimum obligations (a 'floor') but also maximum levels of protections ('ceiling')."

Setting aside the ceiling part of the sentence, my question is just whether you would agree with the proposition that TRIPS's minimum obligations could fairly be characterized as a floor of protection?

PROFESSOR GERVAIS: Again, in most cases, unless increasing protection would violate some other provision of TRIPS or one of the agreements incorporated into TRIPS.

MR. BERENGAUT: Given the influence of TRIPS on Chapter 17, in your view, would you agree also that Chapter 17 incorporates a floor of protection which states "may exceed but not contravene"?

PROFESSOR GERVAIS: Generally speaking, yes.

MR. BERENGAUT: Let's take a look at Chapter 17, and that's tab 7 of your binder. If you could please look at page 333, which has Article 1709(1) in it.

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PROFESSOR GERVAIS: I see it, yes. The point I made previously is in 1702 on the previous page, but okay, I'm on 1709 now.

MR. BERENGAUT: I'm happy to read 1702 into the record for context. Article 1702: More Extensive Protection. "A party may implement in its domestic law more extensive protection of intellectual property rights than is required under this Agreement, provided that such protection is not inconsistent with this Agreement."

Now, your view -- and I think this is a fair characterization but you'll correct me -- is that countries have broad flexibilities in implementing the patentability requirements identified in Article 1709(1). Is that fair?

PROFESSOR GERVAIS: Yes, I think it's fair.

MR. BERENGAUT: Let's explore that concept with an example. You mentioned in your opening presentation the concept of novelty, right?

PROFESSOR GERVAIS: I did.

MR. BERENGAUT: And that is also sometimes referred to as the requirement that an invention be new, correct?

PROFESSOR GERVAIS: Yes.

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MR. BERENGAUT: And when a Patent Office is evaluating a patent application, they consider prior art in determining whether that invention is novel, right?

PROFESSOR GERVAIS: Correct.

MR. BERENGAUT: Sometimes patent prosecutions can take several years?

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: Suppose, hypothetically, Canada passed a law that said, for purposes of novelty, examiners should consider as prior art anything that was published up to three years after a patent application is filed, and let's say, Professor, that after the hearing today, I go home and I invent a flying car and I tomorrow file a patent application for that flying car in Canada, and two years pass when my patent application is being prosecuted, and then you invent the same flying car and you publish an article about it and the patent examiner who is reviewing my application reads your article about your flying car and she says to me, sorry, your application fails for lack of novelty because your invention of a flying car is not new.

My question is whether, in your opinion, that law would violate Article 1709(1)?

PROFESSOR GERVAIS: 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 GERVAIS: 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.

So that's kind of the longer answer.

If you're going to do a Vienna analysis of each of these terms in context, you'd have to figure what the terms mean, what they're there for, why they came into this Treaty, what the state practice has been -- you have several factors that would -- I think Professor Dinwoodie at Oxford has a very good expression that I like. He says these treaties confine, they don't define, so there are confines, there are limits to the leeway, otherwise, the Treaty means nothing, but the question is where is that limit.

I'm happy to discuss hypotheticals with you but the answer will be I'm not sure that line is exactly for each of these terms.

MR. BERENGAUT: Thank you.

In your reports you discuss the WIPO negotiations regarding a potential substantive patent law treaty. Is that right?

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: If we could turn to tab 1 of the binder paragraph 29 of your First Report.

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: This is where you

discuss that topic, in this section of your report?

PROFESSOR GERVAIS: Yes, I do.

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?

PROFESSOR GERVAIS: Yes, that's right.

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?

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

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?

PROFESSOR GERVAIS: There was not consensus.

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

proposition?

PROFESSOR GERVAIS: That's state practice as reported to WIPO. I consider that a valid empirical basis for that claim, yes.

MR. BERENGAUT: By the same token, then, Professor, you would agree with me that evidence of commonalities would show areas where the parties did have consensus, right?

PROFESSOR GERVAIS: No. Commonality and consensus are two different terms. There might be commonalities; it doesn't mean they have consensus. It means there were commonalities, there are commonalities, and there are differences. That's the whole point of these reports. That's why they're -- if you look at the instructions that the previous expert was shown, the secretariat was asked to identify commonality and differences, and to say there's consensus on this part when there's a difference mentioned in the following paragraph is, to me, stretching that data a little too far.

MR. BERENGAUT: Let's explore that difference between commonalities and consensus that I think you're trying to draw. Let me pose a different hypothetical to you. Let's say that you and I were trying to reach consensus on an international

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convention for drivers' licenses for driving tests. In my country you get a license if you are an adequate driver and in your country you get a license if you are an able driver, and we are trying to reach agreement on the test.

If you wanted to include as part of the test a mountain driving skill and I didn't, that would be a point of difference, right?

PROFESSOR GERVAIS: For example, yes.

MR. BERENGAUT: But if we both agreed that drivers who show up to take their tests and are completely intoxicated would mean that the drivers were neither an adequate driver nor an able driver, and if we could reach agreement on that, wouldn't that be a point on which we had consensus?

PROFESSOR GERVAIS: It depends. If we're only trying to discuss whether the rule for drivers' licenses is able or adequate and we decide on some way to define "able" or "adequate", or we say "able" may be deemed synonymous with "adequate," do we have consensus on that particular point -- yes.

If we are trying to decide what are the rules that apply to drivers in our two states and that's paragraph 381 of this whole document, then yes, you could say we have consensus on 381. But

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that's why I'm drawing a little bit of -- people can agree on something. It doesn't mean they agree on utility. It might mean they agree on how utility applies to one particular type of invention, on a particular type of claim. That's why I'm resisting saying "consensus" because to me that's a very strong term.

MR. BERENGAUT: Would you agree that it's possible to have consensus on some subtopics, and at the same time not have consensus on a topic as a whole?

PROFESSOR GERVAIS: Theoretically, sure.

MR. BERENGAUT: Let's go to paragraph 32 of your Second Report, tab 2. You write "As an initial matter, I note that Mr. Thomas makes much of the fact that he personally attended the negotiations on the PLT and SPLT. I do not deny that useful knowledge can be gained by attending these sessions in person in terms of atmosphere or personal discussions with delegates. That knowledge is not, however, a substitute for objective interpretation from published documents."

