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4	IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN
5	OF THE NORTH AMERICAN FREE TRADE AGREEMENT
6	AND THE UNCITRAL ARBITRATION RULES (1976)
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8	Case No. UNCT/14/2
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10	ELI LILLY AND COMPANY
11	Claimant
12	vs.
13	
14	GOVERNMENT OF CANADA
15	Respondent
16	
17	MINUTES OF ARBITRATION
18	Washington, D.C.
19	
20	Friday, 3 June 2016
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24	(Pages 1223-1561)
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<p>1 3 June 2016</p> <p>2 INDEX</p> <p>3</p> <p>4 BRUCE LEVIN (Continued)</p> <p>5 Cross-Examination by Ms. Zeman1230</p> <p>6 Redirect Examination by Mr. Smith1262</p> <p>7 Questions by The Arbitral Tribunal1263</p> <p>8</p> <p>9 ROBERT MERGES</p> <p>10 Presentation by Professor Merges.....1281</p> <p>11 Direct Examination by Ms. Cheek1298</p> <p>12 Cross-Examination by Mr. Luz1307</p> <p>13 Redirect Examination by Ms. Cheek1383</p> <p>14 Questions by The Arbitral Tribunal1393</p> <p>15 Redirect Examination by Ms. Cheek1416</p> <p>16</p> <p>17 STEPHEN GARY KUNIN</p> <p>18 Presentation by Mr. Kunin.....1419</p> <p>19 Cross-Examination by Mr. Luz1425</p> <p>20</p> <p>21 TIMOTHY RICHARD HOLBROOK</p> <p>22 Presentation by Professor Holbrook.....1444</p> <p>23 Cross-Examination by Mr. Smith1458</p> <p>24 Questions by The Arbitral Tribunal1557</p> <p>25</p> <p>www.dianaburden.com</p>	<p>1 THE PRESIDENT: Good morning, ladies</p> <p>2 and gentlemen. We resume the hearing on Day 5. The</p> <p>3 Tribunal's first question is what is now the actual</p> <p>4 running order of the experts for today -- because we</p> <p>5 were confronted with the interpreters this morning,</p> <p>6 the Spanish interpreters, only to have to tell them</p> <p>7 that we understand them only to be needed on Monday.</p> <p>8 MS. CHEEK: Mr. President, the Spanish</p> <p>9 interpreters will only be needed on Monday.</p> <p>10 THE PRESIDENT: Could you then help us</p> <p>11 with, after Professor Levin, who we have then next?</p> <p>12 Because I understood there was a change yesterday.</p> <p>13 MS. CHEEK: Yes. So it will be</p> <p>14 Professor Merges, Mr. Kunin, Professor Holbrook,</p> <p>15 Mr. Jay Erstling. That's the switch, I believe. We</p> <p>16 need to hold the Mexican witnesses to Monday. One of</p> <p>17 them has a son who's graduating tomorrow in Mexico</p> <p>18 City, so the switch will be we will move up</p> <p>19 Mr. Erstling and Mr. Reed.</p> <p>20 THE PRESIDENT: Then we have on Monday</p> <p>21 Ms. Gonzalez, Mr. Salazar, Mr. Lindner and Professor</p> <p>22 Gervais. Am I correct?</p> <p>23 MS. CHEEK: And Mr. Thomas.</p> <p>24 THE PRESIDENT: Ms. Cheek, any other</p> <p>25 matter of household or administrative or</p> <p>www.dianaburden.com</p>
<p>1229</p> <p>1 organizational matter you would like to raise at this</p> <p>2 point?</p> <p>3 MS. CHEEK: Nothing from Claimant.</p> <p>4 MR. SPELLISCY: Nothing from</p> <p>5 Respondent.</p> <p>6 THE PRESIDENT: I think we are then at</p> <p>7 cross-examination. Ms. Zeman, please proceed. And</p> <p>8 good morning, Professor Levin.</p> <p>9 PROFESSOR LEVIN: Good morning,</p> <p>10 Mr. President. Mr. President, I understand you had</p> <p>11 asked a question yesterday and I am prepared to</p> <p>12 answer it if you wish.</p> <p>13 THE PRESIDENT: Not now. I think I</p> <p>14 will suggest we continue first with the</p> <p>15 cross-examination and see whether the question still</p> <p>16 remains after we have the redirect, because actually</p> <p>17 that is the proper Tribunal time. We have to wait</p> <p>18 until the parties have asked the questions.</p> <p>19 Sometimes we ask questions in the middle for a</p> <p>20 discrete point, but we try to avoid it.</p> <p>21 But thank you anyway for thinking</p> <p>22 about it. We will come back after the redirect.</p> <p>23 PROFESSOR LEVIN: May I ask one more</p> <p>24 question? My understanding was my book was going to</p> <p>25 contain certain pages from the textbook, but I'm</p> <p>www.dianaburden.com</p>	<p>1230</p> <p>1 having trouble finding them. Is that correct?</p> <p>2 MR. SMITH: May I answer that</p> <p>3 question, Mr. President?</p> <p>4 THE PRESIDENT: Yes, please,</p> <p>5 Mr. Smith.</p> <p>6 MR. SMITH: Those pages do not appear</p> <p>7 in the binder that Respondent intends to discuss with</p> <p>8 you on cross.</p> <p>9 PROFESSOR LEVIN: I see.</p> <p>10 THE PRESIDENT: Ms. Zeman, please</p> <p>11 proceed.</p> <p>12 CROSS-EXAMINATION ON BEHALF OF THE RESPONDENT</p> <p>13 MS. ZEMAN: Good morning, Professor</p> <p>14 Levin. My name is Krista Zeman. I am counsel for</p> <p>15 Canada in this arbitration, and I will have a few</p> <p>16 questions for you this morning to make sure that I</p> <p>17 understand your expert opinion in this proceeding.</p> <p>18 If at any point my question is unclear, let me know</p> <p>19 and I will do my best to reframe.</p> <p>20 In front of you you have a rather</p> <p>21 large binder. I promise that it is not as</p> <p>22 intimidating as it looks. You'll find appendix C to</p> <p>23 your report in the front cover, it's loose, as well</p> <p>24 as a sheet that contains your errata that you filed</p> <p>25 to the Tribunal last week, and we'll be referring to</p> <p>www.dianaburden.com</p>

<p>1 those frequently through the next few minutes. 2 I'd like to start by asking what you 3 were asked to do by counsel in this case. On slide 4 36 your presentation yesterday, which I believe can 5 be found in your smaller binder, you say that you 6 were asked to "assess the statistical significance of 7 certain differences in the proportions of patent 8 lawsuits in which court sustained validity 9 challenges." Is that right? 10 PROFESSOR LEVIN: The sentence 11 continues with three particular bullets, yes. 12 MS. ZEMAN: To answer this inquiry 13 that you've laid out on slide 3, you requested and 14 received a dataset. Is that correct? 15 PROFESSOR LEVIN: Yes. 16 MS. ZEMAN: And that dataset you 17 appended as appendix C to your report, and then the 18 errata and updates. Is that right? 19 PROFESSOR LEVIN: Yes. 20 MS. ZEMAN: And that data set contains 21 a list of patent cases or lawsuits litigated in the 22 Canadian Federal courts between January 1, 1980 and 23 April 22, 2016 as updated. Is that right? 24 PROFESSOR LEVIN: April 22, 2016, yes. 25 MS. ZEMAN: And each unit of analysis</p> <p>www.dianaburden.com</p>	<p>1 was coded for the type of patent case. Is that 2 right? 3 PROFESSOR LEVIN: Case, correct. 4 MS. ZEMAN: So either pharmaceutical 5 or non-pharmaceutical patent case, correct? That was 6 one of the codings? 7 PROFESSOR LEVIN: Yes. 8 MS. ZEMAN: And each unit was also 9 coded for the outcome of challenges to various 10 grounds of patent validity. Is that right? 11 PROFESSOR LEVIN: Yes. 12 MS. ZEMAN: You did not code the 13 dataset. Is that correct? 14 PROFESSOR LEVIN: Correct. 15 MS. ZEMAN: And you did not do any 16 independent verification of the accuracy or 17 appropriateness of the dataset. Is that right? 18 PROFESSOR LEVIN: Correct. 19 MS. ZEMAN: I'd venture that you've 20 seen your fair share of datasets throughout your 21 career. Would that be accurate? 22 PROFESSOR LEVIN: I think so. 23 MS. ZEMAN: And that you've seen a 24 wide range in terms of quality of datasets? 25 PROFESSOR LEVIN: Yes.</p> <p>www.dianaburden.com</p>
<p>1233</p> <p>1 MS. ZEMAN: And you'd agree that the 2 quality of a dataset has a profound impact on the 3 quality of the statistical conclusions drawn from it? 4 PROFESSOR LEVIN: It may or may not, 5 depending on what you mean by "quality." 6 MS. ZEMAN: You'd agree that a sound 7 methodology for collecting and presenting data is an 8 important part of what contributes to the quality of 9 a dataset? 10 PROFESSOR LEVIN: Would you repeat the 11 first part of the question? 12 MS. ZEMAN: Sure. Would you agree 13 that a sound methodology for collecting and 14 presenting data is an important part of what 15 contributes to the quality of a dataset? 16 PROFESSOR LEVIN: I would agree with 17 that, yes. 18 MS. ZEMAN: For example, a sound 19 methodology treats like cases alike. Is that right? 20 PROFESSOR LEVIN: I'm not sure what 21 you mean by "like cases alike." 22 MS. ZEMAN: If you're looking at 23 apples and apples you would compare apples and 24 apples? 25 PROFESSOR LEVIN: If I was asked to</p> <p>www.dianaburden.com</p>	<p>1234</p> <p>1 compare apples with apples, yes. 2 MS. ZEMAN: A sound methodology treats 3 units of analyses consistently. Is that right? 4 PROFESSOR LEVIN: Yes. 5 MS. ZEMAN: And your unit of analysis 6 was patent lawsuits, right? 7 PROFESSOR LEVIN: Yes. That was one 8 of them. 9 MS. ZEMAN: So let's take a look at 10 the dataset provided to you at Annex C, which is the 11 loose document there. Just turn to any page. So 12 each unit or lawsuit has a single code for "useful." 13 Is that right? 14 PROFESSOR LEVIN: Well, there are 15 actually three codes. There's a "yes" for "useful," 16 a "no" or an "N" for "not useful," and a dash for 17 "not challenged on that ground." 18 MS. ZEMAN: Three possible codes for 19 "useful?" 20 PROFESSOR LEVIN: Yes. 21 MS. ZEMAN: But each unit is assigned 22 one code. Is that right? 23 PROFESSOR LEVIN: Yes. 24 MS. ZEMAN: But sometimes in one case 25 there's more than one possible outcome to select. Is</p> <p>www.dianaburden.com</p>

<p>1 that right?</p> <p>2 PROFESSOR LEVIN: I don't follow what</p> <p>3 you mean.</p> <p>4 MS. ZEMAN: Let's have you look at an</p> <p>5 example. On page 18 of Annex C about midway -- I'll</p> <p>6 wait for you to get there.</p> <p>7 PROFESSOR LEVIN: Yes.</p> <p>8 MS. ZEMAN: About midway down you see</p> <p>9 the case Novartis Pharmaceuticals Canada, Inc. v Teva</p> <p>10 Canada with the trial court neutral citation 2013 FC</p> <p>11 283. Do you see that?</p> <p>12 PROFESSOR LEVIN: Yes.</p> <p>13 MS. ZEMAN: And this case is coded as</p> <p>14 a pharmaceutical case. Is that right?</p> <p>15 PROFESSOR LEVIN: Yes.</p> <p>16 MS. ZEMAN: And it is coded as "N" for</p> <p>17 "utility." Is that correct?</p> <p>18 PROFESSOR LEVIN: Yes.</p> <p>19 MS. ZEMAN: Meaning that a validity</p> <p>20 challenge to utility was sustained, if I take the</p> <p>21 language from your presentation. Is that accurate?</p> <p>22 PROFESSOR LEVIN: Yes.</p> <p>23 MS. ZEMAN: This case is at tab 2 of</p> <p>24 your big binder. This is Exhibit C-244. If you turn</p> <p>25 to paragraph 170.</p> <p>www.dianaburden.com</p>	<p>1 PROFESSOR LEVIN: Yes.</p> <p>2 MS. ZEMAN: You see the court says, "I</p> <p>3 find that Teva's allegations as to lack of utility of</p> <p>4 claim 14 of the '895 patent are justified."</p> <p>5 PROFESSOR LEVIN: I see that, yes.</p> <p>6 MS. ZEMAN: In paragraph 172, the</p> <p>7 court says, "I find that Teva's allegations as to</p> <p>8 lack of utility in respect of claims 1 and 2 of the</p> <p>9 '937 patent not to be justified." You see that?</p> <p>10 PROFESSOR LEVIN: Yes.</p> <p>11 MS. ZEMAN: So these paragraphs state</p> <p>12 opposite conclusions about lack of utility. Is that</p> <p>13 right?</p> <p>14 PROFESSOR LEVIN: I'm not a lawyer,</p> <p>15 but my understanding is they're speaking to different</p> <p>16 claims within a patent.</p> <p>17 MS. ZEMAN: But one of them says</p> <p>18 "justified" and one of them says "not justified." Do</p> <p>19 you see that?</p> <p>20 PROFESSOR LEVIN: Yes.</p> <p>21 MS. ZEMAN: You'd agree those are</p> <p>22 opposite conclusions?</p> <p>23 PROFESSOR LEVIN: With respect to</p> <p>24 those claims, yes.</p> <p>25 MS. ZEMAN: So in this case there are</p> <p>www.dianaburden.com</p>
<p>1237</p> <p>1 two possible utility outcomes to select from for</p> <p>2 coding. Is that right?</p> <p>3 PROFESSOR LEVIN: There are two</p> <p>4 possible outcomes for the unit of claims within the</p> <p>5 patent within this case.</p> <p>6 MS. ZEMAN: For the unit of claims.</p> <p>7 Okay. But in your dataset your unit was a case. Is</p> <p>8 that right?</p> <p>9 PROFESSOR LEVIN: Yes.</p> <p>10 MS. ZEMAN: So with two findings --</p> <p>11 two opposite findings in one unit, you have an option</p> <p>12 of selecting "Y" or "N" in this case. Is that right?</p> <p>13 PROFESSOR LEVIN: One has to have a</p> <p>14 rule for coding the case based on the contained</p> <p>15 within information. Those rules were laid out at the</p> <p>16 beginning of my Appendix C.</p> <p>17 MS. ZEMAN: So this case, for example,</p> <p>18 was coded "N" for utility, right?</p> <p>19 PROFESSOR LEVIN: Yes.</p> <p>20 MS. ZEMAN: And if I follow the logic,</p> <p>21 in a case where there are opposite findings on</p> <p>22 utility, a single finding of invalidity is sufficient</p> <p>23 to code the case as "N." Is that right?</p> <p>24 PROFESSOR LEVIN: There's a caveat.</p> <p>25 You just switched units to patent. So the rule for</p> <p>www.dianaburden.com</p>	<p>1238</p> <p>1 coding the case was if one or more patents was found</p> <p>2 invalid then the case was coded as invalid. Previous</p> <p>3 to that you were talking about different claims.</p> <p>4 MS. ZEMAN: I believe I was asking you</p> <p>5 about the case, that there are two possible ways to</p> <p>6 code this case based on the conclusions of the court.</p> <p>7 PROFESSOR LEVIN: As I testified, you</p> <p>8 have to have a rule. The rules were clearly laid out</p> <p>9 at the beginning of the appendix. My understanding</p> <p>10 of the rule is the case depended on what was going on</p> <p>11 at the level of patents, not below that with the</p> <p>12 level of claims. So if a case had one or more</p> <p>13 patents held invalid on utility grounds, for example,</p> <p>14 the case would be coded no for utility.</p> <p>15 MS. ZEMAN: Like this one?</p> <p>16 PROFESSOR LEVIN: Yes.</p> <p>17 MS. ZEMAN: And you see in paragraph</p> <p>18 170 here that the court says allegations of lack of</p> <p>19 utility of claim 14. Do you see that?</p> <p>20 PROFESSOR LEVIN: Yes.</p> <p>21 MS. ZEMAN: And, in 172, in respect of</p> <p>22 claims 1 and 2 of a patent?</p> <p>23 PROFESSOR LEVIN: Yes. But again, I</p> <p>24 reiterate, it's important to keep our units clearly</p> <p>25 separated. Here we're talking about claims at</p> <p>www.dianaburden.com</p>

<p>1 paragraphs 170 and 172. 2 MS. ZEMAN: So in one case where 3 there's more than one patent and more than one patent 4 had claims found invalid, like in this one, it would 5 be coded "N" for utility. Is that right? 6 PROFESSOR LEVIN: It would have to 7 depend on what was going on at the level of patent to 8 declare what was going on at the case. 9 MS. ZEMAN: And in this case that we 10 looked at, you agree that paragraph 170 refers to the 11 '895 patent, and paragraph 172 relates to the '937 12 patent. You see that? 13 PROFESSOR LEVIN: Yes. 14 MS. ZEMAN: So this is a case where 15 there are two separate patents with separate 16 invalidity findings. 17 PROFESSOR LEVIN: That's correct. And 18 because one of them was held to be not valid, that 19 caused the case to be coded not valid. 20 MS. ZEMAN: So let's take a look at 21 another example to make sure that I understand. 22 At tab 3 of your binder is Exhibit 23 C-120. This is another case that involves a choice 24 of coding options for utility. This is Eurocopter v 25 Bell Helicopter. At paragraph 360, the court sets</p> <p>www.dianaburden.com</p>	<p>1 out its conclusions with respect to utility. It 2 finds, first, that "the utility of an embodiment 3 included in claim 15 (offset forwards) has been 4 demonstrated at the Canadian filing date..." 5 PROFESSOR LEVIN: Yes. 6 MS. ZEMAN: So that's one validity 7 challenge rejected? 8 PROFESSOR LEVIN: Yes. 9 MS. ZEMAN: Then it concludes that 10 "there is a lack of demonstrated utility or sound 11 prediction with respect to an embodiment included in 12 claim 16 (offset backwards)." You see that? 13 PROFESSOR LEVIN: Yes. 14 MS. ZEMAN: That would be one validity 15 challenge sustained? 16 PROFESSOR LEVIN: Yes, to the claim. 17 MS. ZEMAN: Again, we have one patent 18 lawsuit case and a choice of two coding possibilities 19 on grounds of utility, correct? 20 PROFESSOR LEVIN: Once again, we have 21 to be precise about what level of unit are we talking 22 about. My reading of paragraph 360 is there was a 23 claim that was held invalid. 24 MS. ZEMAN: And so when there's a 25 claim held invalid, you ignore the finding of</p> <p>www.dianaburden.com</p>
<p>1241</p> <p>1 inutility and code this case as "Y" for utility. Is 2 that correct? 3 PROFESSOR LEVIN: Well, I didn't 4 ignore anything. Others were doing the coding. My 5 understanding of the rule was that at the level of 6 claims, if there was at least one claim upheld for a 7 given patent, the so-called split claim situation 8 like we have in Eurocopter, then the patent would be 9 coded as valid, in which case if all of the patents 10 involved in the case were upheld, it would be coded 11 valid. 12 MS. ZEMAN: And it was the Claimant 13 who gave you this rule. Is that correct? 14 PROFESSOR LEVIN: They were the ones 15 who decided on the coding rules. I did have a 16 conversation on statistical grounds to make sure that 17 was a statistically appropriate coding rule, but the 18 substance of the rule was Claimant's decision. 19 MS. ZEMAN: I'd like to look at just 20 one more example here at tab 4 of your binder. 21 THE PRESIDENT: Ms. Zeman, before you 22 move on, this is the case we find in the annex on 23 page 17 in the middle? 24 MS. ZEMAN: Yes, correct. 25 THE PRESIDENT: It is C-120, simply</p> <p>www.dianaburden.com</p>	<p>1242</p> <p>1 for the record, so we can follow the transcript. 2 MS. ZEMAN: Yes, Exhibit C-120. At 3 tab 4 of your binder is Exhibit R-484 and is another 4 case that presented a coding choice for validity 5 challenges on grounds of utility. This is Uponor AB 6 v Heatlink Group. This is one of the cases that was 7 updated in your update. Is that correct? 8 PROFESSOR LEVIN: Yes. 9 MS. ZEMAN: At paragraphs 163 and 164 10 of the decision the court sets out the first finding 11 on utility. In paragraph 164 it says, "...claims 2 12 and 3 and all of claims 4 to 18, as they depend on 13 either claim 2 or 3, are invalid on the basis of 14 inutility." You see that? 15 PROFESSOR LEVIN: Yes. 16 MS. ZEMAN: It says, "As are apparatus 17 claims relating to filters 36 and 37, and claim 38, 18 as it depends from claim 36 or 37." You see that? 19 PROFESSOR LEVIN: Yes. 20 MS. ZEMAN: And at paragraph 166, the 21 last sentence, which is on the next page, there is 22 another finding. It says, "Claim 21 and each of 23 claims 22 to 38... are invalid for lack of utility." 24 You see that? 25 PROFESSOR LEVIN: Yes.</p> <p>www.dianaburden.com</p>

<p>1 MS. ZEMAN: And at paragraph 168 it 2 says that claims 7 and 8 are also valid for lack of 3 utility? 4 PROFESSOR LEVIN: Yes. 5 MS. ZEMAN: But claims 9 and 10 are 6 not invalid for inutility. 7 PROFESSOR LEVIN: Yes. 8 MS. ZEMAN: So you agree that, once 9 again, in this case there is a choice as to possible 10 coding for utility? 11 PROFESSOR LEVIN: There is no choice 12 once you have decided on the coding rule. 13 MS. ZEMAN: And this case is included 14 in your updated case list, which should also be 15 loose. It is the second to last one under item 3, 16 and it is coded "Y" for utility. Is that correct? 17 PROFESSOR LEVIN: Yes. 18 MS. ZEMAN: So Eurocopter and Uponor 19 are cases that you critiqued Dr. Brisebois for coding 20 as cases in which a patent both won and lost a 21 utility-based validity challenge. Is that right? 22 PROFESSOR LEVIN: Yes. 23 MS. ZEMAN: You believe his coding was 24 improper because it changed the unit of analysis, 25 correct?</p> <p>www.dianaburden.com</p>	<p>1 PROFESSOR LEVIN: I believe I 2 testified it was improper because it violated a 3 fundamental statistical principle, that the coding at 4 a given unit of analysis has to be mutually exclusive 5 and exhaustive. Dr. Brisebois' choice was not 6 mutually exclusive nor exhaustive. 7 MS. ZEMAN: But you recognize that 8 with his coding, the results lose their statistical 9 significance, correct? 10 PROFESSOR LEVIN: I testified that, 11 yes. 12 MS. ZEMAN: Now, if Eurocopter and 13 Uponor had been coded "N" in your dataset instead of 14 "Y" and everything else remained the same, your 15 conclusion would lose its statistical significance, 16 too, wouldn't it? 17 PROFESSOR LEVIN: If one used that 18 invalid coding, as I testified yesterday, the P-value 19 would be greater than .05, yes. 20 MS. ZEMAN: In your presentation of 21 demonstratives yesterday, which are found at tab 4 of 22 your smaller binder, you included three updated 23 tables in response to Dr. Brisebois' suggested 24 changes to the dataset that was provided to you. Is 25 that right?</p> <p>www.dianaburden.com</p>
<p>1245</p> <p>1 PROFESSOR LEVIN: Yes. 2 MS. ZEMAN: In your direct examination 3 Mr. Smith asked you -- 4 PROFESSOR LEVIN: Well, may I revise 5 that? I see more than three tables. 6 MS. ZEMAN: Sure. I'm looking at 7 updated tables 1B, 1C and 1D, which are at 8 demonstrative slides 6, 7 and 8. So you agree that 9 these three tables are produced in response to 10 observations made by Dr. Brisebois in the dataset 11 provided to you. Is that accurate? 12 PROFESSOR LEVIN: Yes. 13 MS. ZEMAN: In your direct 14 examination, presenting this first table, Mr. Smith 15 asked you what you had done in response to paragraphs 16 20 to 26 of Dr. Brisebois' Second Report where he 17 explains why he believes including PM(NOC) rulings is 18 inappropriate. Is that right? 19 PROFESSOR LEVIN: Yes. 20 MS. ZEMAN: And this updated table 1B 21 at demonstrative slide 6 excludes PM(NOC) rulings. 22 Is that right? 23 PROFESSOR LEVIN: Yes. 24 MS. ZEMAN: But it still counts patent 25 lawsuits rather than patents. Is that right?</p> <p>www.dianaburden.com</p>	<p>1246</p> <p>1 PROFESSOR LEVIN: I thought this was 2 patents but I could be wrong. 3 MS. ZEMAN: I see the heading here 4 says "Type of patent case," and if you compare that 5 with the next one which says "Type of patent," 6 perhaps does that clarify? 7 PROFESSOR LEVIN: Yes. I think that's 8 right, yes. 9 MS. ZEMAN: So Mr. Smith then asked 10 you to address paragraph 17 of Dr. Brisebois' Second 11 Report where he explains why he believes patents 12 should be counted instead of patent lawsuits. Is 13 that right? 14 PROFESSOR LEVIN: Yes. 15 MS. ZEMAN: And you presented updated 16 table 1C at demonstrative slide 7 that counts patents 17 instead of lawsuits. That's right? 18 PROFESSOR LEVIN: Yes. 19 MS. ZEMAN: But this slide includes 20 PM(NOC) rulings. Is that right? 21 PROFESSOR LEVIN: Yes. 22 MS. ZEMAN: In neither of these 23 updates did you present the updates cumulatively. Is 24 that right? 25 PROFESSOR LEVIN: What do you mean by</p> <p>www.dianaburden.com</p>

<p>1 "cumulatively"? 2 MS. ZEMAN: With both of those 3 suggestions included together. 4 PROFESSOR LEVIN: The suggestion to 5 count actions only -- I don't understand what you're 6 referring to. 7 MS. ZEMAN: The suggestion to count 8 actions only and patents only. You did not present a 9 table that included both of those updates together. 10 Is that right? 11 PROFESSOR LEVIN: That's right. 12 MS. ZEMAN: Is it your understanding 13 that Dr. Brisebois considered the errors to be 14 cumulative? 15 PROFESSOR LEVIN: I don't know. 16 MS. ZEMAN: Mr. Smith also asked you 17 about three individual cases that Dr. Brisebois 18 viewed as miscoded in paragraphs 7 to 10 of his 19 report, and you presented updated table 1D at 20 demonstrative slide 8 to reflect his suggested 21 treatment of two of those three cases. Is that 22 right? 23 PROFESSOR LEVIN: Yes. 24 MS. ZEMAN: Bayer and Wenzel? 25 PROFESSOR LEVIN: Yes.</p> <p>www.dianaburden.com</p>	<p>1 MS. ZEMAN: This table does consider 2 the update for counting patents instead of lawsuits 3 cumulatively with the miscoding update, is that 4 right? 5 PROFESSOR LEVIN: This considers 6 patents and all corrections and updated data. 7 MS. ZEMAN: But it does not include 8 the update excluding PM(NOC) rulings. Is that right? 9 PROFESSOR LEVIN: Yes. 10 MS. ZEMAN: And you do not reproduce a 11 table reflecting Dr. Brisebois' suggestions to code 12 Eurocopter and related cases. Is that right? 13 PROFESSOR LEVIN: Yes. 14 MS. ZEMAN: The dataset provided to 15 you does not make any distinction between utility and 16 promise utility outcomes. Is that right? 17 PROFESSOR LEVIN: Not to my knowledge. 18 MS. ZEMAN: So you also did not make 19 any distinction between utility and promise utility 20 outcomes in your analysis. Is that right? 21 PROFESSOR LEVIN: I did not, no. 22 MS. ZEMAN: Assume for me for a moment 23 that promise utility outcomes -- let's call them 24 promise outcomes for ease of speaking -- are not 25 entirely the same as utility outcomes. And assume</p> <p>www.dianaburden.com</p>
<p>1249</p> <p>1 that promise outcomes are a subset of utility 2 outcomes such that all promise outcomes are utility 3 outcomes but that not all utility outcomes are 4 promise outcomes. With me? 5 PROFESSOR LEVIN: I am certainly not 6 an expert on patent law, but I'm trying to follow 7 you. 8 MS. ZEMAN: You're familiar with 9 subsets? 10 PROFESSOR LEVIN: Yes, I am. 11 MS. ZEMAN: We can call them A and B. 12 Let's say that A is a subset of B, and all A outcomes 13 are B outcomes, but not all B outcomes are A 14 outcomes. 15 PROFESSOR LEVIN: I understand your 16 meaning. 17 MS. ZEMAN: And assume that you do not 18 know what proportion of B outcomes are A outcomes. 19 In that situation, you'd agree with me that 20 conclusions with respect to the broader group of B 21 outcomes would not necessarily apply equally to the 22 group of A outcomes. 23 PROFESSOR LEVIN: You're assuming that 24 you would only be analyzing the subset cases rather 25 than all utility cases?</p> <p>www.dianaburden.com</p>	<p>1250</p> <p>1 MS. ZEMAN: Assuming that you are only 2 analyzing the broader subset. 3 PROFESSOR LEVIN: The broader subset? 4 MS. ZEMAN: Yes. 5 PROFESSOR LEVIN: And your question 6 was that it would not be correct to assume that 7 findings would necessarily apply to the subset? 8 MS. ZEMAN: Equally, yes. 9 PROFESSOR LEVIN: I would have to look 10 at the particular data to make such a determination. 11 MS. ZEMAN: But you have not looked at 12 that data? 13 PROFESSOR LEVIN: That's correct. 14 MS. ZEMAN: Let's go back to slide 3 15 of your presentation for a moment. This is at tab 3 16 of your small binder. 17 PROFESSOR LEVIN: Yes. 18 MS. ZEMAN: Here you were asked to 19 look at pre-2005 and post-2005 periods. Is that 20 correct? 21 PROFESSOR LEVIN: Yes. 22 MS. ZEMAN: And your cut-off date 23 between the two periods was January 1, 2005. Is that 24 right? 25 PROFESSOR LEVIN: Yes.</p> <p>www.dianaburden.com</p>

<p>1 MS. ZEMAN: And that's because the 2 promise utility doctrine came into existence then. 3 Is that your understanding? 4 PROFESSOR LEVIN: I don't know for 5 sure that it was my understanding. 6 MS. ZEMAN: At tab 7 of the big red 7 binder in front of you -- 8 PROFESSOR LEVIN: Tab 7? 9 MS. ZEMAN: Yes -- is slide 70 from 10 the Claimant's opening presentation, which updated 11 its figure 3 from its Memorial. This updated figure 12 is based on your report as updated. Is that correct? 13 I think it's very faintly written on the bottom. 14 PROFESSOR LEVIN: What was faintly 15 written on the bottom? 16 MS. ZEMAN: The reference to your 17 report. 18 PROFESSOR LEVIN: I can't see it. 19 MS. ZEMAN: Do you recognize these 20 numbers as consistent with the ones that you 21 presented? 22 PROFESSOR LEVIN: I believe they are, 23 yes. 24 MS. ZEMAN: And you presented the 25 right half of this in your presentation yesterday.</p> <p>www.dianaburden.com</p>	<p>1 Is that correct? 2 PROFESSOR LEVIN: Yes. 3 MS. ZEMAN: I'd like to look at the 4 top two circles for a moment, pharmaceutical cases 5 before 2005 and after 2005. This figure and your 6 numbers show 0 percent inutility outcomes for 7 pharmaceutical cases from 1980 to 2004. Is that 8 right? 9 PROFESSOR LEVIN: Yes. 10 MS. ZEMAN: And 41 percent inutility 11 outcomes for pharmaceutical cases from 2005 to 2016. 12 Is that right? 13 PROFESSOR LEVIN: Yes. 14 MS. ZEMAN: Divided as in your report 15 at January 1, 2005. Is that right? 16 PROFESSOR LEVIN: Yes. 17 MS. ZEMAN: At tab 8 of your binder is 18 an excerpt from the Claimant's Memorial where the 19 original figure 3 appeared. At paragraph 222, it 20 states, "...as Figure 3 indicates, since the Federal 21 Courts' application of the promise utility doctrine 22 began in 2005, inutility findings have jumped from 23 zero to 40 percent" -- as it was then -- "for 24 pharmaceutical patents...." 25 Is that right? That's what it says?</p> <p>www.dianaburden.com</p>
<p>1253</p> <p>1 PROFESSOR LEVIN: That's the first 2 part of the sentence, yes. 3 MS. ZEMAN: And then it introduces 4 Figure 3. 5 PROFESSOR LEVIN: Yes. 6 MS. ZEMAN: So, based on this 7 statement and your understanding, it would be logical 8 to conclude that the courts began their application 9 of the promise utility doctrine on January 1, 2005. 10 Would you agree? 11 PROFESSOR LEVIN: I don't know. I'm 12 not an expert on the law. I don't know when the 13 courts did what. 14 MS. ZEMAN: Let me put it this way: 15 If you were interested in measuring the impact of the 16 promise utility doctrine and it came into existence 17 at a certain moment in time, it would be logical to 18 conduct your analysis as of the date that it came 19 into existence. Would you agree with that? 20 PROFESSOR LEVIN: It would be logical, 21 yes. 22 MS. ZEMAN: The Claimant's Canadian 23 legal expert, Professor Siebrasse, has identified 24 three cases specifically as the beginning of the 25 promise utility doctrine in Canada. At tab 9 of your</p> <p>www.dianaburden.com</p>	<p>1254</p> <p>1 binder is an excerpt from Professor Siebrasse's first 2 Expert Report where at paragraph 72 he states, "The 3 substantive requirement that utility be assessed by 4 reference to the 'promise of the patent,' was adopted 5 at the trial level beginning in 2005 and affirmed by 6 the Court of Appeal in 2008. The change had no basis 7 in prior case law or the Act." You see that? 8 PROFESSOR LEVIN: I see that. 9 MS. ZEMAN: There's a footnote 98 -- 10 MR. SMITH: Mr. President, if I may, 11 Professor Levin has already indicated that he is not 12 an expert on Canadian law, and I just wanted to check 13 on this line of questioning, which has been going 14 on -- 15 THE PRESIDENT: The line of 16 questioning is simply going to where he draws the 17 line of 2005. Overruled. 18 MS. ZEMAN: In footnote 98 he 19 identifies three cases, Bristol-Myers Squibb v Apotex 20 Inc. 2005, FC 1348; Pfizer Canada Inc. v Apotex Inc., 21 2005 FC 1205; and Aventis Pharma Inc. v Apotex Inc., 22 2005 FC 1283. 23 You see that? 24 PROFESSOR LEVIN: I see that. 25 MS. ZEMAN: Let's take a look at these</p> <p>www.dianaburden.com</p>

<p>1 cases. The first one is at tab 10 of your binder. 2 This is Exhibit C-520. Bristol-Myers Squibb v Apotex 3 Inc. 4 THE PRESIDENT: For the record, as it 5 has been an issue, Professor Levin, you have heard 6 yesterday in note 98 as you see it in tab 9 yesterday 7 there was a correction made in the footnote that what 8 was C-190 actually should be C-520, which now 9 Ms. Zeman takes you to. 10 MS. ZEMAN: Yes. 11 PROFESSOR LEVIN: Thank you, 12 Mr. President. Mr. President, may I also correct one 13 thing that you stated a moment ago? I did not draw 14 the line at the year 2005. That was a legal 15 decision. 16 THE PRESIDENT: Sorry, it was 17 instruction, but we see whether it works out with the 18 dataset as you've analyzed. 19 PROFESSOR LEVIN: Yes. 20 MS. ZEMAN: At tab 10, Exhibit C-520, 21 this decision is dated October 3, 2005, correct? 22 PROFESSOR LEVIN: Which page are you 23 on? 24 MS. ZEMAN: The very first page. 25 PROFESSOR LEVIN: Of tab?</p> <p>www.dianaburden.com</p>	<p>1 MS. ZEMAN: Tab 10. 2 PROFESSOR LEVIN: I see on the third 3 line a date October 3, 2005, yes. 4 MS. ZEMAN: And the second case 5 Professor Siebrasse identifies is at tab 11 of your 6 binder. This is Exhibit C-250. It is Pfizer Canada 7 Inc. v Apotex Inc. You see the judgment rendered on 8 September 28, 2005, correct? 9 PROFESSOR LEVIN: I see that. 10 MS. ZEMAN: And the third case he 11 identifies is at tab 12 of your binder. This is 12 Exhibit C-209, Aventis Pharma Inc. v Apotex Inc., and 13 the judgment was rendered on September 20, 2005, 14 correct? 15 PROFESSOR LEVIN: Yes. 16 MS. ZEMAN: Now, if I took Professor 17 Siebrasse at his word and I was interested in 18 measuring the impact of the promise utility doctrine, 19 you'd agree that I should start measuring as of 20 September 20, 2005 at the earliest? 21 PROFESSOR LEVIN: I believe you're 22 asking me for a judgment on what is the best and 23 appropriate way to measure a legal question, and 24 that's not why I'm here. 25 MS. ZEMAN: Let's find these cases in</p> <p>www.dianaburden.com</p>
<p>1257</p> <p>1 the dataset that you were asked to analyze. At Annex 2 C, at page 10, do you see Aventis Pharma Inc. v 3 Apotex Inc. 2005 FC 1283 in the middle? 4 PROFESSOR LEVIN: Yes. 5 MS. ZEMAN: This was the earliest 6 possible promise utility case identified by 7 Professor Siebrasse? 8 PROFESSOR LEVIN: I don't know. 9 MS. ZEMAN: This was one of the cases 10 in the footnote in the dates that we looked at? 11 PROFESSOR LEVIN: All right. 12 MS. ZEMAN: So let's take a look at 13 the cases that came before it in 2005. Immediately 14 preceding that case in Annex C is Pfizer Canada Inc. 15 v Canada (Minister of Health) 2005 FC 1205. This is 16 the second decision identified by Professor Siebrasse 17 in his report so September 28, 2005, if you recall? 18 PROFESSOR LEVIN: Yes. 19 MS. ZEMAN: The next one up on that 20 page, you see a utility outcome for Abbott 21 Laboratories v Canada (Minister of Health), the trial 22 court neutral citation 2005 FC 1059. There is a 23 utility outcome for that case? 24 PROFESSOR LEVIN: Yes. 25 MS. ZEMAN: And this case is coded as</p> <p>www.dianaburden.com</p>	<p>1258</p> <p>1 a pharmaceutical case. Is that correct? 2 PROFESSOR LEVIN: Yes. 3 MS. ZEMAN: And it is coded as "N" for 4 utility? 5 PROFESSOR LEVIN: Yes. 6 MS. ZEMAN: And there is no appellate 7 history for this case. Is that right? 8 PROFESSOR LEVIN: That's what it says. 9 MS. ZEMAN: And that means, based on 10 the rules provided to you, that the final decision 11 for statistical counting purposes here would be the 12 date of the trial level decision. Is that correct? 13 PROFESSOR LEVIN: I really didn't pay 14 much attention to the legal decision of the appellate 15 history. I was told that that was the rule that was 16 used, but I don't know what the subsequent or prior 17 history was. I didn't question the dating. 18 MS. ZEMAN: Sure. But based on the 19 set as presented to you, it says no appellate 20 history. We can agree on that? 21 PROFESSOR LEVIN: I see it. 22 MS. ZEMAN: This case is at tab 13 of 23 your binder. It is Exhibit C-441. On the first page 24 the judgment rendered was on August 10, 2005. 25 Correct?</p> <p>www.dianaburden.com</p>

<p>1 PROFESSOR LEVIN: You're asking about 2 the date? 3 MS. ZEMAN: Yes. 4 PROFESSOR LEVIN: August 10, 2005. I 5 see that. 6 MS. ZEMAN: If we go back to your case 7 list on page 9, at the very bottom there is another 8 case with a utility outcome in 2005. It is Merck & 9 Co Inc. v Apotex Inc., 2005 FC 755. 10 PROFESSOR LEVIN: Yes. 11 MS. ZEMAN: You see this case is coded 12 as a pharmaceutical case? 13 PROFESSOR LEVIN: Yes. 14 MS. ZEMAN: And it is coded "N" for 15 utility, correct? 16 PROFESSOR LEVIN: Yes. 17 MS. ZEMAN: This trial decision is at 18 tab 14 of your binder. It is Exhibit C-354, and this 19 judgment was rendered on May 26, 2005. Is that 20 correct? 21 PROFESSOR LEVIN: Yes. 22 MS. ZEMAN: So that leaves us with two 23 pharmaceutical patent cases coded invalid for utility 24 after January 1, 2005 but prior to September 20, 25 2005. You agree?</p> <p>www.dianaburden.com</p>	<p>1 PROFESSOR LEVIN: Yes. 2 MS. ZEMAN: Now let's go back to tab 7 3 of your big binder. If this dataset had been divided 4 as of September 20, 2005 instead of January 1, you'd 5 agree that you would add two invalidity 6 pharmaceutical cases to the top left-hand pie chart. 7 Is that correct? 8 PROFESSOR LEVIN: I don't know. I 9 haven't been following your dating. But if you're 10 saying you're changing the dates, of course the 11 numbers would change. 12 MS. ZEMAN: Right. And you agree that 13 there are two cases between those two dates that were 14 coded "invalid for utility" that were pharmaceutical 15 cases? 16 PROFESSOR LEVIN: Yes. 17 MS. ZEMAN: And so, if you added those 18 two cases on the left, you would then have five total 19 inutility finding -- let me try that again. 20 You would have five total decided 21 validity challenges on the basis of utility for 22 pharmaceutical cases. Is that right? 23 PROFESSOR LEVIN: I suppose so, yes. 24 MS. ZEMAN: And two out of five is 25 40 percent. Is that right?</p> <p>www.dianaburden.com</p>
<p>1261</p> <p>1 PROFESSOR LEVIN: Yes. 2 MS. ZEMAN: And not zero percent? 3 PROFESSOR LEVIN: That's 4 mathematically correct, yes. 5 MS. ZEMAN: One final question for 6 you, Professor Levin -- 7 PROFESSOR LEVIN: I don't see the 8 relevance of that for my primary findings. 9 MS. ZEMAN: One final question. You 10 agree that conclusions of statistical significance 11 are not the same as conclusions as to legal 12 significance? 13 PROFESSOR LEVIN: There is a 14 distinction. 15 MS. ZEMAN: I have no further 16 questions. 17 THE PRESIDENT: Mr. Smith, do you have 18 redirect? 19 MR. SMITH: May we confer for one 20 moment? 21 THE PRESIDENT: Sure. 22 MR. SMITH: I'm ready to proceed. 23 THE PRESIDENT: Thank you. 24 25</p> <p>www.dianaburden.com</p>	<p>1262</p> <p>1 REDIRECT EXAMINATION ON BEHALF OF THE CLAIMANT 2 MR. SMITH: Professor Levin, you were 3 asked by Ms. Zeman about the importance of a dataset 4 being reliable. I want to ask if you have, from a 5 statistical perspective, any concerns about the 6 reliability of this dataset that you have analyzed? 7 PROFESSOR LEVIN: No, I don't. 8 MR. SMITH: Professor Levin, you 9 mentioned at the end of that line of questioning 10 regarding a shift in the date at which cases are 11 separated, that you did not see the relevance of that 12 change to your analysis. Could you please explain 13 why you did not see the relevance of that change? 14 PROFESSOR LEVIN: Yes. The question 15 referred to the pre-2005 period. My first primary 16 finding concerns the comparison of pharmaceutical and 17 non-pharmaceutical cases post-2005, so for two 18 reasons. No. 1, looking at the date prior to 2005 19 doesn't speak to the post-2005 period, nor does it 20 include the non-pharmaceutical cases that are a 21 necessary part of the task of measuring 22 disproportionate impact. 23 MR. SMITH: Mr. President, I have no 24 further questions. Thank you, Professor Levin. 25 THE PRESIDENT: Thank you. Any</p> <p>www.dianaburden.com</p>

