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<p>1568</p> <p>1 the closings we come up with a number of questions.</p> <p>2 The Tribunal was also thinking that it</p> <p>3 might be useful after all to have post hearing briefs</p> <p>4 to see how -- and this is now the way we consider the</p> <p>5 post-hearing briefs -- how the evidence we have heard</p> <p>6 over the days of the hearing ties into your case, and</p> <p>7 then summaries for the positions of each of the</p> <p>8 parties on each of the main issues in this case, so</p> <p>9 that we will correctly capture them in the arbitral</p> <p>10 award.</p> <p>11 MS. CHEEK: That's very helpful.</p> <p>12 Thank you.</p> <p>13 THE PRESIDENT: And you give the</p> <p>14 reference to the main documents and transcripts in</p> <p>15 those summaries of your case in the post-hearing</p> <p>16 brief.</p> <p>17 MS. CHEEK: Very good. We'll proceed</p> <p>18 accordingly.</p> <p>19 THE PRESIDENT: We don't want to miss</p> <p>20 an issue. That's the point. Anything else?</p> <p>21 MR. SPELLISCY: Not from Respondent.</p> <p>22 THE PRESIDENT: Thank you.</p> <p>23 JAY ERSTLING.</p> <p>24 THE PRESIDENT: Mr. Erstling, good</p> <p>25 morning.</p> <p>www.dianaburden.com</p>	<p>1569</p> <p>1 PROFESSOR ERSTLING: Good morning.</p> <p>2 THE PRESIDENT: Would you please state</p> <p>3 your full name for the record?</p> <p>4 PROFESSOR ERSTLING: My name is Jay</p> <p>5 Erstling.</p> <p>6 THE PRESIDENT: Professor Erstling,</p> <p>7 you are an expert testifying here for the Claimant.</p> <p>8 PROFESSOR ERSTLING: Yes.</p> <p>9 THE PRESIDENT: If any question is</p> <p>10 unclear to you, either because of language or for any</p> <p>11 other reason, please do seek a clarification because,</p> <p>12 if you don't do so, the Tribunal will assume that</p> <p>13 you've understood the question and that your answer</p> <p>14 corresponds to the question.</p> <p>15 PROFESSOR ERSTLING: Thank you.</p> <p>16 THE PRESIDENT: You will appreciate</p> <p>17 that testifying, be it before a court or an arbitral</p> <p>18 tribunal, is a very serious matter. In that</p> <p>19 connection, the Tribunal expects you to give the</p> <p>20 statement, the text of which is in front of you.</p> <p>21 PROFESSOR ERSTLING: I solemnly</p> <p>22 declare upon my honor and conscience that my</p> <p>23 statement will be in accordance with my sincere</p> <p>24 belief.</p> <p>25 THE PRESIDENT: Thank you. Could you</p> <p>www.dianaburden.com</p>

<p>1570</p> <p>1 please go to your first Expert Report, which is dated 2 September 27, 2014 and go to page 15, and confirm for 3 the record that the signature appearing above your 4 name is your signature? 5 PROFESSOR ERSTLING: Yes, it is. 6 THE PRESIDENT: Then could you go to 7 your second Expert Report which is dated 8 September 10, 2015 and go to page 12, and confirm for 9 the record that the signature above your name is your 10 signature? 11 PROFESSOR ERSTLING: Yes, it is. 12 THE PRESIDENT: In addition to the 13 errata you find in tab 3 of your bundle, is there any 14 other correction you wish to make to either report? 15 PROFESSOR ERSTLING: Not that I'm 16 aware of, Mr. President. 17 THE PRESIDENT: Before we start direct 18 examination I have one question, because I have been 19 teaching at WIPO in the beginning of the '90s, so it 20 is not a disclosure at all but I simply want to 21 clarify one thing how I have to pronounce it. At the 22 time when I was teaching I was also drafting the 23 first set of Arbitration Rules, together with a 24 number of others at WIPO, and at that time I was 25 given to use what we believed was the politically</p> <p>www.dianaburden.com</p>	<p>1571</p> <p>1 correct pronunciation of "Wipo". We said "Wipo". 2 But they said no, no, the man on the 13th floor says 3 you may not use Wipo, you have to use W-I-P-O, 4 because he considered that Wipo was a detergent in 5 the bathroom! 6 PROFESSOR ERSTLING: That's right. 7 THE PRESIDENT: I wonder, do we 8 correct it also now amongst IP lawyers, so that we 9 use the correct pronunciation? Which is it? 10 PROFESSOR ERSTLING: Now it's okay to 11 say "Wipo". 12 THE PRESIDENT: Okay. Ms. Cheek? 13 MS. CHEEK: Ms. Wagner will direct the 14 examination of Mr. Erstling. 15 MS. WAGNER: Good morning, 16 Professor Erstling. We can begin by having you 17 deliver your presentation, please. 18 PRESENTATION BY PROFESSOR ERSTLING 19 PROFESSOR ERSTLING: Thank you. My 20 name is Jay Erstling and, as my background indicates, 21 a major force in my life has been the 22 Patent Cooperation Treaty, or PCT, as it's known, and 23 the PCT continues to be a major factor in my teaching 24 and practice. For that reason, Eli Lilly has asked 25 me to serve as an expert witness in this matter on</p> <p>www.dianaburden.com</p>
<p>1572</p> <p>1 the role of the PCT, on the PCT's industrial 2 applicability standard, and on Canada's sound 3 prediction requirement as it relates to the PCT's 4 form and contents requirements, as that has bearing 5 on this case in view of the invalidation of the 6 Stratterra patent, which was a PCT application. 7 The PCT is at the very heart of the 8 international patent system, and since, 9 Mr. President, you spent time in WIPO, you probably 10 have an understanding of the role that the PCT plays 11 in WIPO. The PCT is a multilateral treaty that was 12 adopted in 1970 and came into effect in 1978 that 13 establishes an international patent application 14 filing system. 15 Among its many advantages, it allows a 16 patent applicant to file a single international 17 patent application that has effect in all PCT member 18 countries instead of having to file an individual 19 application in every country in which the applicant 20 wants to have protection. 21 The PCT system is governed by the text 22 of the Treaty as well as by a detailed set of 23 regulations. Currently there are 148 contracting 24 states. Canada has been a member of the Treaty since 25 1990. The Treaty is extremely widely used, including</p> <p>www.dianaburden.com</p>	<p>1573</p> <p>1 in Canada. 2 The PCT is divided into two phases. 3 There's an international phase and a national phase. 4 During the international phase, an international 5 application is processed. It's subject to an 6 international search of the prior art and a 7 preliminary examination as to its patentability, and 8 the application is published. 9 Article 33 of the PCT, for the 10 purposes of international preliminary examination, 11 provides definitions of the substantive conditions of 12 patentability, of novelty, of inventive step and of 13 industrial applicability which, according to the PCT, 14 as well as NAFTA and TRIPS and other international 15 instruments, is synonymous with utility. 16 Article 33 defines industrial 17 applicability by saying that an invention is 18 industrially applicable if it can be made or used in 19 a technological sense in any kind of industry with 20 industry having the broadest definition. This is a 21 longstanding, non-controversial and generally 22 accepted definition of industrial applicability. 23 It's actually a very low bar and, among the 24 substantive conditions of patentability, it's the 25 lowest bar.</p> <p>www.dianaburden.com</p>

<p>1 Its purpose is to root out inventions 2 that defy laws of nature, that are simply not 3 operable, or workable, or inventions the use of which 4 has not yet been determined. 5 In the second phase, the national 6 phase of the PCT process, an international 7 application is converted into national applications 8 in all the countries in which the applicant actually 9 wants to pursue patent protection, and from that 10 point on national prosecution takes place. 11 To be clear, there is nothing in the 12 PCT that is an effort to create substantive patent 13 law. The PCT does not harmonize patent law, nor does 14 it constrain Canada's substantive utility test that 15 it can apply in the national phase. PCT 16 Article 27(5) makes clear that nothing in the Treaty 17 or the regulations is intended to be construed as 18 prescribing anything that would limit the freedom of 19 a contracting state to adopt the substantive 20 conditions of its patentability that it wishes. 21 In a similar vein, PCT Article 27(6) 22 provides that national laws may require applicants to 23 furnish evidence in respect of substantive conditions 24 of patentability. There is nothing in the PCT to 25 constrain a member country from requiring the</p> <p>www.dianaburden.com</p>	<p>1574</p> <p>1 submission of additional evidence in the national 2 phase. 3 The records of the Washington 4 Diplomatic Conference, which was the diplomatic 5 conference that adopted the PCT, provide that the 6 sort of evidence that member states might want to 7 include might be things like affidavits or laboratory 8 notes in order to demonstrate that an invention is 9 usable or operational. 10 This, in fact, is actually consistent 11 with the right for an applicant to submit informal 12 contents during the international phase, but what the 13 PCT does do is to constrain member countries from 14 requiring form and contents requirements that are 15 different from or additional to those which are 16 provided for in the Treaty and the regulations. In 17 fact, Article 27(5), which I just mentioned, goes on 18 to say that contracting states are free to apply 19 criteria of national law in respect of conditions of 20 patentability provided that those don't constitute 21 conditions constituting requirements as to the form 22 and contents of applications. 23 This, in my opinion, is an extremely 24 important provision because it strikes a balance 25 between the right of member countries to set the</p> <p>www.dianaburden.com</p> <p>1575</p>
<p>1 substantive conditions of patentability where they 2 would like and as they would like, even if they want 3 to be an outlier. It at the same time balances that 4 with the need of PCT applicants to be able to rely on 5 the fact that if their international application is 6 good as to form and contents in the international 7 phase, it will be good as to form and contents in the 8 national phase, and nothing more will be required in 9 the international application itself. 10 The drafters of the PCT were fairly 11 explicit in defining what they mean by form and 12 contents. The post-conference documents which form 13 an integral part of the records of the Diplomatic 14 Conference provide that form and contents mean not 15 only the physical requirements and the identification 16 data, but also the form and manner of describing and 17 claiming. 18 In addition, the records of the 19 Diplomatic Conference make reference to the 20 provisions of the PCT and the rules that relate -- 21 excuse me. When I say "rules," there's a quirk in 22 the PCT that the body of rules is referred to as 23 "regulations," but the individual regulations are 24 referred to as rules, so I tend to use the two 25 interchangeably, and if I confuse you please forgive</p> <p>www.dianaburden.com</p>	<p>1576</p> <p>1 me. 2 But the records refer to both the 3 provisions of the Treaty and the provisions of the 4 regulations that relate to form and contents, that 5 are the form and contents requirements, and those 6 include Article 5 of the Treaty which relates to the 7 description, and rule 5.1 of the regulations, which 8 relates to the manner of the description. 9 As I mentioned, rule 5.1 governs the 10 manner of description, and it includes the 11 description of a claimed invention's industrial 12 applicability. It provides the form and contents 13 requirements. And what rule 5.1(a)(vi) provides is 14 that, in order to meet the form and contents 15 requirement, an applicant in the international 16 application must indicate explicitly, when it's not 17 obvious from the description or the nature of the 18 invention, the way in which an invention is capable 19 of exploitation in industry and the way in which it 20 could be made and used or, if it can only be used, 21 the way in which it can be used. Nothing more is 22 required, and nothing more may be required. 23 In fact, the international search and 24 preliminary examination guidelines of the PCT make it 25 clear that in most cases, industrial applicability</p> <p>www.dianaburden.com</p> <p>1577</p>

<p>1 will be self-evident and nothing more will be 2 required. 3 So, to put together what I've said, 4 under the PCT, during the national phase, Canada can 5 set the substantive test for utility wherever it 6 chooses, but what Canada is constrained from doing 7 and what the PCT constrains is as a matter of form 8 and contents. Canada may not require an 9 international application to include contents that go 10 beyond what the PCT requires. It is constrained by 11 the PCT as to what, as a matter of form and contents, 12 a member country may require the international 13 application to include for the substantive 14 patentability requirement. If it wants more, it can 15 ask for it, but it can't require that it be in the 16 international application. 17 Canada's rule for evidence of sound 18 prediction, as a result, is incompatible with the 19 PCT. In Canada, evidence of soundly predicted 20 utility will only be considered if it's in the 21 application. It won't be considered if it's not. As 22 a result, Canada's requirement to include evidence of 23 sound prediction imposes a requirement on the 24 contents of international applications that is, in 25 fact, both different from and additional to what the</p> <p>www.dianaburden.com</p>	<p>1578</p> <p>1 PCT specifies, and I believe that is in contravention 2 of Article 27(1). 3 The consequences of this are, in fact, 4 quite grave, because failure to include evidence of 5 soundly predicted utility in the international 6 application can result in invalidation of the patent 7 or denial of the patent application. The situation 8 really puts applicants in a bind, and it requires 9 applicants to make a choice that in most cases 10 neither alternative is acceptable. Canada's 11 additional contents requirements for evidence of 12 sound prediction threaten an applicant's right of 13 priority, which is not only a fundamental feature of 14 the PCT and a fundamental right of the PCT but it is 15 also really a foundational right of the international 16 patent system as well. It requires applicants to 17 make a choice. 18 If an applicant amends the application 19 to meet the evidentiary requirement, it risks losing 20 its priority date because it may have added new 21 matter, which means that the applicant may not get a 22 patent at all. But if the applicant chooses not to 23 amend, then the applicant risks denial or invalidity 24 for lack of utility. For all these reasons, it is my 25 opinion that Canada's requirement to include evidence</p> <p>www.dianaburden.com</p> <p>1579</p>
<p>1 of sound prediction in the international application 2 undermines a core objective of the PCT. 3 Thank you. 4 MS. WAGNER: Thank you. I have no 5 questions for direct examination. 6 THE PRESIDENT: For cross-examination. 7 Mr. Spelliscy, you will conduct the 8 cross-examination? 9 CROSS-EXAMINATION ON BEHALF OF THE RESPONDENT 10 MR. SPELLISCY: Good morning, 11 Professor Erstling. We appreciate you being here on 12 a Saturday. My name is Shane Spelliscy. I'm senior 13 counsel for the Government of Canada. I'm going to 14 ask you a few questions and my goal today is just to 15 understand a little bit more about the opinions you 16 have submitted on behalf of the Claimant in this 17 arbitration. 18 I don't expect that we're going to go 19 for very long today, you'll be glad to know -- 20 PROFESSOR ERSTLING: Thank you. 21 MR. SPELLISCY: -- but if we do need a 22 break at any point let me know and I'll find a point 23 to take one, but I don't think we'll be going very 24 long. 25 As an initial matter, let me clarify</p> <p>www.dianaburden.com</p> <p>1580</p>	<p>1 the extent of your opinion. I think I understand 2 from your presentation now, but let me turn to 3 paragraph 1 of your Second Report. There you say in 4 the fourth sentence, "The fundamental point of my 5 initial report, apparently missed by Mr. Reed, is 6 that Canada's new requirement to include proof or 7 evidence of soundly predicted utility in the patent 8 application is a matter of form and contents governed 9 by the PCT and is at odds with the structure and 10 purpose of the PCT." Do you see that? 11 PROFESSOR ERSTLING: Yes. 12 MR. SPELLISCY: So you are offering 13 here no opinion in your report or in your testimony 14 this morning on the rule in Canadian law that utility 15 will be judged against the promise of a patent, 16 correct? 17 PROFESSOR ERSTLING: The extent of my 18 opinion is that the heightened evidentiary 19 requirement of sound prediction is at odds with the 20 PCT. 21 MR. SPELLISCY: I'm not sure that was 22 a direct answer. I understand that's the first part 23 of what you said there. I'm trying to make sure, 24 you've offered no opinion in your report on the rule 25 in Canada that the utility will be judged against the</p> <p>www.dianaburden.com</p> <p>1581</p>

<p>1582</p> <p>1 promise of the patent, correct?</p> <p>2 PROFESSOR ERSTLING: That's right.</p> <p>3 MR. SPELLISCY: And you've offered no</p> <p>4 opinion on the rule in Canadian law that utility must</p> <p>5 be soundly predicted or demonstrated at the time of</p> <p>6 filing, the rule regarding what we've called here</p> <p>7 post-filing evidence, correct?</p> <p>8 PROFESSOR ERSTLING: Could you repeat</p> <p>9 that question? Because I'm not sure.</p> <p>10 MR. SPELLISCY: Sure. You've offered</p> <p>11 no opinion on the rule in Canadian law that utility</p> <p>12 must be soundly predicted or demonstrated at the time</p> <p>13 of filing, correct?</p> <p>14 PROFESSOR ERSTLING: That is correct,</p> <p>15 because my opinion goes to the ability to</p> <p>16 substantiate that that requirement has been met,</p> <p>17 under the PCT.</p> <p>18 MR. SPELLISCY: Under the PCT, right.</p> <p>19 Great. You said today several times and emphasized</p> <p>20 that the PCT does not govern Canada's substantive</p> <p>21 utility requirement, and you say in paragraph 4 "on</p> <p>22 this point Mr. Reed and I agree."</p> <p>23 So you would agree with me that under</p> <p>24 the PCT it is perfectly acceptable for Canada to say</p> <p>25 that, in order to establish the utility of an</p> <p>www.dianaburden.com</p>	<p>1583</p> <p>1 invention, the inventor must, if relying on a sound</p> <p>2 prediction, have a factual basis and a sound line of</p> <p>3 reasoning as of the filing date, correct?</p> <p>4 PROFESSOR ERSTLING: Under the PCT,</p> <p>5 the PCT, because it is not a substantive law treaty,</p> <p>6 makes no judgment about the substantive conditions of</p> <p>7 patentability that member countries prescribe. So</p> <p>8 under the PCT, a country can be unique, it could be</p> <p>9 an outlier, and in accordance with the PCT as a</p> <p>10 matter of substantive law, that could be okay.</p> <p>11 MR. SPELLISCY: In paragraph 4 of your</p> <p>12 Second Report you do also say that "the PCT does</p> <p>13 govern what must (and need not) be disclosed in an</p> <p>14 international patent application regarding the</p> <p>15 utility of an invention." That's what I'd like to</p> <p>16 explore with you a little bit further now that we've</p> <p>17 got that clarified.</p> <p>18 Let's turn to tab 1 in the much</p> <p>19 smaller red binder that you have in front of you</p> <p>20 there. This is Exhibit C-100. This is an article</p> <p>21 that you wrote in 2012, correct?</p> <p>22 PROFESSOR ERSTLING: That I co-wrote.</p> <p>23 MR. SPELLISCY: Right. I wanted to</p> <p>24 turn to page 29 of that article. I'm looking in the</p> <p>25 long paragraph here, the first sentence. You're</p> <p>www.dianaburden.com</p>
<p>1584</p> <p>1 writing about, in this article, the Canadian doctrine</p> <p>2 of sound prediction, correct?</p> <p>3 PROFESSOR ERSTLING: Correct.</p> <p>4 MR. SPELLISCY: Closer to the bottom</p> <p>5 of the page, say about two-thirds of the way down,</p> <p>6 you'll see a sentence that starts, midway through,</p> <p>7 "...Canadian law invokes" and you call it "the</p> <p>8 heightened evidentiary standard." I think that's</p> <p>9 what you were talking about a minute ago, that this</p> <p>10 was in your view a heightened evidentiary standard,</p> <p>11 talking about as a heightened evidentiary standard,</p> <p>12 the sound prediction rule, correct?</p> <p>13 PROFESSOR ERSTLING: Yes.</p> <p>14 MR. SPELLISCY: To clarify, what we</p> <p>15 are discussing, then, in your view is an evidentiary</p> <p>16 requirement in Canadian law. Is that right?</p> <p>17 PROFESSOR ERSTLING: It is the</p> <p>18 requirement that the international application</p> <p>19 contain in the application the evidence that</p> <p>20 demonstrates that sound prediction has been met.</p> <p>21 MR. SPELLISCY: And that is, in your</p> <p>22 view, an evidentiary standard or an evidentiary</p> <p>23 requirement, correct?</p> <p>24 PROFESSOR ERSTLING: Yes, with the</p> <p>25 term "evidentiary" being understood in a broad sense,</p> <p>www.dianaburden.com</p>	<p>1585</p> <p>1 in a contents informational sense, not in the strict</p> <p>2 submission of evidence in a trial court setting type</p> <p>3 of sense.</p> <p>4 MR. SPELLISCY: Let me also just</p> <p>5 clarify a few things about your experience upon which</p> <p>6 your opinion is based, and I would actually like to</p> <p>7 come to your First Report and the disclosure you make</p> <p>8 about your relationship with the Claimant here.</p> <p>9 Let's turn to page 3 of your First</p> <p>10 Report and paragraph 9. In this paragraph you</p> <p>11 disclose that in May 2009 you were retained by the</p> <p>12 Claimant, Eli Lilly, to review the Canadian Federal</p> <p>13 Court decisions relating to Raloxifene and to discuss</p> <p>14 your view of those decisions in the context of the</p> <p>15 PCT requirements for patent applications, correct?</p> <p>16 PROFESSOR ERSTLING: Yes.</p> <p>17 MR. SPELLISCY: When you say Federal</p> <p>18 Court decisions in that paragraph, you're talking</p> <p>19 about both the Federal Court and the Federal Court of</p> <p>20 Appeal, correct?</p> <p>21 PROFESSOR ERSTLING: Yes. Although I</p> <p>22 believe my focus was on the Federal Court of Appeal.</p> <p>23 MR. SPELLISCY: Right, because you</p> <p>24 were preparing an affidavit to be submitted by the</p> <p>25 Claimant, Eli Lilly, in the Supreme Court of Canada</p> <p>www.dianaburden.com</p>

<p>1 in support of their application for leave to appeal, 2 correct? 3 PROFESSOR ERSTLING: I did, yes. 4 MR. SPELLISCY: That request for leave 5 to appeal was denied in October of 2009. Is that 6 right? 7 PROFESSOR ERSTLING: I knew that it 8 was denied. I was not aware of when. 9 MR. SPELLISCY: But you knew it was 10 denied? 11 PROFESSOR ERSTLING: Yes. 12 MR. SPELLISCY: Then you say after 13 that, in January 2012, the Claimant requested you -- 14 or your firm, you say, but I take it it was you -- to 15 prepare a study on the utility requirements in 16 Canada, correct? 17 PROFESSOR ERSTLING: That's correct. 18 MR. SPELLISCY: In fact, that was a 19 study we looked at a few minutes ago at tab 1 of your 20 binder, C-100, right? 21 PROFESSOR ERSTLING: Yes. 22 MR. SPELLISCY: That was a study 23 Eli Lilly requested you prepare? 24 PROFESSOR ERSTLING: Right. They 25 requested the study which we then published -- "we"</p> <p>www.dianaburden.com</p>	<p>1586</p> <p>1 being my co-authors and I. 2 MR. SPELLISCY: Right, your 3 co-authors, who are partners at the firm where you 4 are counsel, correct? 5 PROFESSOR ERSTLING: That's correct. 6 MR. SPELLISCY: Eli Lilly has also 7 requested that you present this paper at at least two 8 conferences that you disclosed in your report, one in 9 Ottawa and one in Chicago. Is that right? 10 PROFESSOR ERSTLING: That's correct. 11 MR. SPELLISCY: And Eli Lilly has 12 supported your attendance at these conferences? Did 13 they pay for it? 14 PROFESSOR ERSTLING: I actually do not 15 remember. 16 THE PRESIDENT: Excuse me, 17 Mr. Spelliscy. What do you mean by "supported"? 18 Paying the tickets and the hotel? 19 MR. SPELLISCY: Yes. They paid for 20 it. 21 PROFESSOR ERSTLING: I don't recall. 22 MR. SPELLISCY: Let's turn to the 23 paper again, tab 1, C-100. Let's look at page 14 24 this time. In the top paragraph -- I should say I 25 think -- if you go back to page 13 for a second,</p> <p>www.dianaburden.com</p>
<p>1588</p> <p>1 you'll see that you have a little C that says 2 "Canada," so this is a section where you talk about 3 Canada, is that correct, the Canadian law? 4 PROFESSOR ERSTLING: Yes. 5 MR. SPELLISCY: If you come to page 14 6 in the top paragraph, you and your co-authors write, 7 "In its interpretation of the statute, the Supreme 8 Court of Canada has held that utility does not exist 9 if 'the invention will not work, either in the sense 10 that it will not operate at all or, more broadly, 11 that it will not do what the specification 12 promises..." 13 You see that? 14 PROFESSOR ERSTLING: Yes. 15 MR. SPELLISCY: And you have a 16 footnote 65 right at the end. That sentence does 17 continue, but footnotes 55 and 56 actually refer to 18 the same case. If you go down to footnote 65, the 19 case you cite for that is the Consolboard decision in 20 1981, correct? 21 PROFESSOR ERSTLING: Yes. 22 MR. SPELLISCY: That's the same case 23 you actually cite in footnote 66, the Consolboard 24 decision, 1981. Is that right? 25 PROFESSOR ERSTLING: Yes.</p> <p>www.dianaburden.com</p>	<p>1589</p> <p>1 MR. SPELLISCY: You also cite in 2 footnote 66 the Unifloc decision from 1943, correct? 3 PROFESSOR ERSTLING: That's correct. 4 MR. SPELLISCY: So your research 5 prepared at the request of the Claimant into the 6 utility requirement in Canada led you to Consolboard 7 for the doctrine of promise utility, correct? 8 PROFESSOR ERSTLING: Well, it did but 9 in a backwards sort of way. Our focus was on the 10 sound prediction requirement. We are not Canadian 11 attorneys, I am certainly not a Canadian attorney, 12 and I have no expertise in Canadian law, so we began 13 by looking at sources like MOPOP, and MOPOP cited 14 Consolboard and so we cited Consolboard. But it was 15 really to establish, in our view, what the state of 16 utility is in Canada so that we could at that point 17 focus on sound prediction. It was really simply to 18 place it in a very broad context; it was not to rely 19 on it at all. 20 MR. SPELLISCY: But, in terms of 21 placing the promise doctrine in the very broad 22 context, in writing this article you felt that the 23 Consolboard decision in 1981 provided you with all 24 the context you need for the rule you cite here. Is 25 that correct?</p> <p>www.dianaburden.com</p>

<p>1590</p> <p>1 PROFESSOR ERSTLING: Well, actually it 2 was MOPOP that probably led us to this that allowed 3 us to rely on it. As you could tell from this 4 article, this is not an in-depth exploration. This 5 is really an attempt to present a very high level 6 approach with the emphasis on sound prediction being 7 at variance from or different from utility in the 8 United States or industrial applicability in Europe. 9 MR. SPELLISCY: I understand the point 10 of the article; I'm just not sure I've understood 11 what you said there. When I look at footnote 65, I 12 see the first reference is to Consolboard with a 13 specific page cite, 525, and then I see it says "see 14 also MOPOP", so your primary reference is to 15 Consolboard there, is it not? 16 PROFESSOR ERSTLING: In terms of 17 citation, in terms of our research, the research 18 methodology that we used to get there, MOPOP came 19 first. 20 MR. SPELLISCY: And, in fact, 21 Consolboard and Unifloc are the only two Canadian law 22 cases that you cite at all in those two footnotes, 23 correct? 24 PROFESSOR ERSTLING: Yes, in those two 25 footnotes.</p> <p>www.dianaburden.com</p>	<p>1591</p> <p>1 MR. SPELLISCY: I'd like now to turn 2 to tab 3 of your binder. 3 PROFESSOR ERSTLING: Of my binder? 4 MR. SPELLISCY: Not your binder, 5 sorry. The red binder. 6 PROFESSOR ERSTLING: Okay. 7 MR. SPELLISCY: Tab 3 is Exhibit 8 R-200, and it's the decision of Justice Hughes of the 9 Federal Court in 2008 related to the Raloxifene 10 decision. Do you see that? 11 PROFESSOR ERSTLING: Yes. 12 MR. SPELLISCY: And this is the 13 decision -- at least one of the decisions -- that you 14 say you reviewed in preparing your affidavit in 15 support of the Claimant's application for leave to 16 appeal to the Supreme Court of Canada, correct? 17 PROFESSOR ERSTLING: This is the lower 18 court decision, the decision upon which I really did 19 not rely. 20 MR. SPELLISCY: In your witness 21 statement you did say you read the Federal Court 22 decisions, plural? 23 PROFESSOR ERSTLING: Yes. There's a 24 difference between reading and reading. 25 MR. SPELLISCY: I just want to turn to</p> <p>www.dianaburden.com</p>
<p>1592</p> <p>1 page 46 of this decision. Let's look to paragraph 2 165. You see here that Justice Hughes notes that the 3 Claimant, Eli Lilly, in 2008 makes an argument about 4 a disclosure requirement for sound prediction based 5 on the PCT, correct? 6 PROFESSOR ERSTLING: Yes. 7 MR. SPELLISCY: If you go down to 8 paragraphs 167 and to 168 you will see that Eli Lilly 9 argued in front of Justice Hughes in 2008 that 10 article 27(1) means that the disclosure need only set 11 out the invention and that no further disclosure can 12 be required. Do you see that? 13 PROFESSOR ERSTLING: Yes. 14 MR. SPELLISCY: This is the same 15 argument that you made in the affidavit which you 16 filed in support of Eli Lilly's application for leave 17 to appeal to the Supreme Court a year later. Is that 18 right? 19 PROFESSOR ERSTLING: Yes. That no 20 further disclosure is required in the international 21 application, and that further disclosure can be 22 supplied subsequently in the international phase. 23 MR. SPELLISCY: If we look at 24 paragraph 169 of the decision it says "Eli Lilly 25 argues" -- in the first sentence -- "Eli Lilly argues</p> <p>www.dianaburden.com</p>	<p>1593</p> <p>1 that the 'form and contents' provision at the end 2 limits the necessity to make disclosure." Do you see 3 that? 4 PROFESSOR ERSTLING: Yes. 5 MR. SPELLISCY: This is the same 6 argument you're making today in this Tribunal, right? 7 PROFESSOR ERSTLING: I assume that -- 8 well, no, I actually shouldn't assume. Could you 9 explain what "form and contents provision" at the end 10 refers to? 11 MR. SPELLISCY: I think he's saying 12 "...in the end limit the necessity to make the 13 disclosure. I do not consider..." You would agree 14 with me that Eli Lilly argued in this case, which you 15 reviewed, that the form and contents provisions of 16 the PCT limit the necessity to make disclosure, 17 correct? 18 PROFESSOR ERSTLING: I would not argue 19 that it limits the necessity to make disclosure. 20 What I would argue is that it limits the requirement 21 to make disclosure in the international application 22 and to be penalized for not making that disclosure in 23 the international application, as opposed to 24 requiring that it be allowed to make it subsequently 25 in the national phase, and the reason for that is</p> <p>www.dianaburden.com</p>

<p>1594</p> <p>1 that the very purpose and objective of the PCT is to 2 allow the single application to be able to be relied 3 upon in the national phase, and, where there is a 4 need to meet additional substantive conditions of 5 patentability requirements, to be able to make those 6 subsequently, if every country were allowed to make 7 form and contents requirements, then the purpose and 8 objective of the PCT would be undermined completely. 9 In fact, there would be no basis for having a PCT at 10 all. 11 MR. SPELLISCY: You would agree with 12 me, Mr. Erstling, that that was the argument that Eli 13 Lilly was making in the Federal courts in Canada, 14 correct? 15 PROFESSOR ERSTLING: Well, I can only 16 base it on what I read in the decision. I was not 17 privy to the argument that Eli Lilly actually made. 18 Eli Lilly never spelled out that argument to me. 19 Based on the decision here, I would assume that, on 20 the basis of the decision, yes, that is the argument, 21 but I have no personal knowledge of the argument that 22 Eli Lilly made. 23 MR. SPELLISCY: But you were 24 retained -- I don't understand, Mr. Erstling. You 25 were retained by Eli Lilly to file an affidavit in</p> <p>www.dianaburden.com</p>	<p>1595</p> <p>1 support of their application for leave to appeal this 2 issue to the Supreme Court. I assume you were 3 retained not on Canadian law but on PCT issues, 4 correct? 5 PROFESSOR ERSTLING: Yes. 6 MR. SPELLISCY: So you understood, in 7 making that affidavit, what Eli Lilly was arguing, 8 correct? 9 PROFESSOR ERSTLING: Yes. 10 MR. SPELLISCY: So you understood 11 essentially that Eli Lilly started arguing -- or had 12 made the arguments in 2008 in front of the Federal 13 Court that you're making here now, and that you made 14 in your affidavit in 2009 to the Supreme Court, 15 correct? 16 PROFESSOR ERSTLING: What I can agree 17 to is that my presentation here is consistent with my 18 affidavit in 2009. 19 MR. SPELLISCY: You would agree with 20 me, by reading on in 169 and by knowing the result in 21 this case, that the Federal Court in the trial that 22 Justice Hughes heard, provided reasons for but then 23 disagreed with Eli Lilly's argument on the meaning of 24 the PCT, correct? 25 PROFESSOR ERSTLING: I would agree</p> <p>www.dianaburden.com</p>
<p>1596</p> <p>1 that the court disagreed with Eli Lilly. 2 MR. SPELLISCY: You would agree that 3 the judge provided reasons for doing so, too, 4 correct? You can review, if you like, paragraphs 165 5 through 169. 6 PROFESSOR ERSTLING: With all due 7 respect, I would disagree with the decision of the 8 court. 9 MR. SPELLISCY: I understand you would 10 disagree with the substance; my question is the court 11 did provide reasons for its decision, correct? 12 PROFESSOR ERSTLING: It did. 13 MR. SPELLISCY: Thank you. We'll get 14 to your disagreement with the substance in a second. 15 If you could turn to tab 4 of your binder, this is 16 Exhibit R-354, and this is the decision of the 17 Federal Court of Appeal March 25, 2009. This was the 18 one that you read in more detail, you said, in 19 preparation for the submission of your affidavit, 20 correct? 21 PROFESSOR ERSTLING: Yes. 22 MR. SPELLISCY: And the Federal Court 23 of Appeal also considered Eli Lilly's arguments on 24 the PCT, correct? 25 PROFESSOR ERSTLING: If my</p> <p>www.dianaburden.com</p>	<p>1597</p> <p>1 recollection is correct, there was a summary 2 dismissal of the argument, so I don't know to what 3 extent the court considered it on the basis of this 4 decision. 5 MR. SPELLISCY: Let's turn to page 6 6 and turn to paragraph 19. You would agree that the 7 issue of compliance with the PCT was presented to the 8 Federal Court of Appeal by the Appellant, Eli Lilly, 9 correct? 10 PROFESSOR ERSTLING: Yes. 11 MR. SPELLISCY: And they argued that 12 requiring the complete disclosure of the factual 13 basis underlying the sound prediction is inconsistent 14 with the Patent Cooperation Treaty, correct? 15 PROFESSOR ERSTLING: Yes. 16 MR. SPELLISCY: And that's the same 17 argument you're presenting to this Tribunal here 18 today, correct? 19 PROFESSOR ERSTLING: Basically, yes. 20 MR. SPELLISCY: The Federal Court of 21 Appeal rejected this and said, "However, this 22 treaty... contemplates the supremacy of national law 23 in setting the rules for substantive conditions of 24 patentability... We are concerned here with 25 substantive conditions of patentability."</p> <p>www.dianaburden.com</p>

<p>1598</p> <p>1 You see that?</p> <p>2 PROFESSOR ERSTLING: I do.</p> <p>3 MR. SPELLISCY: I understand you</p> <p>4 describe that as summary but you would agree that the</p> <p>5 issue was presented to the Federal Court of Appeal</p> <p>6 and the Federal Court of Appeal did issue a ruling on</p> <p>7 it, correct?</p> <p>8 PROFESSOR ERSTLING: It did, and</p> <p>9 again, with all due respect, I would disagree with</p> <p>10 the Federal Court's determination of what is a</p> <p>11 substantive condition of patentability.</p> <p>12 MR. SPELLISCY: That's what I</p> <p>13 understood. So you would now like this Chapter 11</p> <p>14 Tribunal to say that the Claimant, Eli Lilly, and</p> <p>15 you, rather than the Federal Canadian courts, were</p> <p>16 right about the meaning of the PCT, right?</p> <p>17 PROFESSOR ERSTLING: I would actually!</p> <p>18 MR. SPELLISCY: You would. Let's turn</p> <p>19 to tab 7 of your binder. This is -- it's not the</p> <p>20 whole patent -- sorry, I'm wrong, I'm at tab 5. It's</p> <p>21 not the whole Patent Cooperation Treaty -- I'm sure</p> <p>22 you know better than I -- for the record, this is</p> <p>23 from Exhibit C-106, an excerpt of the</p> <p>24 Patent Cooperation Treaty. As you flip it over,</p> <p>25 you'll see that there are a couple of excerpts in</p> <p>www.dianaburden.com</p>	<p>1599</p> <p>1 here, and I want you to go to the second excerpt, the</p> <p>2 third page in here, Article 59 on page 46 of the PCT</p> <p>3 titled "Disputes." Are you with me?</p> <p>4 PROFESSOR ERSTLING: Yes.</p> <p>5 MR. SPELLISCY: It says, "Subject to</p> <p>6 Article 64(5), any dispute between two or more</p> <p>7 Contracting States concerning the interpretation or</p> <p>8 application of this Treaty or the Regulations, not</p> <p>9 settled by negotiation, may, by any one of the States</p> <p>10 concerned, be brought before the International Court</p> <p>11 of Justice by application in conformity with the</p> <p>12 Statute of the Court, unless the States concerned</p> <p>13 agree on some other method of settlement."</p> <p>14 See that?</p> <p>15 PROFESSOR ERSTLING: I do.</p> <p>16 MR. SPELLISCY: So the PCT only</p> <p>17 contemplates state-to-state dispute settlement over</p> <p>18 the interpretation and application of the PCT,</p> <p>19 correct?</p> <p>20 PROFESSOR ERSTLING: Within the PCT</p> <p>21 itself, but it also says that it's subject to</p> <p>22 Article 64(5). Do you have reference to that? I</p> <p>23 have a recollection but it is a recollection only, as</p> <p>24 to what 64(5) provides.</p> <p>25 THE PRESIDENT: Has such a declaration</p> <p>www.dianaburden.com</p>
<p>1600</p> <p>1 been made by Canada and the United States? Sorry,</p> <p>2 I'm already one question ahead.</p> <p>3 MR. SPELLISCY: Yes. Article 64(5)</p> <p>4 says, "Each State may declare that it does not</p> <p>5 consider itself bound by Article 59."</p> <p>6 PROFESSOR ERSTLING: I don't know the</p> <p>7 information offhand, but if I may -- and I really</p> <p>8 have no basis for this -- it is my understanding that</p> <p>9 the United States made such a declaration. But I am</p> <p>10 not sure.</p> <p>11 MR. SPELLISCY: But what this is</p> <p>12 really just saying is, unless you have declared that</p> <p>13 you don't want disputes resolved by the ICJ under</p> <p>14 64(5), unless you do not want to be bound on the</p> <p>15 dispute settlement provisions under 64(5), disputes</p> <p>16 may be taken to the International Court of Justice,</p> <p>17 correct?</p> <p>18 PROFESSOR ERSTLING: That is correct,</p> <p>19 but Article 59 is sort of standard language in</p> <p>20 international IP treaties and it does require</p> <p>21 state-to-state. It makes no provision for private</p> <p>22 parties. There is no private party dispute</p> <p>23 resolution procedure. Again, I'm speaking out of</p> <p>24 turn but it is my understanding or my belief that the</p> <p>25 United States routinely makes these sorts of -- that</p> <p>www.dianaburden.com</p>	<p>1601</p> <p>1 they declared that they are not bound.</p> <p>2 MR. SPELLISCY: Unfortunately they</p> <p>3 decided not to join us on a Saturday so maybe we'll</p> <p>4 have to look it up ourselves. We can confirm,</p> <p>5 though, not a single one of Canada's Treaty partners</p> <p>6 under the PCT have ever brought a dispute against</p> <p>7 Canada concerning its interpretation application of</p> <p>8 the PCT, correct?</p> <p>9 PROFESSOR ERSTLING: I don't think any</p> <p>10 state has ever brought an action against any other</p> <p>11 state on the basis of the PCT before the</p> <p>12 International Court of Justice.</p> <p>13 MR. SPELLISCY: So the answer is no,</p> <p>14 none of Canada's Treaty partners under the PCT have</p> <p>15 brought a dispute complaining that Canada is</p> <p>16 violating the PCT, correct?</p> <p>17 PROFESSOR ERSTLING: That is correct.</p> <p>18 MR. SPELLISCY: Let's turn back to</p> <p>19 paragraph 1 of your Second Report.</p> <p>20 PROFESSOR ERSTLING: That is in which</p> <p>21 binder?</p> <p>22 MR. SPELLISCY: It would have been</p> <p>23 provided to you by your counsel in the large binder,</p> <p>24 at tabs 1 and 2. No. 2 is your Second Report. I'm</p> <p>25 looking at the sentence in paragraph 1 that starts</p> <p>www.dianaburden.com</p>

<p>1602</p> <p>1 about halfway down the right side, the sentence that 2 says, it was "the fundamental point of my initial 3 report" and I want to understand the idea, you say 4 that Canada's "new requirement to include proof or 5 evidence of... utility...." 6 Let me understand a little bit about 7 that. You earlier testified that you're certainly 8 not an expert in Canadian law, correct? 9 PROFESSOR ERSTLING: That is correct. 10 MR. SPELLISCY: And, in terms of 11 concluding to this Tribunal that this is a new 12 requirement, you don't cite any authority there that 13 I see. Is that right? 14 PROFESSOR ERSTLING: That's correct. 15 MR. SPELLISCY: So was this an 16 instruction of Canadian counsel that this is a new 17 requirement? 18 PROFESSOR ERSTLING: No. This was my 19 understanding that it was a requirement brought into 20 effect relatively recently. I may be getting the 21 case wrong, but I believe it was in the AZT case. 22 MR. SPELLISCY: You said earlier today 23 that the PCT has not harmonized substantive patent 24 law but we were talking about disclosure. So I'd 25 like now to understand a little bit more your</p> <p>www.dianaburden.com</p>	<p>1603</p> <p>1 opinions on disclosure. 2 PROFESSOR ERSTLING: May I just add a 3 little bit more about that, about the harmonization 4 part? What the PCT is, as I mentioned, it is not a 5 substantive law treaty and it does not harmonize law, 6 but it's a treaty that is informed by and reflects 7 international understandings and norms about patent 8 law and particularly about the substantive conditions 9 of patent law, so it never created its own law. 10 What it does is reflect, really, 11 prevailing standards, and that's, in my opinion, what 12 allows the Treaty to be successful. 13 MR. SPELLISCY: I think we'll hear 14 from some experts later today more on that topic. 15 I'd like to focus more on the disclosure that you 16 said was the -- the evidentiary requirement of the 17 disclosure requirement that you focused on in your 18 report. 19 Again, let's go back to tab 5, which 20 is the excerpts from the PCT. I want to look at 21 Article 5, which is called "The Description," 22 correct? 23 PROFESSOR ERSTLING: Yes. 24 MR. SPELLISCY: So all the PCT 25 provides, you would agree with me, is that "The</p> <p>www.dianaburden.com</p>
<p>1604</p> <p>1 description shall disclose the invention in a manner 2 sufficiently clear and complete for the invention to 3 be carried out by a person skilled in the art.," 4 correct? 5 PROFESSOR ERSTLING: Correct. 6 MR. SPELLISCY: The text of the PCT 7 itself provides no further information on what a 8 "sufficiently clear and complete" disclosure is, 9 correct? 10 PROFESSOR ERSTLING: That's correct. 11 MR. SPELLISCY: Let's turn to tab 7 in 12 your red binder, Exhibit R-040. As you know, these 13 are the regulations which provide rules under the 14 Patent Cooperation Treaty. I want to turn to Rule 5, 15 which is the rule related to the description. If we 16 look to 5.1(a), it starts with -- 17 PROFESSOR ERSTLING: Excuse me, I'm 18 not... 19 MR. SPELLISCY: Are you in tab 7? 20 You're there? 21 PROFESSOR ERSTLING: I am there, yes. 22 MR. SPELLISCY: Rule 5.1(a) under The 23 Description, "The description shall first state the 24 title of the invention as appearing in the request 25 and shall;" then it contains a number of numerettes</p> <p>www.dianaburden.com</p>	<p>1605</p> <p>1 that are requirements that the description must 2 contain, correct? 3 PROFESSOR ERSTLING: Correct. 4 MR. SPELLISCY: I want to look at 5 No. (iii) on the next page. Page 29, No. (iii). The 6 description must "disclose the invention, as claimed, 7 in such terms that the technical problem (even if not 8 expressly stated as such) and its solution can be 9 understood, and state the advantageous effects, if 10 any, of the invention with reference to the 11 background art." 12 So the description must disclose the 13 invention as claimed, right? 14 PROFESSOR ERSTLING: That's correct. 15 MR. SPELLISCY: In fact, if we further 16 understand this -- now, I should say the PCT or the 17 regulations don't provide any further detail as to 18 what it means to disclose the invention as claimed in 19 No. (iii), correct? 20 PROFESSOR ERSTLING: Because the 21 disclosure requirement and the utility requirement 22 are different things -- and if you would look at 23 5.1(a)(vi), that provides the description that is 24 required for utility, for industrial applicability. 25 MR. SPELLISCY: That's a separate</p> <p>www.dianaburden.com</p>