Do you see that?

PROFESSOR GERVAIS: I do.

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MR. BERENGAUT: Just to be clear, Professor, the WIPO sessions to which Mr. Thomas refers that you're discussing in this paragraph, you did not attend those sessions, correct?

PROFESSOR GERVAIS: Correct.

MR. BERENGAUT: But I take it, from your perspective, when you say "a substitute for objective interpretation from published documents", that in your view that's what you had provided in your report, an objective interpretation from published documents?

PROFESSOR GERVAIS: Would you repeat that? I'm sorry.

MR. BERENGAUT: Sorry, that was an unclear question.

My question is whether, in your view, you have provided an objective interpretation from published documents in your report?

PROFESSOR GERVAIS: That's what I tried to do, certainly.

MR. BERENGAUT: In paragraph 31 of your first statement, back to tab 1, you refer to a 2000 WIPO document.

PROFESSOR GERVAIS: I see it, yes.

MR. BERENGAUT: Which you maintain

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shows that "utility" and "industrial applicability" do not have the same meaning. Do you see that?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: You would agree, however, that this document also shows that those two standards are part of the same singular requirement, correct?

PROFESSOR GERVAIS: I'm not sure what that means, frankly. What same singular requirement are you referring to?

MR. BERENGAUT: Let's look at the document that's at tab 8 of your binder.

PROFESSOR GERVAIS: Tab 8?

MR. BERENGAUT: Yes. For the record, this is R-221. In your report, Professor, you quote paragraphs 24(a) and 24(b). Is that right?

PROFESSOR GERVAIS: One second. I will go back and check. Yes.

MR. BERENGAUT: Let's take a look at the previous paragraph, paragraph 23, which you do not quote in your report. It states that, "'Industrial applicability' or 'utility' in certain countries is the third widely recognized requirement of patentability." Do you see that?

PROFESSOR GERVAIS: I do.

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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 synonymity with utility, and then inventive step and possible synonymity 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

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inoperable?

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

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perpetual motion machine, no, at least on the page 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

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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

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?

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.

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?

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.

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?

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

MR. BERENGAUT: Let me repeat it.

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

document.

MR. BERENGAUT: That's fine. Apart from this section, there's no other section that you thought was relevant to discuss in your report, right?

PROFESSOR GERVAIS: To mention at least, yes, obviously, because that's the only one I did.

MR. BERENGAUT: Back to First Report, tab 1.

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: You next note that there were --

PROFESSOR GERVAIS: Next to what, sorry?

MR. BERENGAUT: Paragraph 35.

PROFESSOR GERVAIS: Okay.

MR. BERENGAUT: And you discussed this during your opening presentation as well, that there were a few different proposals on how to define utility and industrial applicability. I'd like to focus you on the final sentence of paragraph 35 where you state, "The 'utility' requirement... reappeared in the following draft in May 2002." Do you see that?

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PROFESSOR GERVAIS: I do.
MR. BERENGAUT: Let's take a quick look at that document. That's tab 10, R-227.
PROFESSOR GERVAIS: Okay.
MR. BERENGAUT: You refer to page 24 of that document, I believe.
PROFESSOR GERVAIS: 22 does not have a page --
MR. BERENGAUT: The page numbers are at the top of the document.
PROFESSOR GERVAIS: I mean in my reference to this document I don't think that I referred to specific page -- oh, yes, I do. I'm sorry. I missed it. Yes. Okay. 24.
MR. BERENGAUT: Just to confirm, this is the language you were quoting, the paragraph beginning numbered 4, which has the bracketed definition of industrial applicability/utility?
PROFESSOR GERVAIS: Yeah, I believe it's underlined because it reappeared from the previous draft -- or appeared from the previous draft.
MR. BERENGAUT: Professor, were you aware that there were notes that accompanied this proposal?

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PROFESSOR GERVAIS: There always are.
MR. BERENGAUT: Let's take a look at those notes. That's behind the next tab, C-407. If you could turn to page 21.
PROFESSOR GERVAIS: Yes.
MR. BERENGAUT: These notes state -- and let me just read this paragraph: "This paragraph contains the condition of patentability of industrial applicability/utility. In order to reflect the debate at the SCP, three alternatives are proposed in this provision: The second and third alternative reflect the standard contained in many national/regional legislation concerning industrial applicability and utility, respectively. The first alternative attempts to take into consideration the essence of both requirements, including real practices, and reflects a more global approach, whereby an invention would have to be able to made or used in any field of commercial activity."
Do you see that?
PROFESSOR GERVAIS: Yes, I do.
MR. BERENGAUT: These notes are prepared by the International Bureau of WIPO. Is that right?
PROFESSOR GERVAIS: Typically, yes.

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MR. BERENGAUT: And you would agree that this language shows that the International Bureau at this time thought that industrial applicability and utility shared a common essence?
PROFESSOR GERVAIS: No, it doesn't use those words at all. I'm sorry, I don't see those words. Consideration of the essence -- it says "to take into consideration the essence of both requirements." It's trying to take into account the essence of both requirements. It doesn't actually say that the essence is the same but it's trying to take into consideration the essence of both. It doesn't say the essence is identical, and their very documents prove that they're not.
MR. BERENGAUT: So you read this clause as saying that there are two independent and different essences of the two requirements?
PROFESSOR GERVAIS: No, sir, no. I believe that they're very closely related; they overlap to large degree but they're not identical. The WIPO documents made that quite clear. They're not identical and within both families there are divergences as well. I don't know that this means that the essence of both is the same. If that's what it means, then I certainly don't think that's

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correct, unless, frankly, we could debate -- the word "essence" strikes me as a nice word for a metaphysical debate, and I don't mean to be facetious, but it's very hard to know what that means, "essence" of a requirement.
MR. BERENGAUT: The sentence referencing the first alternative, which "takes into consideration the essence of both requirements, including real practices", do you see that clause?
PROFESSOR GERVAIS: Yes, I do.
MR. BERENGAUT: Would you agree that that shows that the International Bureau thought that a unified definition of the two concepts would reflect real practices at the time?
PROFESSOR GERVAIS: Well, here's my trouble in answering your question. This is a 2002 document, therefore prepared between the 2001 and 2003 reports that were discussed with the previous expert, and he said the word "practice" means legislation, in the International Bureau's mind. So if he means that it would capture the essence of requirements in rules and regulations, that's one thing. If it means practice like I think practice means practice, it's a very honorable proposal to try to unify the standard. There are several people who

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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 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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MR. BERENGAUT: And are you aware of any substantive differences between the three bracketed definitions in the document we just looked at, and the three definitions that you included in your slide in your expert presentation?