<p>1 application for redirect?</p> <p>2 MS. ZEMAN: None.</p> <p>3 QUESTIONS BY THE ARBITRAL TRIBUNAL</p> <p>4 SIR DANIEL BETHLEHEM: Professor</p> <p>5 Levin, I'm just a little confused about this answer.</p> <p>6 If we go back to this tab 7, I understood from your</p> <p>7 response to Ms. Zeman that you said that,</p> <p>8 notwithstanding that there would be a variation of</p> <p>9 the inutility percentage to 40 percent, it would not</p> <p>10 make any difference to your analysis. Is that</p> <p>11 correct?</p> <p>12 PROFESSOR LEVIN: To the primary</p> <p>13 finding, the first task about looking post-2005, yes.</p> <p>14 SIR DANIEL BETHLEHEM: Right. Now,</p> <p>15 accepting that there may be variations, I just don't</p> <p>16 have my mind around these numbers but, assuming that</p> <p>17 there is a 40 percent inutility in the period</p> <p>18 1980-2004 and roughly -- no doubt that number would</p> <p>19 change -- roughly a 40 percent inutility in the</p> <p>20 period 2005-2016, is that not significant?</p> <p>21 PROFESSOR LEVIN: We need to clearly</p> <p>22 distinguish the various questions. We have four</p> <p>23 charts in front of us, four pie charts, and you can</p> <p>24 make different comparisons of different sorts. So my</p> <p>25 primary affirmative point, Question No. 1 that I was</p> <p>www.dianaburden.com</p>	<p>1 asked, was to compare pharmaceutical and</p> <p>2 non-pharmaceutical cases post-2005. That has nothing</p> <p>3 to do with what happened pre.</p> <p>4 SIR DANIEL BETHLEHEM: Let me just</p> <p>5 stop you there. So I appreciate, from what you've</p> <p>6 just said, that the change in the numbering would not</p> <p>7 have any impact necessarily on your assessment of the</p> <p>8 differential effect between pharmaceutical and</p> <p>9 non-pharmaceutical patents.</p> <p>10 PROFESSOR LEVIN: Yes, that's correct.</p> <p>11 SIR DANIEL BETHLEHEM: But as regards</p> <p>12 the change over time, simply as regards</p> <p>13 pharmaceutical patents, that is relevant, isn't it?</p> <p>14 PROFESSOR LEVIN: Yes. It would alter</p> <p>15 the proportions of inutility cases in the</p> <p>16 pharmaceutical sector pre versus post. However, as I</p> <p>17 testified in regard to table 2 of my report, that is</p> <p>18 a very treacherous, shall we say, comparison because</p> <p>19 of the small numbers involved. If we're going to</p> <p>20 rely, as I believe Respondent might, on the lack of</p> <p>21 statistical significance between those two</p> <p>22 proportions and draw from that conclusion, therefore,</p> <p>23 that they were identical in truth, that's problematic</p> <p>24 because of low power.</p> <p>25 I'd also like to add that I consider a</p> <p>www.dianaburden.com</p>
<p>1265</p> <p>1 more relevant question the comparison of pharma and</p> <p>2 non-pharma pre versus post, so that's a difference</p> <p>3 between pharma and non-pharma pre, and did that</p> <p>4 increase significantly to pharma versus non-pharma</p> <p>5 post-2005. Because that speaks to the question</p> <p>6 directly of whether the impact of the law as it</p> <p>7 impacts pharmaceutical versus non-pharmaceutical</p> <p>8 itself had a change over time. You can't get that</p> <p>9 from just looking at pharmaceutical alone.</p> <p>10 SIR DANIEL BETHLEHEM: In your</p> <p>11 presentation yesterday, you concluded -- I don't have</p> <p>12 the -- well, I do actually have the citation in the</p> <p>13 transcript but it's not relevant to turn it up, it's</p> <p>14 at 17:42:15 -- your conclusion was that the</p> <p>15 conclusions are consistent with the Claimant's view</p> <p>16 that Canadian utility law had a disproportionate</p> <p>17 impact on the pharmaceutical sector since 2000. That</p> <p>18 was your conclusion?</p> <p>19 PROFESSOR LEVIN: Yes.</p> <p>20 SIR DANIEL BETHLEHEM: This is a</p> <p>21 conclusion that goes to causation, doesn't it? I</p> <p>22 mean you are saying that it's Canadian utility law</p> <p>23 that had a disproportionate impact on the</p> <p>24 pharmaceutical sector since 2000?</p> <p>25 PROFESSOR LEVIN: That is Claimant's</p> <p>www.dianaburden.com</p>	<p>1266</p> <p>1 alternative hypothesis. It is causal, yes.</p> <p>2 SIR DANIEL BETHLEHEM: But your</p> <p>3 conclusion is a causation conclusion? I mean in that</p> <p>4 statement that I've just read, which is in the</p> <p>5 transcript, you are saying it's the Canadian utility</p> <p>6 law that had a disproportionate impact on the</p> <p>7 pharmaceutical sector?</p> <p>8 PROFESSOR LEVIN: The statement was</p> <p>9 "it is consistent with." I'm not opining about</p> <p>10 causality as a statistician in this case. But it is</p> <p>11 consistent.</p> <p>12 SIR DANIEL BETHLEHEM: That's</p> <p>13 precisely what I wanted to get at, whether you were</p> <p>14 opining on causality or not, because from the</p> <p>15 statement in the transcript it sounds as if you were</p> <p>16 opining on causality, and my question to you is could</p> <p>17 there have been other causes of the impact on a</p> <p>18 pharmaceutical sector, decisions on utility apart</p> <p>19 from the Canadian utility law. I mean, for example,</p> <p>20 an increase in pharmaceutical patent invalidity</p> <p>21 actions or something of that nature.</p> <p>22 PROFESSOR LEVIN: I'd like to answer</p> <p>23 your question in two, or possibly three, parts.</p> <p>24 First on the general point I am not opining on</p> <p>25 causality. I was not asked to do that; I am not</p> <p>www.dianaburden.com</p>

<p>1 qualified to offer on opinion. I offered a 2 statistical opinion which is the rejection of the 3 null hypothesis was consistent with a causal 4 hypothesis, that of Claimants. I agree there could 5 be other causes; I'm not here to say one way or the 6 other. 7 On the specific example you just 8 mentioned -- and I'd appreciate it if you would 9 repeat that example, but I wanted to say that there 10 was a problem with that. 11 SIR DANIEL BETHLEHEM: I don't have 12 the words in my mind and I don't propose to go back 13 to the transcript because I was rather thinking 14 aloud. I'm just trying to identify whether there may 15 have been other causes of a disproportionate impact 16 on the pharmaceutical sector apart from the Canadian 17 utility doctrine which would not have been captured 18 by the statistical analysis. For example, simply an 19 increase in the number of pharmaceutical cases which 20 had nothing to do with the utility doctrine, but 21 simply because there was some other reason for the 22 increase in pharmaceutical cases. 23 PROFESSOR LEVIN: Well, thank you. 24 That was precisely what you had said and you 25 refreshed my memory. That would not be an example</p> <p style="text-align: center;">www.dianaburden.com</p>	<p>1 that would alter my analysis. I don't disagree that 2 there are other possible causes. I have not 3 considered that question. I can't. But the mere 4 increase in the number of pharmaceutical cases over 5 time would not invalidate the statistical approach 6 because the treatment of the 2 by 2 table takes 7 account of the sample sizes. So just because there 8 were more pharmaceutical challenges post-2005 than 9 pre-2005 does not mean that the difference between 10 pharmaceutical and non-pharmaceutical would 11 necessarily be anything but zero. So I'm objecting 12 to the particular -- or I'm disagreeing with the 13 particular example you're proposing. 14 I believe Dr. Brisebois also used that 15 as a threat to validity, but that is not a proper 16 threat for an alternative causal explanation. 17 SIR DANIEL BETHLEHEM: Thank you. 18 THE PRESIDENT: Professor Levin, I 19 asked yesterday regarding your presentation at slide 20 6. I think it is in front of you. 21 PROFESSOR LEVIN: Yes. 22 THE PRESIDENT: Could you please tell 23 me -- you started yesterday but you didn't finish and 24 I would like to give you the opportunity to finish 25 your answer -- how you calculated the P-value here of</p> <p style="text-align: center;">www.dianaburden.com</p>
<p style="text-align: right;">1269</p> <p>1 .0245. 2 PROFESSOR LEVIN: Yes. I'll be happy 3 to demonstrate that. Mr. President, I'd also like to 4 offer that all of the formulas I'm going to show you 5 are contained in my textbook, Statistics for Lawyers, 6 at pages 126 through 129. 7 THE PRESIDENT: Thank you. This is 8 commercial time. Okay. 9 PROFESSOR LEVIN: Thank you. 10 MR. BORN: Can we order on-line? 11 THE PRESIDENT: Please go ahead. 12 Statistics for Lawyers. The questions of 13 Mr. Bethlehem were also questions about correlation 14 and association, is that correct? 15 PROFESSOR LEVIN: I'm sorry? 16 THE PRESIDENT: His questions also 17 related to correlation and association, as 18 I understand the statistics go, but in your 19 examination you only had the specific question, the 20 what-you-know hypothesis, and that's what you were 21 examining? 22 PROFESSOR LEVIN: Yes. Causality and 23 correlation are actually two different things. 24 THE PRESIDENT: Exactly. Please go 25 ahead.</p> <p style="text-align: center;">www.dianaburden.com</p>	<p style="text-align: right;">1270</p> <p>1 SIR DANIEL BETHLEHEM: Should we say 2 please bear in mind that whatever you do on the board 3 is going to have to be transcribed, so you may want 4 to speak it out. 5 THE PRESIDENT: The Secretary will 6 take a picture. She is very good at picture-taking. 7 Please go ahead. 8 (Professor Levin drew on the white board) 9 PROFESSOR LEVIN: We have the 2 by 2 10 table here. I will simply reproduce it. The first 11 column is invalid, the second row is valid, the first 12 row is pharmaceutical, the second row is 13 non-pharmaceutical. 14 The calculation of the P-value is best 15 explained in three steps. The key idea is called the 16 binomial coefficient, and it is written this way. 17 I'm going to use an example that appeared in my 18 report. If you look at my report at footnote 6, I 19 believe it is. 20 THE PRESIDENT: It's footnote 5, I 21 think. 22 PROFESSOR LEVIN: Footnote 5, yes. 23 Page 6, footnote 5. Thank you. 24 You'll see a symbol there that is 71 25 which appears above the number 63, and it also is</p> <p style="text-align: center;">www.dianaburden.com</p>

<p>1 equal to 71 appearing over the number 8, and there is 2 a value here in excess of 10 billion. The exact 3 number is 10,639,125,640. This is called the 4 binomial coefficient. It's read 71 choose 63, and it 5 gives the number of ways of choosing a subset of size 6 63 from an urn with 71 chips. The reason that 71 7 choose 63 is the same as 71 choose 8 is because, as 8 you recall the graphical display, there are this many 9 ways of choosing 63 chips and letting them remain in 10 the urn, while the complementary eight chips are 11 withdrawn.</p> <p>12 So in general a binomial coefficient, 13 generally if we say A choose B, would be the number 14 of ways of withdrawing a subset of size B from a 15 group of chips of size A. The formula for a binomial 16 coefficient is you take the top number and you 17 multiply by successively smaller numbers, A, A minus 18 1, A minus 2, A minus 3 and so on, for a total of B 19 factors, so there are B product terms here.</p> <p>20 And then one divides by what's called 21 B factorial. That's the product of the B integers, 22 B, B minus 1, B minus 2 all the way down to 3, 2 and 23 1. So that is a calculating formula for how many 24 subsets of size B from a set of A.</p> <p>25 Second step is saying well, okay,</p> <p>www.dianaburden.com</p>	<p>1 that's the total number of ways we can withdraw the A 2 chips from the urn. How many of them would result in 3 a split such as we see inside the table? To 4 calculate that, we need to ask well, how many ways 5 among the 25 invalid or red chips are there of 6 choosing none from non-pharma and, therefore, 25 from 7 pharma. That's another binomial coefficient. We'll 8 write that down here, 25 choose zero, and there's 9 only way of doing it. You reach in and you get no 10 red chips in the non-pharmaceutical. There's only 11 one way of doing it. 25 choose zero, or for that 12 matter any number choose zero, is one. The reason 13 being, it's the same as 25 choose 25. How many ways 14 are there of choosing 25 chips out of 25. There's 15 only one way of doing it. You choose them all.</p> <p>16 At the same time we have the valid 17 cases. And here, by chance, how many different ways 18 would there be of choosing eight out of the 46 valid 19 chips? The answer is another binomial coefficient, 20 46 choose 8. So 46 choose 8 goes here, and the 21 product of these two binomial coefficients is, 22 therefore, the number of ways of reaching into the 23 urn and getting the inside of this table as shown.</p> <p>24 So if we take the product of these two 25 numbers and divide by 71 choose 8, this is the</p> <p>www.dianaburden.com</p>
<p>1273</p> <p>1 probability of that table. This second number is 2 another very large number, I don't remember it off 3 the top of my head, I could calculate it if you want 4 the numerical value, but that calculation -- 46 times 5 45 times 44 down to 45 divided by 8 times 7 times 6 6 times 5 down to 1 -- that is the fraction that -- 7 this, and then that divided by that 10 billion number 8 is the probability.</p> <p>9 So all together this is the 10 probability of the table, and in this example, that 11 was the value, .0245.</p> <p>12 The third step doesn't apply to the 13 particular table here because this table is as 14 extreme as you can get. There are no pharmaceutical 15 invalidations. In general, if this were not zero, 16 one would have to add the other probabilities of the 17 tables consistent with these margins, and the sum of 18 probabilities as just calculated, over all those 19 tables as extreme or more extreme, that's the 20 P-value.</p> <p>21 THE PRESIDENT: How sensitive is this? 22 If you take, for example, the 25/0, which you say is 23 an extreme case, you would have a situation 24/1. 24 How would that affect the P-value? 25 PROFESSOR LEVIN: Yes. The particular</p> <p>www.dianaburden.com</p>	<p>1274</p> <p>1 facts in the present case hinge on the second row. 2 The variations we've been discussing in the pharma 3 case, whether you change the numbers a little bit, 4 code it differently, really are not what's relevant 5 in terms of the quantitative value here.</p> <p>6 If you made that 1 and that 7 -- 7 THE PRESIDENT: No, no. Simply stay 8 only with 1 because I know we, as professors, love to 9 change hypotheses, but let's stick to 1. 24/1.</p> <p>10 PROFESSOR LEVIN: Yes. I believe that 11 would not be statistically significant. Notice that 12 there would still be a substantial difference in the 13 proportions. You'd have something close to 40 versus 14 1 and 8. That's 12 1/2 percent. You'd still have a 15 30, roughly, percentage point substantive difference, 16 but I believe that would not be significant.</p> <p>17 THE PRESIDENT: The last question is 18 the -- I don't know whether you call the number 19 itself, the number of cases, the population? 20 PROFESSOR LEVIN: Yes.</p> <p>21 THE PRESIDENT: Is the population not 22 somewhat small here in this case to make these type 23 of calculations? 24 PROFESSOR LEVIN: My answer to that is 25 no. Yes, we have the universe or the population</p> <p>www.dianaburden.com</p>

<p>1 involved here. This is the census, another word. 2 The data are what they are. 3 The size of the two groups -- in 4 particular if you were pointing to that 8 as a small 5 number -- the smallness of that margin is taken 6 account of by the P-value. One of the things which I 7 state in footnote 7, I believe, of my report is that 8 there's something of an asymmetry here, which is that 9 in small numbers, if you get a significant result, 10 that's somewhat remarkable. Typically it means that 11 you're dealing with a large difference, a large 12 effect. If you do not get a significant result in a 13 low power situation, as I mentioned, one cannot 14 conclude, oppositely, that therefore nothing is going 15 on. It is not statistically significant, but there's 16 a danger, a probability of making a type 2 error. A 17 type 2 error is an error of omission, where something 18 really is going on but you failed to declare it as 19 statistically significant. 20 So I am not particularly concerned 21 with the smallness of the numbers in the fact that 22 there's still a significant difference. 23 As far as other concerns with small 24 samples, let me just reiterate that this is not a 25 sample. This is a universe. This is the population.</p> <p>www.dianaburden.com</p>	<p>1 There are concerns when you're sampling for a survey 2 or you're doing an exit poll. If you interview too 3 few people there's a danger, or if you're doing an 4 unscientific survey, a sample of convenience, but 5 those issues are not here. These are the population. 6 THE PRESIDENT: I ask you the question 7 because, if you go back to tab 7 of the purple 8 binder, if I may call it, the red binder. 9 PROFESSOR LEVIN: The red binder, yes. 10 THE PRESIDENT: At the end of your 11 cross-examination you were asked the questions about 12 this slide, and you were asked by counsel, look, 13 assume now that it's not the 1st of January 2005, but 14 now it's September 2005. Mathematically it affected 15 the pie chart on the left. 16 PROFESSOR LEVIN: Yes. 17 THE PRESIDENT: Is that correct? 18 Mathematically, leaving aside all other observations 19 you can make here? And what it showed is that, 20 because you had such a small number, suddenly you got 21 40 percent or so on the left pie of inutility? 22 PROFESSOR LEVIN: Yes. 23 THE PRESIDENT: Is that because the 24 sheer number you have is not too sensitive to make 25 actually a meaningful -- you say statistically</p> <p>www.dianaburden.com</p>
<p>1277</p> <p>1 significant -- analysis here? 2 PROFESSOR LEVIN: The point you're 3 raising is exactly the point I drew as an important 4 caveat when I testified about table 2. If you 5 recall, I said I draw no conclusion from the lack of 6 significance between pre and post, and the reason is 7 precisely that. The number of cases pre-2005 8 challenged on utility was too small. 9 I could imagine, pushing to a logical 10 extreme, suppose there were no challenges prior to 11 2005, obviously we could not draw any conclusion. So 12 we don't draw any conclusion. 13 THE PRESIDENT: Thank you. Any 14 follow-up questions? Mr. Smith? 15 MR. SMITH: No follow-up questions, 16 Mr. President. 17 MS. ZEMAN: None. 18 THE PRESIDENT: Thank you. I stand 19 corrected, Professor Levin, in that yesterday you 20 were right that Ronald Fisher was actually the one 21 who popularized it but I maintain that still 22 Professor Laplace was the original inventor of this 23 P-value. Can we agree on that? 24 PROFESSOR LEVIN: I agree, 25 Mr. President. In fact, in two different</p> <p>www.dianaburden.com</p>	<p>1278</p> <p>1 applications. One was the sex ratio at birth of 2 French boys and girls, and the other was inclination 3 of comets. 4 THE PRESIDENT: But this does not go 5 to this case. 6 Thank you very much for testifying. 7 You are now excused as a witness and released. 8 Ten minutes recess. 9 (Recess taken) 10 MS. CHEEK: I do have a housekeeping 11 matter before the next witness. It is the Tribunal's 12 lucky day in that Statistics for Lawyers is already 13 in the record at C-395, although not the pages to 14 which Professor Levin referred, which were pages 15 123-125, I believe. We will go ahead and submit an 16 amended C-395 that includes the pages that Professor 17 Levin referenced. 18 THE PRESIDENT: Thank you. 19 ROBERT MERGES 20 THE PRESIDENT: Good morning, 21 Professor Merges. 22 PROFESSOR MERGES: Good morning, 23 Chairman and other members of the Tribunal. 24 THE PRESIDENT: Could you please state 25 your full name for the record.</p> <p>www.dianaburden.com</p>

<p>1 PROFESSOR MERGES: Robert Patrick 2 Merges. 3 THE PRESIDENT: You appear as an 4 expert witness for the Claimant? 5 PROFESSOR MERGES: Yes, that's right. 6 THE PRESIDENT: If any question is 7 unclear to you, either because of language or for any 8 other reason, please do seek a clarification because, 9 if you don't do so, the Tribunal will assume that 10 you've understood the question and that your answer 11 corresponds to the question. 12 PROFESSOR MERGES: Understood. 13 THE PRESIDENT: Professor Merges, you 14 will appreciate that testifying, be it before a court 15 or an arbitral tribunal, is a very serious matter. 16 In that connection, the Tribunal expects you to make 17 the declaration, the text of which is in front of 18 you. 19 PROFESSOR MERGES: Yes. This is the 20 expert declaration. I solemnly declare upon my honor 21 and conscience that my statement will be in 22 accordance with my sincere belief. 23 THE PRESIDENT: Thank you. Could you 24 please go to your Expert Report? 25 PROFESSOR MERGES: Yes.</p> <p>www.dianaburden.com</p>	<p>1 THE PRESIDENT: Page 21? The Expert 2 Report is dated September 29, 2014. Please confirm 3 for the record that the signature appearing above 4 your name is your signature? 5 PROFESSOR MERGES: Yes, that's me. 6 THE PRESIDENT: Could you then go to 7 your second Expert Report and go to page 22? The 8 second Expert Report is dated September 10, 2015. 9 Could you confirm for the record that the signature 10 appearing above your name is your signature? 11 PROFESSOR MERGES: Yes, that's mine. 12 THE PRESIDENT: Are there any 13 corrections you wish to make to either report? 14 PROFESSOR MERGES: There's a small 15 errata in the First Report, Mr. Chairman. If you 16 look at paragraph 6 in that First Report, in that 17 paragraph I am citing to an academic study that was 18 done by John Allison and Mark Lemley published in 19 1998. Do you see the reference there? 20 THE PRESIDENT: It is footnote 6, 21 isn't it? 22 PROFESSOR MERGES: Yes, that's the 23 one. In that paragraph I have overstated the rate of 24 invalidity of utility challenges. The table from 25 which I drew that number -- this is going to be</p> <p>www.dianaburden.com</p>
<p>1281</p> <p>1 à propos of our prior conversation. The table lists 2 the number of patents that were invalidated and if 3 you see my statement I say .7 percent of the cases. 4 The true figure there should be .41 percent, so I 5 have overstated the -- well, in fact, I've under 6 stated how rare utility cases are in U.S. law because 7 I took it from the wrong table. 8 THE PRESIDENT: Any other correction? 9 PROFESSOR MERGES: That's the only one 10 I have. 11 MS. CHEEK: I will be conducting the 12 direct examination of Professor Merges. 13 Professor Merges, could you please provide your 14 presentation for the Tribunal. 15 PRESENTATION BY PROFESSOR MERGES 16 PROFESSOR MERGES: Yes, I will. 17 First of all, who am I? I am a 18 Professor at U.S. Berkeley where I teach patent law, 19 intellectual property, also transnational 20 intellectual property contracts. I'm the author of 21 several case books. Patent Law and Policy, which is 22 now in its 6th edition, I'm working on the 7th these 23 days, which I think is the most widely adopted patent 24 case book in the U.S. I'm also co-author of a basic 25 text on intellectual property law which, as you know,</p> <p>www.dianaburden.com</p>	<p>1282</p> <p>1 covers copyright patent and trademark, and the 7th 2 edition of that book has just come out this month. 3 I'm also the author of many scholarly 4 books and articles on intellectual property, in 5 particular patent law and probably most particularly 6 law and economics of patent law would be sort of my 7 sub-specialty. 8 I have been teaching patent law in one 9 form or another coming up on 30 years, and I also 10 teach, as I say, intellectual property for most of 11 those 30 years. That's my basic background. 12 I've got several major points to make, 13 which I'll try to be concise about. The first is 14 that the traditional utility test in the U.S. 15 presents a very low bar to patentability and is 16 usually, almost always, very easily satisfied. It's 17 really quite a minor test in U.S. patent law. 18 The second point is that utility 19 doctrine has been stable for many years. The utility 20 test under U.S. law has been a low bar for a long 21 time and remains so today. 22 The third point that I'll try to 23 emphasize is that utility, like all the different 24 requirements for patentability, is quite distinct 25 from non-obviousness, from enablement, from novelty.</p> <p>www.dianaburden.com</p>

<p>1 It has its own role to play, and it's wrong to 2 conflate utility with the other requirements of U.S. 3 patent law.</p> <p>4 The fourth point I'll make is somewhat 5 of a comparative point, and that's that Canada's 6 promise utility doctrine really has no parallel in 7 U.S. law or, I would say, in traditional utility 8 doctrine generally.</p> <p>9 So those are the major points that I 10 will cover.</p> <p>11 Let me start with the first one which 12 is patentability is a low bar. As you've heard by 13 now several times, utility is often just presumed. A 14 well-established utility for an invention is just 15 presumed by the examiner. So in a typical case 16 involving, let's say, a mechanical invention, the 17 economical new mouse trap, or gearshifter for a 18 bicycle or something like that, almost on the title 19 of the patent you can see it has a utility. If you 20 build a structure, you can tell what it's used for, 21 and so the examiner mentally just checks that box and 22 it's quite straightforward.</p> <p>23 The same would be true if you're 24 presented with a patent on an electrical circuit, 25 something like that. If you're going to have a</p> <p>www.dianaburden.com</p>	<p>1 patent that's titled, you know, "motion detector 2 circuit" the use is quite apparent on the face of it, 3 and that's the end of the discussion in many cases.</p> <p>4 That probably is the reason why 5 utility is the least likely requirement of 6 patentability to result in patent invalidation. As I 7 was saying, updating my figures drawing from that 8 Allison and Lemley study, in that study, which is 9 drawn from seven years of cases, there was only one 10 case over those seven years where utility was the 11 ground of invalidity.</p> <p>12 By the way, I noticed that in your 13 binder the citation to that case gives the wrong 14 year, so for my report it's tab 4. For you, it's 15 Exhibit No. C-167. The year cited in the citation is 16 1988 but I think that study was published in 1998, 17 from what I recall. In any event, it wouldn't make 18 much difference because utility does not change very 19 much over time.</p> <p>20 I say it's a stable doctrine. By that 21 I mean that it's been in place for many years, and in 22 terms of its fundamental attributes it has not 23 changed very much. One of the important statements 24 of utility and the standard for it was in the Supreme 25 Court case <i>Brenner v Manson</i> in 1965, which stated</p> <p>www.dianaburden.com</p>
<p>1285</p> <p>1 that you need to have a practical utility in order to 2 have a patentable subject matter, and by "practical" 3 what the Supreme Court meant in that case was simply 4 not related to pure research objectives. So there's 5 kind of a very straightforward dichotomy there. 6 There's pure research, theoretical interest only, and 7 then there's the world of practical commerce, 8 practical or substantial utility, and that's the 9 line. It's a pretty straightforward line and it's 10 not a very high bar.</p> <p>11 As that case established, and as many 12 subsequent cases have held, the basic standard is 13 just operability. The invention just has to work. 14 And when I say "the invention" I mean the claimed 15 invention, because that's where we look to see what 16 the nature of the invention is. So when we ask does 17 this invention have utility, we simply say does the 18 claimed invention work for its basic purpose. That's 19 really the question, and it's very straightforward.</p> <p>20 There are a lot of degrees of efficacy 21 or attributes of performance that go well beyond 22 workability or operability. U.S. patent law has 23 never required that you prove any of those higher 24 levels of performance. That is not necessary. The 25 claimed invention has to work. Simple,</p> <p>www.dianaburden.com</p>	<p>1286</p> <p>1 straightforward.</p> <p>2 There is, of course, with any 3 doctrinal area certain common law development. I 4 believe, Mr. Chairman, you were asking one of the 5 witnesses -- maybe it was you, Sir Daniel -- to go to 6 the root of foundation of the utility standard, which 7 is just the word "new" and "useful" in a lot of 8 Patent Acts, so we have to take off from a single 9 word, "useful," and develop a body of law to apply 10 the specific technologies and specific situations.</p> <p>11 So like a lot of issues in patent law there is a 12 foundation -- actually in our system there's a 13 foundation in the constitution of the U.S. system -- 14 and then there's an embodiment of the constitutional 15 principles in a simple statute. Single word, section 16 101, "useful." So common law elaboration and 17 application of the basic concept is, of course, 18 necessary.</p> <p>19 The key is that as you look at the 20 development of the doctrine it's important to sort of 21 keep your eye on the ball, because, like any 22 doctrine, there are moments of ferment and there are 23 times when the doctrine is being adapted to new 24 conditions, but the fundamental test is the outcome, 25 is the rate of invalidity changing in a radical way,</p> <p>www.dianaburden.com</p>

<p>1 and from that measure I am very confident in saying 2 utility in the U.S. doesn't change and hasn't 3 changed. It's a very stable, a very, very persistent 4 standard and test, and although new areas come and 5 go, it is basically the same. 6 Utility in pharmaceuticals and 7 chemicals, of course, is one of those areas where 8 we've had to adapt the basic principle of utility and 9 what it means to be useful. As you've heard I think 10 a couple of times, what's distinctive about this 11 field technologically is that unlike, say, the 12 mechanical arts or, as I was saying, the electrical 13 field -- "electrical field" is a bit of a pun but I 14 didn't intend it -- unlike those areas in 15 pharmaceuticals and chemicals we often -- I say 16 "we" -- researchers build structures before they know 17 for sure what they might do. Sometimes it's just an 18 organic chemist who is purely interested in 19 synthesizing a new class of molecules just to see if 20 the darn things will hold together. Sometimes it's a 21 researcher who has an intuition that this class of 22 compounds might behave similarly to a class of 23 compounds that's understood, but it's not a proven 24 theory. It is an intuition based on their sense of 25 how these chemical structures work. And it's really</p> <p>www.dianaburden.com</p>	<p>1 important, I think, to get some context to think 2 about the way chemists kind of view the world. 3 They're very spatial thinkers. If you've ever had 4 any interactions, they love these ball and stick 5 models and they're always playing with chemical 6 structures in three dimensions, and a lot of times 7 the birth of a new chemical or pharmaceutical 8 compound invention will be somebody who says, you 9 know, this is an interesting class of compounds, I 10 wonder if I could get it to hold together and I 11 wonder if it would behave similarly to this other 12 class of compounds that is shaped somewhat the same. 13 And it starts with that kind of intuition. 14 But the point is, unlike when you 15 build a mouse trap where you know the purpose when 16 you set out, "I want to trap mice," or an electrical 17 circuit, "I want to sense motion," you don't do the 18 same thing. You have an intuition what it might be 19 good for and then there's a lot of work that goes 20 into just building the thing. 21 The point is we have structure before 22 we know for sure what the function and use is, and 23 that's very distinctive to the chemical fields. Even 24 so, the same standard basically applies. If you can 25 show operability for that compound or class of</p> <p>www.dianaburden.com</p>
<p>1289</p> <p>1 compound in the claimed invention, then you have met 2 the utility standard. 3 So chemical and pharmaceutical 4 research is a little different from other research, 5 but the utility standard is the same. It doesn't 6 change. Same standard. The field's a little 7 different; the standard doesn't change. 8 I want to go on to talk about how 9 utility is distinct from other doctrines. 10 We talk often about the basic 11 requirements of patentability, and it's important to 12 separate them out and understand that each has its 13 own function. This is a body of law in the U.S. 14 that's over 200 years old and it has streamlined over 15 the years, and so we can infer that a test that has 16 survived ever since the first Patent Act in 1790, 17 from the days of Joseph Story and Thomas Jefferson 18 and Alexander Hamilton, if it survived it must be 19 some useful purpose. Utility does serve an important 20 function but it is distinct from the other 21 requirements of patentability. 22 I teach often in a seminar that we 23 have, we call it the IP Boot Camp. When a new 24 Federal district court judge is appointed they will 25 often sign up for our boot camp at Berkeley, and</p> <p>www.dianaburden.com</p>	<p>1290</p> <p>1 these are the trial court judges in our Federal 2 system and they're going to have to be dealing with 3 intellectual property cases and some have a 4 background in this area and some don't, so we have a 5 set of very simple visuals we use to teach them the 6 basic requirements of patentability -- I often will 7 teach the patent section of this seminar -- and we 8 use a series of hurdles, because I think it's the 9 easiest visually. 10 The first hurdle is utility and we 11 have trouble on the little PowerPoint, you know, 12 finding a hurdle that looks that low. It's almost 13 like kind of stepping over a curb. It's the first 14 hurdle and it's distinct. Then, of course, you go on 15 to novelty, and then you go on to non-obviousness and 16 go on to disclosure, but we teach it sequentially for 17 a reason because they're logically interrelated, and 18 conflating them, I think, is a major conceptual 19 mistake, for reasons that hopefully we will see. 20 The primary conflation I see going on 21 at times is between utility and the disclosure 22 requirements of U.S. law, which are listed in section 23 112 of our statute, primarily enablement and written 24 description relevant for our purposes. 25 A simple point, enablement and written</p> <p>www.dianaburden.com</p>

<p>1 description are not co-extensive with utility. They 2 are very different tests. Disclosure under section 3 112 has a very distinct purpose from the requirement 4 of utility.</p> <p>5 So how do we know that? How do we 6 know they're not the same test? Because many patents 7 are invalidated for failure to meet the section 112 8 requirements when those same patents satisfy the 9 utility standard. Many, many patents that are 10 invalidated for 112 have satisfied section 101. Why? 11 Utility is much easier to meet and 112 is doing 12 different work. That's the primary reason.</p> <p>13 So in what way is utility different 14 from some of these other standards? It is a 15 straightforward, very simple threshold requirement 16 and I like to teach it as a very binary question. 17 Does your invention work or not? Is it operable or 18 not? Very simple.</p> <p>19 Enablement and written description are 20 keyed to how broad your claim is, right? You've 21 heard a lot about genus and species because that's a 22 concept we use in patent law a lot, and you have to 23 think about a patent claim as covering a 24 technological space, right? It's a set of words that 25 defines a verbal boundary and inside that boundary</p> <p>www.dianaburden.com</p>	<p>1 are many different embodiments which are things that 2 are covered by that verbal formula. Enablement and 3 written description have to do with have you taught 4 enough to merit or deserve the breadth of your 5 claims. Narrow claims, less teaching. Broad claims, 6 more teaching. There's a sense of commensurateness 7 that's built into enablement and written description.</p> <p>8 Utility is very different. We ask is 9 the claimed invention workable, is it operable, does 10 it basically work. We look at the nature of the 11 invention from the claims and then we simply ask has 12 it been shown or is it self-evident that it works, 13 and, if so, you clear that first hurdle very, very 14 easily.</p> <p>15 I'll probably have a chance to go 16 through that a little bit more, but I need to proceed 17 on.</p> <p>18 Now we get to the promise utility 19 doctrine, which is really why we're here. I could 20 just say straightforwardly there's nothing in U.S. 21 utility law that's at all like the promise utility 22 doctrine. There's certainly nothing in our law of 23 utility where you would find that it drives such 24 extreme outcomes. You wouldn't find an area of law 25 where utility is invalidating 40 percent of the cases</p> <p>www.dianaburden.com</p>
<p>1293</p> <p>1 that are challenged on the grounds of utility. You 2 can look in vain for utility cases in any given week 3 or month of the U.S. patent quarterly. That's our 4 little weekly publication that comes out, and if 5 you're sort of a patent nerd like I am you read it 6 every week. And you can go years -- a year anyway -- 7 without seeing a utility case under U.S. law. You 8 can see many cases where enablement and written 9 description come into play but utility is very rare.</p> <p>10 So why is the promise utility doctrine 11 different? It's because the statements about 12 performance characteristics or qualities or features 13 of the invention, which are stated in the written 14 description part of the patent, the part that comes 15 before the claims, in the promise utility doctrine 16 world those statements are combed through and 17 scrutinized very carefully, whereas under utility 18 doctrine that is not the case. There is not this 19 same search for this kind of magical promise. We 20 just say what is the claimed invention, does it work, 21 and it's a very different kind of inquiry.</p> <p>22 Again, you can get caught up in 23 doctrine but, you know, I think the key is to keep 24 your eye on the ball. Outcomes. Utility in the U.S. 25 rarely invalidates a patent. Promise utility in</p> <p>www.dianaburden.com</p>	<p>1294</p> <p>1 Canada, major problem. How do we know? Here we are, 2 right?</p> <p>3 Let's take a look at a couple of 4 different patents in this case, a couple of data 5 points on what I'm talking about. The first is the 6 atomoxetine or Strattera patent. What is the claim? 7 The use of atomoxetine for treating ADHD. What is 8 the evidence introduced? It's a peer-reviewed, 9 double blind, pilot study and it is published in a 10 scientific journal, and it shows the statistically 11 significant efficacy; more than half the patients 12 showed improvement based on the protocol.</p> <p>13 The U.S. law of utility, I think, as 14 applied to that invention, was an easy call. It was 15 not challenged for lack of utility by the examiner, 16 and so the examiner just checked the box. The 17 claimed invention, use of atomoxetine, was basically 18 operable. The study showed that. Some related 19 animal studies and other data showed the same thing. 20 The Canadian court combed through the specification, 21 that is to say the written description not the claims 22 part of the patent, and said implicit in this 23 promise -- I don't think the word "promise" appears 24 in the patent -- implicit in this promise is that 25 atomoxetine will work in the longer term. Claimed</p> <p>www.dianaburden.com</p>

<p>1 invention: Use of atomoxetine for treating. 2 Promise: It will work in the long term. We just 3 don't see anything like that in U.S. utility law. 4 Now go on to olanzapine where the 5 claim is to the use of olanzapine to treat 6 schizophrenia -- a very serious disorder, as we know. 7 Again, the court combed through 8 statements in the specification and found some 9 statements in the specification that the compound in 10 question had marked superiority and a better side 11 effects profile and some higher activity -- 12 completely boilerplate and standard language in 13 patents, for reasons that have been explained and 14 that I can explain further. My point is you wouldn't 15 see that kind of scrutiny of the detailed statements 16 in the written description portion when the proof of 17 operability was so straightforward, as it was in this 18 case where animal studies, and some prior studies had 19 shown clearly that olanzapine was effective. 20 In fact, olanzapine was selected from 21 a broad -- very broad -- genus patent, which is sort 22 of the Granddaddy in this area of so-called tricyclic 23 compounds, which were found to have significant 24 neurobiological impact. That was the patent that was 25 expired and is in a sense off-stage in the olanzapine</p> <p>www.dianaburden.com</p>	<p>1 case. 2 Under U.S. law a selection invention 3 pretty much per se has utility because it's chosen 4 from a genus which itself is part of an issued patent 5 and therefore has utility. So to get that first 6 patent on a very broad class of compounds, you had to 7 show that it had utility, and the inventor was able 8 to do that quite easily because these tricyclic 9 compounds at the time were a hot research area and 10 there was lots of activity and people knew there was 11 something very promising about them with respect to 12 neurobiological results. 13 So picking a species out of that genus 14 per se has utility. It's one member of a set which 15 is shown to be useful. End of discussion. Detailed 16 scrutiny of other statements about what this compound 17 does and how it operates or might operate is not 18 necessary under U.S. utility law, and I would say 19 under classic sort of canonical U.S. utility law. 20 What does U.S. utility law say about 21 these kinds of statements that you might find in a 22 specification or in other statements related to the 23 patent? We can just take one case out of many. This 24 is the Transco Products case -- and I'm running short 25 on time so I think I'll just end with this. The</p> <p>www.dianaburden.com</p>
<p>1297</p> <p>1 Transco Products case was a case about an insulating 2 wrap that was used inside of a nuclear power plant, 3 so very, very high temperature environment -- 4 THE PRESIDENT: You are in injury 5 time. I will give you two extra minutes. 6 PROFESSOR MERGES: Thank you very 7 much. I must have earned some extra time. 8 So this is a patent on a wrap that 9 goes around pipes in a nuclear reactor, and in order 10 to keep the wrap on the pipes they use Velcro 11 closures, and the claim specified that the hook and 12 loop or closure mechanism had to be made of nylon. 13 The accused infringer said it's a high temperature 14 environment, regular standard off-the-shelf Velcro is 15 going to melt, and they said therefore it doesn't 16 have any utility. And what the court held was that 17 this kind of long-term effectiveness, that it has to 18 last a long time and not melt, that's not required. 19 The closures will hold that fiberglass wrap on the 20 pipes without any problem, and there's nothing that 21 requires long-term efficacy for the life of the 22 nuclear power plant or anything that extreme. 23 So it's a very straightforward test, 24 workability and operability, and the cases are very 25 clear.</p> <p>www.dianaburden.com</p>	<p>1298</p> <p>1 In the FDA approval context you don't 2 have to show that your drug is actually ready to be 3 put in bottles and given to patients by the millions. 4 There are important policy reasons why we wouldn't 5 want to set the utility standard that stringently. 6 We wouldn't want to set utility at a level that 7 requires that much proof, and I'm sure I can work 8 that into my answers on cross. 9 So let me just end by saying utility 10 in the U.S. is a very low bar; we focus on the 11 claimed invention, and we just ask whether it's 12 workable. The promise utility doctrine, whatever it 13 is, is very different from that. 14 MS. CHEEK: I do have a few questions 15 for Professor Merges on direct. 16 THE PRESIDENT: Please proceed. 17 DIRECT EXAMINATION ON BEHALF OF THE CLAIMANT 18 MS. CHEEK: In his Second Report 19 Professor Holbrook contends that the U.S. doctrines 20 of utility, enablement and written description are 21 closely related and "often rise or fall together" 22 (paragraph 25 of Professor Holbrook's report.) What 23 is your reaction to Professor Holbrook's claim that 24 these doctrines often "rise and fall together"? 25 PROFESSOR MERGES: I really just don't</p> <p>www.dianaburden.com</p>

<p>1 think there's any support for that because the</p> <p>2 studies that we see, for example in that</p> <p>3 Allison/Lemley study from the American Intellectual</p> <p>4 Property Law Association quarterly journal, again,</p> <p>5 one patent in that study out of 239 cases was</p> <p>6 invalidated for lack of utility. The figure for</p> <p>7 enablement and written description escapes me but I</p> <p>8 can guarantee it was much higher.</p> <p>9 In a subsequent study that Lemley,</p> <p>10 Allison and I think a third co-author published just</p> <p>11 last year in the University of Chicago or somewhere,</p> <p>12 some study I saw, I think the general going rate is</p> <p>13 that about 20 percent of cases where enablement and</p> <p>14 written description are argued end up in</p> <p>15 invalidations. So you have .41 percent of cases in</p> <p>16 one study and 20 percent or so in others, and just in</p> <p>17 terms of, I think, our common sense notion, in my</p> <p>18 patent class I teach one day on utility and it's a</p> <p>19 very straightforward test. I make a couple of</p> <p>20 points.</p> <p>21 Written description enablement is a</p> <p>22 four or five-day marathon with all kinds of</p> <p>23 complexities to it, so I just disagree with that.</p> <p>24 MS. CHEEK: In Professor Holbrook's</p> <p>25 Second Report, he discusses a new case, In re Glass,</p> <p>www.dianaburden.com</p>	<p>1 which is R-395, and is also at tab 5 of the direct</p> <p>2 binder, although I know you're familiar with the</p> <p>3 case. Professor Holbrook discussed this case at</p> <p>4 paragraphs 40 and 41 of his report.</p> <p>5 In particular, Professor Holbrook says</p> <p>6 In re Glass is "a clear example of where the U.S. PTO</p> <p>7 and Court refused to look at post-filing evidence."</p> <p>8 As to the admissibility of post-filing evidence, what</p> <p>9 is your view of In re Glass?</p> <p>10 PROFESSOR MERGES: Well, In re Glass</p> <p>11 is an enablement case, so it's not really relevant to</p> <p>12 utility. It's on a different topic.</p> <p>13 MS. CHEEK: Professor Merges, during</p> <p>14 this hearing witnesses have discussed utility and</p> <p>15 non-obviousness and the relationship, if any, between</p> <p>16 the two. Are utility and non-obviousness</p> <p>17 requirements related in the United States?</p> <p>18 PROFESSOR MERGES: No. Again, to use</p> <p>19 that visual metaphor, they're very different hurdles</p> <p>20 in the race and they're completely conceptually</p> <p>21 independent. Non-obviousness has to do with how</p> <p>22 significant your invention was compared to the prior</p> <p>23 art, whether you have presented an invention that's</p> <p>24 essentially non-trivial, and utility just has to do</p> <p>25 with whether or not your invention works. So, again,</p> <p>www.dianaburden.com</p>
<p>1301</p> <p>1 there are many inventions that work but which are</p> <p>2 completely anticipated or obvious in light of the</p> <p>3 prior art. They're very different requirements.</p> <p>4 MS. CHEEK: Under U.S. law, if a</p> <p>5 patentee asserts an advantage related to</p> <p>6 non-obviousness, does that have any bearing on the</p> <p>7 utility of the invention?</p> <p>8 PROFESSOR MERGES: No. There are a</p> <p>9 number of situations where an inventor might describe</p> <p>10 some advantages of an invention, and there are a</p> <p>11 number of reasons why they might do so. One of the</p> <p>12 topics that's been under discussion is the question</p> <p>13 of selection patents and the discussion of</p> <p>14 advantages, and in the selection patent context it's</p> <p>15 important to know that if the advantages, or even the</p> <p>16 lack of disadvantages, are not apparent or obvious to</p> <p>17 somebody skilled in the art, then that's a good</p> <p>18 ground for arguing that your selection patent is</p> <p>19 non-obvious. In other words, if you select a species</p> <p>20 out of a broad genus, it is sometimes very helpful to</p> <p>21 say in your specification -- that is to say in the</p> <p>22 written description part of your patent, not the</p> <p>23 claims -- it's sometimes helpful to say that this</p> <p>24 species has or is expected to have some advantageous</p> <p>25 properties, and that can lay the foundation for an</p> <p>www.dianaburden.com</p>	<p>1302</p> <p>1 argument that that selection of that particular</p> <p>2 species is non-obvious and is an improvement, even</p> <p>3 though it's a member of a prior disclosed and</p> <p>4 patented genus.</p> <p>5 That would be an example of where a</p> <p>6 statement of advantageous features would be made for</p> <p>7 purposes of non-obviousness. Again, those statements</p> <p>8 are irrelevant from the point of view of utility.</p> <p>9 Utility is measured by the claimed invention, not by</p> <p>10 statements about features and qualities that you</p> <p>11 might make in the written description. Is the</p> <p>12 claimed invention operable? Does it work? That's</p> <p>13 very different from there may be some advantages of</p> <p>14 this species chosen out from this broad class. Those</p> <p>15 are two completely different things.</p> <p>16 MS. CHEEK: Professor Merges,</p> <p>17 Professor Holbrook in his Second Report at paragraphs</p> <p>18 45 to 47 discusses two U.S. cases. One is Alice v</p> <p>19 CLS Bank, which is R-108. The other is Ariad v</p> <p>20 Lilly, which is R-99. Professor Holbrook says that</p> <p>21 your reports ignore the "dramatic impact" of these</p> <p>22 two cases and that in his view, these two cases,</p> <p>23 Alice and Ariad represent "significant changes" to</p> <p>24 U.S. patent law. I'd like to ask for your view on</p> <p>25 each of those cases. In the first instance do you</p> <p>www.dianaburden.com</p>

<p>1 agree with Professor Holbrook that Ariad v Lilly, 2 which is R-99, had a dramatic impact on U.S. patent 3 law? 4 PROFESSOR MERGES: The Ariad case 5 confirmed that section 112, disclosure requirement in 6 the U.S, has a separate component called "written 7 description" but that was a body of law that had been 8 developing for some years and Ariad just confirmed, 9 yes, this is a part of the statute. I don't think 10 that that represented anything like a dramatic 11 change. 12 How would you know? Again, look at 13 outcomes. Many cases that are decided after Ariad 14 might cite the written description requirement to 15 invalidate a patent, but those same cases probably 16 would have cited the enablement requirement before 17 the Ariad case. So we've moved a little among 18 doctrinal headings and that, of course, has an impact 19 to some degree on practitioners, who may have to 20 couch their arguments differently. 21 But what's the bottom line? How do 22 you tell if an area of law has changed? Outcomes. 23 Have they radically changed after Ariad? I don't 24 think so. The other was CLS Bank v Alice? 25 MS. CHEEK: Yes. I'll just go ahead</p> <p>www.dianaburden.com</p>	<p>1 and ask you a question on that as well. Do you agree 2 with Professor Holbrook that the Alice v CLS Bank 3 case had a dramatic impact on U.S. patent law? 4 PROFESSOR MERGES: Well, first of all, 5 it's important to say that the Alice case just came 6 down just about two years ago now, in 2014, and 7 that's not really enough time to judge dramatic 8 impact. The Alice case was I'll certainly say 9 noteworthy. The Alice case was an important case, 10 but I just don't think we have enough data. Now, the 11 early cases, post Alice, that applied that case and 12 its holding very strictly -- and, by the way, it was 13 a case about business methods or software. It was a 14 case about can you patent stuff like that. Can you 15 get a patent on a business method. Can you get a 16 patent on a business method as implemented in a 17 computer program. So that was the topic. 18 The cases that came out immediately 19 after seemed to apply that case and its holding very 20 rigorously, so there was a little bit of concern. 21 Wow, what's happening? But we've had some more 22 recent cases that push back against it and, as a 23 result, it's a little hard to say how things have 24 really changed and shaken out. I think there's a 25 scenario under which Alice might be an important case</p> <p>www.dianaburden.com</p>
<p>1 that changes the law, but I'm just not ready to say 2 that it's been a big shift as of today. 3 MS. CHEEK: In Professor Holbrook's 4 Second Report at paragraphs 13-22 he addresses the 5 reduction to practice requirement in U.S. law, and in 6 particular Professor Holbrook says at paragraph 13 7 that "reduction to practice requires demonstration 8 that an invention works," and then he goes on in 9 paragraph 19 and says, "Under Professor Merges' view 10 of the law, no such proof that the invention actually 11 worked would ever be required. The requirement for 12 reduction to practice shows he is wrong." 13 In your view, Professor Merges, is 14 that a fair description of the U.S. reduction to 15 practice rule? 16 PROFESSOR MERGES: No. Reduction to 17 practice, again, is about a very, very different 18 topic from the one that brings us here. It comes up 19 in a situation where you have two inventors, both of 20 whom have invented the same thing at more or less the 21 same time, and under the U.S. patent system, until 22 very recently, we had a priority rule that said the 23 first person to invent gets the patent. Now, it 24 turns out that invention is not a discrete event. 25 There's no Eureka moment at which the invention comes</p> <p>www.dianaburden.com</p>	<p>1 into being, so we break it down into stages. 2 Typically we talk about conception and then reduction 3 to practice. Then we have filing of a patent, 4 typically. 5 When you break it down into those 6 stages and you're fighting about patent priority, if 7 you are relying on an argument that involves 8 reduction to practice you do have to show that you 9 actually built an embodiment, but that's driven by 10 the requirement of that body of law. And, by the 11 way, there are two ways that you can meet the 12 reduction to practice requirement. One is that you 13 can show, with credible evidence from data, 14 supporting affidavits, witnesses, et cetera, "Yes, I 15 actually built the thing on date X." 16 The other way is you can show that "I 17 wrote up a fully enabling patent application and 18 filed it on date X," and that we call constructive 19 reduction to practice. So in the very doctrine 20 itself that we're talking about, it belies the idea 21 that you need to actually build something because 22 constructive reduction to practice doesn't require 23 that. A fully enabling patent application is the 24 logical equivalent of a built structure under patent 25 law. As a result, even within that doctrine it's not</p> <p>www.dianaburden.com</p>