<p>1 requirement. We're going to get to that requirement. 2 You would agree with me that section (iii) has to 3 disclose the invention as claimed. You just said 4 that -- and I think you say in your report that -- 5 disclosure is not at issue here, correct? 6 PROFESSOR ERSTLING: Disclosure in 7 terms of meeting the sufficiency and enablement 8 requirement is not at issue here because that is 9 different from what is required for utility or 10 industrial applicability. 11 MR. SPELLISCY: Let me try and 12 understand that, because I'm not sure that I do. If 13 we can turn to tab 8 in your binder, this is an 14 excerpt from R-042, and you'll see at the top it's an 15 excerpt from the PCT Applicant's Guide. The date at 16 the bottom is July 24, 2014. Do you see that? 17 PROFESSOR ERSTLING: Yes, which I 18 don't think is the most recent version, but the 19 differences would be minor. 20 MR. SPELLISCY: I want to look at 21 5.094 first, how the description must be drafted. It 22 says, "The description must disclose the invention in 23 a manner sufficiently clear and complete for it to be 24 carried out by a person skilled in the art," in the 25 first sentence in 5.094. Do you see that?</p> <p>www.dianaburden.com</p>	<p>1606</p> <p>1 SIR DANIEL BETHLEHEM: Page 29? 2 MR. SPELLISCY: It is page 29. 3 PROFESSOR ERSTLING: Yes. 4 MR. SPELLISCY: Next paragraph, 5.095, 5 says on the same page, "The details required for the 6 disclosure of the invention so that it can be carried 7 out by a person skilled in the art depend on the 8 practice of the national Offices. It is therefore 9 recommended that due account be taken of national 10 practice (for instance in Japan and the United States 11 of America) when the description is drafted. The 12 need to amend the description during the national 13 phase may thus be avoided." 14 Do you see that? 15 PROFESSOR ERSTLING: Yes. 16 MR. SPELLISCY: So the WIPO Applicant 17 Guide is warning applicants in the international 18 phase to take account of national laws regarding what 19 is required in the disclosure. Is that right? 20 PROFESSOR ERSTLING: It is. However, 21 this is not the chapter of the search and examination 22 guidelines that deals with meeting the utility 23 requirement. 24 MR. SPELLISCY: Right, the search and 25 examination guidelines are for the advisory opinion</p> <p>www.dianaburden.com</p>
<p>1608</p> <p>1 in the international preliminary examination, 2 correct? 3 PROFESSOR ERSTLING: Yes. 4 MR. SPELLISCY: This is a guide 5 directed to applicants on how to file their 6 application, correct? 7 PROFESSOR ERSTLING: That's correct. 8 MR. SPELLISCY: So the PCT WIPO is 9 warning applicants when they're drafting disclosure 10 that due account be taken of national practice. We 11 agree on that, right? 12 PROFESSOR ERSTLING: Yes, that's 13 correct. 14 MR. SPELLISCY: Turn to tab 9 of your 15 little red binder, which is an excerpt from R-043. 16 PROFESSOR ERSTLING: May I just add 17 one thing more to the question? 18 MR. SPELLISCY: Sure. 19 PROFESSOR ERSTLING: The Applicant's 20 Guide is -- you are absolutely correct -- telling 21 applicants that they need to take due account of 22 national practice, but it's national practice that is 23 generally contemplated and anticipated in the PCT 24 practice and in actual national practice throughout 25 the world, and so what I don't think the paragraph</p> <p>www.dianaburden.com</p>	<p>1609</p> <p>1 that you cited necessarily puts applicants on warning 2 that it needs to be aware of every distinct practice 3 or substantive condition that may apply in all 148 4 member countries. Again, because the PCT is sort of 5 rooted in common understandings, provisions that are 6 unique or outlying provisions, I don't think there is 7 in the PCT a sense that applicants need to be aware 8 of national practice to the degree that I think your 9 question may allude to, if that makes sense. 10 MR. SPELLISCY: Can you go back to tab 11 8, and let's look at the paragraph again. 12 PROFESSOR ERSTLING: Where in tab 8? 13 MR. SPELLISCY: It's at page 29, 14 R-042, paragraph 5.095. Can you point me to where it 15 says what you just told me in that paragraph? 16 PROFESSOR ERSTLING: I can't point you 17 exactly to that. I think that is implied. The 18 paragraph also provides that the purpose of 19 attempting to be aware of national practice is to 20 avoid the need, or to minimize the need because there 21 generally is usually a need, to amend the description 22 during the national phase. And in Canada, because of 23 the evidentiary rule of sound prediction, the ability 24 to amend the description during the national phase is 25 both limited and is accompanied by an increased risk.</p> <p>www.dianaburden.com</p>

<p>1610</p> <p>1 So I believe that what is underlying in this is that, 2 if there is a need to amend the description, which 3 applicants should try to minimize, the amendments 4 that will be made during the national phase won't end 5 up being penalties, or even resulting in the loss of 6 a priority right, for example. 7 MR. SPELLISCY: Right. So if 8 applicants -- what WIPO is telling applicants is that 9 if applicants take due account of national practice 10 when the description is drafted they may avoid the 11 need to amend the description and avoid the priority 12 problems that you are mentioning, correct? 13 PROFESSOR ERSTLING: Yes, that's 14 correct. 15 MR. SPELLISCY: Let's turn to tab 9 16 again, R-043. These are excerpts from the 17 practitioner's guide to the PCT authored by yourself, 18 Mr. Helfgott and Mr. Reed? 19 PROFESSOR ERSTLING: That's correct. 20 MR. SPELLISCY: I want to turn to 21 what's page 200 in this excerpt, in this exhibit -- 22 page 200 in the book. There is a heading No. 2 that 23 says "Different laws in Different Countries." 24 Mr. Helfgott wrote this chapter, correct? 25 PROFESSOR ERSTLING: That's correct.</p> <p>www.dianaburden.com</p>	<p>1611</p> <p>1 MR. SPELLISCY: He wrote "In order to 2 be sure that your PCT application will be a viable 3 application in foreign countries, care must be given 4 to the various laws in foreign countries that may be 5 different from those in the United States. In many 6 cases the patent laws of many countries have been 7 harmonized, but there are still differences, and 8 these must be considered." 9 You would agree with Mr. Helfgott? 10 PROFESSOR ERSTLING: I would. He put 11 this in a chapter that was suggestions and 12 recommendations for solid drafting. The provision 13 goes on to say, if I remember correctly, that what 14 Mr. Helfgott was really -- was primarily referring to 15 was the situation in the United States where we were 16 at that point transitioning from a first-to-invent to 17 a first-to-file system and that, as a result of that, 18 being aware of needing to file applications early 19 became more important and that we, in the United 20 States, have a grace period that few countries have, 21 and that the awareness that most countries do not 22 have a grace period and a disclosure can immediately 23 eliminate your right to seek a patent in a country 24 needed to be taken into consideration. 25 It was really at that high level, not</p> <p>www.dianaburden.com</p>
<p>1612</p> <p>1 that you needed to get into the weeds of the national 2 laws of every PCT member country. 3 MR. SPELLISCY: I understand that's 4 the example that he gives in the following 5 paragraphs. What he says is the differences between 6 the various laws in foreign countries must be 7 considered. That's what he writes, right? 8 PROFESSOR ERSTLING: That's correct. 9 MR. SPELLISCY: And, as you indicated, 10 you agree with that, correct? 11 PROFESSOR ERSTLING: I agree with that 12 in the context in which it was stated. 13 MR. SPELLISCY: I want to now refer 14 you and discuss with you your view that you raised 15 earlier on the disclosure requirements. You 16 mentioned earlier but if we come to paragraph 14 of 17 your Second Report, I think this is what we just 18 talked about in the last sentence in this paragraph. 19 You say: "The PCT recognizes the need for adequate 20 disclosure by expressly requiring that the claims in 21 an international application shall be fully supported 22 by the description." Then you write, "But the 23 disclosure requirement is not at issue here." That's 24 the last part that I want to focus on. 25 If you could turn to tab 3 of your</p> <p>www.dianaburden.com</p>	<p>1613</p> <p>1 binder, which is Exhibit R-200, this is the Federal 2 Court decision of Justice Hughes in the Raloxifene 3 case. 4 PROFESSOR ERSTLING: I'm confused. In 5 which binder am I now? 6 MR. SPELLISCY: I'm always taking you 7 to the red binder. By referring to it as "your" 8 binder doesn't mean you take ownership of it, but 9 you're welcome to keep it, probably. 10 Tab 3, R-200, is the Justice Hughes 11 decision in the trial court level in the Raloxifene 12 case. I want to turn to page 20 now in this 13 decision. Look at paragraph 68 and the last line in 14 that paragraph. I'm going to go through a couple of 15 examples here just to show you some text, and then 16 I'll ask you some questions. 17 Justice Hughes writes, "We have 18 reached the point of the 'bargain' theory in which a 19 monopoly is exchanged for disclosure, a matter that 20 is important in consideration of sound prediction and 21 sufficiency." Do you see that? The last sentence? 22 PROFESSOR ERSTLING: Yes. 23 MR. SPELLISCY: If we keep going in 24 this decision and turn to page 46 now and to 25 paragraph 163, the very last sentence here which is</p> <p>www.dianaburden.com</p>

<p>1614</p> <p>1 the holding, "Thus, for lack of disclosure, there was 2 no sound prediction." Correct? You see that? 3 PROFESSOR ERSTLING: Yes. I'm just 4 reading the whole paragraph. 5 MR. SPELLISCY: Sure. 6 PROFESSOR ERSTLING: Yes. 7 MR. SPELLISCY: If we keep going in 8 this decision to page 49, I guess it's paragraph 183 9 although it's really between 183 and 184, there is a 10 section that says "In Summary," and if we look at the 11 summary the Federal Court provided in the fourth 12 bullet we see that it rules, "Apotex's allegation in 13 respect of lack of sound prediction is justified 14 because the '356 patent lacks adequate disclosure." 15 Correct? 16 PROFESSOR ERSTLING: That's what it 17 says, yes. 18 MR. SPELLISCY: So you would agree 19 with me that the Federal Court of Canada, the trial 20 level, in making its decision saw this as a 21 disclosure requirement, correct? 22 PROFESSOR ERSTLING: Yes, it did. 23 MR. SPELLISCY: Let's turn to tab 4, 24 which is the Federal Court of Appeal decision again, 25 R-354. Let's turn to page 4 in this decision,</p> <p>www.dianaburden.com</p>	<p>1615</p> <p>1 paragraph 3. 2 The Federal Court of Appeal says, "The 3 Federal Court judge dismissed Eli Lilly's application 4 on the basis that Apotex's allegation in respect of 5 lack of sound prediction was justified because the 6 '356 patent lacks adequate disclosure." 7 You see that? 8 PROFESSOR ERSTLING: Yes, I do. 9 MR. SPELLISCY: Turn to page 6 and 10 paragraph 15. The Federal Court of Appeal concludes, 11 "In my respectful view, the Federal Court judge 12 proceeded on proper principle when he held, relying 13 on AZT, that when a patent is based on a sound 14 prediction, the disclosure must include the 15 prediction. As the prediction was made sound by the 16 Hong Kong study, this study had to be disclosed." 17 Are you there with me on that? 18 PROFESSOR ERSTLING: Yes, I am. 19 MR. SPELLISCY: So you would agree 20 with me that the Federal Court of Appeal also viewed 21 it as disclosure that was at issue, correct? 22 PROFESSOR ERSTLING: Yes to a certain 23 extent, which I -- so I think there are two issues 24 here. 25 First of all, in accordance with the</p> <p>www.dianaburden.com</p>
<p>1616</p> <p>1 PCT, the PCT is not saying that there cannot be 2 disclosure of utility. It's simply saying that the 3 requirement, if it is beyond which the PCT requires, 4 that additional disclosure, to use that term, needs 5 to be allowed to be made by the applicant in the 6 national phase. It's simply that it just can't be 7 required in the application. It doesn't mean that it 8 can't be required. 9 In addition there's disclosure of 10 utility, which I would assume this is talking about, 11 and disclosure of enablement and sufficiency, and 12 that is where my report said there is a distinction. 13 There are the substantive conditions of 14 patentability, and obviously they must be met. They 15 are met through the written description and through 16 the disclosure, but disclosure for the purpose of 17 enablement and sufficiency and disclosure for the 18 purpose of utility are not necessarily the same 19 thing. 20 But the most important thing in all of 21 this with respect to utility is, from a PCT 22 perspective, that it's simply that an applicant 23 should not be penalized, an application should not be 24 denied or a patent invalidated because the disclosure 25 which goes beyond that which the PCT requires was not</p> <p>www.dianaburden.com</p>	<p>1617</p> <p>1 in the international application. 2 MR. SPELLISCY: So as I understand 3 your opinion, then, you're basing this on rule 4 5.1(a)(vi) of the regulations. I think you said even 5 in your presentation that the PCT requirements mean 6 that there can be, at most, an express statement of 7 utility required and nothing more, correct? 8 PROFESSOR ERSTLING: That in order to 9 meet the form and contents requirement there needs to 10 be an explicit statement when an implicit 11 understanding isn't just readily available, and that 12 again reflecting the prevailing international norm. 13 MR. SPELLISCY: So we would agree that 14 an implicit statement is less than an express 15 statement? 16 PROFESSOR ERSTLING: Well, it could be 17 inherent in the nature of the invention itself. As 18 the search and examination guidelines state, in most 19 cases the utility will be self-evident. 20 MR. SPELLISCY: And if it is not 21 self-evident, the most that can be required is an 22 express statement, is what you're saying, correct? 23 PROFESSOR ERSTLING: Yes. And then in 24 the national phase, if a member country requires 25 more, it can require more. It just can't penalize</p> <p>www.dianaburden.com</p>

<p>1618</p> <p>1 the applicant for not having included that in the 2 application. 3 MR. SPELLISCY: There's where I'm not 4 sure I follow. Your opinion, then, is that, even if 5 the expressly stated utility in an international 6 application is not specific, substantial and 7 credible, nothing more can be required as long as 8 it's expressly stated. Is that your opinion? 9 PROFESSOR ERSTLING: No, because 10 significant, substantive and credible is the 11 substantive rule, condition, upon which that 12 statement will be judged. There are two different 13 things. There's the judging of the statement and the 14 statement itself. In most cases, if it is not deemed 15 to meet the substantive requirement of utility, the 16 examiner will simply ask for more. 17 MR. SPELLISCY: But there's where I 18 don't understand, Mr. Erstling, because you said that 19 at most what can be required is an express statement 20 of utility, but then you've just said that an express 21 statement of utility is not all that's required; it 22 has to be an express statement of utility that is 23 specific, substantial, credible, because you said 24 that's the substantive rule upon which the statement 25 will be judged. Those two are in conflict, are they</p> <p>www.dianaburden.com</p>	<p>1619</p> <p>1 not? 2 PROFESSOR ERSTLING: No, not in my 3 view -- actually, not at all. The drafter of the 4 application, in order to meet the form and contents 5 requirement, needs to include, where it's not 6 inherent, an explicit statement of the way in which 7 the invention can be exploited industrially, or the 8 way in which it can be made and used. It's then up 9 to the examiner to determine whether that statement 10 meets the substantive condition of patentability. 11 There's one thing that is what the law 12 requires, and then there's the information that you 13 provide in the application upon which that 14 requirement will be judged. 15 MR. SPELLISCY: So it is up to the 16 examiner to determine whether that statement meets 17 the substantive condition of patentability. That's 18 what you just said, correct? I'm reading from the 19 transcript, if that helps -- which I have and you 20 don't! 21 PROFESSOR ERSTLING: I know. That's 22 unfair, you know! 23 Well, it is the role of the examiner 24 to determine whether the conditions of patentability 25 have been complied with or not.</p> <p>www.dianaburden.com</p>
<p>1620</p> <p>1 MR. SPELLISCY: And the PCT has 2 nothing to say on what those substantive conditions 3 of patentability are, correct? 4 PROFESSOR ERSTLING: That's correct. 5 MR. SPELLISCY: Thank you, 6 Mr. Erstling. I don't have any other questions this 7 morning. 8 THE PRESIDENT: Thank you. Any 9 questions for redirect? 10 MS. WAGNER: I do have one or two, if 11 I can have two minutes to shuffle my notes. 12 THE PRESIDENT: Please go ahead. 13 RE-DIRECT EXAMINATION ON BEHALF OF THE CLAIMANT 14 MS. WAGNER: Good morning again, 15 Professor Erstling. Can we go back to tab 8 in your 16 binder, which is the cross-examination binder. The 17 discussion was at page 29. 18 Mr. Spelliscy was asking you about 19 section 5.094 and section 5.095, and the tenor of the 20 question is related to 5.095 specifically and the 21 need for applicants to take due account of national 22 practice, which is what it states here. 23 Would applicants consider disclosure 24 of proof of utility to be part of the requirements 25 that they need to take account of here?</p> <p>www.dianaburden.com</p>	<p>1621</p> <p>1 PROFESSOR ERSTLING: I don't think so. 2 I think what they would assume is that, in accordance 3 with standard practice, utility is something that's 4 simply stated, and then it's evaluated on those 5 grounds. To my knowledge, Canada is the only country 6 that requires proof. 7 MS. WAGNER: Thank you. And where 8 does Canada require that proof, to be clear? 9 PROFESSOR ERSTLING: Proof that the 10 invention, the utility of the invention, has been 11 soundly predicted. 12 MS. WAGNER: And where is it required 13 in Canada? 14 PROFESSOR ERSTLING: Oh, in the 15 application as filed. 16 MS. WAGNER: One other question. You 17 had an exchange with Mr. Spelliscy at the end of the 18 cross-examination there about specific, substantial 19 and credible. If there was just an express statement 20 of utility where one is required in the application, 21 then how does the member country have an opportunity 22 to evaluate whether that statement is specific, 23 substantial or credible? How and what can they ask 24 for, and in what context? 25 PROFESSOR ERSTLING: Well, in most</p> <p>www.dianaburden.com</p>

<p>1622</p> <p>1 cases an examiner would look at what the claimed 2 invention is and on that basis determine whether it 3 is useful or, in an industrial applicability 4 standard, whether it has an application in industry. 5 In general, if there is doubt, then 6 the examiner would in some way reach out to the 7 applicant. It may be raising an issue in an office 8 action to which the applicant could respond, or it 9 may be, depending upon national practice, in informal 10 give-and-take with the examiner, but there generally 11 would be an opportunity to, if there were doubt, to 12 be able to overcome that doubt. 13 MS. WAGNER: And, putting Canada 14 aside, would that material to be provided to overcome 15 the doubt have to be in the application? 16 PROFESSOR ERSTLING: No. It would 17 generally be supporting material that would be 18 supplied post-filing. 19 MS. WAGNER: And is there a particular 20 format that the supporting material would take, or... 21 PROFESSOR ERSTLING: No, not -- it 22 could be in the form of affidavits. It could be in 23 the form of supplying evidence or certificates of 24 clinical data. It could be, where there is doubt, 25 anything that would overcome that doubt.</p> <p>www.dianaburden.com</p>	<p>1623</p> <p>1 MS. WAGNER: Thank you, 2 Professor Erstling. 3 THE PRESIDENT: Any application for 4 recross? 5 MR. SPELLISCY: None. 6 THE PRESIDENT: Thank you. Question 7 by Sir Daniel. 8 QUESTIONS BY THE ARBITRAL TRIBUNAL 9 SIR DANIEL BETHLEHEM: Thank you very 10 much, Professor Erstling. My questions, as usual, on 11 these topics come with a caveat of my ignorance. 12 Unlike our President I did not spend my formative 13 years in the bowels -- or even the 13th floor -- of 14 WIPO. I'm a little bit more familiar with some of 15 the other Geneva organizations closer to the lake. 16 PROFESSOR ERSTLING: I know which one! 17 SIR DANIEL BETHLEHEM: I'd just like 18 to try and situate some of your observations in that 19 context. In your presentation -- and this was a 20 theme that you came back to in the context of the 21 cross-examination -- your testimony was that Canada's 22 rule for evidence of sound prediction is in breach of 23 Article 27(1) of the PCT. Counsel for Canada took 24 you to Article 59 relating to the settlement of 25 disputes in ICJ, and I'd note just as an aside that,</p> <p>www.dianaburden.com</p>
<p>1624</p> <p>1 certainly as I see the PCT website, neither Canada 2 nor the United States has made a declaration under 3 Article 64 paragraph 5. 4 I'm less interested in that. What I'd 5 like to try and explore is whether there are other 6 mechanisms within the PCT Office, the one that you 7 were the Director of, in which issues of 8 compatibility or incompatibility would have been 9 addressed, something akin to the way, for example, in 10 which the World Trade Organisation may, through its 11 trade policy review mechanism or something of that 12 nature, focus on these issues. 13 My first question is just to ask you 14 if you could describe or explain for me what a 15 notification of incompatibility is under the PCT 16 rules, and whether this would have any relevance to 17 our discussion? 18 PROFESSOR ERSTLING: To be perfectly 19 honest, I actually don't know what a notification of 20 incompatibility would be or what form it would take. 21 If you're speaking within Article 59, again -- 22 SIR DANIEL BETHLEHEM: No. Let me 23 clarify, excuse me. I'm not speaking within the 24 context of Article 59, but I see across a number of 25 the rules that there is an opportunity for</p> <p>www.dianaburden.com</p>	<p>1625</p> <p>1 Intellectual Property Offices in States to make 2 declarations of incompatibility. 3 PROFESSOR ERSTLING: Yes -- oh, so 4 when the PCT rules are amended, which is a matter of 5 general consensus and takes an enormously long time 6 for consideration, in certain cases the adoption of 7 the rule will be contrary to countries' national 8 laws, and in those cases what often happens is the 9 country doesn't want to block the adoption of the 10 rule but it says that it cannot currently accept that 11 rule because it is in contravention of its national 12 law. So, in those cases, countries are free to file 13 notices of incompatibility to let the world know that 14 the rule will not apply to them until such time as 15 they are able to amend their national law. And then 16 they withdraw the notice of incompatibility. 17 SIR DANIEL BETHLEHEM: Are issues of 18 incompatibility, whether or not the subject of a 19 notification of incompatibility, are those issues 20 discussed within the Office that you used to head? 21 PROFESSOR ERSTLING: Only on an 22 informal basis. We would receive complaints. 23 Sometimes they were complaints that particularly the 24 legal division of the office would receive. It would 25 always respond by saying that under the PCT, the</p> <p>www.dianaburden.com</p>

<p>1 Office of the PCT, the International Bureau, didn't 2 have authority to be able to either issue notices of 3 violation or really take any effective measure, but 4 it would occasionally attempt to exert informal 5 influence or undertake discussions. 6 SIR DANIEL BETHLEHEM: So would 7 complaints come to your office in the form of, as it 8 were, informal comments, observations in the 9 corridor, observations in the meetings of contracting 10 parties? Would there be formal communications, a 11 state saying "We are concerned about the law of a 12 particular state"? 13 PROFESSOR ERSTLING: No. The comments 14 would generally come from the applicants themselves 15 who felt that they may have been aggrieved. In most 16 cases it is when they have entered the national 17 phase. Sometimes it's in the international phase. 18 Those are not a regular occurrence. 19 What the office of the PCT maintains 20 is a helpline, and sometimes that's where these 21 questions or problems arise. Sometimes it's in the 22 form of letters. 23 SIR DANIEL BETHLEHEM: Your testimony 24 that Canada's rule for evidence of sound prediction 25 is in breach of Article 27(1) seems to go to a pretty</p> <p>www.dianaburden.com</p>	<p>1626</p> <p>1 fundamental aspect of the way in which the PCT 2 operates. In the light of what you've just said, and 3 given that you were the director of the Office 4 between 2002 and 2007, which covers a very important 5 part of the period that we're looking at, would you 6 have expected to receive, or to your recollection did 7 you receive, from applicants, from the United States, 8 from other states, any complaints about Canada's 9 sound prediction law? 10 PROFESSOR ERSTLING: I can't point to 11 anything in particular that I recall, but when I was 12 contacted by Eli Lilly in 2009 -- although I was 13 really very, very ignorant of the situation -- it 14 wasn't a surprise. It was not the first time that I 15 had heard about this. But to put it in the exact 16 context, I just can't recall. 17 SIR DANIEL BETHLEHEM: But there's 18 nothing -- in case I've sort of missed it -- in your 19 reports which puts a sort of finger on any 20 communication or internal consideration or anything 21 of that nature which would indicate that what you 22 said in your report -- which is much more 23 contemporaneous with this dispute -- had a reference 24 back to concerns which were expressed at the time 25 that you were the director of the Office?</p> <p>www.dianaburden.com</p> <p>1627</p>
<p>1 PROFESSOR ERSTLING: Yes. That's 2 correct. There's nothing in particular that I could 3 point to. 4 If I may just add a little bit, 5 because I think I gave you a very inadequate answer 6 to your question about the way that consultations 7 take place, there are often discussions 8 country-to-country that the Office itself is not 9 privy to. The way the Office is structured there are 10 formal meetings where different offices could get 11 together, so there is a group -- now I think it's 12 15 -- of international search and preliminary 13 examination authorities, and both Canada and the 14 United States are international search and 15 preliminary examination authorities. That group of 16 offices will get together generally in Geneva to look 17 at some technical issues. 18 There's also a very large annual 19 meeting of the Assembly of the PCT with all of the 20 member states, and there are then also working group 21 meetings that take place. In those the Office of the 22 PCT plays obviously a very direct role, but then 23 there are lots of -- as you would know from your 24 experience -- discussions in the hallways as well. 25 SIR DANIEL BETHLEHEM: May we assume,</p> <p>www.dianaburden.com</p> <p>1628</p>	<p>1 in the light of what you've just said, though, that 2 if you haven't referred to any documents, as it were, 3 coming out of the Office of the PCT, that there is 4 nothing, to your knowledge or recollection, that's 5 relevant to this case that comes out of these types 6 of meetings? 7 PROFESSOR ERSTLING: That is true, 8 with the one exception of, particularly in the rules, 9 when countries have a substantive condition of 10 patentability that is somewhat different, the country 11 has the opportunity in several meetings to bring that 12 up and to make sure that that is explicitly included 13 in the rules. For example, the explicit provision 14 concerning best mode. There are not very many -- 15 there are very few countries that require best mode, 16 but the rule specifically says that you have to 17 provide for best mode, or furnishing of nucleotide or 18 amino acid sequence listings, so there would be the 19 possibility, to the extent that a country would want 20 its requirement to be embodied within the PCT rules, 21 to bring those up and to have those added to the 22 rules. 23 SIR DANIEL BETHLEHEM: Thank you very 24 much. 25 THE PRESIDENT: A question by</p> <p>www.dianaburden.com</p> <p>1629</p>

<p>1630</p> <p>1 Mr. Born.</p> <p>2 MR. BORN: Just a very brief question,</p> <p>3 and I don't recall it being addressed in either of</p> <p>4 your two reports so it may take you outside of your</p> <p>5 zone of comfort.</p> <p>6 Can we look at Article 59 of the PCT</p> <p>7 again? It's at tab 5 of the red binder. I suppose</p> <p>8 it's in the white binder, but look in tab 5. You can</p> <p>9 help me with this. If there are not Article 64(5)</p> <p>10 declarations, then, if I understand it, Article 59</p> <p>11 would provide a submission to ICJ jurisdiction for</p> <p>12 state-to-state disputes about the PCT. Is that</p> <p>13 right?</p> <p>14 PROFESSOR ERSTLING: Yes, that's</p> <p>15 correct, unless the states agree on some other way</p> <p>16 of resolving.</p> <p>17 MR. BORN: That was my question. It's</p> <p>18 not, so far as I understand it, an exclusive means of</p> <p>19 dispute resolution. It's mandatory if it hasn't been</p> <p>20 opted out of under Article 64(5), but it's not</p> <p>21 exclusive in the sense that any two states, any group</p> <p>22 of states, are free to agree to an alternative</p> <p>23 mechanism?</p> <p>24 PROFESSOR ERSTLING: Yes, that's</p> <p>25 correct. That's my understanding.</p> <p>www.dianaburden.com</p>	<p>1631</p> <p>1 MR. BORN: Does it apply to disputes</p> <p>2 about the PCT, questions of interpretation in the</p> <p>3 PCT, other than state-to-state disputes?</p> <p>4 PROFESSOR ERSTLING: No. My</p> <p>5 understanding is that the provision of Article 59 is</p> <p>6 to deal with state-to-state disputes.</p> <p>7 MR. BORN: You may not know the answer</p> <p>8 to this but, in the Raloxifene litigation in Canada,</p> <p>9 was there any suggestion the Canadian court couldn't</p> <p>10 interpret, look to the terms of the PCT, in that</p> <p>11 litigation?</p> <p>12 PROFESSOR ERSTLING: You're right, I</p> <p>13 don't know the answer to that.</p> <p>14 MR. BORN: Thank you. No further</p> <p>15 questions.</p> <p>16 THE PRESIDENT: Any follow-up</p> <p>17 questions?</p> <p>18 MS. WAGNER: No questions, thank you.</p> <p>19 MR. SPELLISCY: None, thank you.</p> <p>20 THE PRESIDENT: Mr. Erstling, thank</p> <p>21 you for testifying. You are now released as a</p> <p>22 witness and are excused.</p> <p>23 PROFESSOR ERSTLING: Thank you.</p> <p>24 THE PRESIDENT: Recess until 11:00.</p> <p>25 (Recess taken)</p> <p>www.dianaburden.com</p>
<p>1632</p> <p>1 THEODORE DAVID REED</p> <p>2 THE PRESIDENT: Good morning,</p> <p>3 Mr. Reed.</p> <p>4 MR. REED: Good morning.</p> <p>5 THE PRESIDENT: Could you please state</p> <p>6 your full name for the record?</p> <p>7 MR. REED: My name is Theodore David</p> <p>8 Reed. Go by David.</p> <p>9 THE PRESIDENT: Mr. Reed, if any</p> <p>10 question is unclear to you, either because of</p> <p>11 language or for any other reason, please do seek a</p> <p>12 clarification because, if you don't do so, the</p> <p>13 Tribunal will assume that you've understood the</p> <p>14 question --</p> <p>15 MR. REED: I think everything is fine</p> <p>16 as it currently stands.</p> <p>17 THE PRESIDENT: -- and that your</p> <p>18 answer corresponds to the question.</p> <p>19 MR. REED: I missed that.</p> <p>20 THE PRESIDENT: Again, if you do not</p> <p>21 seek clarification for a question the Tribunal</p> <p>22 assumes that you understood the question and that</p> <p>23 your answer corresponds to the question.</p> <p>24 MR. REED: Okay.</p> <p>25 THE PRESIDENT: You understand that?</p> <p>www.dianaburden.com</p>	<p>1633</p> <p>1 MR. REED: Yes. I think so.</p> <p>2 THE PRESIDENT: If you think so,</p> <p>3 that's not enough for me. You must be certain.</p> <p>4 Mr. Reed, you will appreciate that</p> <p>5 testifying, be it before a court or an arbitral</p> <p>6 tribunal, is a very serious matter. In that</p> <p>7 connection, the Tribunal expects you to give the</p> <p>8 declaration, the text of which is in front of you.</p> <p>9 MR. REED: I solemnly declare upon my</p> <p>10 honor and conscience that my statements will be in</p> <p>11 accordance with my sincere belief.</p> <p>12 THE PRESIDENT: Thank you. You will</p> <p>13 be assisted by the unlimitedly resourceful secretary</p> <p>14 of the Tribunal. Can you hear me?</p> <p>15 MR. REED: Yes, much better.</p> <p>16 THE PRESIDENT: One thing I must make</p> <p>17 clear because I don't think you understood everything</p> <p>18 I told you in the beginning.</p> <p>19 If any question is unclear, either</p> <p>20 because of language or for any other reason, do seek</p> <p>21 a clarification because, if you don't do so, the</p> <p>22 Tribunal assumes you have understood the question and</p> <p>23 that your answer corresponds to the question?</p> <p>24 MR. REED: Very well. I understood</p> <p>25 that completely.</p> <p>www.dianaburden.com</p>

<p>1634</p> <p>1 THE PRESIDENT: Good. Mr. Reed, could 2 you please go to your expert reports, and go first to 3 the First Report which is dated 26 January 2015? 4 Could you go to page 24? 5 MR. REED: Yes, I've found page 24. 6 THE PRESIDENT: Could you please 7 confirm for the record that the signature appearing 8 above your name is your signature? 9 MR. REED: The signature is mine, yes. 10 THE PRESIDENT: Could you please go to 11 the Second Report dated December 7, 2015, and go to 12 page 14 and confirm for the record that the signature 13 appearing above your name is your signature? 14 MR. REED: Yes, that is my signature. 15 THE PRESIDENT: Mr. Reed, is there any 16 correction you wish to make to either report? 17 MR. REED: No, not at this time. 18 THE PRESIDENT: Thank you. 19 Mr. Spelliscy, you have the privilege of starting the 20 direct examination. 21 MR. SPELLISCY: Good morning, 22 Mr. Reed. I know you have a presentation to present, 23 so please go ahead. 24 PRESENTATION BY MR. REED 25 MR. REED: Okay. Thank you.</p> <p>www.dianaburden.com</p>	<p>1635</p> <p>1 A number of the things in my 2 presentation were covered by Mr. Erstling and some of 3 the things we just heard during his 4 cross-examination, but I'll go ahead and start and 5 give the same comments that I planned to give when I 6 came in this morning. 7 As I say, my name is David Reed, and 8 I'm here today to talk about the PCT and some of its 9 features based on my experience as a long-time 10 practitioner under PCT, as well as over nine years of 11 teaching the PCT as an independent consultant for 12 WIPO. My teaching was primarily limited to the 13 United States and a few excursions into Canada 14 teaching the basics of the PCT. 15 First of all, I'd like to give you a 16 little background about myself. I have a Bachelor of 17 Science degree in Chemical Engineering from 18 Northwestern University, and I have also supplemented 19 that with some postgraduate studies also in Chemical 20 Engineering at the University of Cincinnati following 21 my employment at Procter & Gamble. In 1966 following 22 graduation I joined the Procter & Gamble company in 23 Cincinnati, Ohio as a development engineer working on 24 new products and new processes for the 25 Procter & Gamble company.</p> <p>www.dianaburden.com</p>
<p>1636</p> <p>1 In about 1980, I was taken off of my 2 product development duties and put onto a special 3 assignment to assist trial counsel in a number of 4 product liability lawsuits, and also to assist 5 Procter & Gamble's counsel in a number of patent 6 lawsuits. I became very interested in patent law and 7 in 1988 I took and passed the U.S. patent bar and 8 became a registered agent before the USPTO. 9 During my time at Procter & Gamble, 10 starting in 1990 in response to the needs of the 11 company, we converted our practice from a practice 12 under direct national practice under the Paris 13 Convention to a practice under the Patent Cooperation 14 Treaty. Since that conversion in late 1990, I have 15 either been the agent of record or have managed the 16 agents of record in over 9,000 PCT filings. 17 There was a time when P&G was the 18 largest single user of the PCT in the world. Long 19 since -- long ago we lost that title, but we had it 20 for a short period of time. But because of the wide 21 use we had of the PCT and the success we made in 22 utilizing the PCT, WIPO approached me in 1996 and 23 asked me if I would be available to go to countries 24 that were considering joining the PCT, or countries 25 that were just learning to use the PCT having joined</p> <p>www.dianaburden.com</p>	<p>1637</p> <p>1 the PCT, and lecture on P&G's practice on PCT, how it 2 worked, and the advantages we received. 3 THE PRESIDENT: Mr. Reed, on this 4 point -- because you have heard, with 5 Professor Erstling, that I have been also involved in 6 WIPO -- that was a different involvement. You have 7 been involved in teaching how the PCT works, I 8 understand; I have been involved in, A, drafting the 9 Arbitration Rules and B, in workshops on the WIPO 10 arbitration schemes. That's a different type of 11 instruction than what you have done. 12 So simply to be very clear for the 13 parties, we have never met before, never worked 14 together before, never taught together before. There 15 was a whole other part of WIPO. 16 MR. REED: Not only that, I was not 17 really invited to go to Geneva very often. We always 18 just went to foreign countries, so we would never run 19 into each other. 20 THE PRESIDENT: Okay. Good. 21 MR. REED: In 2006 I retired from P&G 22 after 40 years of service and, as I retired, WIPO 23 approached me and asked me if I would pass on my role 24 of relating Procter & Gamble's practice under the PCT 25 and take over operating a help desk as well as going</p> <p>www.dianaburden.com</p>

<p>1638</p> <p>1 around the United States giving PCT seminars, 2 teaching practitioners how to use the PCT to their 3 greatest advantage, and I did that full-time starting 4 in 2006 until 2014. At the end of 2014 I stopped 5 doing that, and am now looking forward to full 6 retirement.</p> <p>7 We've been talking about the PCT. 8 Exactly what is the PCT? The Patent Cooperation 9 Treaty is an international patent filing system. 10 Please note, it just works for filing patent 11 applications; it does not grant applications. 12 In my personal opinion, the PCT is the 13 greatest single advancement in foreign patent 14 practice since the advent of the Paris Convention in 15 1883.</p> <p>16 Under the PCT, the applicant will file 17 a single application in their home country, in 18 general; also in general in their home language; and 19 establish a filing date in all PCT contracting 20 states. There are currently 148 of them.</p> <p>21 In the process of the PCT, the 22 applicant will receive some very valuable information 23 regarding the prior art that can be found through the 24 international search, possibly get information 25 regarding the comparison of their particular claimed</p> <p>www.dianaburden.com</p>	<p>1639</p> <p>1 invention on novelty, inventive step, industrial 2 applicability.</p> <p>3 The PCT has also standardized some 4 formalities. Those are listed in Articles 3 through 5 7 and further detailed in Rules 5 through 8. But 6 primarily the PCT is set up to say that you need to 7 have a description in your application, you need to 8 have at least one claim; drawings if they're 9 necessary -- in many applications they're not 10 necessary; you want an abstract so that people can 11 search and find the information in your particular 12 case when it gets published, and finally a request 13 form that's going to contain a request to process 14 under the PCT, as well as bibliographic information 15 related to the particular application.</p> <p>16 We took a look at Rule 5.1. It was on 17 the screen a little bit earlier. As far as the 18 description is concerned, it was talking about such 19 things as wanting a description of what the prior art 20 is, the closest prior art, what the technical field 21 is -- a number of formal categories of what WIPO or 22 what the PCT says should be included in a PCT 23 application.</p> <p>24 In addition to those categories, we 25 also took a look at Rule 5.1(a)(vi). 5.1(vi) calls</p> <p>www.dianaburden.com</p>
<p>1640</p> <p>1 for an explicit statement, if it's not obvious based 2 on the description or the nature of the invention, an 3 explicit statement as to how the invention can be 4 exploited or used in the industry. Think of that in 5 the context of this particular proceedings as having 6 utility. And also how it can be made and used.</p> <p>7 The PCT process itself, once you have 8 the application, consists of two phases. 9 Mr. Erstling covered this to some 10 degree but the two phases are an international phase 11 in which the PCT is processed under the PCT 12 regulations. At the end of this international phase, 13 which is 30 months from the earliest claimed priority 14 date, the application if you're going to proceed to 15 seek patent protection then moves into the national 16 phase where the application is converted into a 17 national application for national processing.</p> <p>18 During this international phase, as I 19 mentioned, you will get a search. The particular 20 application will be sent to an international 21 searching authority. The searching authority will 22 look to find any relevant prior art that might affect 23 the novelty or inventive step of the particular 24 application.</p> <p>25 Since 2004, when there was a change in</p> <p>www.dianaburden.com</p>	<p>1641</p> <p>1 the PCT, post-2004 you will also get a written 2 opinion from the searching examiner where the 3 examiner will take the art found in the search report 4 and apply it against the novelty and inventive step 5 of your particular application. Prior to 2004 this 6 was not automatic and did not happen in the first 7 part of the international phase, but could be 8 obtained by applicants through payment of a fee and 9 making a request to go into what we would call 10 Chapter 2 examination, and Chapter 2 was a separate 11 process that an applicant can use or may choose not 12 to use, depending on what their particular needs are.</p> <p>13 In the search of prior art and also of 14 the written opinion, the examiners will follow the 15 guidelines that are provided under the WIPO as to how 16 to go ahead and examine the application. In addition 17 to working with the examiner to come up with the 18 final report as to whether the invention appears to 19 be novel or appears to be inventive or have 20 industrial application or utility, these are judged 21 against the guidelines in the PCT in Article 33.</p> <p>22 Please note that anything that comes 23 out of the PCT does not relate to the patentability 24 of the particular invention under any given national 25 law. Article 33 does give the standards that you can</p> <p>www.dianaburden.com</p>

<p>1 go in and see what the examiner is using to make the 2 judgments on that, but, again, any report or any 3 final report coming out of the examination process 4 under the PCT is merely advisory and does not have 5 any bearing on whether the application is truly 6 patentable or not patentable under any national law. 7 Also, if you go into preliminary 8 examination under Chapter 2 of the PCT, you also have 9 the opportunity to amend the application as well as 10 work with the examiner. In today's world, if you 11 have a written opinion that came with the search 12 report and you choose to rebut that with the 13 international examiner, you may go ahead and do that 14 under Chapter 2 of the Treaty. 15 Additionally, the PCT standardizes 16 formal requirements for all the contracting states, 17 and that really kind of gets down to the guts of what 18 we're going to be talking about today, the formality 19 standardization that occurs under PCT versus the 20 substantive requirements of patentability. 21 One thing we have to emphasize is that 22 the PCT does not grant patents. Granting of patents 23 is solely the responsibility and right of each 24 contracting state, and a contracting state will make 25 the judgment as to whether a patent should be granted</p> <p>www.dianaburden.com</p>	<p>1642</p> <p>1 or not under their own national laws. Second of 2 all -- I believe Mr. Erstling and I agree on this -- 3 the PCT does not standardize or harmonize national 4 laws or the conditions required to determine 5 patentability. Those are left to each of the 6 individual countries to set as they see fit. 7 Mr. Erstling in his report indicated, 8 again based on Rule 5.1(vi), I believe it is, that 9 unless it's obvious from the description and nature 10 of the invention, the author should write into the 11 application an explicit statement on the subject of 12 industrial applicability, utility, how the particular 13 invention can be used in industry, which is one of 14 the pillars, if you will, of patentability, along 15 with novelty or inventive step. 16 He then further goes on to take a look 17 at Article 27(1) which states that no national office 18 can have requirements that are in addition to or 19 different from those that are set forth in the PCT, 20 and that is based on looking at the form and 21 contents, as is described in Article 27(1). 22 Mr. Erstling then opines that Canada's requirement 23 regarding a factual basis and reasoning for leading 24 to a sound prediction is, in fact, a requirement of 25 form and contents different from or additional to</p> <p>www.dianaburden.com</p> <p>1643</p>
<p>1644</p> <p>1 what is called for in the PCT, because all the PCT 2 says is that you need an explicit statement regarding 3 utility if the utility is not, in fact, obvious from 4 the description or the nature of the invention. 5 Based on that he feels that the 6 Canadian requirement that the factual basis leading 7 to a sound prediction of utility be in the 8 application beginning at the date of filing is a 9 requirement of form and contents, and is in violation 10 of Article 27. 11 I disagree. Article 27(1) restricts 12 the form and contents that national law can require 13 in an international application. But what do we mean 14 by form and contents? If we take a look at the notes 15 from the Washington Conference on the PCT in 1970 and 16 see what they had to say about Article 27(1), the 17 first thing we see is something that Mr. Erstling put 18 up in a slide earlier talking about the description, 19 claims, et cetera. But the last sentence of that 20 particular comment was not put onto that slide, and 21 I'd like to go ahead and correct that now. It says 22 "The words 'form or contents' are used merely to 23 emphasize something that should go without saying, 24 namely that the requirements of substantive patent 25 law (criteria of patentability, et cetera) are not</p> <p>www.dianaburden.com</p>	<p>1645</p> <p>1 meant." 2 What Article 27(1) has to do with is 3 form and contents from the standpoint of broad 4 categories of material that are required to be 5 covered in the application, and not in any way to get 6 involved in restricting substantive criteria of 7 patent law which are not meant by the words "form and 8 contents." 9 The standardization of formal 10 requirements and just formal requirements is riddled 11 throughout the PCT. If you look at the WIPO training 12 material such as the PCT Applicant's Guide in section 13 4.011, if you look at material posted on the WIPO 14 website, the material supplied to me by WIPO for 15 teaching PCT, if you look at the Washington 16 Conference papers, in many cases they all talk about 17 the "standardization of formal requirements", so that 18 if your application is in good shape from a formality 19 standpoint, it will be accepted in each individual 20 country. 21 So, again, the form and contents does 22 not relate to substantive issues of patentability. 23 Those are left to the individual countries. As a 24 matter of fact, we looked at Article 27(5), which 25 we'll take a look at again here in a minute, which</p> <p>www.dianaburden.com</p>

<p>1 indicates that national laws can have any substantive 2 criterion that they want for determining 3 patentability. 4 27(5), as I mentioned, gives national 5 law complete freedom to prescribe substantive 6 conditions of patentability. Utility, like novelty 7 and inventive step, is a substantive condition of 8 patentability. 9 I mentioned the examination that is 10 put on by WIPO comes with every case after 2004 (it 11 could be ordered pre-2004) where an international 12 examiner will take a look at the particular 13 application. Insofar as utility or industrial 14 applicability is concerned, we have to go to the 15 international search and examination guidelines, 16 Chapter 14 and the annex to Chapter 14. 17 In that, when we take a look at 18 utility, utility has to be specific. It has to be 19 substantial and it has to be credible. Those are the 20 three things we heard yesterday as far as U.S. law, 21 the same three criteria for determining of utility. 22 But if all we have in the application, if all that 23 can be required to be in the application, is an 24 explicit statement of what the utility might be, 25 where are we going to find out if that particular</p> <p>www.dianaburden.com</p>	<p>1 application or invention has utility that is 2 substantial, specific and credible? The PCT 3 guidelines themselves send the people, send the 4 examiners, to the description. There's got to be 5 more in there in order to make a case for utility 6 than just an explicit statement, even during the PCT. 7 You can't send it in. The examination, at least in 8 today's world, is going to be conducted on the 9 application as it is filed. You can't add new 10 matter. In fact, indeed in today's world, when this 11 is put forth, there's not even an opportunity to 12 amend the case to add anything that might be 13 considered missing. 14 Also, form and contents does not 15 encompass what is required for sufficient disclosure 16 of the invention, including its utility under 17 national law. Let's take a look at the PCT 18 Applicant's Guide, and I think this was put up a 19 little bit earlier. The Applicant's Guide informs 20 the users and says "details required for the 21 disclosure of the invention so that it can be carried 22 out by a person skilled in the art depends on the 23 practices of national Offices" and warns applicants 24 "that due account be taken of national practice... 25 when the description is drafted."</p> <p>www.dianaburden.com</p>
<p>1 Based on everything I've seen in the 2 PCT, the use I've done in my over 9,000 applications, 3 et cetera, the PCT does not limit the right of a 4 contracting states to require, at the time of filing, 5 the disclosure of a factual basis and the reasoning 6 leading to a sound prediction of utility. These are 7 substantive conditions of patentability under 8 Canadian law and do not fall under the restrictions 9 of Article 27(1). 10 Thank you. 11 THE PRESIDENT: Thank you. 12 MR. SPELLISCY: We have no additional 13 questions on direct examination. 14 THE PRESIDENT: Thank you. 15 Cross-examination? 16 MS. CHEEK: Ms. Wagner will be 17 conducting the examination of Mr. Reed. 18 THE PRESIDENT: Ms. Wagner, please 19 proceed. 20 CROSS-EXAMINATION ON BEHALF OF THE CLAIMANT 21 MS. WAGNER: Good morning, Mr. Reed. 22 MR. REED: Good morning. 23 MS. WAGNER: I just want to pick up on 24 something you've just dealt with in your 25 presentation. We're just going to be on hold for a</p> <p>www.dianaburden.com</p>	<p>1 moment while everyone has the appropriate materials. 2 (Distributed) 3 SIR DANIEL BETHLEHEM: Is this bundle 4 the same just with the expert reports switched 5 around? 6 MS. WAGNER: That is entirely 7 possible, but I would actually have to check the 8 table of contents. It is a different binder, so 9 there may be -- 10 THE PRESIDENT: The binder is 11 different and the Expert Reports contained in it are 12 different. 13 MS. WAGNER: That's right, yes. 14 THE PRESIDENT: I think tab 5 is the 15 same, isn't it? It is again the Washington 16 Conference, which makes it so voluminous. 17 MS. WAGNER: I regret the number of 18 trees that have been killed in this process. The 19 exhibits are all the same; they're just ordered 20 differently. 21 SIR DANIEL BETHLEHEM: So, in fact, we 22 can just refer to this one? 23 MS. WAGNER: We can. Because I've 24 been working from the cross-examination binder it 25 might take me a moment to cross-reference tabs as I'm</p> <p>www.dianaburden.com</p>