PROFESSOR GERVAIS: Well, yes, and certainly I can -- the most documented is test instruments and lab instruments which some people view as not being exploited in the field of commercial activity because they're used for research. They would typically pass the utility requirement, and the report again that is cited by the Professors who filed the brief on your side identifies a very detailed study of this issue that shows that, in fact, the way that the UK courts have moved away from industrial applicability to cover those types of inventions is by adopting the substantial, credible and specific utility standard that is, in fact, not their standard. So it's a very interesting thing that I think is happening in this particular area.

There are differences between -- the words themselves, if they meant the same thing, would not -- it's not just a matter of nomenclature. The reason that countries hold on to these words has to

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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

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the question correctly, is there a difference between the alternatives in paragraph 4 of page 24 of SCP 7/3 and SCP 8/2, Article 12, paragraph 4, and I will give you an answer if you give me a chance to read these two. (Pause)

Well, the difference is that the definition of industry in alternative B of the next meeting, which is a paraphrase of Article 5 of the Paris Convention, has disappeared, but otherwise there's no other difference. There's no difference in alternative A language.

MR. BERENGAUT: Thank you. You also have discussed the 2001 and 2003 surveys.

PROFESSOR GERVAIS: I certainly mentioned it, yes.

MR. BERENGAUT: In your First Report paragraph 39 you referred to the 2003 survey, and in your Second Report, paragraph 45, you discussed the 2001 survey?

PROFESSOR GERVAIS: Correct.

MR. BERENGAUT: Let's take them in chronological order so reverse order from your statements, beginning with the 2001 survey which you discuss at the end of your Second Report in tab 2.

PROFESSOR GERVAIS: Do you have a

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paragraph number?
MR. BERENGAUT: 47.
PROFESSOR GERVAIS: Yes.
MR. BERENGAUT: You say that this document shows that "notions of utility and industrial applicability vary significantly by jurisdiction." Do you see that?
PROFESSOR GERVAIS: I do.
MR. BERENGAUT: And you quote paragraphs 2-5 for that proposition.
PROFESSOR GERVAIS: Yes.
MR. BERENGAUT: Let's take a look at the document. It's tab 12. Paragraphs 2-5 are in the section "Definitions and examples of 'industrial applicability'," is that right?
PROFESSOR GERVAIS: Yes.
MR. BERENGAUT: You mentioned that, in your view, the document shows that notions of utility and industrial applicability vary significantly by jurisdiction, but you would also agree that this document recognizes that there is an overlap between the two standards. Is that right?
PROFESSOR GERVAIS: I do recognize that, definitely, yes.
MR. BERENGAUT: And, following the

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paragraphs that you quoted, there is a section about examples, beginning with paragraph 7. Do you see that?
PROFESSOR GERVAIS: Yes, I do.
MR. BERENGAUT: And in paragraph 7, it lists several examples of inventions that fail the industrial applicability standard in "more than one country." Do you see that?
PROFESSOR GERVAIS: Paragraph 7, yes.
MR. BERENGAUT: The perpetual motion machine is back?
PROFESSOR GERVAIS: It's the classroom textbook example.
MR. BERENGAUT: There's a ghost catcher?
PROFESSOR GERVAIS: Yes. That would go well with your flying car.
MR. BERENGAUT: And you're not aware that there is an operable ghost catcher, are you?
PROFESSOR GERVAIS: I don't know that there is one, despite Hollywood.
MR. BERENGAUT: There's also a method for preventing the increase in ultraviolet ray associated with the destruction of ozone layer by covering the whole surface of the earth with an

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

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

when this document was created?
PROFESSOR GERVAIS: To my knowledge, no.
MR. BERENGAUT: Let's look at the next paragraph, which you just mentioned, which states -- this is paragraph 15 on page 4 -- "Case law determining whether an applicant identifies any specific utility for the claimed invention or has not been developed, in particular, in the field of chemistry and pharmacology. For example, indicating that the compound may be useful in treating unspecified disorders, or that the compound has useful biological properties, would not be sufficient to define a specific utility for the compound."
Do you see that?
PROFESSOR GERVAIS: I did. I just read it.
MR. BERENGAUT: So I would again ask the question whether, even in light of this paragraph, there is any indication in any of these examples of a pharmaceutical invention that claimed to treat a specific medical condition and actually treated that medical condition being found to lack utility.
PROFESSOR GERVAIS: In this

paragraph, no.
MR. BERENGAUT: Are you aware of any other paragraphs which address that situation in this document?
PROFESSOR GERVAIS: Aware? No. And I'd have to read the rest of it, but I'm not aware of something in this document, no.
MR. BERENGAUT: Let's go back to your second statement, back to the same paragraph, paragraph 47 where you're talking still about the same survey, and we'll head back there in a minute, but in the beginning of paragraph 47, another point you make about this 2001 survey is that "...the promise of the patent approach was acknowledged internationally at least as early as 2001 not just without critical commentary, but as an example of utility." Do you see that?
PROFESSOR GERVAIS: I do.
MR. BERENGAUT: And you quote to paragraphs 13 and 19 for that proposition?
PROFESSOR GERVAIS: I do.
MR. BERENGAUT: Let's head back to the 2001 study, which is back on tab 12.
Paragraph 13 is the first paragraph to which you were referring?