<p>1 required that you actually make something or that you 2 actually construct something, and lots of cases turn 3 on constructive reduction to practice. 4 MS. CHEEK: Thank you, Professor 5 Merges. I have no further questions. 6 THE PRESIDENT: Thank you. Mr. Luz, 7 you are conducting the cross-examination for 8 Respondent? 9 MR. LUZ: Mr. President. 10 CROSS-EXAMINATION ON BEHALF OF THE RESPONDENT 11 MR. LUZ: Good morning, 12 Professor Merges. 13 PROFESSOR MERGES: Good morning. 14 MR. LUZ: My name is Mark Luz. I'm 15 senior counsel for the Government of Canada and I'll 16 be doing the cross-examination this morning, just 17 asking you a few questions about your expert opinions 18 in this arbitration. I'll try and ask them as 19 clearly as I can, but if there's a question you don't 20 understand, please go ahead and let me know and I'll 21 try and rephrase it. Is that alright? 22 PROFESSOR MERGES: Yes. 23 MR. LUZ: Do you have your expert 24 reports in front of you and the cross-examination 25 binder in front of you?</p> <p>www.dianaburden.com</p>	<p>1 PROFESSOR MERGES: Let's check that. 2 Yes. 3 MR. LUZ: I'll just get some 4 background questions first about your background and 5 expertise. You teach patent law at the University of 6 California Berkeley. Is that right? 7 PROFESSOR MERGES: Yes. 8 MR. LUZ: And are you called to the 9 Bar of California? 10 PROFESSOR MERGES: Yes. 11 MR. LUZ: Are you called to the Bar of 12 any other U.S. state? 13 PROFESSOR MERGES: No. 14 MR. LUZ: Are you called to the Bar of 15 any Canadian province? 16 PROFESSOR MERGES: No. 17 MR. LUZ: And are you admitted to 18 practice in front of any Canadian court? 19 PROFESSOR MERGES: No. 20 MR. LUZ: And you're not licensed to 21 provide legal advice on Canadian law? 22 PROFESSOR MERGES: Not in the way I 23 think you're asking. 24 MR. LUZ: You've never published an 25 article about Canadian patent law, have you?</p> <p>www.dianaburden.com</p>
<p>1309</p> <p>1 PROFESSOR MERGES: I might have cited 2 Canadian sources here and there, but I don't think 3 it's been the primary focus of anything. 4 MR. LUZ: We looked on Westlaw, we 5 didn't find any citations, but I'll take your word 6 that you may have done that at some point. 7 You've never published an article on 8 any other aspect of Canadian law? Canadian 9 evidentiary law, statutory interpretation, 10 constitutional law, anything in Canada? 11 PROFESSOR MERGES: I think nothing 12 specific to Canada, but I did write a book years ago 13 on the law and policy of outer space, and I think 14 some of the positions taken by the various Canadian 15 representatives to UN bodies on the Moon Treaty and 16 things like that, I think they probably came up 17 because there used to be a space law center at 18 McGill, and a number of experts were affiliated with 19 that. That would be the closest probably that I've 20 come. 21 MR. LUZ: As a McGill graduate, I'm 22 going to have to go and look up your book and read 23 all about it. 24 You have your expert reports with you? 25 PROFESSOR MERGES: Yes.</p> <p>www.dianaburden.com</p>	<p>1310</p> <p>1 MR. LUZ: You discuss in those expert 2 reports the Novopharm v Eli Lilly atomoxetine case 3 and the Lilly v Novopharm olanzapine cases in your 4 expert reports. Is that right? 5 PROFESSOR MERGES: Yes. Do you want 6 to refer to a specific paragraph? 7 MR. LUZ: Sure. If you go to 8 paragraph 44 of your First Report, you talk about 9 olanzapine, and you cite at footnote 57, Eli Lilly 10 Canada Inc. v Novopharm 2011 FC 1288, Exhibit C-146. 11 You see that? 12 PROFESSOR MERGES: Yes. 13 MR. LUZ: With respect to atomoxetine, 14 if you flip back to paragraph 36, here you discuss 15 the Canadian Federal Court decision invalidating Eli 16 Lilly's Canadian atomoxetine, Strattera patent, and 17 you go on to quote from the Court in footnote 47 -- I 18 should say it's actually cited in footnote 46 where 19 you write Novopharm Ltd v Eli Lilly & Co 2010 FC 915, 20 Exhibit C-160. You see that? 21 PROFESSOR MERGES: Yes. 22 MR. LUZ: Then in paragraph 38 you 23 refer to the Federal Court of Appeal judgment in 24 Novopharm v Eli Lilly & Co. You can see the citation 25 at footnote 50, Novopharm Ltd v Eli Lilly & Co, 2011</p> <p>www.dianaburden.com</p>

<p>1 FCA 220 (2011) (Exhibit C-163). You see that?</p> <p>2 PROFESSOR MERGES: Yes.</p> <p>3 MR. LUZ: Other than those three court</p> <p>4 judgments, do you cite any other Canadian patent law</p> <p>5 judgments in either of your expert reports?</p> <p>6 PROFESSOR MERGES: What do you mean by</p> <p>7 "patent law judgments"?</p> <p>8 MR. LUZ: Any Canadian court judgments</p> <p>9 other than the three that we just referred to? I</p> <p>10 could rephrase it. Is it not true that there are no</p> <p>11 other Canadian case law judgments cited in either one</p> <p>12 of your reports?</p> <p>13 PROFESSOR MERGES: Let's take a quick</p> <p>14 flip through to make sure.</p> <p>15 MR. LUZ: It may take a little while</p> <p>16 to look through, but I was unable to find any. And</p> <p>17 if you don't recall any?</p> <p>18 PROFESSOR MERGES: I don't recall any.</p> <p>19 That's why I was looking.</p> <p>20 MR. LUZ: Then I'll also rephrase this</p> <p>21 in the form of a question. Do you cite any other</p> <p>22 Canadian patent law academic articles or books in</p> <p>23 either of your expert reports?</p> <p>24 MS. CHEEK: Excuse me, Mr. President.</p> <p>25 We've put forward Professor Merges as an expert on</p> <p>www.dianaburden.com</p>	<p>1 U.S. patent law, so I'm not sure the relevance of</p> <p>2 your line of questioning.</p> <p>3 MR. LUZ: I'm just trying to establish</p> <p>4 there's no explanation in his expert reports of where</p> <p>5 he got his understanding of Canadian law other than</p> <p>6 the three judgments. I'm trying to establish what</p> <p>7 that comes from. We don't have to go through his</p> <p>8 expert reports because I can confirm that there are</p> <p>9 no Canadian case law sources or academic texts in</p> <p>10 either one.</p> <p>11 THE PRESIDENT: It makes the</p> <p>12 comparison. Overruled. You have to answer the</p> <p>13 question, Professor.</p> <p>14 MR. LUZ: You don't cite any Canadian</p> <p>15 patent law, academic texts or books in either one of</p> <p>16 your reports, do you?</p> <p>17 PROFESSOR MERGES: Not that I</p> <p>18 remember. I don't think so.</p> <p>19 MR. LUZ: And you don't even cite the</p> <p>20 Canadian Patent Act in either one of your reports, do</p> <p>21 you?</p> <p>22 PROFESSOR MERGES: It's cited in the</p> <p>23 cases that I read.</p> <p>24 MR. LUZ: And did you read any of the</p> <p>25 cases that were cited in the three judgments that you</p> <p>www.dianaburden.com</p>
<p>1313</p> <p>1 read?</p> <p>2 PROFESSOR MERGES: I certainly read</p> <p>3 the counterpart cases in the U.S, read the patents,</p> <p>4 some of the studies that were cited in the patents.</p> <p>5 MR. LUZ: But at this time you don't</p> <p>6 recall reading any of those cases from your</p> <p>7 recollection?</p> <p>8 PROFESSOR MERGES: I'm trying to</p> <p>9 remember. I certainly haven't made an extensive</p> <p>10 canvass of Canadian cases, but I read the cases in</p> <p>11 front of me carefully.</p> <p>12 MR. LUZ: Thank you.</p> <p>13 In your reports you don't give your</p> <p>14 personal opinion as to the timing of when the</p> <p>15 Canadian promise utility doctrine, as it is called,</p> <p>16 emerged in Canadian law, do you?</p> <p>17 PROFESSOR MERGES: So what do you mean</p> <p>18 exactly by "timing"?</p> <p>19 MR. LUZ: As to whether or not -- you</p> <p>20 don't make any -- you don't offer an opinion as to</p> <p>21 whether or not the promise utility doctrine is new,</p> <p>22 old, you give no view on its timing and emergence in</p> <p>23 Canadian law?</p> <p>24 PROFESSOR MERGES: The contrast is</p> <p>25 between traditional accepted principles of utility</p> <p>www.dianaburden.com</p>	<p>1314</p> <p>1 and what I read in the cases characterizing it as the</p> <p>2 promise utility doctrine.</p> <p>3 MR. LUZ: I'm sorry, I didn't</p> <p>4 understand that. You don't offer an opinion as to</p> <p>5 the timing of the emergence of the promise utility</p> <p>6 doctrine in Canadian jurisprudence, do you?</p> <p>7 PROFESSOR MERGES: The precise date on</p> <p>8 which the promise utility doctrine was born or</p> <p>9 created? That's what you're asking?</p> <p>10 MR. LUZ: Right.</p> <p>11 PROFESSOR MERGES: The answer to that</p> <p>12 is no.</p> <p>13 MR. LUZ: And you don't give your</p> <p>14 personal opinion as to whether or not the promise</p> <p>15 doctrine is grounded in Canadian jurisprudence or</p> <p>16 patent law scholarship?</p> <p>17 PROFESSOR MERGES: Most of my</p> <p>18 statements are about the soundness of doctrine</p> <p>19 per se.</p> <p>20 MR. LUZ: So the answer to my last</p> <p>21 question is no?</p> <p>22 PROFESSOR MERGES: Yes, I did not</p> <p>23 canvass Canadian academic works or secondary</p> <p>24 authorities. I just applied the traditional, classic</p> <p>25 rule of utility and compared it to what I read in the</p> <p>www.dianaburden.com</p>

<p>1 Canadian cases. 2 MR. LUZ: The traditional, classic 3 rule of utility as understood in the United States? 4 PROFESSOR MERGES: As understood 5 worldwide, as evidenced by the fact, for example, 6 that the olanzapine patent was filed in 81 7 jurisdictions and there was only one out of 81 that 8 had a problem with utility. 9 MR. LUZ: You're appearing here as an 10 expert on United States law. Is that right? 11 PROFESSOR MERGES: Yes. 12 MR. LUZ: Not Canadian law? 13 PROFESSOR MERGES: In my role I felt 14 it necessary to make comparative points between U.S. 15 law and some Canadian cases. 16 MR. LUZ: I'll ask the question again. 17 You're appearing here as an expert on U.S. law and 18 not Canadian law? 19 PROFESSOR MERGES: That is my role, an 20 expert on U.S. law. 21 MR. LUZ: And you're appearing here as 22 an expert on U.S. law, not on international law? 23 THE PRESIDENT: Mr. Luz, it is not 24 international law but comparative law. That's the 25 question.</p> <p>www.dianaburden.com</p>	<p>1 MR. LUZ: Yes, or I could correct it 2 to say public international law. 3 THE PRESIDENT: If you go in that 4 direction, then we are in another field now. 5 MR. LUZ: I'll move on from this. 6 Could you get your First Report and go 7 to paragraph 10? Do you have it there? 8 PROFESSOR MERGES: Yes. 9 MR. LUZ: So under the heading "U.S. 10 Patentability Requirements" you say that "An 11 invention must be useful, novel and non-obvious to 12 qualify for a U.S. patent." You see that, right? 13 PROFESSOR MERGES: Yes. Sentence 1, 14 paragraph 10. 15 MR. LUZ: You refer to 35 U.S.C 16 sections 101, 102, 103. Those are the relevant 17 sections of the U.S. Patent Act, U.S. Code? 18 PROFESSOR MERGES: Yes. 19 MR. LUZ: In the second sentence you 20 say, "It must also be adequately disclosed." Section 21 12. I think that's what you referred to earlier this 22 morning as to enablement and written description 23 requirements? 24 PROFESSOR MERGES: The proper cite is 25 section 112.</p> <p>www.dianaburden.com</p>
<p>1317</p> <p>1 MR. LUZ: Sorry, did I not say that? 2 PROFESSOR MERGES: Maybe I misheard. 3 MR. LUZ: I apologize. Section 112. 4 I want to come back to specific parts 5 of the patentability requirements in a moment, but 6 let's step back for a second to talk about basic 7 nature of patent rights. The Patent Office in the 8 United States gets tens of thousands of patent 9 applications every year, right? 10 PROFESSOR MERGES: Yes, hundreds of 11 thousands. 12 MR. LUZ: So examiners only have 13 limited time and resources to expect those patent 14 applications. Is that right? 15 PROFESSOR MERGES: Yes. 16 MR. LUZ: So when a patent is issued, 17 there's a statutory presumption of validity. Is that 18 right? 19 PROFESSOR MERGES: Yes. 20 MR. LUZ: And patentees know that, if 21 the patent is challenged later on in litigation, a 22 court may declare the patent to be invalid. Is that 23 right? 24 PROFESSOR MERGES: Yes. Invalidity is 25 specifically listed as a defense to patent</p> <p>www.dianaburden.com</p>	<p>1318</p> <p>1 infringement in the statute. 2 MR. LUZ: So, even though a patent has 3 been issued and it is presumed valid, if a court 4 finds that it does not meet the various requirements 5 that we discussed -- enablement, written description, 6 utility -- it can be declared invalid by a court? 7 PROFESSOR MERGES: Yes. 8 MR. LUZ: So the question of ultimate 9 validity or invalidity is determined by a court? 10 PROFESSOR MERGES: That's not quite 11 accurate. 12 MR. LUZ: How so, if you can clarify? 13 PROFESSOR MERGES: When you say "the 14 ultimate," one interpretation of that is the last in 15 time, and for many patent applications the examiner's 16 decision is the ultimate decision because the 17 applicant decides not to pursue the case further. In 18 a second set of cases, the applicant decides to 19 appeal the examiner's rejection, and so in those 20 cases the ultimate decision might be an 21 administrative tribunal called the Patent Trial and 22 Appeal Board, and in yet a third class of cases an 23 already issued patent can be submitted to the same 24 administrative court under an administrative 25 procedure called an inter partes review, and under</p> <p>www.dianaburden.com</p>

<p>1 that procedure the patent can be declared invalid. 2 So there are a number of ways that the "ultimate" 3 decision on validity will fall to an organization 4 other than the court. 5 MR. LUZ: You once wrote and described 6 the uncertainty regarding patent rights in the 7 following way: that all patents are probabilistic 8 rights until the last court has spoken. Do you 9 remember writing that? 10 PROFESSOR MERGES: You'll have to 11 point me to that reference. It rings a bell but that 12 one's not coming to mind. 13 MR. LUZ: Page 5 of your first Expert 14 Report. Do you have it there? 15 PROFESSOR MERGES: Yes. 16 MR. LUZ: Look at paragraph 8. 17 There's an article cited to yourself along with some 18 of your co-authors titled High Technology 19 Entrepreneurs and the Patent System. That's C-270. 20 It's tab 6 in your binder. It's a 2009 article of 21 yours. If you turn page 1315. 22 PROFESSOR MERGES: Yes, 1315. 23 MR. LUZ: Under the heading 24 "Technology entrepreneurs must reckon with patents 25 held by others," the last paragraph there where it</p> <p>www.dianaburden.com</p>	<p>1 starts off with "Another downside of patents in a 2 startup's competitive environment is the threat of 3 patent disputes and, when negotiation fails, costly 4 litigation." You see that paragraph? 5 PROFESSOR MERGES: Yes. 6 MR. LUZ: And then about halfway down 7 or closer to the end, "These accusations of 8 infringement are particularly problematic when the 9 underlying patent being wielded against the startup 10 is more likely than not invalid." And there's a 11 footnote and you write: "All patents are 12 probabilistic rights until the last court has 13 spoken." Do you see that? 14 PROFESSOR MERGES: Yes, but let me 15 give this some context now. I think you started 16 reading from the word "accusations of infringement." 17 Am I right about that? 18 MR. LUZ: Yes. 19 PROFESSOR MERGES: Remember now, the 20 sentence begins -- 21 MR. LUZ: "These accusations" -- 22 THE PRESIDENT: Could you start again 23 your answer? You are saying "You pointed to 24 accusations and said no, it should read these 25 accusations." Please repeat your answer because the</p> <p>www.dianaburden.com</p>
<p>1 court reporters didn't catch it. 2 PROFESSOR MERGES: Okay. I was 3 referring to the fact that this is a paragraph about 4 a particular set of accusations. It's about a 5 particular type of patent litigation here, so we're 6 talking here about a situation where a start-up 7 company might confront a patent litigation typically 8 early in its history, and as part of our survey we 9 wanted to know what the experience of the survey 10 companies was in that context, so it's important to 11 give that because this is not a blanket discussion of 12 all patent litigation. It's a subset of cases 13 involving one subset of patentees. So the patentee 14 subset is start-up companies and the subset of cases 15 is cases where the start-ups have been threatened 16 with a patent, typically from a big incumbent, you 17 know, an existing company. So I just wanted to give 18 that as context here. 19 MR. LUZ: So when you write that all 20 probabilistic patents -- 21 THE PRESIDENT: All patents. 22 MR. LUZ: Sorry, "All patents are 23 probabilistic rights until the last court has spoken" 24 and you cite to an article by Mark Lemley and 25 Carl Shapiro probabilistic patents, which we will get</p> <p>www.dianaburden.com</p>	<p>1 to in just a second. Mark Lemley is one of your 2 co-authors of a book that you wrote, Intellectual 3 Property in the New Technological Age? 4 PROFESSOR MERGES: That's one of the 5 books we co-authored. There's two others. 6 MR. LUZ: So, just before we get to 7 that article and probabilistic rights until the last 8 court has spoken, let me put to you a few questions. 9 Most patents are never ultimately litigated. Is that 10 right? Thousands are issued -- tens of thousands are 11 issued every year. Most of them never end up in 12 court. 13 PROFESSOR MERGES: True. 14 MR. LUZ: And litigation is more 15 likely when a patent is commercially valuable, right? 16 There's not much point in going to litigation unless 17 there's high stakes involved. 18 PROFESSOR MERGES: That's not 19 completely true. There are multiple reasons why 20 companies engage in patent litigation. 21 Unfortunately, sometimes the patents are not 22 particularly valuable. They may be initiating 23 litigation simply to try to negotiate a settlement 24 and, in fact, the patents are not very valuable. 25 They may be using patent litigation for strategic</p> <p>www.dianaburden.com</p>

<p>1 purposes to slow down a new entrant or to sort of 2 harass a competitor. There's a lot of different 3 scenarios under which patents are litigated. 4 MR. LUZ: But if it does make it all 5 the way to litigation and the parties don't settle, 6 either on the courthouse steps or beforehand, the 7 risk that a patent will be declared invalid is 8 substantial, isn't it? 9 PROFESSOR MERGES: That really depends 10 on the case. For example, in a situation where a 11 patent has already been validated and challenged in 12 an administrative tribunal, there's a very strong 13 sense that that patent is going to be very hard to 14 invalidate. There are also patents that have been 15 tested in prior litigation and survived a number of 16 invalidity challenges. So it's a very, very fact 17 specific inquiry when you're asking what is the risk 18 of a particular patent invalidation. It's very 19 specific. 20 MR. LUZ: Before we get to that 21 article I just want to pick up on something you just 22 said. You said that -- I'm sorry, that at the 23 Patent Office inter partes review, if a patent is -- 24 I don't think you said declared invalid, but -- 25 PROFESSOR MERGES: I was making the</p> <p>www.dianaburden.com</p>	<p>1 opposite statement. Where its validity has been 2 affirmed. 3 THE PRESIDENT: Let Mr. Luz first 4 finish his question. 5 MR. LUZ: Could you explain that last 6 point as to why at the Patent Office or the 7 administrative review of a patent it may not get to 8 litigation because the incentives are opposite? 9 MS. CHEEK: I'm sorry, what's the 10 question? 11 MR. LUZ: I'll skip that line of 12 questioning. We'll come back to it at some point. 13 Let's turn to the article, 14 probabilistic rights. That is tab 3 in your binder 15 which is R-473. Probabilistic Patents. Turn to 16 page 76. 17 I'll read you a couple of paragraphs 18 from this article that you had cited when you wrote 19 that "patents are probabilistic rights until the last 20 court has spoken," and then I'll ask you some 21 questions about that, if that's okay? 22 It starts off on page 76, "The risk 23 that a patent will be declared invalid is 24 substantial. Roughly half of all litigated patents 25 are found to be invalid, including some of great</p> <p>www.dianaburden.com</p>
<p>1325</p> <p>1 commercial significance." It goes on to give a 2 couple of examples including the U.S. Court of 3 Appeals for the Federal Circuit invalidation of Eli 4 Lilly's patent on Prozac in 2000. 5 The second paragraph starts off with: 6 "Virtually all property rights contain some element 7 of uncertainty." Then halfway through the paragraph, 8 so we don't have to bore everyone with the whole 9 thing, "But the uncertainty associated with patents 10 is especially striking, and indeed is fundamental to 11 understanding the effects of patents on innovation 12 and competition." You see that? 13 PROFESSOR MERGES: Yes, I see that 14 sentence. 15 MR. LUZ: Then at the bottom of that 16 same paragraph: "Uncertainty about validity and 17 scope are critical when studying the enforcement and 18 litigation of patents." 19 If you flip down to the last page of 20 that article, which is page 95, the Conclusion, you 21 see that under the heading "Conclusion"? 22 PROFESSOR MERGES: Yes. 23 MR. LUZ: I'll read some of this and 24 ask you some questions about it. "The patent system 25 does not grant an absolute right to inventors to</p> <p>www.dianaburden.com</p>	<p>1326</p> <p>1 exclude others from practicing their inventions, as 2 many economic models assume. Rather, the patent 3 system gives the patent holder a right to try to 4 exclude others by asserting its patent against them 5 in court. The actual scope of a patent right, and 6 even whether the right will withstand litigation at 7 all, are uncertain and contingent questions. This 8 uncertainty is not an accident or mistake. Rather, 9 it is an inherent part of our patent system, an 10 accommodation to the hundreds of thousands of patent 11 applications filed each year, the inability of third 12 parties to participate effectively in determining 13 whether a patent should issue, and the fact that for 14 the vast majority of issued patents, scope and 15 validity are of little or no commercial 16 significance." 17 So when you wrote "all" -- I don't 18 want to misquote -- "all patents are probabilistic 19 rights until the last court has spoken," I think this 20 is what you mean. You get a presumption of validity 21 when you get your patent. Is that right? 22 PROFESSOR MERGES: I think we covered 23 that, yes. 24 MR. LUZ: But you don't have an 25 assurance of validity?</p> <p>www.dianaburden.com</p>

<p>1 PROFESSOR MERGES: If I get the 2 question right, you mean when the patent is issued? 3 MR. LUZ: That's right. 4 PROFESSOR MERGES: This is the moment 5 of issuance? 6 MR. LUZ: Right. 7 PROFESSOR MERGES: There's no 8 guarantee. 9 MR. LUZ: And there's also no 10 guarantee that over the course of the life of the 11 patent the laws are not going to develop over the 12 course of the life of that patent. Is that right? 13 PROFESSOR MERGES: I wouldn't quite go 14 that far. 15 MR. LUZ: Let's talk about -- 16 PROFESSOR MERGES: I can give you an 17 example? 18 MR. LUZ: Sure, go ahead. 19 PROFESSOR MERGES: Just, for example, 20 under our takings jurisprudence, under the 5th 21 Amendment of our Constitution, it is possible to 22 argue that an extremely radical change in patent 23 doctrine would amount to what's known as a regulatory 24 taking, and that would be a kind of significant 25 change in the law which would require compensation to</p> <p>www.dianaburden.com</p>	<p>1 all patentees. The upshot of that is that in a sense 2 that's one risk that patentees do not assume, the 3 risk of a radical change that goes to the level of a 4 taking. 5 So, just to be clear, that's an 6 example where your legitimate, as they say, 7 investment-backed expectations would be recognized by 8 the law. So I think the broader point is that it's 9 not the case that all patents are fraught with 10 massive risk of legal change and it's just a complete 11 crap shoot. That's kind of what you're saying and I 12 wouldn't go that far. 13 MR. LUZ: You said under takings 14 jurisprudence it's possible to argue. Has there ever 15 been a case in the United States where an invalidated 16 patent -- the U.S. government has been ordered to pay 17 compensation under the U.S. takings clause? 18 PROFESSOR MERGES: There have been 19 some cases involving seizures of patents in the old 20 days, and there's a case not too long ago involving 21 the mandated disclosure of a trade secret which said 22 that the trade secret has the status of property, and 23 so a lot of scholars assume that if a trade secret is 24 considered property by the Supreme Court, then 25 certainly a patent which is named as a property right</p> <p>www.dianaburden.com</p>
<p>1329</p> <p>1 in the patent statute says it shall have the 2 attributes of personal property. That would surely 3 be treated as a property right. So possibly by 4 extension. 5 MR. LUZ: But has there been a case 6 that a court has invalidated a patent and the U.S. 7 government has been ordered to pay compensation under 8 the takings clause because of the judicial 9 invalidation of a patent? 10 PROFESSOR MERGES: I think it would 11 take a really significant change in the law for that 12 to happen. Something along the lines of increasing 13 invalidity from zero percent to 40 percent in some 14 category. Something really significant like that. 15 MR. LUZ: Thank you. You talked in 16 your opening presentation about the common law 17 tradition in patent law. You did talk about it for 18 utility and I think you were probably inspired by 19 your textbook which you cite a few times in your 20 Expert Report. Let's take a look at tab 7 of your 21 binder. I should just note for the record the pages 22 are from CE-272 and R-56. Both parties liked your 23 textbook so much that we both cited different pages, 24 so just for convenience in the binder we have merged 25 them together.</p> <p>www.dianaburden.com</p>	<p>1330</p> <p>1 Turn to page 209, the second 2 paragraph. Can you read that second paragraph? 3 PROFESSOR MERGES: -- I never read my 4 book while I'm teaching, by the way. 5 MR. LUZ: I'm happy to read it. I 6 don't want you to get bored listening to me ask 7 questions. 8 PROFESSOR MERGES: I think it might 9 have a dramatic flourish. "Two statutory provisions 10 form the basis for the utility requirement. The 11 first is section 101 which, as discussed in Chapter 12 2, descends directly from language authored by Thomas 13 Jefferson and enacted into law in 1793. Section 101 14 explicitly requires that inventions be 'useful' in 15 order to receive patent protection. The second 16 statutory basis is section 112 which requires a 17 patent applicant to disclose 'the manner and process 18 of making and using (the invention)'. Thus, the 19 utility requirement is founded upon a mere two words 20 in the statute. [useful and using] As with 21 patentable subject matter, the law of utility has 22 been developed largely by the courts in a common law 23 fashion, without detailed guidance from Congress." 24 MR. LUZ: Thank you. I'll come back 25 to utility in section 101 and 112 in a second but</p> <p>www.dianaburden.com</p>

<p>1 that last sentence that the law of utility -- and, as 2 you said this morning, patent law generally has 3 developed largely by the courts in a common law 4 fashion -- you say the common law tradition in 5 developing patent law, that means judicial precedent 6 develops over years, decades and so on based on 7 accumulating cases that appear before the courts. Is 8 that right? Is that what you mean?</p> <p>9 PROFESSOR MERGES: As the common law 10 rule, the stable rule, is applied to new fact 11 situations, we have common law development.</p> <p>12 MR. LUZ: So sometimes judicial 13 interpretations can be developed slowly -- slowly or 14 more rapidly depending on the volume of cases that 15 come before the courts, the type of cases, the 16 specific issues before the courts. Is that right?</p> <p>17 PROFESSOR MERGES: I just didn't quite 18 catch the first -- judicial something? I missed it.</p> <p>19 MR. LUZ: Case law can develop 20 sometimes slowly, sometimes quickly depending on the 21 kinds of cases that are coming before the courts. 22 Would you agree with that?</p> <p>23 PROFESSOR MERGES: Yes. The volume of 24 case law can vary in particular doctrinal areas, 25 given external developments.</p> <p>www.dianaburden.com</p>	<p>1 MR. LUZ: And, as is the common law 2 tradition, courts look back to their jurisprudence, 3 sometimes recent jurisprudence, sometimes old 4 jurisprudence, to develop the law. Is that right?</p> <p>5 PROFESSOR MERGES: Certainly they 6 sometimes cite older cases to apply the basic rules 7 to new facts, I would say that.</p> <p>8 MR. LUZ: You talked about the written 9 description requirement in your opening presentation 10 this morning, so let's go to that because I think 11 that's a good example of the common law tradition 12 developing. Turn to paragraph 15 of your first 13 Expert Report. Do you have it?</p> <p>14 PROFESSOR MERGES: I'm getting there. 15 Yes.</p> <p>16 MR. LUZ: Paragraph 15 starts off with 17 "Section 112(a) ensures adequate disclosure of an 18 invention. It contains two distinct requirements, 19 enablement and written description." You see that?</p> <p>20 PROFESSOR MERGES: Yes.</p> <p>21 MR. LUZ: But the view that 22 section 112 contains a written description 23 requirement that is separate and distinct from 24 enablement is a new development in U.S. case law, 25 isn't it?</p> <p>www.dianaburden.com</p>
<p>1333</p> <p>1 PROFESSOR MERGES: How are you 2 defining "new"?</p> <p>3 MR. LUZ: Well, it wasn't until the 4 late 1990s that the courts resuscitated the doctrine 5 from past jurisprudence and now applied as an 6 independent and stiff basis for invalidity of 7 patents.</p> <p>8 PROFESSOR MERGES: Do you have a 9 source for that?</p> <p>10 MR. LUZ: I do. Let's go back to your 11 textbook. Tab 7.</p> <p>12 PROFESSOR MERGES: Yes.</p> <p>13 MR. LUZ: Pages 291 to 292. I'll just 14 note again it's Exhibit C-272 and R-56. Just before 15 we go through this, written description manifests 16 itself when patent applicants amend their 17 specifications adding new distinctions to narrow 18 their claims, right?</p> <p>19 PROFESSOR MERGES: No.</p> <p>20 MR. LUZ: It might come into play when 21 you claim too broadly?</p> <p>22 PROFESSOR MERGES: That's more 23 accurate. The correction is it doesn't apply only 24 when you amend your claims.</p> <p>25 MR. LUZ: Understood.</p> <p>www.dianaburden.com</p>	<p>1334</p> <p>1 So, starting at page 291, you start 2 off here that "The idea of a more rigorous written 3 description doctrine" -- and we'll put this into 4 place, into context, just as we read, so just bear 5 with me for a moment because I'll read something, 6 then I'll ask you to read something, then I'll ask 7 you some questions based on what you've written here 8 -- "The idea of a more rigorous written description 9 doctrine seems to have taken root in a judicial 10 desire to rein in the free and easy ways of patent 11 drafters. The particular object of the judges' 12 displeasure was amendment practice. Patent lawyers 13 are adept at filing a patent application that broadly 14 (if sometimes vaguely) describes an invention but 15 that also includes many possible permutations of the 16 general invention."</p> <p>17 Let's skip down to the last paragraph 18 on that page. It says, "This type of practice is a 19 standard... gamesmanship that lawyers have long 20 tried. When the competitor's product is particularly 21 innovative compared to the originally claimed 22 invention, this practice may be described as 23 'misappropriation by amendment'." And you cite an 24 article that you wrote. The next sentence, "The 25 practice could be curtailed." Do you mind reading</p> <p>www.dianaburden.com</p>

<p>1 from that point, "the practice could be curtailed,"</p> <p>2 and over to 292 until the paragraph ends?</p> <p>3 MS. CHEEK: Excuse me, Mr. President.</p> <p>4 Certainly Mr. Luz has every right to establish the</p> <p>5 foundation for his questions but since he's the</p> <p>6 question asker, perhaps we wouldn't need to have</p> <p>7 Mr. Merges be the reader.</p> <p>8 MR. LUZ: I'm happy to read it.</p> <p>9 THE PRESIDENT: Sustained. If you</p> <p>10 need more time to read your own work, please say so.</p> <p>11 PROFESSOR MERGES: Did you ask me</p> <p>12 whether I need more time to read it?</p> <p>13 THE PRESIDENT: Yes, and read it in</p> <p>14 context, if you want to read pages 291, 292. You</p> <p>15 don't need to read it aloud.</p> <p>16 PROFESSOR MERGES: Okay.</p> <p>17 MR. LUZ: I'm happy to read it.</p> <p>18 THE PRESIDENT: No, it's not</p> <p>19 necessary. We can read, too.</p> <p>20 MR. LUZ: No, I'll read it and then</p> <p>21 I'll ask you some questions about --</p> <p>22 THE PRESIDENT: Professor Merges, have</p> <p>23 you had sufficient time to refamiliarize yourself</p> <p>24 with what you wrote?</p> <p>25 PROFESSOR MERGES: Not quite.</p> <p>www.dianaburden.com</p>	<p>1 THE PRESIDENT: Please take your time.</p> <p>2 PROFESSOR MERGES: Okay, because this</p> <p>3 is a long chapter here.</p> <p>4 THE PRESIDENT: Simply start for</p> <p>5 yourself to read 291 and go to 292, and then, I</p> <p>6 suggest, Mr. Luz you ask your question. Tell us when</p> <p>7 you are finished, Professor Merges. (Pause)</p> <p>8 PROFESSOR MERGES: Okay. I'm there.</p> <p>9 MR. LUZ: I'll read this last part and</p> <p>10 then I'll ask you some questions about this. "The</p> <p>11 practice" -- and we're referring to misappropriation</p> <p>12 by amendment -- "The practice could be curtailed by</p> <p>13 adjustments to a number of different patent</p> <p>14 doctrines, including imposing a more rigorous</p> <p>15 non-obviousness requirement, demanding a greater</p> <p>16 degree of enablement and interpreting claims more</p> <p>17 narrowly. Nevertheless, although the Federal Circuit</p> <p>18 seems to have been bothered by the misappropriation</p> <p>19 by amendment practice, the court did not attack the</p> <p>20 practice with the obviousness, enablement or</p> <p>21 infringement doctrines. Instead, the court rooted</p> <p>22 around in the treasure chest of minor and discarded</p> <p>23 doctrines and came up with what it thought was an</p> <p>24 overlooked gem." So the first obvious question is</p> <p>25 there's not actually a treasure chest of doctrine up</p> <p>www.dianaburden.com</p>
<p>1337</p> <p>1 in the attic where the courts root around for</p> <p>2 doctrines. It's just a figure of speech you're</p> <p>3 using?</p> <p>4 PROFESSOR MERGES: I think you know</p> <p>5 the answer to that. It's something referred to as a</p> <p>6 metaphor. Some writers use them, some don't.</p> <p>7 MR. LUZ: You suggest here that the</p> <p>8 court had other options to deal with the problem that</p> <p>9 they faced -- to deal with claim amendments and</p> <p>10 overbroad claims. They could have dealt with</p> <p>11 enablement or obviousness but, instead, they -- as</p> <p>12 you used the metaphor -- came up with an overlooked</p> <p>13 gem from old and discarded doctrines. Is that right?</p> <p>14 So the court had options, different ways of dealing</p> <p>15 with the problem that they faced.</p> <p>16 PROFESSOR MERGES: Yes. I'm talking</p> <p>17 about how they chose, as I say, to attack this</p> <p>18 practice.</p> <p>19 MR. LUZ: Then you say further down on</p> <p>20 292 that, "Early cases reveal a certain amount of</p> <p>21 judicial trepidation over the doctrine." You go on</p> <p>22 to write, "The written description holding was often</p> <p>23 stated almost in the alternative, with the</p> <p>24 aforementioned new matter rule, or traditional</p> <p>25 enablement requirement, bearing at least part of the</p> <p>www.dianaburden.com</p>	<p>1338</p> <p>1 decisional weight. And almost every opinion relying</p> <p>2 on written description requirement elicited a</p> <p>3 strenuous dissent emphasizing either the</p> <p>4 requirement's redundancy or its lack of clarity... It</p> <p>5 is therefore no surprise that the written description</p> <p>6 requirement, having met with a cool reception, had</p> <p>7 faded almost completely from subsequent decisions in</p> <p>8 the late '70s and 1980s."</p> <p>9 You go on: "Not for good, however.</p> <p>10 Beginning in the late 1990s, the Federal Circuit</p> <p>11 resuscitated the doctrine. First sparingly, and with</p> <p>12 increasing frequency as of late, the court has</p> <p>13 pointedly deployed 'written description' as an</p> <p>14 independent, and often very stiff, requirement."</p> <p>15 As you alluded to there is long case</p> <p>16 history but it had disappeared for a number of</p> <p>17 decades and only re-emerged in the late 1990s. Is</p> <p>18 that right?</p> <p>19 PROFESSOR MERGES: When you say "long"</p> <p>20 now, the first citation on 292 is to a case from</p> <p>21 1971.</p> <p>22 MR. LUZ: But again, it had -- as a</p> <p>23 separate requirement from enablement, distinct from</p> <p>24 enablement, that is a recent development in U.S. law?</p> <p>25 PROFESSOR MERGES: I wouldn't quite go</p> <p>www.dianaburden.com</p>

<p>1 that far. There were antecedents and early instances 2 of it. The article I cite by Professor Mark Janis at 3 the top of 291 talks about its "humble" origins, and 4 in that line of work he and others had traced back to 5 some of its, you might say, early glimmerings, I 6 would say.</p> <p>7 MR. LUZ: Can you turn to tab 14?</p> <p>8 PROFESSOR MERGES: Could I add one 9 point about page 292? I said there that "as of late" 10 it's become a very stiff requirement, and I was 11 referring of course to cases right about the time 12 that I was writing this, what I would call sort of 13 one of these minor perturbations. The ultimate test 14 always is outcomes, and the incidence of invalidity 15 under section 112 has not changed fundamentally since 16 the written description doctrine has been talked 17 about more. I just want to make that clear.</p> <p>18 MR. LUZ: Turn to tab 14, Exhibit 19 R-120. This is a book by Janice Mueller, Patent Law. 20 Page 153, Federal Circuit's Expansion of the Written 21 Description Requirement. "Beginning in 1997 with 22 Regents of the University of California v 23 Eli Lilly & Co, the Federal Circuit has expanded 24 written description of the invention analysis to 25 consider the validity of unamended originally filed</p> <p>www.dianaburden.com</p>	<p>1 claims, (i.e. claims presented in a patent 2 application when it was filed and not amended 3 thereafter). In the view of this author, this is an 4 anomalous application of written description 5 principles, contrary to binding precedent. 6 Nevertheless, the Federal Circuit adopted this view 7 en banc in its 2010 Ariad decision, so Ariad 8 represents the controlling law unless and until the 9 Supreme Court were to overrule it."</p> <p>10 You talked about Ariad this morning 11 during your opening statement. Is that right?</p> <p>12 PROFESSOR MERGES: Yes, it was one of 13 the questions on direct.</p> <p>14 MR. LUZ: So, according to at least 15 one esteemed author, this was definitely an emergence 16 starting in 1997 with one case and in her view -- her 17 view -- contrary to binding precedent, but she 18 acknowledges that's the law until the Supreme Court 19 says otherwise. Is that right?</p> <p>20 PROFESSOR MERGES: That is Janice, 21 yes, stating her view, in the view of this author, 22 yes. That's Janice's view.</p> <p>23 MR. LUZ: Let's look at the actual 24 case, Ariad, which you talked about earlier this 25 morning in your opening, tab 8. This is R-120, the</p> <p>www.dianaburden.com</p>
<p>1341</p> <p>1 actual Ariad judgment. Now, as you said this 2 morning, this was -- and as reflecting what we just 3 read, this was a case involving Eli Lilly with gene 4 fragments -- well, you know the case very well, you 5 were talking about it this morning, but it represents 6 the confirmation that written description is a 7 separate and distinct requirement from that of 8 enablement. Is that right?</p> <p>9 PROFESSOR MERGES: That's the holding, 10 but this is not a case about gene fragments.</p> <p>11 MR. LUZ: I apologize. I was thinking 12 of another one.</p> <p>13 PROFESSOR MERGES: It's necrosis 14 factor, which is a whole different can of worms.</p> <p>15 MR. LUZ: So, if we flip to page 1368, 16 just for the record I'm going to correct the exhibit 17 number. I accidentally said R-120. It's actually 18 C-278 or R-99.</p> <p>19 There were two dissents in this case, 20 were there not?</p> <p>21 PROFESSOR MERGES: I know there's at 22 least, the Rader dissent. Let me just check. I 23 usually teach the Rader dissent because --</p> <p>24 MR. LUZ: Let's go to the Rader 25 dissent because it's colorful. If you go to</p> <p>www.dianaburden.com</p>	<p>1342</p> <p>1 page 361.</p> <p>2 PROFESSOR MERGES: Do you mean 1361 in 3 the opinion?</p> <p>4 MR. LUZ: 1361 in the opinion.</p> <p>5 PROFESSOR MERGES: Just for 6 correction, after the majority opinion, which is of 7 course the holding, Judge Newman gave some 8 "additional" views, sort of a quasi concurrence. 9 Judge Gajarsa gave a concurrence and then we come to 10 the Rader dissent, which is also part of the 11 concurrence, but yes, here we are.</p> <p>12 MR. LUZ: At the bottom there under 13 the heading I, or Part I, he writes "The frailties of 14 this court's 'written description' doctrine have been 15 exhaustively documented in previous opinions." It 16 goes over to 1362 and he lists a very long litany of 17 cases, many of which he seemed to be dissenting on.</p> <p>18 Then on the left-hand column at the 19 bottom, in referring to all of the precedent before, 20 he says, "These earlier writings document the 21 embarrassingly thin (perhaps even mistaken) 22 justifications for the minting of this new 23 description doctrine in 1997 and the extensive 24 academic criticism of this product of judicial 25 imagination." You see that?</p> <p>www.dianaburden.com</p>

<p>1 PROFESSOR MERGES: Yes. 2 MR. LUZ: So there was another dissent 3 with conservatively less colorful language. 4 Judge Linn, if you turn to 1368, this is from the 5 dissent of Circuit Judge Linn, at the bottom of the 6 page in the right-hand corner she writes, under the 7 heading "Stare Decisis," I cannot accept the 8 majority's conclusion that the current written 9 description doctrine adopted in the Regents of the 10 University of California v Eli Lilly & Co, 1997... 11 was created not by the Federal Circuit in 1997, but 12 by the Supreme Court as early as the 19th century, 13 and therefore carries weighty stare decisis effect. 14 In my view, Ariad thoroughly refutes these 15 arguments." 16 So her view is that the view of 19th 17 century Supreme Court rulings doesn't provide a basis 18 for this new written description requirement. Is 19 that right? 20 PROFESSOR MERGES: Are you referring 21 to the Rader dissent? Where? You threw me when you 22 said "she." 23 MR. LUZ: I'm sorry. I'm referring to 24 the Linn dissent. This is on page 1368. 25 PROFESSOR MERGES: Yes, okay. He.</p> <p>www.dianaburden.com</p>	<p>1 MR. LUZ: Apologies for that. 2 PROFESSOR MERGES: No problem. 3 MR. LUZ: Page 1368, bottom right 4 corner under "Stare Decisis." 5 PROFESSOR MERGES: Yes. 6 MR. LUZ: Here she is saying that her 7 view -- 8 PROFESSOR MERGES: His view. 9 MR. LUZ: I'm sorry? 10 PROFESSOR MERGES: No. 11 MR. LUZ: Her view is that 19th 12 century Supreme Court precedent is not a basis for 13 this new written description or requirement. 14 MR. BORN: So is Judge Linn a man or a 15 woman? 16 MR. LUZ: It's a he. I'm sorry. Did 17 I say she? I apologize. 18 PROFESSOR MERGES: I've interrupted 19 this proceedings a couple times. I'm trying not to 20 do that. 21 MR. LUZ: There's obviously some 22 dissonance at least amongst two judges. 23 PROFESSOR MERGES: Mr. and Ms. Linn, 24 they have a disagreement on it. 25 MR. LUZ: Sure. But let's turn to</p> <p>www.dianaburden.com</p>
<p>1345</p> <p>1 page 1360 and see what a concurring judge, Judge 2 Gajarsa, said. Right under Gajarsa, Circuit Judge, 3 concurring: "I join the opinion of the court but 4 write separately to explain my reasons for doing so. 5 Whether there is a freestanding written description 6 requirement pursuant to section 112, paragraph 1, is 7 a matter of statutory interpretation as the majority 8 correctly notes. In my judgment, the text of section 9 112 paragraph 1 is a model of legislative ambiguity. 10 The interpretation of the statute, therefore, is one 11 over which reasonable people can disagree and indeed, 12 reasonable people have so disagreed for the better 13 part of a decade." 14 It goes on to cite a couple of cases 15 and he finishes that paragraph saying, "While not 16 entirely free from doubt, the majority's 17 interpretation of section 112 paragraph 1 is 18 reasonable, and for the need to provide some clarity 19 to this otherwise conflicting area of our law, I 20 concur with the majority's opinion that the statute 21 may be interpreted to set forth an independent 22 written description requirement." 23 Do you agree with Judge Gajarsa that 24 the statute, section 112 of the Patent Act, generally 25 is a model of legislative ambiguity over which</p> <p>www.dianaburden.com</p>	<p>1346</p> <p>1 reasonable minds can disagree? 2 PROFESSOR MERGES: I don't know that 3 it's a "model." I agree more with his statement at 4 the top in the right column. I do not believe that 5 this issue has a significant practical impact. That 6 I subscribe to 100 percent. A lot of it is just 7 doctrinal wrangling and moving the headers around, 8 basically. Again, what we care about is outcomes. 9 Did this set of outcomes change after written 10 description? In my view, no. 11 MR. LUZ: Mr. President, I have about 12 half an hour more. Should we just continue on? I 13 don't want Professor Merges to feel -- if we want to 14 take a break. 15 PROFESSOR MERGES: I can talk about 16 this stuff all day. 17 MR. LUZ: I'm happy to continue. 18 Let's talk about the utility requirement standard. I 19 think you testified this morning and we read in your 20 case book earlier on that utility requirement in the 21 United States is only founded on two words in the 22 statute, the first being section 101 requires 23 inventions to be useful and the second statutory 24 basis is section 112 which requires a patent to 25 disclose the manner and process of making and using</p> <p>www.dianaburden.com</p>