<p>1650</p> <p>1 going through.</p> <p>2 THE PRESIDENT: Please proceed on the</p> <p>3 bundle you have just given to us.</p> <p>4 MS. WAGNER: Thank you.</p> <p>5 Mr. Reed, you were discussing in your</p> <p>6 presentation that -- actually I don't think your</p> <p>7 slides are numbered but it's the slide the title of</p> <p>8 which is "My opinion of Canada's rights (continued)"?</p> <p>9 MR. REED: They are numbered.</p> <p>10 MS. WAGNER: They are numbered. Slide</p> <p>11 7. You're correct.</p> <p>12 MR. REED: Slide 7. Okay.</p> <p>13 MS. WAGNER: You have at point 3, "The</p> <p>14 PCT advisory examination process itself requires more</p> <p>15 than an explicit statement of utility under some</p> <p>16 circumstances", and you refer to the Search and</p> <p>17 Examination Guidelines.</p> <p>18 Just to be clear on what that</p> <p>19 information might require, you'd agree that it might</p> <p>20 require things like prior art to be included in the</p> <p>21 application?</p> <p>22 MR. REED: Chapter 14 has to do with</p> <p>23 utility or industrial applicability. I don't see</p> <p>24 where prior art has any relevance to that particular</p> <p>25 question.</p> <p>www.dianaburden.com</p>	<p>1651</p> <p>1 MS. WAGNER: It might include things</p> <p>2 about the technical field to which the invention</p> <p>3 relates?</p> <p>4 MR. REED: I guess it could. That is</p> <p>5 a specific thing. That is part of the description.</p> <p>6 MS. WAGNER: That's right, yes. And</p> <p>7 it might include information such as information</p> <p>8 relating to dosing in a drug context?</p> <p>9 MR. REED: I really know little or</p> <p>10 nothing about the pharmaceutical industry, so I'm</p> <p>11 sure I'm even qualified to answer that.</p> <p>12 MS. WAGNER: That would be information</p> <p>13 that could be used to assess credibility of the use</p> <p>14 of a drug? Dosing information?</p> <p>15 MR. REED: Again, I have no knowledge</p> <p>16 of the pharmaceutical industry, so whether dosing</p> <p>17 information has anything to do with the use of a</p> <p>18 drug. I realize that's the instructions on how to</p> <p>19 administer it but it has nothing to do with the</p> <p>20 effects or...</p> <p>21 MS. WAGNER: And the method of</p> <p>22 administration might be something you could use to</p> <p>23 assess credibility?</p> <p>24 MR. REED: I can't see how the method</p> <p>25 of administering, whether you get a shot or take a</p> <p>www.dianaburden.com</p>
<p>1652</p> <p>1 pill or whatever, has anything to do with credibility</p> <p>2 regarding utility.</p> <p>3 MS. WAGNER: But you don't actually</p> <p>4 know because you're not familiar with the</p> <p>5 pharmaceutical industry?</p> <p>6 MR. REED: I am not familiar with the</p> <p>7 pharmaceutical industry.</p> <p>8 MS. WAGNER: Thank you. I just want</p> <p>9 to start with some questions about the PCT process,</p> <p>10 which you did outline. I just want to make sure that</p> <p>11 I have the sequencing correct in all of this. It's a</p> <p>12 bit complicated.</p> <p>13 In most circumstances what happens is</p> <p>14 that an applicant who wishes to obtain a patent will</p> <p>15 file an initial application somewhere in the world?</p> <p>16 MR. REED: In a Paris Convention or</p> <p>17 WTO country.</p> <p>18 MS. WAGNER: And that will be referred</p> <p>19 to as a "local" or "national" application?</p> <p>20 MR. REED: That's what I would call</p> <p>21 it, yes.</p> <p>22 MS. WAGNER: That would also be</p> <p>23 normally referred to as the "priority" application?</p> <p>24 MR. REED: If a subsequent case is</p> <p>25 filed in other jurisdictions within 12 months, it</p> <p>www.dianaburden.com</p>	<p>1653</p> <p>1 could be the priority application, yes.</p> <p>2 MS. WAGNER: Then, if the applicant</p> <p>3 wants to use the PCT system for filing their</p> <p>4 application globally, then within 12 months of that</p> <p>5 priority application they'll file their PCT</p> <p>6 application?</p> <p>7 MR. REED: In general, that's what</p> <p>8 they would do, yes.</p> <p>9 MS. WAGNER: And they will do that</p> <p>10 either with the office of a PCT contracting state, or</p> <p>11 directly with the International Bureau of WIPO. Is</p> <p>12 that correct?</p> <p>13 MR. REED: Yes. I would say they do</p> <p>14 it with the receiving office for the state in which</p> <p>15 they live. It's not with any -- they don't get to</p> <p>16 choose any receiving office. There are competent</p> <p>17 receiving offices, and the International Bureau is</p> <p>18 competent for residents and nationals of all PCT</p> <p>19 contracting states.</p> <p>20 MS. WAGNER: So when it's filed with a</p> <p>21 particular country then you'd normally refer to that</p> <p>22 country as a receiving office as the correct</p> <p>23 terminology?</p> <p>24 MR. REED: Right. Not every country</p> <p>25 that is in the PCT has a receiving office, but most</p> <p>www.dianaburden.com</p>

<p>1 of them do.</p> <p>2 MS. WAGNER: So then the filing of</p> <p>3 that international application starts off the PCT</p> <p>4 international phase?</p> <p>5 MR. REED: Yes.</p> <p>6 MS. WAGNER: And later on in that</p> <p>7 process at some point, that's when the PCT will do</p> <p>8 the international search?</p> <p>9 MR. REED: Yes.</p> <p>10 MS. WAGNER: And preliminary</p> <p>11 examination?</p> <p>12 MR. REED: After 2004, yes.</p> <p>13 MS. WAGNER: And at that stage at some</p> <p>14 point, again, the PCT will issue a non-binding</p> <p>15 opinion as to whether the international application</p> <p>16 meets patentability criteria?</p> <p>17 MR. REED: Again, after 2004, they</p> <p>18 will issue the written opinion that will express</p> <p>19 based on the prior art whether it's novel, inventive</p> <p>20 or industrially applicable. Prior to 2004, the</p> <p>21 applicant would have had to pay a fee and submit a</p> <p>22 demand for preliminary examination to start the</p> <p>23 process and get the written opinion.</p> <p>24 MS. WAGNER: I think I got it.</p> <p>25 MR. REED: Okay.</p> <p>www.dianaburden.com</p>	<p>1654</p>	<p>1 MS. WAGNER: And when the PCT</p> <p>2 international phase ends, then the applicant enters</p> <p>3 the national phase?</p> <p>4 MR. REED: Must do it within -- under</p> <p>5 the PCT the international phase ends at 30 months</p> <p>6 from priority. However, many countries will give you</p> <p>7 a little extra time, like Europe gives you 31 months.</p> <p>8 I think there's actually a country that gives you</p> <p>9 33 months. And the most generous is Canada, for</p> <p>10 instance, because for a very small fee, 200 Canadian</p> <p>11 dollars, you can get a 12-month extension. But it's</p> <p>12 not really a late fee. The \$200 is a late fee.</p> <p>13 MS. WAGNER: Good on Canada.</p> <p>14 And then they enter the national phase</p> <p>15 by converting the PCT international application into</p> <p>16 a national application in those Patent Offices in</p> <p>17 which they are seeking patent protection, correct?</p> <p>18 MR. REED: Yes.</p> <p>19 MS. WAGNER: So let's look at -- can</p> <p>20 you turn up tab 3, this is the Patent Cooperation</p> <p>21 Treaty itself, and I am looking at page 22.</p> <p>22 MR. REED: Okay. I've got page 22</p> <p>23 now.</p> <p>24 MS. WAGNER: Article 27 is listed</p> <p>25 there, and it deals with national requirements.</p> <p>www.dianaburden.com</p>	<p>1655</p>
<p>1 MR. REED: Uh-huh.</p> <p>2 MS. WAGNER: Correct? And Article 27</p> <p>3 is basically meant to address what happens in what we</p> <p>4 had established was called the national phase.</p> <p>5 MR. REED: Yes, it does. It has to do</p> <p>6 with what the national offices can and cannot</p> <p>7 require.</p> <p>8 MS. WAGNER: And basically the</p> <p>9 national requirements concern, as you said, the</p> <p>10 requirements that may be imposed by PCT member</p> <p>11 countries in, I guess, the last stage of the process</p> <p>12 when the PCT member country files in a member</p> <p>13 country, correct?</p> <p>14 MR. REED: I'm not sure I understood</p> <p>15 that. Try it again?</p> <p>16 MS. WAGNER: The national requirements</p> <p>17 in Article 27 deal with the requirements that may be</p> <p>18 imposed by PCT member countries when an applicant</p> <p>19 enters the national phase?</p> <p>20 MR. REED: Okay. I'll buy that.</p> <p>21 MS. WAGNER: And one of the</p> <p>22 requirements we've been discussing today is</p> <p>23 Article 27(1), and that's the one that says "No</p> <p>24 national law shall require compliance with</p> <p>25 requirements relating to the form and contents of the</p> <p>www.dianaburden.com</p>	<p>1656</p>	<p>1 international application different from and</p> <p>2 additional to those which are provided in this Treaty</p> <p>3 or Regulations."</p> <p>4 MR. REED: Accurately quoted.</p> <p>5 MS. WAGNER: And you may not agree</p> <p>6 with me on what "form and contents" means, but you do</p> <p>7 agree that Article 27 is addressing what happens in</p> <p>8 the national phase?</p> <p>9 MR. REED: Yes.</p> <p>10 MS. WAGNER: In several paragraphs of</p> <p>11 your reports you made the observation -- and I'll</p> <p>12 take you to them, so no surprises -- you made the</p> <p>13 observation that a PCT application will be received</p> <p>14 into the international phase of the PCT if it</p> <p>15 complies with basic form and contents requirements.</p> <p>16 MR. REED: I'd like to see the page.</p> <p>17 I'm not sure -- those don't sound like my words, but</p> <p>18 they might be.</p> <p>19 MS. WAGNER: Let's go to your First</p> <p>20 Report. I'm at tab 1. We'll go to paragraph 11.</p> <p>21 You can feel free to read the whole paragraph but I'm</p> <p>22 going to be looking at the part that starts "So long"</p> <p>23 on the next page.</p> <p>24 MR. REED: Okay.</p> <p>25 MS. WAGNER: So the part that I'm</p> <p>www.dianaburden.com</p>	<p>1657</p>

<p>1658</p> <p>1 reading, just so it's in the record, starts "So long" 2 and it's on, again, page 6, not page 5, "So long as 3 the international application complies with the basic 4 'form and contents' requirements of the PCT, (i.e. 5 contains a title, request, claims, description of the 6 invention and drawings (if required), formatted in 7 accordance with PCT requirements), the application 8 will be accepted into the international phase of the 9 PCT and be eligible for continuation into the 10 national phase. Fulfillment of the PCT's 'form and 11 contents' requirements is typically reviewed by 12 clerks." 13 So basically what you've said in that 14 paragraph is all that's required for this is a title, 15 request, claims, description of the invention, 16 drawings, all formatted in accordance with the PCT 17 requirements, and so, in your view, it's more of a 18 cursory review, correct? 19 MR. REED: There are no technical 20 examiners for applications at the time of filing. 21 MS. WAGNER: In fact, you said it's 22 typically reviewed by clerks? 23 MR. REED: That is typically true. 24 MS. WAGNER: Can you turn to paragraph 25 27 as well of your First Report? Again, we're</p> <p>www.dianaburden.com</p>	<p>1659</p> <p>1 talking about acceptance of the international 2 application under the PCT, and basically the same 3 type of thing is said. You say in the second 4 sentence, "Such standardization of formalities avoids 5 the need for applicants to redraft an application 6 merely to comply with national requirements 7 concerning the general presentation of information." 8 MR. REED: Okay. 9 MS. WAGNER: So I take your point in 10 these paragraphs to be that the PCT form and contents 11 requirement really shouldn't be taken as establishing 12 any significant requirements as to form and content 13 other than the fact that there are headings required, 14 because it seems apparent that the acceptance into 15 the international phase is somewhat automatic. I 16 guess it's not automatic, they're checking, but it's 17 a matter of formalities and it's reviewed by clerks. 18 MR. REED: To my knowledge, it's a 19 matter of formalities, yes. In order to get a PCT 20 filing date, which is actually the entrance, then you 21 need to have something that looks like a description. 22 They don't get involved as to what's in there. 23 Something that looks like a claim needs to be 24 there -- I'm trying to remember -- there are three or 25 four other little things that are strictly</p> <p>www.dianaburden.com</p>
<p>1660</p> <p>1 formalities of what one needs to get a filing date. 2 MS. WAGNER: The same types of 3 comments are made I think again in paragraph 37 of 4 your report. 5 MR. REED: I didn't realize I was so 6 redundant. I've got 37. 7 MS. WAGNER: Actually the 8 statements -- we don't need to read them out -- but 9 similar statements are made at the end of paragraph 10 37. 11 MR. REED: Okay. 12 MS. WAGNER: I'm actually going to be 13 referring you to tab 5. These are the records of the 14 Washington Diplomatic Conference on the Patent 15 Co-operation Treaty. 16 Regarding these records, at paragraph 17 13 of your Second Report you had discussed these 18 records generally, and you've said that they comprise 19 extensive written materials explaining the meaning of 20 the Treaty and how it should be interpreted and 21 applied, correct? 22 MR. REED: I don't know. I'd have to 23 find my Second Report. 24 MS. WAGNER: It's at tab 2. I'm 25 looking at paragraph 13.</p> <p>www.dianaburden.com</p>	<p>1661</p> <p>1 MR. REED: Okay. 2 MS. WAGNER: You've also said that 3 these records serve as an annotated PCT text 4 explaining what the contracting states intended by 5 each article. Correct? 6 MR. REED: Are those the words I used? 7 MS. WAGNER: I hope so. 8 MR. REED: Hang on a second. Could 9 you repeat the question? 10 MS. WAGNER: Sure. You've also said 11 that these records serve as an annotated PCT text 12 explaining what the contracting states intended by 13 each article. 14 MR. REED: I'm trying to find those 15 words about "contracting states" in paragraph 13 in 16 my report, and for some reason I'm missing it. 17 THE PRESIDENT: It is the first line 18 on page 5, of your second expert witness report. 19 MR. REED: I see that now, yes. Thank 20 you so much. 21 MS. WAGNER: While you're there, 22 you've also said that the Washington Conference 23 papers provide important context in interpreting the 24 PCT, correct? 25 MR. REED: Yes.</p> <p>www.dianaburden.com</p>

<p>1662</p> <p>1 MS. WAGNER: Let's turn back to those 2 Washington Diplomatic Conference records. They were 3 at tab 5. I'm going to be looking at page 21. 4 MR. REED: Okay. 5 MS. WAGNER: And so this is 6 Article 11, and if I have it correct, what this 7 article does is address the filing date and effects 8 of the international application. 9 MR. REED: Hang on a second. It's 10 been a while since I've read 11. 11 MS. WAGNER: It's C-112 in the record 12 as well. 13 MR. REED: I've read Article 11. 14 MS. WAGNER: So this is what happens 15 when the receiving -- or this governs the receipt of 16 the international application by the receiving 17 office, correct? Accurate? 18 MR. REED: For purposes of obtaining 19 the filing date, yes. 20 MS. WAGNER: So one of the criteria 21 for obtaining the filing date is that the 22 international application contains some elements, and 23 those are listed in Article 11(1)(iii). 24 MR. REED: Okay. 25 MS. WAGNER: And I guess the one</p> <p>www.dianaburden.com</p>	<p>1663</p> <p>1 that's probably most pertinent to us is on the next 2 page, and it's item (d) at the top there. It has to 3 contain a part which on the face of it appears to be 4 a description. 5 MR. REED: Yes. 6 MS. WAGNER: And, if we look at the 7 notes below -- and they are in tiny writing, but if 8 you go back to page 21 and you look at the notes to 9 paragraph 1(iii) it says "the designation of at least 10 one Contracting State is indispensable, but otherwise 11 the international filing date will be accorded, even 12 if the other elements enumerated in this provision do 13 not comply with the requirements of form and contents 14 provided for in the Treaty and Regulations." 15 MR. REED: Accurately quoted. 16 MS. WAGNER: Accurately quoted, and, 17 if you look at the following page but again sticking 18 in the notes -- 19 MR. REED: Oh, okay, in the notes. 20 MS. WAGNER: In the notes but on the 21 following page, sorry to take to you these teeny tiny 22 notes again, right at the top there it says "as to 23 (d) [which is the description] it will not matter, in 24 particular, if the description does not comply with 25 Article 5 (clarity and completeness of the</p> <p>www.dianaburden.com</p>
<p>1664</p> <p>1 description) and Rule 5 (manner of the description), 2 or if the claims do not comply with Article 6" -- I'm 3 skipping some here -- "and Rule 6." 4 Then if you go down just to the bottom 5 of that paragraph it says, "All the receiving Office 6 is allowed to do is check whether the application 7 contains passages which, on their face, appear to be 8 a description and a claim or claims." 9 And that's consistent with your 10 experience, I take it? 11 MR. REED: Yes. 12 MS. WAGNER: And this article, again, 13 governs what the receiving Office has to do when it 14 receives an application in terms of assigning the 15 filing date, correct? 16 MR. REED: I think so. 17 MS. WAGNER: Close? Accurate? 18 MR. REED: I'm just sitting here -- 19 there is an initial examination that determines 20 whether the application has a filing date but then 21 there are further examinations down the road a little 22 bit. Maybe in the receiving Office, maybe in the 23 International Bureau. I'm not exactly sure if I 24 remember correctly. 25 MS. WAGNER: Understood. But the fact</p> <p>www.dianaburden.com</p>	<p>1665</p> <p>1 that the receiving Office only does the facial review 2 of the application doesn't have anything to do with 3 whether the PCT application actually meets the form 4 and contents requirements, correct? 5 MR. REED: No, they just want 6 something that looks like a description. Something 7 that looks like a claim. 8 MS. WAGNER: And so the paragraphs in 9 your report that we have discussed, which deal with 10 the receiving Office and what they do, actually don't 11 have anything to do with whether form and contents 12 requirements are actually met? 13 MR. REED: I'd have to go back and 14 read the report again to see what the context of that 15 is. 16 MS. WAGNER: Well, we reviewed the 17 three paragraphs where that was in your report. 18 MR. REED: You may remember them, but 19 I don't. 20 MS. WAGNER: Do you want to go back 21 and review those three paragraphs? 22 MR. REED: Yeah. 23 MS. WAGNER: I can point you to them. 24 MR. REED: We were in the Second 25 Report?</p> <p>www.dianaburden.com</p>

<p>1666</p> <p>1 MS. WAGNER: First Report. And they 2 are paragraph 11, 27 and 37. 3 MR. REED: Okay. 4 MS. WAGNER: So the fact that the 5 receiving office does this cursory review has nothing 6 to do with the actual meaning of form and contents in 7 the PCT, correct? 8 MR. REED: It has nothing to do with 9 the actual meaning of -- 10 MS. WAGNER: Of form and contents, 11 because it's just a cursory review. They are not 12 determining whether form and contents requirements 13 are met, correct? 14 MR. REED: They're following the PCT 15 rules and regulations and we looked at -- what is it, 16 Rule 11 or Article 11? I forget which. 17 MS. WAGNER: Article 11, the cursory 18 review for receiving Office purposes, does not 19 establish that the form and contents requirements are 20 actually met, correct? 21 MR. REED: Not with the first -- I'd 22 have to go back and look at the receiving Office 23 guidelines, and I have not done that. 24 MS. WAGNER: We've just read, sir, 25 that it's a "facial review," as per these records --</p> <p>www.dianaburden.com</p>	<p>1667</p> <p>1 MR. REED: It is. 2 MS. WAGNER: -- of the Washington 3 Conference that you say are authoritative as to 4 interpretation. It's a facial review, correct? 5 MR. REED: It's a facial review but 6 you also have to look at the receiving Office. It's 7 a big place. There may be multiple reviews. And 8 there's also review by the International Bureau when 9 it gets to Geneva. 10 MS. WAGNER: That's right, but that 11 may be a different form of review, and the fact that 12 it's a cursory review before the receiving Office is 13 not the end of the story, correct? 14 MR. REED: Is not the end of the 15 story. 16 MS. WAGNER: Can you turn to paragraph 17 32 of your Second Report, please? It's at tab 2. 18 What you say is that "If it is not 19 obvious from the disclosure that the invention has 20 utility, Chapter 14 requires the IPEA examiner" -- I 21 take it that's the examiner in the international 22 phase? 23 MR. REED: The International 24 Preliminary Examining Authority. Yes, the 25 international phase.</p> <p>www.dianaburden.com</p>
<p>1668</p> <p>1 MS. WAGNER: "the Guidelines require 2 the IPEA examiner to look to the claimed invention 3 and the guidelines to determine whether the claimed 4 invention has utility." And you indicate further, 5 "The Appendix prescribes a three-pronged test for 6 this purpose of the IPEA advisory opinion. The 7 examiner must determine if the claimed invention has 8 utility that is, (a), specific, (b), substantial and 9 (c), credible." 10 I want to look specifically at 11 paragraph 33. 12 MR. REED: Of the Second Report? 13 MS. WAGNER: In the same place, just 14 below 32 -- in fact, let's just go back to 32 for one 15 brief moment. In the first sentence you said that 16 the guidelines require "the IPEA examiner to look at 17 the claimed invention and the Guidelines to determine 18 whether the claimed invention has utility," correct? 19 That's the exercise -- 20 MR. REED: Yes. 21 MS. WAGNER: -- described? 22 In paragraph 33 you say that "The IPEA 23 examiner may need to revert to the three-pronged test 24 when an IA" -- I take it that's an International 25 Application -- "claims a selection invention singling</p> <p>www.dianaburden.com</p>	<p>1669</p> <p>1 out specific members of a known generic group and 2 asserting that the selected species have unexpected 3 higher efficacy than other members of the genus and 4 this discovery advances the state of the art 5 sufficiently to warrant a separate additional term of 6 exclusivity." 7 MR. REED: Okay. 8 MS. WAGNER: And you go on to say, 9 "This is particularly relevant when the same 10 applicant has already enjoyed patent protection for 11 the selected species (compound) in a granted patent 12 claiming the entire genus. In the absence of 13 evidence in the application at the time of filing 14 clearly showing that the selected species (compound) 15 has superior efficacy compared to other members of 16 the genus, it is highly unlikely a POSITA" -- I take 17 it that's a "person of ordinary skill in the art" -- 18 "could review the disclosure and conclude the claims 19 covering the selected species (compounds) actually 20 possess the utility (and the unexpectedly higher 21 efficacy) necessary to justify a second term of 22 exclusivity." 23 So your testimony here relates to a 24 pretty specific area of patent law, and that relates 25 to patentability criteria as they apply to a</p> <p>www.dianaburden.com</p>

<p>1670</p> <p>1 particular type of invention and that's known as 2 "selection" patents? 3 MR. REED: Okay. That's what I called 4 it. I don't know whether it's a standard term or 5 not. I've heard somebody here use it yesterday. 6 MS. WAGNER: Do you have any 7 particular expertise in the law relating to selection 8 patents? 9 MR. REED: No. 10 MS. WAGNER: Did you prepare and file 11 applications for selection inventions when you were 12 at P&G, to your recollection? 13 MR. REED: You know I don't know 14 because I didn't write them. 15 MS. WAGNER: And you don't recall 16 having any involvement with those particular 17 applications? 18 MR. REED: No, other than the fact 19 that -- no, I don't, other than the fact that they 20 exist, and if looking for the patentability is based 21 on the superior performance or the superior benefit 22 that's unexpected, I have no particular expertise. 23 MS. WAGNER: So what is your authority 24 for asserting that the guidelines -- the 25 International Preliminary Guidelines, is that the</p> <p>www.dianaburden.com</p>	<p>1671</p> <p>1 correct term? 2 MR. REED: Go ahead. 3 MS. WAGNER: -- treat selection 4 inventions in a particular way when it comes to 5 utility? What's your authority for that? 6 MR. REED: I'm not sure that I said 7 the guidelines treat things in a certain way. I said 8 this was an example that I thought is a place where 9 the examiner may -- and not "must" but "may" -- have 10 to revert to the three-pronged test to make sure that 11 the utility of the invention -- because without the 12 improved benefit -- 13 MS. WAGNER: So there's nothing -- 14 MR. REED: -- the claims aren't novel. 15 THE PRESIDENT: Could you let the 16 expert finish the answer? 17 MS. WAGNER: Apologies. Please go 18 ahead. 19 MR. REED: Without the improved 20 benefit for known material the claims aren't novel. 21 MS. WAGNER: So that was just based on 22 your general understanding of selection inventions? 23 MR. REED: Yes, it was. 24 MS. WAGNER: And it wasn't based on 25 anything in the guidelines?</p> <p>www.dianaburden.com</p>
<p>1672</p> <p>1 MR. REED: No, I didn't see in the 2 guidelines about selection invention, but I haven't 3 read them for a few days. 4 MS. WAGNER: Are you aware that it's 5 only in Canada that the disclosed advantages of a 6 selection invention are treated as being the utility 7 of that invention? 8 MR. REED: I have no knowledge at all 9 of that. 10 MS. WAGNER: And are you aware that 11 Canadian law has only recently treated selection 12 inventions in this way? 13 MR. REED: I don't know anything about 14 Canadian law and how they operate up there. 15 MS. WAGNER: So your understanding in 16 paragraph 33 was simply based on a general 17 understanding that utility is related to selection 18 inventions? 19 MR. REED: Well, it was more for the 20 three-pronged test, which it happens to be for 21 utility, yes. 22 MS. WAGNER: And you don't have any 23 experience that that's how selection compounds have 24 been treated in the United States? 25 MR. REED: No, no knowledge at all.</p> <p>www.dianaburden.com</p>	<p>1673</p> <p>1 MS. WAGNER: Or any other 2 jurisdiction? 3 MR. REED: Nor any other jurisdiction. 4 MS. WAGNER: Thank you. 5 Let's go back to your First Report 6 which is at tab 1. 7 I want to make sure that I understand 8 your testimony as to the meaning of "form and 9 contents" in the PCT system. Let's go to paragraph 10 35. What you say in paragraph 35 is that -- and I'm 11 looking about midway through the second sentence -- 12 "...the PCT itself, in confirming the meaning of 13 'form and contents', simply lists broad categories of 14 information that must be included in the 15 international application, and provides directions as 16 to their order and format of presentation." 17 MR. REED: Okay. 18 MS. WAGNER: So, in general, in your 19 view, "form and contents" in the PCT just refers to 20 these broad categories of information? 21 MR. REED: That is correct. 22 MS. WAGNER: And in paragraph 36 you 23 detail those broad categories and you indicate that 24 they conclude a request and a description and one or 25 more claims and one or more drawings (where required)</p> <p>www.dianaburden.com</p>

<p>1 and an abstract. Correct? 2 MR. REED: Actually that's -- I 3 believe that's in the Articles, but then we also get 4 into some of the stuff under rule 5.1 in a little 5 more detail, but ... 6 THE PRESIDENT: Please speak up. 7 MR. REED: I'm sorry. I said rule 5.1 8 gives a little more detail but yes, that's basically 9 the first cut of the broad categories. 10 MS. WAGNER: If we turn back to 11 paragraph 33, which is my reference point for this, 12 if I understand you correctly, in your view the PCT 13 places no constraints on the actual contents of the 14 PCT application insofar as those contents relate to 15 substantive patentability criteria? 16 MR. REED: That is my position, yes. 17 MS. WAGNER: One of those substantive 18 patentability criteria is industrial applicability 19 or, otherwise stated, utility, correct? 20 MR. REED: Okay. 21 MS. WAGNER: Agree? 22 MR. REED: I agree. 23 MS. WAGNER: If you go to paragraph 39 24 of your statement. I'm looking specifically at the 25 last sentence. It's your opinion that disclosure</p> <p>www.dianaburden.com</p>	<p>1 requirements related to industrial applicability, or 2 utility, are a substantive condition of 3 patentability? 4 MR. REED: Okay. 5 MS. WAGNER: So in that context you 6 say that the PCT rightfully places the decision 7 whether a given application has met those 8 requirements, the disclosure requirements, on the 9 national Patent Offices. Correct? 10 MR. REED: Yes. 11 MS. WAGNER: That's the framework of 12 the PCT, in your opinion? 13 MR. REED: Yes. 14 MS. WAGNER: We have also heard this 15 morning that PCT rule 5.1(a)(vi) essentially says 16 that an applicant has to explicitly state the utility 17 of an invention if it wouldn't be apparent. Accurate 18 characterization? 19 MR. REED: It's a characterization, 20 but it sounds proper. 21 MS. WAGNER: But it would be your 22 opinion that the PCT does not constrain PCT members, 23 member countries, from requiring that an applicant 24 disclose something additional about utility in the 25 application?</p> <p>www.dianaburden.com</p>
<p>1 MR. REED: Say that again? 2 MS. WAGNER: It would be your opinion 3 that the PCT doesn't restrain or constrain PCT member 4 countries from requiring an applicant to disclose 5 something additional about utility in the 6 application? 7 MR. REED: Yes. 8 MS. WAGNER: Because utility is a 9 substantive condition of patentability. 10 MR. REED: It certainly is. 11 MS. WAGNER: And, in your view, that's 12 not governed by the PCT? 13 MR. REED: That is correct. 14 MS. WAGNER: I'm going to put a 15 hypothetical to you. I think it's a simple one. My 16 hypothetical is imagine that rule 5.1 didn't say 17 anything about utility at all. Just silent. If that 18 were the case, is it still your position that a PCT 19 member country could, nonetheless, require an 20 applicant to explicitly state a utility if that were 21 part of its national law? 22 MR. REED: Yes. 23 MS. WAGNER: All right. And you think 24 your view is widely shared? 25 MR. REED: I have no idea.</p> <p>www.dianaburden.com</p>	<p>1 MS. WAGNER: Do you think that PCT 2 member countries would subscribe to this view? 3 MR. REED: I don't know. I have no 4 idea what they would subscribe to or not subscribe 5 to. 6 MS. WAGNER: So it's your view based 7 on your own interpretation of the Treaty? 8 MR. REED: My own interpretation, and 9 all my experience, yes. 10 MS. WAGNER: Let's go to tab 5, which 11 is Exhibit C-112. These are the records of the 12 Washington Diplomatic Conference. Just to give us 13 some context, if we go about three pages into the 14 Editor's note -- 15 MR. REED: I'm on page 13. Is that 16 right? 17 MS. WAGNER: No, just three pages into 18 the exhibit. We've got records of the Washington 19 Diplomatic Conference and then the Editor's note, 20 about three pages in. 21 MR. REED: I see it. 22 MS. WAGNER: It says this conference 23 took place from May 25 to June 19, 1970? 24 THE PRESIDENT: The second paragraph, 25 Mr. Reed, of the Editor's note.</p> <p>www.dianaburden.com</p>

<p>1678</p> <p>1 MR. REED: I didn't know there was a 2 question on the table. 3 THE PRESIDENT: There was a reference 4 to it. I think the question is still coming. 5 MR. REED: I see it. 6 MS. WAGNER: So you see it? 7 MR. REED: Yeah. 8 MS. WAGNER: Right below that it says 9 that the final text of the Treaty and rules was 10 signed at the close of the Conference on June 19, 11 1970. 12 MR. REED: Okay. 13 MS. WAGNER: See that there? 14 MR. REED: Yes. 15 MS. WAGNER: You weren't there? 16 MR. REED: I was not there. 17 MS. WAGNER: I didn't expect you to 18 be. So these notes essentially reflect the minutes 19 of the final negotiations of the text of the 20 Patent Cooperation Treaty. Is that a correct 21 understanding? 22 MR. REED: Is that what it says? I 23 don't know that it reflects the minutes per se. 24 MS. WAGNER: I think it does say that. 25 MR. REED: It may. I've not read this</p> <p>www.dianaburden.com</p>	<p>1679</p> <p>1 paragraph before. 2 MS. WAGNER: Well, what I'm looking at 3 is the second to last paragraph at the bottom. It 4 refers to the "minutes of the Conference." 5 MR. REED: Okay. I see that. 6 MS. WAGNER: To provide you with the 7 context, I am going to be referring to some material 8 that is the minutes of the Main Committee, which 9 start on page 591. We're not actually going to go to 10 page 591, because that's just the start. We're going 11 to go to page 635. These are, again, teeny, tiny 12 little numbers at the top of the page there. 13 MR. REED: I found it. 14 MS. WAGNER: So, as it turns out, my 15 hypothetical was not that hypothetical. Were you 16 aware that, during the latter PCT negotiations, there 17 were proposals to dispose of the requirement to 18 explicitly state a utility if one were not apparent? 19 MR. REED: I was not aware of that. 20 MS. WAGNER: I was not either until 21 very recently. If you look at page 635 -- 22 MR. REED: You say there was a 23 proposal to eliminate that, but they did not 24 eliminate it? 25 MS. WAGNER: They did not eliminate</p> <p>www.dianaburden.com</p>
<p>1680</p> <p>1 it. It is there today, as we have seen. 2 MR. REED: Yes, it is. 3 MS. WAGNER: Right. So if you look 4 down at the bottom of page 635, there's a paragraph 5 896. 6 MR. REED: Okay. 7 MS. WAGNER: All I'm doing here is 8 just providing the frame of reference for these 9 proposals to eliminate. So "Mr. Lips (Switzerland) 10 moved the proposal of his Delegation concerning item 11 (vi) contained in his documents PCT/DC/17. In most 12 cases, the use or industrial manufacturer of an 13 invention was obvious and required no special 14 explanation such as that envisioned in item (vi) of 15 the Draft. Consequently, item (vi) should read as 16 follows: 'indicate the way in which the subject of 17 the invention can be made and used in industry, if 18 such indications cannot be implied from those 19 indications mentioned in the preceding items of 20 paragraph (a).' In 99 percent of the cases, the said 21 implication would be possible and no specific 22 statement would be necessary." 23 Then, 897, we have the proposal of 24 France "referring to the proposal of his Delegation 25 contained in document PCT/DC/21, said that item (vi)</p> <p>www.dianaburden.com</p>	<p>1681</p> <p>1 should be made entirely optional and should refer 2 only to the general notion of 'industrial 3 applications' without providing any exact and 4 restricted definition. The industrial character or 5 industrial application of the invention was in most 6 cases so obvious from the general description of the 7 invention that it required no special explanation. 8 Consequently, item (vi) could read as follows: 9 'possibly indicate the possibilities of industrial 10 application of the invention'. 11 So those were the proposals, but if 12 you look at paragraph 901.1, which is just three 13 paragraphs below that text that I just read out from 14 France, 901.1, we have here -- and you can have a 15 chance here to review it -- but we have here a 16 Mr. McKie from the United States, and he felt that, 17 as far as the United States of America was concerned, 18 a statement on the utility of the invention was a 19 minimum requirement. So I take it he's disagreeing 20 with the proposal. Do you agree that he was 21 disagreeing with the proposal? 22 MR. REED: I do. There wasn't a 23 question on the table so... 24 MS. WAGNER: Then at 904, we also have 25 Poland, Mr. Gierczak. He was also appearing to</p> <p>www.dianaburden.com</p>

<p>1682</p> <p>1 oppose those proposals. I'll give you a chance to 2 read it and you can let me know if you agree. 3 MR. REED: Okay. 4 MS. WAGNER: Now, at 908.1, we have 5 Mr. Bogsch, the Secretary General -- 6 MR. REED: Bogsch. 7 MS. WAGNER: Thank you. I notice you 8 didn't correct me on the Polish gentleman's name. 9 That's all right. I didn't know it either. 10 I'm going to read this out, and then 11 I'm going to characterize it and ask you a question 12 if you agree. So he says, Mr. Bogsch, that "an 13 international application served not only the purpose 14 of international search but also the purpose of being 15 an application in each of the designated States. 16 Therefore, it was extremely important that the 17 international application should contain all the 18 elements which made it possible for the Contracting 19 States to regard it as an equivalent of a national 20 application. It was for that reason, and mainly for 21 that reason, that the PCT defined with precision the 22 formalities and the minimum contents of international 23 applications." 24 So I'm going to put it in my own 25 words, but in general do you agree that what the</p> <p>www.dianaburden.com</p>	<p>1683</p> <p>1 Secretary General is saying is that, if a PCT member 2 country is going to require an applicant to 3 explicitly state a utility, then we need to make sure 4 the PCT also requires the applicant to explicitly 5 state the utility, otherwise the application might 6 not have what it needs? 7 MR. REED: I think that's fair. 8 MS. WAGNER: You think that's fair? 9 Okay. 10 Now let's go to paragraph 910. Next 11 page. And we have Mr. Fergusson of the United 12 Kingdom. Again, I'm going to read out what he says, 13 and then let's see if we agree what he's saying. 14 He said that he "fully agreed with the 15 explanation given by the Secretary General of the 16 Conference. Since the delegation of the United 17 States of America had indicated that any broadening 18 of the provision under discussion would put the 19 applicant in jeopardy in the United States of 20 America, it would be extremely difficult to accept 21 the proposals of the Delegations of Switzerland and 22 France. It would be best to leave the text as it 23 appeared in the Alternative Draft." 24 Again, to paraphrase, speaking 25 generally, do you agree that what the UK delegate is</p> <p>www.dianaburden.com</p>
<p>1684</p> <p>1 saying is this: If the PCT does not require an 2 applicant to explicitly state a utility and the 3 United States does require the applicant to 4 explicitly state a utility, then there's a potential 5 problem because the applicant who uses the PCT system 6 might be in jeopardy when they go to file in the 7 United States? 8 MR. SPELLISCY: I've let this go on 9 for a while. We can all read it. I'm not sure that 10 Mr. Reed has any particular expertise to interpret 11 what the delegation of the United Kingdom or other 12 delegations were saying. I'm happy to have him 13 answer the question, but I really wonder, concerning 14 what other delegations and other people were saying, 15 whether he has any expertise that he can offer on 16 that. 17 MR. REED: Not only that, I've never 18 seen any of this stuff before, so I'm just reading it 19 for the first time myself. 20 MS. WAGNER: I am laying the 21 foundation for an ultimate question. 22 THE PRESIDENT: Overruled. Please 23 proceed. 24 MR. REED: Okay. 25 MS. WAGNER: So my question is this:</p> <p>www.dianaburden.com</p>	<p>1685</p> <p>1 The reason that a PCT applicant would be put in 2 jeopardy, if the PCT did not say you had to 3 explicitly state a utility but a member country's 4 laws required you to state a utility, that their 5 application would not have what it needed to satisfy 6 that member country, correct? 7 MR. REED: It was a little convoluted. 8 Try it one more time, please. 9 MS. WAGNER: Do you agree that a PCT 10 applicant will be put in jeopardy if the PCT does not 11 require an explicit statement of utility but a member 12 country does? 13 MR. REED: We're talking explicit 14 statement of utility which is basically the language 15 in 5.1(a)(vi). 16 MS. WAGNER: That's what I'm asking 17 you. If the PCT, as per this proposal, did not 18 require an explicit statement of utility but a member 19 country did require an explicit statement of utility, 20 then the PCT or the applicant would be put in 21 jeopardy when they go to file in the member country, 22 correct? 23 MR. REED: But the PCT does not 24 require an explicit statement of utility if it's 25 obvious from the description or nature of the</p> <p>www.dianaburden.com</p>

<p>1686</p> <p>1 invention.</p> <p>2 MS. WAGNER: That's correct, but the</p> <p>3 proposal here was to get rid altogether of that</p> <p>4 requirement to state an explicit statement of utility</p> <p>5 if it were not apparent. That was the proposal.</p> <p>6 MR. REED: But it didn't happen.</p> <p>7 MS. WAGNER: It didn't happen but, if</p> <p>8 it had happened and there were no requirement in the</p> <p>9 PCT to state an explicit utility, if a member country</p> <p>10 did require it, that would put the applicant in</p> <p>11 jeopardy when they go to file in the member country,</p> <p>12 correct?</p> <p>13 MR. REED: As far as I'm concerned, if</p> <p>14 they knew their national laws they would build it in</p> <p>15 for that particular country anyway, and not rely on</p> <p>16 the PCT.</p> <p>17 MS. WAGNER: And, in your view, a</p> <p>18 member country would not be constrained -- the fact</p> <p>19 that the applicant might be put in jeopardy would not</p> <p>20 constrain the member country from imposing that</p> <p>21 obligation, correct?</p> <p>22 MR. REED: The national law for</p> <p>23 substantive material or criterion for patentability</p> <p>24 is given totally to the national law, whether it's in</p> <p>25 the PCT or not.</p> <p>www.dianaburden.com</p>	<p>1687</p> <p>1 MS. WAGNER: So the member country</p> <p>2 should not feel constrained about imposing that</p> <p>3 requirement, even if the PCT does not, in your view?</p> <p>4 MR. REED: As long as it's part of</p> <p>5 their national law. Again, it cannot fall under the</p> <p>6 definition of form and contents of the PCT. They</p> <p>7 would have to take a look at that.</p> <p>8 MS. WAGNER: And you have already --</p> <p>9 we have already -- you have already answered that</p> <p>10 question because you have already said that requiring</p> <p>11 an explicit statement of utility, because it relates</p> <p>12 to a substantive criteria of patentability, is not a</p> <p>13 matter of form and contents under the PCT.</p> <p>14 MR. REED: The material that -- the</p> <p>15 explicit statement is part of the formality, is part</p> <p>16 of the form and contents, and they can't require</p> <p>17 more, but they can require more on utility to get</p> <p>18 into the substantive aspects of patentability under</p> <p>19 each national law.</p> <p>20 MS. WAGNER: In your view, if the PCT</p> <p>21 was silent about utility, member countries could not</p> <p>22 ask them to make an explicit statement of utility?</p> <p>23 Is that now your view? Because that's different than</p> <p>24 the testimony you gave earlier.</p> <p>25 MR. REED: That's not -- then I must</p> <p>www.dianaburden.com</p>
<p>1688</p> <p>1 have misunderstood my testimony because -- say that</p> <p>2 one again because I'm not going to -- I'm trying to</p> <p>3 go back and reconstruct what we talked about.</p> <p>4 MS. WAGNER: If the PCT were silent as</p> <p>5 to whether an applicant had to state a utility, so</p> <p>6 there was nothing in there --</p> <p>7 MR. REED: That's a hypothetical.</p> <p>8 MS. WAGNER: It's a hypothetical --</p> <p>9 then a member country could still require them to</p> <p>10 state a utility. Is that your response?</p> <p>11 MR. REED: Yes, again, in their</p> <p>12 national law.</p> <p>13 MS. WAGNER: Correct. Looking again</p> <p>14 at 914.2, first column of page 637, it is in fact the</p> <p>15 last passage I will read to you -- I stand corrected.</p> <p>16 I have two passages to read to you and they will be</p> <p>17 the last two passages I will read to you.</p> <p>18 If you go to 636, previous page, and</p> <p>19 it's right at the bottom in the second column and</p> <p>20 it's 914.1, we have Mr. McKie of the United States</p> <p>21 and he says: "Section 112 of the U.S. Patent Statute</p> <p>22 required the specification to contain 'a written</p> <p>23 description of the invention and of the manner and</p> <p>24 process of making and using it, in such full, clear,</p> <p>25 concise and exact terms as to enable any person</p> <p>www.dianaburden.com</p>	<p>1689</p> <p>1 skilled in the art to which it pertains or with which</p> <p>2 it is most nearly connected to make and use the</p> <p>3 same'. Naturally, in the case of a chair, both the</p> <p>4 method of making it and the purpose for which it was</p> <p>5 used were so obvious, particularly to a person</p> <p>6 skilled in the art, that a statement on neither point</p> <p>7 would be required. However, the verb 'indicate' in</p> <p>8 the Alternative Draft took care of the problem since</p> <p>9 the indication could take many forms; for example, in</p> <p>10 the case of a chair, it could take the form of merely</p> <p>11 showing the chair."</p> <p>12 So I guess what he's saying here is</p> <p>13 that you don't always have to explicitly state a</p> <p>14 utility in the case of a chair; it would be obvious.</p> <p>15 MR. REED: From the standpoint of rule</p> <p>16 5.1(a)(vi), I think that would probably be obvious.</p> <p>17 MS. WAGNER: Then one last passage.</p> <p>18 914.2. This is the United States saying, "It was in</p> <p>19 view of Article 27(1) -- which provided that no</p> <p>20 Contracting State had the right to require compliance</p> <p>21 with requirements relating to the form or contents of</p> <p>22 the international application different from or</p> <p>23 additional to those which were provided for in the</p> <p>24 PCT -- that it was essential that the Rules</p> <p>25 concerning the description be such that they did not</p> <p>www.dianaburden.com</p>