PROFESSOR GERVAIS: Yes, I believe it was on the slides that were used for the examination of the previous expert.
MR. BERENGAUT: And there are no examples given in this paragraph about how this standard was being employed in practice, are there?
PROFESSOR GERVAIS: Examples? No.
MR. BERENGAUT: Now let's look at paragraph 19, which is the other paragraph you cited.
PROFESSOR GERVAIS: Yes.
MR. BERENGAUT: Paragraph 19 does have two examples. "In addition, the following inventions are considered not meeting the requirement that an invention be 'useful'." The first one is "An invention related to control circuits for gas discharge lamps. The specification indicated that the invention would reduce heat generation in the ballast. However, the evidence was that some circuits falling within the scope of the claims failed to work and caused lamp failure because of excessive heat generation. Consequently, the promise of the invention was not fulfilled." Do you see that?
PROFESSOR GERVAIS: I do.
MR. BERENGAUT: In this example, the

lamp did not work, correct?
PROFESSOR GERVAIS: Well, it did not work as claimed, I suppose. It doesn't say didn't work at all; it said there was eventually failure causing excessive heat generation, so it may have worked for a while. I don't know. The example isn't precise enough.
MR. BERENGAUT: So, despite the reference to the fact that excessive heat generation caused lamp failure, you're unsure whether the lamp worked in that example?
PROFESSOR GERVAIS: It eventually failed. It doesn't mean that it didn't work at the beginning, is what I'm saying.
MR. BERENGAUT: Okay. In the next example is the promise of a cheese for permanent keeping. Are you aware of an invention that is operable that keeps cheese permanently?
PROFESSOR GERVAIS: No, I am not.
MR. BERENGAUT: Let's go to the 2003 study, which is R-230, and it's behind tab 13.
PROFESSOR GERVAIS: Okay.
MR. BERENGAUT: Now, you make, I think this is fair to say, many of the same points about the 2003 study as you do about the 2001 study. Is

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: Excuse me. You're 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

first. This is back behind tab 13.
PROFESSOR GERVAIS: Yes.
MR. BERENGAUT: I don't see the reference to the standards differing substantially in that paragraph.
PROFESSOR GERVAIS: You are correct. I'm quoting the wrong paragraph. I apologize profusely.
MR. BERENGAUT: I think the paragraph you meant to quote there, if I'm right, is paragraph 1?
PROFESSOR GERVAIS: Okay.
MR. BERENGAUT: Which towards the end of the paragraph says, "Further, it reviews those areas in which there is a substantial overlap of practices as well as those in which the two requirements differ substantially."
PROFESSOR GERVAIS: I'd certainly like to go through the document to know. I don't think I would have mistaken 1 for 56, but clearly 56 is the wrong paragraph. I apologize for that.
MR. BERENGAUT: Let's take a look at paragraph 1 where the sentence appears that I just read.
PROFESSOR GERVAIS: The main point

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 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?

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PROFESSOR GERVAIS: Yeah, the "not many" is a little bit like the previous discussion about many, several and some. I would have to see the dataset, how many countries replied. It's very hard to interpret out of context why -- was the survey specifically asking SCP members, for example? I don't know. Therefore, I don't know what to make of this other than the fact that it clearly says "not many examples fall under this category."

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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frequency of utility invalidations or industrial applicability invalidations varied across countries, right?

PROFESSOR GERVAIS: No, there is empirical data on that, but I don't have it in front of me.

MR. BERENGAUT: Let's go back to your First Report, paragraph 41.

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: Here you say "...the Report included in the competing definitions of utility the Canadian 'promise' approach as one of the several approaches." Do you see that?

PROFESSOR GERVAIS: Yes, I do.

MR. BERENGAUT: And at the bottom of paragraph 41 you quote paragraphs 41 and 46 of the 2003 survey, right?

PROFESSOR GERVAIS: It looks like, yes.

MR. BERENGAUT: Let's head back to the survey.

PROFESSOR GERVAIS: Which tab again? 12?

MR. BERENGAUT: 13. Paragraphs 41 and 46 were the two paragraphs you quoted. Let's start

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with paragraph 40, which is "Under the law of Canada, the term 'invention' means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter. Utility means having industrial or commercial value in a manner that benefits the public. For example, a perpetual motion machine that serves no useful purpose does not comply with the utility requirement."

Do you see that?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: The perpetual motion machine is back.

PROFESSOR GERVAIS: Again.

MR. BERENGAUT: Again, no references in this paragraph to a pharmaceutical invention that claims to treat a condition and actually treats that condition being invalidated because it does not comply with the utility requirement, correct?

PROFESSOR GERVAIS: In this paragraph, no.

MR. BERENGAUT: The next paragraph is paragraph 41 which, as you have quoted in your testimony, or in your report, contains a reference to

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promise. Now, there are no examples in this paragraph of an invention that would fail under this language regarding promise, correct?

PROFESSOR GERVAIS: There's a distinction drawn between promise and sound prediction which some previous experts have kind of melded, but if you look at the first part of the paragraph referring to promise, there is an example given for the second sound prediction.

MR. BERENGAUT: And that example is --

PROFESSOR GERVAIS: The genus example.

MR. BERENGAUT: For the record that is "...if the claim includes so many species that not all of them could have been tested and found by the inventor to have the promised utility, the claim is invalid, absent a possible showing by the patentee that the entire claim could be soundly predicted to have the requisite utility ('sound prediction')."

PROFESSOR GERVAIS: That is right.

MR. BERENGAUT: So, again, in this paragraph no examples of a pharmaceutical invention that claimed to treat a specific condition and actually treat that condition being found to lack utility, correct?

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PROFESSOR GERVAIS: It's getting pretty close to that, because it's interesting how it refers to promise and then sound prediction in the last part of the paragraph. You know, what is the promised utility of the species within the genus? Maybe it is to treat a particular disease. The level of abstraction is too high for me to be able to answer your question. I don't know what the drafter of the end of 41 had in mind.

MR. BERENGAUT: So the answer to my question is you don't know?

PROFESSOR GERVAIS: I don't know what this person had in mind when they were talking about what is the promised utility of the species within the genus, yes.

MR. BERENGAUT: There is no suggestion in paragraphs 41 or 40 that the promise approach, as you call it, in Canada would lead to different practical outcomes from any other country, is there?

PROFESSOR GERVAIS: It doesn't compare promise among different SCP members, so I don't know how it could.

MR. BERENGAUT: Next topic. In your report you talk about the joint proposal. This is paragraph 44. You testified that "After several

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rounds of negotiations on the basis of those WIPO documents, the United States, the European Union and Japan presented in 2004 a proposal (the 'Joint Proposal') to try to move the debate forward."