<p>1 the invention. Is that right?</p> <p>2 PROFESSOR MERGES: I want to go back</p> <p>3 to that tab to make sure I don't mess it up.</p> <p>4 MR. LUZ: We can go back to the</p> <p>5 statute itself. It's tab 2.</p> <p>6 PROFESSOR MERGES: No, I want to know</p> <p>7 what I said about it. That's what you're reading, I</p> <p>8 think.</p> <p>9 MR. LUZ: Sure. Tab 7, which is</p> <p>10 Exhibit --</p> <p>11 PROFESSOR MERGES: Yes, second</p> <p>12 paragraph 209. Is that where you are?</p> <p>13 MR. LUZ: That's right. So there's</p> <p>14 two provisions here where utility comes in. The word</p> <p>15 "useful" in section 101, and then what's called the</p> <p>16 "how to use" prong of section 112. Is that right?</p> <p>17 PROFESSOR MERGES: Usually we would</p> <p>18 refer to it as the "how to use" prong of the</p> <p>19 enablement requirement within section 112, but in the</p> <p>20 spirit of your question, yeah, I think.</p> <p>21 MR. LUZ: So useful -- enablement as a</p> <p>22 matter of law incorporates utility because it's the</p> <p>23 matter of use.</p> <p>24 PROFESSOR MERGES: I don't think it's</p> <p>25 right to say that enablement incorporates utility. I</p> <p>www.dianaburden.com</p>	<p>1 think the "how to use" prong of enablement is</p> <p>2 logically connected to the utility requirement. I</p> <p>3 would say that. But incorporation sounds like -- is</p> <p>4 further than I would go.</p> <p>5 MR. LUZ: The word "useful" is not</p> <p>6 defined in the statute but the U.S. courts have</p> <p>7 interpreted that word to mean substantial, specific</p> <p>8 and credible utility. Is that right?</p> <p>9 PROFESSOR MERGES: Yeah, you can find</p> <p>10 a cite for that proposition. That's a pretty</p> <p>11 standard proposition.</p> <p>12 MR. LUZ: Those words "substantial,"</p> <p>13 "specific" and "credible" do not appear in the</p> <p>14 statute itself?</p> <p>15 PROFESSOR MERGES: They may at</p> <p>16 disparate locations but not together referring to</p> <p>17 utility, so I don't want to be coy. No.</p> <p>18 MR. LUZ: But they are the legal</p> <p>19 requirements to meet utility in section 101?</p> <p>20 PROFESSOR MERGES: They're a common</p> <p>21 way to summarize the core elements of the utility</p> <p>22 requirement. That's what I would say.</p> <p>23 MR. LUZ: Professor Merges, the</p> <p>24 strictness by which the U.S. courts applied the</p> <p>25 utility requirement has ebbed and flowed since the</p> <p>www.dianaburden.com</p>
<p>1349</p> <p>1 1966 Brenner v Manson decision is that right? Would</p> <p>2 you agree with that?</p> <p>3 PROFESSOR MERGES: Are you reading</p> <p>4 from somewhere?</p> <p>5 MR. LUZ: No, I'm just asking your</p> <p>6 opinion as to whether you would agree with the</p> <p>7 statement that the strictness by which the utility</p> <p>8 requirement has been enforced has ebbed and flowed.</p> <p>9 PROFESSOR MERGES: I'm afraid we're</p> <p>10 going to have to talk about metaphors again because</p> <p>11 ebb and flow has a tidal feel which represents --</p> <p>12 depending on what tide you're talking about. I would</p> <p>13 say it ebbs and flows in the same way a stream</p> <p>14 300 miles inland ebbs and flows. There's actually a</p> <p>15 little tide, and if you were careful you could</p> <p>16 measure it but it's not particularly noticeable, not</p> <p>17 like you would experience right at the coast which is</p> <p>18 a big -- you know. It's not a tidal bore, like we</p> <p>19 might see in New Brunswick or something like that.</p> <p>20 MR. LUZ: Let's go to paragraph 22 of</p> <p>21 your first report. Page 9.</p> <p>22 PROFESSOR MERGES: Yes.</p> <p>23 MR. LUZ: You write, "A substantial</p> <p>24 utility has also been described as practical utility,</p> <p>25 which is how the Supreme Court described the</p> <p>www.dianaburden.com</p>	<p>1350</p> <p>1 requirement in Brenner v Manson." That's the case</p> <p>2 from 1966. "Substantiality means essentially</p> <p>3 something more than a research interest or, in some</p> <p>4 cases, something beyond a nominal asserted use. A</p> <p>5 good example of nominal use is In re Fisher." I want</p> <p>6 to talk about the Fisher case and ask you about it</p> <p>7 but before we get there, which is a 2005 case, let's</p> <p>8 back up a little bit. I'll ask you to look at tab 21</p> <p>9 of your binder which is Exhibit C-286. See this?</p> <p>10 This is an article that you wrote with a co-author in</p> <p>11 1995.</p> <p>12 PROFESSOR MERGES: Yes, I see.</p> <p>13 MR. LUZ: So I don't want to go</p> <p>14 through this whole thing, but starting on page 3 we</p> <p>15 have a discussion starting on utility and going on</p> <p>16 page 4, 5. I'm interested to read starting on</p> <p>17 page 7. This is an article you're writing in 1995.</p> <p>18 In the middle -- are you with me, Professor Merges?</p> <p>19 PROFESSOR MERGES: You mentioned a lot</p> <p>20 of pages.</p> <p>21 MR. LUZ: I'm sorry. Page 7.</p> <p>22 PROFESSOR MERGES: We're on page 7.</p> <p>23 MR. LUZ: The first paragraph starts</p> <p>24 with: "This question has been particularly difficult</p> <p>25 to answer for pharmaceutical inventions." I won't go</p> <p>www.dianaburden.com</p>

<p>1 back to what the question is. 2 PROFESSOR MERGES: But you know I 3 will. 4 MR. LUZ: You're more than welcome to. 5 The question is actually on page 6. "How far must an 6 inventor go to establish that such an invention 7 offers a specific benefit in a currently available 8 form?" Then you go over to page 7, "This question 9 has been particularly difficult to answer for 10 pharmaceutical inventions which often involves 11 separately discovered products and uses." You see 12 that? 13 PROFESSOR MERGES: Yes. Top of 7. 14 MR. LUZ: Then you go on to discuss a 15 case Cross v Iizuka, where the Federal Circuit 16 acknowledged that "in vitro testing is but an 17 intermediate link in a screening chain which may 18 eventually lead to the use of the drug as a 19 therapeutic agent in humans,"but nonetheless 20 concluded that this link was sufficient to establish 21 a practical utility for the compound, noting: 22 'Successful in vitro testing will marshal resources 23 and direct the expenditure of effort in further in 24 vivo testing of the most potent compounds, thereby 25 providing an immediate benefit to the public,</p> <p>www.dianaburden.com</p>	<p>1 analogous to the benefit provided by the showing of 2 an in vivo utility." 3 That's a case -- as we said, the 4 citation is in footnote 18 from 1985. 5 The last sentence says, "This suggests 6 a more hospitable attitude toward the patenting of 7 early stage pharmaceutical inventions than would be 8 supported under a strict reading of Brenner v 9 Manson." That's the United States Supreme Court case 10 from 1966. Is that right? 11 PROFESSOR MERGES: That's the last 12 sentence of the first paragraph on 7, yes. 13 MR. LUZ: I'll just read this last 14 paragraph, and then I'll ask you a few questions 15 about it. "However, in recent years, biotechnology 16 patent practitioners" -- prior to 1995 when you wrote 17 this -- "perceived an increasing strictness on the 18 part of the PTO in its application of the utility 19 requirement, particularly in the context of claims to 20 methods of treatment or to pharmaceutical 21 compositions. A series of decisions from the PTO 22 Board of Patent Appeals and Interferences reflects 23 this trend, which may be finally coming to an end in 24 light of the very recent developments in the PTO and 25 the Federal Circuit."</p> <p>www.dianaburden.com</p>
<p>1353</p> <p>1 So here you are writing in 1995 saying 2 that there has been -- that at one point the utility 3 requirement has been a more hospitable attitude 4 towards patenting of early stage pharmaceutical 5 inventions, but in recent years -- I assume in the 6 early 1990s, biotechnology patent practitioners 7 perceived an increasing strictness on the part of the 8 PTO in its application of the utility requirement. 9 What was happening around this time in 10 the mid 1990s that would be driving an increasing 11 strictness in the utility requirement to be applied? 12 PROFESSOR MERGES: Well, the sentence 13 refers to the perceptions of biotech patent 14 practitioners, for one thing, so it may be difficult 15 for me to say what they thought was going on. I'm 16 not sure that addresses your question. 17 MR. LUZ: Let's go to the Fisher case, 18 because I think that actually sort of exemplifies the 19 kinds of things that were happening in the mid 1990s 20 and early 2000s. Tab 4, Exhibit C-84. Just a 21 reminder, the Fisher case is something that you 22 discuss in your Expert Report. Are you with me, 23 Professor Merges? 24 PROFESSOR MERGES: Got it. 25 MR. LUZ: This was, for some</p> <p>www.dianaburden.com</p>	<p>1354</p> <p>1 background, this was a case about expressed sequence 2 tags, or ESTs. From what I understand, purified 3 nucleic acid sequences that encode proteins and 4 fragments, I think in this case to do with maze 5 plants. 6 PROFESSOR MERGES: Not quite. A very, 7 very important key that you kind of left out. 8 MR. LUZ: Please go ahead and fill it 9 in. Briefly just say what ESTs are for laymen to 10 understand. 11 PROFESSOR MERGES: Short fragments of 12 full genes. Little -- call them snippets. They were 13 not the coding sequence of a full gene. Some simple 14 science you guys probably know. Genes code for 15 proteins. That's what our genetic material does. 16 Codes for all the proteins in our body. These 17 snippets were little fragments of genes that the 18 scientists knew were active in various cells. They 19 weren't the whole genes themselves. They were just 20 little snippets which they tried to patent in large 21 numbers, for reasons I can explain if you want. 22 MR. LUZ: Okay. Thank you. 23 So in this case the court ruled that 24 those ESTs failed for utility. Is that right? 25 PROFESSOR MERGES: The patent</p> <p>www.dianaburden.com</p>

<p>1 applications were denied because the claimed 2 inventions didn't meet the utility requirement. 3 That's how I would state it. 4 MR. LUZ: Then it went before the 5 court to determine timely whether the patent was 6 valid. 7 PROFESSOR MERGES: Yes, the board 8 decision was appealed, and then that's where we get 9 this administrative appeal. In re Fisher. 10 MR. LUZ: Page 1370. At the bottom of 11 page 1370 on the right-hand column near the bottom, 12 the court observed, "Contrary to Fisher's argument 13 that section 101 only requires an invention that is 14 not frivolous, injurious to the well being, good 15 policy or good morals of society, the Supreme 16 Court" -- and we'll see in a moment it's referring to 17 Brenner v Manson -- "appeared to reject Justice 18 Story's de minimis view of utility." Page 1371 19 towards the end, "In its place the Supreme Court 20 announced a more rigorous test..." and it goes on to 21 say -- 22 PROFESSOR MERGES: Where are you here? 23 MR. LUZ: Page 1371. 24 PROFESSOR MERGES: Which column? 25 MR. LUZ: Left-hand side. Before the</p> <p>www.dianaburden.com</p>	<p>1 block quote. 2 "In its place the Supreme Court 3 announced a more rigorous test" -- this is Brenner v 4 Manson. "The basic <i>quid pro quo</i> contemplated by the 5 constitution and the congress for granting the patent 6 monopoly is the benefit derived by the public in an 7 invention with a substantial utility." That's where 8 the substantial utility aspect comes in, right? 9 PROFESSOR MERGES: You're asking me is 10 that sort of where it entered the law? 11 MR. LUZ: Substantial utility is not 12 in the Patent Act, but this is where it entered the 13 law? 14 PROFESSOR MERGES: No. I'm saying 15 it's not in the Patent Act, I agree with that. 16 Second question, is this where it entered the law. 17 That, I'm not so sure of. You'd have to look at the 18 CCPA decisions prior to Brenner and look for 19 references to "substantial." They use some synonyms, 20 practical, substantial, real world. So I just can't 21 ascribe that this is the sort of origin of the 22 substantial utility requirement. 23 MR. LUZ: But the ultimate decision 24 was that the majority just didn't think that these 25 ESTs, which the court acknowledged could be used to</p> <p>www.dianaburden.com</p>
<p>1357</p> <p>1 detect the presence of genetic material having the 2 same structure, it didn't think that it had enough 3 specific and substantial utility to be useful. Is 4 that right? 5 PROFESSOR MERGES: Practically 6 speaking, they had no use. So you may think why 7 would these people try to patent this stuff that had 8 no use? It was a business model, really. It was an 9 idea where if we got a bunch of sequence tags, then 10 when other people later figured out what these genes 11 do, we would take our sequence tags down off the 12 shelf and say, oh, well, your long gene sequence 13 which now codes for a valuable protein because it's a 14 human therapy, we own a piece of it. So for you to 15 use your gene you have to infringe our patents. So 16 the whole trick was we're going to randomly 17 characterize gene snippets, put them in the closet 18 and wait until somebody else did the work that 19 created the real value. And that's a classic case, 20 sometimes call it nominal utility, where you're just 21 trying to free ride on other people's work. You're 22 saying I'm going to try to get some patents that 23 don't really teach anything valuable, they don't have 24 a use, and when somebody discovers a real use -- the 25 uses that they listed in the patent were</p> <p>www.dianaburden.com</p>	<p>1358</p> <p>1 characterized in this opinion as nominal, and I could 2 describe them. They were basically use the gene 3 fragments to go look for genes, but they didn't say 4 anything about what those genes did or what they 5 coded for. 6 So you could think of it as getting 7 patents on a whole bunch of keys and waiting for 8 somebody else to develop a lock that they worked in. 9 And that was the game that they were preventing in 10 this opinion. That's a classic example of somebody 11 who hasn't done enough work to show that the 12 invention, the claimed invention, is operative. They 13 just didn't have it. 14 MR. LUZ: Judge Rader, again, 15 disagreed. He said he had the de minimis view of 16 utility. 17 PROFESSOR MERGES: Can I interrupt you 18 there? The de minimis view they're talking about 19 here is very old, from Justice Story, early 19th 20 century. Strictly speaking, dictum because Justice 21 Story not only was a Supreme Court justice, but he 22 had a little publishing business so he would 23 sometimes put addenda on his opinions, hoping to sell 24 more books. In one of these addenda he said useful 25 under the patent statute, in his view, means anything</p> <p>www.dianaburden.com</p>

<p>1 that's not injurious. And that's the de minimis 2 view. So that which is useful is that which is not 3 intentionally created to harm people. So that's been 4 used to get rid of patents on nuclear bombs and 5 torture devices and things like that. That's a 6 so-called beneficial utility requirement. So that's 7 what they're referring to as de minimis here. Even 8 Rader believes, you will see, that something is 9 required. He just disagreed as to whether that 10 something was present in this case or not.</p> <p>11 MR. LUZ: So just bringing up what he 12 said, let's turn to what Judge Rader said, page 1380. 13 At the bottom of 1380 he writes, "The board and this 14 court acknowledge that ESTs perform a function, that 15 they have a utility, but proceed quickly to a value 16 judgment that the utility would not produce enough 17 valuable information. The board instead complains 18 that the information these ESTs supply is too 19 insubstantial to merit protection."</p> <p>20 As we've seen, there is some 21 dissonance in the court as to what is a substantial 22 utility to fulfill to actually qualify for patent. 23 Is that right?</p> <p>24 PROFESSOR MERGES: No. There's a 25 dissent in this case from Judge Rader, known to hold</p> <p>www.dianaburden.com</p>	<p>1 strong and sometimes minority views, and I don't 2 think it's right to characterize this as somehow 3 representative of the state of the law.</p> <p>4 Fisher was a case that involved patent 5 applications on these little gene snippets which 6 required an application of utility doctrine to this 7 new kind of technological ideas. It's typical of 8 cases sort of at the forefront where you get a little 9 bit of ferment or wavering. Or you might say at the 10 cutting edge of the law opinions can differ, but 11 you're talking about arguments about whether the line 12 is here or here. Here or here. These are small 13 arguments. When you compare that standard, even the 14 one they're arguing about, to promise utility, that's 15 way out here. That's far beyond anything that Rader 16 or the majority are talking about because you're 17 scrutinizing the specification saying what about 18 performance characteristics. Nobody is talking about 19 that. They're saying is the claimed invention 20 workable. They disagree about the definition of 21 workability, and Rader's view here is distinctly in 22 the minority. Most people accepted Fisher as being 23 pretty much the straightforward application of 24 utility, and it's the classic example of why we don't 25 allow patents to attach too early in time before</p> <p>www.dianaburden.com</p>
<p>1361</p> <p>1 you've done anything. That leads to the possibility 2 of stockpiling stuff that's really not valuable until 3 somebody else does the work. And we don't like to 4 see that.</p> <p>5 MR. LUZ: Professor Merges, would you 6 agree that the 2005 Fisher case was a return to a 7 more rigorous and heightened utility criteria?</p> <p>8 PROFESSOR MERGES: Are you reading 9 from something?</p> <p>10 MR. LUZ: I'm asking you a question if 11 you would agree with my statement that the 2005 12 Fisher case was a return to a more rigorous and 13 heightened utility criteria back to the Brenner case 14 from 1966? Do you agree with that?</p> <p>15 PROFESSOR MERGES: I would have to see 16 the context for the statement to make sure that I was 17 really safe here.</p> <p>18 MR. LUZ: Sure. Tab 14.</p> <p>19 PROFESSOR MERGES: Nice try, though.</p> <p>20 MR. LUZ: Exhibit R-120, page 330.</p> <p>21 PROFESSOR MERGES: Tab 14, did you 22 say?</p> <p>23 MR. LUZ: Yes. Tab 14.</p> <p>24 PROFESSOR MERGES: Okay, go.</p> <p>25 MR. LUZ: Janice Mueller's book,</p> <p>www.dianaburden.com</p>	<p>1362</p> <p>1 Patent Law. Page 330 at the bottom, under the 2 heading Genetic Inventions.</p> <p>3 "In the wake of the USPTO's 2001 4 promulgation of the utility examination guidelines 5 discussed above, a test case was brought to clarify 6 the standards for applying the section 101 utility 7 requirement to patent claims reciting ESTs (expressed 8 sequence tags). The result in <i>In re Fisher</i> was a 9 return by the Federal Circuit in 2005 to the rigorous 10 utility criteria announced almost 40 years earlier by 11 the Supreme Court in <i>Brenner v Manson</i>. It remains to 12 be seen whether this resurrection of <i>Manson</i> signals a 13 heightened utility requirement for all inventions or 14 will, instead, be limited to those inventions 15 involving genetic materials such as EST."</p> <p>16 I'll ask my question again. Do you 17 agree that the 2005 Fisher case was a return to a 18 more rigorous and heightened utility requirement from 19 the 1966 Brenner case?</p> <p>20 PROFESSOR MERGES: No, I would 21 disagree with that. For example, the key case in 22 utility is <i>In re Brana</i> 1995, and that is very 23 consistent with the <i>Manson</i> case in many ways.</p> <p>24 MR. LUZ: Mr. President, are we 25 breaking for lunch?</p> <p>www.dianaburden.com</p>

<p>1 THE PRESIDENT: You have how many more 2 minutes of cross-examination? 3 MR. LUZ: I have about 15 more 4 minutes. 5 THE PRESIDENT: We will break for 6 lunch and resume at 1:30. Professor Merges, it means 7 you are under testimony, and you're not allowed to 8 discuss this case with anyone. 9 PROFESSOR MERGES: Understood. 10 THE PRESIDENT: Recess until 1:30. 11 (Lunch recess) 12 THE PRESIDENT: We will continue the 13 hearing. I understand there are a few household 14 matters. Ms. Cheek? 15 MS. CHEEK: Thank you, Mr. President. 16 As you can imagine the parties continued to confer on 17 the schedule in this proceeding and have recognized 18 that perhaps yesterday we were a bit ambitious. It's 19 the parties' view that we should sit tomorrow because 20 we do not believe that the two latter witnesses that 21 we were hoping to examine today, Mr. Erstling and 22 Mr. Reed, would be completed today and so we'd like 23 to hold those witnesses until tomorrow. We recognize 24 there are logistical issues related to that so we 25 wanted to raise it now, but the parties are in</p> <p>www.dianaburden.com</p>	<p>1 agreement that that would be the preferred approach. 2 Additionally, as long as we are going 3 to sit tomorrow -- and we don't expect to sit all 4 day, but we do believe that we should then go ahead 5 and hear the other two international law witnesses, 6 Mr. Thomas and Professor Gervais, and so we would 7 propose that we would sit tomorrow and hear those 8 four witnesses and then finish with the Mexican law 9 witnesses on Monday. 10 THE PRESIDENT: I think there is a 11 problem, at least for certain members of the 12 Tribunal. 13 This is also subject now to whether 14 the World Bank has the facilities available, because 15 I understand they have been released in the meantime. 16 The Secretary of the Tribunal will investigate 17 whether it's still possible tomorrow. The 18 alternative is we do Monday and we run over a little 19 bit on Tuesday. 20 MS. CHEEK: That would be an 21 alternative that we've discussed, and the parties' 22 preference would be to proceed as outlined on 23 Saturday if that's possible. 24 THE PRESIDENT: I understand, because 25 you would like to have your Tuesday available for</p> <p>www.dianaburden.com</p>
<p>1 preparing. 2 SIR DANIEL BETHLEHEM: Is there 3 another possibility, if the facility here is not 4 available -- we had originally scheduled to run on 5 through to Thursday -- that you take Monday/Tuesday 6 for your witnesses, and then have the preparation 7 date on Wednesday with the closings on Thursday? 8 That's presumably another option. 9 MS. CHEEK: Perhaps we could wait to 10 hear from ICSID as to what the realm of possibility 11 is for tomorrow, and then we could confer 12 additionally. 13 THE PRESIDENT: Mr. Spelliscy, is that 14 also correct from your side? 15 MR. SPELLISCY: Yes, I think we can 16 proceed on that. If possible we'd prefer to sit 17 tomorrow but, if not, we can start back-up planning. 18 THE PRESIDENT: Let's first check it 19 with ICSID and the World Bank. In the meantime we 20 can continue with the cross-examination by Mr. Luz. 21 MR. LUZ: Thank you, Mr. President 22 Professor Merges, can you take Professor Holbrook's 23 Expert Report, the first one, paragraph 49 on 24 page 21. It's tab 6 in your opening binder. "In the 25 context of determining whether sufficient 'utility as</p> <p>www.dianaburden.com</p>	<p>1 a drug, medicant, and the like in human therapy' has 2 been alleged, 'it is proper for the examiner to ask 3 for substantiating evidence unless one with ordinary 4 skill in the art would accept the allegations as 5 obviously correct'." There's a citation down to 6 Rasmusson. Mere plausibility is insufficient to 7 demonstrate enablement. Enablement must be 8 demonstrated as of the filing date." 9 The case that Professor Holbrook 10 refers to, Rasmusson v SmithKline Beecham Corp, are 11 you familiar with that case? 12 PROFESSOR MERGES: Yes. I know it's 13 out there. I haven't seen it in a while. Do we have 14 it here? 15 MR. LUZ: We do. It's cited in a few 16 other places in Professor Holbrook's Expert Report 17 but you don't respond to it or say anything about it 18 in your Expert Report, but I can take you to it and 19 we can talk about that it. 20 PROFESSOR MERGES: Tab 12, R-063. 21 MR. LUZ: That's the right one. I'm 22 going to help you and everyone else. Keep your thumb 23 on tab 12 but go back to tab 7, which is back to your 24 textbook. Again, that's C-272, R-56 and turn to 25 page 213. You have a summary of the case and we can</p> <p>www.dianaburden.com</p>

<p>1 turn to the case itself. Under the section you see 2 in bold, 6, the timing of proof see that. 3 PROFESSOR MERGES: Yes. 4 MR. LUZ: "In contrast to Cortright, 5 the court's decision in Rasmusson v 6 SmithKline Beecham Corp, 413 F.3d 1318, (Fed Cir 7 2005) establishes that an inventor making a 8 controversial assertion of utility may have to 9 provide proof of the asserted utility at the time of 10 application. Rasmusson sought to patent a process of 11 treating prostate cancer in humans by 'administering 12 a therapeutically effective amount [finasteride]'. 13 The disclosed process does indeed work, and Rasmusson 14 argued that his application was 'enabling because a 15 person of ordinary skill in the art could perform the 16 steps of the disclosed method without the need for 17 any experimentation'. Both the PTO and the Federal 18 Circuit rejected that argument and held that 19 Rasmusson's invention was not enabling because, based 20 on the evidence that Rasmusson had at the time of 21 filing, 'a person of ordinary skill in the art would 22 not have believed that finasteride was effective in 23 treating prostate cancer.' Evidence obtained after 24 the filing date was 'too late.'" See that? 25 PROFESSOR MERGES: Yes.</p> <p>www.dianaburden.com</p>	<p>1 MR. LUZ: Let's flip back to tab 12, 2 the actual judgment. 3 PROFESSOR MERGES: Got it. 4 MR. LUZ: As you've summarized there, 5 there was a question of whether or not the original 6 patentee is entitled to the patent even though 7 there's no doubt that -- so the patentee sought a 8 patent for a process of treating prostate cancer in 9 humans by administering a chemical compound, 10 finasteride, and this case was one where there was a 11 debate as to who had priority over the patent, 12 Rasmusson, who had filed for the patent in 1987, or 13 SmithKline Beecham, who filed later. 14 If you'll take a look at page 5, so on 15 the right-hand column, it's in the middle of that 16 paragraph where it starts with "In order to obtain 17 priority date." Do you see that? 18 PROFESSOR MERGES: Got it. 19 MR. LUZ: "In order to obtain a 20 priority date earlier June 27, 1990" -- which was the 21 key date, the subsequent patent by SmithKline Beecham 22 -- "Rasmusson needed to provide experimental proof 23 that his invention could be effective in treating 24 cancer. Because Rasmusson failed to do so and 25 obtained a priority date only as of the filing date</p> <p>www.dianaburden.com</p>
<p>1369</p> <p>1 of his '296 application, the Board was correct to 2 find that all applications prior to that application 3 were not enabled, and that Rasmusson was not entitled 4 to a priority date earlier than the priority date of 5 SmithKline's '310 and '553 patents..." 6 So here the question was what kind of 7 evidence do you have at the time of your filing, is 8 that right? 9 PROFESSOR MERGES: When you say the 10 issue, what -- 11 MR. LUZ: To determine who had 12 priority over the patent. 13 PROFESSOR MERGES: Say the question 14 again. The issue is? 15 MR. LUZ: The issue is whether or not 16 Rasmusson had evidence or some kind of proof to 17 establish utility at the filing date. Is that right? 18 PROFESSOR MERGES: So the general 19 standard is that you have to have evidence that 20 someone skilled in the art would recognize that the 21 claimed invention had utility, had a purpose, worked. 22 MR. LUZ: Let me back up before I get 23 back to this. I asked you earlier about the 24 relationship between the utility standard in section 25 101 and the enablement standard in section 112. If</p> <p>www.dianaburden.com</p>	<p>1370</p> <p>1 you look at page 4 of the Rasmusson case -- we'll put 2 the priority date and so on on hold for a moment -- 3 page 4 in the left-hand column, "In order to satisfy 4 the enablement requirement of section 112, an 5 applicant must describe the manner of making and 6 using the invention 'in such full, clear, concise and 7 exact terms as to enable any person skilled in the 8 art... to make and use the same... As this court has 9 explained, the how to use prong of section 112 10 incorporates as a matter of law the requirement of 35 11 U.S.C. 101" -- utility -- "that the specification 12 disclose as a matter of fact a practical utility for 13 the invention." 14 So as a matter of law section 101, 15 utility, is in the how to use prong of section 112. 16 That's what the court is saying. 17 PROFESSOR MERGES: Not quite in those 18 words. They didn't say "is in the" requirement. You 19 read the statement. 20 MR. LUZ: Right. "As this court has 21 explained, the how to use prong of section 112 22 incorporates as a matter of law the requirement of 35 23 U.S.C. section 101 that the specification disclose as 24 a matter of fact a practical utility for the 25 invention."</p> <p>www.dianaburden.com</p>

<p>1 So section 112 as a matter of law 2 incorporates section 101. 3 PROFESSOR MERGES: Not quite. The 4 utility requirement is necessary but not sufficient 5 to satisfy the how to use prong of section 112. So 6 in the sense of it being logically inclusive or 7 prior, that's the relationship. "Incorporates" is a 8 little bit too loose, I think. If you have no use 9 for your invention how can you possibly satisfy a 10 requirement that says you have to teach people how to 11 use it if there's no use. As a logical matter it's 12 prior to the larger consideration, that's what 13 they're trying to say. 14 MR. LUZ: If you go back to the bottom 15 of page 5, again, we're going back to the question of 16 whether or not, as was stated there, the original 17 patentee needed to provide experimental proof that 18 his invention could be effective in treating cancer. 19 At the bottom, "Rasmusson argues that the enablement 20 requirement of section 112 does not mandate a showing 21 of utility or, if it does, it mandates only a showing 22 that it is 'not implausible' that the invention will 23 work for its intended purpose. As we have explained, 24 we have required a greater measure of proof, and for 25 good reason. If mere plausibility were the test for</p> <p>www.dianaburden.com</p>	<p>1 enablement under section 112, applicants could obtain 2 patent rights to 'inventions' consisting of little 3 more than respectable guesses as to the likelihood of 4 their success. When one of the guesses later proved 5 true, the 'inventor' would be rewarded the spoils 6 instead of the party who demonstrated that the method 7 actually worked. That scenario is not consistent 8 with the statutory requirement that the inventor 9 enable an invention rather than merely proposing an 10 unproved hypothesis." 11 So what the court is saying is that 12 mere plausibility is not sufficient to establish 13 enablement. Is that right? 14 PROFESSOR MERGES: That's in the 15 paragraph you just read, yes. 16 MR. LUZ: The court is saying that 17 making respectable guesses is not good enough. You 18 can't get a patent for an unproven hypothesis. Is 19 that right? That's what the court says. 20 PROFESSOR MERGES: I don't see those 21 words there. I think you are paraphrasing and maybe 22 extrapolating a little bit. Did I miss them? 23 MR. LUZ: "As we have explained we 24 have required a greater measure of proof, and for 25 good reason. If mere plausibility were the test for</p> <p>www.dianaburden.com</p>
<p>1373</p> <p>1 enablement under section 112, applicants could obtain 2 patent rights to inventions consisting of little more 3 than respectable guesses as to the likelihood of 4 success. When one of the guesses later proved true, 5 the inventor would be rewarded the spoils instead of 6 the party who had demonstrated that method actually 7 worked. That scenario is not consistent with the 8 statutory requirement that the inventor enable the 9 invention rather than merely proposing an unproven 10 hypothesis." 11 So respectable guess and unproven 12 hypothesis is not good enough for enablement. 13 PROFESSOR MERGES: Of course, it all 14 depends on the nature of the claimed invention and 15 the level of skill in the field, level of skill in 16 the art, and the content of the prior art. These 17 cases are all very fact intensive in the sense that 18 in this case it was a cancer treatment, and it 19 involved inhibition of a protein that was thought to 20 be one of the causes of cancer. In that kind of case 21 the question is often whether one of skill in the art 22 would recognize that this compound falls into a class 23 or category that has been shown to have some 24 effectiveness, and the way I read this is the court 25 said on the state of these facts somebody skilled in</p> <p>www.dianaburden.com</p>	<p>1374</p> <p>1 the art would not believe that they had established 2 utility -- 3 MR. LUZ: At the time of filing, 4 sorry, just to clarify, is that what you mean? 5 PROFESSOR MERGES: Yes, although we 6 can introduce evidence pertaining to the accuracy of 7 statements in the specification. They go to the 8 state of affairs at the time of filing. 9 MR. LUZ: But the fact that we know 10 that, subsequent to the time of filing, the chemical 11 finasteride worked, it was chemically successful, but 12 because he didn't have that evidence at the time in 13 1987 when he filed for his patent, that wasn't good 14 enough, as you wrote in your textbook. The evidence 15 was too late. 16 PROFESSOR MERGES: Okay. So Rasmusson 17 argued that it worked, it was enabling -- okay, got 18 it. "They held that Rasmusson's invention was not 19 enabling because based on the evidence Rasmusson had 20 at the time of filing, a person of ordinary skill in 21 the art would not have believed that finasteride was 22 effective in treating prostate cancer." That's 23 pretty much what I just said. 24 MR. LUZ: "Evidence obtained after the 25 filing date was too late."</p> <p>www.dianaburden.com</p>

<p>1 PROFESSOR MERGES: Yes, in this case, 2 because the state of the art at the time of filing 3 was not such that somebody skilled in the art would 4 recognize that this compound was going to be 5 effective in treating cancer. That's not true in 6 every case. 7 MR. LUZ: Turn to your first 8 statement, paragraph 16. You see it? 9 PROFESSOR MERGES: Yes, paragraph 16, 10 page 7. 11 MR. LUZ: It's the paragraph that 12 starts off with "There is a well-understood 13 relationship between utility and the disclosure 14 requirements of 35 U.S.C.112." And you go on to say, 15 "Part of the disclosure required by the enablement 16 doctrine is that the applicant must describe 'how to 17 use' [the claimed] invention," and I think we were 18 just talking about that in Rasmusson, saying that 19 section 101 and section 112 are legally linked. 20 PROFESSOR MERGES: Yes. 21 MR. LUZ: Then at the bottom of that 22 paragraph you write, "This relationship leads to 23 confusion at times, but the law is actually quite 24 clear: Utility is a standalone requirement under 25 section 101, although it is relevant to the</p> <p>www.dianaburden.com</p>	<p>1 enablement standard." 2 And you site In re '318 Patent 3 Infringement Litigation, which is C-279. It's 4 another case about speculation that I'd like to ask 5 you a few questions about. Again, I'll make it 6 easier for you by turning to your textbook, tab 7, 7 C-272, R-56, page 253. Do you remember this case? 8 You cited it in your First Report. 9 PROFESSOR MERGES: Let's make sure I'm 10 focusing on the same case. You've got it at page 253 11 of the case book? 12 MR. LUZ: Yes -- well, it's a summary 13 of it but before we get there, since you cited it in 14 your First Report, I'm assuming you're at least 15 somewhat familiar with the case? 16 PROFESSOR MERGES: Yes. 17 MR. LUZ: Let's go back to your 18 textbook, 253, at the bottom. "Prophecy, Speculation 19 and Enablement. Consider a case where, 1, a 20 researcher speculates that a specific invention will 21 have a specific use; 2, the researcher files a patent 22 application disclosing the invention and the specific 23 use; and, 3, the researcher's speculation turns out 24 to be 100 percent accurate. Is the researcher's 25 patent valid? 'No' is the answer provided by the</p> <p>www.dianaburden.com</p>
<p>1377</p> <p>1 court in Janssen Pharmaceuticals v Teva Pharm U.S.A, 2 the In re '318 Patent Infringement Litigation." 3 Let's turn to that case. That is at 4 tab 9. Exhibit C-279. Again, this was a case where 5 post-filing commercial success and evidence did not 6 seem to be taken into account in terms of 7 establishing patent validity. Just some background 8 on this case. 9 PROFESSOR MERGES: Can I interrupt? 10 If, let's say, non-obviousness had been an issue then 11 commercial success might have been relevant. It's 12 not universally barred from consideration in patent 13 law. A lot has to do again with the state of the 14 art. So this is early days of Alzheimer's research 15 where the mechanism -- actually we still don't know 16 very much about it, and so on that state of facts it 17 could be difficult to establish that you've shown 18 utility or workability, because it's too early in the 19 field for simply a listing of a compound to establish 20 a per se utility. It's not true in every case; it 21 really depends on the state of the art. 22 MR. LUZ: So this was the one where a 23 patent for a method of treating Alzheimer's -- the 24 patent was issued in 1987 and then it was approved by 25 the FDA for use in the treatment of moderate</p> <p>www.dianaburden.com</p>	<p>1378</p> <p>1 Alzheimer's. That was in 2001. Then in 2009, 2 22 years later, the patent was invalidated. So let's 3 see why. Turn to page 1324. Are you with me? 4 PROFESSOR MERGES: Yes. 5 MR. LUZ: We're looking at paragraph 6 9. "The utility requirement prevents mere ideas from 7 being patented." A little bit further down, "The 8 utility requirement also prevents the patenting of a 9 mere research proposal or an invention that is simply 10 an object of research." You see that? 11 PROFESSOR MERGES: Yes, that's 12 headnote 10-13. I see it. 13 MR. LUZ: Then on the right-hand 14 column of the same page, paragraphs 14-16: 15 "Typically, patent applications claiming new methods 16 of treatment are supported by test results." You see 17 that? 18 PROFESSOR MERGES: Is that the 19 sentence just before it says "But it is clear that 20 testing need not be conducted by the inventor"? Is 21 that the one? Just before that sentence? Yes. 22 MR. LUZ: Then on page 1325, the next 23 page over, paragraph 17. "In this case, however, 24 neither in vitro test results nor animal test results 25 involving the use of galantamine to treat</p> <p>www.dianaburden.com</p>

<p>1 Alzheimer's-like conditions were provided. The 2 results from the '318 patent's proposed animal tests 3 of galantamine for treating symptoms of Alzheimer's 4 disease were not available at the time of the 5 application, and the district court properly held 6 that they could not be used to establish enablement." 7 PROFESSOR MERGES: Yes, and of course, 8 again, that had to do with the state of the art at 9 the time this patent application was filed. The 10 galantamine is a compound -- it's interesting. It 11 appears in a natural product, a flower, a little 12 snowdrop, the Eurasian snowdrop, and it was one of 13 these things where chemists had an interest in the 14 compound, but because the mechanism for Alzheimer's 15 is not particularly well known even to cite animal 16 studies for related compounds in that setting, this 17 court said, was not enough to show that it would work 18 because it was just too early in the history of that 19 field, but in many cases, once you have the 20 characteristics of the compound well understood, 21 citing animal or even in vitro studies of related 22 compounds could be enough to support workability for 23 the claimed invention. 24 So '318 is in no sense any kind of 25 blanket rule. It just shows again that the standard</p> <p>www.dianaburden.com</p>	<p>1 is the claimed invention shown to be useful, 2 basically operational, to somebody skilled in the 3 art. That's the standard. 4 MR. LUZ: Then page 1327, right-hand 5 column. "Thus, at the end" -- sorry, do you see 6 where I am? 7 PROFESSOR MERGES: Yes. 8 MR. LUZ: "Thus, at the end of the 9 day, the specification, even read in the light of the 10 knowledge of those skilled in the art, does no more 11 than state a hypothesis and propose testing to 12 determine the accuracy of that hypothesis. That is 13 not sufficient." 14 Then the court ended up ruling that 15 "The '318 patent's description of using galantamine 16 to treat Alzheimer's disease does not satisfy the 17 enablement requirement because the '318 patent's 18 application did not establish utility." 19 PROFESSOR MERGES: I should say the 20 specification in this case, the written description, 21 was one page. It was put together very quickly. 22 They were trying to get something in the 23 Patent Office as quickly as they could. You might 24 say why would they ever do that, why not wait until 25 you had a better developed factual basis, but the</p> <p>www.dianaburden.com</p>
<p>1381</p> <p>1 answer is right here in the Rasmusson case, which is 2 to say there are always other people breathing down 3 your neck, especially in a hot field like 4 Alzheimer's. So there is a constant trade-off that 5 you have. 6 They know the standard quite well but 7 they try to get something in early because they know 8 other people are racing for the same result, and 9 sometimes you end up putting it in too early and it 10 is characterized as speculation or an educated guess 11 but, again, that comes from the high-risk context 12 that we're talking about, which is multiple 13 researchers in pharmaceutical companies, and in some 14 cases universities. They're all circling around 15 these hot prospects and priority, being first, is 16 absolutely crucial. So that's the tension that leads 17 you to a case where the court might call it 18 speculation. Again, you can contrast the 19 specification in that case with many specifications, 20 like the one for Strattera in the Canadian patent or 21 olanzapine, much more extensive discussion of the 22 invention, the prior art, much better sense for 23 somebody skilled in the art that this thing 24 definitely has a use, simply because of the state 25 that the field has reached in its development.</p> <p>www.dianaburden.com</p>	<p>1382</p> <p>1 MR. LUZ: So the fact that the testing 2 that they got came afterwards didn't change the fact 3 that they didn't have the tests available at the time 4 they filed for their patent and, therefore, it was 5 invalid for lack of enablement because of utility. 6 PROFESSOR MERGES: Often after-filed 7 evidence is admissible and used when it's used to 8 substantiate doubts that somebody skilled in the art 9 might have, pertaining to the accuracy of statements 10 that are already in the specification, so it's 11 important to know that even after-filed evidence is 12 always directed at the accuracy of statements that 13 are already in the written description of the patent 14 application. And in this case what the court was 15 saying is that the evidence introduced goes well 16 beyond; it doesn't pertain to the accuracy of 17 statements in the specification. 18 There's nothing wrong with the animal 19 studies cited in the specification; they just weren't 20 pertinent to the workability of this particular 21 invention. So the court said in this case this 22 post-filing evidence doesn't help you; it doesn't 23 pertain to the accuracy of statements in the 24 application that you yourself filed. 25 That's really what they're saying.</p> <p>www.dianaburden.com</p>

<p>1 MR. LUZ: So these things can be 2 case-specific. 3 PROFESSOR MERGES: Depending on the 4 state of the art looking at the claimed invention. 5 MR. LUZ: Thank you. I don't have any 6 more questions, Mr. President. 7 THE PRESIDENT: Thank you. Ms. Cheek, 8 questions for redirect? 9 MS. CHEEK: I do believe I'll have a 10 few questions, if I could just have one moment? 11 REDIRECT EXAMINATION ON BEHALF OF THE CLAIMANT 12 MS. CHEEK: Professor Merges, can you 13 explain to the Tribunal whether you consider yourself 14 qualified to provide an opinion on comparative law 15 with regard to the utility requirement? 16 PROFESSOR MERGES: Yes. I would 17 provide a couple of reasons for that. One of the 18 courses that I teach is called Transnational 19 Intellectual Property Law, and picking up on Chairman 20 van den Berg's distinction earlier, it is both an 21 international law course in the sense that I try to 22 cover the treaties, et cetera, but it's also a 23 comparative law course, primarily focusing on the law 24 of Europe, China, the U.S, but broadly covering other 25 jurisdictions when they're relevant. So I think I</p> <p>www.dianaburden.com</p>	<p>1 have a general feel for the way patentability 2 requirements, at least the core ones, work in the 3 main in at least, you know, many important cases. 4 Just looking at the international 5 treaties which try to harmonize these areas of law, 6 when it refers to in the NAFTA treaty novelty and 7 non-obviousness, there's already a sense of some kind 8 of conceptual overlap and harmony just to say we're 9 unifying these standards. There's a sense we 10 understand, we know what we're talking about. 11 The same is true when you look at the 12 patent statutes in many other countries. You see a 13 kind of convergence on the basic principles. And so 14 I feel pretty comfortable in saying I have a decent 15 feel for the basic -- not every case, not every 16 wiggle in the doctrinal fabric, but a basic feel for 17 the major requirements of patentability and how they 18 work, and I feel pretty comfortable looking at the 19 Canadian cases in that context. 20 To me, especially compared to the U.S. 21 standard but even compared to a sort of general sense 22 of a consensus standard, they just seem like extreme 23 outliers to me. 24 MS. CHEEK: Professor Merges, you were 25 asked about several cases related to section 112, and</p> <p>www.dianaburden.com</p>
<p>1385</p> <p>1 I believe that you stated that there's a logical 2 relationship between section 112, which is the 3 enablement requirement, the disclosure requirement in 4 the U.S., and section 101, which is the utility 5 requirement in the U.S. 6 I was wondering if you'd care to 7 explain what the logical relationship is between 8 those two requirements? 9 PROFESSOR MERGES: I think the best 10 way to put it is that meeting the utility standard is 11 necessary but not sufficient to meeting the how to 12 use standard in section 112. That's probably the 13 cleanest way that I could say it. 14 Again, if you don't have any use at 15 all then you can't say that you've taught somebody 16 how to use your invention, but, of course, having 17 said it's basically workable, I've taught you how to 18 use it, that may be a far cry from teaching somebody 19 of skill in the art how to use the claimed subject 20 matter. Sometimes this is a complicated sort of 21 issue. 22 Maybe it's better if I just kind of -- 23 would it be okay if I drew a diagram? Is that 24 kosher? No? 25 THE PRESIDENT: Okay.</p> <p>www.dianaburden.com</p>	<p>1386</p> <p>1 (Professor Merges drew on the white board) 2 PROFESSOR MERGES: I'll just explain 3 it first. I think of utility as this very simple 4 threshold requirement. It's kind of binary, as I 5 said in my reports. The nature of section 112, 6 disclosure requirements, is that they have to be 7 proportional or commensurate to the scope of the 8 patent claim, right? 9 So we look to the claimed invention 10 when we ask is it useful, does it have a purpose, but 11 that's very different from the character of the 12 inquiry where we ask have you earned and merited the 13 breadth of your claims. That is much more a question 14 of have you disclosed or taught enough to merit the 15 scope of the claims that you're trying to get in your 16 patent. 17 So I sketch it out. I think of 18 utility as just this very simple threshold, and I 19 think of the section 112 requirements as being much 20 more of a continuous function where the degree of 21 disclosure earns you broader claim scope. So if 22 you'll indulge me a quick sketch, what you have is a 23 sort of a timeline here where you're talking about 24 the research effort or the amount of information 25 you've disclosed. If you want to sort of make an</p> <p>www.dianaburden.com</p>