<p>1 require a change in the U.S. patent law which the 2 United States of America could not effectuate." 3 So, as I understood your testimony -- 4 THE PRESIDENT: So what was the 5 question? 6 MS. WAGNER: I'm now asking the 7 question. 8 If I understood your testimony, if the 9 PCT did not require an explicit statement of utility, 10 as was considered here, and the United States did 11 require this under national law or any other member 12 country did require this, it would simply be up to 13 the applicant to make sure that they had complied 14 with that requirement before they filed their PCT 15 application. 16 MR. REED: That's certainly what I 17 would do in the practice. 18 MS. WAGNER: But you'll agree with me 19 that the delegate from the United States did not 20 share your view? 21 MR. REED: I'm not sure -- I never 22 compared what was in here with what my view was. Let 23 me take a look. Apparently he didn't if he's talking 24 about a requirement to change U.S. patent law, which 25 wasn't going to happen.</p> <p>www.dianaburden.com</p>	<p>1690</p> <p>1 MS. WAGNER: Thank you. Those are all 2 my questions. 3 THE PRESIDENT: Thank you. 4 Mr. Spelliscy, are there any questions for redirect? 5 MR. SPELLISCY: If you'll give me a 6 minute or two, there may be one or two. I'm 7 conscious of the time. I don't think redirect would 8 take too long. We could probably, if there's any, 9 get it in before lunch. (Pause) 10 We have no questions for Mr. Reed. 11 MS. WAGNER: Mr. President, I would 12 beg your indulgence to ask one further question 13 because it actually just came to my attention at this 14 moment. I promise it does not involve reading any 15 passages from anything whatever. 16 THE PRESIDENT: I will allow the 17 question. 18 FURTHER CROSS-EXAMINATION ON BEHALF OF THE CLAIMANT 19 MS. WAGNER: Can you just turn to your 20 Second Report? I'm just looking at the header of the 21 report, so not actually in the text, and it's labeled 22 "Rejoinder of Canada". Also on the front page you 23 have address information that's from the Trade Law 24 Bureau. I'm just wondering why those indications 25 appear on your report?</p> <p>www.dianaburden.com</p>
<p>1692</p> <p>1 MR. REED: Clearly the report is 2 submitted to the people in Canada and must have been 3 printed. I assume that was on the top of the page 4 that I signed. 5 MS. WAGNER: So you didn't add that? 6 Canada added that? 7 MR. REED: I guess they must have. I 8 certainly didn't add it. 9 MS. WAGNER: Thank you. 10 THE PRESIDENT: Any question for 11 redirect, Mr. Spelliscy? 12 MR. SPELLISCY: Just one related to 13 that last question. 14 DIRECT EXAMINATION ON BEHALF OF THE RESPONDENT 15 MR. SPELLISCY: Mr. Reed, did we help 16 you with the formatting of your report? 17 MR. REED: Not at all. 18 MR. SPELLISCY: Thank you. 19 THE PRESIDENT: Mr. Reed, thank you 20 for testifying. You are now released and excused as 21 an expert witness. 22 MR. REED: Thank you very much. 23 THE PRESIDENT: We have lunch recess 24 until 1:30. 25 (Recess taken)</p> <p>www.dianaburden.com</p>	<p>1693</p> <p>1 PHILIP MORTIMER THOMAS 2 THE PRESIDENT: Good afternoon, 3 Mr. Thomas. 4 MR. THOMAS: Good afternoon. 5 THE PRESIDENT: Could you please state 6 your full name for the record? 7 MR. THOMAS: My name is Philip 8 Mortimer Thomas. 9 THE PRESIDENT: Mr. Thomas, you appear 10 as an expert witness for the Claimant? 11 MR. THOMAS: Yes. 12 THE PRESIDENT: If any question is 13 unclear to you, either because of language or for any 14 other reason, please do seek a clarification because, 15 if you don't do so, the Tribunal will assume that 16 you've understood the question and that your answer 17 corresponds to the question. 18 Mr. Thomas, you will appreciate that 19 testifying, be it before a court or an arbitral 20 tribunal, is a very serious matter. In that 21 connection, the Tribunal expects you to give the 22 statement which is in front of you. 23 MR. THOMAS: I solemnly declare upon 24 my honor and conscience that my statement will be in 25 accordance with my sincere belief.</p> <p>www.dianaburden.com</p>

<p>1694</p> <p>1 THE PRESIDENT: Mr. Thomas, could you 2 please go to your Expert Report? 3 MR. THOMAS: Yes, sir. 4 THE PRESIDENT: And go to page 13. 5 The Expert Report is dated September 7, 2015? 6 MR. THOMAS: Yes. 7 THE PRESIDENT: Could you confirm for 8 the record that the signature appearing above your 9 name is your signature? 10 MR. THOMAS: Yes, it is. 11 THE PRESIDENT: Is there any 12 correction you wish to make to your report? 13 MR. THOMAS: Yes, sir, there's one 14 typographical error which I'd like to correct, just 15 for the sake of completeness on page 8, paragraph 24. 16 There's an incorrect date in the third last line of 17 that paragraph, a reference to the study on 18 industrial applicability utility prepared by the WIPO 19 Secretariat. The reference should be in 2003. 20 THE PRESIDENT: Thank you. Ms. Cheek? 21 MS. CHEEK: Mr. Berengaut will handle 22 the examination of Mr. Thomas. 23 THE PRESIDENT: Please proceed with 24 direct examination. 25 MR. BERENGAUT: Mr. Thomas, please</p> <p>www.dianaburden.com</p>	<p>1695</p> <p>1 proceed with your presentation. 2 PRESENTATION BY MR. THOMAS 3 MR. THOMAS: Thank you, Mr. President, 4 and members of the Tribunal, for this opportunity to 5 present a summary of my Expert Report. It concerns 6 some negotiations which took place at the World 7 Intellectual Property Organization, or WIPO, over a 8 period of -- well, in total a couple of decades, two 9 sets of negotiations concerning substantive patent 10 law and in particular, attempts to achieve some 11 harmonization of substantive patent law, and my 12 report is directed particularly to one question which 13 arose in those negotiations, namely the question of a 14 requirement that an invention have utility in order 15 to be patentable. 16 The fundamental point I'd like to make 17 at the outset is that the central tenet or the core 18 principle of the utility requirement was not the 19 subject of controversy during any negotiations which 20 I took part in in my career, so I mention the central 21 tenet or core principle which I describe as being 22 that an invention must have some practical use. That 23 is to say, it must have some practical use in order 24 to qualify for the grant of a patent, but there are 25 some things to bear in mind with this requirement.</p> <p>www.dianaburden.com</p>
<p>1696</p> <p>1 In practice, very few inventions are 2 denied patentability on the basis of the utility 3 requirement. Very rarely is an application rejected 4 or a patent invalidated for want of utility. It is a 5 very low bar to patentability. Different legislation 6 uses different language in order to implement or 7 elaborate this requirement, but the fact that there 8 are those differences was not controversial. In 9 particular, that central tenet of the requirement was 10 not a point of controversy in either of the two sets 11 of negotiations which my report deals with. 12 In the set of negotiations for 13 adoption of what was then called the Patent Law 14 Treaty, which took place in the 1980s and resulted in 15 a Diplomatic Conference in 1991, in those discussions 16 the central tenet of this requirement was not 17 controversial. I mention here the basic proposal, 18 that was the name given to the draft which was put to 19 that Diplomatic Conference. 20 Then again, later, in the early 2000s, 21 attempts were made within WIPO, within international 22 discussions under the aegis of WIPO, to conclude a 23 substantive patent law treaty. Once again, in those 24 negotiations the utility requirement was not a point 25 of controversy.</p> <p>www.dianaburden.com</p>	<p>1697</p> <p>1 Now, I mentioned that the 2 implementation in legislation in different 3 jurisdictions is most certainly different from one 4 jurisdiction to another. There is no agreement on 5 the language in which this requirement should be 6 implemented, but the thing my report focuses on is 7 the practical results of the application of the 8 requirement and, in essence, the practical results of 9 implementing that requirement were the same 10 everywhere and, in fact, very few applications were 11 rejected on the basis of non-utility. 12 What was important for negotiating 13 countries? Well, they wanted the inventors and their 14 enterprises to be able to obtain patents in other 15 countries in a consistent way based on similar 16 principles which would apply in their own country. 17 Of course, they also had an interest in the way in 18 which their Patent Offices worked in implementing the 19 requirements. 20 There was no agreed wording, no agreed 21 definition included in various legislation but, since 22 the practical outcomes were the same, there was 23 simply no need for an agreed wording. It wasn't a 24 vital issue in negotiations; it was not 25 controversial.</p> <p>www.dianaburden.com</p>

<p>1 I say this as someone who worked in 2 WIPO for nearly 20 years. One of my positions in 3 WIPO was as director of the Patent Policy Department, 4 and in that capacity I supervised staff whose 5 responsibility was preparing draft texts of the 6 SPLT -- the Substantive Patent Law Treaty, the draft 7 Substantive Patent Law Treaty -- and I took part in 8 all meetings of the WIPO body which considered those 9 drafts, the Standing Committee on the law of patents, 10 or SCP. Prior to that, I'd been in the Australian 11 Patent Office, which I left as an assistant 12 commissioner responsible for policy and legislation 13 matters. 14 Well, I said at the outset that I 15 don't believe that the utility requirement was the 16 subject of controversy, but of those sets of 17 negotiations concerning substantive patent law 18 harmonization were indeed very controversial. What 19 was the problem? Well, there were several but I 20 think the two main ones were, in the case of the SPLT 21 in 2000 to 2004 -- the first of the issues which was 22 a real sticking point was that a number of provisions 23 in the draft depended on the perceived desire of many 24 countries to see everyone operate under what was 25 called a first-to-file patent system under which</p> <p>www.dianaburden.com</p>	<p>1698</p> <p>1 rights to a patent are determined by who is the first 2 to file an application. 3 On the other hand, the United States 4 operated a first-to-invent system under which the 5 rights to a patent would in general go to the first 6 person to invent the application, as distinct from 7 the first to file an application. The United States 8 was unable to undertake to make that change and other 9 countries said, without first-to-file we're not going 10 to go ahead, so the SPLT didn't go ahead. 11 Then there were other issues which 12 related to negotiations in other fora, outside WIPO 13 as well as within WIPO, concerning patents related to 14 genetic resources, the patenting of living things and 15 requirements of patent applications -- sorry, of 16 patents on genetic material and patents where genetic 17 material was involved. 18 The first-to-file argument had 19 contributed to the failure, first, of the basic 20 proposal in 1991. There was a Diplomatic Conference 21 held. No treaty was concluded. And in 2004, a 22 decision was made that no Diplomatic Conference would 23 be held so the draft SPLT was never concluded as a 24 treaty. 25 Professor Gervais in his Expert Report</p> <p>www.dianaburden.com</p> <p>1699</p>
<p>1700</p> <p>1 emphasizes what he sees as the importance of the 2 utility requirement as an issue of controversy which 3 contributed to the failure of the negotiations over 4 the draft SPLT. I do not agree with that assessment. 5 There was controversy. Some controversy spilled over 6 from other issues but the central tenet of the 7 industrial applicability or utility requirement was 8 not controversial. 9 The bottom line is that, yes, there 10 are differences in implementation of the utility 11 requirement in legislation. Very big differences, in 12 fact. Many countries have similar laws, many 13 countries have very different laws, but when it comes 14 to the filing of applications and the assessment of 15 the validity of granted patents, there's really no 16 difference in the practical outcomes that arise. 17 Very few applications are rejected on the basis of 18 utility requirement. Very few. 19 Now, I'm speaking partly from the 20 point of view of my experience in negotiations in 21 international discussions, but there's a documentary 22 record of those discussions, and in that documentary 23 record one does not find controversy in connection 24 with the core principle of the utility requirement. 25 There was simply no such controversy. There was</p> <p>www.dianaburden.com</p>	<p>1701</p> <p>1 controversy in the negotiations, some of that flowed 2 over from other issues, but it wasn't concerning the 3 core of the utility requirement. The controversy was 4 not concerning the core of the requirement. 5 So what do the documents say? Well, 6 first of all, that there was a very limited 7 discussion of utility. There was no controversy, 8 however, over the core principle involved, the 9 central tenet involved. At one stage a WIPO study on 10 utility was prepared at the request of member states. 11 It's referred to both in my Report and by 12 Professor Gervais in his reports. That WIPO study on 13 utility highlighted commonalities, highlighted 14 differences, but when it came to the crunch it wasn't 15 even discussed within the standing committee on the 16 law of patents. It was just there, but it attracted 17 no interest. There's certainly no basis for saying 18 there was any controversial discussion on the basis 19 of it. Indeed, there was no discussion of that 20 study. 21 Another point raised is in connection 22 with various draft provisions of the SPLT over a 23 period of years in which there are alternative texts 24 set out. But those texts aren't there because 25 there's a great controversial discussion about which</p> <p>www.dianaburden.com</p>

<p>1702</p> <p>1 ones are the best; they're simply there because they 2 reflect the standard contained in existing 3 legislation, in existing definitions, and from time 4 to time an attempt at a wording which might bridge 5 the differences and be acceptable to everyone. Well, 6 those differences were never resolved. There are 7 differences in legislative language but, in terms of 8 the practical outcome, the patents are very, very 9 seldom found invalid, and applications are very, very 10 seldom rejected on the basis of utility requirements, 11 at least at the time when these negotiations took 12 place.</p> <p>13 In summary, yes, there was controversy 14 over patent law harmonization discussions. The basic 15 proposal in 1991 was the subject of a failed 16 Diplomatic Conference. No treaty was adopted. In 17 2004, a planned Diplomatic Conference never went 18 ahead because the controversy was such that countries 19 felt that a diplomatic conference was pointless. But 20 on neither occasion was the utility requirement a 21 reason for either failure.</p> <p>22 The simple position is that the 23 central tenet of that requirement, the core principle 24 involved, has not attracted controversy in 25 international negotiations at WIPO concerning patent</p> <p>www.dianaburden.com</p>	<p>1703</p> <p>1 law, namely that an invention have some practical 2 use, and that is not a controversial point.</p> <p>3 The fact that there was some 4 controversy spilling over from other matters doesn't 5 mean that the core notion of the utility requirement 6 was a source of controversy in itself.</p> <p>7 Thank you, sir.</p> <p>8 MR. BERENGAUT: Thank you, Mr. Thomas.</p> <p>9 DIRECT EXAMINATION ON BEHALF OF THE CLAIMANT</p> <p>10 MR. BERENGAUT: You mentioned a 2003 11 study on utility. In his Second Report 12 Professor Gervais discusses a 2001 study on utility, 13 which he says -- and I quote from paragraph 47 of his 14 Second Report -- shows that the "promise of the 15 patent approach was acknowledged internationally at 16 least as early as 2001, not just without any critical 17 commentary but as an example of utility."</p> <p>18 Are you familiar with the 2001 study 19 on utility, and how would you respond to 20 Professor Gervais' characterization of it?</p> <p>21 MR. THOMAS: Yes, well, there are a 22 couple of points to be made, I think.</p> <p>23 I am familiar with the studies in 2001 24 and 2003. In fact, they both related to the same 25 exercise. The International Bureau asked for</p> <p>www.dianaburden.com</p>
<p>1704</p> <p>1 information from member states and produced a study 2 which summarized that information. In looking 3 particularly at the 2001 study, since 4 Professor Gervais mentions that expressly in his 5 Second Report, the word "promise" is most certainly 6 used, but to suggest that a promise approach is 7 discussed in that study would exaggerate the position 8 I think. There was a mention of promise in 9 connection with one country's national law, and I 10 think it becomes apparent from the 2001 study that 11 that country concerned was Canada, but there's no 12 elaboration of what the approach was on promise, and 13 certainly there's nothing there which would suggest 14 that anything was taking place such as is currently 15 the subject of some contention in these proceedings.</p> <p>16 So yes, promise is mentioned, but an 17 approach as to promise is most certainly not 18 described in that study or in its later embodiment.</p> <p>19 The other point to make is that, in 20 referring to the matter of promise being acknowledged 21 by the Committee, well, the 2001 study was on the 22 table. It was an informal document, but it was made 23 available to members of the committee. The 2003 24 study was submitted as a formal document. But on 25 neither occasion did the committee acknowledge the</p> <p>www.dianaburden.com</p>	<p>1705</p> <p>1 report. It was not mentioned by any delegation in 2 the reported minutes -- in the minutes reporting the 3 results of the Committee's deliberations. It was not 4 noted or discussed by the Committee. So I think to 5 say that the promise approach was acknowledged as a 6 result of that study would not be a correct 7 statement.</p> <p>8 MR. BERENGAUT: Thank you, Mr. Thomas.</p> <p>9 I have no further direct examination questions.</p> <p>10 THE PRESIDENT: Thank you.</p> <p>11 Mr. Spelliscy, you will be conducting the 12 cross-examination for the Respondent?</p> <p>13 CROSS-EXAMINATION ON BEHALF OF THE RESPONDENT</p> <p>14 MR. SPELLISCY: Good afternoon, 15 Mr. Thomas. My name is Shane Spelliscy, senior 16 counsel for Canada. I'm going to ask you a few 17 questions with the goal of understanding some of what 18 is in your Expert Report. If you don't understand 19 me, do ask. I'll try and speak loudly and clearly. 20 I also don't think we'll go for very long today, but 21 if you do need a break, just let me know and we can 22 deal with it.</p> <p>23 I'd like to start just by clarifying 24 something in your opinion which I think you just 25 covered there. When I turn to your report, page 3 of</p> <p>www.dianaburden.com</p>

<p>1706</p> <p>1 your report, you've got a heading, heading 2, that 2 says "Overview of Patent Law Harmonization in the 3 Context of WIPO." Do you see that? 4 MR. THOMAS: Yes, I do. 5 MR. SPELLISCY: I would just like to 6 confirm that you would agree with me today that there 7 has been no "patent law harmonization in the context 8 of WIPO," correct? 9 MR. THOMAS: Yes, in general, that is 10 true, yes. 11 MR. SPELLISCY: So your overview in 12 your statement here is about efforts to achieve 13 patent law harmonization, and not the actual 14 achievement of harmonization, correct? 15 MR. THOMAS: It's an overview of 16 really discussions or negotiations about patent law 17 harmonization, yes. 18 MR. SPELLISCY: And efforts to achieve 19 harmonization, correct? 20 MR. THOMAS: Yes. 21 MR. SPELLISCY: And those efforts have 22 all, as you've just noted in your presentation, 23 they've all failed, correct? 24 MR. THOMAS: That is substantially 25 correct, yes.</p> <p>www.dianaburden.com</p>	<p>1707</p> <p>1 MR. SPELLISCY: Let's stay on page 3 2 of your opinion. Go to the bullet right above that 3 heading, so it's a bullet in paragraph 5, the third 4 bullet, where you say, "As suggested by the 5 double-barreled term by which it has come to be 6 known, the industrial applicability (utility) 7 requirement is given effect using somewhat varying 8 language under different national legal systems. It 9 is, however, understood to achieve the same practical 10 results." 11 And I think you addressed this again 12 in your presentation this morning. So that I 13 understand, in terms of patent law your opinion is 14 that the language used to describe a requirement in 15 the national regime is not as important as the 16 results that the requirement seeks to achieve. Is 17 that right? 18 MR. THOMAS: I didn't say that it 19 was -- that I don't think that it was not as 20 important. I said that when it comes to what 21 countries want in negotiations, they want to see 22 consistent treatment for their applicants in other 23 countries, and to that extent, it's not so -- the 24 important thing to them -- yes, I can use the word 25 "important" in a clear way, I think -- it is</p> <p>www.dianaburden.com</p>
<p>1708</p> <p>1 important to them that their applicants receive such 2 treatment in other countries, that the practical 3 outcome of filing applications and of obtaining 4 patents is substantially the same in other countries, 5 and the fact that different language may be used in 6 legislation is -- well, a subsidiary matter. 7 MR. SPELLISCY: Turn to paragraph 11 8 of your report. Here you're talking in the third 9 sentence, when you're talking about this different 10 terminology, "Different countries use different 11 terminology to implement the requirement" -- and 12 you're talking about industrial applicability or 13 utility -- "in their legislation. But the industrial 14 applicability (utility) standard is, as further 15 discussed below, applied in a manner that is 16 remarkably similar around the world. It is a low bar 17 that is rarely the basis for a rejection or 18 invalidation." 19 See that? 20 MR. THOMAS: Yes. 21 MR. SPELLISCY: In the next paragraph 22 you say in the first sentence that there is a 23 substantial consistency of practice with regard to 24 the core utility or industrial applicability 25 requirement. See that?</p> <p>www.dianaburden.com</p>	<p>1709</p> <p>1 MR. THOMAS: Yes. 2 MR. SPELLISCY: One more. In 3 paragraph 24 you state in the third sentence, 4 "Nevertheless, the documentary record reflects the 5 common understanding among WIPO member states of how 6 the industrial applicability (utility) requirement 7 operated in practice." 8 You see that? 9 MR. THOMAS: Yes, I see it. 10 MR. SPELLISCY: So we've got three 11 things here. We've got in your view that it is 12 applied in a manner that is remarkably similar, that 13 there is consistency of practice, and that there was 14 a common understanding of operation in practice, 15 correct? 16 MR. THOMAS: Yes, I think that's 17 correct. 18 MR. SPELLISCY: Let's turn to tab 1 in 19 the red binder you were given, Exhibit R-407, the 20 April 2001 paper, the informal paper that you were 21 just referring to in your direct testimony. 22 MR. THOMAS: Yes. 23 MR. SPELLISCY: You were at WIPO when 24 this document was prepared, correct? 25 MR. THOMAS: Yes.</p> <p>www.dianaburden.com</p>

<p>1710</p> <p>1 MR. SPELLISCY: You were on the 2 secretariat for the Standing Committee on patents 3 when it was prepared? 4 MR. THOMAS: Yeah, I was a member of 5 the secretariat participating at all the meetings 6 that considered draft SPLT meetings. There were 7 earlier meetings with the SCP which I would not have 8 been present at. 9 MR. SPELLISCY: But you were on the 10 secretariat at the time this paper was prepared, 11 correct? 12 MR. THOMAS: Yes. 13 MR. SPELLISCY: In fact, this paper 14 was being prepared, it says on the right above the 15 summary box, April of 2001. You see that? 16 MR. THOMAS: Yes. 17 MR. SPELLISCY: So this paper was 18 actually being prepared at the same time that the 19 secretariat was producing the first proposed draft of 20 the SPLT, correct? 21 MR. THOMAS: I can't say from 22 immediate recollection whether it was the first draft 23 but yes, they were certainly being prepared at about 24 the same time. 25 MR. SPELLISCY: At around an early</p> <p>www.dianaburden.com</p>	<p>1711</p> <p>1 draft. 2 Let's look at the first numbered 3 paragraph in this document. It notes in the first 4 sentence that, "At the fourth session of the SCP (in 5 November of 2000) it was suggested that the 6 International Bureau further study the application of 7 the 'industrial applicability/utility' requirement in 8 various countries." 9 You see that? 10 MR. THOMAS: I do. 11 MR. SPELLISCY: Stay on page 1 and 12 look at the summary in the little box that was 13 prepared by the International Bureau of the results 14 of its further study of how the requirement was 15 applied in countries around the world. It says in 16 the first sentence, "The present paper, based on 17 information received by SCP members, reveals that 18 there is a wide range of differences among SCP 19 members concerning the interpretation and practice 20 relating to the 'industrial applicability... 21 requirement'." You see that? 22 MR. THOMAS: I see it. 23 MR. SPELLISCY: So, in the three 24 paragraphs in your report that we looked at, you 25 concluded -- and you didn't reference any</p> <p>www.dianaburden.com</p>
<p>1712</p> <p>1 documents -- that there was consistency in the 2 application and the practice of the industrial 3 applicability and utility requirement, and a common 4 understanding of how it operated in practice, but you 5 would agree with me, would you not, that this 6 document from 2001, prepared by the International 7 Bureau from information received by members of the 8 standing patent committee, concludes otherwise. It 9 concludes there's wide -- or it says there is a wide 10 range of differences in how it is interpreted and the 11 practice relating to it, correct? 12 MR. THOMAS: Can I say that the word 13 "practice" is not used in an entirely consistent way 14 in all places. There are two notions associated with 15 the practice I think in this area. One would involve 16 the subsidiary legislation, regulations, guidelines 17 which were followed by examiners, for example, and 18 concern more definitional matters and more details of 19 exactly how a requirement was implemented. 20 On the other hand, there's a notion of 21 practice in terms of the practical outcome of the 22 consideration of applications and patents from the 23 point of view of compliance with this requirement, 24 and I think that second one is the kind of practice 25 which my report emphasizes, the practical outcomes of</p> <p>www.dianaburden.com</p>	<p>1713</p> <p>1 handling applications. The fact that there was 2 difference in guidelines and in regulations in 3 different countries is something which is very 4 clearly the case, but there was consistent practice 5 in the practical outcomes in the sense that very few 6 applications at this stage were rejected on the basis 7 of the utility requirement. It was a low bar to 8 patentability, and I can't recall whether that 9 statement is made clearly in the 2001 version of this 10 study, but it most certainly is made clear in the 11 2003 version, which is somewhat more complete. 12 MR. SPELLISCY: We'll get to the 2003. 13 Come back to paragraph 11, the first one we looked at 14 in your report. 15 MR. THOMAS: Sorry, that was paragraph 16 11? 17 MR. SPELLISCY: 11, yes. You 18 concluded that it is applied in a manner that is 19 remarkably similar around the world. It is a low 20 bar, and I think that's what you were just saying. 21 But I'm looking at the first page of R-407, the first 22 paragraph. It seems to me that the standing 23 committee on patents requested the International 24 Bureau study the same thing, the application of the 25 industrial applicability requirement in various</p> <p>www.dianaburden.com</p>

<p>1714</p> <p>1 countries. Would you not agree that comment on how 2 it is applied is the same as the study on 3 application? 4 MR. THOMAS: Well, it could be -- it's 5 a question of what it's focusing on. If one looks at 6 the wording of the legislation, not the wording of 7 the regulations, the wording of the practice 8 guidelines, yes, there are most certainly 9 differences. Absolutely. 10 If one looks at what happens as a 11 result, the outcome of applying those things, the 12 result's the same everywhere. The applications are 13 very seldom -- were very seldom rejected on the basis 14 of non-compliance with the utility requirement. 15 MR. SPELLISCY: Let's stay on the 2001 16 report. To be clear, you responded to this report 17 today. You didn't cite this report, or you didn't 18 review this report prior to preparing your Expert 19 Report? 20 MR. THOMAS: I'm sorry, I didn't catch 21 that, sir. 22 MR. SPELLISCY: It's a terrible 23 question. 24 You didn't review this 2001 report 25 prior to preparing your Expert Report in this</p> <p>www.dianaburden.com</p>	<p>1715</p> <p>1 arbitration. Is that right? 2 MR. THOMAS: I think if you look at 3 the 2003 report it explains -- I would rather use the 4 word "study" because it wasn't really reporting on 5 anything, it was summarizing a lot of results, but if 6 you look at the 2003 study, it refers expressly to 7 this earlier study as being a preliminary version -- 8 I can't remember the exact words, I'd have to refresh 9 my memory, but it is this is a preliminary version of 10 a more complete study issued in 2003, which I most 11 certainly did refer to in my report, yes. 12 I was aware from that report that this 13 study was there, yes. 14 MR. SPELLISCY: My question was did 15 you go back actually and look at this study prior to 16 submitting your Expert Report? 17 MR. THOMAS: Did I go back and look at 18 the 2001 study? I don't believe so, no. 19 MR. SPELLISCY: Let's come to a 20 paragraph that you briefly talked about I think in 21 your direct examination in response to the question 22 of my colleague, Mr. Berengaut. Turn to paragraph 13 23 on page 4. 24 Paragraph 13 says, "Under the law of 25 another country, the term 'invention' means any new</p> <p>www.dianaburden.com</p>
<p>1716</p> <p>1 and useful art, process, machine..." and it goes on. 2 The second sentence says, "An invention lacks utility 3 if it is not operable or it will not do what the 4 specification promised it will do ('false promise')." 5 You see that? 6 MR. THOMAS: I see it. 7 MR. SPELLISCY: I think you said just 8 a few moments ago that you don't believe this 9 represents the promise doctrine in Canadian law. Is 10 that right? 11 MR. THOMAS: I don't think I said 12 that. I think I said that the references to the 13 promise doctrine are explained in a way which I would 14 think falls short of setting out what the promise 15 approach was. I think the word "approach" was used 16 in the quotation read to me. 17 MR. SPELLISCY: Right. Are you 18 familiar with Canadian law? 19 MR. THOMAS: No, I'm not, sir. I have 20 a passing familiarity but I am not an expert in 21 Canadian law, and nor is my report based on the 22 assumption that I am an expert in Canadian law. 23 MR. SPELLISCY: Let me understand how 24 these were put together. These were contributions 25 from members of the SCP, right? This was the</p> <p>www.dianaburden.com</p>	<p>1717</p> <p>1 secretariat summarizing the information it was told, 2 correct? 3 MR. THOMAS: Yes. 4 MR. SPELLISCY: So the information -- 5 and I think you agreed earlier -- the law of another 6 country, the generic reference, this is a reference 7 to the law of Canada, correct? 8 MR. THOMAS: I think if you look at 9 the 2003 study, which is the more complete version of 10 this one, it becomes clear that what is contained 11 here in paragraph 13 does, indeed, relate to the law 12 in Canada, yes. 13 MR. SPELLISCY: So this would have 14 been, then, Canada informing the SCP of what its law 15 was, correct? 16 MR. THOMAS: Canada replied in 17 response to a survey saying what its law was. I 18 don't know that this was informing the SCP or that 19 the SCP -- there's no evidence -- there's no basis 20 for saying the SCP even took note of this report. 21 Indeed, I should perhaps just clarify 22 that the 2001 report was an informal document. It 23 would have been made available to member states but 24 it was not submitted as a formal document to the 25 Committee. Nonetheless, it certainly would have been</p> <p>www.dianaburden.com</p>

<p>1718</p> <p>1 present in the meeting room and available to the 2 member states. 3 MR. SPELLISCY: And it would 4 accurately reflect what the International Bureau was 5 told, correct? 6 MR. THOMAS: The content of this 7 study? 8 MR. SPELLISCY: Yes. 9 MR. THOMAS: As long as the 10 International Bureau was careful in what it did. It 11 would certainly reflect accurately what the 12 International Bureau did, and hopefully it would 13 reflect accurately the responses that had been 14 received at that date to the survey that was 15 undertaken. 16 MR. SPELLISCY: This paper was dated 17 April 2001, so you would agree with me, then, that 18 this information must have been provided by Canada 19 prior to that date, correct? 20 MR. THOMAS: Yes. 21 MR. SPELLISCY: And you said earlier 22 this report was available to all members of the SCP, 23 correct? 24 MR. THOMAS: Yes, it would have been 25 made available. I can't say that I have any</p> <p>www.dianaburden.com</p>	<p>1719</p> <p>1 knowledge of exactly how it was made available, but 2 it was certainly made available to all SCP members. 3 MR. SPELLISCY: And, as you've said 4 today -- and in your report as well -- you can recall 5 no other state raising any concerns about the 6 consistency of this statement with the core utility 7 requirement, correct? 8 MR. THOMAS: According to the minutes 9 of the meeting which was held and the later meeting 10 considering the 2003 draft, there was no discussion 11 of this document at all. It's not mentioned in the 12 minutes of the 2001 meeting, and it's mentioned in 13 the context of the 2003 meeting simply by virtue of 14 the fact that it was available, but it's not noted or 15 discussed by either the committee as a whole or by 16 any delegation. 17 MR. SPELLISCY: So no concerns were 18 raised then, correct? 19 MR. THOMAS: There were no concerns 20 raised, nor was there any approval raised. It simply 21 wasn't discussed. 22 MR. SPELLISCY: And no one raised any 23 concerns to you on the secretariat, even outside of 24 the plenary session, that wouldn't be reflected in 25 the minutes, correct?</p> <p>www.dianaburden.com</p>
<p>1720</p> <p>1 MR. THOMAS: No one said anything to 2 me, to my recollection, at all about this study. I 3 would venture to say it would have been of passing 4 interest. 5 MR. SPELLISCY: I want to talk about 6 the statement you were discussing earlier in 7 paragraph 11 in which you say industrial 8 applicability is a low bar on which few patents are 9 refused. I want to understand that a little bit 10 better. I want to understand that in the context of 11 paragraph 12. You seem to be saying "Given the 12 substantial consistency of practice with regard to 13 the core industrial applicability... requirement... 14 the issue was not considered to be a priority for 15 harmonization." 16 Am I correct to understand, then, that 17 your view is that it is a low bar that is rarely the 18 basis for rejection, and that's because there is some 19 sort of core agreement on utility? 20 MR. THOMAS: I don't think there's a 21 core agreement on utility, if that means that there's 22 a core agreement on how it should be defined or 23 elaborated in national legislation. In that respect 24 there's no core agreement. But what negotiating 25 countries wanted to see was their applicants, their</p> <p>www.dianaburden.com</p>	<p>1721</p> <p>1 inventors, their enterprises, getting patents in 2 other countries, and in this particular case for 3 useful inventions, and, by and large, patents were 4 granted in all countries for useful inventions with 5 much the same result. So there didn't have to be 6 agreement on any definition of utility. 7 MR. SPELLISCY: Let me come, then, to 8 tab 1 in your binder again, Exhibit R-407. Turn to 9 page 6, so we can see what the members were telling 10 WIPO or the International Bureau about that. I want 11 to look at paragraph 20. 12 Here it states, "Many Offices 13 indicated that, in practice, the requirement 14 concerning industrial applicability/utility was not 15 often imposed. As several Offices mentioned, the 16 main reason for that is that the requirement 17 concerning industrial applicability/utility is 18 closely related to other requirements, such as 19 sufficient disclosure... requirement, the definition 20 of 'invention', exclusions from patentable subject 21 matter and the requirement concerning inventive 22 step." 23 Do you see that? 24 MR. THOMAS: Yes, I see it. 25 MR. SPELLISCY: So this International</p> <p>www.dianaburden.com</p>

<p>1722</p> <p>1 Bureau study reports that the reason member states 2 are saying that utility is not often imposed is 3 because it's covered in the same -- it's closely 4 related to and achieves the same other things they 5 were doing under other doctrines, like sufficient 6 disclosure, definition of invention, obviousness. 7 Correct?</p> <p>8 MR. THOMAS: It says that it's closely 9 related to in the view of some countries, yes, and 10 certainly the discussions of various matters come up 11 under different heads.</p> <p>12 MR. SPELLISCY: It doesn't say "some 13 countries." It says "many Offices," correct?</p> <p>14 MR. THOMAS: I'm sorry?</p> <p>15 MR. SPELLISCY: I think in your answer 16 it says "some countries" say that, but it actually 17 says "many Offices" indicated that. You see that?</p> <p>18 MR. THOMAS: Yes, I see that. I don't 19 have a count in my mind.</p> <p>20 THE PRESIDENT: Sorry, I think "Many 21 Offices indicated that" -- if you quote from 22 paragraph 20 -- and then "several Offices."</p> <p>23 MR. SPELLISCY: I see. Fair enough.</p> <p>24 THE PRESIDENT: So what you should 25 have been asked was "several" Offices, not "some"</p> <p>www.dianaburden.com</p>	<p>1723</p> <p>1 offices.</p> <p>2 MR. THOMAS: I focused on only one 3 part of the question and not the other, but I'm 4 indebted to you, sir.</p> <p>5 THE PRESIDENT: You were asked that 6 "many" offices did it because you had earlier 7 testified it was "some" Offices, but now it turns out 8 to be "several Offices," if you read the second 9 sentence.</p> <p>10 MR. THOMAS: The first sentence refers 11 to "many Offices" and the second sentence to "several 12 Offices". Personally I find no embarrassment in the 13 fact that my report said "some" in the circumstances.</p> <p>14 MR. SPELLISCY: I want to understand a 15 little bit why you say utility was not being 16 discussed. In paragraph 12 in that sentence it says, 17 "Given the substantial consistency of practice, the 18 issue was not considered to be a priority for 19 harmonization," in the first sentence of paragraph 20 12.</p> <p>21 MR. THOMAS: I'm sorry, we're now back 22 in my report?</p> <p>23 MR. SPELLISCY: Yes, your report.</p> <p>24 MR. THOMAS: Were you asking a 25 question about my report now?</p> <p>www.dianaburden.com</p>
<p>1724</p> <p>1 MR. SPELLISCY: Yes, your report, 2 paragraph 12.</p> <p>3 MR. THOMAS: I'm sorry, could you 4 repeat the question?</p> <p>5 MR. SPELLISCY: You said in the first 6 line, "Given the substantial consistency of 7 practice... The issue was not considered to be a 8 priority for harmonization" about utility. I just 9 wanted to understand that statement a little bit 10 more.</p> <p>11 Let's look again at the 2001 study and 12 turn to page 6 again, which is where we were in that 13 paragraph 24. It says, "It is apparent that the 14 notions of 'industrial applicability' and 'utility' 15 are broad and, at least in part, overlap. Further, 16 they relate to other substantive requirements of 17 patentability. Therefore, for the purposes of full 18 harmonization of substantive patent law, the 19 industrial applicability/utility requirement cannot 20 be considered separately from other requirements. In 21 this regard, the SCP may wish to consider the 22 possibility of examining substantive patentability 23 requirements as a whole, without giving too much 24 focus on the terminology 'industrial applicability' 25 or 'utility'."</p> <p>www.dianaburden.com</p>	<p>1725</p> <p>1 Do you see that?</p> <p>2 MR. THOMAS: I see it.</p> <p>3 MR. SPELLISCY: You would agree with 4 me that far from saying utility and industrial 5 applicability need not be addressed because there is 6 a common agreement, this paper concludes that, in 7 fact, they cannot be considered separately from other 8 requirements and that the SCP should examine the 9 patentability requirements as a whole, correct?</p> <p>10 MR. THOMAS: Yes, yes, I understand 11 what you're asking, I understand what you're saying, 12 but I'm not quite sure what you're asking me to say.</p> <p>13 MR. SPELLISCY: You would agree that 14 the International Bureau here in 2001 is not 15 concluding, as you did, that there is no reason to 16 examine, or no reason to consider it a priority to 17 harmonize utility. Its telling it's members that 18 utility must be considered and it must be considered 19 with other requirements, correct?</p> <p>20 MR. THOMAS: This suggestion by the 21 International Bureau is that the SCP "may" wish to 22 consider -- I wouldn't use the word "must" -- but it 23 may wish to consider the possibility of doing these 24 things, but in practice the SCP did not so proceed, 25 and I think that is borne out in the statement made</p> <p>www.dianaburden.com</p>

<p>1726</p> <p>1 in paragraph 12 of my report. Priority was not given 2 to this matter.</p> <p>3 MR. SPELLISCY: We're going to come 4 back and discuss that in a second in terms of the 5 priority given to this matter. Maybe let's do it 6 right now. Let's come to tab 3 in your binder, which 7 is the 2003 report that you did cite, the WIPO 8 report, Exhibit R-230, titled "'Industrial 9 applicability' and 'utility' requirements."</p> <p>10 This document is an official WIPO 11 report, correct?</p> <p>12 MR. THOMAS: It's an official WIPO 13 document, yes, and it's a report in the sense that 14 it's a study based on responses given by member 15 states.</p> <p>16 MR. SPELLISCY: And it was prepared 17 now during the middle of the SPLT negotiations, 18 correct?</p> <p>19 MR. THOMAS: It was issued. It was 20 prepared, as pointed out in paragraph 2 of the 21 report, there's a reference there which, in fact, is 22 to the study at tab 1, but the preparation of this 23 would have taken place continuously over the period 24 from whenever the invitation to respond to the survey 25 was first issued, which would have been sometime in</p> <p>www.dianaburden.com</p>	<p>1727</p> <p>1 2001. So yes, this study was prepared in 2003 after 2 a period of some two years when responses to the 3 survey had been received.</p> <p>4 MR. SPELLISCY: So that I understand, 5 then, when work is being done on one of the early 6 drafts in 2001 of the SPLT, the International Bureau 7 has been requested to prepare an informal paper. 8 Upon receipt of that informal paper, as we see in 9 this at paragraph 1 --</p> <p>10 MR. THOMAS: I was just going to ask 11 if you could clarify where you're quoting from?</p> <p>12 MR. SPELLISCY: We're talking about 13 what we saw in 2001 on the request to prepare the 14 informal paper. We can go back and look at it if you 15 want. But then it gets to 2002 and in the first line 16 of the first paragraph it says "At the 8th session of 17 the Standing Committee... held in Geneva... the 18 International Bureau was mandated to prepare a study 19 regarding commonalities and differences between the 20 'industrial applicability' and the 'utility' 21 standards."</p> <p>22 What I am trying to understand, 23 Mr. Thomas, is why the standing committee would 24 mandate the International Bureau to continue work on 25 the informal paper and devote resources to that, when</p> <p>www.dianaburden.com</p>
<p>1728</p> <p>1 I thought it was your testimony that the 2001 paper 2 wouldn't even have gotten much notice?</p> <p>3 MR. THOMAS: Well, the first point to 4 make is you've got to understand what was meant by 5 the word "mandated." I would have to refresh my 6 memory, but I think I'm confident enough to suggest 7 that there were two delegations which made a 8 suggestion that such a study be prepared, and then 9 the chair concluded -- there was no other remark -- 10 the chair concluded that the International Bureau 11 should go ahead to prepare this study, so I don't 12 think the word "mandated" should be read in a very 13 exalted kind of way.</p> <p>14 Why was it done? Because some 15 delegations requested it. The more important thing 16 is what happened to the study when it was prepared, 17 when the mandated study was prepared? The answer is 18 it was submitted to the committee with a request -- a 19 suggestion at the end, there's a paragraph right at 20 the end of the study -- which says "The SCP is 21 invited to note the contents of this document." When 22 one looks at the minutes of the meeting which 23 considered the document, the only reference to it is 24 the fact that it was on the table. There was no 25 noting, no acknowledging, no approval -- nothing.</p> <p>www.dianaburden.com</p>	<p>1729</p> <p>1 There was no discussion on it.</p> <p>2 MR. SPELLISCY: Let me understand, 3 though, Mr. Thomas. So in November of 2000 -- and 4 then again in November of 2002 -- the International 5 Bureau of WIPO was first requested and then mandated 6 by the chair, you said, to prepare studies on the 7 commonalities and differences between industrial 8 applicability and utility, correct?</p> <p>9 MR. THOMAS: Yes.</p> <p>10 MR. SPELLISCY: And you would agree 11 with me, would you not, that, being requested to 12 devote secretariat resources to the preparation of 13 two separate reports within two years is not 14 consistent with your view that the members were not 15 concerned with the differences in commonalities in 16 these two requirements, correct?</p> <p>17 MR. THOMAS: Well, the fact that the 18 study wasn't discussed or raised in discussions by 19 the Committee doesn't really bear out the suggestion 20 that it was regarded as having high importance, I 21 don't think.</p> <p>22 MR. SPELLISCY: You would agree with 23 me certainly that it had high enough importance that 24 the member states requested that the secretariat and 25 the International Bureau devote its resources to this</p> <p>www.dianaburden.com</p>

<p>1730</p> <p>1 study on two separate occasions within a two-year 2 period, correct? 3 MR. THOMAS: The International Bureau 4 was certainly asked to prepare the study, yes. There 5 were member states who -- I should say which, 6 perhaps -- would wish to see a result of this study, 7 and they may well have found it interesting, but they 8 didn't say so in meetings of the SCP. 9 MR. SPELLISCY: And these studies were 10 available to them, though, right? 11 MR. THOMAS: I'm sorry? 12 MR. SPELLISCY: Both of these studies. 13 This study too. This 2003 study was made available 14 to member states, correct? 15 MR. THOMAS: Both studies were 16 available to member states, yes, although one was a 17 formal document, one was an informal document. But 18 yes, they were certainly both available. 19 MR. SPELLISCY: In your report, 20 Mr. Thomas, in paragraph 30, in the second sentence, 21 you say, talking about this 2003 study, that the 22 study was "undertaken by the International Bureau in 23 light of the differences in domestic nomenclature." 24 You see that? 25 MR. THOMAS: Yes.</p> <p>www.dianaburden.com</p>	<p>1731</p> <p>1 MR. SPELLISCY: Let's look at the 2 study in tab 3 again. We just read the sentence, but 3 I want to read it again, at least the last part of 4 it. The first sentence in tab 3, first page in the 5 introduction in the first paragraph. 6 "...the International Bureau was 7 mandated to prepare a study regarding the 8 commonalities and differences between the 'industrial 9 applicability' and the 'utility' standards." They're 10 not being mandated here to prepare a study on 11 differences in nomenclature only, are they, 12 Mr. Thomas? 13 MR. THOMAS: No, it doesn't -- it's 14 not restrictive at all. 15 MR. SPELLISCY: In fact, do you know 16 if the word "nomenclature" is mentioned a single time 17 in this study? 18 MR. THOMAS: Well, the word 19 "nomenclature" I think is referring to -- maybe I 20 could have used a better word in my report, but I'm 21 talking about the wording used in legislation or 22 other formal regulations or other formal documents 23 setting out the requirement. 24 MR. SPELLISCY: Let's turn to page 7 25 of this report, this report we're in right now, tab</p> <p>www.dianaburden.com</p>
<p>1732</p> <p>1 3. 2 MR. THOMAS: The last one we mentioned 3 was my report, so I just want to clarify. 4 MR. SPELLISCY: Tab 3, page 7, 5 paragraph 25. The WIPO study in the first line 6 concludes that, "As described above, national and 7 regional laws and practices concerning the industrial 8 applicability requirement vary significantly.," 9 correct? 10 MR. THOMAS: Yes. Here I think we 11 should be clear that the word "practices" almost 12 certainly refers to regulations and guidelines rather 13 than practical outcomes. 14 MR. SPELLISCY: I understand that, but 15 what it's saying is there's significant variance in 16 the standard, correct? 17 MR. THOMAS: There most certainly is. 18 MR. SPELLISCY: If we turn to page 13 19 in this report, paragraph 49, we get to the 20 conclusion on utility. The conclusion is, "As in the 21 case of the industrial applicability requirement, 22 practices in the countries which require utility (or 23 usefulness) vary." Then it goes on to say, "As a 24 general rule, however, certain characteristics 25 commonly applicable to the utility requirement can be</p> <p>www.dianaburden.com</p>	<p>1733</p> <p>1 identified." 2 Do you see that? 3 MR. THOMAS: Yes, I see that. 4 MR. SPELLISCY: So the report here is 5 again noting that, even though there are certain 6 characteristics commonly applicable, that there is, 7 again, variation in the practices of countries, 8 correct? 9 MR. THOMAS: Yes. 10 MR. SPELLISCY: I want to understand 11 again what would have been known at the time this was 12 submitted because this is, again -- you said it was 13 available to all SCP members, so let's come back to 14 page 11 and paragraph 40 of this report. 15 MR. THOMAS: I think just to 16 clarify -- I'm not sure I heard you correctly, but 17 did you say SCP members? It was available to all SCP 18 members, yes. Indeed, it would be publicly 19 available. 20 MR. SPELLISCY: It would have been 21 published on the WIPO website? 22 MR. THOMAS: Yes, it would -- I can't 23 speak as a matter of confirmed fact but I'm sure this 24 would have been made available to anyone who wanted 25 it.</p> <p>www.dianaburden.com</p>