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: And, just for clarity, the reference in this sentence to "those WIPO documents," that is the WIPO documents we've just been discussing, correct?

PROFESSOR GERVAIS: They're the ones referenced in the paragraphs that precede in my report.

MR. BERENGAUT: Now, you quote the joint proposal in paragraph 45 of your report, which is R-235. Do you see that?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: In paragraph 46 you note that, "Utility and industrial applicability are not included in the list of issues suggested to be ripe for possible international harmonization or even discussion in the SPLT context, rather, that requirement was seen as best left to the discretion and interpretation of Member states themselves."

Do you see that?

PROFESSOR GERVAIS: I do.

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MR. BERENGAUT: You add in the next paragraph that, "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,

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and then basically leaves it out. It doesn't, I believe, say why it leaves it out directly, and what they say is "We've decided to advance negotiations and are submitting this document." If you read from the bottom of that first page it says, "It has been apparent, however, that an expansive SPLT, including all issues currently included [this would include industrial applicability] might not be achievable in the near future. For this reason, the Trilateral Offices have come to the conclusion that their future... should be based on the following five guiding principles:," and then they provide their list.

I do not know what, again, they were thinking. I wasn't there. I'm just reading the documents and drawing conclusions from what it says.

MR. BERENGAUT: And, just to ask my specific question again, nothing in this document says why utility specifically was left off the agenda, right?

PROFESSOR GERVAIS: Not that I can see.

MR. BERENGAUT: Well, isn't it possible, then, Professor, that the reason utility was left off the agenda was because negotiators did

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not think it was a priority to harmonize those definitions?
PROFESSOR GERVAIS: 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 GERVAIS: 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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international harmonization of substantive patent law." And you note that this Tegernsee Report does not discuss the harmonization of utility or industrial applicability. That's a quote from the middle of paragraph 53.
PROFESSOR GERVAIS: I see it.
MR. BERENGAUT: Now, your opinion is that the reason utility/industrial applicability was not included in the Tegernsee Report was because it was the subject of disagreement, right?
PROFESSOR GERVAIS: I don't know for a fact that that's what happened but I do not draw inference from the fact that it's not on the list, that there was agreement, because every document I see points me in the other direction.
MR. BERENGAUT: Again, I think you mentioned this but, just to be clear, you were not involved in the process of putting together the Tegernsee Report?
PROFESSOR GERVAIS: No, no.
MR. BERENGAUT: And this report is R-240, and it's behind tab 15 of your binder.
PROFESSOR GERVAIS: Okay.
MR. BERENGAUT: This is a considerably longer document but my question about this document

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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 GERVAIS: 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 GERVAIS: 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

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tell us. But I do not read the idea that it's not a priority, which I see is beside the point, as meaning that there's agreement, which I see as actually being the point. I don't see the agreement being reflected here or in any other document that has been cited that I can see.
MR. BERENGAUT: Going back to paragraph 53 of your First Report, you cite the USPTO notice of a Roundtable on the Tegernsee Group report, and you note about it that, again, utility and industrial applicability are left out. Do you see that?
PROFESSOR GERVAIS: I do.
MR. BERENGAUT: Let's take a look at that document. It's tab 16 of your binder. This document didn't indicate any concern about practical differences in utility/industrial applicability requirements across jurisdictions, did it?
PROFESSOR GERVAIS: I'm just reading it to get -- no, it's referring to issues that are "most suitable for further progress," and that list does not include industrial applicability or utility, in the middle of the second column on page 56071.
MR. BERENGAUT: So, again, the document doesn't indicate any concern about practical

differences in utility/industrial applicability requirements across jurisdictions?

PROFESSOR GERVAIS: I don't see any, no.

MR. BERENGAUT: No indication why utility or industrial applicability were left off the agenda for the session?

PROFESSOR GERVAIS: Well, the words mean what they mean. It says "issues most suitable for further progress." This one is not most suitable for further progress. It doesn't tell us why.

MR. BERENGAUT: Were you aware, Professor, that other countries also responded to the requests for feedback from the Tegernsee Group?

PROFESSOR GERVAIS: I haven't read those submissions.

MR. BERENGAUT: Let's take a look at a few examples. Tab 17 of your binder, the next page, C-340, is the Japanese report. If you could turn, please, to the last page, page 21?

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: Where it said "At the last part of the questionnaire survey based on questionnaires made by the Tegernsee Expert Group, there was a question. 'Other than these four issues,

is there any issue that has caused problems due to differences in laws practiced in each country?' For this question, the JPO received many responses. The main issues that the respondents raised are as follows: Standards used to determine inventive step; standards used to determine novelty; descriptive requirements for specifications; description of claims (for example, multiple dependent form claims, product-by-process claims); limitations to amendments, et cetera."

Do you see that?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: Now, industrial applicability or utility is not on this list, correct?

PROFESSOR GERVAIS: It is not identified as a main issue, that's right.

MR. BERENGAUT: So, from the Japanese perspective, you would agree there is no indication that industrial applicability/utility "caused problems due to differences in laws practiced in each jurisdiction." Right?

PROFESSOR GERVAIS: Well, it's not identified as a main issue. We can draw whatever inference we want from that. It doesn't mean that

it's not an issue. As I said, utility, typically for many types of inventions, is not an issue outside of the pharmaceutical field. So I'm not particularly surprised by this but I'm reading this for the first time. Why it's not a main issue, was it an issue at all, I don't know.

MR. BERENGAUT: Let's take a look at another example. Tab 18. This is from Germany. Let's take a look at page 2 which lists responses regarding several patent law topics. Do you see that?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: B), c), d), e) and f). Now, industrial applicability/utility does not appear on this list, correct?

PROFESSOR GERVAIS: Would you be able to -- obviously -- oh, I see a) is there. Okay. Well, again, they refer to main results of the evaluation and, you're absolutely correct, industrial applicability is not in the list of these main results.

MR. BERENGAUT: And in the final section, f), it states "Other areas requiring harmonization." It states, "While the need for harmonization is deemed to be constantly high for the

four aforementioned fields of law... there are no other obvious topics deemed to be similarly important by the applicants." Do you see that?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: Doesn't this suggest that, from Germany's perspective as well, industrial applicability/utility was not an important topic to put on the table for harmonization?