<p>1 economic model out of it, you can even turn this into 2 the amount of money that's expended, and it goes up 3 over time.</p> <p>4 So you think of the raw, pure idea 5 that comes to you in the middle of the night without 6 any work or investment yet, that's down here, that's 7 kind of zero disclosure. Haven't told anybody, 8 haven't done anything.</p> <p>9 The next point might be the point 10 where you take a completely blue sky idea and you 11 write it down on a piece of paper, and you say 12 wouldn't it be great to have a pocket-sized device 13 that allows human flight, something like that.</p> <p>14 If you were to file that paper in the 15 Patent Office with absolutely no disclosure, having 16 taught nobody anything except "Here's my idea," 17 clearly that's not workable. You haven't done 18 anything yet. So the next few stages are stages 19 where you start to either describe the idea with more 20 precision so that somebody skilled in the art can 21 understand what you're talking about and can see, oh, 22 I can see the use of that, or where you actually 23 start to experiment, do some testing, and do some 24 preliminary screening to see if your idea meets the 25 proof of concept. Then, as you go along, you expend</p> <p>www.dianaburden.com</p>	<p>1 more resources and you disclose more information and 2 so on and so forth.</p> <p>3 In the pharmaceutical field this early 4 stage might be as simple as saying there are some 5 interesting molecules, they're structurally similar 6 to some others, we know that there's general function 7 in this field, and so I think borrowing these 8 neighboring compounds and trying them out might have 9 a use. That might be enough to show right there that 10 it's workable.</p> <p>11 There may be other stages where you 12 try them in a petri dish in the lab and test them on 13 well-accepted lab proxies for operativeness, and then 14 there might be animal studies in mice or hamsters or 15 dogs or horses, or whatever. Then you go on to 16 trying in a few limited patients in Phase I, 17 Phase II, Phase III.</p> <p>18 Anyway, let me get to the point of 19 this diagram. So, as you go along, you have your 20 sort of level of expenditure and once you hit this 21 stage here usually, pretty close to the bottom, this 22 is resources over time here, once you hit that, 23 you've established it and that's it. So it's just 24 kind of a binary function, okay, I've shown 25 workability.</p> <p>www.dianaburden.com</p>
<p>1389</p> <p>1 THE PRESIDENT: Could you help me, 2 what's on the X axis and the Y axis?</p> <p>3 PROFESSOR MERGES: Yes. So this is 4 time as time goes along, and this is the amount of 5 information that you've disclosed for. So in the 6 enablement context it's more like that where, as time 7 goes on and you are investing more resources, the 8 amount of information you're disclosing is increasing 9 and that allows you to get broader claims, but well 10 beyond this point here you're adding information and 11 you are earning yourself, in a sense, broader claims. 12 So it's a very simple kind of threshold idea that it 13 doesn't take very much information, and that happens 14 fairly early in the scheme of things.</p> <p>15 The point is, once you've established 16 utility for a class of things, you're done. Utility 17 gets checked on the box. The reason people go on and 18 do more, the reason that we see more disclosure 19 beyond just workability, is that you are trying to 20 show that you deserve broader claims, and that's 21 basically how patent law kind of works.</p> <p>22 MS. CHEEK: If I take you to tab 8, 23 that's the Ariad case that you've discussed a few 24 times today. The Ariad case is C-278 and R-99. This 25 is a case about the section 112 disclosure</p> <p>www.dianaburden.com</p>	<p>1390</p> <p>1 requirements you were describing, correct? You were 2 asked some questions on page 1360, and page 1360 is 3 Judge Gajarsa's concurrence.</p> <p>4 PROFESSOR MERGES: Yes.</p> <p>5 MS. CHEEK: I believe you took us to 6 the top of the second column where Judge Gajarsa 7 stated, "I do not believe that this issue had a 8 significant, practical impact." Was there anything 9 you cared to elaborate on having drawn our attention 10 to that statement in Judge Gajarsa's concurrence?</p> <p>11 PROFESSOR MERGES: Well, yeah, it goes 12 to the point that I was trying to make before, which 13 is it's interesting to talk about doctrine and 14 changes in doctrinal language, but the take-home 15 value of most of this stuff has to do with outcomes. 16 So the question is does the recent line of written 17 description cases produce significantly different 18 outcomes as compared to the pre-existing line of 19 enablement cases. You see that Judge Gajarsa is 20 saying he doesn't think there's any significant, 21 practical impact, meaning the doctrine language may 22 change but the basic test seems to be the same. Then 23 he cites, as he says further down, "Empirical 24 evidence demonstrates that outside the priority 25 context the written description doctrine seldom</p> <p>www.dianaburden.com</p>

<p>1 serves as a separate vehicle for invalidating 2 claims," and he cites a blog post from Professor 3 Dennis Crouch, University of Missouri. Actually, 4 that is a working paper, I should say. He has a 5 prominent blog but this particular piece of 6 scholarship is a working paper that's posted, and he 7 did a study and you can see the results there. 8 Basically it says having or not having written 9 description doesn't change things very much. 10 MS. CHEEK: I believe my last 11 question, Professor Merges, is, in your view, is 12 patent law just a grab bag or, in other words, does 13 it matter under which patentability requirement a 14 patent is invalidated? 15 Just to repeat my question, my 16 question was is patent law, in your view, a grab bag? 17 Does it matter under which patentability requirement 18 a patent is invalidated? 19 PROFESSOR MERGES: Well, two parts. 20 One, is it a grab bag? I don't think so, and I 21 certainly hope not. I don't like to think that I 22 devote so much of my time to a grab bag field. 23 Does it matter under which heading we 24 invalidated patents? Well, I would say just to be 25 specific, I mean, if you were a patentee, then at the</p> <p>www.dianaburden.com</p>	<p>1 end of the day your patent is either valid or invalid 2 and doctrinal discussions may or may not soothe your 3 hurt, but if your patent is invalid, it's invalid. 4 So at that level, again, of ultimate 5 outcomes for the patentee, it may not make much 6 difference, but I would say in terms of doctrinal 7 clarity and in terms of the way patent law is 8 structured, to kind of rephrase the question, one way 9 to hear the question is do we really need all these 10 different requirements of patentability, why don't we 11 just say well, you either deserve one or you don't. 12 It's an up or down. The reason is each one plays a 13 distinct role, and they are sequenced and structured 14 in this way I think for a purpose. 15 Does that answer your question? 16 MS. CHEEK: It does. Thank you, 17 Professor Merges. I have no further questions, 18 Mr. President. 19 THE PRESIDENT: Thank you. Any 20 application for recross? 21 MR. LUZ: None, Mr. President. Thank 22 you. 23 QUESTIONS BY THE ARBITRAL TRIBUNAL 24 SIR DANIEL BETHLEHEM: Professor 25 Merges, you'll forgive my questions because they</p> <p>www.dianaburden.com</p>
<p>1 betray ignorance. We've heard a lot of very 2 interesting and informative stuff going to the detail 3 of the cases. What I'd like to try and do is sort of 4 zoom out to 15,000-foot and try and get a broader 5 sense of some of the things that you've said. As I 6 say, forgive my ignorance. 7 The first question I'd like to ask, 8 just to situate some of this in my own mind, is is 9 the phenomenon of new use and selection patents 10 particular to the chemical and biotech fields, or 11 does it apply more broadly? 12 PROFESSOR MERGES: In a general sense, 13 Sir Daniel, it does apply more broadly. There are 14 situations outside chemical and pharma where there 15 might be a new use allegation. 16 SIR DANIEL BETHLEHEM: So they apply 17 more broadly. Do they have a predominant role? I'm 18 trying to get a feel for whether, when we talk about 19 new use and selection patents, the thing that would 20 come to the mind of an expert like yourself is well, 21 we're probably talking about chemical patents or 22 biotech patents. 23 PROFESSOR MERGES: Yes. In the main, 24 yes. And, again, is it okay if I -- 25 SIR DANIEL BETHLEHEM: Please do.</p> <p>www.dianaburden.com</p>	<p>1 PROFESSOR MERGES: The reason for that 2 is, again, I was trying to describe how chemists 3 think and how these basic chemical inventions come 4 about. As I said, these are researchers, they think 5 very spatially, so they may look at a molecule or a 6 class of molecules and say you know, I think there 7 may be something interesting there. And when they 8 start to think about how they might synthesize, make 9 a brand-new compound that maybe works like another 10 family of compounds, and they hope maybe even better, 11 they can start playing around with the basic 12 difficulty of putting the thing together. But the 13 point is that these chemical inventions, especially 14 when you have a whole new class of compounds, you can 15 discover kind of a backbone or a core to this thing 16 that has many, many variants, and it's actually quite 17 common. 18 The original patent on the entire 19 class from which olanzapine was drawn -- I think you 20 saw in the Canadian case -- the patent claimed a 21 family of compounds in the trillions. That just 22 boggles the mind, and you think how can that possibly 23 be. 24 The inventor was the first to discover 25 that particular type of what they call a tricyclic</p> <p>www.dianaburden.com</p>

<p>1 ring, three geometric structures at the core of it, 2 that that could be the basis of a whole bunch of 3 compounds that he expected would have this 4 characteristic of affecting the central nervous 5 system, because the basic shape of this kind of 6 general class of compounds had been shown to have 7 some efficacy.</p> <p>8 So when he first synthesized that he 9 obviously synthesized a few actual real chemicals, 10 and then they characterized their structure in 11 various ways with crystallography and this kind of 12 thing, but to a chemist they instantly realized that 13 this core structure can have many, many variants. If 14 you were to see a diagram of this original patent 15 it's basically two hexagons and an oddly shaped 16 pentagon next to it, and they're all attached 17 adjacent, but at each point in each hexagon and the 18 odd-shaped pentagon imagine a little line coming off, 19 and that line points to a whole set of things that 20 can be attached there, right.</p> <p>21 Now, if you just take one point on one 22 hexagon, there might be several families of things 23 that can be attached there, so you run this whole 24 analysis again at another level, which is just for 25 this side group, and the way this happens in chemical</p> <p>www.dianaburden.com</p>	<p>1 practice is you say the side group, R1, can be 2 selected from the group consisting of -- and then you 3 have another family of side groups where X1 in that 4 can be selected from the family consisting of.</p> <p>5 Anyway, pretty quickly you get to the 6 point where this core structure to a chemist can 7 suggest an overall structure that has all these 8 variants, and that's how you get such a broad claim. 9 So it's non-obvious at the time; it's very 10 significant; and chemists can understand that there's 11 a basic connective tissue amongst all the possible 12 members of this giant set, and that connective tissue 13 is they share the common core which has been 14 suggested to have some efficacy.</p> <p>15 Now, what happens in the selection 16 context is either you're looking for some 17 advantageous properties, either you've run up against 18 the limits of the candidates you selected originally 19 from this giant set, or -- I think this happened in 20 olanzapine -- you're running into negative side 21 effects and you're saying okay, the basic structure 22 seems to have some efficacy, the family members we 23 chose from the giant family are not performing well, 24 these are misbehaving children and we've got to go 25 back and look for some others, right.</p> <p>www.dianaburden.com</p>
<p>1397</p> <p>1 The way selection invention law works 2 is you ask yourself from the perspective of somebody 3 skilled in the art just at the moment before you 4 select and test that one new candidate, the one you 5 select from the big group, what would somebody of 6 skill in the art have said about that. Do you 7 think -- this hypothetical person of skill in the 8 art -- do you think this particular species, this 9 little family member, is going to be especially 10 effective? Do you have any reason to think that? Or 11 do you think it going to be especially good about 12 avoiding the negative consequences, and if that 13 person would say no, I have no reason to think it's 14 any better or worse than the vast number of 15 hypothetical members of this giant set, and if it 16 turns out to have these advantageous properties, or 17 if it avoids the negative consequences, we say that's 18 a significant invention because from the point of 19 view prior to the invention, which was the picking 20 out and testing, no one would have predicted it would 21 be particularly successful. So that's how selection 22 inventions come to be.</p> <p>23 My students will always ask, wait a 24 minute, was the first patent, the big giant one, was 25 that enabled? And I say yes, because you teach how</p> <p>www.dianaburden.com</p>	<p>1398</p> <p>1 to make and use. And they say how can the selection 2 invention be non-obvious, when the whole thing was 3 enabled 13 years ago? And this is the answer. Do 4 you see what I'm getting at? So it's non-obvious 5 that that particular one would work so well, either 6 because it's advantageous or avoids the negative.</p> <p>7 SIR DANIEL BETHLEHEM: Or because you 8 start off with the number of trillion and then you've 9 got to whittle it down. It's very interesting. The 10 word that you used I think in your response here was 11 that chemists think spatially and I'm not sure that 12 lawyers think spatially so perhaps we have to try and 13 get our minds around it. But in your opening 14 presentation, the word that you used was "intuitive" 15 to describe the same thing, and you were very visual 16 in describing how chemists sit in their labs and 17 they've got everything joined up and it's an 18 intuitive process.</p> <p>19 What I'd be interested to know -- and 20 I'd like to take both the question and your answers 21 away from the specific facts of this case and just 22 deal with a generality -- does intuitive innovation 23 in the chemical and biotech fields give rise to 24 special patentability challenges, for example, 25 because the intuition may not have a sufficiently</p> <p>www.dianaburden.com</p>

<p>1 real foundation but you nonetheless are seeking a 2 monopoly? 3 PROFESSOR MERGES: Yes. I was trying 4 to explain a couple of things. I think that's a fair 5 question. 6 The research process often begins with 7 an intuition, but what I was referring to 8 specifically was in the context of the selection 9 invention, a particular researcher might be, you 10 might say, a little bit ahead of the average person 11 of skill in the art, and that might lead them to say 12 "I feel that these compounds are going to have some 13 advantageous properties." 14 This really doesn't pertain to utility 15 because, again, in order to get the original big 16 giant family patent, you have to show utility for 17 that, and, as I was saying earlier in my testimony, 18 utility for selection inventions is sort of a 19 non-issue because you're picking a family member from 20 a family that's already been blessed as having 21 utility, so when I was talking about intuition really 22 what I was getting at is why would you ever write in 23 a patent specification "This thing has advantageous 24 properties" if you don't have absolute, complete, 25 utter convincing to persons skilled in the art</p> <p>www.dianaburden.com</p>	<p>1 evidence that that is true at that time. Why would 2 you do that? And the answer is that you believe it's 3 coming; you have a good sense that the advantageous 4 properties is coming. 5 Now, you may have that evidence on 6 hand when you file. It's possible. But it's also 7 possible that the actual verification of the 8 advantages comes later. Now, we're not talking about 9 verification of a use; we're talking about 10 verification of advantageous properties or properties 11 that avoid negative consequences. 12 SIR DANIEL BETHLEHEM: I suppose what 13 I'm trying to understand -- and I think I understand 14 your testimony about the utility of the original 15 patent -- I'm trying to understand whether in the 16 context of new use or selection patents, where the 17 utility for the new patent may not have been obvious 18 right at the beginning, whether there is a policy 19 rationale, if I can put it in those terms, for a 20 second utility assessment. 21 You seem to be saying that, once 22 you've established utility for the genus, then 23 utility is established for ever more, and I just want 24 to clarify that. 25 PROFESSOR MERGES: In my opinion I</p> <p>www.dianaburden.com</p>
<p>1401</p> <p>1 don't think there's a viable policy rationale for 2 that, because it really helps, I think, to apply a 3 very consistent standard and to say a selection 4 invention like any other invention has to meet the 5 requirements of patentability. That's what we do 6 with non-obviousness. Even though you can 7 characterize it as a special class of cases, the 8 standard is still the same, and I would say that's 9 true of utility. So, again, you can establish that 10 this big giant family has general utility and, 11 indeed, you have to to get that first patent. 12 If you're selecting something from 13 that group, you know that it already has a proven 14 track record of a general utility because the first 15 patent issued. And, as a result, I think that it 16 would be really burdensome, and I don't see it would 17 serve any good purpose to set another utility 18 requirement for the selection invention later. To 19 me, that wouldn't make any sense, and that goes back 20 in my mind to the basic rationale for having a fairly 21 low utility standard. 22 SIR DANIEL BETHLEHEM: Is this the 23 difference or where you part way with the Canadian 24 approach? You're saying it wouldn't make sense to 25 have that additional standard to some extent -- and I</p> <p>www.dianaburden.com</p>	<p>1402</p> <p>1 don't characterize the Respondent's case but to some 2 extent there's an element of well, in certain 3 circumstances the promise of utility, even in cases 4 in which there may have been an original patent, as a 5 policy matter may be important. So is this your 6 point of divergence on the Canadian promise standard? 7 PROFESSOR MERGES: I guess my point of 8 divergence would be whatever that is, if you were to 9 do that, to me could not be classified as a utility 10 requirement. Whatever that was. Because the basic 11 standard for utility is, again, quite straightforward 12 and quite consistent and so to have a special 13 doctrine of utility, if you agree we're going to 14 apply utility and then you start making special 15 cases, to me it doesn't seem as though you would be 16 consistent with the traditional utility test. So if 17 you're saying might there be -- and I can't think of 18 a good policy rationale to say we need to make it 19 more difficult, for whatever reason, to get a 20 selection invention patent. I can't think of a good 21 reason. Because if you make it more difficult to get 22 a selection invention patent, it could lead people to 23 say once we get this big family patent, we really 24 don't have much of an incentive to keep looking 25 inside that class. Let's get our people to go and</p> <p>www.dianaburden.com</p>

<p>1 look at brand-new families of compounds. And I think 2 the problem with that is you'd miss some excellent 3 opportunities, like olanzapine. 4 I mean, there's no reason to think 5 that it would be better, it turned out to be better, 6 so if you made it more difficult, you go to the 7 patent committee at the company and they say well, 8 you know, looking around inside what's already been 9 patented, there's kind of a disincentive to do that 10 so we want you to go look elsewhere. I think you 11 would leave on the table some potentially valuable 12 inventions. 13 SIR DANIEL BETHLEHEM: Presumably 14 that's a policy choice? You could presumably have, 15 if we take it out of the realm of judge-made law to 16 the realm of a legislator, you could have legislators 17 sitting in Canada and the US and UK, wherever else, 18 debating exactly this in deciding where they wanted 19 to draw the line? As I understand what you've just 20 said is a policy choice. 21 PROFESSOR MERGES: Yes, and I think 22 that's where you'd have to say, if you had completely 23 unfettered discretion, could you have that policy 24 conversation and, of course, the answer is yes. If 25 you were to say have you constrained yourself by</p> <p>www.dianaburden.com</p>	<p>1 signing an international treaty, it's not really my 2 remit, but I would say that changes the nature of the 3 question. 4 SIR DANIEL BETHLEHEM: As an expert in 5 the field -- and I introduce the question in these 6 terms just to clarify that I'm not asking you to 7 speculate, I'm asking for your expert opinion -- why 8 is there this difference, as you see it, in the 9 development of Canadian law on the one hand in this 10 area and the development of U.S. law, leaving aside 11 any question of the whimsy of the judge? Has it got 12 something to do with the corporate structure of the 13 Canadian versus the U.S. pharmaceutical sector? Has 14 it got to do with the differences in the legal 15 framework? Has it got to do with the fact that there 16 may be just immensely creative Canadian patent 17 lawyers and less creative U.S. patent lawyers? Why 18 are we seeing this difference? 19 PROFESSOR MERGES: The line between my 20 expert opinion and speculation here is tricky. 21 SIR DANIEL BETHLEHEM: I don't invite 22 you to speculate. If you've got an expert opinion to 23 offer I'd be delighted to hear it, but I don't invite 24 you to speculate. 25 PROFESSOR MERGES: I don't think I can</p> <p>www.dianaburden.com</p>
<p>1 touch that, and I don't really know. 2 SIR DANIEL BETHLEHEM: Two more brief 3 questions. 4 You described in your closing 5 observations in your response to the redirect that, 6 in your view, the Canadian promise doctrine was -- I 7 think the words that you used were an extreme 8 outlier, and I'd like to know whether you have in 9 mind when you used the words "extreme outlier" that 10 you think it is irrational or whether you think it is 11 different, an outlier. 12 PROFESSOR MERGES: That I can answer. 13 I would say both in the sense that I think that 14 conventional, traditional, standard utility law makes 15 sense. To me it serves a valuable purpose. And when 16 you say -- if you were to make the standard much more 17 stringent what effects would that have, would that be 18 a good move, my answer is the reason we settled on a 19 very consistent and quite modest standard, those were 20 good reasons. As you move it further and further 21 out, as you make it harder and harder to establish 22 utility, I think you're deviating from the basic 23 policy goal that's built into the traditional utility 24 requirement. So this is all very abstract. I can 25 make it more concrete, I think.</p> <p>www.dianaburden.com</p>	<p>1 SIR DANIEL BETHLEHEM: Before you do, 2 let me just clarify. By "irrational" I didn't intend 3 to inquire as to whether you thought it was an 4 unsustainable policy approach. I'm trying to use 5 "irrational" in a legal context that the decisions of 6 the Canadian courts, to Mr. Justice Binnie and others 7 in AZT, were irrational in the sense that they ought 8 to be reviewed. That kind of irrationality. 9 PROFESSOR MERGES: In the sense of not 10 based on sound reasoning? 11 SIR DANIEL BETHLEHEM: Not based on 12 sound reasoning. 13 PROFESSOR MERGES: Yeah, I would still 14 say to me they seem irrational. And why would that 15 be so? And I don't mean to denigrate individual 16 judges. This is something I know something about, so 17 it's my opinion. What are the consequences of 18 requiring much more effort, much more disclosure to 19 establish utility? It goes back to the sort of core 20 of what utility is trying to do, so it's general to a 21 class of problems. At what point in the development 22 of some resource do we legally grant a property 23 right? When do we do that. 24 Now, the concern with speculation is 25 that if we set that point too early, if we make it</p> <p>www.dianaburden.com</p>

<p>1 too easy, in my example where I said you just write 2 down on a piece of paper "Here's an idea," why can't 3 you patent that? What would be wrong? The answer is 4 people would spend all day in rooms writing down 5 ideas and sending them to the Patent Office. So what 6 you get there is too much effort diverted to a not 7 very productive activity, which is writing things on 8 pieces of paper. 9 That's the concern with speculation. 10 What's the concern on the other side? This is 11 reflected in my report, I think paragraph 44, it's 12 reflected in the Federal Circuit case of In re Bana, 13 and a lot of writing in this field. 14 The problem with setting the 15 requirement too far the other way, the problem with 16 requiring too much investment effort, whatever you 17 want to describe it as, is that you drive people out 18 of the field because you make it so that, before you 19 know you'll have exclusivity; before you know that 20 you will be able to develop this field on your own, 21 you have to spend a huge amount of money, and right 22 up until the point when you get your patent right, 23 there's a lot of risk. So the more money you have to 24 spend, the more effort you have to expend before you 25 assign the property right, the more risk there is for</p> <p>www.dianaburden.com</p>	<p>1 the people who are trying to decide am I going to try 2 to pursue that right or not. 3 So you could imagine, just in this 4 trade-off idea, there are economic models that 5 suggest this, but I think utility law tries to strike 6 this kind of balance, and the reason it's concerned 7 with requiring too much effort, too much investment, 8 is that it will drive researchers and investors from 9 the field. 10 It's always important to keep in mind 11 that we talk in terms of researchers but they have to 12 go to a lab that somebody paid for and the somebody 13 is investors, and investors are the ones who care 14 about exclusivity. They're the ones who say: If 15 you're right about your molecule, Mr. Chemist, I'm 16 going to need a patent right in order to spend what's 17 required after you get it all the way to the end 18 until we can sell a drug product, and that's ten, 19 12 years and a billion dollars. I got to have 20 something that I can rely on if I'm going to invest 21 that kind of money. 22 So it's a question of at what point in 23 this process do we assign a property right, at what 24 stage. Utility sets it early -- not too early. Pure 25 idea.</p> <p>www.dianaburden.com</p>
<p>1409</p> <p>1 There's a good analogy in the law of 2 hard rock mining, silver and gold, at least in the 3 US. In the US in order to get a mining claim you 4 have to show a certain amount of what's called 5 improvement which means you have to spend some money 6 on it and that's to keep people from running around 7 the Sierras, or whatever mountains you care to name 8 and just staking claims and saying, well, I own this. 9 Again, the concern is you'll stake the claims and 10 wait until somebody else finds the gold and you are 11 free-riding and that's no good. 12 But we don't require to spend so much 13 that you're sinking a mine shaft and employing 75 14 people and spending millions of dollars. Why not? 15 Because right up to the point where you get your 16 right that's all at risk. If somebody says now we 17 decided not to give you the right -- 18 The point is there's a consensus that 19 it makes sense to set it at a substantial but not 20 really, really significant level. 21 SIR DANIEL BETHLEHEM: I just have one 22 last question. You spoke a little bit in response to 23 the redirect about unifying standards. On 24 1 January 1994, when NAFTA entered into force, 25 Article 1709 provided a framework for patent law</p> <p>www.dianaburden.com</p>	<p>1410</p> <p>1 across the three countries. Did Article 1709 2 introduce a new substantive law into U.S. patent 3 law -- not a procedural framework but a new 4 substantive law of patents into U.S. patent law? 5 PROFESSOR MERGES: I think it's a good 6 question. I don't know that that hypothesis or 7 proposition has really been tested. I mean my best 8 answer is I don't know. 9 SIR DANIEL BETHLEHEM: It's being 10 tested here. 11 PROFESSOR MERGES: True. You were 12 asking about U.S. law. So what I mean to say is that 13 since then I don't think there have been any 14 changes -- 15 THE PRESIDENT: If you don't know, 16 don't speculate, please. 17 PROFESSOR MERGES: I don't think there 18 have been any changes so big that we know. There 19 hasn't been a test case. 20 SIR DANIEL BETHLEHEM: Thank you. 21 MR. BORN: Just very briefly, in tab 22 8, the Ariad decision that you've already discussed a 23 couple of times, there's a discussion of the concept 24 of stare decisis, both in the majority at page 1347 25 and then in Judge Lynn's dissent on page 1368.</p> <p>www.dianaburden.com</p>

<p>1 Staying on the first reference at 2 1347, the majority cites the Supreme Court for the 3 concept that we, a court, must be cautious before 4 adopting changes that disrupt the settled 5 expectations of the inventing community. 6 My question is we all -- or at least 7 all of us common lawyers -- are familiar with the 8 notion of stare decisis. How precisely does it apply 9 in the context of U.S. patent law? 10 PROFESSOR MERGES: I think it applies 11 exactly to the same degree it applies in all areas of 12 U.S. law. I don't think patent law is in any sense 13 an exception subject to the same principles. 14 MR. BORN: My understanding was that 15 actually U.S. stare decisis laws applied in different 16 ways in different fields. If you were in a 17 legislative field where Congress could fix mistakes 18 then it was one rule, and in constitutional fields it 19 was different. But I guess I'm wrong. 20 PROFESSOR MERGES: Stare decisis, a 21 very broad topic. In its general sense I think it's 22 consistent. It means decided law is fixed. 23 MR. BORN: Thank you. 24 THE PRESIDENT: Professor Merges, 25 could you please go to slide 8 of your opening</p> <p>www.dianaburden.com</p>	<p>1 presentation, tab 3. 2 PROFESSOR MERGES: There it is. I 3 didn't realize I had it. Yes, slide 8. 4 THE PRESIDENT: Here you state utility 5 is distinct from other doctrines, and here you're 6 within the United States patent law. You have two 7 bullet points. One bullet point deals with utility, 8 novelty and non-obviousness, and the other one with 9 enablement and written description. You see that? 10 PROFESSOR MERGES: Yes. 11 THE PRESIDENT: You say that utility, 12 novelty and non-obviousness are basic requirements 13 for patentability, correct? And then you state 14 further that enablement and written description serve 15 distinct goals. And the method you described -- and 16 please correct me if I'm wrong -- is that in your 17 sequence you first go for utility, you state in your 18 expert opinion there's a low threshold and you move 19 to novelty and non-obviousness, and distinctly you 20 deal with enablement and written description. 21 Is that the analysis also sequentially 22 you do it under U.S. law? 23 PROFESSOR MERGES: There may be slight 24 variation from that basic sequence in particular 25 cases. It's conventional to do it that way because</p> <p>www.dianaburden.com</p>
<p>1413</p> <p>1 that's the order of the statute, so utility is 101, 2 novelty is 102, non-obviousness is 103, and 3 enablement and written description is 112. It just 4 follows from the structure. 5 THE PRESIDENT: Could it be that 6 certain aspects are overlapping? 7 PROFESSOR MERGES: Certainly at a high 8 level there are overlaps in the concepts. 9 THE PRESIDENT: Or what you say 10 interacting? What's the interaction between which of 11 those elements you see here of the doctrine? 12 PROFESSOR MERGES: I didn't quite 13 catch that last -- 14 THE PRESIDENT: Which of the elements 15 you see here in the two bullet points are 16 interacting, according to you, under U.S. law? 17 PROFESSOR MERGES: Well, in a sense 18 they all interacting because they all apply to each 19 patent, but, just to take an example, novelty you 20 could think of as a kind of extreme case or extreme 21 form of non-obviousness. Novelty says if the same 22 exact thing is out there, you can't patent it, and 23 non-obviousness says if something is a trivial 24 advance you can't patent, and the most simple example 25 of a trivial advance is something that's already out</p> <p>www.dianaburden.com</p>	<p>1414</p> <p>1 there. 2 THE PRESIDENT: Is it fair to say that 3 in one court case you may see a focus on 4 non-obviousness and in another case on novelty, and 5 it depends on how the courts litigated it or how the 6 judge approaches it? 7 PROFESSOR MERGES: I think there's a 8 certain amount of discretion, although sometimes the 9 Federal Circuit has tried to impose a kind of 10 doctrinal ordering. 11 THE PRESIDENT: Now, in the beginning 12 of your cross-examination you have testified about 13 your knowledge of Canadian patent law. You remember 14 that? 15 PROFESSOR MERGES: Yes. 16 THE PRESIDENT: How far does it go? 17 Obviously you have given opinions on utility, on the 18 promise utility doctrine. So you have studied under 19 Canadian law utility requirements. Is that correct? 20 PROFESSOR MERGES: Particularly in the 21 cases that we talked about, yes. 22 THE PRESIDENT: Have you also studied 23 other aspects of Canadian patent law? 24 PROFESSOR MERGES: Not in a systematic 25 way.</p> <p>www.dianaburden.com</p>

<p>1 THE PRESIDENT: Then you are not 2 capable of telling me which are the corresponding 3 concepts of what you see here on slide 8 under U.S. 4 law? 5 PROFESSOR MERGES: I think you meant 6 under Canadian law? 7 THE PRESIDENT: No, on the Canadian -- 8 sorry, what you see on slide 8 is U.S. law. What are 9 the corresponding concepts under Canadian law? 10 PROFESSOR MERGES: Well, I know from 11 the NAFTA treaty that utility, novelty and -- 12 THE PRESIDENT: No, sorry, I'm asking 13 you about Canadian law. 14 PROFESSOR MERGES: Yes. 15 THE PRESIDENT: So you only know or 16 what you have studied is the utility requirement of 17 Canadian patent law. Is that correct? 18 PROFESSOR MERGES: Yes. 19 THE PRESIDENT: But you have not 20 studied the other elements? 21 PROFESSOR MERGES: Not in any depth. 22 THE PRESIDENT: So you do not know 23 whether they are overlapping or interacting? 24 PROFESSOR MERGES: No. 25 THE PRESIDENT: Thank you. I have</p> <p>www.dianaburden.com</p>	<p>1 nothing further. 2 Any follow-up questions? 3 MS. CHEEK: I do believe I have one 4 follow-up question. 5 REDIRECT EXAMINATION ON BEHALF OF THE CLAIMANT 6 MS. CHEEK: Professor Merges, you were 7 asked by Sir Daniel a question about 1709(1) of 8 NAFTA. Then you said there had not yet been a test 9 case about U.S. law. In your view, does 1709(1) of 10 NAFTA constrain U.S. substantive law developments? 11 PROFESSOR MERGES: Yes, I believe it 12 does. I don't think that Congress could amend the 13 Patent Act consistent with NAFTA and eliminate one of 14 the tests, for example, non-obviousness, novelty. I 15 don't think that they could define one of those 16 standards in a way that's completely radically 17 different from the historical standard and still be 18 in compliance. I mean that's my view. 19 MS. CHEEK: I have no further 20 questions, Mr. President. 21 THE PRESIDENT: Mr. Luz, any follow-up 22 questions for the Respondent? 23 MR. LUZ: No follow-up questions. 24 THE PRESIDENT: Thank you, Professor 25 Merges, for testifying. You are now released as an</p> <p>www.dianaburden.com</p>
<p>1417</p> <p>1 expert witness and excused. 2 PROFESSOR MERGES: Thank you very 3 much. 4 THE PRESIDENT: Say ten minutes break 5 15? 10 minutes. 6 <i>(Recess taken)</i> 7 STEPHEN GARY KUNIN 8 THE PRESIDENT: Good afternoon, 9 Mr. Kunin. 10 MR. KUNIN: Good afternoon. 11 THE PRESIDENT: Please state your full 12 name for the record. 13 MR. KUNIN: My name is Stephen Gary 14 Kunin. 15 THE PRESIDENT: Mr. Kunin, you appear 16 as an expert witness for the Claimant. If any 17 question is unclear to you, either because of 18 language or for any other reason, please do seek a 19 clarification because, if you don't do so, the 20 Tribunal will assume that you've understood the 21 question and that your answer corresponds to the 22 question. 23 Mr. Kunin, you will appreciate that 24 testifying, be it before a court or an arbitral 25 tribunal, is a very serious matter. In that</p> <p>www.dianaburden.com</p>	<p>1418</p> <p>1 connection, the Tribunal expects you to give the 2 statement, the text of which is in front of you. 3 MR. KUNIN: I solemnly declare upon my 4 honor and conscience that my statement will be in 5 accordance with my sincere belief. 6 THE PRESIDENT: Thank you, Mr. Kunin. 7 Could you please go to your first Expert Report, 8 which is dated September 26, 2014. Go to page 20. 9 MR. KUNIN: I have it in front of me. 10 THE PRESIDENT: Could you please 11 confirm for the record that the signature appearing 12 above your name is your signature? 13 MR. KUNIN: It is. 14 THE PRESIDENT: Could you please go to 15 the second, the Reply Expert Report, page 8? That is 16 dated September 9, 2015. Could you confirm for the 17 record that the signature above your name is your 18 signature? 19 MR. KUNIN: I do. 20 THE PRESIDENT: Is there any 21 correction you wish to make to either report? 22 MR. KUNIN: No, I have no corrections. 23 THE PRESIDENT: Thank you. Ms. Cheek, 24 direct, please. 25 MS. CHEEK: Mr. Kunin, can you please</p> <p>www.dianaburden.com</p>

<p>1 present your presentation for the Tribunal?</p> <p>2 PRESENTATION BY MR. KUNIN</p> <p>3 MR. KUNIN: Yes. Thank you.</p> <p>4 Again, I'm Stephen Kunin. I'm a</p> <p>5 partner in the Oblon firm in Alexandria, Virginia. I</p> <p>6 spent more than 34 years at the U.S. Patent and</p> <p>7 Trademark Office in many capacities. I was the</p> <p>8 deputy Commissioner for patent examination policy,</p> <p>9 deputy assistant Commissioner for a patent examining</p> <p>10 group director in two different examining groups;</p> <p>11 supervisory patent examiner and a patent examiner.</p> <p>12 Today I'm going to focus my testimony</p> <p>13 on USPTO practice and procedure as set forth in the</p> <p>14 USPTO's manual of patent examining procedure known as</p> <p>15 MPEP. This provides guidance to practitioners and</p> <p>16 examiners on PTO practices and procedures. It</p> <p>17 reflects the USPTO's interpretation of U.S. law.</p> <p>18 New editions and revisions are issued</p> <p>19 on a regular basis, and most specifically I'm going</p> <p>20 to talk about the 1992, 1995 and 2001 examination</p> <p>21 guidelines on utility which have been incorporated</p> <p>22 into the MPEP.</p> <p>23 To begin with, in the United States</p> <p>24 and in the guidelines, the focus is on the claimed</p> <p>25 invention. The applicant need only have a single</p> <p>www.dianaburden.com</p>	<p>1 asserted or well-established utility, which is</p> <p>2 specific, substantial and credible. The same utility</p> <p>3 standard applies to all invention types. It's a low</p> <p>4 and easy standard to meet.</p> <p>5 As you can see here in the right part</p> <p>6 of this slide and you'll see in subsequent slides I</p> <p>7 make reference to the specific sections of the MPEP</p> <p>8 that support the statements that I'm making. Again,</p> <p>9 the focus, importantly, is on the claimed invention</p> <p>10 with respect to satisfying the utility requirement.</p> <p>11 Only one well established or asserted utility that is</p> <p>12 specific, substantial and credible is required for</p> <p>13 the claimed invention. A well-established utility</p> <p>14 for classes of compounds with similar structures will</p> <p>15 suffice to meet the utility requirement.</p> <p>16 It's common and sensible for an</p> <p>17 applicant to identify several utilities.</p> <p>18 Importantly, in the guidance provided to patent</p> <p>19 examiners in the MPEP, even when there are additional</p> <p>20 statements in the description, even if incredible,</p> <p>21 they alone cannot be the grounds for an examiner</p> <p>22 defined lack of utility.</p> <p>23 The utility standard is the same for</p> <p>24 all inventions. This includes treatment of human and</p> <p>25 animal disorders. The utility standard is not a high</p> <p>www.dianaburden.com</p>
<p>1421</p> <p>1 bar for pharmaceutical claims. It's not an onerous</p> <p>2 standard. Any public benefit satisfies section 101,</p> <p>3 utility, even if it's not in commercially available</p> <p>4 form. Also, importantly, as you'll see from the</p> <p>5 guidelines, mere identification of a pharmacological</p> <p>6 activity relevant to an asserted use is sufficient.</p> <p>7 For example, if the compound is</p> <p>8 asserted to reduce blood pressure, control bad</p> <p>9 cholesterol, that's the kind of pharmacological</p> <p>10 activity that is relevant to the asserted use.</p> <p>11 Human clinical data is not required to</p> <p>12 establish utility. The mere initiation of clinical</p> <p>13 trials creates a presumption that the claimed</p> <p>14 invention is useful. The claimed invention is</p> <p>15 presumed to have utility, so the burden is on the</p> <p>16 examiner when making a rejection for lack of utility,</p> <p>17 to show that there is a lack of utility. The</p> <p>18 applicant is not required to show evidence of utility</p> <p>19 unless the examiner is making such a rejection that</p> <p>20 the claimed utility is not specific, substantial and</p> <p>21 credible.</p> <p>22 Even where the credibility is</p> <p>23 questioned by the examiner, the evidence that the</p> <p>24 applicant provides need be only necessary and</p> <p>25 reasonably supportive of the utility. This can be</p> <p>www.dianaburden.com</p>	<p>1422</p> <p>1 done through showing structurally similar compounds</p> <p>2 with an established utility. It also can be shown</p> <p>3 through data from in vitro or in vivo animal testing</p> <p>4 that reasonably correlates to treatment in humans.</p> <p>5 Even in such circumstance the evidence need not</p> <p>6 establish utility with statistical certainty.</p> <p>7 Specific guidance is provided in the</p> <p>8 MPEP with respect to applicants being able to submit</p> <p>9 post-filing or post-priority evidence to rebut the</p> <p>10 examiner's prima facie showing of lack of utility.</p> <p>11 Again, this evidence need only relate to the</p> <p>12 examiner's rejection, and confirm that the claimed</p> <p>13 invention had utility at the time of filing.</p> <p>14 The 1992 and 1995 as well as the 2001</p> <p>15 utility guidelines all provided guidance to examiners</p> <p>16 as to the same utility requirement. As you've</p> <p>17 already heard in testimony from others, in the United</p> <p>18 States the Supreme Court decision in 1966 basically</p> <p>19 is the standard that the three guidelines that I've</p> <p>20 identified here are based.</p> <p>21 There have been changes semantically</p> <p>22 in the terminology in the utility guidelines, but</p> <p>23 these did not substantively change the standard. So</p> <p>24 you'll see when you look at the 1992 and</p> <p>25 1995 guidelines words such as "definite,"</p> <p>www.dianaburden.com</p>

<p>1 "practical," "real-world," "credible," and then, 2 comparing those to the 2001 utility guidelines, the 3 terms "specific," "substantial" and "credible" are 4 basically synonymous with the standards, again which 5 all came from the Supreme Court case from 1996 in the 6 United States.</p> <p>7 The 2001 utility guidelines did not 8 change the utility standard applied by the USPTO. If 9 you look at the In re Fisher case, you'll see that in 10 the Fisher case what the Federal Circuit does is it 11 looks at the utility guidelines and essentially says 12 that the utility guidelines are consistent with the 13 standard applied by that court, and also makes 14 reference to the fact that the basic standards for 15 utility again come from the Brenner v Manson 1966 16 case.</p> <p>17 Now, the 2001 utility guidelines 18 provided more precise and methodological guidance to 19 examiners on how to apply the utility standard to new 20 technology such as uncharacterized gene fragments. 21 You'll see here -- and I'm not going to go through 22 this in any detail -- but in the Manual of Patent 23 Examining Procedure in section 2107(II), there is the 24 systematic structured methodology which I am 25 referring to in my reports, which is reflected in the</p> <p>www.dianaburden.com</p>	<p>1 examination guidelines themselves.</p> <p>2 With respect to utility rejections the 3 USPTO has a Tribunal called the Patent Trial and 4 Appeal Board. It reviews patent examiners' decisions 5 in refusing to allow applicants' claims. I looked at 6 the website (you'll see in my report where I've 7 identified the URL for the PTAB website) and looked 8 at the decisions over a ten-year period essentially 9 before and after the 2001 guidelines went into 10 effect, and from these decisions and my review of the 11 PTO's annual reports I determined that fewer than 12 1 percent of all final ex parte PTAB decisions 13 involved a lack of utility rejection.</p> <p>14 Now, I didn't divide them in terms of 15 where the examiner's rejection was sustained or the 16 examiner's rejection was reversed; I just at a very 17 high level indicated the percent of the decisions 18 that included a utility rejection.</p> <p>19 The MPEP, again the section that I 20 mentioned is cited here in the right part of the 21 slide, indicates that rejections for lack of utility, 22 for credible utility, are rare and my review of the 23 PTAB decisions is consistent with that. Lack of 24 utility rejections are primarily involving inoperable 25 inventions or those contrary to laws of science. The</p> <p>www.dianaburden.com</p>
<p>1425</p> <p>1 classic example is a perpetual motion machine. 2 Unsurprisingly, when I reviewed the 3 file histories of the Zyprexa and Strattera patents 4 in the United States, I found that the examiners did 5 not raise a question of lack of utility. The 6 prosecution history is really focused on the question 7 of non-obviousness of the claims, so the examiners 8 essentially following the guidelines found the 9 patents complied with the utility standard.</p> <p>10 Thank you.</p> <p>11 THE PRESIDENT: Thank you.</p> <p>12 MS. CHEEK: I have no direct questions 13 for Mr. Kunin.</p> <p>14 THE PRESIDENT: Thank you.</p> <p>15 CROSS-EXAMINATION ON BEHALF OF THE RESPONDENT</p> <p>16 MR. LUZ: Good afternoon, Mr. Kunin.</p> <p>17 MR. KUNIN: Good afternoon.</p> <p>18 MR. LUZ: My name is Mark Luz. I'm 19 senior counsel for the Government of Canada. I'll be 20 asking you a few questions about the two expert 21 reports that you submitted in this arbitration.</p> <p>22 Just housekeeping matters, because I 23 think I already know the answers, but just for the 24 record, you said that you've been practicing law at 25 the Oblon law firm subsequent to your career at the</p> <p>www.dianaburden.com</p>	<p>1426</p> <p>1 U.S. Patent and Trademark Office?</p> <p>2 MR. KUNIN: Yes. I'm in my 12th year 3 in private practice.</p> <p>4 MR. LUZ: You're not a Canadian 5 lawyer?</p> <p>6 MR. KUNIN: I'm not a Canadian lawyer.</p> <p>7 MR. LUZ: So you're not holding 8 yourself out as an expert on Canadian patent law?</p> <p>9 MR. KUNIN: No. In fact, I think 10 you'll see from the expert reports I'm holding myself 11 as an expert on PTO practice and procedure.</p> <p>12 MR. LUZ: Thank you. You just went in 13 your presentation this morning to slide 20, which is 14 behind tab 1 of your binder.</p> <p>15 MR. KUNIN: I have that in front of 16 me, yes.</p> <p>17 MR. LUZ: You indicate here that you 18 had done a search for rejections by USPTO based on 19 lack of utility?</p> <p>20 MR. KUNIN: Yes. If you'll permit me 21 to do so, if we go to my second Expert Report and we 22 go to page 2 and, in particular, the footnote that is 23 at the bottom of that page, this is what I was 24 referring to in my presentation.</p> <p>25 MR. LUZ: Let's just say -- I'll read</p> <p>www.dianaburden.com</p>