<p>1734</p> <p>1 MR. SPELLISCY: So we're going to 2 start on page 11 and paragraph 40, where it says 3 "Under the law of Canada". Earlier we had talked 4 about the 2001 report which had just mentioned the 5 laws of another country. 6 MR. THOMAS: I apologize for 7 interrupting, but I didn't catch the reference. 8 MR. SPELLISCY: Page 11, paragraph 40. 9 MR. THOMAS: Yes, thank you. 10 MR. SPELLISCY: First line, "Under the 11 law of Canada..." 12 MR. THOMAS: Yes. 13 MR. SPELLISCY: As we discussed 14 earlier this is the follow-on, and what makes you 15 conclude here that the "another country" that is 16 referred to in the informal paper is, in fact, the 17 laws of Canada. That's the reference, right? 18 MR. THOMAS: That's right, and it 19 follows in I think the next two paragraphs. 20 MR. SPELLISCY: If we come to the next 21 paragraph, paragraph 41, we see that what Canada told 22 in response to the report -- or in response to this 23 study was that "A finding that the alleged invention 24 is not useful may be expressed in a way that the 25 invention will not work, either in the sense that it</p> <p>www.dianaburden.com</p>	<p>1735</p> <p>1 will not operate at all or, more broadly, that it 2 will not do what the specification promised it would 3 do ('false promise')." See that? 4 MR. THOMAS: I see it. 5 MR. SPELLISCY: The same language from 6 the 2001 report, correct? 7 MR. THOMAS: I think you'll find that 8 the whole of this paragraph is not identical to the 9 2001 study, but it may well be that that sentence is. 10 MR. SPELLISCY: Again, as you said 11 earlier, this is in 2003, and this document you said 12 wasn't discussed by members of the SCP, correct? 13 MR. THOMAS: I didn't catch the -- 14 MR. SPELLISCY: This was in 2003, and 15 you said that this document was never discussed by 16 members of the SCP? 17 MR. THOMAS: I think I said no 18 discussion was reported in the minutes. I can't say 19 what countries may have discussed among themselves 20 but, as a matter of the committee discussions, no, it 21 was not discussed. 22 MR. SPELLISCY: And no concerns, to 23 your knowledge, as a member of the secretariat there 24 attending every meeting, no concerns, to your 25 knowledge, were ever raised about this Canadian</p> <p>www.dianaburden.com</p>
<p>1736</p> <p>1 standard, correct? 2 MR. THOMAS: That is correct. 3 THE PRESIDENT: One question, if I 4 may. You see the reference in footnote 14 -- this is 5 a question actually to Respondent, not to the 6 expert -- and you see there the Canadian Patent Act 7 annotated by Mr. Barrigar in 1999, and he quotes it, 8 and when I see this quote it seems similar to the 9 Halsbury 3rd Edition, if I recall it. I see the 10 words "more broadly." Is this reference in the 11 record? 12 MR. SPELLISCY: I don't think that 13 reference is. 14 THE PRESIDENT: Can we make a mental 15 note that this one will be a Tribunal question? 16 Sorry for interrupting. 17 MR. SPELLISCY: Let's turn to page 14, 18 paragraph 52 of this report. Here the International 19 Bureau has reported, "As in the case of the 20 industrial applicability requirement, the utility 21 requirement also relates to other patentability 22 requirements, in particular, requirements concerning 23 the disclosure of the claimed invention. Since the 24 required utility could not be a speculative one, it 25 is also related to a principle that the scope of the</p> <p>www.dianaburden.com</p>	<p>1737</p> <p>1 claims is commensurate with the invention as 2 disclosed. Under national practices, this aspect is 3 found, in particular, in relation to expressions such 4 as 'credible utility', 'sound prediction' and 'false 5 suggestion'." See that? 6 MR. THOMAS: Yes. 7 MR. SPELLISCY: So you would agree 8 with me that, in fact, in 2003, the members of the 9 SCP were at least all informed that utility and 10 disclosure were related, correct? 11 MR. THOMAS: The members of the SCP 12 were informed of everything that's in this study, and 13 equally didn't discuss it. 14 MR. SPELLISCY: You would also see the 15 reference to "sound prediction" there in the last 16 line, correct? 17 MR. THOMAS: Yes, I can see that. 18 MR. SPELLISCY: And if you come back 19 to paragraph 41 in the discussion of Canada you see 20 there again that the Canadian delegate, I guess, has 21 made reference to the sound prediction doctrine in 22 Canada, correct? The very end of the paragraph? 23 MR. THOMAS: I think one does have to 24 be careful about saying "Canadian delegate" because 25 that implies it was a statement made in the meeting,</p> <p>www.dianaburden.com</p>

<p>1738</p> <p>1 which there's no record of at all. But this, I feel 2 sure, would have been based on information supplied 3 by the Canadian Government in response to the survey. 4 MR. SPELLISCY: Right, so the Canadian 5 Government is referencing the doctrine of sound 6 prediction, and then WIPO is reporting that they've 7 been told that, under national practices, utility is 8 found in relation with things like disclosure and 9 including sound prediction, correct? That it relates 10 to those patentability requirements? 11 MR. THOMAS: The information here was 12 related by the International Bureau based on 13 information from the Canadian Government included in 14 the study, which was presented to the Committee, yes. 15 Yes, that's certainly the case. 16 MR. SPELLISCY: Thank you, Mr. Thomas. 17 I have nothing further. 18 MR. BERENGAUT: Nothing for redirect, 19 Mr. President. 20 THE PRESIDENT: Mr. Thomas, thank you 21 for testifying. You are now released as an expert 22 witness and excused. 23 MR. THOMAS: Thank you, sir. 24 THE PRESIDENT: Recess for ten 25 minutes.</p> <p>www.dianaburden.com</p>	<p>1739</p> <p>1 (Recess taken) 2 DANIEL GERVAIS 3 THE PRESIDENT: Good afternoon, 4 Professor Gervais. 5 PROFESSOR GERVAIS: Good afternoon, 6 Professor van den Berg. 7 THE PRESIDENT: Could you please state 8 your full name? 9 PROFESSOR GERVAIS: Daniel Gervais. 10 THE PRESIDENT: You appear as an 11 expert witness for the Respondent? 12 PROFESSOR GERVAIS: Yes, sir. 13 THE PRESIDENT: If any question is 14 unclear to you, either because of language or for any 15 other reason, please do seek a clarification because, 16 if you don't do so, the Tribunal will assume that 17 you've understood the question and that your answer 18 corresponds to the question. 19 PROFESSOR GERVAIS: I understand. 20 THE PRESIDENT: Professor Gervais, you 21 will appreciate that testifying, be it before a court 22 or an arbitral tribunal, is a very serious matter. 23 PROFESSOR GERVAIS: Very much so. 24 THE PRESIDENT: In that connection, 25 the Tribunal expects you to give the statement which</p> <p>www.dianaburden.com</p>
<p>1740</p> <p>1 is in front of you. 2 PROFESSOR GERVAIS: I solemnly 3 declare upon my honor and conscience that my 4 statement will be in accordance with my sincere 5 belief. 6 THE PRESIDENT: Thank you. Can you go 7 to your First Report? This is dated January 23, 8 2015. Please go to page 27 and confirm that the 9 signature appearing above your name is your 10 signature? 11 PROFESSOR GERVAIS: It is. 12 THE PRESIDENT: Can you please go to 13 your Second Report dated December 7, 2015, page 16, 14 and confirm also for the record that the signature 15 appearing above your name is your signature? 16 PROFESSOR GERVAIS: It is. 17 THE PRESIDENT: Thank you. Is there 18 any correction you wish to make to either report? 19 PROFESSOR GERVAIS: No, sir. 20 THE PRESIDENT: Mr. Spelliscy? 21 MR. SPELLISCY: Professor Gervais, I 22 know you have a presentation to give, so I invite you 23 to give it now. 24 PROFESSOR GERVAIS: Thank you. 25</p> <p>www.dianaburden.com</p>	<p>1741</p> <p>1 PRESENTATION BY PROFESSOR GERVAIS 2 PROFESSOR GERVAIS: Thank you very 3 much, Mr. President, members of the Tribunal, for 4 giving me this opportunity to appear before you in 5 this particularly important matter. I will be 6 relatively brief, a very quick overview of my 7 qualifications. 8 I am currently full professor of law 9 at Vanderbilt University and director of the IP 10 Program. I used to work at WIPO as head of section, 11 and before that at what we now call the WTO (in those 12 days it was called the GATT) during the TRIPS 13 negotiations. I then authored a book reference text 14 on the TRIPS Agreement which has been cited in 15 several countries. I'm also a member of both the 16 Academy of Europe and the American Law Institute. 17 There are essentially three main 18 points made in my two reports, and I've tried to 19 summarize them in view of the Claimant's new line of 20 argument on the baseline. 21 Essentially, the three major 22 substantive patentability criteria, the ones that are 23 named in both NAFTA and the TRIPS Agreement, are, in 24 fact, named, defined and applied differently around 25 the world, and this changes not just geographically</p> <p>www.dianaburden.com</p>

<p>1742</p> <p>1 but also through time. These are, as the Claimant 2 now acknowledges, not harmonization. 3 There is no international treaty, and 4 this would include both NAFTA and TRIPS, that 5 establishes a legal obligation to use a specific or 6 particular definition or application of any of the 7 substantive patentability criteria in the examination 8 of domestic patent applications. 9 Third, states all apply other factors 10 or criteria before a patent will be granted, most 11 notably disclosure of an invention as of the date of 12 application. 13 Very simple examples of all three. 14 Novelty: Here, we have apparent agreement on naming 15 the criterion but, in fact, there are three versions 16 that have existed since NAFTA -- first-to-file, 17 first-to-invent, and now the new system which the 18 U.S. at least refers to as first-inventor-to-file. 19 There are differences in countries in terms of how 20 they measure novelty, whether novelty needs to be 21 absolute or relative, by which -- 22 MR. BERENGAUT: I'm sorry to interrupt 23 but I don't see references in these slides to 24 Professor Gervais' reports, and I don't believe he 25 addressed these topics in his reports.</p> <p>www.dianaburden.com</p>	<p>1743</p> <p>1 MR. SPELLISCY: The patentability 2 criteria were addressed in all of his reports and 3 yes, there are no references to slides. 4 THE PRESIDENT: Overruled. Please 5 proceed. 6 PROFESSOR GERVAIS: Thank you, sir. 7 When it comes to inventiveness and 8 non-obviousness the same difference is applied but 9 there is that additional difference in terminology. 10 If you were to look around the world you would see 11 differences in the necessary height of the inventive 12 step, to use the metaphor of the step, but also the 13 way that courts have developed tests to assess 14 obviousness or inventive step. And I believe 15 Professor Holbrook has a very good explanation of the 16 major change in U.S. law following the KSR case on 17 that issue. 18 On utility and industrial 19 applicability, again we have two different words. 20 Some national laws, as the previous expert 21 acknowledged, define them quite differently. 22 Adjectives are used very often in conjunction with 23 utility, words like "credible," "substantial," 24 "practical," "specific," and in previous literature 25 there was also reference made to "operable utility,"</p> <p>www.dianaburden.com</p>
<p>1744</p> <p>1 "beneficial utility," what one of the amicus briefs I 2 think refers to as "Jeffersonian utility." 3 The law has changed and continues to 4 change on this. U.S. law certainly changed, at least 5 as far as I'm concerned, after the Juicy Whip case. 6 Laws do and will continue to change. 7 The 2001 study that is referred to in 8 my report, that was highlighted in a previous 9 expert's testimony, makes very clear that this is not 10 just a matter of nomenclature but a matter of 11 practice. The word "practice" is there; it's quite 12 clear. 13 The overlap between utility and other 14 requirements is also noted, and I would draw the 15 Tribunal's attention to the fact that enablement is 16 specifically mentioned. The relationship between 17 utility and enablement, for example, in U.S. law is 18 particularly clear, and I would be happy to say more 19 about that later. 20 Promise utility is specifically 21 mentioned. I don't quite know what promise utility 22 is but I'm using the term because I've seen it used 23 in briefs. I think it means that if you promise 24 something in your patent application then you must 25 deliver on that promise, which first of all strikes</p> <p>www.dianaburden.com</p>	<p>1745</p> <p>1 me as entirely consistent with the contract or 2 bargain approach to patent law. You promise 3 something and then you have to deliver, as you would 4 in that context. But also, it has a specific history 5 in patent law, and this is reflected in this WIPO 6 report. 7 Now, Mr. Thomas reads the fact that 8 there was no discussion as perhaps a lack of 9 controversy. I beg to differ. I think that you 10 could also see it differently, and I will show you 11 what I mean in just two minutes, if you'll bear with 12 me. 13 I do want to say first, though, that 14 there have been a series of efforts to harmonize all 15 patentability criteria and they have, as we've seen 16 before, all failed. The lack of agreement is there. 17 The reason for lack of agreement is partly because 18 countries want to keep the ability to define these 19 criteria. They know that their courts will continue 20 to change the way that these criteria are applied and 21 defined. 22 Mr. Thomas' conclusion on some sort of 23 common understanding of the core strikes me as not 24 entirely convincing. I noted that he refers several 25 times to his beliefs in his report. The reports from</p> <p>www.dianaburden.com</p>

<p>1746</p> <p>1 his own organization and my former organization, for 2 that matter, that I cite do seem to go the other way. 3 But, in fact, he does cite one document -- and I feel 4 I have to show this -- he cites one document which is 5 the SCP/8-2 document which is also mentioned in 6 SCP/8-9, which is R-229. This is paragraph 28 of his 7 report. This is the part that he cites. He says: 8 Look, there is a proposal here. It proves that it 9 would have been possible to reconcile all of these 10 definitions. 11 Unfortunately, it doesn't mention in 12 the quote that this was alternative A, that there 13 were two other alternatives put to the member states. 14 And, perhaps more importantly, the report of that 15 meeting says this: "The chair summarized the 16 discussions on this paragraph, the one I just quoted 17 from, as follows: Three delegations supported 18 alternative A, while a majority... expressed their 19 preference for B." One delegation (the United States 20 if you read the report) supported alternative C -- 21 not surprisingly, it's the US language -- and then a 22 suggestion by one delegation that alternative C be 23 retained, and then some members proposed to modify A 24 and B. 25 So to say that there was no discussion</p> <p>www.dianaburden.com</p>	<p>1747</p> <p>1 of utility ever at WIPO or that there was no 2 controversy strikes me as a slight 3 oversimplification. 4 NAFTA, like TRIPS, does not require 5 one way of defining these criteria. 1709(1), which 6 corresponds to TRIPS 27.1, is not harmonizing this 7 terminology. There is, as I say, in my report a 8 negotiation. Some countries wanted industrial 9 applicability; others wanted utility. They could not 10 agree. They could not agree to state that these were 11 synonymous terms for, I believe, the simple reason 12 that they're not. 13 So some convoluted language was found 14 in the end to find an agreement in the footnote to 15 TRIPS, and in the case of NAFTA it's in the paragraph 16 itself, using this interesting English expression 17 that the terms "may be deemed" to be synonymous. 18 This is not a nomenclature issue only. 19 It is, as the WIPO documents show, because there were 20 significant differences not just in terminology but 21 in actual practice. 22 These differences existed at the time. 23 They have continued to exist. In fact, to me this is 24 nothing surprising. Utility will continue to vary as 25 either new types of inventions or new understandings</p> <p>www.dianaburden.com</p>
<p>1748</p> <p>1 of new technologies evolve; how lawyers approach 2 these issues in courts, how courts make policy, 3 because most patent policy is made by courts, very 4 few patent laws are amended on the level of how to 5 define these criteria. So when the Claimant says -- 6 and I really tried hard to understand their baseline 7 argument and perhaps in cross-examination I'll get a 8 better understanding, but I honestly do not know what 9 the difference is between saying there's a baseline, 10 which I think is better viewed here as a ceiling, 11 basically a very low level of utility, and saying 12 that's the international norm, not documented but 13 that's it, and saying there's no harmonization. So I 14 would suggest that that's a distinction without a 15 difference. 16 NAFTA does not require the parties 17 adopt the PCT definition of industrial applicability. 18 The PCT and the Paris Convention were both well-known 19 at the time that NAFTA was signed and TRIPS. Neither 20 one of those agreements incorporated the PCT, but 21 they both incorporated the Paris Convention. 22 Therefore, not being in the "must comply" list of 23 treaties in NAFTA is, I think, relevant. 24 More importantly I think the PCT as 25 I've always understood it, and I will plainly admit</p> <p>www.dianaburden.com</p>	<p>1749</p> <p>1 I'm not a PCT expert but I have read the PCT many 2 times and I always thought that it meant what it 3 says, which, as you see on this slide, strikes me as 4 fairly clear. 5 Finally my last point is this. I 6 think other criteria always apply, and I'd be happy 7 to spend some time explaining how the language in 8 both NAFTA and TRIPS evolved, but basically there was 9 a clear understanding that the three patentability 10 criteria were not the entire list of conditions that 11 an applicant must comply with to obtain a patent. 12 In the case of TRIPS, we see this 13 explicitly in Article 29, which in part resembles 14 Article 5 PCT, and in Professor Holbrook's report we 15 also see quite clearly that the U.S. has specific 16 requirements in terms of written description and 17 enablement. 18 How the patent bargain, therefore, is 19 applied will change and evolve from jurisdiction to 20 jurisdiction, and over time I would submit that this 21 is the nature of the common law process, when the 22 policy is mostly made in and by courts, and I would 23 also stress that the disclosure and enablement 24 obligations that are not mentioned in 27 or 1709(1) 25 are core in implementing the bargain.</p> <p>www.dianaburden.com</p>

<p>1750</p> <p>1 With that, I very much look forward to 2 the discussion. Thank you very much. 3 MR. SPELLISCY: There are no questions 4 on direct. 5 THE PRESIDENT: Thank you. Please 6 proceed, Mr. Berengaut. 7 CROSS-EXAMINATION ON BEHALF OF THE CLAIMANT 8 MR. BERENGAUT: Good afternoon, 9 Professor Gervais, my name is Alex Berengaut. 10 If you could please turn to tab 2 of 11 your binder? 12 PROFESSOR GERVAIS: Yes. That would 13 be my Second Report. 14 MR. BERENGAUT: That's right. If you 15 could please look at paragraph 4, where you write, 16 beginning in the second sentence, "In particular, its 17 Reply Memorial argues that there is a baseline in 18 that Chapter 17 of NAFTA creates a minimum set of 19 defined requirements that the NAFTA parties may 20 exceed but not contravene." 21 Do you see that? 22 PROFESSOR GERVAIS: I do. 23 MR. BERENGAUT: I take it you disagree 24 with that proposition? 25 PROFESSOR GERVAIS: No, I don't -- of</p> <p>www.dianaburden.com</p>	<p>1751</p> <p>1 my statement -- this is my characterization of your 2 argument. 3 MR. BERENGAUT: I take it you disagree 4 with the proposition that you are characterizing in 5 Claimant's Reply Memorial. 6 PROFESSOR GERVAIS: I'm sorry. Let 7 me read this again. So you say, okay, there's a 8 baseline that Chapter 17 creates a minimum set of 9 defined requirements the NAFTA parties may exceed but 10 not contravene. What is it -- you're asking me if I 11 stand by that statement? 12 MR. BERENGAUT: In this sentence, 13 Professor, you say that the Reply Memorial -- that's 14 Claimant's Reply Memorial, correct? 15 PROFESSOR GERVAIS: I believe so. 16 MR. BERENGAUT: Were you referring to 17 a different Reply Memorial? 18 PROFESSOR GERVAIS: No. I'm only 19 aware of one. 20 MR. BERENGAUT: Claimant's Reply 21 Memorial argues that there is "a baseline in that 22 Chapter 17 of NAFTA creates a minimum set of defined 23 requirements that the NAFTA parties may exceed but 24 not contravene." 25 In that sentence you are</p> <p>www.dianaburden.com</p>
<p>1752</p> <p>1 characterizing your understanding of a point made in 2 the Reply Memorial, correct? 3 PROFESSOR GERVAIS: Correct. 4 MR. BERENGAUT: My question to you is 5 whether you agree or disagree with that point stated 6 in the Reply Memorial, as you understand it. 7 PROFESSOR GERVAIS: Oh, I understand. 8 You're not asking if I agree with my characterization 9 but with the baseline argument. I don't agree with 10 the baseline argument, correct. I apologize, I 11 misunderstood the first time. 12 MR. BERENGAUT: You would agree, 13 Professor, that in your view the TRIPS Agreement is 14 relevant to the interpretation of Chapter 17, 15 correct? 16 PROFESSOR GERVAIS: Relevant, yes. 17 MR. BERENGAUT: Let's turn to your 18 first statement, which is in tab 1. 19 PROFESSOR GERVAIS: First Report? 20 Yes. 21 MR. BERENGAUT: If you could please 22 turn to paragraph 25 of your First Report, which is 23 on page 9. 24 PROFESSOR GERVAIS: Yes. 25 MR. BERENGAUT: There you excerpt a</p> <p>www.dianaburden.com</p>	<p>1753</p> <p>1 WIPO report which states, "It is to be noted that the 2 TRIPS Agreement provides for minimum requirements." 3 Do you see that? 4 PROFESSOR GERVAIS: I do. 5 MR. BERENGAUT: Do you agree with the 6 statement in this report that the TRIPS Agreement 7 provides for minimum requirements? 8 PROFESSOR GERVAIS: It provides for 9 minimum requirements subject to being consistent with 10 the agreement, yes, so you can go above without 11 contradicting the agreement or the terms of Article 1 12 of TRIPS. 13 MR. BERENGAUT: And when you say "go 14 above," you mean provide additional intellectual 15 property protection, correct? 16 PROFESSOR GERVAIS: In most cases 17 that would be the case, yes. 18 MR. BERENGAUT: In the next paragraph 19 you quote a different WIPO report which states "WTO 20 members have the flexibility to design their national 21 intellectual property IP systems within the minimum 22 standards set by the TRIPS Agreement." Do you see 23 that? 24 PROFESSOR GERVAIS: I do. 25 MR. BERENGAUT: I take it you would</p> <p>www.dianaburden.com</p>

<p>1754</p> <p>1 agree here as well that the TRIPS Agreement 2 incorporates minimum standards? 3 PROFESSOR GERVAIS: It does, subject 4 to what I said before. 5 MR. BERENGAT: Let's take a look at 6 your treatise which is in tab 6. This is C-336. If 7 you could please turn to page 174? 8 PROFESSOR GERVAIS: Yes. 9 MR. BERENGAT: The first full 10 paragraph begins "Article 1.1" where you write 11 "Article 1.1 also indicates that Member countries may 12 go beyond TRIPS, which thus sets minimum standards." 13 PROFESSOR GERVAIS: Yes. 14 MR. BERENGAT: My question is just: 15 I take it that's a reference to the same point you 16 just made in response to my previous questions about 17 the WIPO documents? 18 PROFESSOR GERVAIS: Correct. Of 19 course, you'd have to read the whole paragraph to see 20 what actually it says, but yes. 21 MR. BERENGAT: On that point I note 22 in the final sentence of the paragraph you write, 23 "This is related to the" -- no, fair enough, you're 24 talking about other things, and if you want to read 25 additional aspects of the paragraph in context I</p> <p>www.dianaburden.com</p>	<p>1755</p> <p>1 totally understand, but my question is related to one 2 clause in this sentence. This final sentence reads, 3 "This is related to the idea (or theory) that TRIPS 4 contains not just minimum obligations (a 'floor') but 5 also maximum levels of protections ('ceiling')." 6 Setting aside the ceiling part of the 7 sentence, my question is just whether you would agree 8 with the proposition that TRIPS's minimum obligations 9 could fairly be characterized as a floor of 10 protection? 11 PROFESSOR GERVAIS: Again, in most 12 cases, unless increasing protection would violate 13 some other provision of TRIPS or one of the 14 agreements incorporated into TRIPS. 15 MR. BERENGAT: Given the influence of 16 TRIPS on Chapter 17, in your view, would you agree 17 also that Chapter 17 incorporates a floor of 18 protection which states "may exceed but not 19 contravene"? 20 PROFESSOR GERVAIS: Generally 21 speaking, yes. 22 MR. BERENGAT: Let's take a look at 23 Chapter 17, and that's tab 7 of your binder. If you 24 could please look at page 333, which has 25 Article 1709(1) in it.</p> <p>www.dianaburden.com</p>
<p>1756</p> <p>1 PROFESSOR GERVAIS: I see it, yes. 2 The point I made previously is in 1702 on the 3 previous page, but okay, I'm on 1709 now. 4 MR. BERENGAT: I'm happy to read 1702 5 into the record for context. Article 1702: More 6 Extensive Protection. "A party may implement in its 7 domestic law more extensive protection of 8 intellectual property rights than is required under 9 this Agreement, provided that such protection is not 10 inconsistent with this Agreement." 11 Now, your view -- and I think this is 12 a fair characterization but you'll correct me -- is 13 that countries have broad flexibilities in 14 implementing the patentability requirements 15 identified in Article 1709(1). Is that fair? 16 PROFESSOR GERVAIS: Yes, I think it's 17 fair. 18 MR. BERENGAT: Let's explore that 19 concept with an example. You mentioned in your 20 opening presentation the concept of novelty, right? 21 PROFESSOR GERVAIS: I did. 22 MR. BERENGAT: And that is also 23 sometimes referred to as the requirement that an 24 invention be new, correct? 25 PROFESSOR GERVAIS: Yes.</p> <p>www.dianaburden.com</p>	<p>1757</p> <p>1 MR. BERENGAT: And when a 2 Patent Office is evaluating a patent application, 3 they consider prior art in determining whether that 4 invention is novel, right? 5 PROFESSOR GERVAIS: Correct. 6 MR. BERENGAT: Sometimes patent 7 prosecutions can take several years? 8 PROFESSOR GERVAIS: Yes. 9 MR. BERENGAT: Suppose, 10 hypothetically, Canada passed a law that said, for 11 purposes of novelty, examiners should consider as 12 prior art anything that was published up to three 13 years after a patent application is filed, and let's 14 say, Professor, that after the hearing today, I go 15 home and I invent a flying car and I tomorrow file a 16 patent application for that flying car in Canada, and 17 two years pass when my patent application is being 18 prosecuted, and then you invent the same flying car 19 and you publish an article about it and the patent 20 examiner who is reviewing my application reads your 21 article about your flying car and she says to me, 22 sorry, your application fails for lack of novelty 23 because your invention of a flying car is not new. 24 My question is whether, in your 25 opinion, that law would violate Article 1709(1)?</p> <p>www.dianaburden.com</p>

<p>1 PROFESSOR GERVAIS: Well, there are 2 two answers I can give you to that question. One is 3 three words and the other is five minutes. The three 4 words is "I don't know." The five minutes is "I can 5 explain why." 6 MR. BERENGAUT: Please -- maybe not 7 for five minutes because we don't have all that much 8 time. 9 PROFESSOR GERVAIS: It's probably one 10 of the core questions, as I see it, in the case. So 11 it's how you interpret the terms of Article 1709. 12 Clearly, there would be interpretations of the terms 13 that are contained in 1709 that would go outside of 14 boundaries. This is a notion that is well known 15 certainly in trade law. 16 I could quote, or maybe not quote from 17 but certainly cite Appellate Body and other Panel 18 Reports in the WTO on this issue which is you have, 19 as a member of the WTO applying TRIPS, leeway but 20 it's finite, and the question is where does that 21 limit find itself. So is the example that you give 22 me beyond that limit? Possibly. I might even say 23 probably, given that you've really pushed it really 24 far, but do I know with certainty where the limit is? 25 No, I don't.</p> <p>www.dianaburden.com</p>	<p>1758</p> <p>1 So that's kind of the longer answer. 2 If you're going to do a Vienna 3 analysis of each of these terms in context, you'd 4 have to figure what the terms mean, what they're 5 there for, why they came into this Treaty, what the 6 state practice has been -- you have several factors 7 that would -- I think Professor Dinwoodie at Oxford 8 has a very good expression that I like. He says 9 these treaties confine, they don't define, so there 10 are confines, there are limits to the leeway, 11 otherwise, the Treaty means nothing, but the question 12 is where is that limit. 13 I'm happy to discuss hypotheticals 14 with you but the answer will be I'm not sure that 15 line is exactly for each of these terms. 16 MR. BERENGAUT: Thank you. 17 In your reports you discuss the WIPO 18 negotiations regarding a potential substantive patent 19 law treaty. Is that right? 20 PROFESSOR GERVAIS: Yes. 21 MR. BERENGAUT: If we could turn to 22 tab 1 of the binder paragraph 29 of your First 23 Report. 24 PROFESSOR GERVAIS: Yes. 25 MR. BERENGAUT: This is where you</p> <p>www.dianaburden.com</p> <p>1759</p>
<p>1 discuss that topic, in this section of your report? 2 PROFESSOR GERVAIS: Yes, I do. 3 MR. BERENGAUT: Your conclusion with 4 regard to your review of these WIPO documents -- and 5 now I'm quoting from paragraph 28 of your report -- 6 is that there was "no consensus" on utility and 7 industrial applicability. Is that right? 8 PROFESSOR GERVAIS: Yes, that's 9 right. 10 MR. BERENGAUT: Now, in a number of 11 places in your report you quote from WIPO documents 12 statements to the effect that there are differences 13 between utility and industrial applicability. Is 14 that right? 15 PROFESSOR GERVAIS: And within each 16 group of countries applying both or either doctrines 17 there are differences within each group as well, yes. 18 MR. BERENGAUT: And the reason you do 19 this, I take it, is because in your view, these 20 statements of difference evidence the fact that there 21 was not consensus. Is that fair? 22 PROFESSOR GERVAIS: There was not 23 consensus. 24 MR. BERENGAUT: And the statements of 25 difference, in your view, are evidence of that</p> <p>www.dianaburden.com</p>	<p>1760</p> <p>1 proposition? 2 PROFESSOR GERVAIS: That's state 3 practice as reported to WIPO. I consider that a 4 valid empirical basis for that claim, yes. 5 MR. BERENGAUT: By the same token, 6 then, Professor, you would agree with me that 7 evidence of commonalities would show areas where the 8 parties did have consensus, right? 9 PROFESSOR GERVAIS: No. Commonality 10 and consensus are two different terms. There might 11 be commonalities; it doesn't mean they have 12 consensus. It means there were commonalities, there 13 are commonalities, and there are differences. That's 14 the whole point of these reports. That's why 15 they're -- if you look at the instructions that the 16 previous expert was shown, the secretariat was asked 17 to identify commonality and differences, and to say 18 there's consensus on this part when there's a 19 difference mentioned in the following paragraph is, 20 to me, stretching that data a little too far. 21 MR. BERENGAUT: Let's explore that 22 difference between commonalities and consensus that I 23 think you're trying to draw. Let me pose a different 24 hypothetical to you. Let's say that you and I were 25 trying to reach consensus on an international</p> <p>www.dianaburden.com</p> <p>1761</p>

<p>1762</p> <p>1 convention for drivers' licenses for driving tests. 2 In my country you get a license if you are an 3 adequate driver and in your country you get a license 4 if you are an able driver, and we are trying to reach 5 agreement on the test. 6 If you wanted to include as part of 7 the test a mountain driving skill and I didn't, that 8 would be a point of difference, right? 9 PROFESSOR GERVAIS: For example, yes. 10 MR. BERENGAUT: But if we both agreed 11 that drivers who show up to take their tests and are 12 completely intoxicated would mean that the drivers 13 were neither an adequate driver nor an able driver, 14 and if we could reach agreement on that, wouldn't 15 that be a point on which we had consensus? 16 PROFESSOR GERVAIS: It depends. If 17 we're only trying to discuss whether the rule for 18 drivers' licenses is able or adequate and we decide 19 on some way to define "able" or "adequate", or we say 20 "able" may be deemed synonymous with "adequate," do 21 we have consensus on that particular point -- yes. 22 If we are trying to decide what are 23 the rules that apply to drivers in our two states and 24 that's paragraph 381 of this whole document, then 25 yes, you could say we have consensus on 381. But</p> <p>www.dianaburden.com</p>	<p>1763</p> <p>1 that's why I'm drawing a little bit of -- people can 2 agree on something. It doesn't mean they agree on 3 utility. It might mean they agree on how utility 4 applies to one particular type of invention, on a 5 particular type of claim. That's why I'm resisting 6 saying "consensus" because to me that's a very strong 7 term. 8 MR. BERENGAUT: Would you agree that 9 it's possible to have consensus on some subtopics, 10 and at the same time not have consensus on a topic as 11 a whole? 12 PROFESSOR GERVAIS: Theoretically, 13 sure. 14 MR. BERENGAUT: Let's go to paragraph 15 32 of your Second Report, tab 2. You write "As an 16 initial matter, I note that Mr. Thomas makes much of 17 the fact that he personally attended the negotiations 18 on the PLT and SPLT. I do not deny that useful 19 knowledge can be gained by attending these sessions 20 in person in terms of atmosphere or personal 21 discussions with delegates. That knowledge is not, 22 however, a substitute for objective interpretation 23 from published documents." 24 Do you see that? 25 PROFESSOR GERVAIS: I do.</p> <p>www.dianaburden.com</p>
<p>1764</p> <p>1 MR. BERENGAUT: Just to be clear, 2 Professor, the WIPO sessions to which Mr. Thomas 3 refers that you're discussing in this paragraph, you 4 did not attend those sessions, correct? 5 PROFESSOR GERVAIS: Correct. 6 MR. BERENGAUT: But I take it, from 7 your perspective, when you say "a substitute for 8 objective interpretation from published documents", 9 that in your view that's what you had provided in 10 your report, an objective interpretation from 11 published documents? 12 PROFESSOR GERVAIS: Would you repeat 13 that? I'm sorry. 14 MR. BERENGAUT: Sorry, that was an 15 unclear question. 16 My question is whether, in your view, 17 you have provided an objective interpretation from 18 published documents in your report? 19 PROFESSOR GERVAIS: That's what I 20 tried to do, certainly. 21 MR. BERENGAUT: In paragraph 31 of 22 your first statement, back to tab 1, you refer to a 23 2000 WIPO document. 24 PROFESSOR GERVAIS: I see it, yes. 25 MR. BERENGAUT: Which you maintain</p> <p>www.dianaburden.com</p>	<p>1765</p> <p>1 shows that "utility" and "industrial applicability" 2 do not have the same meaning. Do you see that? 3 PROFESSOR GERVAIS: I do. 4 MR. BERENGAUT: You would agree, 5 however, that this document also shows that those two 6 standards are part of the same singular requirement, 7 correct? 8 PROFESSOR GERVAIS: I'm not sure what 9 that means, frankly. What same singular requirement 10 are you referring to? 11 MR. BERENGAUT: Let's look at the 12 document that's at tab 8 of your binder. 13 PROFESSOR GERVAIS: Tab 8? 14 MR. BERENGAUT: Yes. For the record, 15 this is R-221. In your report, Professor, you quote 16 paragraphs 24(a) and 24(b). Is that right? 17 PROFESSOR GERVAIS: One second. I 18 will go back and check. Yes. 19 MR. BERENGAUT: Let's take a look at 20 the previous paragraph, paragraph 23, which you do 21 not quote in your report. It states that, 22 "'Industrial applicability' or 'utility' in certain 23 countries is the third widely recognized requirement 24 of patentability." Do you see that? 25 PROFESSOR GERVAIS: I do.</p> <p>www.dianaburden.com</p>

<p>1766</p> <p>1 MR. BERENGAUT: Doesn't this sentence 2 indicate that industrial applicability and utility 3 are part of the same requirement of patentability? 4 PROFESSOR GERVAIS: Now I understand 5 the question. 6 Well, yes, there are three widely 7 recognized requirements of patentability in 1709 and 8 27(1), novelty, industrial applicability with the 9 possible synonymity with utility, and then inventive 10 step and possible synonymity with non-obviousness. I 11 would add disclosure to that. But yes, absolutely, 12 this is a widely recognized requirement. 13 MR. BERENGAUT: The only identified 14 practical example of something which would fail the 15 industrial applicability or utility standard in this 16 paragraph is a perpetual motion machine, correct? 17 PROFESSOR GERVAIS: Yes, that's the 18 classic example most people use. 19 MR. BERENGAUT: Perpetual motion 20 machines are necessarily inoperable? 21 PROFESSOR GERVAIS: Well, as 22 I understand it they kind of go against the laws of 23 physics. 24 MR. BERENGAUT: And devices that go 25 against the laws of physics are necessarily</p> <p>www.dianaburden.com</p>	<p>1767</p> <p>1 inoperable? 2 PROFESSOR GERVAIS: I believe, if it 3 cannot work, it's probably not very useful. 4 MR. BERENGAUT: There are no examples 5 of inventions in this document that fail utility or 6 industrial applicability because they do not live up 7 to a self-described promise. Is that right? 8 PROFESSOR GERVAIS: In this 9 document -- not in the paragraph I'm looking at. I'd 10 have to look at the entire document. I don't know. 11 MR. BERENGAUT: You're not aware of 12 any indication in this source that the differences 13 between utility and industrial applicability have any 14 practical consequences, are you? 15 PROFESSOR GERVAIS: Oh, if you look 16 at those two definitions they could definitely have 17 practical implications. If you look at the last line 18 of what it says on utility, if you're going to start 19 measuring social benefit you're definitely going to 20 be somewhere probably a little different than 21 industrial applicability. 22 MR. BERENGAUT: There are no examples 23 that are identified which would satisfy one standard 24 but not the other, correct? 25 PROFESSOR GERVAIS: Other than the</p> <p>www.dianaburden.com</p>
<p>1768</p> <p>1 perpetual motion machine, no, at least on the page 2 I'm looking at. I did not re-read this entire 3 document. 4 MR. BERENGAUT: Let's go back to your 5 First Report, tab 1, paragraph 32. 6 In paragraph 32 you note that 7 following the report that we just discussed there 8 were comments that were submitted from various 9 countries, including Canada and the United States. 10 Do you see that? 11 PROFESSOR GERVAIS: I do. 12 MR. BERENGAUT: You refer to 13 paragraphs 84 and 85 from those comments, correct? 14 PROFESSOR GERVAIS: Yes. 15 MR. BERENGAUT: This is R-222. Let's 16 look at the document. It's tab 9. 17 PROFESSOR GERVAIS: Okay. 18 MR. BERENGAUT: Paragraphs 84 and 85 19 are on page 15. 20 PROFESSOR GERVAIS: Yeah. They're 21 the first two paragraphs after the opening by the 22 Chair. 23 MR. BERENGAUT: These comments that 24 you quote do not indicate the extent to which utility 25 and industrial applicability differ, if at all, do</p> <p>www.dianaburden.com</p>	<p>1769</p> <p>1 they? 2 PROFESSOR GERVAIS: Well, then I need 3 to re-read them entirely. So your question again is 4 whether there's a difference between industrial 5 applicability and utility? 6 MR. BERENGAUT: My question is that 7 these comments which you quote do not indicate the 8 extent to which utility and industrial applicability 9 differ, if at all? 10 PROFESSOR GERVAIS: Actually I 11 disagree with that. The last line of 84, the 12 International Bureau, the secretariat, answering 13 questions from both Canada and the United States, 14 said that the private purpose phrase that is in the 15 paragraph in my report that we just quoted from 16 related to industrial applicability, not to utility, 17 and therefore at least the person from the 18 International Bureau thought that there was a 19 difference. 20 Now, what was going through that 21 person's mind, obviously I do not know. 22 MR. BERENGAUT: And that difference 23 pertained to inventions "which may only be used for 24 private purposes." Is that right? 25 PROFESSOR GERVAIS: Yes. There's a</p> <p>www.dianaburden.com</p>

<p>1770</p> <p>1 similar debate concerning test equipment, lab 2 equipment, that can be useful without necessarily 3 being in industry, and there's a long debate that is 4 referred to in one of the amicus briefs on the 5 Claimant's side by a group of law professors to a 6 document that explains this in great detail. These 7 two notions are not identical, and that's one place 8 where they differ quite significantly. 9 MR. BERENGAUT: Apart from this 10 reference to inventions which may only be used for 11 private purposes, there is no indication in this 12 document about the extent to which the utility and 13 industrial applicability standards differ, is there? 14 PROFESSOR GERVAIS: I've answered the 15 question. I'm not sure what else to tell you. 16 Paragraph 84 makes a distinction. You're asking me 17 the entire document? Again, I would have to read the 18 document. I cannot tell you what's in the rest of 19 the document. 20 MR. BERENGAUT: You're not aware of 21 any other -- 22 PROFESSOR GERVAIS: No, I'm not. 23 MR. BERENGAUT: -- section? 24 Again, setting aside inventions which 25 may be used for private purpose, there's nothing in</p> <p>www.dianaburden.com</p>	<p>1771</p> <p>1 this document which suggests the extent to which any 2 differences between the industrial applicability and 3 utility requirements would have any practical, real 4 world consequences, is there? 5 PROFESSOR GERVAIS: Other than use 6 for private purposes in paragraph 84 there's nothing 7 else. In the rest of the document, I do not know. 8 MR. BERENGAUT: And, again, the only 9 example of an invention which would fail the 10 industrial applicability requirement -- this is 11 paragraph 87 -- is the perpetual motion machine 12 again. You see that? 13 PROFESSOR GERVAIS: In paragraph 87, 14 yes, and it actually says more examples should be 15 provided. I don't know if they are elsewhere in the 16 document or not. 17 MR. BERENGAUT: So there's no 18 indication in this document that you're aware of 19 suggesting that any country thought that an invention 20 which claimed to treat a condition and actually 21 treated that condition being found to lack utility, 22 is there? 23 PROFESSOR GERVAIS: I do not 24 understand the question. I'm sorry. 25 MR. BERENGAUT: Let me repeat it.</p> <p>www.dianaburden.com</p>
<p>1772</p> <p>1 PROFESSOR GERVAIS: A condition? I'm 2 sorry, I don't know what you mean. 3 MR. BERENGAUT: There is no indication 4 in this document that you're aware of that any 5 country thought that an invention which claimed to 6 treat a medical condition -- 7 PROFESSOR GERVAIS: Oh, a medical -- 8 MR. BERENGAUT: That actually treated 9 that medical condition, being found to lack utility, 10 is there? 11 PROFESSOR GERVAIS: Am I aware in 12 this document of a reference to that? No. 13 MR. BERENGAUT: Same question with 14 regard to industrial applicability. 15 PROFESSOR GERVAIS: Same question 16 being a medical condition being treated and a 17 reference in this document? No, I would have to read 18 the document. I'm only looking at a few paragraphs 19 in front of me now. 20 MR. BERENGAUT: Well, I assume you 21 read the whole document before you quoted it in your 22 report. 23 PROFESSOR GERVAIS: I did, but this 24 was several months ago, and I'm afraid my memory 25 isn't good enough to recall the entirety of this</p> <p>www.dianaburden.com</p>	<p>1773</p> <p>1 document. 2 MR. BERENGAUT: That's fine. Apart 3 from this section, there's no other section that you 4 thought was relevant to discuss in your report, 5 right? 6 PROFESSOR GERVAIS: To mention at 7 least, yes, obviously, because that's the only one I 8 did. 9 MR. BERENGAUT: Back to First Report, 10 tab 1. 11 PROFESSOR GERVAIS: Yes. 12 MR. BERENGAUT: You next note that 13 there were -- 14 PROFESSOR GERVAIS: Next to what, 15 sorry? 16 MR. BERENGAUT: Paragraph 35. 17 PROFESSOR GERVAIS: Okay. 18 MR. BERENGAUT: And you discussed this 19 during your opening presentation as well, that there 20 were a few different proposals on how to define 21 utility and industrial applicability. I'd like to 22 focus you on the final sentence of paragraph 35 where 23 you state, "The 'utility' requirement... reappeared 24 in the following draft in May 2002." Do you see 25 that?</p> <p>www.dianaburden.com</p>