PROFESSOR GERVAIS: That's a reasonable inference.

MR. BERENGAUT: Let's go back to your First Report.

PROFESSOR GERVAIS: But do you know by any chance how many countries have replied to this? Because we have two. I wondered if others did. Anyway, tab 2, yes.

MR. BERENGAUT: Back to your First Report, please, tab 1, paragraph 31. In paragraph 31 of your first statement you quote a discussion of utility in a WIPO document, and we looked at this document earlier.

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: And I believe we agreed, but just to confirm, that the reason you thought this language regarding differences was

relevant is because it showed from your perspective a lack of consensus regarding those concepts.

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.

MR. BERENGAUT: Paragraph 50 and 51, this is a reference to a joint report of the WTO, WIPO and WHO.

PROFESSOR GERVAIS: Yes. The first time these three published a joint report, I believe.

MR. BERENGAUT: And the report notes, and you quote a paragraph of the report and you quote paragraph 57. Do you see that?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: Let's take a look at that document. That's at R-220 behind tab 5.

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: You quoted paragraph 57 of the report.

PROFESSOR GERVAIS: Page or paragraph?

MR. BERENGAUT: Page 57, excuse me.

PROFESSOR GERVAIS: Yes.

MR. BERENGAUT: On page 59 of the report it discusses industrial applicability/utility, correct?

PROFESSOR GERVAIS: It does.

MR. BERENGAUT: I'm at the right-hand column, top of the page of 59. "Industrial applicability (or utility) means that the invention can be made or used in any industry, including agriculture, or that it has a specific, credible and substantial utility. In general, the application of this requirement does not pose practical problems."

Do you see that?

PROFESSOR GERVAIS: Yeah, I agree with that. For most types of inventions, it doesn't. That paragraph is quoted in my Second Report, by the way.

MR. BERENGAUT: Right. I was going to go there next. And I appreciate you discuss it your Second Report. You do not quote it in your First Report, correct?

PROFESSOR GERVAIS: No. The reason I did is because the way that I thought my first quote was mishandled in the Reply Memorial.

MR. BERENGAUT: Right. I will take you there next. I'm not trying to --

PROFESSOR GERVAIS: Well, you decide.

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?

PROFESSOR GERVAIS: I do.

MR. BERENGAUT: Paragraphs 39-44, where you take issue with Claimant stating that you omitted the paragraph from page 59 from your report .

PROFESSOR GERVAIS: Uh-huh.

MR. BERENGAUT: What I'm interested in 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?

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 -- I have said that before and I stand by it -- with utility/industrial applicability than there would be with novelty or inventive step. That's how I read "in general," and I do not agree that there's a single definition in that paragraph.

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.

PROFESSOR GERVAIS: Which I reformulated as "meet the criteria", if you keep reading.

MR. BERENGAUT: Or meet the criteria. Now, in this paragraph, there is no discussion of difficulties faced by the pharmaceutical industry, is there?

PROFESSOR GERVAIS: Well, it says -- it mentions biotech, which I believe is not that far from pharma, but what I take issue with is saying this report by these three organizations says there's only issue with biotech. It doesn't. It says, however, in this area there are considerations; there might well be other areas, we don't know, but it certainly uses biotech as an example.

MR. BERENGAUT: The sentence that you're referring to regarding biotechnology reads, "However, in the area of biotechnology it needs some consideration given concerns that patent applications claiming gene-related inventions would block the use of the claimed gene sequence for uses that were not yet known by the applicant and therefore would not justify the grant of a patent in respect of a function which the applicant was not even aware of."

Do you see that?

PROFESSOR GERVAIS: I do. That is the example given.

MR. BERENGAUT: There's no indication

in this paragraph that, apart from this one area of biotechnology, in the broader context of pharmaceutical inventions, utility "needs some consideration," is there?

PROFESSOR GERVAIS: Not in this paragraph, but it is certainly my opinion that a chair and a new chemical molecule will not necessarily be looked at in the same fashion by an examiner in terms of utility. Professor Holbrook has a significant discussion of that, I believe, in his report.

MR. BERENGAUT: If I may have one moment to confer with my colleagues, Mr. President.

Thank you, Mr. President. We have no further questions.

THE PRESIDENT: Thank you.

MR. SPELLISCY: May I have one or two minutes, or maybe five minutes, for a quick discussion? If I have any redirect, it would be very short.

THE PRESIDENT: A five-minute recess. Professor Gervais, you are under testimony. You are not allowed to discuss the case with anyone.

(Recess taken)

THE PRESIDENT: Please.

REDIRECT EXAMINATION ON BEHALF OF THE RESPONDENT

MR. SPELLISCY: Good afternoon, Mr. Gervais, I just have one simple question on clarification.

A couple of times you mentioned a study cited by one of the amici in this case. I won't ask you questions about it because I don't know if it is yet in the record, but can you give us the author or the title of that study?

PROFESSOR GERVAIS: Yes. It's a study by the London School of Economics by Dr. Thambisetty. I would strongly, if I may, suggest that it's worth reading. It's very, very relevant to this case. It's produced by the law professors who produced an amicus brief on Claimant's behalf.

MR. SPELLISCY: Pursuant to the Tribunal's procedure, we'll make sure to get a copy of it onto the record, give it an R number and produce it to the Claimant.

MS. CHEEK: I think, given the procedural rules on documents, the parties will need to confer as to whether or not that document can be admitted to the record.

THE PRESIDENT: The document is not yet in the record?

MR. SPELLISCY: It's a document referred to in one of the amicus submissions. In the Tribunal's Order, right before the hearing, on 24 hours' notice before using it or referring to it, we can put it in the record.

THE PRESIDENT: First to confer.

MS. CHEEK: But I just got notice.

MR. SPELLISCY: And I haven't put it into the record yet but, 24 hours from now, it will be there.

THE PRESIDENT: Okay. Sir Daniel has a question or two.

QUESTIONS BY THE ARBITRAL TRIBUNAL

SIR DANIEL BETHLEHEM: Just a couple of technical questions, if I may, and they may not be relevant at all but I just want to clarify.