<p>1 it into the record -- footnote 8 on page 2 of your 2 second Expert Report, I'll read paragraph 6, to which 3 the footnote is: "In my experience, rejections of 4 claims by patent examiners on the basis of lack of 5 utility under 35 U.S.C. section 101 are rare for 6 pharmaceutical inventions as well as for all other 7 inventions." And the footnote is what you were 8 talking about: "To confirm my conclusion that 9 rejections of claims by USPTO examiners based on lack 10 of utility are rare, I conducted an exemplary search 11 of final ex parte PTAB decisions on the USPTO's 12 website" -- then you give the website -- "involving 13 lack of utility rejections for a ten year period 14 (1998-2008) and determined from this data and the 15 USPTO annual reports that fewer than 1 percent of all 16 final ex parte PTAB decisions involved lack of 17 utility rejections." 18 Just for clarification, PTAB, can you 19 say what that acronym is, so we know what it is? 20 MR. KUNIN: Yes. In fact, in my 21 presentation I indicated it's the Patent Trial and 22 Appeal Board (PTAB). That is the Tribunal of the 23 USPTO that will review patent examiners' decisions 24 that are adverse to the applicant, and permit the 25 applicant to get an appeal to this tribunal of</p> <p>www.dianaburden.com</p>	<p>1 lawyers to review the correctness of the examiner's 2 determination. 3 MR. LUZ: So you did a search for 4 rejections of claims by examiners based on section 5 101 utility, as you say here on footnote 8. Did you 6 do the same search for rejections based on 7 enablement? 8 MR. KUNIN: I did not. 9 MR. LUZ: Did you do the same search 10 for rejections based on written description? 11 MR. KUNIN: I did not. 12 MR. LUZ: Did you do the same type of 13 search for rejections based on obviousness? 14 MR. KUNIN: I did not. 15 MR. LUZ: Novelty? 16 MR. KUNIN: I did not. 17 MR. LUZ: Do you have your first 18 Expert Report there? 19 MR. KUNIN: I do. 20 MR. LUZ: If you'd turn to paragraph 21 41, the 2001 Utility Guidelines, this is I think what 22 you were just talking about, "The 8th edition of MPEP 23 incorporated the 2001 Utility Guidelines. The 2001 24 Utility Guidelines were published to provide 25 examiners with updated guidance on the application of</p> <p>www.dianaburden.com</p>
<p>1429</p> <p>1 the utility standards, especially as applied to 2 examination of claims directed to uncharacterized 3 gene fragments in the field of biotechnology. I was 4 personally involved in drafting these guidelines." 5 Before we go on, Mr. Kunin, 6 uncharacterized gene fragments, what was happening at 7 the time that that prompted the review of the Utility 8 Guidelines because of uncharacterized gene fragments? 9 MR. KUNIN: Well, if I may, I've 10 noticed in the notebook that you've provided me that 11 you've made reference to a 2000 publication article 12 that I authored, which is, I guess, under tab 20. 13 MR. LUZ: I was going to take you 14 there eventually. Actually, before we get there, 15 just because I know I was about to take you there, 16 but just for the Tribunal's and for everyone's 17 benefit, I believe this is the article that you 18 describe in your second Expert Report at paragraph 19 13, if you'd turn to that, and then we'll go to your 20 article. 21 So your second Expert Report, 22 paragraph 13. 23 MR. KUNIN: Yes. 24 MR. LUZ: So "In paragraph 65 of his 25 Expert Report Professor Holbrook suggested that my</p> <p>www.dianaburden.com</p>	<p>1430</p> <p>1 reference to the 2001 Guidelines as 'a more stringent 2 test' was evidence that the law of utility changed in 3 the United States. I disagree." 4 So I think the article that you wanted 5 to turn to at tab 20 is the article that you were 6 talking about? 7 MR. KUNIN: Yes, that is correct. 8 MR. LUZ: Let's go to that article, 9 tab 20. For the record, it's Exhibit R-119. 10 MR. KUNIN: And the reason why I bring 11 this up is because I understood your question to give 12 a little bit of a historical retrospective of the 13 history with respect to the promulgation of Utility 14 Guidelines, and the introduction to this article 15 gives such a retrospective. Let me turn to the 16 section dealing with the Utility Guidelines. So what 17 this article -- 18 MR. LUZ: Sorry, Mr. Kunin. Are you 19 turning to a particular page? 20 MR. KUNIN: I am just preparing myself 21 but not going to a particular page to point to some 22 specific section. 23 THE PRESIDENT: Mr. Kunin, could you 24 limit yourself to answering the questions? 25 MR. LUZ: I'm happy to allow the</p> <p>www.dianaburden.com</p>

<p>1 witness to elaborate a little bit, but a little bit. 2 I think maybe I can help guide you with this because 3 I did ask what was happening specifically with the 4 gene sequences that led to the promulgation of the 5 2001 guidelines. 6 MR. KUNIN: So I apologize -- 7 THE PRESIDENT: No, no. It's fine. 8 Anything you miss out on explanation will undoubtedly 9 be picked up in redirect. Can you repeat the 10 question? 11 MR. LUZ: Yes, if you could provide 12 some background as to what led to the promulgation of 13 these 2001 guidelines in the context of the gene 14 sequences that you referred to earlier. 15 MR. KUNIN: Yes. So the USPTO had 16 published some proposed guidelines on the written 17 description requirement. As a result of public 18 comments received, there was an interest on the part 19 of the public for the USPTO to also update its 20 Utility Guidelines with respect to the discussions 21 taking place in the public with respect to the 22 express sequence tags. As you indicated with a 23 previous witness this led to ultimately the In re 24 Fisher case, and this article gives a historical 25 retrospective that, as a result of the impetus from</p> <p>www.dianaburden.com</p>	<p>1 public comments, the USPTO chose to issue what became 2 the 2001 Utility Guidelines in addition to the 3 written description guidelines to address the request 4 from the public. 5 MR. LUZ: So to summarize, there was a 6 development in technology that was happening in the 7 1990s that pushed the utility issue further into the 8 fore for the Patent Office? 9 MR. KUNIN: Yes. And on page 93 of 10 the article in the background section, you will see 11 that there is a very brief description here with 12 respect to express sequence tags and the 12 comments 13 received. 14 MR. LUZ: Thank you. We talked about 15 the reference in Professor Holbrook's Expert Report, 16 so let's go to the specific part of your article from 17 2000. If you'd turn to page 100, it's the very last 18 page. 19 MR. KUNIN: I have that in front of 20 me. 21 MR. LUZ: It says: "With the Office 22 applying a more stringent test for utility than in 23 its earlier set of guidelines, it fully expects to be 24 challenged by applicants who view the law 25 differently. Therefore, it may remain for the Board</p> <p>www.dianaburden.com</p>
<p>1433</p> <p>1 of Patent Appeals and Interferences and the federal 2 courts to determine the true scope of the 3 substantiality criterion of the utility requirement 4 on a case-by-case basis." 5 Let's turn back to paragraph 14 of 6 your second witness statement. Paragraph 14, "In my 7 article identified in footnote 132 of the Holbrook 8 Report" -- which is what we were just reading, 9 Exhibit R-119 -- "I used the term 'stringent' in the 10 dictionary sense of being more 'precise'. 11 I don't mean to be facetious but was 12 there a dictionary in particular that you got the 13 definition of "stringent" and "precise" to be, or 14 were you using that as a euphemism? 15 MR. KUNIN: No. Actually I'm aware of 16 a dictionary that includes "precise" as one of a 17 number of different definitions. I think to some 18 degree here, you know, maybe I was starting to put a 19 biotech hat on, because in discussing some aspects of 20 biotech policy, the notion of precision and 21 stringency are common terminology, so this is 22 essentially to explain what I meant, but in the 23 paragraph 15 you'll also see -- and we can go back to 24 those pages in my actual article -- that is the 25 substance behind my statement of that's what I meant</p> <p>www.dianaburden.com</p>	<p>1434</p> <p>1 by the word "stringent." 2 MR. LUZ: We'll come back to your 3 article in a second but let's go to tab 10 of your 4 binder, which is R-55, and this is a copy of a book 5 Intellectual Property in the New Technological Age. 6 MS. CHEEK: I'm sorry, this is the 7 same exhibit, Professor Merges' book? 8 MR. LUZ: This one is tab 10, R-55. I 9 think it's a different exhibit than what we had been 10 looking at before. It's the same binder. 11 MS. CHEEK: We have R-55 as 12 Intellectual Property in the New Technological Age by 13 Professor Merges, Menell and Lemley. 14 THE PRESIDENT: Are you referring, 15 Ms. Cheek, to the other one in tab 7? It's another 16 book by the Professor, as I understand it. 17 MS. CHEEK: Yes. Professor Merges has 18 authored multiple books. I just was a bit confused 19 that Mr. Kunin, who is here to testify on Office 20 practice, was now going to get cross-examined based 21 on Professor Merges' book. A confusion on my part. 22 Perhaps not. 23 THE PRESIDENT: I'll allow the 24 question. Please go ahead. 25 MR. LUZ: I'll just read a description</p> <p>www.dianaburden.com</p>

<p>1 to ask Mr. Kunin if he agrees with the 2 characterization. 3 MS. CHEEK: Sure. I'm sorry, what 4 page? 5 MR. LUZ: 175. The Note on 6 Patent Office Utility Guidelines. It says, "The 7 Patent and Trademark Office has promulgated 8 guidelines for determining the specific utility of an 9 invention. See Utility Examination Guidelines" and 10 it gives the 2001 reference. "The PTO guidelines 11 require that an asserted utility be 'specific, 12 credible and substantial'. The credibility element 13 was well known; it is the basis of utility rejections 14 for farfetched inventions such as perpetual motion 15 machines. The novel aspects of the guidelines were 16 1, the definition of a 'specific' utility and 2, the 17 addition of a new requirement of 'substantial' 18 utility." 19 Let's turn back to your article. I 20 know you actually wrote about this specifically on 21 page 96, tab 20. Do you see the section there, 22 "Comparison with Prior Guidelines." 23 MR. KUNIN: Yes. 24 MR. LUZ: I'll just read that, and I 25 think you'll see what Professor Merges had suggested</p> <p>www.dianaburden.com</p>	<p>1 is reflected in your article as well. 2 "The Revised Utility Guidelines and 3 accompanying examiner training materials differ from 4 the prior guidelines in two important respects. 5 First, the perspective has shifted from emphasizing 6 the credibility of any specific asserted utility to 7 determining whether an asserted utility is specific 8 and substantial." 9 So is that the new novel aspect of the 10 2001 guidelines, the perspective has shifted away 11 from just credibility to determining whether the 12 asserted utility is specific and substantial? 13 MR. KUNIN: Well, I don't agree. If 14 we go to page 97 of the article, which discusses that 15 the standard is the Brenner v Manson standard, and as 16 I have previously indicated even in my presentation, 17 that that is the standard that has been consistent 18 through the '92, '95 and 2001 guidelines. So the 19 standard hasn't changed. 20 Now, the question with respect to 21 emphasis, I think goes to providing the 22 embellishment, the clarification that's set forth in 23 the guidelines so that each of these three criteria 24 are fully explained in the 2001 guidelines but, 25 again, consistent with Brenner.</p> <p>www.dianaburden.com</p>
<p>1437</p> <p>1 MR. LUZ: We'll come back to Brenner 2 in just a moment but, if you go to the next 3 paragraph, page 96, halfway through, right after 4 footnote 70 it says, "The prior guidelines placed a 5 great deal of emphasis on the credibility of any 6 asserted utility. At the time the prior Guidelines 7 were published, it seemed that in certain types of 8 cases the PTO may have been too restrictive in its 9 interpretation of the statute." I'm assuming you're 10 saying that's referring to the 95 guidelines. Is 11 that right? 12 MR. KUNIN: Yes. 13 MR. LUZ: "...and the prior guidelines 14 were promulgated in response to such concerns." What 15 you're saying here is there was a perception that the 16 PTO may have been too restrictive in its 17 interpretation and the prior guidelines were 18 promulgated in response to such concerns? 19 MR. KUNIN: Well, I think that if we 20 go on to the top of page 97, it will give you a clear 21 appreciation, because at the top of 97 there's a 22 discussion with respect to the view of the disclosure 23 in any other evidence of record that is probative of 24 applicant assertions, so I think the commentary here 25 is the standard really is not a different standard.</p> <p>www.dianaburden.com</p>	<p>1438</p> <p>1 What the situation I think was 2 relative to the '95 guidelines is that, in terms of 3 how the PTO was considering the evidence, the PTO was 4 essentially being too restrictive and, therefore, it 5 was the specific treatment of the evidence, and that 6 is what the clarification was, to basically point out 7 that the standard hasn't changed, you just need to 8 recognize what is necessary to establish utility and, 9 when that is present, the claims don't lack utility. 10 MR. LUZ: Let's just read on from 11 page 96 onto the top of 97. "The revision [the 2001 12 guidelines] continues to note that the credibility is 13 assessed from the perspective of one of ordinary 14 skill in the art in view of the disclosure and any 15 other evidence of record, (eg test data, affidavits 16 or declarations from experts in the art, patents or 17 printed publications) that is probative of the 18 applicant's assertions). However, the issue of 19 whether any asserted utility is specific and 20 substantial is the core issue addressed therein. The 21 revision is not intended to change current PTO 22 practice with regard to assessing the credibility of 23 any asserted utility." 24 So here you're saying nothing is 25 changing on the credibility side of things but, in</p> <p>www.dianaburden.com</p>

<p>1 terms of specific and substantial, that is the core 2 issue that is being addressed in the 2001 guidelines, 3 whereas that wasn't the case before? 4 MR. KUNIN: I disagree with that. 5 MR. LUZ: After that you talk about 6 Brenner v Manson. 7 MR. KUNIN: Yes. 8 MR. LUZ: If you'd turn to tab 14, 9 I'll just read you something and ask you a question 10 based on that. This is Exhibit R-120, page 330. 11 That is Janice Mueller writing: "In the wake of the 12 USPTO's 2001 promulgation of the Utility Examination 13 Guidelines discussed above, a test case was brought 14 to clarify the standards for applying the 101 utility 15 requirement to patent claims reciting ESTs (expressed 16 sequence tags). The result in In re Fisher was a 17 return to the Federal Circuit in 2005 to the rigorous 18 utility criteria announced almost 40 years earlier by 19 the Supreme Court in Brenner v Manson." 20 I think as we just read and, as you 21 said, the 2001 utility guidelines was a re-emphasis 22 on the Brenner v Manson specific and substantial 23 utility criteria, whereas prior to that that was not 24 the emphasis. Is that right? 25 MR. KUNIN: Well, I don't know what</p> <p>www.dianaburden.com</p>	<p>1 you mean in terms of emphasis because if we look 2 systematically at the '92 and '95 guidelines as well 3 as the 2001 guidelines, we'll see that the 4 requirements from Brenner v Manson were there. They 5 were in the guidelines. They may have used the word 6 "definite" as opposed to "specific" in certain 7 sections, but they also talked in terms of practical 8 utility, substantial utility, real world value. So 9 the standard, I don't believe, changed. 10 Now, from the standpoint of the 11 question of emphasis the whole aspect of examination 12 guidelines is to provide clear guidance to the 13 examiner, so that if there is a standard that 14 involves three parts, the examiners need to 15 appreciate that the standard involves three parts. 16 So from the standpoint of emphasis I look at emphasis 17 in terms of that, again, the ordered structure set 18 forth in the guidelines so the examiner can 19 systematically go through and see whether there's 20 well established or asserted specific, substantial 21 and credible utility. So, going through each one, 22 I'm not sure I would necessarily say there's any 23 specific emphasis over one over the other. They're 24 all three parts of the same standard. 25 MR. LUZ: Thank you, Mr. Kunin. I</p> <p>www.dianaburden.com</p>
<p>1441</p> <p>1 don't have any other questions. 2 THE PRESIDENT: Any questions on 3 redirect, Ms. Cheek? 4 MS. CHEEK: I have no questions for 5 Mr. Kunin. 6 THE PRESIDENT: Nor has the Tribunal. 7 Thank you, Mr. Kunin, for testifying. You are now 8 released as a witness and excused. Five minutes 9 change over for the next expert. 10 <i>(Recess taken)</i> 11 THE PRESIDENT: Ms. Cheek? 12 MS. CHEEK: The testimony earlier 13 today of Professor Levin and Professor Merges, as you 14 are aware, both of them provided you with some 15 demonstratives by drawing various things on the 16 easel. I'd like to formally move each of their 17 demonstratives into the record as demonstratives. I 18 think for Professor Levin it would be Levin 1, 2, 3 19 and Merges Demonstrative 1. 20 THE PRESIDENT: Actually, they were 21 already in the record except they had no number. We 22 have to give them a number. 23 MS. CHEEK: I believe Professor Levin 24 has two pieces of paper, so we will note those in 25 this sequential order of Demonstrative 1 and</p> <p>www.dianaburden.com</p>	<p>1442</p> <p>1 Demonstrative 2, and then Professor Merges has one 2 piece of paper, so we'll denote that as Demonstrative 3 1. 4 THE PRESIDENT: Thank you. Any 5 further housekeeping? 6 MS. CHEEK: That's all. 7 TIMOTHY RICHARD HOLBROOK 8 THE PRESIDENT: Professor Holbrook, 9 good afternoon. 10 PROFESSOR HOLBROOK: Good afternoon. 11 THE PRESIDENT: Could you please state 12 your full name for the record? 13 PROFESSOR HOLBROOK: Timothy Richard 14 Holbrook. 15 THE PRESIDENT: You are appearing as 16 an expert witness for the Respondent. If any 17 question is unclear to you, either because of 18 language or for any other reason, please do seek a 19 clarification because, if you don't do so, the 20 Tribunal assumes you've understood the question and 21 that your answer corresponds to the question. 22 PROFESSOR HOLBROOK: Understood. 23 THE PRESIDENT: You will appreciate 24 that testifying, be it before a court or an arbitral 25 tribunal, is a very serious matter. In that</p> <p>www.dianaburden.com</p>

<p>1 connection, the Tribunal expects you to give the 2 statement, the text of which is in front of you. 3 PROFESSOR HOLBROOK: I solemnly 4 declare upon my honor and conscience that my 5 statement will be in accordance with my sincere 6 belief. 7 THE PRESIDENT: Professor Holbrook, 8 could you please go to your Expert Report dated 9 January 26, 2015? 10 PROFESSOR HOLBROOK: Yes. 11 THE PRESIDENT: Page 35, and confirm 12 for the record that the signature appearing above 13 your name is your signature? 14 PROFESSOR HOLBROOK: That is my 15 signature. 16 THE PRESIDENT: Could you please go to 17 the second Expert Report dated December 5, 2015. Go 18 to page 21, and that is dated December 5, 2015. 19 Could you confirm for the record that the signature 20 appearing above your name is your signature? 21 PROFESSOR HOLBROOK: That is my 22 signature. 23 THE PRESIDENT: Could you please tell 24 me whether you would like to correct either report? 25 PROFESSOR HOLBROOK: I have no</p> <p>www.dianaburden.com</p>	<p>1 corrections. 2 THE PRESIDENT: Mr. Luz or 3 Mr. Spelliscy, are you at least introducing the 4 direct, if I may call it that way? 5 MR. LUZ: We'll introduce Professor 6 Holbrook to allow you to start off with your 7 presentation. Go ahead. 8 PRESENTATION BY PROFESSOR HOLBROOK 9 PROFESSOR HOLBROOK: Thank you so 10 much. First a little bit about who I am, just to 11 give an overview. I am a professor at the Emory 12 University School of Law in Atlanta Georgia. I have 13 been a professor there since 2009. Previously I was 14 on the faculty of the Chicago-Kent College of Law, at 15 the Illinois Institute of Technology, unsurprisingly 16 in Chicago. 17 I earned my Law degree at Yale Law 18 School, my JD, and I have a BS in Chemical 19 Engineering from North Carolina State University, 20 where I graduated summa cum laude. 21 My publications include a textbook, a 22 case book, Patent Litigation and Strategy, with Judge 23 Kimberly Moore of the Federal Circuit and John 24 Murphy, and I've authored over 40 articles and book 25 chapters primarily on patent law.</p> <p>www.dianaburden.com</p>
<p>1445</p> <p>1 Today in my discussion I'd like to 2 take a step back and think about a certain tension, 3 two tensions that all patent systems across the world 4 encounter. The first relates to timing. Is there an 5 invention yet? We don't want people applying for 6 patents when they haven't created anything yet. So 7 the systems have to ensure that there is actually an 8 invention, not mere speculation, not a research plan. 9 Now, the systems are clear. They 10 don't actually have to have created something 11 tangible to file an application. You could use what 12 in the States we would call prophetic examples, but 13 even with those prophetic examples you're going to 14 have to predict an outcome. Now, that can be 15 difficult in certain technological fields where such 16 prediction is unpredictable, where minor changes can 17 affect large changes in outcome. 18 A second -- and as Professor Merges 19 noted related -- issue is scope. It's related in 20 that it also relates to time. Over time you may be 21 able to claim more broadly and extrapolate. This is 22 a question of how much protection should the inventor 23 get. You have to ensure sufficient protection to the 24 patentee to maintain the incentives of the patent 25 system, but you don't want to give too much</p> <p>www.dianaburden.com</p>	<p>1446</p> <p>1 protection, rewarding a windfall for work that that 2 inventor did not actually accomplish. For example, 3 if someone cures a particular form of cancer it would 4 seem unfair to give them a patent that covers a cure 5 for all cancer, if that's not what they created. 6 These tensions and issues pervade all 7 patent systems, but countries may vary in which 8 doctrinal bucket they use to address these concerns. 9 My understanding of Canadian utility doctrine, that's 10 the primary home that Canada uses to address these 11 problems. In the United States we use a number of 12 different doctrines, different doctrinal buckets, but 13 the policies that they're concerned with are exactly 14 the same. So, for example, using Canadian 15 terminology of selection patents, the United States 16 is also concerned with whether or not these selection 17 patents, these claims to species have unexpected 18 results. We tend to police that concern through the 19 obviousness doctrine, however. 20 Also with respect to utility doctrine, 21 particularly with method of use claims, we do address 22 those concerns in the United States through utility 23 but also written description and enablement, and so 24 my goal today is to lay out how U.S. law addresses 25 these concerns, drawing comparisons to the Canadian</p> <p>www.dianaburden.com</p>

<p>1 doctrine as I go along.</p> <p>2 As I mentioned, the U.S. patent system</p> <p>3 uses three different doctrinal levers to address</p> <p>4 these tensions. One, utility, which we've heard a</p> <p>5 lot about today. The invention must be useful.</p> <p>6 Enablement, the patent must disclose how to make and</p> <p>7 use the invention. And written description. The</p> <p>8 inventor must provide a description of the invention</p> <p>9 that demonstrates his or her possession of the</p> <p>10 invention.</p> <p>11 All three of these doctrines are</p> <p>12 measured as of the filing date. That is our snapshot</p> <p>13 in time where we make the assessment of whether the</p> <p>14 conditions have been satisfied. And they are closely</p> <p>15 related. In fact, as we discussed earlier, the</p> <p>16 Federal Circuit has specifically said in the</p> <p>17 Rasmusson case section 112, the enablement provision,</p> <p>18 incorporates section 101 utility as a matter of law.</p> <p>19 So not only are they closely related, they are</p> <p>20 intertwined and one is absolutely inextricably tied</p> <p>21 to the other.</p> <p>22 Enablement and written description are</p> <p>23 also closely related. In the words of the Federal</p> <p>24 Circuit in the en banc case Ariad they note they</p> <p>25 "often rise or fall together," so the Federal Circuit</p> <p>www.dianaburden.com</p>	<p>1 itself acknowledges that those two doctrines are very</p> <p>2 closely tied.</p> <p>3 So I'm going to unpack those doctrines</p> <p>4 under U.S. law individually. The first is utility.</p> <p>5 We see here that in section 101 you have the word</p> <p>6 "useful." As Professor Merges' textbook noted you</p> <p>7 also see section 112 noting you have to have</p> <p>8 disclosure of how to use the invention as well. The</p> <p>9 idea here for utility is, as the Federal Circuit has</p> <p>10 noted, to prevent mere ideas from being patented.</p> <p>11 The Supreme Court has stated that a patent is "not a</p> <p>12 hunting license. It is not a reward for the search,</p> <p>13 but compensation for its successful conclusion."</p> <p>14 All of the U.S. experts agree that the</p> <p>15 standard is uniform and generally it's low, but some</p> <p>16 technologies will encounter the utility standard</p> <p>17 differently. So if I can use an analogy, think about</p> <p>18 high jump, right? The bar is the same height for</p> <p>19 every jumper but on average some jumpers have more</p> <p>20 difficulty clearing that bar. Someone who is</p> <p>21 particularly short may have far more difficulty</p> <p>22 clearing the bar, even if it is the same height.</p> <p>23 That's how utility operates with respect to certain</p> <p>24 technologies like chemistry, pharmaceuticals and</p> <p>25 biotechnology. The standard is the same, but the way</p> <p>www.dianaburden.com</p>
<p>1449</p> <p>1 those technologies encounter the standard is going to</p> <p>2 be different.</p> <p>3 As we've heard already, utility in</p> <p>4 U.S. law has three basic requirements. The asserted</p> <p>5 utility must be credible, which also relates to</p> <p>6 operability. The utility has to be substantial. The</p> <p>7 utility has to be specific. As to credible utility</p> <p>8 or operability, this is asking the question does the</p> <p>9 invention actually work at all, and, more</p> <p>10 particularly, would one of skill in the art believe</p> <p>11 at the time of the filing date that the invention</p> <p>12 will work.</p> <p>13 Some inventions will always be</p> <p>14 inoperable. They will be incredible. A perpetual</p> <p>15 motion machine is an example. It violates the laws</p> <p>16 of thermodynamics. There will never be a patent on a</p> <p>17 perpetual motion machine. But there are other</p> <p>18 categories of inventions where that credibility and</p> <p>19 operability may change over time, and that's where</p> <p>20 you have to explore what is the evidence for whether</p> <p>21 the invention works. Baldness treatments used to be</p> <p>22 viewed as inherently incredible, inoperable. That is</p> <p>23 no longer the case. But that was a change over time.</p> <p>24 Now, it is true for compounds, one</p> <p>25 utility is enough, but we always have to focus, as</p> <p>www.dianaburden.com</p>	<p>1450</p> <p>1 everyone has emphasized, on the claims. You can't do</p> <p>2 a utility analysis under U.S. law without focusing on</p> <p>3 the language of the claims. So, for example, in In</p> <p>4 re Gottlieb, it is true, one use disclosed was enough</p> <p>5 to satisfy utility in that case. The other uses</p> <p>6 which were not supported were deemed irrelevant. But</p> <p>7 that's because it was a compound claim.</p> <p>8 If that patent had claimed methods of</p> <p>9 using the compound to effect those other disclosed</p> <p>10 utilities that were not only supported, those claims</p> <p>11 would have been invalid for lack of utility, so the</p> <p>12 type of claim becomes very important.</p> <p>13 You can also see the importance of</p> <p>14 interpretation of claims and how that can impact</p> <p>15 utility. In the Raytheon case one of the claims was</p> <p>16 actually invalidated as inoperable because there was</p> <p>17 a limitation in the claim that everyone agreed it</p> <p>18 actually could not work that way. It was required.</p> <p>19 That utility was required by the claim.</p> <p>20 The other claims did not contain that</p> <p>21 requirement but that was a question of claim</p> <p>22 construction. The district court below had actually</p> <p>23 decided those claims required that inoperable</p> <p>24 component. The Federal Circuit disagreed, said it</p> <p>25 didn't require that dynamic, and concluded the claims</p> <p>www.dianaburden.com</p>

<p>1 were operable, but the key to the holding was what 2 did the claims mean. That's the important takeaway 3 from Raytheon.</p> <p>4 A substantial utility -- and I won't 5 spend much time here; we've all discussed these and 6 are all pretty much in agreement about what these 7 mean -- substantial utility is a practice or real 8 world utility. There must be an immediate benefit to 9 the public; examples where there is not substantial 10 utility, the use as a chemical intermediary, or a 11 starting point for more research. A specific utility 12 is one which is not so vague as to be meaningless. 13 The suggestion that a chemical has biological 14 activity will not be enough.</p> <p>15 So that's the basic standard for 16 utility. But, as I mentioned, U.S. patent law also 17 addresses many of the concerns of timing through 18 enablement. This statutory provision is section 19 112(a). You'll see references to section 112 20 paragraph 1 because we recently amended our statute 21 to change some of the nomenclature. That provision 22 requires the specification to contain a written 23 description of the manner and process of making and 24 using it -- "it" being the invention -- in such full, 25 clear, concise and exact terms as to enable any</p> <p>www.dianaburden.com</p>	<p>1 person skilled in the art to make and use the same. 2 So there again you see the language "use" and "make." 3 Both of components.</p> <p>4 The test the courts have adopted to 5 assess whether enablement is satisfied is whether the 6 invention can be made and used without undue 7 experimentation. Some experimentation, that's okay. 8 Too much experimentation, that's a violation of the 9 enablement requirement. Here we note again, if a 10 claim fails to meet the utility requirement because 11 it is not useful or operative, then it also fails to 12 meet the how to use aspect of enablement, so utility 13 and enablement go hand-in-hand in the U.S.</p> <p>14 Enablement does act to police claim 15 scope, the breadth. In In re Wright as an example -- 16 and I give you a graphical example -- the inventor 17 had discovered a vaccine for a specific virus, the 18 prog avian sarcoma virus, and there is no doubt he 19 deserved a claim covering that virus, that vaccine. 20 But he also wrote broader claims. One was to avian 21 RNA viruses, a vaccine for avian RNA viruses 22 generally, and one was so broad that it was all RNA 23 viruses, which would actually include a vaccine for 24 the HIV virus, which to this day we do not have a 25 vaccine for. So clearly he had not enabled, he had</p> <p>www.dianaburden.com</p>
<p>1453</p> <p>1 not taught anyone to make and use a vaccine for HIV, 2 so that claim was denied as too broad. Not enabled.</p> <p>3 Interestingly here he was also denied 4 protection for the avian RNA viruses generally. They 5 noted "Wright has failed to establish by evidence or 6 arguments that in February of 1983 a skilled 7 scientist would have believed reasonably that 8 Wright's success with a particular strain of an avian 9 RNA virus could be extrapolated with a reasonable 10 expectation of success to other avian RNA viruses."</p> <p>11 You get this idea of prediction, how 12 widely can you speculate.</p> <p>13 So enablement does act to constrain 14 scope. Broad genus claims, if they contain too many 15 inoperable embodiments, lots of chemicals that 16 actually don't work, and we take undue 17 experimentation to figure out which ones do, that's a 18 violation of enablement. As the Federal Circuit has 19 noted, typically patent applications claiming new 20 methods of treatments are supported by test results. 21 These would be called working examples, actual 22 examples, and the Canadian law, my understanding is, 23 referred to demonstration, where there's an actual 24 experiment done.</p> <p>25 Now, U.S. law does allow prophetic</p> <p>www.dianaburden.com</p>	<p>1454</p> <p>1 examples where you are predicting what will happen, 2 but prophetic examples still must satisfy the undue 3 experimentation test, so the overall assessment of 4 enablement is governed by what have been called the 5 Wands factors, named after the case that elaborated 6 them. The quantity of experimentation necessary -- 7 that makes sense if our test is undue 8 experimentation; the amount of direction or guidance 9 present in the patent -- how much does the 10 specification disclose; the presence or absence of 11 working examples -- that's have you actually done 12 something, clearly working examples are far more 13 helpful in satisfying enablement; the nature of the 14 invention -- curing cancer is hard, you probably 15 aren't going to be able to have broad claim scope if 16 you're trying to treat a very complicated disease; 17 the state of the prior art -- what is known, what can 18 we expect, how much can we predict; the relative 19 skill of those in the art; predictability or 20 unpredictability of the art. So this gets to the 21 same concept that we see in Canadian utility law of 22 sound prediction. That you are allowed to sort of 23 anticipate, even using prophetic examples, but you're 24 going to have to give a good explanation as to why 25 that prediction works and unpredictable arts, that</p> <p>www.dianaburden.com</p>

<p>1 may be difficult to accomplish. And, finally, the 2 breadth of the claims are, of course, relevant. 3 The last requirement that polices 4 these timing concerns of is there an invention and 5 how much protection should you get is the written 6 description requirement. The statute is pretty 7 straightforward, it doesn't elaborate much. It says 8 "The specification shall contain a written 9 description of the invention." That's all it tells 10 us. 11 The courts have interpreted that 12 provision as follows. The patent disclosure must 13 "reasonably convey to those skilled in the art that 14 the inventor had possession of the claimed subject 15 matter as of the filing date." This is an "objective 16 inquiry into the four corners of the specification." 17 So in this way it actually polices 18 both concerns. Is there invention at all, the first 19 policy concern, and, if so, how broad of protection 20 should you get. The court noted, "Written 21 description of the invention plays a vital role in 22 curtailing claims that do not require undue 23 experimentation to make and use, and thus satisfy 24 enablement, but that have not been invented, and thus 25 cannot be described." That's the threshold question,</p> <p>www.dianaburden.com</p>	<p>1 is there an invention at all. 2 The court then goes on to note that 3 written description plays a second function. Written 4 description "also ensures that when a patent claims a 5 genus by its function or result, the specification 6 recites sufficient materials to accomplish that 7 function." So you see both policies being vindicated 8 in written description. 9 Now, all of these are assessed as of 10 the filing date, and, generally speaking, post-filing 11 evidence of a lack of utility or enablement is always 12 going to be relevant. If it doesn't work now, five 13 years later, it's highly unlikely that it worked at 14 the time of the application. But generally 15 post-filing evidence supporting utility is not relied 16 upon by the courts. The reason is simple. It risks 17 incorporating later developments in technology, 18 things that are not reflected at the state of the art 19 as the filing. 20 Now, the courts have recognized -- the 21 Federal Circuit has recognized what another court, a 22 district court, has characterized as a narrow 23 exception. That you can use post-filing evidence 24 supporting enablement and utility if it pertains to 25 the accuracy of a statement already in the</p> <p>www.dianaburden.com</p>
<p>1457</p> <p>1 specification, but the courts have warned that is a 2 narrow exception, because you do not want that later 3 evidence to actually reflect advances in the state of 4 the art because that would be unfair. You hadn't 5 invented it at that time. 6 So, in summary, utility in the United 7 States polices the threshold issue is there invention 8 or not. Enablement to some extent does that as well. 9 It also polices scope. 10 Recognized for a method, generally the 11 how to use prong is all we're worried about. You're 12 simply saying how to do something. And so if you 13 haven't explained how to do something, you haven't 14 invented anything yet at all. 15 Written description, similarly, asks 16 has the inventor possessed this invention at all or 17 not. So in the ways that the Canadian utility 18 doctrine polices these policy concerns, we see those 19 concerns policed in the United States through these 20 three different doctrines. Thank you. 21 MR. LUZ: Mr. President, Canada does 22 not have any direct examination questions for 23 Professor Holbrook, so we turn him over to the 24 Claimant. 25 THE PRESIDENT: Thank you. The cross</p> <p>www.dianaburden.com</p>	<p>1458</p> <p>1 will be conducted by -- 2 MS. CHEEK: Mr. Smith will be 3 examining. 4 THE PRESIDENT: Please proceed. 5 CROSS-EXAMINATION ON BEHALF OF THE CLAIMANT 6 MR. SMITH: Thank you, Mr. President. 7 We have cross-examination binders to hand you. I 8 want to note for the record that, in addition to the 9 exhibits that are on the first page and tabbed in the 10 binder, there's one additional insert I'd like to 11 include. It's in the record. It is Exhibit C-73. 12 It's excerpts from the U.S. Code, specifically the 13 U.S. Patent Act. I apologize for it not being tabbed 14 and in the binder, but it's a short exhibit and we're 15 handing it out along with the binders. (Handed) 16 Professor Holbrook, I'd like to begin 17 today by talking first about your mandate as an 18 expert witness in this case, the role you were asked 19 to perform. The specific question -- and perhaps it 20 would be helpful to turn to tab 1, your First Report, 21 and specifically to page 3, paragraph 6, the specific 22 question you indicate there that you were asked to 23 address in your reports is whether U.S. law has rules 24 that are "equivalent to the different concepts found 25 in Canada's utility requirement." Is that correct?</p> <p>www.dianaburden.com</p>

<p>1 PROFESSOR HOLBROOK: Correct, and gave 2 examples that followed after. 3 MR. SMITH: Right. So you say that 4 your report and your testimony explores that basic 5 question, right? 6 PROFESSOR HOLBROOK: Correct. 7 MR. SMITH: And specifically, as you 8 mentioned, you say that you examined whether U.S. 9 patent law has any rules equivalent -- and here I'm 10 quoting -- to the "promise of the patent," 11 "demonstration versus sound prediction," "rules 12 against post-filing evidence" and "appropriate 13 disclosure of the basis of the sound prediction." Is 14 that correct? 15 PROFESSOR HOLBROOK: That's what the 16 report says, yes. 17 MR. SMITH: Is that what you provided 18 to -- 19 PROFESSOR HOLBROOK: I believe it's 20 what I provided. 21 MR. SMITH: So to answer that 22 comparative question of equivalence, you first had to 23 make sure that you were fully up-to-date on U.S. 24 utility law, correct? 25 PROFESSOR HOLBROOK: Correct.</p> <p>www.dianaburden.com</p>	<p>1 MR. SMITH: You reviewed and relied 2 upon U.S. case law on utility? 3 PROFESSOR HOLBROOK: Yes. 4 MR. SMITH: You reviewed and relied 5 upon patent law treatises and textbooks? 6 PROFESSOR HOLBROOK: Yes. 7 MR. SMITH: You reviewed and relied 8 upon the MPEP, the Manual of Patent Examination 9 Procedure, of the U.S. Patent Office? 10 PROFESSOR HOLBROOK: Yes. 11 MR. SMITH: You also reviewed and 12 relied upon publications of academic scholars? 13 PROFESSOR HOLBROOK: Yes. 14 MR. SMITH: You also reviewed the 15 expert reports offered in this case by Professor 16 Merges and Mr. Kunin? 17 PROFESSOR HOLBROOK: Yes. 18 MR. SMITH: Is it fair to say that 19 your review of the relevant sources on U.S. utility 20 law was comprehensive? 21 PROFESSOR HOLBROOK: Yes. 22 MR. SMITH: So that U.S. law is the 23 first half of your comparative analysis of 24 equivalence, correct? 25 PROFESSOR HOLBROOK: Correct.</p> <p>www.dianaburden.com</p>
<p>1461</p> <p>1 MR. SMITH: But to determine if these 2 U.S. patentability rules are equivalent to Canada's 3 utility requirement, you obviously need to be 4 familiar with Canada's utility requirement as well? 5 PROFESSOR HOLBROOK: That is correct. 6 MR. SMITH: And you are, in fact, 7 familiar with Canada's utility requirement as it 8 exists today? 9 PROFESSOR HOLBROOK: I believe that I 10 am, as laid out in the reports. I can tell you how I 11 came to that conclusion. 12 MR. SMITH: Well -- 13 PROFESSOR HOLBROOK: I would not say 14 I'm an expert in Canadian law. 15 MR. SMITH: I did not intend to ask 16 whether you were an expert, and I apologize for 17 speaking over you. 18 And you are correct, you do offer a 19 summary of your familiarity review of Canadian law in 20 your report. Let's turn to that. It's the same 21 page, paragraph 5. In that passage you summarized 22 this understanding you have of the Canadian rules 23 concerning utility. Is that right? 24 PROFESSOR HOLBROOK: Yes. 25 MR. SMITH: This page does not have</p> <p>www.dianaburden.com</p>	<p>1462</p> <p>1 any footnotes, does it? 2 PROFESSOR HOLBROOK: It does not. 3 MR. SMITH: Because your report does 4 not identify or disclose the basis of your 5 understanding of Canada's utility requirement, I'd 6 like to ask a few questions about how you became 7 familiar with Canada's utility doctrine. 8 PROFESSOR HOLBROOK: Of course. 9 MR. SMITH: You obtained that 10 understanding only after being retained in this case? 11 PROFESSOR HOLBROOK: Correct. 12 MR. SMITH: You had not studied, 13 taught, published on Canadian utility law before 14 that? 15 PROFESSOR HOLBROOK: No. 16 MR. SMITH: I promise not to ask you a 17 long line of questions about your admissions to the 18 Canadian Bar. We stipulated you're not an expert in 19 Canadian law. You agree with that? 20 PROFESSOR HOLBROOK: Yes. 21 MR. SMITH: But did you review 22 contemporary Canadian cases set out in the last ten 23 years? 24 PROFESSOR HOLBROOK: I reviewed the 25 two cases at issue in this arbitration. I reviewed</p> <p>www.dianaburden.com</p>

<p>1 literature discussing the issues which are cited in 2 the footnote 1. I also consulted with the Canadian 3 representatives so they could help me understand the 4 nature of the doctrine in Canada. 5 MR. SMITH: Let me unpack that. You 6 reviewed the decisions at issue in this case, meaning 7 the Canadian trial court and appellate decisions 8 regarding Lilly's Zyprexa and Strattera patents? 9 PROFESSOR HOLBROOK: Correct. 10 MR. SMITH: And you say you reviewed 11 scholarly work or sources indicated in footnote 1? 12 PROFESSOR HOLBROOK: Yes. 13 MR. SMITH: And only those in footnote 14 1? 15 PROFESSOR HOLBROOK: Well, scholarly 16 resources -- 17 MR. SMITH: Any other -- 18 PROFESSOR HOLBROOK: The other 19 resources I reviewed include the Expert Reports of 20 the Canadian experts. 21 MR. SMITH: So you reviewed the 22 reports of Mr. Dimock and Mr. Gillen? 23 PROFESSOR HOLBROOK: Mr. Dimock. 24 MR. SMITH: Only Mr. Dimock? 25 PROFESSOR HOLBROOK: I believe so.</p> <p>www.dianaburden.com</p>	<p>1 MR. SMITH: Did you review the reports 2 of Professor Siebrasse? 3 PROFESSOR HOLBROOK: I did. 4 MR. SMITH: And Mr. Wilson? 5 PROFESSOR HOLBROOK: I don't recall 6 reviewing Mr. Wilson. 7 MR. SMITH: And Mr. Reddon? 8 PROFESSOR HOLBROOK: I did not review 9 his. 10 MR. SMITH: Did you review all of the 11 decisions pertaining to the patents at issue in this 12 case? 13 PROFESSOR HOLBROOK: I'm not clear 14 which all of the decisions -- in Canada and the 15 United States or across the globe? 16 MR. SMITH: I mean in Canada. Let me 17 clarify. I believe you said when you read the 18 decisions at issue in this case you were referring to 19 the actions for infringement that were decided in 20 this case. Is that correct? 21 PROFESSOR HOLBROOK: Correct. 22 MR. SMITH: In Canada. Did you read 23 the litigation during what was called the PM(NOC) 24 stage, the prior proceedings with regard to Zyprexa 25 in particular?</p> <p>www.dianaburden.com</p>
<p>1465</p> <p>1 PROFESSOR HOLBROOK: I did not. 2 MR. SMITH: Did you read the full 3 series of decisions in the action? Because there was 4 a remand in that case, as you may recall. 5 PROFESSOR HOLBROOK: I did read that. 6 MR. SMITH: Which Zyprexa decisions 7 did you review? 8 PROFESSOR HOLBROOK: I reviewed -- and 9 I'm going to use terminology that's probably U.S. 10 based since I don't know exactly the terminology -- 11 the initial decision, the appeal and I reviewed the 12 remand, I believe. 13 MR. SMITH: So I'd like to explore -- 14 thank you for providing that information about the 15 basis of your understanding. I'd like to explore at 16 a high level the substance of your understanding as 17 well -- and again, I'm not asking you to opine on 18 Canadian law as an expert in that field. I want just 19 to understand what you understand Canadian law to be. 20 At paragraph 5 of your report you 21 write, "My understanding is that in Canada, where a 22 patentee has asserted or promised a certain degree of 23 utility, the applicant will be held to that promised 24 utility." Is that correct? 25 PROFESSOR HOLBROOK: Yes.</p> <p>www.dianaburden.com</p>	<p>1466</p> <p>1 MR. SMITH: Is it also your 2 understanding that this promised utility might be 3 different from the claimed utility? 4 PROFESSOR HOLBROOK: My understanding 5 is that that question doesn't make sense, that the 6 claimed utility is in part determined by construing 7 the claim, and once you've actually looked at the 8 claim that's when you determine what the promised 9 utility is. So I don't know exactly what you mean by 10 the claimed utility. I think it's inextricable. 11 MR. SMITH: So it's your understanding 12 that a Canadian court would not look to isolated 13 statements in the disclosure of the application to 14 identify the utility of the patent? 15 PROFESSOR HOLBROOK: My understanding 16 is they would start with the claim language and look 17 at what the language requires, and then they would 18 look to the specification to inform the analysis of 19 what that claim does require. 20 MR. SMITH: But only for that limited 21 purpose, to inform the analysis of what the claim 22 requires? 23 PROFESSOR HOLBROOK: For purposes of 24 utility, for the promise? 25 MR. SMITH: Yes.</p> <p>www.dianaburden.com</p>

<p>1 PROFESSOR HOLBROOK: That's my 2 understanding, yes. 3 MR. SMITH: They'd be restricted to 4 what the claim requires and to assertions in the 5 disclosure that help them interpret what the claim 6 requires. 7 PROFESSOR HOLBROOK: Correct. And 8 consulting of the specification may determine what 9 the claim requires. 10 MR. SMITH: Is it your understanding 11 that, if a patent claimed a specific use, use of a 12 compound for the treatment of a disease, that use may 13 not define the standard against which utility is 14 measured if the court finds a higher promise of 15 utility in the specification related to that claim? 16 PROFESSOR HOLBROOK: If the court 17 determines that what the promise is and what the 18 claim requires is something that is from the 19 specification, then that is what the claim then 20 requires and you must demonstrate that utility. 21 MR. SMITH: Is it your understanding 22 that a promised utility in Canada may be an elevated 23 utility? 24 PROFESSOR HOLBROOK: It's not my 25 understanding.</p> <p>www.dianaburden.com</p>	<p>1 MR. SMITH: You believe there's only 2 one utility in Canada -- 3 PROFESSOR HOLBROOK: Well, so 4 previously you said -- you were talking about an 5 elevated utility versus the claim. Are now you 6 talking about more broadly utility doctrine in 7 Canada? 8 MR. SMITH: Yes. 9 PROFESSOR HOLBROOK: Okay. So more 10 broadly utility doctrine in Canada, if there is no 11 promise in the patent, then you would fall back to 12 the scintilla, right, that that's sufficient to 13 satisfy utility. So there is a bifurcation in the 14 way that you analyze utility. That's my 15 understanding. 16 MR. SMITH: At paragraph 5 you also 17 write, "Courts will construe the patent specification 18 in light of principles of construction to determine 19 whether there is a promise and if so, its content." 20 right? 21 PROFESSOR HOLBROOK: Correct. 22 MR. SMITH: Is it also your 23 understanding that in Canada statements about the 24 invention's performance made in the disclosure may be 25 construed by a court as promises of utility?</p> <p>www.dianaburden.com</p>
<p>1469</p> <p>1 PROFESSOR HOLBROOK: At this point 2 we're going into such specificity about Canadian law 3 that I'm not comfortable answering that definitively. 4 My understanding is that they look generally to the 5 specification, assess what is required by the claim, 6 and if that is the promise then it's incorporated 7 back in. 8 MR. SMITH: At paragraph 5 you also 9 write "My understanding is that in Canada a patentee 10 is required to have made its invention, including 11 having some basis for the promised utility of the 12 invention, not later than the filing date," and also 13 that post-filing evidence is typically not admitted 14 to support allegations of sound prediction as of the 15 date of filing. Is that correct? 16 PROFESSOR HOLBROOK: That's what the 17 report says, yes. 18 MR. SMITH: And that's your view? 19 PROFESSOR HOLBROOK: My understanding 20 is yes, that demonstration, which is like the United 21 States working examples but you don't have to have 22 actual examples. You can do sound prediction, which 23 is like the United States prophetic examples. 24 MR. SMITH: So it's your understanding 25 that post-filing evidence can never be relied upon to</p> <p>www.dianaburden.com</p>	<p>1470</p> <p>1 establish utility in Canada. Is that correct? 2 PROFESSOR HOLBROOK: That's my 3 understanding. 4 MR. SMITH: Is it also your 5 understanding that a promise of utility can be true 6 in fact but still be the basis for invalidation if 7 the patentee does not persuade the court that the 8 promise was demonstrated or soundly predicted at the 9 filing date? 10 PROFESSOR HOLBROOK: Correct. 11 MR. SMITH: At paragraph 5, you write, 12 "In the context of utility that is merely 13 'predicted', my understanding is that Canadian courts 14 require the basis for the sound prediction of 15 utility -- in the form of some factual basis and line 16 of reasoning -- to be disclosed in the patent 17 specification." Correct? 18 PROFESSOR HOLBROOK: Correct. 19 MR. SMITH: So it's your understanding 20 that evidence to support a sound prediction of 21 utility must be included in the patent application or 22 it will not be considered in Canada? 23 PROFESSOR HOLBROOK: Must be 24 considered in the patent -- 25 MR. SMITH: Must be --</p> <p>www.dianaburden.com</p>