<p>1774</p> <p>1 PROFESSOR GERVAIS: I do. 2 MR. BERENGAUT: Let's take a quick 3 look at that document. That's tab 10, R-227. 4 PROFESSOR GERVAIS: Okay. 5 MR. BERENGAUT: You refer to page 24 6 of that document, I believe. 7 PROFESSOR GERVAIS: 22 does not have 8 a page -- 9 MR. BERENGAUT: The page numbers are 10 at the top of the document. 11 PROFESSOR GERVAIS: I mean in my 12 reference to this document I don't think that I 13 referred to specific page -- oh, yes, I do. I'm 14 sorry. I missed it. Yes. Okay. 24. 15 MR. BERENGAUT: Just to confirm, this 16 is the language you were quoting, the paragraph 17 beginning numbered 4, which has the bracketed 18 definition of industrial applicability/utility? 19 PROFESSOR GERVAIS: Yeah, I believe 20 it's underlined because it reappeared from the 21 previous draft -- or appeared from the previous 22 draft. 23 MR. BERENGAUT: Professor, were you 24 aware that there were notes that accompanied this 25 proposal?</p> <p>www.dianaburden.com</p>	<p>1775</p> <p>1 PROFESSOR GERVAIS: There always are. 2 MR. BERENGAUT: Let's take a look at 3 those notes. That's behind the next tab, C-407. If 4 you could turn to page 21. 5 PROFESSOR GERVAIS: Yes. 6 MR. BERENGAUT: These notes state -- 7 and let me just read this paragraph: "This paragraph 8 contains the condition of patentability of industrial 9 applicability/utility. In order to reflect the 10 debate at the SCP, three alternatives are proposed in 11 this provision: The second and third alternative 12 reflect the standard contained in many 13 national/regional legislation concerning industrial 14 applicability and utility, respectively. The first 15 alternative attempts to take into consideration the 16 essence of both requirements, including real 17 practices, and reflects a more global approach, 18 whereby an invention would have to be able to made or 19 used in any field of commercial activity." 20 Do you see that? 21 PROFESSOR GERVAIS: Yes, I do. 22 MR. BERENGAUT: These notes are 23 prepared by the International Bureau of WIPO. Is 24 that right? 25 PROFESSOR GERVAIS: Typically, yes.</p> <p>www.dianaburden.com</p>
<p>1776</p> <p>1 MR. BERENGAUT: And you would agree 2 that this language shows that the International 3 Bureau at this time thought that industrial 4 applicability and utility shared a common essence? 5 PROFESSOR GERVAIS: No, it doesn't 6 use those words at all. I'm sorry, I don't see those 7 words. Consideration of the essence -- it says "to 8 take into consideration the essence of both 9 requirements." It's trying to take into account the 10 essence of both requirements. It doesn't actually 11 say that the essence is the same but it's trying to 12 take into consideration the essence of both. It 13 doesn't say the essence is identical, and their very 14 documents prove that they're not. 15 MR. BERENGAUT: So you read this 16 clause as saying that there are two independent and 17 different essences of the two requirements? 18 PROFESSOR GERVAIS: No, sir, no. I 19 believe that they're very closely related; they 20 overlap to large degree but they're not identical. 21 The WIPO documents made that quite clear. They're 22 not identical and within both families there are 23 divergences as well. I don't know that this means 24 that the essence of both is the same. If that's what 25 it means, then I certainly don't think that's</p> <p>www.dianaburden.com</p>	<p>1777</p> <p>1 correct, unless, frankly, we could debate -- the word 2 "essence" strikes me as a nice word for a 3 metaphysical debate, and I don't mean to be 4 facetious, but it's very hard to know what that 5 means, "essence" of a requirement. 6 MR. BERENGAUT: The sentence 7 referencing the first alternative, which "takes into 8 consideration the essence of both requirements, 9 including real practices", do you see that clause? 10 PROFESSOR GERVAIS: Yes, I do. 11 MR. BERENGAUT: Would you agree that 12 that shows that the International Bureau thought that 13 a unified definition of the two concepts would 14 reflect real practices at the time? 15 PROFESSOR GERVAIS: Well, here's my 16 trouble in answering your question. This is a 2002 17 document, therefore prepared between the 2001 and 18 2003 reports that were discussed with the previous 19 expert, and he said the word "practice" means 20 legislation, in the International Bureau's mind. So 21 if he means that it would capture the essence of 22 requirements in rules and regulations, that's one 23 thing. If it means practice like I think practice 24 means practice, it's a very honorable proposal to try 25 to unify the standard. There are several people who</p> <p>www.dianaburden.com</p>

<p>1778</p> <p>1 would like to have a global patent standard. We 2 don't have one. And, as I tried to show in my 3 presentation, when the three proposals were put to 4 the member states, the majority did not support the 5 first alternative, which meant to unify. They went 6 with the second one. And then there was support for 7 the third amendment, so I'm not sure how to answer 8 your question.</p> <p>9 MR. BERENGAUT: Just so we're clear, 10 when you say the second and third alternatives, those 11 are the alternatives referenced in this paragraph 12 which reflect the standards contained in national 13 regional legislation. Is that right?</p> <p>14 PROFESSOR GERVAIS: No. I mean the 15 three in the following meeting, in SCP 8. This is 16 SCP 7. The following meeting. The ones that were on 17 my slide were from the following meeting.</p> <p>18 MR. BERENGAUT: You would agree that 19 the second and third alternatives reflected in the 20 bracketed language we just looked at correspond to 21 this paragraph and its statement that they reflect 22 the standard contained in many national regional 23 legislation?</p> <p>24 PROFESSOR GERVAIS: That's what the 25 document says.</p> <p>www.dianaburden.com</p>	<p>1779</p> <p>1 MR. BERENGAUT: And are you aware of 2 any substantive differences between the three 3 bracketed definitions in the document we just looked 4 at, and the three definitions that you included in 5 your slide in your expert presentation?</p> <p>6 PROFESSOR GERVAIS: Well, yes, and 7 certainly I can -- the most documented is test 8 instruments and lab instruments which some people 9 view as not being exploited in the field of 10 commercial activity because they're used for 11 research. They would typically pass the utility 12 requirement, and the report again that is cited by 13 the Professors who filed the brief on your side 14 identifies a very detailed study of this issue that 15 shows that, in fact, the way that the UK courts have 16 moved away from industrial applicability to cover 17 those types of inventions is by adopting the 18 substantial, credible and specific utility standard 19 that is, in fact, not their standard. So it's a very 20 interesting thing that I think is happening in this 21 particular area.</p> <p>22 There are differences between -- the 23 words themselves, if they meant the same thing, would 24 not -- it's not just a matter of nomenclature. The 25 reason that countries hold on to these words has to</p> <p>www.dianaburden.com</p>
<p>1780</p> <p>1 be for some reason, and I think that's one example. 2 I'm sure we could come up with more.</p> <p>3 MR. BERENGAUT: I'm a little confused 4 by your answer because I think the example you gave 5 of a difference between the two drafts of the text 6 was a reference to the phrase "in any field of 7 commercial activity." Right?</p> <p>8 PROFESSOR GERVAIS: Yes.</p> <p>9 MR. BERENGAUT: But, as I read it, 10 that phrase appears in both your slide and the three 11 bracketed definitions in tab 10 that we've just been 12 looking at?</p> <p>13 PROFESSOR GERVAIS: Yes. It's 14 alternative A in my slides, correct.</p> <p>15 MR. BERENGAUT: And it also appears in 16 tab 10?</p> <p>17 PROFESSOR GERVAIS: It appears in tab 18 10, yes, it does, which is the previous meeting of 19 the SCP.</p> <p>20 MR. BERENGAUT: So I would again ask 21 you my question, whether you are aware of any 22 substantive differences between tab 10 and the 23 alternatives that you discussed in your slides in 24 your opening presentation.</p> <p>25 PROFESSOR GERVAIS: If I understand</p> <p>www.dianaburden.com</p>	<p>1781</p> <p>1 the question correctly, is there a difference between 2 the alternatives in paragraph 4 of page 24 of SCP 7/3 3 and SCP 8/2, Article 12, paragraph 4, and I will give 4 you an answer if you give me a chance to read these 5 two. (Pause)</p> <p>6 Well, the difference is that the 7 definition of industry in alternative B of the next 8 meeting, which is a paraphrase of Article 5 of the 9 Paris Convention, has disappeared, but otherwise 10 there's no other difference. There's no difference 11 in alternative A language.</p> <p>12 MR. BERENGAUT: Thank you. You also 13 have discussed the 2001 and 2003 surveys.</p> <p>14 PROFESSOR GERVAIS: I certainly 15 mentioned it, yes.</p> <p>16 MR. BERENGAUT: In your First Report 17 paragraph 39 you referred to the 2003 survey, and in 18 your Second Report, paragraph 45, you discussed the 19 2001 survey?</p> <p>20 PROFESSOR GERVAIS: Correct.</p> <p>21 MR. BERENGAUT: Let's take them in 22 chronological order so reverse order from your 23 statements, beginning with the 2001 survey which you 24 discuss at the end of your Second Report in tab 2.</p> <p>25 PROFESSOR GERVAIS: Do you have a</p> <p>www.dianaburden.com</p>

<p>1 paragraph number? 2 MR. BERENGAT: 47. 3 PROFESSOR GERVAIS: Yes. 4 MR. BERENGAT: You say that this 5 document shows that "notions of utility and 6 industrial applicability vary significantly by 7 jurisdiction." Do you see that? 8 PROFESSOR GERVAIS: I do. 9 MR. BERENGAT: And you quote 10 paragraphs 2-5 for that proposition. 11 PROFESSOR GERVAIS: Yes. 12 MR. BERENGAT: Let's take a look at 13 the document. It's tab 12. Paragraphs 2-5 are in 14 the section "Definitions and examples of 'industrial 15 applicability'," is that right? 16 PROFESSOR GERVAIS: Yes. 17 MR. BERENGAT: You mentioned that, in 18 your view, the document shows that notions of utility 19 and industrial applicability vary significantly by 20 jurisdiction, but you would also agree that this 21 document recognizes that there is an overlap between 22 the two standards. Is that right? 23 PROFESSOR GERVAIS: I do recognize 24 that, definitely, yes. 25 MR. BERENGAT: And, following the</p> <p>www.dianaburden.com</p>	<p>1782</p> <p>1 paragraphs that you quoted, there is a section about 2 examples, beginning with paragraph 7. Do you see 3 that? 4 PROFESSOR GERVAIS: Yes, I do. 5 MR. BERENGAT: And in paragraph 7, it 6 lists several examples of inventions that fail the 7 industrial applicability standard in "more than one 8 country." Do you see that? 9 PROFESSOR GERVAIS: Paragraph 7, yes. 10 MR. BERENGAT: The perpetual motion 11 machine is back? 12 PROFESSOR GERVAIS: It's the 13 classroom textbook example. 14 MR. BERENGAT: There's a ghost 15 catcher? 16 PROFESSOR GERVAIS: Yes. That would 17 go well with your flying car. 18 MR. BERENGAT: And you're not aware 19 that there is an operable ghost catcher, are you? 20 PROFESSOR GERVAIS: I don't know that 21 there is one, despite Hollywood. 22 MR. BERENGAT: There's also a method 23 for preventing the increase in ultraviolet ray 24 associated with the destruction of ozone layer by 25 covering the whole surface of the earth with an</p> <p>www.dianaburden.com</p>
<p>1784</p> <p>1 ultraviolet ray absorbing plastic film. Do you see 2 that? 3 PROFESSOR GERVAIS: I do. 4 MR. BERENGAT: Are you aware of an 5 operable device that does that? 6 PROFESSOR GERVAIS: I'm not. 7 MR. BERENGAT: Again, no indication 8 in these examples of a pharmaceutical invention that 9 claimed to treat a medical condition and actually 10 treated that condition being found to lack industrial 11 applicability, is there? 12 PROFESSOR GERVAIS: In those 13 examples, no. 14 MR. BERENGAT: Are you aware of any 15 other examples in this section that provide such an 16 indication? 17 PROFESSOR GERVAIS: I believe there's 18 something later on, a document, but it's been a few 19 months since I've re-read it. Paragraph 15 of the 20 document says, "Case law determining whether an 21 applicant identifies any specific utility for the 22 claimed invention or has not been developed, in 23 particular, in the field of chemistry and 24 pharmacology..." and then they talk about compounds 25 that treat unspecified disorders that has useful</p> <p>www.dianaburden.com</p>	<p>1785</p> <p>1 properties that would not be specific to define a 2 specific utility. So to that extent I guess that's 3 an example that's at least close to what you were 4 asking. 5 MR. BERENGAT: I'm glad you brought 6 us to 15 but, if we may, let's just go to 14 before 7 we get to 15. Now we've moved from the section of 8 the document about industrial applicability to the 9 section that begins "Definitions and examples of 10 'utility.'" Do you see that? 11 PROFESSOR GERVAIS: I do. 12 MR. BERENGAT: Let's look at the 13 preceding paragraph, paragraph 14, where, again in 14 the example section, it begins, "Situations where an 15 invention is found to be inoperative, and therefore 16 lacking utility, seem to be very rare. Examples of 17 such cases include: An invention asserted to change 18 the taste of food using a magnetic field, a flying 19 machine operating on a 'flapping or flutter 20 function', and a method of controlling the aging 21 process'." 22 Do you see that? 23 PROFESSOR GERVAIS: I do. 24 MR. BERENGAT: As far as you are 25 aware, none of these inventions were operable in 2001</p> <p>www.dianaburden.com</p>

<p>1786</p> <p>1 when this document was created?</p> <p>2 PROFESSOR GERVAIS: To my knowledge,</p> <p>3 no.</p> <p>4 MR. BERENGAUT: Let's look at the next</p> <p>5 paragraph, which you just mentioned, which states --</p> <p>6 this is paragraph 15 on page 4 -- "Case law</p> <p>7 determining whether an applicant identifies any</p> <p>8 specific utility for the claimed invention or has not</p> <p>9 been developed, in particular, in the field of</p> <p>10 chemistry and pharmacology. For example, indicating</p> <p>11 that the compound may be useful in treating</p> <p>12 unspecified disorders, or that the compound has</p> <p>13 useful biological properties, would not be sufficient</p> <p>14 to define a specific utility for the compound."</p> <p>15 Do you see that?</p> <p>16 PROFESSOR GERVAIS: I did. I just</p> <p>17 read it.</p> <p>18 MR. BERENGAUT: So I would again ask</p> <p>19 the question whether, even in light of this</p> <p>20 paragraph, there is any indication in any of these</p> <p>21 examples of a pharmaceutical invention that claimed</p> <p>22 to treat a specific medical condition and actually</p> <p>23 treated that medical condition being found to lack</p> <p>24 utility.</p> <p>25 PROFESSOR GERVAIS: In this</p> <p>www.dianaburden.com</p>	<p>1787</p> <p>1 paragraph, no.</p> <p>2 MR. BERENGAUT: Are you aware of any</p> <p>3 other paragraphs which address that situation in this</p> <p>4 document?</p> <p>5 PROFESSOR GERVAIS: Aware? No. And</p> <p>6 I'd have to read the rest of it, but I'm not aware of</p> <p>7 something in this document, no.</p> <p>8 MR. BERENGAUT: Let's go back to your</p> <p>9 second statement, back to the same paragraph,</p> <p>10 paragraph 47 where you're talking still about the</p> <p>11 same survey, and we'll head back there in a minute,</p> <p>12 but in the beginning of paragraph 47, another point</p> <p>13 you make about this 2001 survey is that "...the</p> <p>14 promise of the patent approach was acknowledged</p> <p>15 internationally at least as early as 2001 not just</p> <p>16 without critical commentary, but as an example of</p> <p>17 utility." Do you see that?</p> <p>18 PROFESSOR GERVAIS: I do.</p> <p>19 MR. BERENGAUT: And you quote to</p> <p>20 paragraphs 13 and 19 for that proposition?</p> <p>21 PROFESSOR GERVAIS: I do.</p> <p>22 MR. BERENGAUT: Let's head back to the</p> <p>23 2001 study, which is back on tab 12.</p> <p>24 Paragraph 13 is the first paragraph to</p> <p>25 which you were referring?</p> <p>www.dianaburden.com</p>
<p>1788</p> <p>1 PROFESSOR GERVAIS: Yes, I believe it</p> <p>2 was on the slides that were used for the examination</p> <p>3 of the previous expert.</p> <p>4 MR. BERENGAUT: And there are no</p> <p>5 examples given in this paragraph about how this</p> <p>6 standard was being employed in practice, are there?</p> <p>7 PROFESSOR GERVAIS: Examples? No.</p> <p>8 MR. BERENGAUT: Now let's look at</p> <p>9 paragraph 19, which is the other paragraph you cited.</p> <p>10 PROFESSOR GERVAIS: Yes.</p> <p>11 MR. BERENGAUT: Paragraph 19 does have</p> <p>12 two examples. "In addition, the following inventions</p> <p>13 are considered not meeting the requirement that an</p> <p>14 invention be 'useful.'" The first one is "An</p> <p>15 invention related to control circuits for gas</p> <p>16 discharge lamps. The specification indicated that</p> <p>17 the invention would reduce heat generation in the</p> <p>18 ballast. However, the evidence was that some</p> <p>19 circuits falling within the scope of the claims</p> <p>20 failed to work and caused lamp failure because of</p> <p>21 excessive heat generation. Consequently, the promise</p> <p>22 of the invention was not fulfilled." Do you see</p> <p>23 that?</p> <p>24 PROFESSOR GERVAIS: I do.</p> <p>25 MR. BERENGAUT: In this example, the</p> <p>www.dianaburden.com</p>	<p>1789</p> <p>1 lamp did not work, correct?</p> <p>2 PROFESSOR GERVAIS: Well, it did not</p> <p>3 work as claimed, I suppose. It doesn't say didn't</p> <p>4 work at all; it said there was eventually failure</p> <p>5 causing excessive heat generation, so it may have</p> <p>6 worked for a while. I don't know. The example isn't</p> <p>7 precise enough.</p> <p>8 MR. BERENGAUT: So, despite the</p> <p>9 reference to the fact that excessive heat generation</p> <p>10 caused lamp failure, you're unsure whether the lamp</p> <p>11 worked in that example?</p> <p>12 PROFESSOR GERVAIS: It eventually</p> <p>13 failed. It doesn't mean that it didn't work at the</p> <p>14 beginning, is what I'm saying.</p> <p>15 MR. BERENGAUT: Okay. In the next</p> <p>16 example is the promise of a cheese for permanent</p> <p>17 keeping. Are you aware of an invention that is</p> <p>18 operable that keeps cheese permanently?</p> <p>19 PROFESSOR GERVAIS: No, I am not.</p> <p>20 MR. BERENGAUT: Let's go to the 2003</p> <p>21 study, which is R-230, and it's behind tab 13.</p> <p>22 PROFESSOR GERVAIS: Okay.</p> <p>23 MR. BERENGAUT: Now, you make, I think</p> <p>24 this is fair to say, many of the same points about</p> <p>25 the 2003 study as you do about the 2001 study. Is</p> <p>www.dianaburden.com</p>

<p>1790</p> <p>1 that right?</p> <p>2 PROFESSOR GERVAIS: I make many</p> <p>3 points about both reports.</p> <p>4 MR. BERENGAUT: Okay, that's fine. We</p> <p>5 can go back to your First Report. Let's take a look</p> <p>6 at paragraph 39 of your First Report on page 12.</p> <p>7 Here in the first sentence, the sentence reads</p> <p>8 "First, it" -- and by "It" it means this 2003 report,</p> <p>9 right -- "First, it confirmed that the practice of</p> <p>10 the parties regarding 'industrial applicability' and</p> <p>11 'utility' can 'differ substantially'." Do you see</p> <p>12 that?</p> <p>13 PROFESSOR GERVAIS: I do.</p> <p>14 MR. BERENGAUT: And in footnote 27 --</p> <p>15 PROFESSOR GERVAIS: It's actually a</p> <p>16 quote. There are quotation marks around the words.</p> <p>17 MR. BERENGAUT: Excuse me. You're</p> <p>18 right, it is a quote, and you quote the phrase</p> <p>19 "differ substantially." In footnote 27 you reference</p> <p>20 paragraph 56 of the document for that quote. Do you</p> <p>21 see that?</p> <p>22 PROFESSOR GERVAIS: I do.</p> <p>23 MR. BERENGAUT: This isn't a "gotcha"</p> <p>24 question but I don't think that's the right paragraph</p> <p>25 for that quote so let's take a look at paragraph 56</p> <p>www.dianaburden.com</p>	<p>1791</p> <p>1 first. This is back behind tab 13.</p> <p>2 PROFESSOR GERVAIS: Yes.</p> <p>3 MR. BERENGAUT: I don't see the</p> <p>4 reference to the standards differing substantially in</p> <p>5 that paragraph.</p> <p>6 PROFESSOR GERVAIS: You are correct.</p> <p>7 I'm quoting the wrong paragraph. I apologize</p> <p>8 profusely.</p> <p>9 MR. BERENGAUT: I think the paragraph</p> <p>10 you meant to quote there, if I'm right, is paragraph</p> <p>11 1?</p> <p>12 PROFESSOR GERVAIS: Okay.</p> <p>13 MR. BERENGAUT: Which towards the end</p> <p>14 of the paragraph says, "Further, it reviews those</p> <p>15 areas in which there is a substantial overlap of</p> <p>16 practices as well as those in which the two</p> <p>17 requirements differ substantially."</p> <p>18 PROFESSOR GERVAIS: I'd certainly</p> <p>19 like to go through the document to know. I don't</p> <p>20 think I would have mistaken 1 for 56, but clearly 56</p> <p>21 is the wrong paragraph. I apologize for that.</p> <p>22 MR. BERENGAUT: Let's take a look at</p> <p>23 paragraph 1 where the sentence appears that I just</p> <p>24 read.</p> <p>25 PROFESSOR GERVAIS: The main point</p> <p>www.dianaburden.com</p>
<p>1792</p> <p>1 remains that they differ substantially in some</p> <p>2 respects and they overlap in others. That point</p> <p>3 remains true, independent of which paragraph it's</p> <p>4 from. I certainly apologize for the wrong paragraph</p> <p>5 quote.</p> <p>6 MR. BERENGAUT: I guess where I'm</p> <p>7 getting stuck is that in your report you quote the</p> <p>8 language about them differing substantially, but you</p> <p>9 don't quote the language about the substantial</p> <p>10 overlap of practices, and I guess my question is</p> <p>11 whether, in your view, the language about the</p> <p>12 overlaps was not relevant or whether there was a</p> <p>13 different reason you didn't include it.</p> <p>14 PROFESSOR GERVAIS: No. It's</p> <p>15 relevant. Honestly I would have to go back to this</p> <p>16 report and find where these words appear in the</p> <p>17 report elsewhere and where I would have taken them</p> <p>18 from, but I completely stand by the point on</p> <p>19 substance, that the two differ substantially in some</p> <p>20 respects and overlap in others, as I said earlier.</p> <p>21 MR. BERENGAUT: Okay. So the</p> <p>22 commonalities are discussed in paragraphs 54 and 55</p> <p>23 of SCP 9/5 in tab 13.</p> <p>24 PROFESSOR GERVAIS: I see that.</p> <p>25 MR. BERENGAUT: And the first sentence</p> <p>www.dianaburden.com</p>	<p>1793</p> <p>1 of paragraph 54 reads, "Focusing on the general</p> <p>2 common characteristics of the two requirements, an</p> <p>3 invention that is inoperative, for example, an</p> <p>4 invention which is clearly non-operative in view of</p> <p>5 well-established laws of nature, would not comply</p> <p>6 with both the industrial applicability and utility</p> <p>7 requirements." Do you see that?</p> <p>8 PROFESSOR GERVAIS: Yes, and I agree</p> <p>9 with that statement.</p> <p>10 MR. BERENGAUT: Then let's look at the</p> <p>11 areas of difference, and this is paragraph 56, which</p> <p>12 is the paragraph you referenced in your report. The</p> <p>13 example here of differences is the same one that you</p> <p>14 mentioned earlier in our discussion, which is to say</p> <p>15 that some countries exclude inventions which "could</p> <p>16 apply solely to the private or personal sphere of</p> <p>17 one's own needs." Do you see that?</p> <p>18 PROFESSOR GERVAIS: Or "could be</p> <p>19 applied solely in association with a particular</p> <p>20 person" -- yes, that's what it says.</p> <p>21 MR. BERENGAUT: In fact, this</p> <p>22 paragraph says that there were -- and I'm now about</p> <p>23 halfway into the paragraph -- not many examples of</p> <p>24 inventions falling under this category were suggested</p> <p>25 by the SCP members?</p> <p>www.dianaburden.com</p>

<p>1 PROFESSOR GERVAIS: Yeah, the "not 2 many" is a little bit like the previous discussion 3 about many, several and some. I would have to see 4 the dataset, how many countries replied. It's very 5 hard to interpret out of context why -- was the 6 survey specifically asking SCP members, for example? 7 I don't know. Therefore, I don't know what to make 8 of this other than the fact that it clearly says "not 9 many examples fall under this category." 10 MR. BERENGAUT: There's no indication 11 in this paragraph that countries were divided in how 12 exacting the utility requirement or industrial 13 applicability requirement should be as a general 14 matter, correct? 15 PROFESSOR GERVAIS: How exacting it 16 should be as a general matter? No, it only refers to 17 Australia and Canada, which are talking about utility 18 and benefits to the public, and then they say that 19 private use and utility, because this isn't a matter 20 of industry at that point, can exclude them under a 21 different doctrine. The doctrinal mix is different 22 country-by-country, and here we see a new doctrine, 23 de minimis, that was not mentioned before, to exclude 24 certain inventions. 25 MR. BERENGAUT: No indication that the</p> <p>www.dianaburden.com</p>	<p>1794</p> <p>1 frequency of utility invalidations or industrial 2 applicability invalidations varied across countries, 3 right? 4 PROFESSOR GERVAIS: No, there is 5 empirical data on that, but I don't have it in front 6 of me. 7 MR. BERENGAUT: Let's go back to your 8 First Report, paragraph 41. 9 PROFESSOR GERVAIS: Yes. 10 MR. BERENGAUT: Here you say "...the 11 Report included in the competing definitions of 12 utility the Canadian 'promise' approach as one of the 13 several approaches." Do you see that? 14 PROFESSOR GERVAIS: Yes, I do. 15 MR. BERENGAUT: And at the bottom of 16 paragraph 41 you quote paragraphs 41 and 46 of the 17 2003 survey, right? 18 PROFESSOR GERVAIS: It looks like, 19 yes. 20 MR. BERENGAUT: Let's head back to the 21 survey. 22 PROFESSOR GERVAIS: Which tab again? 23 12? 24 MR. BERENGAUT: 13. Paragraphs 41 and 25 46 were the two paragraphs you quoted. Let's start</p> <p>www.dianaburden.com</p> <p>1795</p>
<p>1 with paragraph 40, which is "Under the law of Canada, 2 the term 'invention' means any new and useful art, 3 process, machine, manufacture or composition of 4 matter, or any new and useful improvement in any art, 5 process, machine, manufacture or composition of 6 matter. Utility means having industrial or 7 commercial value in a manner that benefits the 8 public. For example, a perpetual motion machine that 9 serves no useful purpose does not comply with the 10 utility requirement." 11 Do you see that? 12 PROFESSOR GERVAIS: I do. 13 MR. BERENGAUT: The perpetual motion 14 machine is back. 15 PROFESSOR GERVAIS: Again. 16 MR. BERENGAUT: Again, no references 17 in this paragraph to a pharmaceutical invention that 18 claims to treat a condition and actually treats that 19 condition being invalidated because it does not 20 comply with the utility requirement, correct? 21 PROFESSOR GERVAIS: In this 22 paragraph, no. 23 MR. BERENGAUT: The next paragraph is 24 paragraph 41 which, as you have quoted in your 25 testimony, or in your report, contains a reference to</p> <p>www.dianaburden.com</p>	<p>1796</p> <p>1 promise. Now, there are no examples in this 2 paragraph of an invention that would fail under this 3 language regarding promise, correct? 4 PROFESSOR GERVAIS: There's a 5 distinction drawn between promise and sound 6 prediction which some previous experts have kind of 7 melded, but if you look at the first part of the 8 paragraph referring to promise, there is an example 9 given for the second sound prediction. 10 MR. BERENGAUT: And that example is -- 11 PROFESSOR GERVAIS: The genus 12 example. 13 MR. BERENGAUT: For the record that is 14 "...if the claim includes so many species that not 15 all of them could have been tested and found by the 16 inventor to have the promised utility, the claim is 17 invalid, absent a possible showing by the patentee 18 that the entire claim could be soundly predicted to 19 have the requisite utility ('sound prediction')." 20 PROFESSOR GERVAIS: That is right. 21 MR. BERENGAUT: So, again, in this 22 paragraph no examples of a pharmaceutical invention 23 that claimed to treat a specific condition and 24 actually treat that condition being found to lack 25 utility, correct?</p> <p>www.dianaburden.com</p> <p>1797</p>

<p>1 PROFESSOR GERVAIS: It's getting 2 pretty close to that, because it's interesting how it 3 refers to promise and then sound prediction in the 4 last part of the paragraph. You know, what is the 5 promised utility of the species within the genus? 6 Maybe it is to treat a particular disease. The level 7 of abstraction is too high for me to be able to 8 answer your question. I don't know what the drafter 9 of the end of 41 had in mind. 10 MR. BERENGAUT: So the answer to my 11 question is you don't know? 12 PROFESSOR GERVAIS: I don't know what 13 this person had in mind when they were talking about 14 what is the promised utility of the species within 15 the genus, yes. 16 MR. BERENGAUT: There is no suggestion 17 in paragraphs 41 or 40 that the promise approach, as 18 you call it, in Canada would lead to different 19 practical outcomes from any other country, is there? 20 PROFESSOR GERVAIS: It doesn't 21 compare promise among different SCP members, so I 22 don't know how it could. 23 MR. BERENGAUT: Next topic. In your 24 report you talk about the joint proposal. This is 25 paragraph 44. You testified that "After several</p> <p>www.dianaburden.com</p>	<p>1798</p> <p>1 rounds of negotiations on the basis of those WIPO 2 documents, the United States, the European Union and 3 Japan presented in 2004 a proposal (the 'Joint 4 Proposal') to try to move the debate forward." 5 PROFESSOR GERVAIS: Yes. 6 MR. BERENGAUT: And, just for clarity, 7 the reference in this sentence to "those WIPO 8 documents," that is the WIPO documents we've just 9 been discussing, correct? 10 PROFESSOR GERVAIS: They're the ones 11 referenced in the paragraphs that precede in my 12 report. 13 MR. BERENGAUT: Now, you quote the 14 joint proposal in paragraph 45 of your report, which 15 is R-235. Do you see that? 16 PROFESSOR GERVAIS: I do. 17 MR. BERENGAUT: In paragraph 46 you 18 note that, "Utility and industrial applicability are 19 not included in the list of issues suggested to be 20 ripe for possible international harmonization or even 21 discussion in the SPLT context, rather, that 22 requirement was seen as best left to the discretion 23 and interpretation of Member states themselves." 24 Do you see that? 25 PROFESSOR GERVAIS: I do.</p> <p>www.dianaburden.com</p> <p>1799</p>
<p>1800</p> <p>1 MR. BERENGAUT: You add in the next 2 paragraph that, "If utility, industrial applicability 3 or both had been an easy target for negotiators and 4 an easy 'win' for WIPO and negotiators, it would have 5 been on the list or at the very least been mentioned 6 as such." 7 PROFESSOR GERVAIS: I did write that, 8 yes. 9 MR. BERENGAUT: Now, you were not 10 involved in the preparation of the joint proposal, 11 correct? 12 PROFESSOR GERVAIS: No. 13 MR. BERENGAUT: And nothing in the 14 document, R-235, which is behind tab 14, says why 15 utility was left off the agenda, does it? 16 PROFESSOR GERVAIS: Well, I don't 17 remember seeing anything but, again, I can't exclude 18 it without re-reading the document entirely. Off the 19 top of my head I can't recall. 20 MR. BERENGAUT: Well, this one's only 21 three pages, so if you want to take a moment to 22 refresh your recollection, please go ahead. 23 PROFESSOR GERVAIS: I just did. So 24 the first paragraph actually says there's a list of 25 issues, and it does mention industrial applicability,</p> <p>www.dianaburden.com</p>	<p>1801</p> <p>1 and then basically leaves it out. It doesn't, I 2 believe, say why it leaves it out directly, and what 3 they say is "We've decided to advance negotiations 4 and are submitting this document." If you read from 5 the bottom of that first page it says, "It has been 6 apparent, however, that an expansive SPLT, including 7 all issues currently included [this would include 8 industrial applicability] might not be achievable in 9 the near future. For this reason, the Trilateral 10 Offices have come to the conclusion that their 11 future... should be based on the following five 12 guiding principles;" and then they provide their 13 list. 14 I do not know what, again, they were 15 thinking. I wasn't there. I'm just reading the 16 documents and drawing conclusions from what it says. 17 MR. BERENGAUT: And, just to ask my 18 specific question again, nothing in this document 19 says why utility specifically was left off the 20 agenda, right? 21 PROFESSOR GERVAIS: Not that I can 22 see. 23 MR. BERENGAUT: Well, isn't it 24 possible, then, Professor, that the reason utility 25 was left off the agenda was because negotiators did</p> <p>www.dianaburden.com</p>

<p>1 not think it was a priority to harmonize those 2 definitions? 3 PROFESSOR GERVAIS: It's possible. 4 MR. BERENGAUT: And isn't it possible 5 that the reason they did not think it was a priority 6 to harmonize those definitions was because at the 7 time there was little variation in practical outcomes 8 among countries regarding utility? 9 PROFESSOR GERVAIS: It's possible, 10 but I don't think that was the case. I disagree with 11 the premise of the question. I think that the 2001 12 and 2003 reports, which predate this proposal by just 13 a few months, show wide variations (I'm quoting from 14 those documents) and so the much more likely 15 conclusion to draw is that they didn't think they 16 could get there. If you look at what happened at 17 SCP/8 they tried three alternatives, the chairman 18 floated them and there was no agreement, and they 19 decided let's leave this one off the table, for 20 whatever reason. 21 MR. BERENGAUT: You make a similar 22 point about the Tegernsee Group. Let's go back to 23 your First Report, paragraph 53. 24 This was, as you quote, "a new 25 dialogue on the state of affairs concerning</p> <p>www.dianaburden.com</p>	<p>1802</p> <p>1 international harmonization of substantive patent 2 law." And you note that this Tegernsee Report does 3 not discuss the harmonization of utility or 4 industrial applicability. That's a quote from the 5 middle of paragraph 53. 6 PROFESSOR GERVAIS: I see it. 7 MR. BERENGAUT: Now, your opinion is 8 that the reason utility/industrial applicability was 9 not included in the Tegernsee Report was because it 10 was the subject of disagreement, right? 11 PROFESSOR GERVAIS: I don't know for 12 a fact that that's what happened but I do not draw 13 inference from the fact that it's not on the list, 14 that there was agreement, because every document I 15 see points me in the other direction. 16 MR. BERENGAUT: Again, I think you 17 mentioned this but, just to be clear, you were not 18 involved in the process of putting together the 19 Tegernsee Report? 20 PROFESSOR GERVAIS: No, no. 21 MR. BERENGAUT: And this report is 22 R-240, and it's behind tab 15 of your binder. 23 PROFESSOR GERVAIS: Okay. 24 MR. BERENGAUT: This is a considerably 25 longer document but my question about this document</p> <p>www.dianaburden.com</p> <p>1803</p>
<p>1 is the same. You have not cited to any language in 2 this report explaining why utility or industrial 3 applicability was left out, do you? 4 PROFESSOR GERVAIS: Correct, I don't 5 recall seeing that language in there. I'm not saying 6 it's not, but I do not recall seeing it when I read 7 it. 8 MR. BERENGAUT: So, Professor, isn't 9 it possible that here again, the reason that utility 10 and industrial applicability were not included was 11 because it was not important for parties to harmonize 12 their utility/industrial applicability requirements 13 because they were not causing any problems in 14 practice? 15 PROFESSOR GERVAIS: Theoretically, 16 yes, but I don't know that -- I shouldn't believe 17 empirically that's not supported. I think where I 18 might agree with you is that, if you were to look at 19 empirical data, utility is typically less difficult 20 for most patent applicants, certainly outside the 21 pharmaceutical field, and so if you were to look at 22 the number of patent applications that get in trouble 23 for utility compared to the other requirements, is 24 that why they decided not to discuss industrial 25 applicability and utility? I don't know. They don't</p> <p>www.dianaburden.com</p> <p>1804</p>	<p>1 tell us. But I do not read the idea that it's not a 2 priority, which I see is beside the point, as meaning 3 that there's agreement, which I see as actually being 4 the point. I don't see the agreement being reflected 5 here or in any other document that has been cited 6 that I can see. 7 MR. BERENGAUT: Going back to 8 paragraph 53 of your First Report, you cite the USPTO 9 notice of a Roundtable on the Tegernsee Group report, 10 and you note about it that, again, utility and 11 industrial applicability are left out. Do you see 12 that? 13 PROFESSOR GERVAIS: I do. 14 MR. BERENGAUT: Let's take a look at 15 that document. It's tab 16 of your binder. This 16 document didn't indicate any concern about practical 17 differences in utility/industrial applicability 18 requirements across jurisdictions, did it? 19 PROFESSOR GERVAIS: I'm just reading 20 it to get -- no, it's referring to issues that are 21 "most suitable for further progress," and that list 22 does not include industrial applicability or utility, 23 in the middle of the second column on page 56071. 24 MR. BERENGAUT: So, again, the 25 document doesn't indicate any concern about practical</p> <p>www.dianaburden.com</p> <p>1805</p>

<p>1806</p> <p>1 differences in utility/industrial applicability 2 requirements across jurisdictions? 3 PROFESSOR GERVAIS: I don't see any, 4 no. 5 MR. BERENGAUT: No indication why 6 utility or industrial applicability were left off the 7 agenda for the session? 8 PROFESSOR GERVAIS: Well, the words 9 mean what they mean. It says "issues most suitable 10 for further progress." This one is not most suitable 11 for further progress. It doesn't tell us why. 12 MR. BERENGAUT: Were you aware, 13 Professor, that other countries also responded to the 14 requests for feedback from the Tegernsee Group? 15 PROFESSOR GERVAIS: I haven't read 16 those submissions. 17 MR. BERENGAUT: Let's take a look at a 18 few examples. Tab 17 of your binder, the next page, 19 C-340, is the Japanese report. If you could turn, 20 please, to the last page, page 21? 21 PROFESSOR GERVAIS: Yes. 22 MR. BERENGAUT: Where it said "At the 23 last part of the questionnaire survey based on 24 questionnaires made by the Tegernsee Expert Group, 25 there was a question. 'Other than these four issues,</p> <p>www.dianaburden.com</p>	<p>1807</p> <p>1 is there any issue that has caused problems due to 2 differences in laws practiced in each country?" For 3 this question, the JPO received many responses. The 4 main issues that the respondents raised are as 5 follows: Standards used to determine inventive step; 6 standards used to determine novelty; descriptive 7 requirements for specifications; description of 8 claims (for example, multiple dependent form claims, 9 product-by-process claims); limitations to 10 amendments, et cetera." 11 Do you see that? 12 PROFESSOR GERVAIS: I do. 13 MR. BERENGAUT: Now, industrial 14 applicability or utility is not on this list, 15 correct? 16 PROFESSOR GERVAIS: It is not 17 identified as a main issue, that's right. 18 MR. BERENGAUT: So, from the Japanese 19 perspective, you would agree there is no indication 20 that industrial applicability/utility "caused 21 problems due to differences in laws practiced in each 22 jurisdiction." Right? 23 PROFESSOR GERVAIS: Well, it's not 24 identified as a main issue. We can draw whatever 25 inference we want from that. It doesn't mean that</p> <p>www.dianaburden.com</p>
<p>1808</p> <p>1 it's not an issue. As I said, utility, typically for 2 many types of inventions, is not an issue outside of 3 the pharmaceutical field. So I'm not particularly 4 surprised by this but I'm reading this for the first 5 time. Why it's not a main issue, was it an issue at 6 all, I don't know. 7 MR. BERENGAUT: Let's take a look at 8 another example. Tab 18. This is from Germany. 9 Let's take a look at page 2 which lists responses 10 regarding several patent law topics. Do you see 11 that? 12 PROFESSOR GERVAIS: I do. 13 MR. BERENGAUT: B), c), d), e) and f). 14 Now, industrial applicability/utility does not appear 15 on this list, correct? 16 PROFESSOR GERVAIS: Would you be able 17 to -- obviously -- oh, I see a) is there. Okay. 18 Well, again, they refer to main results of the 19 evaluation and, you're absolutely correct, industrial 20 applicability is not in the list of these main 21 results. 22 MR. BERENGAUT: And in the final 23 section, f), it states "Other areas requiring 24 harmonization." It states, "While the need for 25 harmonization is deemed to be constantly high for the</p> <p>www.dianaburden.com</p>	<p>1809</p> <p>1 four aforementioned fields of law... there are no 2 other obvious topics deemed to be similarly important 3 by the applicants." Do you see that? 4 PROFESSOR GERVAIS: I do. 5 MR. BERENGAUT: Doesn't this suggest 6 that, from Germany's perspective as well, industrial 7 applicability/utility was not an important topic to 8 put on the table for harmonization? 9 PROFESSOR GERVAIS: That's a 10 reasonable inference. 11 MR. BERENGAUT: Let's go back to your 12 First Report. 13 PROFESSOR GERVAIS: But do you know 14 by any chance how many countries have replied to 15 this? Because we have two. I wondered if others 16 did. Anyway, tab 2, yes. 17 MR. BERENGAUT: Back to your First 18 Report, please, tab 1, paragraph 31. In paragraph 31 19 of your first statement you quote a discussion of 20 utility in a WIPO document, and we looked at this 21 document earlier. 22 PROFESSOR GERVAIS: Yes. 23 MR. BERENGAUT: And I believe we 24 agreed, but just to confirm, that the reason you 25 thought this language regarding differences was</p> <p>www.dianaburden.com</p>

<p>1810</p> <p>1 relevant is because it showed from your perspective a 2 lack of consensus regarding those concepts. 3 PROFESSOR GERVAIS: Back to that word 4 again. I am trying very hard in this report to 5 explain that there are two notions, that they're not 6 identical, and that within each family of notions 7 there are variations. With all due respect, I'm not 8 sure -- I'm not trying to show that there is or isn't 9 a consensus. That's not my point. 10 MR. BERENGAUT: Paragraph 50 and 51, 11 this is a reference to a joint report of the WTO, 12 WIPO and WHO. 13 PROFESSOR GERVAIS: Yes. The first 14 time these three published a joint report, I believe. 15 MR. BERENGAUT: And the report notes, 16 and you quote a paragraph of the report and you quote 17 paragraph 57. Do you see that? 18 PROFESSOR GERVAIS: I do. 19 MR. BERENGAUT: Let's take a look at 20 that document. That's at R-220 behind tab 5. 21 PROFESSOR GERVAIS: Yes. 22 MR. BERENGAUT: You quoted paragraph 23 57 of the report. 24 PROFESSOR GERVAIS: Page or 25 paragraph?</p> <p>www.dianaburden.com</p>	<p>1811</p> <p>1 MR. BERENGAUT: Page 57, excuse me. 2 PROFESSOR GERVAIS: Yes. 3 MR. BERENGAUT: On page 59 of the 4 report it discusses industrial applicability/utility, 5 correct? 6 PROFESSOR GERVAIS: It does. 7 MR. BERENGAUT: I'm at the right-hand 8 column, top of the page of 59. "Industrial 9 applicability (or utility) means that the invention 10 can be made or used in any industry, including 11 agriculture, or that it has a specific, credible and 12 substantial utility. In general, the application of 13 this requirement does not pose practical problems." 14 Do you see that? 15 PROFESSOR GERVAIS: Yeah, I agree 16 with that. For most types of inventions, it doesn't. 17 That paragraph is quoted in my Second Report, by the 18 way. 19 MR. BERENGAUT: Right. I was going to 20 go there next. And I appreciate you discuss it your 21 Second Report. You do not quote it in your First 22 Report, correct? 23 PROFESSOR GERVAIS: No. The reason I 24 did is because the way that I thought my first quote 25 was mishandled in the Reply Memorial.</p> <p>www.dianaburden.com</p>
<p>1812</p> <p>1 MR. BERENGAUT: Right. I will take 2 you there next. I'm not trying to -- 3 PROFESSOR GERVAIS: Well, you decide. 4 MR. BERENGAUT: I'm not trying to only 5 show part of the exchange here. 6 So then you go back to this report in 7 your Second -- go back to this document in your 8 Second Report? 9 PROFESSOR GERVAIS: I do. 10 MR. BERENGAUT: Paragraphs 39-44, 11 where you take issue with Claimant stating that you 12 omitted the paragraph from page 59 from your report . 13 PROFESSOR GERVAIS: Uh-huh. 14 MR. BERENGAUT: What I'm interested in 15 is the sentence at the beginning of paragraph 44 that 16 the additional paragraph 149, "changes nothing on 17 substance to [your] conclusion," and I'm having a 18 hard time with that statement because if, in your 19 view, statements to the effect that there were 20 differences between industrial applicability and 21 utility detract from the proposition that there was 22 consensus, surely this statement on page 59, which 23 provides a single definition of both concepts, 24 reflects consensus at least in the content of 25 page 59?</p> <p>www.dianaburden.com</p>	<p>1813</p> <p>1 PROFESSOR GERVAIS: No, I'm sorry, I 2 have to disagree with both the premise and the 3 question. First of all, paragraph 59 does not give a 4 unique definition. There is one definition followed 5 by "or" in the second. And, second, what I said was 6 in general, it is true -- however you define utility 7 and industrial applicability, and it doesn't mean 8 there's consensus on what it means, what it means is, 9 in general, most inventions, certainly outside of 10 biotech and pharma, will easily surpass whatever 11 definition a country adopts, or meet the test. 12 Therefore, there are fewer problems -- 13 I have said that before and I stand by it -- with 14 utility/industrial applicability than there would be 15 with novelty or inventive step. That's how I read 16 "in general," and I do not agree that there's a 17 single definition in that paragraph. 18 MR. BERENGAUT: Professor, in your 19 answer just now, you said what it means is in 20 general, most inventions, certainly outside of 21 biotech and pharma, will easily surpass whatever 22 definition a country adopts. 23 PROFESSOR GERVAIS: Which I 24 reformulated as "meet the criteria", if you keep 25 reading.</p> <p>www.dianaburden.com</p>