At the start of your cross-examination you said -- and I think the language was at 15:05:11, "TRIPS is relevant to the interpretation of NAFTA Chapter 17," and in your First Report you've got quite a lot of information about the origins of NAFTA Chapter 17 being the Dunkel draft in 1991 and so on. So my question is, and although I'm putting it in terms of NAFTA and TRIPS it may have a bearing on the relationship between NAFTA and other intellectual

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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 extent of the inconsistency," so I'd 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?

PROFESSOR GERVAIS: Thank you. That's a great question.

This is an unusual situation, Sir Daniel, because we have a number of countries,

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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 parties use the same language in an agreement which has a very similar object and purpose, which is a trade agreement with an IP chapter, there is definitely relevance in the fact that they have this common origin, and if you look at 1709(1) and 27(1), you see very similar language, the real difference being the footnote in 27 being moved to the text in 1709. In 1709(2) the paragraphs are formatted differently, but the words are almost identical in that section.

Now, I think that the reference to GATT was to obviously not the WTO agreements, because they hadn't been signed, so it was the old trade rules of the GATT 47 that they were making reference

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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

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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

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particular, the book that you've written on the reference guide to TRIPS, and if you can't answer it, please don't --

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

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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

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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.

MR. BORN: 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.

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So I think, first of all, as a matter of international law, you cannot say there's a treaty this country has implemented this way, we think this country is compliant, therefore, everybody must do the exact same thing. Because at that point international law falls apart. Countries must have the opportunity to do things a little differently when they implement a treaty. I think that's not particularly controversial.

What is interesting under the Vienna approach is when you try to interpret words like, for example, here "utility" or any other words in this treaty -- and what I made reference to earlier was the trade law approach, which is not to find one international definition of a term that is not otherwise defined, but to confine it to certain limits.

So if I can give, quickly, two examples, because they're the only two that come to mind, in the China enforcement case at the WTO, which for the record is DS362, the panel discusses a certain meaning of an expression in Article 57 of TRIPS and discusses the Vienna Convention and says there's more than one way to read this. I believe from memory, it would be paragraph 221 of that

report. It's in my book. It might be off by one or two.

It basically goes and says when you implement an intellectual property agreement, you have to have some flexibility. Then, of course, there's the report from the Appellate Body as quoted in my report that discusses Article 1 which specifically says countries can apply this agreement the way that -- I'm not quoting directly -- but have some leeway. And I'm sure the members of the Tribunal are familiar with the jurisprudence of WTO on credible interpretations. In other words, there isn't a single interpretation, but if you look at the continued zeroing case at the appellate body from 2009, which is DS350, you will see a discussion there as well of the appellate body saying, again, Vienna Convention doesn't say you have to define one word one way. There has to be a credible way of defining this word, and then they do the Vienna analysis. That's what I was trying to say when I said there was some leeway but it's finite. When you try to draw that border through hypotheticals, that you get to a point where it becomes very difficult to say it is here. It's a complex notion.

The last thing I would say, though, is

when one country implements it in a way that is mentioned in several international reports, namely promise, that's when my report says it is hard to imagine that's it's outside the boundary. That's my main point.

MR. BORN: Staying for a moment on 1709(1), if I understand your testimony, it is that although there could be different ways of defining new or useful or capable of industrial application, which would be consistent with paragraph 1, there would also be other ways that would be inconsistent with paragraph 1.

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

MR. BORN: Sure.

PROFESSOR GERVAIS: If a country said

we will only consider useful, I'm going to basically take a bit of a risk and stick with pharmaceuticals here, but basically if you were to say a pharmaceutical product is only useful if it cures 100 percent of the patients entirely, that seems excessive to me, for example. Arguably, it's excessive, but would I absolutely say the WTO panel would say that? I wouldn't know for sure.

MR. BORN: Putting aside WTO panels, why would you regard that hypothetical as outside 1709(1)? What are the characteristics of that measure that would put it outside 1709?

PROFESSOR GERVAIS: Well, I'm trying to look for an example where you go beyond utility and industrial applicability eyes. Typically if you look at pharmaceutical inventions, there needs to be evidence that this product will do either what it says or that there will be -- that's the whole debate in the case in that Federal Court of Appeal and the Court of Appeal and the New Jersey court and all these judges that have looked at these compounds have looked at.

There is a threshold. It's very hard to situate it precisely. But I'm saying 100 percent is arguably something -- would I be prepared to argue

that that is inconsistent? Yes.

MR. BORN: Would the reason that it's inconsistent be because, A, it's surprising, as in it hasn't been done before and isn't being done now; B, it's important in that it has significant effects on a fair number of patents; and C, it would be difficult to understand in terms of rationale? Would those sorts of characteristics be what you would look at?

PROFESSOR GERVAIS: Neither A nor B, definitely. C, it depends what it means. So, for example, there's no doubt -- there was a discussion I understood earlier with some other experts that if you have a patent criteria that is reinterpreted by courts, whether that applies to existing patents. And the system breaks down if you have different standards to different patents that are valid at the very same time. So clearly, if you have a country that changes the interpretation and that applies to existing patents, that is the law everywhere that I know. So that's not the reason.

The reason is more a policy, so I'm guessing I'm closer to your C point, which is every country implements the patent bargain differently, but they all try to do the right thing. They try to

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maximize innovation in the right amount of important -- or inventions that matter, I guess to use as simple as possible term, and disclosure, and some countries would add access to this. The bargain is implemented a little differently, but it's not that different.

What is different is the fact that very often the patent statute doesn't say very much, and so then it's left to courts to apply it. And then they see this technology and hear new arguments and they see, well, yes or no, and then it goes to Supreme Court. That's the process. That's the way these things work. But you asked me for a hypothetical. That's the best I can come up with.

MR. BORN: And if I can just push you on your answer on items A and B that I gave you, why wouldn't it be relevant in deciding whether a definition went beyond 1709(1) to see what states generally had done and were doing?

PROFESSOR GERVAIS: Oh, I did not -- I'm so sorry, I did not understand -- your question was about surprising. Is that what you meant?

MR. BORN: Yes.