<p>1 THE PRESIDENT: Hold on. Apply the 2 rule applied to your colleague. 3 MR. SMITH: I will slow down and 4 repeat the question. I apologize. 5 THE PRESIDENT: We call it the Dearden 6 rule. 7 MR. SMITH: The Dearden rule I will do 8 my best to observe. 9 THE PRESIDENT: Please repeat the 10 question. 11 MR. SMITH: I will. Professor 12 Holbrook, is it your understanding that evidence to 13 support a sound prediction of utility must be 14 included in the patent application or will not be 15 considered in Canada? 16 PROFESSOR HOLBROOK: My understanding 17 is it needs to be included. I don't know that I 18 would know definitively that evidence that arose 19 prior to filing cannot be considered. I would think 20 you would be allowed to consider the state of the 21 art. Sound prediction depends on what one skilled in 22 the art would think. I would think he would be able 23 to take evidence on that. I don't know that I 24 believe that's the strict rule. The only strict rule 25 I'm aware of is post-filing evidence.</p> <p>www.dianaburden.com</p>	<p>1 MR. SMITH: Is it your understanding, 2 Professor Holbrook, that in Canada a court may find 3 multiple promises of utility in a single patent? 4 PROFESSOR HOLBROOK: I don't have 5 enough knowledge to know whether that can actually 6 arise or not. 7 MR. SMITH: Assume for the sake of 8 argument that it does. If that were the case, is it 9 your understanding that even if one or more promises 10 are demonstrated or soundly predicted, the patent 11 will be held invalid if a single promise of utility 12 cannot be established. 13 PROFESSOR HOLBROOK: Assuming the 14 claim contains multiple utilities, promises of 15 utility, and one is lacking but one is present, then 16 the claim will be invalidated for want of utility. 17 Is that the question? 18 MR. SMITH: Not the question. 19 You testified earlier that you read 20 the report of Professor Siebrasse, right? 21 PROFESSOR HOLBROOK: I did. 22 MR. SMITH: Do you recall the passage 23 in Professor Siebrasse's report discussing cases in 24 which multiple promises of utility were identified? 25 PROFESSOR HOLBROOK: It would be</p> <p>www.dianaburden.com</p>
<p>1473</p> <p>1 helpful if you could show me where you're referring 2 to. 3 MR. SMITH: I don't have Professor 4 Siebrasse's report in the bundle, and for that I 5 apologize. I just wanted to ask about your 6 familiarity. 7 PROFESSOR HOLBROOK: I'm not going to 8 speculate without seeing what Professor Siebrasse 9 report is. 10 THE PRESIDENT: Unless you show the 11 report to him, I think you shouldn't pursue this line 12 of questioning. 13 MR. SMITH: I was just asking whether 14 he recalled. 15 THE PRESIDENT: He recalls but he 16 would like to see it and then he can answer your 17 question. 18 MR. SMITH: That won't be necessary. 19 Professor Holbrook, are you familiar 20 with the requirement in Canadian patent law for 21 sufficiency of disclosure? 22 PROFESSOR HOLBROOK: I'm aware of its 23 existence. I don't know exactly the contours of it. 24 MR. SMITH: Do you have any 25 understanding of that requirement?</p> <p>www.dianaburden.com</p>	<p>1474</p> <p>1 PROFESSOR HOLBROOK: My understanding 2 is that it is comparable to the TRIPS requirements 3 that you disclose basically how to make the 4 invention, which is comparable to part of the 5 enablement requirement of the United States. 6 MR. SMITH: So, to the extent that you 7 are familiar with it, you understand it to be similar 8 to the U.S. enablement requirement? 9 PROFESSOR HOLBROOK: Requirement to 10 disclose how to make the invention, yes. 11 MR. SMITH: If it were similar to the 12 U.S. enablement requirement, you would agree that it 13 likely would serve similar policy concerns as the 14 U.S. enablement requirement, would you not? 15 PROFESSOR HOLBROOK: With that 16 assumption, yes. 17 MR. SMITH: I'd like to turn back now 18 to U.S. patent law, you'll be relieved to hear. I 19 understand that, of course, to be your principal area 20 of expertise. In particular, I'd like to start by 21 discussing the U.S. utility requirement. 22 PROFESSOR HOLBROOK: Okay. 23 MR. SMITH: In your Second Report in 24 the table of contents, very conveniently, you 25 identified a number of areas of agreement with</p> <p>www.dianaburden.com</p>

<p>1 Professor Merges and Mr. Kunin. 2 PROFESSOR HOLBROOK: Yes. 3 MR. SMITH: If we turn to that, page 1 4 of your section report, you note that you, Professor 5 Merges and Mr. Kunin notably agree on three key 6 points: That the utility requirement is a low bar in 7 the United States; that there is a single standard 8 for utility across all technologies in the United 9 States; and that utility has "greater relevance" in 10 the chemical and pharmaceutical context. Is that 11 correct? 12 PROFESSOR HOLBROOK: That's correct. 13 I believe -- and if I could -- I believe that quote 14 of greater relevance is actually referencing 15 Professor Merges' discussion. 16 MR. SMITH: Yes, and I think that was 17 identified in the agreement between you. Because 18 that's at a relatively high level of generality, I'd 19 like to start by exploring some more specific points. 20 You've indicated -- and I'd like to 21 confirm -- that in the United States the patentee 22 receives an exclusive right to the invention as it is 23 claimed, correct? 24 PROFESSOR HOLBROOK: Correct. 25 MR. SMITH: The language of the claims</p> <p>www.dianaburden.com</p>	<p>1 therefore determines the scope of the patented 2 invention. 3 PROFESSOR HOLBROOK: Yes. 4 MR. SMITH: And the validity of the 5 patent has to be assessed with respect to the claims. 6 PROFESSOR HOLBROOK: Correct. 7 MR. SMITH: And it follows that the 8 utility of a patent as a validity requirement also 9 has to be assessed with respect to the claims. 10 PROFESSOR HOLBROOK: Right. Correct. 11 MR. SMITH: You'd agree with me that 12 assessing utility with respect to the claims is a 13 bedrock principle of U.S. patent law. 14 PROFESSOR HOLBROOK: Yes. 15 MR. SMITH: Would you also agree that 16 it would be highly unusual for a U.S. court to ignore 17 an explicitly claimed use, and identify the standard 18 for utility based on a statement in the disclosure? 19 PROFESSOR HOLBROOK: I don't know that 20 they could do that. I also don't understand the 21 question. So what do you mean by required claimed 22 use? I'm not even following the question at this 23 point. 24 MR. SMITH: Imagine that a claim is 25 regarding the compound for the treatment of a certain</p> <p>www.dianaburden.com</p>
<p>1 disease. 2 PROFESSOR HOLBROOK: Okay. 3 MR. SMITH: And that at some point in 4 the disclosure statements about performance 5 characteristics of the compound in the treatment of 6 disease, et cetera, would be identified. Those I 7 will call performance characteristics. Does that 8 make sense? Would you agree that it would be unusual 9 for a U.S. court to focus on those performance 10 characteristics in the disclosure to determine the 11 standard for utility? 12 PROFESSOR HOLBROOK: Well, you're 13 missing a necessary first step, which is to construe 14 the claim to determine what is actually required. 15 You don't simply look at the claim language in 16 isolation; you have to read the claim and interpret 17 it in light of the specification. In that active 18 interpretation, if the court concludes that those 19 performance aspects are actually required in the 20 claim, then that becomes a limitation of the claim, 21 so those would have to be present and demonstrated. 22 If the court concludes that those 23 performances are not required by the claim, then in 24 that context it would be unusual to invalidate on the 25 basis of those performance ones, but it depends on</p> <p>www.dianaburden.com</p>	<p>1 how does the court interpret the claim. 2 MR. SMITH: Let me ask you a 3 hypothetical. The claim is a compound for the 4 treatment of the common cold but the disclosure 5 indicates that the same compound is also capable of 6 treating baldness. Would that assertion, that 7 performance characteristic with respect to baldness, 8 which is unrelated to the claim, be the basis for the 9 assessment of utility under U.S. law? 10 PROFESSOR HOLBROOK: It would not be 11 the basis for assessment of utility. Of course there 12 would need to be evidence in the specification that 13 it actually does treat a cold, though, so both of 14 those utilities would have to be disclosed. Saying 15 that I'm claiming a method of treating baldness but 16 all I've disclosed in the specification -- I'm sorry. 17 I'm claiming a method of treating a cold but the 18 specification only discloses evidence of baldness, 19 then you're going to lose on utility as well because 20 you have no support for the treatment of a cold. 21 You'll need support for both the cold treatment. 22 Then if you have the baldness treatment on there, 23 that in essence would become irrelevant to the method 24 claim. 25 THE PRESIDENT: May I ask a question,</p> <p>www.dianaburden.com</p>

<p>1 simply because I don't know whether you were here 2 when the discussion was about claim, disclosure and 3 specification under Canadian law. Let's put it this 4 way, they use the terms somewhat loosely. How is it 5 in the U.S. with these the terms of art, if I may 6 call it that way? Is claim disclosure? Is 7 disclosure also called specification? Or are both 8 called specification? 9 PROFESSOR HOLBROOK: There's some 10 slippage in U.S. law, so technically the 11 specification is the description of the invention and 12 the claims. The claims are part of the 13 specification. The non-claim part has historically 14 been called the written description, but in modern 15 times, since there is now a written description 16 requirement under section 112, we tend not to use 17 that terminology as much so we either talk about the 18 disclosure in the claims or we'll talk generically 19 about the specification, which is somewhat inaccurate 20 because it does include the claims. So we're 21 unfortunately not as precise as we probably should 22 be. 23 THE PRESIDENT: You're more or less 24 the same, then, as in Canada? 25 PROFESSOR HOLBROOK: Yes, my</p> <p>www.dianaburden.com</p>	<p>1 understanding. 2 MR. SMITH: Thank you, 3 Professor Holbrook. It's true in U.S. law, is it 4 not, that an invention will be found useful if it 5 works for at least one of its stated purposes? 6 PROFESSOR HOLBROOK: Depending on the 7 nature of the claim, right? Again, if you're 8 claiming a cold treatment and you haven't discovered 9 that but you've discovered other treatments, then no. 10 But if you're claiming a compound and it has multiple 11 ones and the claim is not specific to a compound for 12 treatment of condition X, then yes. 13 MR. SMITH: So if you claim a cold 14 treatment but you also assert in the disclosure 15 unrelated uses regarding baldness and any number of 16 other conditions as long as you are able to establish 17 utility of that claimed treatment for the cold, other 18 statements in the disclosure regarding other uses are 19 irrelevant under U.S. law? 20 PROFESSOR HOLBROOK: Yes. 21 MR. SMITH: And so long as the 22 invention fulfills one of its stated uses it will be 23 patentable? One of its claimed uses? 24 PROFESSOR HOLBROOK: One of its 25 claimed uses as interpreted, so claimed uses once</p> <p>www.dianaburden.com</p>
<p>1481</p> <p>1 you've interpreted the claim. In that way the claim 2 may have multiple utilities that are required. 3 That's the Raytheon case. 4 MR. SMITH: The MPEP, the manual in 5 the USPTO, reflects this fundamental one is enough 6 principle, doesn't it? 7 PROFESSOR HOLBROOK: If you could show 8 me where you're referring to? 9 MR. SMITH: Excerpts from it appear in 10 the binder at tab 6. If you turn to tab 6 the 11 relevant subsection is 2107.02. Just to help you 12 find it, the page number in this exhibit is page 39. 13 PROFESSOR HOLBROOK: 2100-39. I'm 14 there. 15 MR. SMITH: So if we turn to that 16 second paragraph in that section, it says, "It is 17 common and sensible for an applicant to identify 18 several specific utilities for an invention, 19 particularly where the invention is a product, 20 including a composition of matter. However, 21 regardless of the category of invention that is 22 claimed, an applicant need only make one credible 23 assertion of specific utility for the claimed 24 invention to satisfy sections 101 and 112; additional 25 statements of utility, even if not 'credible', do not</p> <p>www.dianaburden.com</p>	<p>1482</p> <p>1 render the claimed invention lacking in utility." 2 You agree that this MPEP provision 3 accurately reflects U.S. law? 4 PROFESSOR HOLBROOK: I think it is not 5 precise, particularly given the previous part about 6 talking about the claimed invention being the focus, 7 and, again, they cite to the Raytheon case and 8 suggest this conclusion. To be clear, the MPEP is 9 not law. It's not binding on the courts. It's only 10 a reflection of practice of the Patent Office, so it 11 could be the case that this is inaccurate. 12 So even in Raytheon, the first claim 13 was held invalid for lack of utility because a 14 required claim limitation didn't work. It was simply 15 impossible to work. The other two claims were found 16 to have satisfied the utility requirement, but that 17 was only after the Federal Circuit rejected the lower 18 court's claim construction that would have 19 incorporated that inoperable part. 20 So the claims can actually contain 21 multiple utilities; it depends what it is. As a 22 generalized statement, like if I have a general 23 compound claim, multiple utilities -- one's enough. 24 For most apparatuses, one's enough. But I think this 25 speaks too broadly and generally and ignores the</p> <p>www.dianaburden.com</p>

<p>1 important context of what does the claim actually 2 require. 3 MR. SMITH: But you agree that, having 4 construed the claim and having identified other uses 5 outside the claim, a court would not find a patent to 6 lack utility if the claimed use was qualified under 7 U.S. law. 8 PROFESSOR HOLBROOK: If the claimed 9 use is not a requirement of the claim? Let me see. 10 If the use in the specification is not a requirement 11 of the claim, then they would not reject that claim 12 on the basis of utility. 13 MR. SMITH: Additional statements of 14 utility that are not credible would not be a basis 15 for denial or invalidation if they were not read into 16 the claim. 17 PROFESSOR HOLBROOK: Correct. 18 MR. SMITH: Under Canadian law, as you 19 understand it, a failure to demonstrate or soundly 20 predict a single promise of utility is a basis for 21 invalidation. Is that correct? 22 PROFESSOR HOLBROOK: If that promise 23 is required by the claim and the claim requires only 24 that promise or other promises, yes. 25 MR. SMITH: And that's so even if</p> <p>www.dianaburden.com</p>	<p>1 other promises of utility are found to have been 2 fulfilled or established. 3 PROFESSOR HOLBROOK: That's my 4 understanding, correct. 5 MR. SMITH: So if the U.S. has a one 6 is enough rule, is it fair to describe Canada's rule 7 as every single one? 8 PROFESSOR HOLBROOK: No, I don't think 9 that's a proper assessment because the U.S. law isn't 10 one is enough. The U.S. law is construe the claim, 11 determine what utility is required by that claim, if 12 the claim requires multiple utilities, then all of 13 those utilities will also have to be satisfied. If 14 the claim is generic to utility, such as a compound, 15 then one is enough. Or for some apparatuses one may 16 be enough. 17 For a method claim one has to be 18 enough. A method of treating baldness, you better 19 have support for the method of treating baldness. So 20 I don't agree with that characterization. 21 MR. SMITH: But, again, if you had 22 support for that method of treating baldness but no 23 support for other assertions of utility not found to 24 be within that claim, those additional statements of 25 utility, even if false, would not be a basis for</p> <p>www.dianaburden.com</p>
<p>1485</p> <p>1 invalidation? 2 PROFESSOR HOLBROOK: Correct. 3 MR. SMITH: Isn't it true in U.S. law 4 that, so long as an invention achieves one stated 5 purpose or one claimed purpose, it has patentable 6 utility even if that use is less useful than existing 7 inventions? 8 PROFESSOR HOLBROOK: So the 9 requirement for utility does not require any 10 invention to be better than the prior art. It just 11 has to be different, for the most part. The 12 exception to that can be selection patents where 13 you're claiming a species and then part of the 14 obviousness analysis would be are there unexpected 15 results. That would be better. But for the most 16 part we don't focus on better; we focus on different. 17 MR. SMITH: So the invention can 18 perform its intended use worse than existing 19 technology, but still deserve patent protection if it 20 is found to be new and non-obvious? 21 PROFESSOR HOLBROOK: Generally 22 speaking, yes. 23 MR. SMITH: The assumption there in 24 U.S. law is that innovation may proceed faster 25 through a one step backward/two steps forward</p> <p>www.dianaburden.com</p>	<p>1486</p> <p>1 approach? 2 PROFESSOR HOLBROOK: Right. It's more 3 of an evolutionary step. You don't know which branch 4 may actually turn out to be the true innovation. 5 MR. SMITH: But, in Canadian law, an 6 inventor may have to establish that the invention is 7 superior to existing technologies if it is found to 8 have promised that in the disclosure. Is that right? 9 PROFESSOR HOLBROOK: If it has made 10 that promise and that is a requirement of the claim, 11 yes, they'll have to demonstrate that. 12 MR. SMITH: There's no requirement in 13 U.S. law that all evidence of an asserted utility be 14 included in the patent application as filed, is 15 there? 16 PROFESSOR HOLBROOK: There's no strict 17 requirement that it be filed that way. If it's 18 self-evident, it doesn't have to be in there. It's 19 preferable to do it. 20 MR. SMITH: There's no loose 21 requirement either, is there? 22 PROFESSOR HOLBROOK: No. I mean it's 23 preferable. I would not advise a client to just file 24 an application without disclosing what the invention 25 actually does.</p> <p>www.dianaburden.com</p>

<p>1 MR. SMITH: And your reports don't 2 point to any such requirement in the MPEP or in the 3 case law? 4 PROFESSOR HOLBROOK: No, although the 5 MPEP notes, as I stated, it's common and sensible for 6 an applicant to identify several specific utilities 7 for an invention, so it's generally the practice to 8 do so. 9 MR. SMITH: In your Second Report you 10 note that affidavits created after the date of filing 11 can be submitted to support utility, right? 12 PROFESSOR HOLBROOK: Generally 13 speaking, yes. 14 MR. SMITH: And those affidavits by 15 definition are not in the patent application, right? 16 PROFESSOR HOLBROOK: They're not in 17 the patent application. 18 MR. SMITH: And that's because there's 19 no obligation to include all evidence of utility in 20 the patent application, right? 21 PROFESSOR HOLBROOK: Correct. 22 MR. SMITH: This rule that applicants 23 can rely on evidence of utility not disclosed in the 24 application, that's also reflected in the MPEP, isn't 25 it?</p> <p>www.dianaburden.com</p>	<p>1 PROFESSOR HOLBROOK: I believe so, but 2 it would be helpful if you could show me to which 3 section you're referring. 4 MR. SMITH: If you'd turn to page 45, 5 2100-45 in the same exhibit, tab 6, Exhibit C-72, the 6 top right. 7 PROFESSOR HOLBROOK: Yes. 8 MR. SMITH: This is in a section 9 discussing consideration of a reply to a prima facie 10 rejection for lack of utility. 11 PROFESSOR HOLBROOK: Yes. 12 MR. SMITH: And the manual states that 13 an applicant can rebut a prima facie rejection by, 14 "using any combination of the following, amendment to 15 the claims, arguments or reasoning or new evidence 16 submitted in an affidavit or declaration or in a 17 printed publication." Correct? 18 PROFESSOR HOLBROOK: Yes. 19 MR. SMITH: So this section makes 20 clear that new evidence of utility can be submitted 21 during the examination process? 22 PROFESSOR HOLBROOK: Yes. 23 MR. SMITH: If the USPTO examiner has 24 doubts about an asserted utility, this is the 25 opportunity for the applicant to respond to those</p> <p>www.dianaburden.com</p>
<p>1 doubts. 2 PROFESSOR HOLBROOK: So if the 3 examiner has brought forward evidence to suggest 4 there's a doubt about the utility, they present that 5 evidence, and then the applicant can respond by 6 amending, by submitting this type of affidavit 7 evidence. Correct. 8 MR. SMITH: So if there's a prediction 9 of utility about which the examiner has some doubt, 10 the examiner will consider evidence that was not 11 disclosed or included in the application, correct? 12 PROFESSOR HOLBROOK: Correct. 13 MR. SMITH: By contrast, in Canadian 14 law, as you understand it, evidence of a sound 15 prediction of utility must be included in the 16 application? 17 PROFESSOR HOLBROOK: Again, my 18 understanding is the main concern is that evidence of 19 sound prediction that is generated after the filing 20 date is not admissible. I'm not entirely certain 21 about the rules, what happened beforehand. My point 22 of contention was about post-filing evidence that is 23 generated to support enablement. 24 MR. SMITH: Let's turn briefly to 25 post-filing evidence. With respect to post-filing</p> <p>www.dianaburden.com</p>	<p>1 evidence -- and I think it would be helpful for us to 2 clarify what we mean by the term "post-filing 3 evidence." 4 PROFESSOR HOLBROOK: Right. 5 MR. SMITH: In your Second Report you 6 make clear that post-filing evidence does not include 7 the affidavits drafted after the application we were 8 just discussing, if they relate to information or 9 studies that predate the application. Is that 10 correct? 11 PROFESSOR HOLBROOK: Correct, because 12 our focus is what is the state of the art at the time 13 of the application, so if your affidavit is saying we 14 performed these experiments five months before we 15 filed the application, that's fine. You're just 16 stating what happened beforehand. There's nothing 17 wrong with that. 18 MR. SMITH: And with respect to 19 utility, you testified the general rule in the U.S. 20 is that utility is assessed as of the application 21 date. 22 PROFESSOR HOLBROOK: That's correct. 23 MR. SMITH: And you've also testified 24 that U.S. law allows post-filing evidence for the 25 purpose of substantiating utility related statements</p> <p>www.dianaburden.com</p>

<p>1 made in the original application. Is that correct? 2 PROFESSOR HOLBROOK: Which rule of law 3 are you referring to, or which statement of mine are 4 you referring to? 5 MR. SMITH: This is in your First 6 Report at tab 1 at paragraph 34. 7 PROFESSOR HOLBROOK: Yes. 8 MR. SMITH: You wrote -- and you're 9 referring to a Federal Circuit case well known, In re 10 Brana? 11 PROFESSOR HOLBROOK: Yes. 12 MR. SMITH: That post-filing evidence 13 was used to substantiate any doubts as to the 14 asserted utility since this pertains to the accuracy 15 of a statement already in the specification. Is that 16 correct? 17 PROFESSOR HOLBROOK: That's correct. 18 Brana involved, arguably -- the case isn't clear -- 19 evidence generated after the filing date to support 20 the utility disclosed. So in that case they said 21 since, even though it was dicta, Brana made clear the 22 specification in the patent disclosure itself was 23 sufficient, so there was never a reason to reach this 24 conclusion, they said we will look at this evidence 25 but only because it's being used in that narrow</p> <p>www.dianaburden.com</p>	<p>1 sense. Brana didn't use the word "narrow" -- I'm 2 taking the narrow exception terminology from the 3 later case Cre-Agri. 4 MR. SMITH: So you agree that there is 5 a rule of US law that allows the patentee or 6 applicant to rely upon post-filing evidence to 7 substantiate doubts as to the asserted utility 8 regarding statements made in the specification. 9 PROFESSOR HOLBROOK: I would say Brana 10 establishes that rule. I would say that In re '318 11 Litigation calls that rule into doubt and limits 12 Brana. It notes that in no case is there ever -- and 13 also in the cases where that has been allowed it's 14 always been superfluous, that the holding of the case 15 has always been the specification has been 16 sufficient. The need to resort to that evidence was 17 unnecessary but they did so anyway. So to the extent 18 it's a rule, it's a rule that's never had any teeth. 19 MR. SMITH: Your testimony is that 20 rule has never had any teeth? 21 PROFESSOR HOLBROOK: Right. In In re 22 Brana the first part of the conclusion said patent 23 specification was sufficient. The only other case 24 that applied the rule where it allowed that evidence 25 to be considered is the parallel case here, and in</p> <p>www.dianaburden.com</p>
<p>1493</p> <p>1 that case the court made clear that if you look at 2 the prior art, if you look at the specification, 3 there was sufficient support for utility in that 4 context, given the facts of that case, and they 5 distinguished from it In re '318 on that basis. 6 MR. SMITH: Bottom line, you agree 7 there are relatively few utility cases in the United 8 States, right? 9 PROFESSOR HOLBROOK: Relatively few 10 cases that only raise the issue of utility. In my 11 view, if we're talking about these ideas, it's 12 utility, it's enablement and written description, but 13 if you're specific to few cases raising section 101 14 utility issues only, yes, there are not that many -- 15 which may not be a bad thing. Maybe applicants are 16 actually doing the right thing in waiting to file at 17 the perfect time. 18 MR. SMITH: You assert that Brana was 19 somehow distinguished in subsequent cases but the 20 Brana rule remains good law, does it not? 21 PROFESSOR HOLBROOK: It technically 22 remains good law, although again In re '318 Patent 23 Litigation case, says Brana only dealt with the 24 context of a patent prosecution, and that again the 25 statement about that rule was not necessary to the</p> <p>www.dianaburden.com</p>	<p>1494</p> <p>1 decision, so it is a rule but it's a rule of very 2 little scope. 3 MR. SMITH: And that rule allows 4 patentees in the United States to rely on post-filing 5 evidence to establish utility in certain 6 circumstances? 7 PROFESSOR HOLBROOK: Not robustly. In 8 re '318 makes it clear that in that case they would 9 not consider post-filing evidence that supported an 10 otherwise inadequate disclosure. Cre-Agri to the 11 same extent. There are other cases that make it 12 clear that is a very narrow exception. 13 MR. SMITH: That exception exists in 14 US law such that patentees can rely on post-filing 15 evidence to establish utility, correct? 16 PROFESSOR HOLBROOK: As a technical 17 matter does Brana establish that rule and is Brana 18 still good law? Yes. But I disagree that it is a 19 robust rule and the courts have been moving to narrow 20 it. And there have been examples where the courts 21 have refused to consider post-filing evidence to 22 support the conclusion of enablement or utility. 23 MR. SMITH: It seems as if you're 24 working very hard to suggest the scope of the rule is 25 narrow, but you do not dispute the existence of the</p> <p>www.dianaburden.com</p>

<p>1 rule, right?</p> <p>2 PROFESSOR HOLBROOK: Correct.</p> <p>3 MR. SMITH: And you do not dispute</p> <p>4 that in Canadian law, by contrast, as you understand</p> <p>5 it, patentees are never allowed to rely on</p> <p>6 post-filing evidence to establish utility, correct?</p> <p>7 PROFESSOR HOLBROOK: My</p> <p>8 understanding -- I view that as shades of gray. Very</p> <p>9 small distinction.</p> <p>10 MR. SMITH: Given all of this we've</p> <p>11 discussed, in terms of the utility standards in the</p> <p>12 U.S. and comparable provisions in the utility</p> <p>13 requirement in Canada, is it fair to say that the</p> <p>14 U.S. utility standard is by no means equivalent to</p> <p>15 the Canadian utility requirement?</p> <p>16 PROFESSOR HOLBROOK: If you're doing a</p> <p>17 strict utility, substantial, credible -- now I'm</p> <p>18 losing track of my own words -- substantial,</p> <p>19 credible, specific utility, that doctrine versus what</p> <p>20 Canada does, they're not comparable but this is not</p> <p>21 the proper basis of comparison.</p> <p>22 MR. SMITH: They're not comparable and</p> <p>23 not equivalent, correct?</p> <p>24 PROFESSOR HOLBROOK: But that's not</p> <p>25 the proper basis of comparison.</p> <p>www.dianaburden.com</p>	<p>1 THE PRESIDENT: Mr. Smith, if we go on</p> <p>2 to 6:00, I think it is appropriate to have a</p> <p>3 five-minute break now for the court reporters.</p> <p>4 MR. SMITH: Yes. This is a good time.</p> <p>5 THE PRESIDENT: Five minutes break.</p> <p>6 Professor Holbrook, you are under testimony. It</p> <p>7 means that you are not allowed to discuss this case</p> <p>8 with anyone.</p> <p>9 <i>(Recess taken)</i></p> <p>10 THE PRESIDENT: Please continue.</p> <p>11 MR. SMITH: Professor Holbrook,</p> <p>12 earlier when you testified about the importance of</p> <p>13 focusing on the claim to assess utility, you</p> <p>14 mentioned a circumstance in which one might look to</p> <p>15 statements in the disclosure to construe the claim.</p> <p>16 PROFESSOR HOLBROOK: Correct.</p> <p>17 MR. SMITH: I just want to be clear</p> <p>18 for the record, you are not suggesting that it would</p> <p>19 be proper to import claim limitations from the</p> <p>20 specification, are you?</p> <p>21 PROFESSOR HOLBROOK: That would be a</p> <p>22 violation of the canon's construction. However, it</p> <p>23 is clear that you consult claims in lieu of the</p> <p>24 specification, and at times the Federal Circuit has</p> <p>25 limited the scope of the claims to the specific</p> <p>www.dianaburden.com</p>
<p>1497</p> <p>1 examples in the specification. So there's a tension</p> <p>2 between that rule and what actually happens.</p> <p>3 MR. SMITH: But that rule, as you</p> <p>4 note, is well established in U.S. law, the</p> <p>5 impropriety of importing claim limitations from the</p> <p>6 specification?</p> <p>7 PROFESSOR HOLBROOK: The impropriety</p> <p>8 of importing claims from the specification is a</p> <p>9 strong rule. However, the claim construction</p> <p>10 doctrines are also clear that a patent applicant can</p> <p>11 act as his or her own lexicographer, so if they give</p> <p>12 a unique express definition in the specification that</p> <p>13 will be used in the claim. Moreover, if they</p> <p>14 disclaim certain subject matter in the claim or in</p> <p>15 the specification, then that disclaimer will be</p> <p>16 imported into the claim and narrow its scope.</p> <p>17 That disclaimer can happen in the</p> <p>18 specification; it can also happen as a result of the</p> <p>19 prosecution record at the Patent Office. In the</p> <p>20 United States, as an act of construing a claim, we</p> <p>21 actually look at what happened during the patent</p> <p>22 application proceedings, and if a patent applicant</p> <p>23 makes representation that surrenders certain things,</p> <p>24 I'm not X, that will be used to restrict the scope of</p> <p>25 the claim.</p> <p>www.dianaburden.com</p>	<p>1498</p> <p>1 MR. SMITH: Professor Holbrook, in</p> <p>2 your Second Report at paragraph 34 you say that</p> <p>3 Professor Merges' assertion that post-filing evidence</p> <p>4 to support utility and enablement is routinely used</p> <p>5 is wrong.</p> <p>6 PROFESSOR HOLBROOK: Correct.</p> <p>7 MR. SMITH: You didn't cite anything</p> <p>8 in support of that assertion, did you?</p> <p>9 PROFESSOR HOLBROOK: I didn't, because</p> <p>10 the citations were in the First Report.</p> <p>11 MR. SMITH: I'm just curious because I</p> <p>12 want to know to what assertion of Professor Merges</p> <p>13 you're referring here. Where did Professor Merges</p> <p>14 assert that post-filing evidence is routinely used to</p> <p>15 support enablement?</p> <p>16 PROFESSOR HOLBROOK: Is there a copy</p> <p>17 of Professor Merges' report.</p> <p>18 MR. SMITH: Yes, those appear at tabs</p> <p>19 17 and 18.</p> <p>20 PROFESSOR HOLBROOK: This is in his</p> <p>21 Second Report, and it also references his First</p> <p>22 Report. Page 10, paragraph 23 of his Second Report,</p> <p>23 and he refers to his First Report at paragraph 8.</p> <p>24 I'll get to that, too.</p> <p>25 In response to my report at paragraph</p> <p>www.dianaburden.com</p>

<p>1 23, page 10, "Professor Holbrook states: 'Contrary 2 to Professor Merges' suggestions post-filing evidence 3 has been allowed in the United States only in narrow 4 circumstances'. Nothing in my first Expert Report 5 diverges from settled U.S. law. As the report states 6 'U.S. law recognizes that evidence introduced after a 7 patent is filed -- including, for example, proof of 8 commercial success -- can definitively establish the 9 presence of utility'. The statement in my initial 10 report is accurate."</p> <p>11 MR. SMITH: So Professor Merges 12 asserted that evidence introduced after a patent is 13 filed can definitively establish the presence of 14 utility?</p> <p>15 PROFESSOR HOLBROOK: Right.</p> <p>16 MR. SMITH: So, again, I ask where did 17 he assert that post-filing evidence is routinely used 18 to support enablement?</p> <p>19 PROFESSOR HOLBROOK: Let me go back to 20 his First Report. So in his First Report, page 4, 21 paragraph 8, he states noting at paragraph 3 the 22 Canadian utility doctrine "rejects post-filing 23 evidence of utility, whereas U.S. law recognizes that 24 evidence introduced after a patent is filed -- 25 including, for example, proof of commercial use --</p> <p>www.dianaburden.com</p>	<p>1 can definitively establish the presence of utility. 2 This acceptance of post-filing evidence marks the 3 U.S. approach as quite different from the Canadian 4 promise doctrine; in effect evidence of this type in 5 the United States merely helps to back up a plausible 6 assertion of utility made at the time of filing. 7 This is clearly different from a stringent 8 requirement of actual proof as of the filing date, 9 which makes for a much more imposing standard." 10 He doesn't use the word "routinely" 11 but there's no suggestion in his report that this 12 actually is rejected and the courts refused to rely 13 upon it in different instances.</p> <p>14 MR. SMITH: Professor Holbrook, you 15 are correct he never uses the word "routinely" in any 16 of the passages you've cited.</p> <p>17 PROFESSOR HOLBROOK: Right.</p> <p>18 MR. SMITH: But what you have not 19 noted is that he also does not use the word 20 "enablement." Isn't that correct?</p> <p>21 PROFESSOR HOLBROOK: Because he 22 falsely believes that enablement and utility are 23 different, and the cases are clear when they reject 24 post-filing evidence, that they're talking both about 25 utility and enablement. The In re Glass case, which</p> <p>www.dianaburden.com</p>
<p>1501</p> <p>1 he dismissed as simply being about enablement, 2 actually discusses how to use. His own testimony 3 demonstrates that the how to use prong of enablement 4 is utility, so In re Glass is in fact about utility. 5 The discussions in the case law about 6 enablement versus utility combine the two. This is 7 not a distinction that the U.S. law recognizes as 8 firmly and succinctly as Professor Merges suggests. 9 MR. SMITH: So when Professor Merges 10 used the word "utility" you believe he used the word 11 incorrectly?</p> <p>12 PROFESSOR HOLBROOK: I believe he used 13 it in a very narrow sense in that he was ignoring the 14 fact that it also includes enablement.</p> <p>15 MR. SMITH: But he never, in either of 16 his reports, asserted that post-filing evidence is 17 routinely used to support enablement, correct?</p> <p>18 PROFESSOR HOLBROOK: He did not use 19 the word "routinely." That was my characterization 20 of his testimony.</p> <p>21 MR. SMITH: And he did not use the 22 word "enablement," correct?</p> <p>23 PROFESSOR HOLBROOK: He did not use 24 the word "enablement."</p> <p>25 MR. SMITH: I'd like to turn now to</p> <p>www.dianaburden.com</p>	<p>1502</p> <p>1 this relationship between enablement and utility and 2 also to written description. Let's start with some 3 basics. You would agree that utility, enablement and 4 written description are distinct requirements in U.S. 5 patent law?</p> <p>6 PROFESSOR HOLBROOK: They are distinct 7 doctrines. I think that what they police and the way 8 that you analyze them overlaps incredibly.</p> <p>9 MR. SMITH: They are distinct 10 doctrines. You agree?</p> <p>11 PROFESSOR HOLBROOK: Yes.</p> <p>12 MR. SMITH: Let's talk about the 13 statutory structure, if we could. I'd like to call 14 your attention to the handout, which is Exhibit C-73.</p> <p>15 PROFESSOR HOLBROOK: I'm there.</p> <p>16 MR. SMITH: On the first page, this is 17 section 101 of the U.S. Patent Act.</p> <p>18 PROFESSOR HOLBROOK: Yes.</p> <p>19 MR. SMITH: And this is the section 20 that covers the utility requirement. Is that 21 correct?</p> <p>22 PROFESSOR HOLBROOK: Part of the 23 utility requirement, where the word "useful" appears.</p> <p>24 MR. SMITH: It says "Whoever invents 25 or discovers any new and useful process machine,</p> <p>www.dianaburden.com</p>

<p>1 manufacturer, composition of matter, et cetera, may 2 obtain a patent therefor," correct? 3 PROFESSOR HOLBROOK: Correct, and any 4 new and useful improvement but, again, the word 5 "useful." 6 MR. SMITH: And its title is 7 "Inventions Patentable"? 8 PROFESSOR HOLBROOK: Correct. 9 MR. SMITH: If we turn the page, 10 section 102 covers and is titled "Conditions for 11 Patentability, Novelty," correct? 12 PROFESSOR HOLBROOK: Correct. 13 MR. SMITH: If we turn the page again, 14 section 103 on the next page, "Conditions for 15 Patentability, Non-obvious Subject-matter," right? 16 PROFESSOR HOLBROOK: Correct. 17 MR. SMITH: If we turn the page yet 18 again, and we come to section 112, this is entitled 19 "Specification"? 20 PROFESSOR HOLBROOK: Correct. 21 MR. SMITH: And it is paragraph (a) 22 that includes both the enablement requirement and the 23 written description requirement. Is that correct? 24 PROFESSOR HOLBROOK: That's correct. 25 MR. SMITH: And it says "The</p> <p>www.dianaburden.com</p>	<p>1 specification shall contain a written description of 2 the invention and of the manner and process of making 3 and using it," so the statutory structure identifies 4 these requirements as distinct requirements, doesn't 5 it? 6 PROFESSOR HOLBROOK: There's been an 7 ongoing debate about whether written description and 8 enablement should be viewed as distinct, but the law 9 as it currently stands interpreting section 112 is 10 yes, they are distinct. But also note that, even in 11 Professor Merges' case book, he notes the source for 12 the utility doctrine is both 112 and 101, and the 13 courts have stated clearly that section 112, the use 14 requirement, incorporates as a matter of law the 15 utility requirement. 16 MR. SMITH: We'll come to that in a 17 moment, but thank you for the preview. This 18 statutory structure is replicated in the manual, the 19 MPEP, is it not? 20 PROFESSOR HOLBROOK: I don't know. 21 MR. SMITH: Let's turn to tab 6. We 22 don't need to go far, just to the table of contents 23 on the first page. The guidelines for the utility 24 requirement appear in 2107. Is that right? 25 PROFESSOR HOLBROOK: Yes.</p> <p>www.dianaburden.com</p>
<p>1505</p> <p>1 MR. SMITH: And the guidelines for 2 section 112 appear elsewhere. Is that right? I 3 believe they start at 2161. That's on the third 4 page. 5 PROFESSOR HOLBROOK: Yes. 6 MR. SMITH: And examiners at the 7 Patent Office treat these requirements -- utility, 8 written description, enablement -- as distinct when 9 examining applications. Is that right? 10 PROFESSOR HOLBROOK: That's not 11 correct. 12 MR. SMITH: When they identify a basis 13 for rejection, they might identify one or more of 14 these requirements. Is that right? 15 PROFESSOR HOLBROOK: They might 16 identify one or more. I don't have the provision in 17 front of me. I seem to recall that examiners are 18 instructed that, if they make a 101 rejection, they 19 should also make a 112 rejection. 20 MR. SMITH: Let's come to that in just 21 a minute. Thank you for the preview again. 22 You've asserted that these three 23 requirements are closely related, right? 24 PROFESSOR HOLBROOK: Yes. 25 MR. SMITH: In fact, you've even</p> <p>www.dianaburden.com</p>	<p>1506</p> <p>1 asserted that these U.S. doctrines of utility, 2 enablement, written description "often rise or fall 3 together." 4 PROFESSOR HOLBROOK: That's not my 5 assertion. That's the statement of the Federal 6 Circuit. 7 MR. SMITH: Let's turn to where you 8 make that assertion. I believe it's at your Second 9 Report, paragraph 25. You say, "As I explained in my 10 opening report, the three doctrines, utility, 11 enablement and written description, are closely 12 related and often rise or fall together." Is that 13 right? 14 PROFESSOR HOLBROOK: I make that 15 statement there, correct. 16 MR. SMITH: You don't cite to the 17 Federal Circuit there, do you? 18 PROFESSOR HOLBROOK: I cite to my 19 previous report, and the previous reports cites the 20 Federal Circuit. 21 MR. SMITH: Let's turn to that. You 22 cite to paragraph 9 of your previous report, is that 23 right? Paragraph 9 of your previous report appears 24 on page 5, right? And paragraph 9 of your First 25 Report also does not have any citations or reference</p> <p>www.dianaburden.com</p>

<p>1 to the Federal Circuit. Is that correct?</p> <p>2 PROFESSOR HOLBROOK: Probably because</p> <p>3 I cited to the wrong paragraph.</p> <p>4 MR. SMITH: But does paragraph 9 even</p> <p>5 assert that the doctrines of utility, enablement and</p> <p>6 written description often rise or fall together?</p> <p>7 THE PRESIDENT: Two things. Can you</p> <p>8 slow down a little bit? Secondly, the expert says he</p> <p>9 cited the wrong paragraph.</p> <p>10 MR. SMITH: I'm coming to that.</p> <p>11 To repeat the question for the record,</p> <p>12 does paragraph 9 assert that these doctrines,</p> <p>13 utility, enablement and written description often</p> <p>14 rise and fall together?</p> <p>15 PROFESSOR HOLBROOK: That paragraph</p> <p>16 doesn't, no.</p> <p>17 MR. SMITH: Paragraph 9, in any event,</p> <p>18 is just a summary introduction.</p> <p>19 PROFESSOR HOLBROOK: I believe I cited</p> <p>20 the wrong paragraph.</p> <p>21 MR. SMITH: If we turn to paragraph</p> <p>22 56, that may be the one you're looking for. You</p> <p>23 write in paragraph 56, "Enablement and the written</p> <p>24 description requirement are distinct but closely</p> <p>25 related requirements."</p> <p>www.dianaburden.com</p>	<p>1 PROFESSOR HOLBROOK: Right, and --</p> <p>2 MR. SMITH: Then you write, "Indeed,</p> <p>3 the Federal Circuit has noted that they usually rise</p> <p>4 and fall together." The "they" in that paragraph I</p> <p>5 presume refers to enablement and written description.</p> <p>6 Is that correct?</p> <p>7 PROFESSOR HOLBROOK: That's correct.</p> <p>8 MR. SMITH: If we go to the footnote,</p> <p>9 you actually provide the quotation and context, and</p> <p>10 that footnote from a 2005 decision says, "Those two</p> <p>11 requirements usually rise and fall together, that is,</p> <p>12 a recitation of how to make and use the invention</p> <p>13 across the full breadth of the claim is ordinarily</p> <p>14 sufficient to demonstrate that the inventor possesses</p> <p>15 the full scope of the invention and vice versa."</p> <p>16 There's no reference to "utility" in</p> <p>17 that quotation, is there?</p> <p>18 PROFESSOR HOLBROOK: Not in that</p> <p>19 quotation. The reference for utility comes from a</p> <p>20 different court, which is the next one. The case law</p> <p>21 does support that, where an invention fails the</p> <p>22 utility requirement, it often will fail the written</p> <p>23 description requirement.</p> <p>24 MR. SMITH: Does that quotation -- now</p> <p>25 you're looking at footnote 107. Is that right?</p> <p>www.dianaburden.com</p>
<p>1509</p> <p>1 PROFESSOR HOLBROOK: Correct.</p> <p>2 MR. SMITH: Does that assert that</p> <p>3 utility, enablement and written description often</p> <p>4 rise and fall together?</p> <p>5 PROFESSOR HOLBROOK: Well, I basically</p> <p>6 took what the Federal Circuit said, it said</p> <p>7 enablement and written description usually rise and</p> <p>8 fall together. Another court said written</p> <p>9 description and utility usually rise and fall</p> <p>10 together. If you realize that enablement</p> <p>11 incorporates utility as stated by the courts,</p> <p>12 typically enablement and utility rise and fall</p> <p>13 together. So if you're wanting to say that that</p> <p>14 extrapolation is my assertion, I'm comfortable with</p> <p>15 that statement, but the root is Federal Circuit</p> <p>16 saying written description and enablement usually</p> <p>17 rise and fall together; district court saying written</p> <p>18 description and utility rise and fall together.</p> <p>19 MR. SMITH: So you defined two</p> <p>20 statements, one from the Federal Circuit and one from</p> <p>21 the district court, combined them, and attributed</p> <p>22 them to the Federal Circuit. Is that correct?</p> <p>23 PROFESSOR HOLBROOK: I didn't</p> <p>24 attribute them to the Federal Circuit. Earlier in</p> <p>25 the other part of the discussion I said they usually</p> <p>www.dianaburden.com</p>	<p>1510</p> <p>1 rise and fall together, but, as you noted, I didn't</p> <p>2 quote the Federal Circuit at that point.</p> <p>3 MR. SMITH: You didn't quote and refer</p> <p>4 to the Federal Circuit in your testimony here today?</p> <p>5 PROFESSOR HOLBROOK: I did, but that</p> <p>6 testimony was actually discussing enablement and</p> <p>7 written description, which was specific to those two</p> <p>8 doctrines.</p> <p>9 MR. SMITH: Let's turn to the manual</p> <p>10 and to the relationship between section 101 utility</p> <p>11 and section 112(a), enablement.</p> <p>12 PROFESSOR HOLBROOK: Remind me which</p> <p>13 tab.</p> <p>14 MR. SMITH: It's tab 6. If you could,</p> <p>15 please turn to page 38, at subsection 4. This is in</p> <p>16 2107.01 of the manual.</p> <p>17 The section begins by stating that a</p> <p>18 deficiency under the utility prong of 101 also</p> <p>19 creates a deficiency under 112(a), correct?</p> <p>20 PROFESSOR HOLBROOK: Correct.</p> <p>21 MR. SMITH: And it then provides</p> <p>22 instructions to examiners later in the passage. In</p> <p>23 the second column over on the right about halfway</p> <p>24 down --</p> <p>25 PROFESSOR HOLBROOK: Yes.</p> <p>www.dianaburden.com</p>