<p>1 MR. BERENGAUT: Or meet the criteria. 2 Now, in this paragraph, there is no discussion of 3 difficulties faced by the pharmaceutical industry, is 4 there? 5 PROFESSOR GERVAIS: Well, it says -- 6 it mentions biotech, which I believe is not that far 7 from pharma, but what I take issue with is saying 8 this report by these three organizations says there's 9 only issue with biotech. It doesn't. It says, 10 however, in this area there are considerations; there 11 might well be other areas, we don't know, but it 12 certainly uses biotech as an example. 13 MR. BERENGAUT: The sentence that 14 you're referring to regarding biotechnology reads, 15 "However, in the area of biotechnology it needs some 16 consideration given concerns that patent applications 17 claiming gene-related inventions would block the use 18 of the claimed gene sequence for uses that were not 19 yet known by the applicant and therefore would not 20 justify the grant of a patent in respect of a 21 function which the applicant was not even aware of." 22 Do you see that? 23 PROFESSOR GERVAIS: I do. That is 24 the example given. 25 MR. BERENGAUT: There's no indication</p> <p>www.dianaburden.com</p>	<p>1814</p> <p>1 in this paragraph that, apart from this one area of 2 biotechnology, in the broader context of 3 pharmaceutical inventions, utility "needs some 4 consideration," is there? 5 PROFESSOR GERVAIS: Not in this 6 paragraph, but it is certainly my opinion that a 7 chair and a new chemical molecule will not 8 necessarily be looked at in the same fashion by an 9 examiner in terms of utility. Professor Holbrook has 10 a significant discussion of that, I believe, in his 11 report. 12 MR. BERENGAUT: If I may have one 13 moment to confer with my colleagues, Mr. President. 14 Thank you, Mr. President. We have no 15 further questions. 16 THE PRESIDENT: Thank you. 17 MR. SPELLISCY: May I have one or two 18 minutes, or maybe five minutes, for a quick 19 discussion? If I have any redirect, it would be very 20 short. 21 THE PRESIDENT: A five-minute recess. 22 Professor Gervais, you are under testimony. You are 23 not allowed to discuss the case with anyone. 24 <i>(Recess taken)</i> 25 THE PRESIDENT: Please.</p> <p>www.dianaburden.com</p> <p>1815</p>
<p>1816</p> <p>1 REDIRECT EXAMINATION ON BEHALF OF THE RESPONDENT 2 MR. SPELLISCY: Good afternoon, 3 Mr. Gervais, I just have one simple question on 4 clarification. 5 A couple of times you mentioned a 6 study cited by one of the amici in this case. I 7 won't ask you questions about it because I don't know 8 if it is yet in the record, but can you give us the 9 author or the title of that study? 10 PROFESSOR GERVAIS: Yes. It's a 11 study by the London School of Economics by 12 Dr. Thambisetty. I would strongly, if I may, suggest 13 that it's worth reading. It's very, very relevant to 14 this case. It's produced by the law professors who 15 produced an amicus brief on Claimant's behalf. 16 MR. SPELLISCY: Pursuant to the 17 Tribunal's procedure, we'll make sure to get a copy 18 of it onto the record, give it an R number and 19 produce it to the Claimant. 20 MS. CHEEK: I think, given the 21 procedural rules on documents, the parties will need 22 to confer as to whether or not that document can be 23 admitted to the record. 24 THE PRESIDENT: The document is not 25 yet in the record?</p> <p>www.dianaburden.com</p>	<p>1817</p> <p>1 MR. SPELLISCY: It's a document 2 referred to in one of the amicus submissions. In the 3 Tribunal's Order, right before the hearing, on 4 24 hours' notice before using it or referring to it, 5 we can put it in the record. 6 THE PRESIDENT: First to confer. 7 MS. CHEEK: But I just got notice. 8 MR. SPELLISCY: And I haven't put it 9 into the record yet but, 24 hours from now, it will 10 be there. 11 THE PRESIDENT: Okay. Sir Daniel has 12 a question or two. 13 QUESTIONS BY THE ARBITRAL TRIBUNAL 14 SIR DANIEL BETHLEHEM: Just a couple 15 of technical questions, if I may, and they may not be 16 relevant at all but I just want to clarify. 17 At the start of your cross-examination 18 you said -- and I think the language was at 15:05:11, 19 "TRIPS is relevant to the interpretation of NAFTA 20 Chapter 17," and in your First Report you've got 21 quite a lot of information about the origins of NAFTA 22 Chapter 17 being the Dunkel draft in 1991 and so on. 23 So my question is, and although I'm putting it in 24 terms of NAFTA and TRIPS it may have a bearing on the 25 relationship between NAFTA and other intellectual</p> <p>www.dianaburden.com</p>

<p>1818</p> <p>1 property agreements as well -- the question is really 2 what is the formal relationship between NAFTA and 3 TRIPS? 4 You've put it in terms of relevance to 5 interpretation, but I have in mind when asking the 6 question Article 103 of NAFTA, which says in 103(1), 7 "The parties affirm their existing rights and 8 obligations with respect to each other under the 9 GATT", and then 103(2), "In the event of any 10 inconsistency between this Agreement and any such 11 other agreements, this Agreement shall prevail to the 12 extent of the inconsistency," so I'd just like to get 13 a sense from you what the formal relationship is 14 between them? Is it 31(3)(c) other relevant rules of 15 international law; is it subsequent agreement? 16 As a subset of that, without asking 17 you to either repeat everything that you've said or 18 for a long excursus, is your sense that there is 19 consistency, or are there important elements of 20 inconsistency which you think are relevant to these 21 proceedings? 22 PROFESSOR GERVAIS: Thank you. 23 That's a great question. 24 This is an unusual situation, 25 Sir Daniel, because we have a number of countries,</p> <p>www.dianaburden.com</p>	<p>1819</p> <p>1 specifically an initial draft prepared by a 2 Washington economist on behalf of the pharmaceutical, 3 entertainment and part of the software industry was 4 circulated informally to governments in the U.S., 5 Europe and Japan, and this unofficial draft became -- 6 that's why I used the expression "molded from the 7 same clay" in my report. It's a really unusual 8 situation where two treaties are molded pretty much 9 by the same parties at the same time. It is not a 10 square 31 application or 32 for that matter, but 11 clearly the point I make is that when the same 12 parties use the same language in an agreement which 13 has a very similar object and purpose, which is a 14 trade agreement with an IP chapter, there is 15 definitely relevance in the fact that they have this 16 common origin, and if you look at 1709(1) and 27(1), 17 you see very similar language, the real difference 18 being the footnote in 27 being moved to the text in 19 1709. In 1709(2) the paragraphs are formatted 20 differently, but the words are almost identical in 21 that section. 22 Now, I think that the reference to 23 GATT was to obviously not the WTO agreements, because 24 they hadn't been signed, so it was the old trade 25 rules of the GATT 47 that they were making reference</p> <p>www.dianaburden.com</p>
<p>1820</p> <p>1 to, and so I think that's what they were trying to do 2 with that safeguard clause. But the text of 27 and 3 1709(1) really has the same parentage, the same 4 origin. 5 What happened to this initial 6 submission by the private consortium was basically 7 that each government amended it to a certain degree 8 and then the European Union in March 1990 and then 9 the Americans and the Japanese and the Australians 10 and a few others submitted their own versions, and 11 this got consolidated in July of 2001 into one draft, 12 which then became the clay from which both NAFTA and 13 TRIPS are molded. 14 So your technical question is an 15 extremely interesting one under 31. This is an 16 unusual situation where two treaties emerge more or 17 less at the same time with more or less the same 18 object and purpose, and with the same language. So I 19 would suggest that it's wise to read them in 20 parallel. 21 Whether I can say formally you have to 22 read one the way you would read the other one, or you 23 would interpret one, under 31 that's not obvious. I 24 don't think the subsequent agreement quite works but 25 technically, it's true, GATT happened a few months</p> <p>www.dianaburden.com</p>	<p>1821</p> <p>1 later -- not GATT but WTO. 2 Am I answering your question 3 sufficiently? 4 SIR DANIEL BETHLEHEM: You are indeed 5 and that's exactly what I was getting at. Let me put 6 just a brief follow-up to you, in light of your 7 answer. 8 Would it be a fair understanding to 9 say that leaving aside any, as it were, technical 10 interpretation of 31(iii)(c) and other relevant rules 11 of international law, what you seem to be saying is 12 that there may be a useful and important relationship 13 between the two because it may be that the parties 14 intended special meanings of terms and that one could 15 derive that. So it may be that there is something in 16 Article 31(4), "A special meaning shall be given to 17 terms if it is established that the parties so 18 intended." Would that be a fair summation, broadly, 19 of what you're saying? 20 PROFESSOR GERVAIS: Yes, you would 21 have to show the intent to create the special meaning 22 on 31(4). That's right. Absolutely. 23 SIR DANIEL BETHLEHEM: The second 24 question that I've got, and this is not part of your 25 evidence but it goes to your expertise and, in</p> <p>www.dianaburden.com</p>

<p>1822</p> <p>1 particular, the book that you've written on the 2 reference guide to TRIPS, and if you can't answer it, 3 please don't --</p> <p>4 PROFESSOR GERVAIS: The book is back 5 there, but otherwise, I will try.</p> <p>6 SIR DANIEL BETHLEHEM: It's simply a 7 question to know whether the transparency 8 requirements of TRIPS in Article 63, which require 9 states to notify inter alia other judicial decisions 10 and whatever in the TRIPS field, whether in your 11 experience and knowledge, states actually do notify 12 notable judicial decisions.</p> <p>13 I see as well paragraph 63(3) says 14 that each member shall be prepared to supply to other 15 members on written request, so not associated with 16 this case. We can put that to the parties as a later 17 question if needs be. If you could tell us whether, 18 in your experience, parties generally do notify 19 significant judicial decisions, and whether there are 20 follow-up questions from other parties in the context 21 of TRIPS?</p> <p>22 PROFESSOR GERVAIS: The short answer 23 is no. 63 is implemented mostly through the WIPO-WTO 24 Cooperation Agreement by which WIPO publishes the 25 laws of its member states on its website, a service</p> <p>www.dianaburden.com</p>	<p>1823</p> <p>1 called WIPO Lex, which works reasonably well for laws 2 and regulations but not court cases.</p> <p>3 There was some discussion of 4 publishing, for example, invalidation decisions in 5 one jurisdiction so that other jurisdictions would 6 have them and, for reasons that may or may not be 7 obvious, there was some resistance to the idea. So 8 that was dropped, and I'd never heard of another 9 project to start a database of judicial decisions. 10 So I think 63 is read as if one government writes to 11 another government and says we would like a copy of 12 this decision, then they would send that to them. 13 But this was -- this is 1993 thinking. I think today 14 we would go on-line for most countries and just find 15 it, but perhaps for some jurisdiction that does not 16 so provide on-line, then you would be able to use 63 17 formally and request a copy.</p> <p>18 SIR DANIEL BETHLEHEM: From what I 19 understand from what you just said, there is nothing 20 to your knowledge and experience, either in a WIPO 21 context or a WTO TRIPS context, in which, for 22 example, an invalidation decision by a national court 23 would be circulated, published internationally on one 24 of those websites?</p> <p>25 PROFESSOR GERVAIS: There is no</p> <p>www.dianaburden.com</p>
<p>1824</p> <p>1 formal mechanisms at WIPO/WTO for that to happen that 2 I'm aware of, no.</p> <p>3 SIR DANIEL BETHLEHEM: Thank you very 4 much.</p> <p>5 THE PRESIDENT: Mr. Born has a few 6 questions.</p> <p>7 MR. BORN: Good evening. 8 PROFESSOR GERVAIS: Good evening. 9 MR. BORN: Can you look in tab 7 of 10 the binder? It's Chapter 17 of NAFTA. 11 PROFESSOR GERVAIS: Yes. 12 MR. BORN: And in particular at 13 Article 1709(1). 14 PROFESSOR GERVAIS: Yes, I'm quite 15 familiar with that. 16 MR. BORN: That's why I'm asking the 17 questions. I take it from your testimony that your 18 view is that paragraph 1 imposes substantive limits 19 of some sort on states but that, in your view, states 20 have -- the NAFTA parties have substantial 21 flexibility with operating within those limits. 22 PROFESSOR GERVAIS: This is a very 23 important point, if I can just give you a slightly 24 more detailed answer. The short answer is yes, but 25 it may not fully satisfy.</p> <p>www.dianaburden.com</p>	<p>1825</p> <p>1 So I think, first of all, as a matter 2 of international law, you cannot say there's a treaty 3 this country has implemented this way, we think this 4 country is compliant, therefore, everybody must do 5 the exact same thing. Because at that point 6 international law falls apart. Countries must have 7 the opportunity to do things a little differently 8 when they implement a treaty. I think that's not 9 particularly controversial.</p> <p>10 What is interesting under the Vienna 11 approach is when you try to interpret words like, for 12 example, here "utility" or any other words in this 13 treaty -- and what I made reference to earlier was 14 the trade law approach, which is not to find one 15 international definition of a term that is not 16 otherwise defined, but to confine it to certain 17 limits.</p> <p>18 So if I can give, quickly, two 19 examples, because they're the only two that come to 20 mind, in the China enforcement case at the WTO, which 21 for the record is DS362, the panel discusses a 22 certain meaning of an expression in Article 57 of 23 TRIPS and discusses the Vienna Convention and says 24 there's more than one way to read this. I believe 25 from memory, it would be paragraph 221 of that</p> <p>www.dianaburden.com</p>

<p>1826</p> <p>1 report. It's in my book. It might be off by one or 2 two. 3 It basically goes and says when you 4 implement an intellectual property agreement, you 5 have to have some flexibility. Then, of course, 6 there's the report from the Appellate Body as quoted 7 in my report that discusses Article 1 which 8 specifically says countries can apply this agreement 9 the way that -- I'm not quoting directly -- but have 10 some leeway. And I'm sure the members of the 11 Tribunal are familiar with the jurisprudence of WTO 12 on credible interpretations. In other words, there 13 isn't a single interpretation, but if you look at the 14 continued zeroing case at the appellate body from 15 2009, which is DS350, you will see a discussion there 16 as well of the appellate body saying, again, Vienna 17 Convention doesn't say you have to define one word 18 one way. There has to be a credible way of defining 19 this word, and then they do the Vienna analysis. 20 That's what I was trying to say when I said there was 21 some leeway but it's finite. When you try to draw 22 that border through hypotheticals, that you get to a 23 point where it becomes very difficult to say it is 24 here. It's a complex notion. 25 The last thing I would say, though, is</p> <p>www.dianaburden.com</p>	<p>1827</p> <p>1 when one country implements it in a way that is 2 mentioned in several international reports, namely 3 promise, that's when my report says it is hard to 4 imagine that's it's outside the boundary. That's my 5 main point. 6 MR. BORN: Staying for a moment on 7 1709(1), if I understand your testimony, it is that 8 although there could be different ways of defining 9 new or useful or capable of industrial application, 10 which would be consistent with paragraph 1, there 11 would also be other ways that would be inconsistent 12 with paragraph 1. 13 PROFESSOR GERVAIS: Theoretically, 14 yes. 15 MR. BORN: Can you help me? Can you 16 give me -- and I know you recoiled from hypotheticals 17 previously. So rather than try to give you one, can 18 I ask you for one? Can you give me an example of a 19 definition of hypothetically useful that would be 20 outside 1709(1)? 21 PROFESSOR GERVAIS: Well, if I 22 preface it with "arguably" because this is always so 23 hard. 24 MR. BORN: Sure. 25 PROFESSOR GERVAIS: If a country said</p> <p>www.dianaburden.com</p>
<p>1828</p> <p>1 we will only consider useful, I'm going to basically 2 take a bit of a risk and stick with pharmaceuticals 3 here, but basically if you were to say a 4 pharmaceutical product is only useful if it cures 5 100 percent of the patients entirely, that seems 6 excessive to me, for example. Arguably, it's 7 excessive, but would I absolutely say the WTO panel 8 would say that? I wouldn't know for sure. 9 MR. BORN: Putting aside WTO panels, 10 why would you regard that hypothetical as outside 11 1709(1)? What are the characteristics of that 12 measure that would put it outside 1709? 13 PROFESSOR GERVAIS: Well, I'm trying 14 to look for an example where you go beyond utility 15 and industrial applicability eyes. Typically if you 16 look at pharmaceutical inventions, there needs to be 17 evidence that this product will do either what it 18 says or that there will be -- that's the whole debate 19 in the case in that Federal Court of Appeal and the 20 Court of Appeal and the New Jersey court and all 21 these judges that have looked at these compounds have 22 looked at. 23 There is a threshold. It's very hard 24 to situate it precisely. But I'm saying 100 percent 25 is arguably something -- would I be prepared to argue</p> <p>www.dianaburden.com</p>	<p>1829</p> <p>1 that that is inconsistent? Yes. 2 MR. BORN: Would the reason that it's 3 inconsistent be because, A, it's surprising, as in it 4 hasn't been done before and isn't being done now; B, 5 it's important in that it has significant effects on 6 a fair number of patents; and C, it would be 7 difficult to understand in terms of rationale? Would 8 those sorts of characteristics be what you would look 9 at? 10 PROFESSOR GERVAIS: Neither A nor B, 11 definitely. C, it depends what it means. So, for 12 example, there's no doubt -- there was a discussion I 13 understood earlier with some other experts that if 14 you have a patent criteria that is reinterpreted by 15 courts, whether that applies to existing patents. 16 And the system breaks down if you have different 17 standards to different patents that are valid at the 18 very same time. So clearly, if you have a country 19 that changes the interpretation and that applies to 20 existing patents, that is the law everywhere that I 21 know. So that's not the reason. 22 The reason is more a policy, so I'm 23 guessing I'm closer to your C point, which is every 24 country implements the patent bargain differently, 25 but they all try to do the right thing. They try to</p> <p>www.dianaburden.com</p>

<p>1830</p> <p>1 maximize innovation in the right amount of 2 important -- or inventions that matter, I guess to 3 use as simple as possible term, and disclosure, and 4 some countries would add access to this. The bargain 5 is implemented a little differently, but it's not 6 that different. 7 What is different is the fact that 8 very often the patent statute doesn't say very much, 9 and so then it's left to courts to apply it. And 10 then they see this technology and hear new arguments 11 and they see, well, yes or no, and then it goes to 12 Supreme Court. That's the process. That's the way 13 these things work. But you asked me for a 14 hypothetical. That's the best I can come up with. 15 MR. BORN: And if I can just push you 16 on your answer on items A and B that I gave you, why 17 wouldn't it be relevant in deciding whether a 18 definition went beyond 1709(1) to see what states 19 generally had done and were doing? 20 PROFESSOR GERVAIS: Oh, I did not -- 21 I'm so sorry, I did not understand -- your question 22 was about surprising. Is that what you meant? 23 MR. BORN: Yes. 24 PROFESSOR GERVAIS: I don't quite 25 understand -- it's not a word I'm familiar with,</p> <p>www.dianaburden.com</p>	<p>1831</p> <p>1 frankly. 2 MR. BORN: That's surprising. 3 PROFESSOR GERVAIS: In this context. 4 So I've heard it, but I don't think that it's used. 5 What I meant, I think, to say is that state practice 6 is obviously relevant. It's a Vienna factor in 7 interpreting how a treaty needs to be applied, which 8 is why I referred to state practice as much as I 9 could in my reports as opposed to either personal 10 beliefs or old recollections. I went to the source 11 documents, and I said this is the empirical data I 12 can find. There is no better source of state 13 practice than states reporting their own practice, 14 which is really what I tried to do. 15 MR. BORN: Thank you. I think I 16 understand now. 17 THE PRESIDENT: The answers you just 18 gave to Mr. Born regarding article 1709(1) of NAFTA, 19 how do they fit into analysis on the basis of 20 Article 31 and 32 of the Vienna Convention on the Law 21 of Treaties? 22 PROFESSOR GERVAIS: You mean the last 23 part of the answer on state practice? 24 THE PRESIDENT: No, at all. Entirely. 25 Would you not start with 31(1)?</p> <p>www.dianaburden.com</p>
<p>1832</p> <p>1 PROFESSOR GERVAIS: Yes. 2 THE PRESIDENT: Is there more to it is 3 my question. Why I asked this question is because 4 you referred to policies, to rationales behind it. 5 How far may you go under Article 31(1) or 31(4)? 6 PROFESSOR GERVAIS: Well, I think you 7 start -- as I always try to summarize 31, text in 8 context in light of object and purpose. So you would 9 look at the text. It doesn't tell you very much 10 about what these words mean. So you look at the 11 context of the other provisions of the patent section 12 and then the other provisions of TRIPS. Possibly 13 even other -- TRIPS or NAFTA, for that matter, 14 because on that provision they are almost identical. 15 THE PRESIDENT: May I stop you there? 16 Are you allowed to look outside this treaty under 17 31(1)? 18 PROFESSOR GERVAIS: Well, that's the 19 whole question of other relevant norms. There's some 20 jurisprudence on what other relevant norms are that 21 I'm sure you're well aware of. Are you allowed to? 22 Yes. 23 THE PRESIDENT: I've seen a number of 24 interpretations under 31(3) that do this. 25 PROFESSOR GERVAIS: Yes.</p> <p>www.dianaburden.com</p>	<p>1833</p> <p>1 THE PRESIDENT: Under 31(1), I have 2 not seen that one. I've seen a lot of things -- 3 PROFESSOR GERVAIS: Well -- sorry. 4 THE PRESIDENT: -- under Vienna, but 5 okay. 6 PROFESSOR GERVAIS: I was talking 7 about 31 globally. Sorry. 8 THE PRESIDENT: Let's take it 9 paragraph by paragraph, because the holistic view of 10 31 is already a dangerous exercise in my view. 11 PROFESSOR GERVAIS: I'm sorry. I 12 missed what you just said. 13 THE PRESIDENT: A holistic enterprise 14 is taking 31 in its entirety. First you start with 1 15 and then go to 2 and then 3 and 4. 16 PROFESSOR GERVAIS: I agree with you, 17 Professor. That's the way to do it. I have this way 18 of summarizing it which probably made it sound a 19 little too holistic. 20 THE PRESIDENT: So you're saying, 1, 21 it doesn't help you because at least you say the 22 words have -- the ordinary meaning of the words you 23 can attribute to them, you don't find them? 24 PROFESSOR GERVAIS: Well, the 25 ordinary meaning of technical terms in the patent</p> <p>www.dianaburden.com</p>

<p>1834</p> <p>1 field is an interesting question to begin with. So 2 you have terms that over time have evolved in two 3 different systems to be used and have been defined by 4 courts in those systems because most statutes do not 5 define utility and industrial applicability very 6 clearly, so you leave it up to a large degree to 7 courts. So you're already looking at a moving target 8 in terms of ordinary meaning on the domestic front, 9 and so if you look at dictionaries here, I don't 10 think they would help you very much. So the text 11 doesn't give you very much. 12 The context is all these doctrinal 13 tools, the three major criteria that are mentioned 14 here, the disclosure requirement, are all part of a 15 doctrinal mix. The United States is a little unique 16 because it adds written description and enablement. 17 Most countries do not have those notions. Certainly 18 not in the same way. So it achieves the doctrinal 19 mix differently. But as I said earlier, you try to 20 get to the same place as a court or as a legislator, 21 you try to get to an implementation of the patent 22 bargain that you think is the best policy. I'm 23 probably not answering your 31 question in terms 24 of -- 25 THE PRESIDENT: You're back to the</p> <p>www.dianaburden.com</p>	<p>1835</p> <p>1 answer you gave to Mr. Born about policies. My 2 question is how do you get to policy here in the 3 legal analysis? 4 PROFESSOR GERVAIS: Well, I don't 5 know that the text tells you very much. The context 6 of 27 or 1709(1) does. It says there are three 7 criteria, and it says if you meet those, then patents 8 should be available. It doesn't say they should be 9 granted. Actually, it's important to note that in 10 the negotiation, that word was actually there, 11 granted, and it was removed. It's, in my book, very 12 clear. They're removed. They didn't want it. They 13 wanted available. So we have a context. The context 14 is availability for patents based on three criteria. 15 It doesn't say these are the only three. So that you 16 have the context that basically the context 17 provides -- the immediate context provides the fact 18 that there's a doctrinal mix there. Then you have 19 the whole patent section which provides the context 20 that you have -- you're dealing with some sort of 21 innovation but not just, because you have this 22 section of -- especially in TRIPS that deals with 23 compulsory licensing and so on. 24 So you have kind of that -- and 25 Article 7 of TRIPS, which deals with the objectives</p> <p>www.dianaburden.com</p>
<p>1836</p> <p>1 and principles of the agreement, emphasizes both the 2 need for innovation and benefits to user and all 3 that. So you're dealing with a context that already 4 provides a little bit more complexity. Then you look 5 at the object and purpose of this agreement and it's, 6 again, about protection of IP and enforcement of IP 7 up to a point. That's where it says, you know, you 8 can do more up to a point unless you're contravening 9 that agreement. It also says that there are a number 10 of areas where countries have flexibility. And 11 again, I go back to Article 1. I go back to the 12 preamble, Article 41. There's several places in this 13 agreement that have significant flexibility. It's 14 meant not to be defining but confining up to a point 15 what countries can and cannot do. 16 THE PRESIDENT: Thank you. 17 PROFESSOR GERVAIS: Is that helping? 18 THE PRESIDENT: Useful. 19 PROFESSOR GERVAIS: The best word to 20 end the day. Or maybe it's not the end of the day. 21 THE PRESIDENT: All right. Any 22 follow-up questions by, first, I think Respondent 23 because it's your expert. 24 MR. SPELLISCY: No follow-up questions 25 for us.</p> <p>www.dianaburden.com</p>	<p>1837</p> <p>1 MR. BERENGAUT: Nor from us. 2 THE PRESIDENT: Thank you, Professor, 3 for testifying. You are now excused as an expert 4 witness and released. 5 PROFESSOR GERVAIS: Thank you, 6 Professor. 7 THE PRESIDENT: That comes to the end 8 of the day. No more witnesses? 9 MS. CHEEK: That's correct. We will 10 adjourn early today. 11 THE PRESIDENT: All right. We resume 12 on Monday morning at 9:00. And all the three Mexican 13 witnesses are then available? 14 MS. CHEEK: That's correct. 15 THE PRESIDENT: Thank you. Have a 16 good weekend. 17 (Hearing adjourned at 5:03 p.m.) 18 19 20 21 22 23 24 25</p> <p>www.dianaburden.com</p>

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1643/16	1715/15	1790/5
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1645/11	1717/8	1791/22
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1668/10	1765/11	1826/13
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1796/8	1682/18	1776/21
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1741/5	1571/3	1641/11
1744/10	1574/22	1642/13
1744/10	1577/22	1649/9
1746/2	1578/8	1656/10
1763/16	1578/12	1656/17
1779/24	1579/20	1657/5
1794/14	1579/21	1665/18
1794/16	1585/11	1667/7
1794/19	1599/9 1600/4	1667/11
1796/4 1796/6	1600/7	1668/23
1819/10	1600/16	1671/9 1671/9
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1725/21	1816/12	1758/16
1725/23	1817/15	1798/6
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1734/24	1817/24	1836/20
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1755/18	1773/24	1580/25
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1762/20	1585/11	1582/23
1769/23	May 25 [1]	1585/4
1770/10	1677/23	1587/16
1770/25	maybe [10]	1593/14
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1785/6	1664/22	1594/18

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1624/14	1725/4	1781/4
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1617/24	1704/1 1709/5	1711/17
1621/21	1710/4	1711/19
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1656/12	1726/14	1718/22
1656/12	1729/24	1719/2 1721/9
1656/18	1730/5	1725/17
1675/23	1730/14	1729/14
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1685/11	1754/11	1735/16
1685/18	1758/19	1737/8
1685/21	1778/4	1737/11
1686/9	1799/23	1741/3
1686/11	1822/14	1746/23
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1715/10	1569/1	1617/18
1717/9	1571/15	1617/21
1724/10	1580/10	1618/14
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1735/1	1620/7	1621/25
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1771/14	1648/22	1681/5 1689/2
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1804/20	1799/4	1565/20
1805/21	moved [4]	1566/10
1806/9	1680/10	1566/15
1806/10	1779/16	1634/24
1811/16	1785/7	1695/2
1813/9	1819/18	Mr. [88]
1813/20	moves [1]	1567/5
1823/14	1640/15	1568/24
1834/4	moving [1]	1570/16
1834/17	1834/7	1571/14
mostly [2]	MR [23]	1572/9 1580/7
1749/22	1563/11	1581/5
1822/23	1564/5 1564/6	1582/22
motion [7]	1564/6 1564/7	1587/17
1766/16	1564/8 1564/9	1594/12
1766/19	1564/14	1594/24
1768/1	1564/20	1610/18
1771/11	1564/20	1610/18
1783/10	1564/21	1610/24

M	1680/9	1715/22
Mr.... [74]	1681/16	1727/23
1611/9	1681/25	1729/3
1611/14	1682/5	1730/20
1618/18	1682/12	1731/12
1620/6	1683/11	1736/7
1620/18	1684/10	1738/16
1621/17	1688/20	1738/19
1630/1	1691/4	1738/20
1631/20	1691/10	1740/20
1632/3 1632/9	1691/11	1741/3 1745/7
1633/4 1634/1	1692/11	1745/22
1634/15	1692/15	1750/6
1634/19	1692/19	1763/16
1634/22	1693/3 1693/9	1764/2
1635/2 1637/3	1693/18	1815/13
1640/9 1643/2	1694/1	1815/14
1643/7	1694/21	1816/3 1824/5
1643/22	1694/22	1831/18
1644/17	1694/25	1835/1
1648/17	1695/3 1703/8	Mr. Barrigar
1648/21	1705/8	[1] 1736/7
1650/5	1705/11	Mr. Berengaut
1677/25	1705/15	[3] 1694/21

M	Mr. Fergusson	1815/13
Mr.	[1] 1683/11	1815/14
Berengaut...	Mr. Gervais	Mr. Reed [18]
[2] 1715/22	[1] 1816/3	1581/5
1750/6	Mr. Gierczak	1582/22
Mr. Bogsch	[1] 1681/25	1610/18
[2] 1682/5	Mr. Helfgott	1632/3 1632/9
1682/12	[4] 1610/18	1633/4 1634/1
Mr. Born [4]	1610/24	1634/15
1630/1 1824/5	1611/9	1634/22
1831/18	1611/14	1637/3
1835/1	Mr. Lips [1]	1648/17
Mr. Erstling	1680/9	1648/21
[13] 1568/24	Mr. McKie [2]	1650/5
1571/14	1681/16	1677/25
1594/12	1688/20	1684/10
1594/24	Mr. President	1691/10
1618/18	[9] 1567/5	1692/15
1620/6	1570/16	1692/19
1631/20	1572/9	Mr. Spelliscy
1635/2 1640/9	1691/11	[9] 1580/7
1643/2 1643/7	1695/3	1587/17
1643/22	1738/19	1620/18
1644/17	1741/3	1621/17

M	1763/16	1648/18
Mr.	1764/2	much [25]
Spelliscy...	Mr. Thomas'	1583/18
[5] 1634/19	[1] 1745/22	1623/10
1691/4	Ms [16]	1627/22
1692/11	1563/19	1629/24
1705/11	1563/22	1633/15
1740/20	1563/22	1661/20
Mr. Thomas	1564/5 1564/7	1692/22
[18] 1693/3	1564/8 1564/9	1721/5
1693/9	1564/10	1724/23
1693/18	1564/14	1728/2
1694/1	1564/21	1739/23
1694/22	1565/6 1565/7	1741/3 1750/1
1694/25	1565/7 1565/8	1750/2 1758/7
1703/8 1705/8	1571/12	1763/16
1705/15	1694/20	1802/14
1727/23	Ms. [3]	1819/8 1824/4
1729/3	1571/13	1830/8 1831/8
1730/20	1648/16	1832/9
1731/12	1648/18	1834/10
1738/16	Ms. Wagner	1834/11
1738/20	[3] 1571/13	1835/5
1745/7	1648/16	multilateral [1]
		1572/11

M	1695/22	1581/17
multiple [2]	1695/23	1582/15
1667/7 1807/8	1718/18	1585/22
must [35]	1725/18	1587/1 1591/3
1577/16	1725/18	1595/17
1582/4	1725/22	1595/17
1582/12	1744/24	1596/10
1583/1	1748/22	1596/25
1583/13	1749/11	1600/8
1605/1 1605/6	1825/4 1825/6	1600/24
1605/12	my [156]	1600/24
1606/21	1569/4	1602/2
1606/22	1569/22	1602/18
1611/3 1611/8	1569/22	1603/11
1612/6	1569/23	1615/11
1615/14	1571/19	1616/12
1616/14	1571/20	1619/2
1633/3	1571/21	1620/11
1633/16	1571/23	1621/5
1655/4 1668/7	1575/23	1623/10
1671/9	1579/24	1623/11
1673/14	1580/12	1623/12
1687/25	1580/14	1624/13
1692/2 1692/7	1581/4	1630/17

M	1679/14	1716/21
my... [118]	1682/24	1720/2
1630/25	1684/25	1722/19
1631/4 1632/7	1688/1	1723/13
1633/9	1690/22	1723/22
1633/10	1691/2	1723/25
1633/11	1691/13	1726/1 1728/5
1634/14	1693/7	1731/20
1635/1 1635/7	1693/24	1732/3 1740/3
1635/9	1693/24	1740/3 1740/4
1635/12	1693/25	1741/6
1635/21	1695/5	1741/18
1636/1 1636/9	1695/11	1744/8 1746/1
1637/23	1695/20	1747/7 1749/5
1638/12	1696/11	1750/9
1648/2 1650/8	1697/6 1698/2	1750/13
1657/17	1700/20	1751/1 1751/1
1659/18	1701/11	1752/4 1752/8
1660/23	1705/15	1754/14
1661/16	1712/25	1754/16
1674/11	1715/9	1755/1 1755/7
1674/16	1715/11	1757/17
1676/15	1715/14	1757/20
1677/8 1677/9	1715/22	1757/24

<p>M</p> <hr/> <p>my..... [34]</p> <p>1762/2</p> <p>1764/16</p> <p>1769/6</p> <p>1769/15</p> <p>1772/24</p> <p>1774/11</p> <p>1777/15</p> <p>1778/2</p> <p>1778/17</p> <p>1780/14</p> <p>1780/21</p> <p>1786/2</p> <p>1792/10</p> <p>1798/10</p> <p>1799/11</p> <p>1800/19</p> <p>1801/17</p> <p>1803/25</p> <p>1810/9</p> <p>1811/17</p> <p>1811/24</p> <p>1815/6</p>	<p>1815/13</p> <p>1817/23</p> <p>1819/7 1826/1</p> <p>1826/7 1827/3</p> <p>1827/4 1831/9</p> <p>1832/3</p> <p>1833/10</p> <p>1835/1</p> <p>1835/11</p> <p>myself [2]</p> <p>1635/16</p> <p>1684/19</p> <hr/> <p>N</p> <hr/> <p>NAFTA [26]</p> <p>1573/14</p> <p>1741/23</p> <p>1742/4</p> <p>1742/16</p> <p>1747/4</p> <p>1747/15</p> <p>1748/16</p> <p>1748/19</p> <p>1748/23</p> <p>1749/8</p>	<p>1750/18</p> <p>1750/19</p> <p>1751/9</p> <p>1751/22</p> <p>1751/23</p> <p>1817/19</p> <p>1817/21</p> <p>1817/24</p> <p>1817/25</p> <p>1818/2 1818/6</p> <p>1820/12</p> <p>1824/10</p> <p>1824/20</p> <p>1831/18</p> <p>1832/13</p> <p>name [21]</p> <p>1569/3 1569/4</p> <p>1570/4 1570/9</p> <p>1571/20</p> <p>1580/12</p> <p>1632/6 1632/7</p> <p>1634/8</p> <p>1634/13</p> <p>1635/7 1682/8</p>
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N	1574/15	1625/11
name... [9]	1574/22	1625/15
1693/6 1693/7	1575/1	1626/16
1694/9	1575/19	1636/12
1696/18	1576/8 1578/4	1640/15
1705/15	1593/25	1640/17
1739/8 1740/9	1594/3	1640/17
1740/15	1597/22	1641/24
1750/9	1607/8 1607/9	1642/6 1643/1
named [2]	1607/12	1643/3
1741/23	1607/18	1643/17
1741/24	1608/10	1644/12
namely [4]	1608/22	1646/1 1646/4
1644/24	1608/22	1647/17
1695/13	1608/24	1647/23
1703/1 1827/2	1609/8	1647/24
naming [1]	1609/19	1652/19
1742/14	1609/22	1655/3
NATALIE [1]	1609/24	1655/14
1564/8	1610/4 1610/9	1655/16
national [88]	1612/1 1616/6	1655/25
1573/3 1574/5	1617/24	1656/4 1656/6
1574/7	1620/21	1656/9
1574/10	1622/9 1625/7	1656/16

N	1778/12	1801/9
national... [28]	1778/22	nearly [2]
1656/19	1823/22	1689/2 1698/2
1656/24	national/regio	necessarily
1657/8	nal [1]	[6] 1609/1
1658/10	1775/13	1616/18
1659/6 1675/9	nationals [1]	1766/20
1676/21	1653/18	1766/25
1682/19	Naturally [1]	1770/2 1815/8
1686/14	1689/3	necessary [6]
1686/22	nature [13]	1567/23
1686/24	1567/4	1639/9
1687/5	1567/11	1639/10
1687/19	1574/2	1669/21
1688/12	1577/17	1680/22
1690/11	1617/17	1743/11
1704/9 1707/8	1624/12	necessity [4]
1707/15	1627/21	1593/2
1720/23	1640/2 1643/9	1593/12
1732/6 1737/2	1644/4	1593/16
1738/7	1685/25	1593/19
1743/20	1749/21	need [32]
1753/20	1793/5	1576/4
1775/13	near [1]	1580/21

N	1705/21	negotiating [2]
need... [30]	1725/5 1769/2	1697/12
1583/13	1808/24	1720/24
1589/24	1816/21	negotiation [3]
1592/10	1836/2	1599/9
1594/4	needed [3]	1747/8
1607/12	1611/24	1835/10
1608/21	1612/1 1685/5	negotiations
1609/7	needing [1]	[25] 1678/19
1609/20	1611/18	1679/16
1609/20	needs [16]	1695/6 1695/9
1609/21	1609/2 1616/4	1695/13
1610/2	1617/9 1619/5	1695/19
1610/11	1636/10	1696/11
1612/19	1641/12	1696/12
1620/21	1659/23	1696/24
1620/25	1660/1 1683/6	1697/24
1639/6 1639/7	1742/20	1698/17
1644/2 1659/5	1793/17	1699/12
1659/21	1814/15	1700/3
1660/8	1815/3	1700/20
1668/23	1822/17	1701/1
1683/3	1828/16	1702/11
1697/23	1831/7	1702/25

N	1637/13	1747/25
negotiations...	1637/13	1747/25
[8] 1706/16	1637/14	1748/1
1707/21	1637/18	1756/24
1726/17	1684/17	1757/23
1741/13	1690/21	1794/22
1759/18	1699/23	1796/2 1796/4
1763/17	1702/6	1802/24
1799/1 1801/3	1702/17	1815/7 1827/9
negotiators	1735/15	1828/20
[3] 1800/3	1823/8	1830/10
1800/4	Nevertheless	next [21]
1801/25	[1] 1709/4	1605/5 1607/4
neither [8]	new [24]	1657/23
1579/10	1579/20	1663/1
1624/1 1689/6	1581/6 1602/4	1683/10
1702/20	1602/11	1708/21
1704/25	1602/16	1734/19
1748/19	1635/24	1734/20
1762/13	1635/24	1753/18
1829/10	1647/9	1773/12
never [13]	1715/25	1773/14
1594/18	1741/19	1775/3 1781/7
1603/9	1742/17	1786/4

N	1592/11	1651/15
next... [7]	1592/19	1656/23
1789/15	1593/8 1594/9	1657/12
1796/23	1594/21	1658/19
1798/23	1600/8	1665/5 1670/9
1800/1	1600/21	1670/18
1806/18	1600/22	1670/19
1811/20	1601/13	1670/22
1812/2	1602/18	1672/1 1672/8
nice [1]	1604/7 1605/5	1672/25
1777/2	1605/5	1672/25
NIKHIL [1]	1605/19	1674/13
1564/8	1614/2 1618/9	1676/25
nine [1]	1619/2	1677/3
1635/10	1622/16	1677/17
no [174]	1622/21	1680/13
1562/6 1571/2	1624/22	1680/21
1571/2 1580/4	1626/13	1681/7 1686/8
1581/13	1631/4	1689/19
1581/24	1631/14	1691/10
1582/3	1631/18	1697/4
1582/11	1634/17	1697/20
1583/6	1643/17	1697/20
1589/12	1648/12	1697/23

N	1723/12	1758/25
no... [110]	1725/15	1760/6 1761/9
1699/21	1725/16	1767/4
1699/22	1728/9	1767/22
1700/15	1728/24	1768/1
1700/25	1728/25	1770/11
1701/7	1728/25	1770/22
1701/17	1729/1	1771/17
1701/17	1731/13	1772/3
1701/19	1735/17	1772/12
1702/16	1735/20	1772/17
1704/11	1735/22	1773/3 1776/5
1705/9 1706/7	1735/24	1776/18
1715/18	1738/1	1776/18
1716/19	1740/19	1778/14
1717/19	1742/3 1743/3	1781/10
1717/19	1745/8	1781/10
1719/5	1746/25	1784/7
1719/10	1747/1	1784/13
1719/17	1748/13	1786/3 1787/1
1719/19	1750/3	1787/5 1787/7
1719/22	1750/25	1788/4 1788/7
1720/1	1751/18	1789/19
1720/24	1754/23	1792/14

N	1823/25	1654/14
no..... [33]	1824/2	1697/11
1794/10	1829/12	1714/14
1794/16	1830/11	1743/8
1794/25	1831/12	1766/10
1795/4 1796/9	1831/24	1793/4
1796/16	1836/24	non-binding
1796/22	1837/8	[1] 1654/14
1797/1	No. [2]	non-complian
1797/22	1601/24	ce [1] 1714/14
1798/16	1610/22	non-controver
1800/12	No. 2 [2]	sial [1]
1802/18	1601/24	1573/21
1803/20	1610/22	non-obviousn
1803/20	nomenclature	ess [2] 1743/8
1805/20	[7] 1730/23	1766/10
1806/4 1806/5	1731/11	non-operative
1807/19	1731/16	[1] 1793/4
1809/1	1731/19	non-utility [1]
1811/23	1744/10	1697/11
1813/1 1814/2	1747/18	none [4]
1814/25	1779/24	1601/14
1815/14	non [7]	1623/5
1822/23	1573/21	1631/19

N	1822/12	1719/14
none... [1]	notably [1]	1744/14
1785/25	1742/11	1745/24
nonetheless	note [17]	1753/1
[2] 1676/19	1623/25	notes [17]
1717/25	1638/10	1575/8 1592/2
norm [2]	1641/22	1620/11
1617/12	1677/14	1644/14
1748/12	1677/19	1663/7 1663/8
normally [2]	1677/25	1663/18
1652/23	1717/20	1663/19
1653/21	1728/21	1663/20
norms [3]	1736/15	1663/22
1603/7	1754/21	1678/18
1832/19	1763/16	1711/3
1832/20	1768/6	1774/24
NORTH [1]	1773/12	1775/3 1775/6
1562/3	1799/18	1775/22
Northwestern	1803/2	1810/15
[1] 1635/18	1805/10	nothing [31]
not [415]	1835/9	1574/11
not with [1]	noted [6]	1574/16
1653/15	1705/4	1574/24
notable [1]	1706/22	1576/8

N nothing... [27] 1577/21 1577/22 1578/1 1617/7 1618/7 1620/2 1627/18 1628/2 1629/4 1651/10 1651/19 1666/5 1666/8 1671/13 1688/6 1704/13 1728/25 1738/17 1738/18 1747/24 1759/11 1770/25 1771/6 1800/13 1801/18 1812/16	1823/19 notice [6] 1625/16 1682/7 1728/2 1805/9 1817/4 1817/7 notices [2] 1625/13 1626/2 notification [3] 1624/15 1624/19 1625/19 notify [3] 1822/9 1822/11 1822/18 noting [2] 1728/25 1733/5 notion [5] 1681/2 1703/5 1712/20 1758/14	1826/24 notions [8] 1712/14 1724/14 1770/7 1782/5 1782/18 1810/5 1810/6 1834/17 novel [5] 1641/19 1654/19 1671/14 1671/20 1757/4 novelty [15] 1573/12 1639/1 1640/23 1641/4 1643/15 1646/6 1742/14 1742/20 1742/20
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N	1628/11	1745/7 1756/3
novelty... [6]	1631/21	1756/11
1756/20	1638/5	1760/5
1757/11	1644/21	1760/10
1757/22	1655/23	1766/4
1766/8 1807/6	1661/19	1769/20
1813/15	1682/4	1772/19
November [3]	1683/10	1785/7 1788/8
1711/5 1729/3	1687/23	1789/23
1729/4	1690/6	1793/22
now [63]	1692/20	1797/1
1568/4 1571/8	1697/1	1799/13
1571/10	1700/19	1800/9 1803/7
1581/2	1723/7	1807/13
1583/16	1723/21	1808/14
1591/1	1723/25	1813/19
1595/13	1726/6	1814/2 1817/9
1598/13	1726/17	1819/22
1602/25	1731/25	1829/4
1605/16	1738/21	1831/16
1612/13	1740/23	1837/3
1613/5	1741/11	nucleotide [1]
1613/12	1742/2	1629/17
1613/24	1742/17	number [18]

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1601/24	1665/17	1706/1 1708/8
1602/3	1665/25	1711/24
1603/18	1666/1	1712/25
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1578/12	1688/9	1618/21
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1578/23	1607/23	1696/24
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1709/6 1711/7	1766/3	1585/15
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1712/19	1773/23	1605/1
1712/23	1777/5	1612/15
1713/7	1779/12	1617/5
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R	1666/19	1753/9
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1645/10	1699/15	1776/10
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1656/16	1724/23	1793/2 1793/7
1656/17	1725/8 1725/9	1804/12
1656/22	1725/19	1804/23
1656/25	1726/9	1805/18
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1586/24	1663/22	1757/4
1587/2 1587/9	1667/10	1759/19
1588/16	1676/23	1760/7 1760/9
1588/24	1677/16	1760/14
1592/18	1678/8 1680/3	1761/8 1762/8
1593/6	1682/9	1765/16
1598/16	1688/19	1767/7
1598/16	1689/20	1769/24
1602/1	1707/2	1773/5
1602/13	1707/17	1775/24
1605/13	1710/14	1778/13
1607/19	1715/1	1780/7
1607/24	1716/10	1782/15
1608/11	1716/17	1782/22
1610/6 1610/7	1716/25	1790/1 1790/9
1611/23	1726/6	1790/18
1612/7	1728/19	1790/24
1630/13	1730/10	1791/10
1631/12	1731/25	1795/3