PROFESSOR GERVAIS: I don't quite understand -- it's not a word I'm familiar with,

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frankly.

MR. BORN: That's surprising.

PROFESSOR GERVAIS: In this context. So I've heard it, but I don't think that it's used. What I meant, I think, to say is that state practice is obviously relevant. It's a Vienna factor in interpreting how a treaty needs to be applied, which is why I referred to state practice as much as I could in my reports as opposed to either personal beliefs or old recollections. I went to the source documents, and I said this is the empirical data I can find. There is no better source of state practice than states reporting their own practice, which is really what I tried to do.

MR. BORN: Thank you. I think I understand now.

THE PRESIDENT: The answers you just gave to Mr. Born regarding article 1709(1) of NAFTA, how do they fit into analysis on the basis of Article 31 and 32 of the Vienna Convention on the Law of Treaties?

PROFESSOR GERVAIS: You mean the last part of the answer on state practice?

THE PRESIDENT: No, at all. Entirely. Would you not start with 31(1)?

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PROFESSOR GERVAIS: Yes.

THE PRESIDENT: Is there more to it is my question. Why I asked this question is because you referred to policies, to rationales behind it. How far may you go under Article 31(1) or 31(4)?

PROFESSOR GERVAIS: Well, I think you start -- as I always try to summarize 31, text in context in light of object and purpose. So you would look at the text. It doesn't tell you very much about what these words mean. So you look at the context of the other provisions of the patent section and then the other provisions of TRIPS. Possibly even other -- TRIPS or NAFTA, for that matter, because on that provision they are almost identical.

THE PRESIDENT: May I stop you there? Are you allowed to look outside this treaty under 31(1)?

PROFESSOR GERVAIS: Well, that's the whole question of other relevant norms. There's some jurisprudence on what other relevant norms are that I'm sure you're well aware of. Are you allowed to? Yes.

THE PRESIDENT: I've seen a number of interpretations under 31(3) that do this.

PROFESSOR GERVAIS: Yes.

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THE PRESIDENT: Under 31(1), I have not seen that one. I've seen a lot of things --

PROFESSOR GERVAIS: Well -- sorry.

THE PRESIDENT: -- under Vienna, but okay.

PROFESSOR GERVAIS: I was talking about 31 globally. Sorry.

THE PRESIDENT: Let's take it paragraph by paragraph, because the holistic view of 31 is already a dangerous exercise in my view.

PROFESSOR GERVAIS: I'm sorry. I missed what you just said.

THE PRESIDENT: A holistic enterprise is taking 31 in its entirety. First you start with 1 and then go to 2 and then 3 and 4.

PROFESSOR GERVAIS: I agree with you, Professor. That's the way to do it. I have this way of summarizing it which probably made it sound a little too holistic.

THE PRESIDENT: So you're saying, 1, it doesn't help you because at least you say the words have -- the ordinary meaning of the words you can attribute to them, you don't find them?

PROFESSOR GERVAIS: Well, the ordinary meaning of technical terms in the patent

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field is an interesting question to begin with. So you have terms that over time have evolved in two different systems to be used and have been defined by courts in those systems because most statutes do not define utility and industrial applicability very clearly, so you leave it up to a large degree to courts. So you're already looking at a moving target in terms of ordinary meaning on the domestic front, and so if you look at dictionaries here, I don't think they would help you very much. So the text doesn't give you very much.

The context is all these doctrinal tools, the three major criteria that are mentioned here, the disclosure requirement, are all part of a doctrinal mix. The United States is a little unique because it adds written description and enablement. Most countries do not have those notions. Certainly not in the same way. So it achieves the doctrinal mix differently. But as I said earlier, you try to get to the same place as a court or as a legislator, you try to get to an implementation of the patent bargain that you think is the best policy. I'm probably not answering your 31 question in terms of --

THE PRESIDENT: You're back to the

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answer you gave to Mr. Born about policies. My question is how do you get to policy here in the legal analysis?

PROFESSOR GERVAIS: Well, I don't know that the text tells you very much. The context of 27 or 1709(1) does. It says there are three criteria, and it says if you meet those, then patents should be available. It doesn't say they should be granted. Actually, it's important to note that in the negotiation, that word was actually there, granted, and it was removed. It's, in my book, very clear. They're removed. They didn't want it. They wanted available. So we have a context. The context is availability for patents based on three criteria. It doesn't say these are the only three. So that you have the context that basically the context provides -- the immediate context provides the fact that there's a doctrinal mix there. Then you have the whole patent section which provides the context that you have -- you're dealing with some sort of innovation but not just, because you have this section of -- especially in TRIPS that deals with compulsory licensing and so on.

So you have kind of that -- and Article 7 of TRIPS, which deals with the objectives

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and principles of the agreement, emphasizes both the need for innovation and benefits to user and all that. So you're dealing with a context that already provides a little bit more complexity. Then you look at the object and purpose of this agreement and it's, again, about protection of IP and enforcement of IP up to a point. That's where it says, you know, you can do more up to a point unless you're contravening that agreement. It also says that there are a number of areas where countries have flexibility. And again, I go back to Article 1. I go back to the preamble, Article 41. There's several places in this agreement that have significant flexibility. It's meant not to be defining but confining up to a point what countries can and cannot do.

THE PRESIDENT: Thank you.

PROFESSOR GERVAIS: Is that helping?

THE PRESIDENT: Useful.

PROFESSOR GERVAIS: The best word to end the day. Or maybe it's not the end of the day.

THE PRESIDENT: All right. Any follow-up questions by, first, I think Respondent because it's your expert.

MR. SPELLISCY: No follow-up questions for us.

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MR. BERENGAUT: Nor from us.

THE PRESIDENT: Thank you, Professor, for testifying. You are now excused as an expert witness and released.

PROFESSOR GERVAIS: Thank you, Professor.

THE PRESIDENT: That comes to the end of the day. No more witnesses?

MS. CHEEK: That's correct. We will adjourn early today.

THE PRESIDENT: All right. We resume on Monday morning at 9:00. And all the three Mexican witnesses are then available?

MS. CHEEK: That's correct.

THE PRESIDENT: Thank you. Have a good weekend.

(Hearing adjourned at 5:03 p.m.)

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