<p>R</p> <p>right..... [15] 1795/17 1797/20 1801/20 1803/10 1807/17 1807/22 1811/7 1811/19 1812/1 1817/3 1821/22 1829/25 1830/1 1836/21 1837/11</p> <p>right-hand [1] 1811/7</p> <p>rightfully [1] 1675/6</p> <p>rights [5] 1650/8 1699/1 1699/5 1756/8 1818/7</p>	<p>ripe [1] 1799/20</p> <p>risk [2] 1609/25 1828/2</p> <p>risks [2] 1579/19 1579/23</p> <p>road [1] 1664/21</p> <p>role [5] 1572/1 1572/10 1619/23 1628/22 1637/23</p> <p>room [1] 1718/1</p> <p>root [1] 1574/1</p> <p>rooted [1] 1609/5</p> <p>rounds [1] 1799/1</p>	<p>Roundtable [1] 1805/9</p> <p>routinely [1] 1600/25</p> <p>rule [38] 1577/7 1577/9 1577/13 1578/17 1581/14 1581/24 1582/4 1582/6 1582/11 1584/12 1589/24 1604/14 1604/15 1604/22 1609/23 1617/3 1618/11 1618/24 1623/22 1625/7 1625/10</p>
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<p>R</p> <p>rule... [17]</p> <p>1625/11</p> <p>1625/14</p> <p>1626/24</p> <p>1629/16</p> <p>1639/16</p> <p>1639/25</p> <p>1643/8 1664/1</p> <p>1664/3</p> <p>1666/16</p> <p>1674/4 1674/7</p> <p>1675/15</p> <p>1676/16</p> <p>1689/15</p> <p>1732/24</p> <p>1762/17</p> <p>Rule 11 [1]</p> <p>1666/16</p> <p>Rule 5 [1]</p> <p>1604/14</p> <p>rules [27]</p> <p>1562/4</p> <p>1570/23</p>	<p>1576/20</p> <p>1576/21</p> <p>1576/22</p> <p>1576/24</p> <p>1597/23</p> <p>1604/13</p> <p>1614/12</p> <p>1624/16</p> <p>1624/25</p> <p>1625/4 1629/8</p> <p>1629/13</p> <p>1629/20</p> <p>1629/22</p> <p>1637/9 1639/5</p> <p>1666/15</p> <p>1678/9</p> <p>1689/24</p> <p>1762/23</p> <p>1777/22</p> <p>1816/21</p> <p>1818/14</p> <p>1819/25</p> <p>1821/10</p> <p>ruling [1]</p>	<p>1598/6</p> <p>run [1]</p> <p>1637/18</p> <p>Ryan [1]</p> <p>1565/19</p> <p>S</p> <p>safeguard [1]</p> <p>1820/2</p> <p>said [72]</p> <p>1571/1 1571/2</p> <p>1578/3</p> <p>1581/23</p> <p>1582/19</p> <p>1590/11</p> <p>1596/18</p> <p>1597/21</p> <p>1602/22</p> <p>1603/16</p> <p>1606/3</p> <p>1616/12</p> <p>1617/4</p> <p>1618/18</p> <p>1618/20</p> <p>1618/23</p>
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1627/2	1719/3 1720/1	1833/12
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1659/3	1735/11	1567/18
1660/18	1735/15	1576/3
1661/2	1735/17	1588/18
1661/10	1754/4	1588/22
1661/22	1757/10	1592/14
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1671/6 1671/7	1777/19	1597/16
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1680/25	1806/22	1635/5
1683/14	1808/1 1813/5	1646/21
1687/10	1813/13	1649/4
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1707/20	1818/17	1659/2 1660/2
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1703/24	1793/13	1580/12
1707/9 1708/4	1804/1 1815/8	1601/3
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1743/8	1820/18	1581/3
1754/15	1825/5	1582/21
1757/18	1829/18	1582/24
1761/5	1834/18	1583/12
1763/10	1834/20	1584/5
1765/2 1765/6	same' [1]	1585/17
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1602/3	1710/21	1762/25
1605/16	1712/12	1764/7
1606/4	1718/25	1776/11
1611/13	1720/3 1720/7	1776/13
1612/19	1722/12	1778/10
1620/2 1635/7	1722/16	1782/4 1789/3
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1653/13	1730/5 1730/8	1794/18
1659/3 1667/3	1730/21	1795/10
1667/18	1732/23	1801/2 1801/3
1668/22	1733/17	1820/21
1669/8	1735/18	1821/9 1825/2
1673/10	1744/18	1826/17
1675/6 1676/1	1745/13	1826/20
1676/16	1746/25	1826/23
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1685/2 1688/1	1753/13	1828/8 1830/8
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1835/15	1732/15	1610/23
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1600/12	1748/13	1615/2
1616/1 1616/2	1763/6	1625/10
1617/22	1776/16	1629/16
1625/25	1789/14	1639/22
1626/11	1804/5 1814/7	1644/2
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1683/1	1821/19	1647/20
1683/13	1826/16	1656/23
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1684/14	says [86]	1664/5
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1689/18	1590/13	1677/22
1701/17	1592/24	1678/8
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1687/5	1831/13	1797/15
1688/11	them [30]	1802/18
1690/14	1568/9	1818/14
1697/13	1625/14	1820/19
1697/16	1638/20	1823/6
1697/18	1654/1	1823/12
1707/22	1657/12	1833/23
1708/1	1660/8	1833/23
1708/13	1665/18	theme [1]

T	1618/20	1682/10
theme... [1]	1619/8	1683/3
1623/20	1619/12	1683/13
themselves	1621/4	1684/4
[5] 1626/14	1621/21	1685/20
1647/3	1622/5	1687/25
1735/19	1625/15	1688/9
1779/23	1628/20	1689/17
1799/23	1628/22	1696/13
then [103]	1630/10	1696/20
1568/7 1570/6	1640/15	1699/11
1579/23	1643/16	1717/14
1584/15	1643/22	1718/17
1586/12	1653/2 1653/4	1719/18
1586/25	1653/21	1720/16
1590/13	1654/2 1655/2	1721/7
1594/7	1655/14	1722/22
1595/22	1659/20	1727/5
1604/25	1664/4	1727/15
1612/22	1664/20	1728/8 1729/4
1613/15	1674/3	1729/5
1617/3	1677/19	1732/23
1617/23	1680/23	1738/6
1618/4	1681/24	1741/13

T	1826/19	1576/21
then... [37]	1830/9	1591/23
1744/24	1830/10	1616/9 1618/3
1745/3	1830/11	1618/13
1746/21	1832/12	1618/17
1746/23	1833/15	1619/11
1757/18	1833/15	1619/12
1761/6	1835/7	1627/17
1762/24	1835/18	1628/2
1766/9 1769/2	1836/4	1628/18
1776/25	1837/13	1647/4
1778/6	THEODORE	1647/11
1784/24	[3] 1566/9	1655/8 1667/8
1793/10	1632/1 1632/7	1671/13
1794/18	Theoretically	1680/4 1684/4
1798/3 1801/1	[3] 1763/12	1691/8
1801/12	1804/15	1694/13
1801/24	1827/13	1694/16
1812/6 1818/9	theory [2]	1700/15
1820/8 1820/8	1613/18	1700/21
1820/12	1755/3	1701/17
1823/12	there [285]	1701/25
1823/16	there's [71]	1704/11
1826/5	1573/3	1704/13

T	1781/10	1749/18
there's... [43]	1781/10	1769/17
1712/9	1783/14	1777/17
1712/20	1783/22	1785/15
1717/19	1784/17	1794/7
1717/19	1794/10	1813/12
1720/20	1797/4	1814/19
1720/21	1800/24	1825/4
1720/24	1805/3 1813/8	these [73]
1726/21	1813/16	1579/24
1728/19	1814/8	1587/12
1732/15	1814/25	1600/25
1738/1 1748/9	1825/2	1604/12
1748/13	1825/24	1610/16
1751/7	1826/6	1611/8
1761/18	1829/12	1623/11
1761/18	1832/19	1624/12
1769/4	1835/18	1626/20
1769/25	1836/12	1629/5
1770/3	therefore [12]	1641/20
1770/25	1607/8	1648/6
1771/6	1682/16	1659/10
1771/17	1724/17	1660/13
1773/3	1748/22	1660/16

T	1745/20	1818/20
these... [58]	1746/9 1747/5	1828/21
1660/17	1747/10	1828/21
1661/3	1747/22	1830/13
1661/11	1748/2 1748/5	1832/10
1663/21	1759/3 1759/9	1834/12
1666/25	1759/15	1835/15
1673/20	1760/4	they [142]
1677/11	1760/19	1567/12
1678/18	1761/14	1571/2 1576/1
1679/11	1763/19	1576/2 1576/2
1680/8	1768/23	1576/11
1702/11	1769/7 1770/6	1586/24
1704/15	1775/6	1587/13
1716/24	1775/22	1587/19
1716/24	1779/25	1597/11
1725/23	1781/4 1784/8	1601/1 1601/1
1729/16	1785/25	1601/2
1730/9	1786/20	1608/21
1730/12	1792/16	1610/10
1742/1	1806/25	1616/14
1742/23	1808/20	1616/14
1742/25	1810/14	1618/25
1745/18	1814/8	1620/25

T	1662/2 1663/7	1692/7
they... [123]	1665/5	1697/13
1621/2	1665/10	1697/17
1621/23	1666/1	1702/1
1625/15	1666/11	1703/24
1625/16	1669/25	1707/21
1625/23	1670/19	1710/23
1626/15	1672/14	1722/4
1626/16	1673/24	1724/16
1643/6	1677/4	1725/7 1730/7
1644/16	1679/23	1730/7
1645/16	1679/25	1730/18
1646/2 1650/9	1684/6	1731/11
1650/10	1685/21	1742/20
1653/8 1653/9	1686/11	1745/15
1653/13	1686/14	1745/19
1653/15	1686/14	1747/9
1653/15	1687/6	1747/10
1654/17	1687/16	1747/23
1655/14	1687/17	1748/21
1655/17	1688/16	1757/3 1759/5
1657/18	1689/25	1759/9
1659/22	1690/13	1761/11
1660/18	1690/14	1763/2 1763/3

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they..... [47]	1804/24	they're [21]
1766/22	1804/25	1608/9 1639/8
1767/6	1806/9	1639/9
1767/16	1808/18	1649/19
1769/1 1770/8	1817/15	1659/16
1771/15	1819/15	1666/14
1776/19	1819/24	1702/1 1731/9
1778/5	1819/25	1747/12
1778/21	1820/1	1759/4
1779/11	1823/12	1761/15
1779/23	1825/8	1768/20
1784/24	1826/19	1776/14
1792/1 1792/2	1829/25	1776/19
1794/18	1829/25	1776/20
1798/13	1830/10	1776/21
1801/3	1830/11	1779/10
1801/12	1831/19	1799/10
1801/14	1832/14	1810/5
1802/5	1834/10	1825/19
1802/15	1835/8	1835/12
1802/15	1835/12	they've [2]
1802/17	1835/12	1706/23
1802/18	they'll [1]	1738/6

T	1618/13	1601/9
thing [20]	1635/1 1635/3	1603/13
1570/21	1639/19	1606/4
1608/17	1646/20	1606/18
1616/19	1650/20	1608/25
1616/20	1651/1	1609/6 1609/8
1619/11	1659/25	1609/17
1633/16	1671/7	1612/17
1642/21	1695/25	1615/23
1644/17	1699/14	1617/4 1621/1
1651/5 1659/3	1709/11	1621/2 1628/5
1697/6	1714/11	1628/11
1707/24	1722/4	1632/15
1713/24	1725/24	1633/1 1633/2
1728/15	1738/8	1633/17
1777/23	1754/24	1640/4
1779/20	1825/7	1647/18
1779/23	1830/13	1649/14
1825/5	1833/2	1650/6
1826/25	think [125]	1654/24
1829/25	1580/23	1655/8 1660/3
things [23]	1581/1 1584/8	1664/16
1575/7 1585/5	1587/25	1676/15
1605/22	1593/11	1676/23

T	1716/11	1748/23
think... [91]	1716/12	1748/24
1677/1 1678/4	1716/14	1749/6
1678/24	1716/15	1756/11
1683/7 1683/8	1717/5 1717/8	1756/16
1689/16	1720/20	1759/7
1691/7	1722/15	1761/23
1698/20	1722/20	1774/12
1703/22	1725/25	1776/25
1704/8	1728/6	1777/23
1704/10	1728/12	1779/20
1705/4	1729/21	1780/1 1780/4
1705/20	1731/19	1789/23
1705/24	1732/10	1790/24
1707/11	1733/15	1791/9
1707/19	1734/19	1791/20
1707/25	1735/7	1802/1 1802/5
1709/16	1735/17	1802/10
1712/15	1736/12	1802/11
1712/24	1737/23	1802/15
1713/20	1744/2	1803/16
1715/2	1744/23	1804/17
1715/20	1745/9	1816/20
1716/7	1748/10	1817/18

T	1709/3 1742/9	1730/20
think..... [16]	1765/23	1731/12
1818/20	1775/11	1738/16
1819/22	1778/7	1738/20
1820/1	1778/10	1745/7
1820/24	1778/19	1763/16
1823/10	thirds [1]	1764/2
1823/13	1584/5	Thomas' [1]
1825/1 1825/3	this [401]	1745/22
1825/8 1831/4	THOMAS [24]	Thomas.....
1831/5	1564/101695 [1]
1831/15	1564/21	1566/15
1832/6	1566/14	those [83]
1834/10	1693/1 1693/3	1568/15
1834/22	1693/8 1693/9	1575/15
1836/22	1693/18	1575/20
thinking [3]	1694/1	1577/5
1568/2	1694/22	1585/14
1801/15	1694/25	1590/22
1823/13	1695/2 1703/8	1590/24
third [11]	1705/8	1594/5 1611/5
1599/2	1705/15	1618/25
1694/16	1727/23	1620/2 1621/4
1707/3 1708/8	1729/3	1625/8

T	1674/14	1767/16
those... [70]	1674/17	1768/13
1625/12	1675/7	1775/3 1776/6
1625/19	1680/18	1776/6
1626/18	1681/11	1778/10
1628/21	1682/1	1779/17
1629/21	1689/23	1784/12
1629/21	1691/1	1791/14
1639/4	1691/24	1791/16
1639/24	1695/13	1799/1 1799/7
1643/5	1696/8	1802/1 1802/6
1643/19	1696/15	1802/14
1645/23	1696/23	1806/16
1646/19	1698/8	1810/2
1655/16	1698/16	1823/24
1657/2	1700/22	1824/21
1657/17	1701/24	1829/8 1834/4
1661/6	1702/6	1834/17
1661/14	1706/21	1835/7
1662/1	1714/11	though [7]
1662/23	1738/10	1601/5 1629/1
1665/21	1741/11	1729/3
1670/16	1748/20	1730/10
1673/23	1764/4 1765/5	1733/5

T	1668/23	1802/17
though... [2]	1671/10	1810/14
1745/13	1672/20	1814/8
1826/25	1677/13	1834/13
thought [11]	1677/17	1835/6
1671/8 1728/1	1677/20	1835/14
1749/2	1681/12	1835/15
1769/18	1709/10	1837/12
1771/19	1711/23	three-pronged
1772/5 1773/4	1741/17	[4] 1668/5
1776/3	1741/21	1668/23
1777/12	1742/13	1671/10
1809/25	1742/15	1672/20
1811/24	1746/17	threshold [1]
threaten [1]	1749/9	1828/23
1579/12	1757/12	through [17]
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1567/23	1766/6	1613/14
1646/20	1775/10	1616/15
1646/21	1778/3	1616/15
1659/24	1778/15	1624/10
1665/17	1779/2 1779/4	1638/23
1665/21	1780/10	1639/4 1639/5
1668/5	1800/21	1641/8 1650/1

T	1587/24	1748/19
through... [6]	1625/5	1749/7
1673/11	1625/14	1749/20
1742/1	1627/14	1752/11
1769/20	1627/24	1758/8
1791/19	1634/17	1763/10
1822/23	1635/9 1636/9	1776/3
1826/22	1636/17	1777/14
throughout [2]	1636/20	1802/7 1808/5
1608/24	1638/3 1648/4	1810/14
1645/11	1655/7	1812/18
thus [3]	1658/20	1819/9
1607/13	1669/13	1820/17
1614/1	1684/19	1829/18
1754/12	1685/8 1691/7	1834/2
tickets [1]	1702/3 1702/4	times [4]
1587/18	1702/11	1582/19
ties [1] 1568/6	1710/10	1745/25
time [50]	1710/18	1749/2 1816/5
1570/22	1710/24	TINA [1]
1570/24	1731/16	1564/10
1572/9 1576/3	1733/11	tiny [3] 1663/7
1582/5	1742/1	1663/21
1582/12	1747/22	1679/11

T	1719/4	1738/7
title [6]	1757/14	tomorrow [1]
1604/24	1823/13	1757/15
1636/19	1837/10	too [7] 1596/3
1650/7 1658/5	today's [3]	1691/8
1658/14	1642/10	1724/23
1816/9	1647/8	1730/13
titled [2]	1647/10	1761/20
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today [18]	1570/23	1833/19
1580/14	1578/3	took [12]
1580/19	1628/11	1623/23
1582/19	1628/16	1636/7
1593/6	1637/14	1639/16
1597/18	1637/14	1639/25
1602/22	1716/24	1677/23
1603/14	1803/18	1689/8 1695/6
1635/8	token [1]	1695/20
1642/18	1761/5	1696/14
1656/22	told [6]	1698/7
1680/1	1609/15	1702/11
1705/20	1633/18	1717/20
1706/6	1717/1 1718/5	tools [1]
1714/17	1734/21	1834/13

T	1695/8	transitioning
top [10]	totally [2]	[1] 1611/16
1587/24	1686/24	transparency
1588/6	1755/1	[1] 1822/7
1606/14	towards [1]	treat [11]
1663/2	1791/13	1671/3 1671/7
1663/22	Tower [1]	1771/20
1679/12	1563/6	1772/6 1784/9
1692/3	trade [10]	1784/25
1774/10	1562/3	1786/22
1800/19	1565/10	1796/18
1811/8	1565/11	1797/23
topic [5]	1624/10	1797/24
1603/14	1624/11	1798/6
1760/1	1691/23	treated [8]
1763/10	1758/15	1672/6
1798/23	1819/14	1672/11
1809/7	1819/24	1672/24
topics [4]	1825/14	1771/21
1623/11	training [1]	1772/8
1742/25	1645/11	1772/16
1808/10	transcript [1]	1784/10
1809/2	1619/19	1786/23
total [1]	transcripts [1]	treaties [6]
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treaties... [6]	1583/5	1699/24
1600/20	1597/14	1702/16
1748/23	1597/22	1742/3 1759/5
1759/9 1819/8	1598/21	1759/11
1820/16	1598/24	1759/19
1831/21	1599/8 1601/5	1825/2 1825/8
treating [1]	1601/14	1825/13
1786/11	1603/5 1603/6	1831/7
treatise [1]	1603/12	1832/16
1754/6	1604/14	trees [1]
treatment [2]	1636/14	1649/18
1707/22	1638/9	trial [5]
1708/2	1642/14	1585/2
treats [1]	1655/21	1595/21
1796/18	1657/2	1613/11
treaty [48]	1660/15	1614/19
1571/22	1660/20	1636/3
1572/11	1663/14	tribunal [30]
1572/22	1677/7 1678/9	1563/3 1567/6
1572/24	1678/20	1567/14
1572/25	1696/14	1567/21
1574/16	1696/23	1568/2
1575/16	1698/6 1698/7	1569/12

T	1826/11	1749/8
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1569/19	1744/15	1753/2 1753/6
1593/6	1816/17	1753/12
1597/17	1817/3	1753/22
1598/14	tried [6]	1754/1
1602/11	1741/18	1754/12
1623/8	1748/6	1755/3
1632/13	1764/20	1755/13
1632/21	1778/2	1755/14
1633/6 1633/7	1802/17	1755/16
1633/14	1831/14	1758/19
1633/22	Trilateral [1]	1817/19
1693/15	1801/9	1817/24
1693/20	TRIPS [37]	1818/3
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1695/4	1741/12	1822/2 1822/8
1736/15	1741/14	1822/10
1739/16	1741/23	1822/21
1739/22	1742/4 1747/4	1823/21
1739/25	1747/6	1825/23
1741/3	1747/15	1832/12
1817/13	1748/19	1832/13

T	1705/19	1810/4 1810/8
TRIPS... [2]	1777/24	1812/2 1812/4
1835/22	1799/4 1822/5	1820/1
1835/25	1825/11	1826/20
TRIPS's [1]	1826/21	1828/13
1755/8	1827/17	turn [47]
trouble [2]	1829/25	1581/2
1777/16	1829/25	1583/18
1804/22	1832/7	1583/24
true [6]	1834/19	1585/9
1629/7	1834/21	1587/22
1658/23	trying [19]	1591/1
1706/10	1581/23	1591/25
1792/3 1813/6	1659/24	1596/15
1820/25	1661/14	1597/5 1597/6
truly [1]	1688/2	1598/18
1642/5	1727/22	1600/24
try [18]	1761/23	1601/18
1606/11	1761/25	1604/11
1610/3	1762/4	1604/14
1623/18	1762/17	1606/13
1624/5	1762/22	1608/14
1656/15	1776/9	1610/15
1685/8	1776/11	1610/20

T	1752/17	1640/8
turn... [28]	1752/22	1640/10
1612/25	1754/7	1688/16
1613/12	1759/21	1688/17
1613/24	1775/4	1691/6 1691/6
1614/23	1806/19	1695/8
1614/25	turns [2]	1696/10
1615/9	1679/14	1698/20
1655/20	1723/7	1712/14
1658/24	two [67]	1727/2 1728/7
1662/1	1573/2	1729/13
1667/16	1576/24	1729/13
1674/10	1584/5 1587/7	1729/16
1691/19	1590/21	1730/1 1730/1
1705/25	1590/22	1734/19
1708/7	1590/24	1741/18
1709/18	1599/6	1743/19
1715/22	1615/23	1745/11
1721/8	1618/12	1746/13
1724/12	1618/25	1757/17
1731/24	1620/10	1758/2
1732/18	1620/11	1761/10
1736/17	1630/4	1762/23
1750/10	1630/21	1765/5

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1770/7	1730/1	
1776/16	type [6]	U.S [11]
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1777/13	1637/10	1646/20
1780/5 1781/5	1659/3 1670/1	1688/21
1782/22	1763/4 1763/5	1690/1
1788/12	types [6]	1690/24
1791/16	1629/5 1660/2	1742/18
1792/19	1747/25	1743/16
1793/2	1779/17	1744/4
1795/25	1808/2	1744/17
1809/15	1811/16	1749/15
1810/5	typically [8]	1819/4
1815/17	1658/11	Uh [2] 1656/1
1817/12	1658/22	1812/13
1819/8	1658/23	Uh-huh [2]
1820/16	1775/25	1656/1
1821/13	1779/11	1812/13
1825/18	1804/19	UK [2]
1825/19	1808/1	1683/25
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1783/23	1600/15	1647/16
1784/1	1601/6	1648/7 1648/8
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1699/8	1604/13	1655/4 1659/2
UNCITRAL [1]	1604/22	1674/4
1562/4	1624/2	1683/18
unclear [6]	1624/15	1687/5
1569/10	1625/25	1687/13
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1709/20	1737/9	1785/3
1709/23	1737/10	1785/25
1710/1 1710/6	1737/12	1787/25
1710/9	1743/2	1788/2
1710/23	1743/10	1793/22
1712/17	1746/13	1793/24
1713/6	1747/10	1794/11
1713/20	1747/19	1795/25
1714/13	1748/18	1798/13
1716/24	1749/10	1800/9
1716/24	1751/16	1801/14
1719/17	1761/12	1803/17
1719/19	1761/24	1804/10
1720/6 1721/3	1762/13	1804/13
1721/9 1722/5	1768/8 1768/8	1804/18
1723/5	1773/13	1804/21
1723/24	1773/20	1806/6

W	1583/13	1607/18
were..... [8]	1583/15	1608/25
1806/12	1584/9	1609/15
1812/19	1584/14	1610/1 1610/8
1814/18	1587/17	1611/13
1819/25	1588/11	1612/5 1612/7
1820/1 1821/9	1589/15	1612/17
1828/3	1590/11	1614/16
1830/19	1593/9	1617/22
weren't [1]	1593/20	1618/19
1678/15	1594/16	1619/11
what [229]	1595/7	1619/18
1567/16	1595/16	1620/2
1570/25	1597/2	1620/22
1575/12	1598/10	1621/2
1576/11	1598/12	1621/23
1577/13	1599/24	1621/24
1578/3 1578/6	1600/11	1622/1 1624/4
1578/7	1603/4	1624/14
1578/10	1603/10	1624/19
1578/11	1603/11	1624/20
1578/25	1604/7	1625/8
1581/23	1605/18	1626/19
1582/6	1606/9	1627/2

W	1656/3 1656/6	1684/14
what... [165]	1657/6 1657/7	1685/5
1627/21	1658/13	1685/16
1629/1	1660/1 1661/4	1688/3
1637/11	1661/12	1689/12
1638/8	1662/6	1690/4
1639/19	1662/14	1690/16
1639/20	1664/13	1690/22
1639/21	1665/10	1690/22
1639/22	1665/14	1696/13
1641/9	1666/15	1697/12
1641/12	1667/18	1698/18
1642/1	1670/3	1698/24
1642/17	1670/23	1700/1 1701/5
1644/1	1673/10	1704/12
1644/13	1677/4	1705/17
1644/16	1678/22	1707/20
1645/2	1679/2	1713/20
1646/24	1682/25	1714/5
1647/15	1683/6	1714/10
1650/18	1683/12	1716/3
1652/13	1683/13	1716/14
1652/20	1683/25	1717/10
1653/7 1656/3	1684/11	1717/14

W	1744/21	1798/8
what..... [90]	1745/11	1798/12
1717/17	1748/8 1749/2	1798/14
1718/4	1751/10	1801/2
1718/10	1754/4	1801/14
1718/11	1754/20	1801/16
1720/24	1759/4 1759/4	1802/16
1721/9	1759/5	1803/12
1722/24	1762/22	1806/9
1725/11	1764/9	1812/14
1725/11	1764/19	1813/5 1813/8
1725/12	1765/8 1765/9	1813/8
1727/13	1767/18	1813/19
1727/22	1769/20	1814/7 1818/2
1728/4	1770/15	1818/13
1728/16	1772/2	1820/1 1820/5
1732/15	1773/14	1821/5
1733/11	1776/24	1821/11
1734/14	1777/4	1821/19
1734/21	1778/24	1823/18
1735/2	1785/3	1823/19
1735/19	1789/14	1825/10
1741/11	1793/20	1825/13
1744/1	1794/7 1798/4	1826/20

W	1807/24	1640/25
what..... [13]	1813/10	1646/17
1828/11	1813/21	1647/10
1828/17	1822/10	1647/25
1829/8	when [76]	1653/20
1829/11	1567/10	1654/7 1655/1
1830/7	1570/22	1656/12
1830/18	1576/21	1656/18
1830/22	1577/16	1662/15
1831/5	1585/17	1664/13
1831/14	1586/8	1667/8
1832/10	1590/11	1668/24
1832/20	1607/11	1669/9
1833/12	1608/9	1670/11
1836/15	1610/10	1671/4 1684/6
what's [4]	1615/12	1685/21
1610/21	1615/13	1686/11
1659/22	1617/10	1700/13
1671/5	1625/4	1701/14
1770/18	1626/16	1702/11
whatever [7]	1627/11	1705/25
1652/1	1629/9 1635/5	1707/20
1691/15	1636/17	1708/9
1802/20	1639/12	1709/23

W	1826/20	1650/24
when... [30]	1826/21	1665/17
1710/3 1727/2	1827/1 1827/3	1671/8
1727/5	whenever [1]	1673/25
1727/25	1726/24	1699/16
1728/16	where [55]	1707/4
1728/17	1576/1 1587/3	1724/12
1728/21	1588/2 1594/3	1727/11
1736/8 1743/7	1609/12	1734/2
1748/5	1609/14	1750/15
1749/21	1611/15	1754/10
1753/13	1616/12	1758/20
1757/1	1618/3	1758/24
1757/17	1618/17	1759/12
1761/18	1619/5 1621/7	1759/25
1764/7 1778/3	1621/12	1761/7 1770/8
1778/10	1621/20	1773/22
1786/1	1622/24	1785/13
1798/13	1626/20	1785/14
1804/6 1818/5	1628/10	1787/10
1819/11	1640/16	1791/23
1825/8	1641/2	1792/6
1825/11	1646/11	1792/16
1826/3	1646/25	1792/17

W	1625/18	1757/24
where... [9]	1641/18	1762/17
1804/17	1642/5	1764/16
1806/22	1642/25	1769/4
1812/11	1651/16	1780/21
1819/8	1651/25	1784/20
1820/16	1654/15	1786/7
1826/23	1654/19	1786/19
1828/14	1664/6	1789/10
1836/7	1664/20	1792/11
1836/10	1665/3	1792/12
whereby [1]	1665/11	1816/22
1775/18	1666/12	1820/21
wherever [1]	1668/3	1822/7
1578/5	1668/18	1822/10
whether [54]	1670/4 1675/7	1822/17
1567/22	1684/15	1822/19
1619/9	1686/24	1829/15
1619/16	1688/5	1830/17
1619/24	1710/22	which [249]
1621/22	1713/8	1569/20
1622/2 1622/4	1742/20	1570/1 1570/7
1624/5	1752/5 1755/7	1571/9 1572/6
1624/16	1757/3	1572/19

W	1606/17	1625/4 1627/1
which... [243]	1608/15	1627/4
1573/13	1610/2	1627/19
1574/3 1574/8	1612/12	1627/21
1575/4	1613/1 1613/5	1627/22
1575/15	1613/18	1627/24
1575/17	1613/25	1633/8 1634/3
1576/12	1614/24	1640/11
1577/6 1577/7	1615/23	1640/13
1577/18	1616/3	1643/13
1577/19	1616/10	1643/17
1577/21	1616/25	1645/7
1579/13	1616/25	1645/24
1579/21	1618/11	1645/25
1585/5	1618/24	1649/16
1586/25	1619/6 1619/8	1650/8 1651/2
1591/18	1619/13	1652/10
1592/15	1619/19	1653/14
1593/14	1620/16	1655/17
1601/20	1620/22	1657/2
1603/19	1622/8	1659/20
1603/21	1623/16	1663/3
1604/13	1624/7	1663/23
1604/15	1624/10	1664/7 1665/9

W	1696/11	1713/11
which.....	1696/14	1715/10
[165] 1666/16	1696/18	1716/13
1672/20	1697/5	1717/9 1719/9
1673/6	1697/16	1720/7 1720/8
1674/11	1697/18	1724/12
1677/10	1698/8	1726/6
1679/8	1698/11	1726/21
1680/16	1698/21	1726/25
1681/12	1698/25	1728/7
1682/18	1699/4	1728/20
1685/14	1699/11	1728/22
1689/1 1689/1	1700/2	1730/5
1689/4	1701/23	1732/22
1689/19	1701/25	1734/4 1738/1
1689/23	1702/4	1738/14
1690/1	1703/13	1739/25
1690/24	1704/2	1741/14
1693/22	1704/13	1742/17
1694/14	1705/24	1742/21
1695/6	1707/5 1710/7	1744/25
1695/12	1712/17	1746/4 1746/5
1695/19	1712/25	1746/6 1747/5
1695/21	1713/3	1748/10

W	1770/24	1793/15
which.....	1771/1 1771/1	1794/17
[88] 1749/3	1771/9	1795/22
1749/13	1771/20	1796/1
1752/18	1772/5	1796/24
1752/22	1774/17	1797/6
1753/1	1777/7 1778/5	1799/14
1753/19	1778/12	1800/14
1754/6	1779/8	1802/12
1754/12	1780/18	1805/2 1805/3
1755/18	1781/8	1808/9
1755/24	1781/23	1812/22
1758/18	1786/5 1786/5	1813/23
1762/15	1787/3	1814/6
1764/2	1787/23	1814/21
1764/25	1787/25	1818/6
1765/20	1788/9	1818/20
1766/14	1789/21	1819/12
1767/23	1791/13	1819/13
1768/24	1791/15	1820/12
1769/7 1769/8	1791/16	1820/12
1769/23	1792/3 1793/4	1822/8
1770/10	1793/11	1822/24
1770/12	1793/14	1823/1

W	white [1]	1754/19
which.....	1630/8	1761/14
[12] 1823/21	who [14]	1762/24
1825/14	1587/3	1763/11
1825/20	1626/15	1772/21
1826/7	1652/14	1783/25
1826/15	1684/5 1698/1	1828/18
1827/10	1699/1 1730/5	1832/19
1829/23	1733/24	1835/19
1831/7	1757/20	whose [1]
1831/14	1762/11	1698/4
1833/18	1777/25	why [24]
1835/19	1779/13	1691/24
1835/25	1810/12	1723/15
while [7]	1816/14	1727/23
1649/1	whole [18]	1728/14
1661/21	1598/20	1758/5 1759/5
1662/10	1598/21	1761/14
1684/9	1614/4	1763/1 1763/5
1746/18	1637/15	1794/5
1789/6	1657/21	1800/14
1808/24	1719/15	1801/2
Whip [1]	1724/23	1801/19
1744/5	1725/9 1735/8	1804/2

W	1569/16	1633/10
why... [10]	1569/23	1633/12
1804/24	1571/13	1638/16
1806/5	1576/7 1576/8	1638/22
1806/11	1578/1 1578/1	1640/19
1808/5 1819/6	1578/20	1640/20
1824/16	1580/7	1640/21
1828/10	1581/15	1641/1 1641/3
1830/16	1581/25	1641/14
1831/8 1832/3	1588/9	1642/24
wide [5]	1588/10	1643/14
1636/20	1588/11	1645/19
1711/18	1592/8 1610/4	1646/12
1712/9 1712/9	1611/2	1648/16
1802/13	1617/19	1652/14
widely [5]	1618/12	1652/18
1572/25	1618/16	1653/9 1654/7
1676/24	1618/25	1654/14
1765/23	1619/14	1654/18
1766/6	1625/7	1654/18
1766/12	1625/14	1655/6
will [98]	1628/16	1657/13
1568/9	1632/13	1658/8
1569/12	1633/4	1663/11

W	1747/24	1570/24
will... [43]	1748/25	1571/1 1571/1
1663/23	1749/19	1571/3 1571/4
1685/10	1759/14	1571/11
1688/15	1765/18	1572/9
1688/16	1781/3 1812/1	1572/11
1688/17	1813/10	1607/16
1691/16	1813/21	1608/8 1610/8
1693/15	1815/7	1623/14
1693/18	1816/21	1635/12
1693/24	1817/9 1822/5	1636/22
1694/21	1826/15	1637/6 1637/9
1705/11	1828/1	1637/15
1716/3 1716/4	1828/17	1637/22
1734/25	1828/18	1639/21
1735/1 1735/2	1837/9	1641/15
1736/15	WILLARD [1]	1645/11
1739/16	1564/9	1645/13
1739/21	WILMER [1]	1645/14
1740/4 1741/5	1563/12	1646/10
1742/10	wilmerhale.co	1653/11
1744/6	m [1] 1563/13	1694/18
1745/10	WIPO [76]	1695/7
1745/19	1570/19	1696/21

W	1753/19	wish [8]
WIPO... [47]	1754/17	1570/14
1696/22	1759/17	1634/16
1698/2 1698/3	1760/4	1694/12
1698/8	1760/11	1724/21
1699/12	1761/3 1764/2	1725/21
1699/13	1764/23	1725/23
1701/9	1775/23	1730/6
1701/12	1776/21	1740/18
1702/25	1799/1 1799/7	wishes [2]
1706/3 1706/8	1799/8 1800/4	1574/20
1709/5	1809/20	1652/14
1709/23	1810/12	withdraw [1]
1721/10	1822/23	1625/16
1726/7	1822/24	within [24]
1726/10	1823/1	1599/20
1726/12	1823/20	1624/6
1729/5 1732/5	1824/1	1624/21
1733/21	WIPO-WTO [1]	1624/23
1738/6	1822/23	1625/20
1741/10	WIPO/WTO [1]	1629/20
1745/5 1747/1	1824/1	1652/25
1747/19	wise [1]	1653/4 1655/4
1753/1	1820/19	1696/21

W	1753/10	wondered [1]
within... [14]	1770/2	1809/15
1696/21	1787/16	wondering [1]
1699/13	1800/18	1691/24
1701/15	1818/16	word [22]
1729/13	witness [9]	1704/5
1730/1	1571/25	1707/24
1753/21	1591/20	1712/12
1760/15	1631/22	1715/4
1760/17	1661/18	1716/15
1776/22	1692/21	1725/22
1788/19	1693/10	1728/5
1798/5	1738/22	1728/12
1798/14	1739/11	1731/16
1810/6	1837/4	1731/18
1824/21	witnesses [2]	1731/20
without [13]	1837/8	1732/11
1644/23	1837/13	1744/11
1671/11	won't [3]	1777/1 1777/2
1671/19	1578/21	1777/19
1681/3 1699/9	1610/4 1816/7	1810/3
1703/16	wonder [2]	1826/17
1724/23	1571/7	1826/19
1748/14	1684/13	1830/25

W	1779/25	workable [1]
word... [2]	1790/16	1574/3
1835/10	1792/16	worked [6]
1836/19	1806/8	1637/2
wording [7]	1819/20	1637/13
1697/20	1825/11	1697/18
1697/23	1825/12	1698/1 1789/6
1702/4 1714/6	1826/12	1789/11
1714/6 1714/7	1832/10	working [4]
1731/21	1833/22	1628/20
words [26]	1833/22	1635/23
1644/22	work [13]	1641/17
1645/7	1588/9	1649/24
1657/17	1642/10	works [4]
1661/6	1727/5	1637/7
1661/15	1727/24	1638/10
1682/25	1734/25	1820/24
1715/8	1741/10	1823/1
1736/10	1767/3	workshops [1]
1743/19	1788/20	1637/9
1743/23	1789/1 1789/3	world [15]
1758/3 1758/4	1789/4	1608/25
1776/6 1776/7	1789/13	1624/10
1779/23	1830/13	1625/13

W	1593/13	1617/13
world... [12]	1593/18	1620/23
1636/18	1593/20	1621/2 1622/1
1642/10	1594/8 1594/9	1622/6
1647/8	1594/11	1622/11
1647/10	1594/19	1622/14
1652/15	1595/19	1622/16
1695/6	1595/25	1622/17
1708/16	1596/2 1596/7	1622/20
1711/15	1596/9 1597/6	1622/25
1713/19	1598/4 1598/9	1624/8
1741/25	1598/13	1624/16
1743/10	1598/17	1624/20
1771/4	1598/18	1624/20
worth [1]	1601/22	1625/22
1816/13	1603/25	1625/24
would [241]	1605/22	1625/24
1567/15	1606/2	1626/4 1626/6
1567/23	1606/19	1626/10
1569/2	1611/9	1626/14
1574/18	1611/10	1627/5
1576/2 1576/2	1614/18	1627/21
1582/23	1615/19	1628/23
1585/6	1616/10	1629/18

W	1686/10	1717/23
would... [179]	1686/14	1717/25
1629/19	1686/18	1718/3
1630/11	1686/19	1718/11
1636/23	1687/7 1689/7	1718/12
1637/18	1689/14	1718/17
1637/23	1689/16	1718/24
1641/9 1649/7	1690/12	1720/3 1720/3
1651/12	1690/17	1725/3
1652/20	1691/7	1725/13
1652/22	1691/11	1726/23
1653/8	1697/16	1726/25
1653/13	1699/5	1727/23
1654/21	1699/22	1728/5
1675/21	1703/19	1729/10
1676/2 1677/2	1704/7	1729/11
1677/4	1704/13	1729/22
1680/21	1705/6 1706/5	1730/6
1680/22	1706/6 1710/7	1733/11
1683/18	1712/5 1712/5	1733/18
1683/20	1712/15	1733/20
1683/22	1714/1 1715/3	1733/22
1685/1 1685/5	1716/13	1733/24
1685/20	1717/13	1735/2 1737/7

W	1763/8	1788/17
would..... [99]	1764/12	1791/20
1737/14	1765/4	1792/15
1738/2 1742/4	1766/11	1792/17
1743/10	1766/14	1793/5 1794/3
1744/14	1767/23	1797/2
1744/18	1770/17	1798/18
1745/3 1746/9	1771/3 1771/9	1800/4 1801/7
1748/14	1772/17	1807/19
1749/20	1775/18	1808/16
1749/22	1776/1	1813/14
1750/12	1777/11	1814/17
1752/12	1777/13	1814/19
1753/17	1777/21	1815/19
1753/25	1778/1	1816/12
1755/7	1778/18	1820/19
1755/12	1779/11	1820/22
1755/16	1779/23	1820/23
1757/25	1780/20	1821/8
1758/12	1782/20	1821/18
1758/13	1783/16	1821/20
1759/7 1761/6	1785/1	1823/5
1761/7 1762/8	1786/13	1823/11
1762/12	1786/18	1823/12

W	1725/22	1616/15
would.....	1728/2	1641/1
[22] 1823/14	1762/14	1641/14
1823/16	1828/8	1642/11
1823/23	1830/17	1654/18
1825/25	write [9]	1654/23
1826/25	1588/6	1660/19
1827/10	1612/22	1688/22
1827/11	1643/10	1749/16
1827/11	1670/14	1822/1
1827/19	1750/15	1822/15
1828/7 1828/8	1754/10	1834/16
1828/10	1754/22	wrong [5]
1828/12	1763/15	1598/20
1828/25	1800/7	1602/21
1829/2 1829/6	writes [3]	1791/7
1829/7 1829/8	1612/7	1791/21
1830/4	1613/17	1792/4
1831/25	1823/10	wrote [4]
1832/8	writing [3]	1583/21
1834/10	1584/1	1583/22
wouldn't [7]	1589/22	1610/24
1675/17	1663/7	1611/1
1719/24	written [12]	WTO [15]

W	1811/15	1585/21
WTO... [15]	year [2]	1586/3
1652/17	1592/17	1586/11
1741/11	1730/1	1586/21
1753/19	years [10]	1587/19
1758/18	1623/13	1588/4
1758/19	1635/10	1588/14
1810/11	1637/22	1588/21
1819/23	1698/2	1588/25
1821/1	1701/23	1590/24
1822/23	1727/2	1591/11
1823/21	1729/13	1591/23
1824/1	1757/7	1592/6
1825/20	1757/13	1592/13
1826/11	1757/17	1592/19
1828/7 1828/9	yes [235]	1593/4
	1567/19	1594/20
Y	1567/25	1595/5 1595/9
Yeah [7]	1569/8 1570/5	1596/21
1665/22	1570/11	1597/10
1678/7 1710/4	1581/11	1597/15
1768/20	1584/13	1597/19
1774/19	1584/24	1599/4 1600/3
1794/1	1585/16	1603/23

Y	1649/13	1676/22
yes... [200]	1651/6	1677/9
1604/21	1652/21	1678/14
1606/17	1653/1 1653/8	1680/2
1607/3	1653/13	1688/11
1607/15	1654/5 1654/9	1693/11
1608/3	1654/12	1694/3 1694/6
1608/12	1655/18	1694/10
1610/13	1656/5 1657/9	1694/13
1613/22	1659/19	1700/9
1614/3 1614/6	1661/19	1702/13
1614/17	1661/25	1703/21
1614/22	1662/19	1704/16
1615/8	1663/5	1706/4 1706/9
1615/18	1664/11	1706/10
1615/22	1667/24	1706/17
1617/23	1668/20	1706/20
1625/3 1628/1	1671/23	1706/25
1630/14	1672/21	1707/24
1630/24	1674/8	1708/20
1633/1	1674/16	1709/1 1709/9
1633/15	1675/10	1709/16
1634/5 1634/9	1675/13	1709/22
1634/14	1676/7	1709/25

Y	1730/16	1755/21
yes..... [121]	1730/18	1756/1
1710/12	1730/25	1756/16
1710/16	1732/10	1756/25
1710/23	1733/3 1733/9	1757/8
1713/17	1733/18	1759/20
1714/8	1733/22	1759/24
1715/11	1734/9	1760/2 1760/8
1715/13	1734/12	1760/17
1717/3	1737/6	1761/4 1762/9
1717/12	1737/17	1762/21
1718/8	1738/14	1762/25
1718/20	1738/15	1764/24
1718/24	1739/12	1765/14
1721/24	1743/3	1765/18
1722/9	1750/12	1766/6
1722/18	1752/16	1766/11
1723/23	1752/20	1766/17
1724/1	1752/24	1768/14
1725/10	1753/10	1769/25
1725/10	1753/17	1771/14
1726/13	1754/8	1773/7
1727/1 1729/9	1754/13	1773/11
1730/4	1754/20	1774/13

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yes..... [47]	1799/5 1800/8	yet [5] 1574/4
1774/14	1804/16	1814/19
1775/5	1806/21	1816/8
1775/21	1809/16	1816/25
1775/25	1809/22	1817/9
1777/10	1810/13	you [839]
1779/6 1780/8	1810/21	you'd [4]
1780/13	1811/2	1650/19
1780/18	1816/10	1653/21
1781/15	1821/20	1754/19
1782/3	1824/11	1759/3
1782/11	1824/14	you'll [10]
1782/16	1824/24	1580/19
1782/24	1827/14	1584/6 1588/1
1783/4 1783/9	1829/1	1598/25
1783/16	1830/11	1606/14
1788/1	1830/23	1690/18
1788/10	1832/1	1691/5 1735/7
1791/2 1793/8	1832/22	1745/11
1793/20	1832/25	1756/12
1795/9	yesterday [3]	you're [50]
1795/14	1567/20	1583/25
1795/19	1646/20	1585/18

Y	1759/2	1569/13
you're... [48]	1761/23	1581/24
1593/6	1764/3	1582/3
1595/13	1767/11	1582/10
1597/17	1767/18	1618/20
1602/7	1767/19	1627/2 1629/1
1604/20	1770/16	1632/13
1613/9 1617/3	1770/20	1648/24
1617/22	1771/18	1658/13
1624/21	1772/4	1660/18
1631/12	1783/18	1661/2
1640/14	1787/10	1661/10
1650/11	1789/10	1661/22
1652/4	1790/17	1693/16
1661/21	1808/19	1706/1
1708/8 1708/9	1814/14	1706/22
1708/12	1821/19	1719/3 1728/4
1725/11	1832/21	1739/17
1725/11	1833/20	1758/23
1725/12	1834/7	1817/20
1727/11	1834/25	1818/4
1751/10	1835/20	1818/17
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ZEMAN [1] 1565/6		
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