<p>1 MR. SMITH: -- it states "To avoid 2 confusion, any lack of utility rejection imposed on 3 the basis of section 101 should be accompanied by 4 rejection based on 112(a)." 5 PROFESSOR HOLBROOK: Correct. 6 MR. SMITH: And it explains that the 7 rejection should indicate that because the invention 8 as claimed does not have utility a person skilled in 9 the art would not be able to use the invention as 10 claimed. Is that correct? 11 PROFESSOR HOLBROOK: Correct. 12 MR. SMITH: So section 101, which 13 presumes a use, or requires a use, I should say, is 14 part of the section 112 enablement requirement on how 15 to use, right? 16 PROFESSOR HOLBROOK: Correct. 17 MR. SMITH: And that's only because 18 one cannot teach how to use without there being a 19 use. 20 PROFESSOR HOLBROOK: Correct. 21 MR. SMITH: The courts have 22 acknowledged this same relationship, right? 23 PROFESSOR HOLBROOK: Correct. 24 MR. SMITH: In fact, the manual quotes 25 from a CCPA decision in 1971 on the left-hand side of</p> <p>www.dianaburden.com</p>	<p>1 the same page in the parenthetical. "If such 2 compositions are in fact useless appellant's 3 specification cannot have taught how to use them." 4 This relationship that the court there 5 and the manual identify is a point of simple logic, 6 is it not? 7 PROFESSOR HOLBROOK: Yes. And now 8 under Rasmussen a point of law, where the Federal 9 Circuit says it incorporates it as a matter of law. 10 MR. SMITH: Sometimes the law does 11 incorporate logic, it is true! 12 PROFESSOR HOLBROOK: Got to make the 13 distinction. 14 MR. SMITH: But the inverse logic is 15 not correct, right? 16 PROFESSOR HOLBROOK: Correct. There 17 are occasions when there may not be a 101 rejection 18 but there is a 112 rejection, that's true. 19 MR. SMITH: So an invention can have a 20 qualifying use but the description may fail to teach 21 how to use the invention? 22 PROFESSOR HOLBROOK: Correct. 23 MR. SMITH: In that case the 24 application would pass the utility test but fail the 25 enablement test?</p> <p>www.dianaburden.com</p>
<p>1513</p> <p>1 PROFESSOR HOLBROOK: Yes. 2 MR. SMITH: And the MPEP does not 3 instruct that, if an examiner denies for 112, the 4 examiner should also deny for 101? 5 PROFESSOR HOLBROOK: Correct. 6 MR. SMITH: And no cases hold that an 7 invalidation for lack of enablement must also be 8 invalidation based on lack of utility? 9 PROFESSOR HOLBROOK: Or, to be more 10 precise, a violation for 112, how to make, would not 11 implicate 101. How to use might? 12 MR. SMITH: Yes. I'm just focused on 13 how to use, and I was not precise. 14 PROFESSOR HOLBROOK: How to use might. 15 There are occasions when it may; occasions when it 16 may not. If you have a large, a broad genus claim 17 with lots of inoperable embodiments in it, or that 18 doesn't teach how to make it or how to use it, I've 19 got to figure out which of these various species 20 actually works. That could be a how to use violation 21 as well. 22 MR. SMITH: So you agree there's no 23 necessary relationship in the other direction? 24 PROFESSOR HOLBROOK: Correct. 25 MR. SMITH: In fact, there's no</p> <p>www.dianaburden.com</p>	<p>1514</p> <p>1 relationship in the other direction. 2 PROFESSOR HOLBROOK: Not correct. 3 MR. SMITH: Are you aware of a case in 4 which a court found an invention to be enabled but 5 not useful? 6 PROFESSOR HOLBROOK: That would be 7 nonsensical because to be enabled it has to be both 8 useful and how to make. You have to teach how to 9 make and use. If it doesn't have a use then you 10 can't use it so no, it's not possible. 11 MR. SMITH: There is no such case? 12 PROFESSOR HOLBROOK: Correct. 13 MR. SMITH: On that basis you agree as 14 well that the requirements of enablement and written 15 description are not co-extensive with the requirement 16 for utility? 17 PROFESSOR HOLBROOK: Absolutely, 18 they're not co-extensive. They're closely related 19 but not co-extensive. 20 MR. SMITH: They are closely related 21 in your view, extrapolating from different courts, 22 you believe that all three rise and fall together. 23 PROFESSOR HOLBROOK: They can rise and 24 fall together. I didn't say necessarily they always 25 rise and fall together, and that's not the court's</p> <p>www.dianaburden.com</p>

<p>1 representation. 2 MR. SMITH: You didn't say 3 necessarily, always, but you did say often, did you 4 not? 5 PROFESSOR HOLBROOK: Yes. 6 MR. SMITH: Not just "can." You said 7 "often." 8 PROFESSOR HOLBROOK: Often. 9 MR. SMITH: One way to test if they 10 rise and fall together is to look at patterns in the 11 cases, right? 12 PROFESSOR HOLBROOK: Uh-huh. 13 MR. SMITH: If we could turn to tab 14 16, this is an empirical study dated 1998 of the 15 validity of litigated patents in the United States. 16 You're familiar with this study? 17 PROFESSOR HOLBROOK: I've read it. I 18 wouldn't say that I've digested it, but I'm familiar 19 with it. 20 MR. SMITH: And you wrote about it in 21 your report? 22 PROFESSOR HOLBROOK: I wrote about it 23 in response to Professor Merges' representation about 24 the data contained in the report. 25 MR. SMITH: So this study covers an</p> <p>www.dianaburden.com</p>	<p>1 almost 8 year period, 1989-1996. It covers 239 cases 2 in which there was a final determination on validity, 3 and the results are reported further into the study 4 at page 208, if you could turn to that. 208 and 209 5 are two tables that report challenges across 6 different grounds, how often such challenges occurred 7 and what the outcomes were. And in table 1, you 8 agree there are 13 findings of invalidity on 9 enablement/written description and one on utility. 10 Is that right. 11 PROFESSOR HOLBROOK: Yes. 12 MR. SMITH: Those are reported 13 separately? 14 PROFESSOR HOLBROOK: Yes. 15 MR. SMITH: And the number of findings 16 with regard to enablement and written description 17 outnumber, 13 to 1, the number of findings of 18 invalidity based on utility? 19 PROFESSOR HOLBROOK: According to that 20 table, yes. 21 MR. SMITH: Table 2 gives the broader 22 number of decisions on these grounds, 36 on 23 enablement and written description. Only five over 24 eight years on utility, correct? 25 PROFESSOR HOLBROOK: According to this</p> <p>www.dianaburden.com</p>
<p>1517</p> <p>1 table, yes. I'm not entirely sure what the basis of 2 that is, claims or cases, but those are the numbers 3 in the table. 4 MR. SMITH: If you are correct that 5 the doctrines often rise and fall together, this is 6 not the pattern you would predict to see, is it? 7 PROFESSOR HOLBROOK: Actually it is, 8 because likely the court isn't going to hold multiple 9 holdings. If it invalidates under one the claim is 10 invalid. The other problem with relying on these 11 data is that this is from 1995 and 1996. The written 12 description requirement is an independent form of 13 invalidation. It doesn't really arise until much 14 later. You don't get confirmation of that until 15 Ariad in the 2000s. So these data would not reflect 16 the changes in the invalidations that have arisen 17 since that form of written description has been 18 embraced by the Federal Circuit. And that's the 19 language that Ariad is referring to. When they're 20 talking about rising and falling together it's that 21 version of the doctrine. These cases would not 22 reflect -- these data would not reflect those cases. 23 MR. SMITH: You heard Professor Merges 24 this morning testify about an update to this study. 25 Is that correct?</p> <p>www.dianaburden.com</p>	<p>1518</p> <p>1 PROFESSOR HOLBROOK: I don't know if 2 it was this study. I know he said there was an 3 update to a study. I don't know that it was this 4 study. 5 MR. SMITH: So you're not familiar 6 with a more recent study by Professors Allison and 7 Lemley regarding validity of litigated patents in the 8 United States? 9 PROFESSOR HOLBROOK: I'm not. 10 MR. SMITH: But you surveyed the 11 literature before submitting your reports, did you 12 not. 13 PROFESSOR HOLBROOK: I didn't survey 14 statistical literature. 15 MR. SMITH: This article appeared in 16 the AIPLA quarterly journal? 17 PROFESSOR HOLBROOK: I don't know I'm 18 not familiar with the article. 19 MR. SMITH: I mean this -- 20 PROFESSOR HOLBROOK: This one? The 21 one in front of me? Yes. 22 MR. SMITH: You and Professor Merges 23 have used some sports metaphors for the utility test, 24 restricted pretty much to track and field. 25 PROFESSOR HOLBROOK: That's what I ran</p> <p>www.dianaburden.com</p>

<p>1 in high school. 2 MR. SMITH: Professor Merges this 3 morning testified about the patentability 4 requirements as a series of hurdles. You've 5 testified this afternoon and in your Second Report 6 about the high jump bar. 7 PROFESSOR HOLBROOK: Correct. 8 MR. SMITH: And you wrote in your 9 Second Report and you summarized this in your 10 introductory remarks as well. We can turn to that. 11 It's your Second Report at note 12 on page 6. So tab 12 2, page 6. The note starts on page 5 and continues 13 on to page 6. 14 You refer to what you believe to be 15 the appropriate comparison and you say the analogy is 16 the nature of a high jumper? 17 PROFESSOR HOLBROOK: Well, I didn't 18 draw that comparison. Professor Merges did in his 19 report. 20 MR. SMITH: Right, but you adopt it 21 and modify it in a way that you believe to be 22 appropriate? 23 PROFESSOR HOLBROOK: Correct. 24 MR. SMITH: And you offered that 25 without reference to Professor Merges this afternoon</p> <p>www.dianaburden.com</p>	<p>1 in your presentation, did you not? 2 PROFESSOR HOLBROOK: Correct. 3 MR. SMITH: So you write, "Even when 4 the bar is at the same height, some high jumpers have 5 more difficulty clearing the bar. For example, on 6 average taller high jumpers are more successful than 7 shorter high jumpers. Even with the bar at the same 8 height on average a shorter jumper will have more 9 difficulty clearing the bar than a taller one. The 10 same applies to patents. Some technologies have an 11 easier time clearing the utility requirement, while 12 others, like pharmaceuticals have a more difficult 13 time on average even though the bar is the same." 14 That's your testimony, right? 15 PROFESSOR HOLBROOK: Yes. 16 MR. SMITH: So you agree that the 17 utility test in the United States, if we conceive of 18 it as a high jump bar, is at the same level for all 19 technologies? 20 PROFESSOR HOLBROOK: Yes. 21 MR. SMITH: But you assert that 22 different jumpers in different fields of technology 23 may have more or less difficulty clearing the bar? 24 PROFESSOR HOLBROOK: Yes. 25 MR. SMITH: And with the bar set at</p> <p>www.dianaburden.com</p>
<p>1521</p> <p>1 the same height, you would expect to see that 2 difference in height reflected in the jumper's 3 performance and results, right? 4 PROFESSOR HOLBROOK: What are you 5 defining as the jumper's performance and results? 6 MR. SMITH: The jumpers you 7 identified. Shorter jumpers and taller jumpers. 8 PROFESSOR HOLBROOK: Right. The 9 taller jumpers, i.e. technologies that are fairly 10 predictable, will clear the bar more readily and will 11 not be an issue. Shorter jumpers, pharmaceuticals, 12 biotech, will encounter this more frequently. 13 MR. SMITH: And you haven't just 14 implied this through this metaphor. You've stated 15 it. You state in your report that utility remains a 16 significant barrier to patentability in the 17 pharmaceutical context. Is that right? 18 PROFESSOR HOLBROOK: Yes. 19 MR. SMITH: Let's turn to where you 20 make that assertion. It's in your First Report at 21 paragraph 18. You see that sentence I just read? 22 PROFESSOR HOLBROOK: I'm sorry, I'm 23 confused with pages versus paragraphs. Is it 24 paragraph or page? 25 MR. SMITH: I apologize. It is</p> <p>www.dianaburden.com</p>	<p>1522</p> <p>1 paragraph 18 on page 7. It's near the bottom of that 2 paragraph as it appears on that page. What you write 3 there is "It remains a significant barrier" -- you're 4 referring to the utility requirement? 5 PROFESSOR HOLBROOK: Yes. 6 MR. SMITH: "To patentability in the 7 pharmaceutical context." 8 PROFESSOR HOLBROOK: Pharmaceutical, 9 chemical and biological inventions. 10 MR. SMITH: And you have a footnote in 11 support of that assertion? 12 PROFESSOR HOLBROOK: Well, I go on 13 and -- or I do have that at footnote 5, and I also 14 rely on Professor Merges' case book discussing the 15 way that chemistry and chemists -- the nature of 16 these technologies results in compounds that you may 17 not know how they work, even though you've created 18 the compound, and that's the reason why they 19 encounter utility differently. 20 MR. SMITH: I see you're now talking 21 about other sentences in the same paragraph. Is that 22 right? 23 PROFESSOR HOLBROOK: Correct. 24 MR. SMITH: So I'm focused on the 25 sentence that says "It remains a significant barrier</p> <p>www.dianaburden.com</p>

<p>1 to patentability in the pharmaceutical context." 2 PROFESSOR HOLBROOK: Yes. 3 MR. SMITH: And you have a footnote in 4 support of that. Footnote 8. 5 PROFESSOR HOLBROOK: Yes. 6 MR. SMITH: And you refer to an 7 empirical study there? 8 PROFESSOR HOLBROOK: Uh-huh. 9 MR. SMITH: You're just referring to a 10 study that Professor Merges put into evidence. Is 11 that correct? 12 PROFESSOR HOLBROOK: Correct, which I 13 believe is the study we were just looking at in the 14 AIPLA law journal. 15 MR. SMITH: You refer to it as a study 16 authored by Professor Merges. 17 PROFESSOR HOLBROOK: I don't refer to 18 it as "authored." I refer to it as "relied upon" by 19 Professor Merges. 20 MR. SMITH: At the bottom of the page, 21 footnote 8, you say "Professor Merges and his 22 co-authors." 23 PROFESSOR HOLBROOK: I may have 24 inadvertently suggested -- I'll have to double check 25 if he's a co-author or not. I don't believe he is,</p> <p>www.dianaburden.com</p>	<p>1 but I'd have to look at the AIPLA quote. 2 MR. SMITH: There's not a reference 3 here to what study exactly you're talking about, but 4 you're testifying now that you're referring to the 5 study we were just looking at? 6 PROFESSOR HOLBROOK: The same. 7 MR. SMITH: This is the study in which 8 there was a single invalidation for lack of utility 9 over an 8-year period? 10 PROFESSOR HOLBROOK: Correct. 11 MR. SMITH: This is the study that 12 doesn't indicate what sector that invalidation 13 occurred in? 14 PROFESSOR HOLBROOK: No, that's a 15 different one. At some point in Merges' report he 16 talks about overall invalidation rates. I think he 17 changed the percentage today, right, and I believe 18 that was across all technological fields. 19 MR. SMITH: We're referring I think to 20 the same study -- 21 PROFESSOR HOLBROOK: Right, and we may 22 be confusing studies here. 23 THE PRESIDENT: Could you repeat your 24 question? 25 MR. SMITH: I want to make sure we're</p> <p>www.dianaburden.com</p>
<p>1525</p> <p>1 talking about the same study. You just indicated the 2 study you're discussing in this footnote is the one 3 we were just talking about, the one that appears in 4 the binder at tab 16. The exhibit number is C-167. 5 It's a study by Professors Allison and Lemley 6 entitled Empirical Evidence on the Validity of 7 Litigated Patents. 8 PROFESSOR HOLBROOK: So I'm beginning 9 to realize, looking at that footnote, there's the 10 AIPLA study, and I do reference a Merges study which 11 I believe is what he referenced today when he changed 12 his percentages. So I believe there are two studies. 13 But I would need to look at the Merges report to 14 confirm that. 15 MR. SMITH: For the record, I can 16 offer that I believe Professor Merges' testimony 17 today was referring to this same study, so we're 18 really just talking about one study. As you may 19 recall this morning, I believe Professor Merges' 20 correction was regarding the very table that we just 21 looked at, table 1 on page 208, and what Professor 22 Merges corrected was his prior reference to 23 0.7 percent as the percentage of cases in which a 24 lack of utility was found, and he noted that that 25 table does not present cases, it presents patents,</p> <p>www.dianaburden.com</p>	<p>1526</p> <p>1 and the actual percentage, 1/239 is .41. 2 Is there another study in the record 3 to which you are referring? 4 PROFESSOR HOLBROOK: I don't know. 5 That's why I'm trying to look at Professor Merges' 6 report to see if I'm referring to that one, or if 7 there's a different one to which I'm referring. 8 THE PRESIDENT: Professor Holbrook, if 9 you look to the footnote on page 1 of the study, 10 there is actually the asterisk, and you see that the 11 authors thank a number of people, and apparently it 12 includes Professor Merges. Is that the basis for 13 your, if I may call it, confusion, whether it's one 14 report or two reports? 15 PROFESSOR HOLBROOK: I think in my 16 mind I just associated Merges as being an author when 17 he, in fact, is not. So that's an inaccurate 18 statement in my footnote about whether he was the 19 author or not of the study, but I believe we are 20 referring to the same study. 21 MR. SMITH: It's also understandable 22 because I believe Professor Merges today testified 23 he's written some three books with one of these 24 authors. 25 PROFESSOR HOLBROOK: He writes a lot</p> <p>www.dianaburden.com</p>

<p>1 with Mark Lemley, who is one of the authors. 2 MR. SMITH: When you assert in your 3 First Report that utility is a significant barrier to 4 patentability in the pharmaceutical context, the only 5 study you cite in reliance on that is this one we've 6 been discussing. Is that correct? 7 PROFESSOR HOLBROOK: Yes. 8 MR. SMITH: That's the study that 9 shows a single invalidation for a lack of utility 10 over an 8-year period? 11 PROFESSOR HOLBROOK: That is that 12 study, yes. 13 MR. SMITH: And that study does not 14 indicate anything about the field of technology in 15 which that single invalidation took place? 16 PROFESSOR HOLBROOK: Correct. 17 MR. SMITH: It's fair to say that 18 study does not really support your assertion, isn't 19 it? 20 PROFESSOR HOLBROOK: No. Empirically 21 speaking if you're talking about litigated patents, 22 then there aren't many litigated patents, but the 23 reality is utility doctrine operates for all patents, 24 right? So we would actually hope in an ideal patent 25 system that there aren't many litigated patents</p> <p>www.dianaburden.com</p>	<p>1 because people are satisfying the conditions. How? 2 By waiting until there's an appropriate amount of 3 discovery to support their assertion of utility. So 4 it doesn't mean it's not a significant barrier simply 5 because they're not being litigated. That is a 6 subset of cases, and the reasons that certain cases 7 are litigated are different than what you actually 8 encounter at the time of the application, and if the 9 inventor and a patent attorney are doing their job, 10 you would hope that there are not many rejections on 11 the basis of utility, something that is completely 12 within the control of the applicant. 13 MR. SMITH: So it's fair to say that, 14 in the absence of litigation, results finding 15 invalidity on the basis of lack of utility, 16 applicants in the United States must be complying 17 with the utility requirement? 18 PROFESSOR HOLBROOK: I'd say there's a 19 good chance that that's happening. It's a low bar. 20 That's not rejected much. That's fine. The 21 litigation statistics don't really tell us much about 22 what's happening at the application stage, what's 23 happening at the invention stage. It just tells us 24 after it gets out are people challenging them on this 25 basis, and we don't know the strategic reasons for</p> <p>www.dianaburden.com</p>
<p>1529</p> <p>1 bringing those challenges. Maybe utility was viable 2 in some of those cases. They opted not to. 3 MR. SMITH: But in many, many cases in 4 the United States patents are granted, and that's 5 based on a finding that they are useful, have a 6 qualifying use, right? 7 PROFESSOR HOLBROOK: Based off the 8 presumption that the disclosed use is satisfied. 9 MR. SMITH: And a subset of those 10 granted patents are litigated, right? 11 PROFESSOR HOLBROOK: Correct. 12 MR. SMITH: And of the subset that are 13 litigated, very, very few of those challenges relate 14 to the utility of the invention, correct? 15 PROFESSOR HOLBROOK: There are very 16 few patents that actually go to litigation. There 17 are a few cases in that study where utility is 18 litigated, correct. 19 MR. SMITH: You did not testify about 20 or offer into evidence any other empirical study of 21 U.S. case law and litigation outcomes, did you? 22 PROFESSOR HOLBROOK: I did not. 23 MR. SMITH: You did not provide any 24 other statistical evidence that utility is a 25 significant barrier for the pharmaceutical sector,</p> <p>www.dianaburden.com</p>	<p>1530</p> <p>1 did you? 2 PROFESSOR HOLBROOK: I did not. 3 MR. SMITH: Turning away from 4 litigation and toward examination, you note and 5 acknowledge the data reported by Mr. Kunin. You do 6 this in your Second Report at paragraph 12. 7 PROFESSOR HOLBROOK: Yes. 8 MR. SMITH: And in footnote 9 you note 9 that Mr. Kunin found utility rejections in only 10 1 percent of the cases over a 10-year period. 11 PROFESSOR HOLBROOK: Correct. 12 MR. SMITH: You note, however, that 13 this does not identify the field of technology in 14 which those rejections took place? 15 PROFESSOR HOLBROOK: Correct. 16 MR. SMITH: And that that would have 17 been a more apt analysis? 18 PROFESSOR HOLBROOK: I think it would 19 be more helpful. 20 MR. SMITH: I'm just quoting -- 21 PROFESSOR HOLBROOK: Yes. 22 MR. SMITH: -- your report, more 23 helpful, more apt. But you didn't perform that more 24 helpful and more apt analysis yourself, did you? 25 PROFESSOR HOLBROOK: I did not.</p> <p>www.dianaburden.com</p>

<p>1 MR. SMITH: You didn't cite to or 2 offer any such analysis performed by anyone else, did 3 you? 4 PROFESSOR HOLBROOK: I did not. 5 MR. SMITH: And you don't dispute the 6 accuracy of Mr. Kunin's statistics on the rarity of 7 utility rejections of the -- 8 PROFESSOR HOLBROOK: No. 9 MR. SMITH: -- PTO? Let's turn back 10 to your high jump bar analogy. You have not provided 11 any empirical data or statistics to support your 12 claim that pharmaceutical inventions in the U.S. have 13 more difficulty than inventions in other fields 14 clearing the high jump bar, right? 15 PROFESSOR HOLBROOK: I have not relied 16 on any empirical evidence. I've relied on 17 characterizations of how the chemical arts and the 18 pharmaceutical arts work. I've relied on the 19 characterizations in the case law about how these 20 technologies encounter the doctrine. 21 MR. SMITH: But empirical studies of 22 patent litigation in the United States are conducted 23 routinely, are they not? 24 PROFESSOR HOLBROOK: They are. 25 MR. SMITH: And you are familiar with</p> <p>www.dianaburden.com</p>	<p>1 at least some of those studies, are you not? 2 PROFESSOR HOLBROOK: I am. 3 MR. SMITH: Yet you did not cite any 4 of those studies in support of your significant 5 barrier assertion? 6 PROFESSOR HOLBROOK: I did not. 7 MR. SMITH: We've been discussing the 8 high jump bar within the United States, and specific 9 to utility, but your testimony as we discussed at the 10 outset was about the comparative analysis of 11 doctrines in both the United States and in Canada. 12 And one question you asked was whether the United 13 States and Canadian utility standards are equivalent, 14 right? So if we could, it might be helpful to extend 15 the high jump bar analogy. If the utility standards 16 in Canada and the United States were equivalent, 17 presumably they would set the high jump bar of 18 utility at the same height, right? 19 PROFESSOR HOLBROOK: Uh-huh. 20 THE PRESIDENT: Yes? 21 PROFESSOR HOLBROOK: Yes. I'm sorry, 22 yes. 23 MR. SMITH: And if the bar for utility 24 in the two jurisdictions were set at the same height, 25 the same jumper, other things equal, should have the</p> <p>www.dianaburden.com</p>
<p>1533</p> <p>1 same result? 2 PROFESSOR HOLBROOK: Not necessarily. 3 MR. SMITH: Perform the same in both 4 countries? 5 PROFESSOR HOLBROOK: Not necessarily. 6 MR. SMITH: We're talking about the 7 utility bar now, and you've said in Canada -- I'm 8 sorry, you said in the United States it's set at a 9 single height for all technologies. 10 PROFESSOR HOLBROOK: Correct? 11 MR. SMITH: And that some jumpers have 12 more difficulty, some less, clearing it? 13 PROFESSOR HOLBROOK: Right. 14 MR. SMITH: Now I'm asking you to 15 hypothesize, if the doctrines in the two 16 countries were equivalent -- 17 PROFESSOR HOLBROOK: Equivalent does 18 not mean equal -- 19 MR. SMITH: I do not need to use the 20 word "equivalent," so let me rephrase the question. 21 If the utility standards in the United States and 22 Canada were similar and required a similar showing 23 for patentee, we might say they set the bar at the 24 same height, right? 25 PROFESSOR HOLBROOK: I would not say</p> <p>www.dianaburden.com</p>	<p>1534</p> <p>1 that similar is same. 2 MR. SMITH: I'm not asking you to 3 adopt that as your view. I'm asking you a 4 hypothetical. 5 PROFESSOR HOLBROOK: Okay. 6 MR. SMITH: Assume that they are the 7 same. 8 PROFESSOR HOLBROOK: Okay. 9 MR. SMITH: Now, the same jumper going 10 through the process in both countries, obtaining a 11 patent, perhaps having it litigated, you would expect 12 to have the same results as to the utility 13 requirement. Is that correct? 14 PROFESSOR HOLBROOK: Same evidence. 15 MR. SMITH: Yes, everything -- 16 PROFESSOR HOLBROOK: Same fact 17 finders? 18 MR. SMITH: Yes. Same patent, same 19 evidence, same fact finders. Assume it's all the 20 same. You would expect the same result, would you 21 not? 22 PROFESSOR HOLBROOK: I personally 23 wouldn't because facts can differ. People of 24 reasonable minds can disagree about what the facts of 25 the case are. At a super abstract level, yes, I</p> <p>www.dianaburden.com</p>

<p>1 would agree, but when you actually talk about how 2 these decisions are made on the ground, I would not 3 agree with that. Particularly if the evidence is 4 different, how people characterize the evidence is 5 different. Now we're talking about dealing with 6 specific facts of cases, and reasonable minds can 7 disagree on those kind of outcomes -- and that's 8 okay.</p> <p>9 MR. SMITH: You agree patents are 10 often filed in multiple jurisdictions?</p> <p>11 PROFESSOR HOLBROOK: Yes.</p> <p>12 MR. SMITH: Including both Canada and 13 the United States?</p> <p>14 PROFESSOR HOLBROOK: Yes.</p> <p>15 MR. SMITH: But you disagree that one 16 way to assess whether the U.S. and Canadian utility 17 requirements are similar would be to look at outcomes 18 with respect to utility in both jurisdictions for the 19 same applicants and the same patents and the same 20 evidence?</p> <p>21 PROFESSOR HOLBROOK: I think that 22 would be troubling because it assumes that the 23 doctrines are exactly the same. It assumes the fact 24 finders would be exactly the same. It assumes the 25 evidence would be exactly the same. All of these</p> <p>www.dianaburden.com</p>	<p>1 cases are very fact intensive, and how a given fact 2 finder, a given tribunal, weighs those facts in light 3 of their own -- I'm not willing to say that you're 4 going to expect uniform decisions across 5 jurisdictions.</p> <p>6 MR. SMITH: Again, I'm not asking you 7 to assume the standards are the same. I'm asking you 8 to assume that, if they were, you'd expect similar 9 results.</p> <p>10 PROFESSOR HOLBROOK: Depending on the 11 facts and the evidence presented. That's the context 12 that becomes important here. So if all evidence is 13 the same, the legal standards are similar, you would 14 hope that they would be -- you would expect them to 15 be the same. I just don't think that's what happens 16 on the ground.</p> <p>17 MR. SMITH: Maybe we can step back 18 from the analogy and ground ourselves in a specific 19 decision. In your First Report you actually do look 20 at one U.S. case that addressed the utility of a 21 patent for an approved pharmaceutical invention that 22 was litigated in both jurisdictions.</p> <p>23 PROFESSOR HOLBROOK: Yes.</p> <p>24 MR. SMITH: That case related to Eli 25 Lilly's patent for Strattera. Is that right?</p> <p>www.dianaburden.com</p>
<p>1537</p> <p>1 PROFESSOR HOLBROOK: Yes.</p> <p>2 MR. SMITH: And that patent for 3 Strattera is the analog to the Canadian patent that's 4 at issue in this arbitration.</p> <p>5 PROFESSOR HOLBROOK: Yes.</p> <p>6 MR. SMITH: So, to go back to your 7 high jump analogy, Lilly's Strattera patent, the same 8 jumper, had to clear the utility bar both in the 9 United States and in Canada.</p> <p>10 PROFESSOR HOLBROOK: Yes.</p> <p>11 MR. SMITH: And you understand that 12 Lilly's patent for Strattera in Canada was 13 invalidated on the sole ground of inutility?</p> <p>14 PROFESSOR HOLBROOK: As I recall -- 15 and this is the selection patent case?</p> <p>16 MR. SMITH: It's not. It's the new 17 use case involving atomoxetine.</p> <p>18 PROFESSOR HOLBROOK: Atomoxetine, 19 okay.</p> <p>20 MR. SMITH: For the treatment of ADHD.</p> <p>21 PROFESSOR HOLBROOK: I don't know the 22 street market names. So this is the new use case.</p> <p>23 MR. SMITH: Your report addresses the 24 validity litigation on the very same patent, 25 atomoxetine, in the United States?</p> <p>www.dianaburden.com</p>	<p>1538</p> <p>1 PROFESSOR HOLBROOK: Yes.</p> <p>2 MR. SMITH: That case was decided by 3 the Federal Circuit on appeal. Is that correct?</p> <p>4 PROFESSOR HOLBROOK: That's correct.</p> <p>5 MR. SMITH: And the Federal Circuit is 6 a court of specialized jurisdiction with expertise in 7 patent law?</p> <p>8 PROFESSOR HOLBROOK: Yes.</p> <p>9 MR. SMITH: And you describe the 10 Federal Circuit's holding in that case at paragraph 11 38 of your First Report?</p> <p>12 PROFESSOR HOLBROOK: Yes.</p> <p>13 MR. SMITH: This is at tab 1. You 14 wrote, "The post-filing evidence confirmed the 15 utility disclosed in the specification and the 16 Federal Circuit noted there was no reason to doubt 17 the assertions of utility made in the specification 18 itself." You wrote further, "The key aspects of the 19 holding were that" -- and you quote here from the 20 ruling -- "the norepinephrine relationship was known, 21 safety for the antidepressant activity had been 22 established, the specification contained a full 23 description of the utility, experimental verification 24 had been obtained before the patent was granted, and 25 the examiner had not requested additional</p> <p>www.dianaburden.com</p>

<p>1 information. There was no evidence that the 2 disclosure is, on its face, contrary to generally 3 accepted scientific principles." 4 Those were all quotes from the 5 decision, and you conclude that, in the Strattera or 6 the atomoxetine case in the United States, the use of 7 post-filing evidence corroborated what was considered 8 the already sufficient disclosure in the patent 9 application by the court. So the Federal Circuit 10 held Lilly's patent for Strattera to be valid, right? 11 PROFESSOR HOLBROOK: Correct. 12 MR. SMITH: So the litigation 13 regarding Lilly's patent for Strattera in Canada in 14 the United States would provide a basis to compare 15 the height of the utility bar in the two countries, 16 wouldn't it? 17 PROFESSOR HOLBROOK: It is one datum. 18 But you'd have to take into account what different 19 evidence was available. I think you have to take 20 into account the context of the case, the context of 21 the fact finders. The lower court here did find the 22 patent to be invalid, so that suggests to me that 23 within the United States it was a close case. The 24 evidence in the case showed that the inventor didn't 25 actually seem to know that the invention would work</p> <p>www.dianaburden.com</p>	<p>1 when it filed. The inventor in the case testified 2 that at the time they filed, there were studies that 3 were going to start, but they weren't certain that 4 the invention was going to work, the method was going 5 to work. 6 So the facts are close. In a close 7 case, even with a similar standard, you may get 8 differing outcomes because reasonable minds can 9 disagree on what's the salience of those particular 10 patents. So it is a basis of comparison, but it's 11 unsurprising to me that you can get different 12 outcomes in different jurisdictions. 13 MR. SMITH: You say the facts were 14 close. 15 PROFESSOR HOLBROOK: In my opinion, 16 they were. 17 MR. SMITH: On what basis do you say 18 that? 19 PROFESSOR HOLBROOK: Can you show me 20 where the decision is in the tab so I can show you to 21 what I'm referring? 22 MR. SMITH: The appellate court 23 decision is in the binder at tab 15. I'll give you a 24 moment to turn to it. 25 PROFESSOR HOLBROOK: So on page 6 the</p> <p>www.dianaburden.com</p>
<p>1541</p> <p>1 court discusses the inventor's testimony 2 specifically -- and I'm not going to be able to 3 pronounce this name, sorry. Dr. Heiligenstein -- 4 apologize if they're in the room. One of the 5 inventors testified about his uncertainty whether 6 this treatment of ADHD would be effective when he and 7 Dr. Tolefson suggested experimental testing for this 8 purpose. "Question: At the time of this filing did 9 you have a reasonable expectation that tomoxetine 10 would work to treat ADHD? Answer: It was a 11 hypothetical. Question: Did you have a reasonable 12 expectation? Answer: Reasonable? Can you define 13 reasonable question? Did you believe it was going to 14 work for ADHD? Answer: No. I wasn't sure that it 15 would work." 16 So when the inventor is testifying 17 that they're not convinced that it's going to work at 18 the time they're filing the application, that, to me, 19 suggests that this is a close case. When the U.S. 20 case law talks about not patenting hypotheses or not 21 patenting research proposals, that type of evidence 22 suggests that you're getting close to that line. So 23 in my opinion, this was a close case. The lower 24 court also invalidated on the basis of lack of 25 utility. So I'm not the only one who thinks that</p> <p>www.dianaburden.com</p>	<p>1542</p> <p>1 this was a close case. 2 MR. SMITH: The Federal Circuit did 3 not think it was a close case, did it? The Federal 4 Circuit reversed the district court, right? 5 PROFESSOR HOLBROOK: They reversed. 6 They didn't characterize whether they thought it was 7 a close case or not. They just reversed. 8 MR. SMITH: The findings of fact of a 9 district court are due deference on appeal, are they 10 not? 11 PROFESSOR HOLBROOK: They are. 12 MR. SMITH: But that deference here 13 must not have been deserved in view of the Federal 14 Circuit because they reversed this ruling with 15 respect to enablement, right? 16 PROFESSOR HOLBROOK: They did reverse. 17 MR. SMITH: And this reversal must be 18 based on the Federal Circuit's view that the holding 19 below was clearly erroneous, right? 20 PROFESSOR HOLBROOK: Depends. Since 21 they couch this in terms of both enablement and 22 utility, the aspects that are utility, that's 23 factual. So yes. The aspects that are enablement, 24 enablement is a legal question. At least the 25 ultimate conclusion is it enabled or not is a legal</p> <p>www.dianaburden.com</p>

<p>1 conclusion based on underlying facts. 2 MR. SMITH: If we compare the 3 litigation regarding Lilly's patent for Strattera in 4 Canada and the U.S., we see, as we've discussed, that 5 Lilly's Strattera patent cleared the utility bar in 6 the U.S. 7 PROFESSOR HOLBROOK: Yes. 8 MR. SMITH: And safely so, you note, 9 given that it's a factual issue in what was reversed. 10 The same patent failed to clear the utility bar in 11 Canada, right? 12 PROFESSOR HOLBROOK: Yes. 13 MR. SMITH: And these divergent 14 outcomes suggests that the high jump bar in the U.S. 15 and Canada are set at different heights, does it not? 16 PROFESSOR HOLBROOK: That's not my 17 take-away. My take-away would be that on the factual 18 issues in this case, the courts disagree. That 19 doesn't necessarily tell me that there is systemic 20 differences in the utility standards. 21 MR. SMITH: We could also add, if we 22 go beyond utility, the written description and 23 enablement requirements to the high jump bar, right? 24 PROFESSOR HOLBROOK: We could. 25 MR. SMITH: And this Strattera patent</p> <p>www.dianaburden.com</p>	<p>1 cleared that bar as well, right? 2 PROFESSOR HOLBROOK: We don't know. 3 MR. SMITH: You don't know if this -- 4 PROFESSOR HOLBROOK: It was not 5 litigated. 6 MR. SMITH: What do you mean when you 7 say "it was not litigated"? 8 PROFESSOR HOLBROOK: Nowhere in here 9 do I see a discussion that someone challenged the 10 basis of the validity of the patent on the grounds of 11 written description. 12 MR. SMITH: I'm sorry. Did I say 13 written description? 14 PROFESSOR HOLBROOK: Yes. 15 MR. SMITH: As to enablement and 16 utility, we're agreed. Is that right? 17 PROFESSOR HOLBROOK: Correct. Here 18 they refer to it as both enablement/utility. 19 MR. SMITH: And there was no finding 20 in this case that the patent lacked a sufficient 21 written description, is there? 22 PROFESSOR HOLBROOK: There was no 23 issue in the case of whether there was a lack of 24 written description. It was not presented in the 25 case.</p> <p>www.dianaburden.com</p>
<p>1545</p> <p>1 MR. SMITH: And it was not presented 2 in the case because it was not challenged. 3 PROFESSOR HOLBROOK: Correct. 4 MR. SMITH: Thank you. 5 There was also validity litigation in 6 the United States regarding the other patent at issue 7 here, the Zyprexa -- the patent for Zyprexa. 8 Olanzapine, as you may know it. And there was no 9 finding of invalidity for Zyprexa based on utility or 10 enablement, was there? 11 PROFESSOR HOLBROOK: Correct. 12 Litigation in the United States focused on 13 obviousness, which is where most of the work for 14 selection patents in the U.S. takes place. 15 MR. SMITH: So Lilly's patents cleared 16 the utility, enablement and written description bars 17 in the United States, right? 18 PROFESSOR HOLBROOK: I would not say 19 that they cleared them, since particularly written 20 description was not challenged. 21 MR. SMITH: There was no finding of 22 invalidity with respect to utility, enablement or 23 written description for Lilly's two patents in the 24 United States, right? 25 PROFESSOR HOLBROOK: That's correct,</p> <p>www.dianaburden.com</p>	<p>1546</p> <p>1 they were not. Those issues were not raised in the 2 litigation, though, so only enablement and utility 3 was raised in the tomoxetine case. 4 MR. SMITH: Both failed to clear the 5 utility bar in Canada. Is that right? 6 PROFESSOR HOLBROOK: Yes. 7 MR. SMITH: Doesn't that suggest to 8 you that Canada has set the utility bar higher than 9 the United States has set the utility, enablement and 10 written description bar? 11 PROFESSOR HOLBROOK: The outcomes of 12 two cases did not, to me, demonstrate that there is a 13 significant difference in the height of utility bar. 14 Outcomes can vary based off similar facts. Moreover, 15 there's no obligation that the laws be exactly the 16 same. They just have to be similar. 17 MR. SMITH: I have some more 18 questions, Mr. President, but -- 19 THE PRESIDENT: How many more minutes 20 do you estimate? 21 MR. SMITH: I think perhaps ten 22 minutes. 23 THE PRESIDENT: Do you have any 24 redirect questions? 25 MR. LUZ: At this point,</p> <p>www.dianaburden.com</p>

<p>1 Mr. President, we don't anticipate having any. 2 THE PRESIDENT: The Tribunal has also 3 one question. Mr. Smith, please continue and finish. 4 MR. SMITH: Thank you, Mr. President. 5 So we've discussed Lilly's Strattera 6 and Zyprexa patents in the United States and Canada, 7 right? 8 PROFESSOR HOLBROOK: Correct. 9 MR. SMITH: What if we broadened the 10 lens a bit? You're aware, are you not, that Lilly's 11 Strattera and Zyprexa patents are not the only 12 pharmaceutical patents to have been found to lack 13 utility in Canada? 14 PROFESSOR HOLBROOK: I'm aware of 15 that. 16 MR. SMITH: You're aware that there 17 are 25 such patents in the pharmaceutical field, 23 18 other than these two? 19 PROFESSOR HOLBROOK: These details I'm 20 not aware of. I just know there are other cases. If 21 there's something in the record you want to point me 22 to that explains this -- 23 MR. SMITH: It's in the submissions of 24 the parties, but just accepting that there is a 25 number greater than 2 and around 20, if we broaden</p> <p>www.dianaburden.com</p>	<p>1 the lens. 2 MR. LUZ: Just for the record, I don't 3 think we agree to the accuracy of those numbers, the 4 way it's been stated. I'm just not sure whether we 5 were talking about invalidations or you were talking 6 more generally. 7 THE PRESIDENT: Shall we leave that 8 part aside for submissions? We can leave that to 9 oral argument. It was not actually a question to 10 Professor Holbrook. 11 MR. SMITH: I'm not sure I understand 12 your suggestion, Mr. President. 13 THE PRESIDENT: I said strike it from 14 the record, this part, because what it is -- so now 15 it disappears from my screen. 16 MR. SMITH: The specific factual 17 number is not material if Professor Holbrook will 18 accept, for the sake of argument, that there are 19 numerous patents that have been found to lack utility 20 in Canada. 21 THE PRESIDENT: You covered that 22 ground. Then you said, look, are you aware of what 23 is in submissions, and you put it not in the way of a 24 question but as an argument. "I submit to you that." 25 And then the other side said, Hey, wait a minute, you</p> <p>www.dianaburden.com</p>
<p>1549</p> <p>1 mischaracterized, at least according to us, the 2 submissions. That's the reason why I say leave it 3 aside. Technically you call it strike it out unless 4 you would like to put it in a question to Professor 5 Holbrook. 6 MR. SMITH: I agree the reference to 7 the submissions and the implications that this is a 8 point of agreement between the parties should be 9 stricken. 10 THE PRESIDENT: Please proceed then. 11 MR. SMITH: So Professor Holbrook, if 12 we broaden the lens beyond the Zyprexa and Strattera 13 patents to look at the broader set of pharmaceutical 14 patents found to lack utility in Canada, that might 15 provide us with a more robust means of assessing 16 whether the utility doctrine in Canada and the 17 combination of the utility, enablement and written 18 description doctrines in the United States are or are 19 not equivalent. Do you agree? 20 PROFESSOR HOLBROOK: That would give a 21 basis. But, again, there's no obligation that they 22 be identical. So we're doing comparisons of 23 doctrines that are similar, but there is no 24 obligation they be identical. So variations in 25 outcomes can be expected.</p> <p>www.dianaburden.com</p>	<p>1550</p> <p>1 MR. SMITH: But to be clear, what I'm 2 assuming in this hypothetical -- it's not even a 3 hypothetical. It's the set of cases in evidence and 4 contested by the parties in this case. That evidence 5 relates to more than 20 high jumpers whose patents 6 cover approved drugs for sale in Canada. You can 7 agree with that as a hypothetical? I mean not as a 8 hypothetical -- 9 PROFESSOR HOLBROOK: As a 10 hypothetical, okay. 11 MR. SMITH: And there is often an 12 incentive to litigate the validity of patents that 13 cover approved drugs with large market shares, right? 14 PROFESSOR HOLBROOK: Yes. 15 MR. SMITH: And that's true both in 16 the United States and in Canada? 17 PROFESSOR HOLBROOK: Yes. 18 MR. SMITH: Some of these patents, 19 therefore, were likely to be litigated both in the 20 United States and in Canada? 21 PROFESSOR HOLBROOK: That could be. I 22 don't know. I don't know what strategic choices they 23 used. It would seem to be a definitive answer yes or 24 no if they're the same patents being litigated. I 25 don't know.</p> <p>www.dianaburden.com</p>

<p>1 MR. SMITH: But if it's the same 2 patents, the same jumpers, they could be challenged 3 on utility, enablement or written description in the 4 United States, right? 5 PROFESSOR HOLBROOK: Correct. And for 6 selection patents, again, we use the obviousness 7 angle. 8 MR. SMITH: And you've talked about 9 the importance of kind of predicting outcomes, 10 patentees with respect to their inventions in your 11 testimony today. 12 PROFESSOR HOLBROOK: I don't know to 13 what you're referring. 14 MR. SMITH: Well, you referred to the 15 importance of being able to predict a result with 16 respect to an invention and not patent it too early. 17 PROFESSOR HOLBROOK: Oh, in terms of 18 prophetic examples, not outcomes in terms of patent 19 litigation. Yes. 20 MR. SMITH: So now I'm asking whether 21 you can help me predict outcomes in this 22 hypothetical. If you are right that the three 23 doctrinal requirements in the United States, 24 enablement, utility, written description, which are 25 the focus of your report, operate in a similar manner</p> <p>www.dianaburden.com</p>	<p>1 as the utility requirement in Canada, what outcomes 2 would you predict with respect to these same high 3 jumpers? 4 PROFESSOR HOLBROOK: I have no idea. 5 It would depend on the facts of each of those cases, 6 what evidence is presented, what's the state of the 7 art, are these actual similar patents or not. The 8 patents may be similar, the claims may differ. Every 9 patent is issued by a different country, so the 10 claims may not actually be the same. The evidence 11 presented could be different. In theory, the 12 specifications could be different. The legal 13 standards are allowed to flux a little bit, and so I 14 would not be willing to speculate that those outcomes 15 necessarily have to be. 16 MR. SMITH: Well, you've reviewed all 17 the relevant U.S. case law, have you not? 18 PROFESSOR HOLBROOK: Yes. 19 MR. SMITH: And your reports do not 20 identify any U.S. case in which a patent found to 21 lack utility in Canada had its analog in the United 22 States ruled invalid for lack of enablement or 23 written description or for inutility. 24 PROFESSOR HOLBROOK: That's not a 25 study I performed. I analyzed the U.S. case law. I</p> <p>www.dianaburden.com</p>
<p>1 didn't go explore were there parallel litigations in 2 Canada for every case that I read. 3 MR. SMITH: But you agree that would 4 be an appropriate comparison to answer the question 5 posed by your report, which is whether the two 6 systems have rules of law that are or are not 7 equivalent? 8 PROFESSOR HOLBROOK: It would be a 9 basis to look and see how the different rules 10 operate, but determining whether those outcomes must 11 be dictated, again, I'm not willing to make that 12 claim. 13 MR. SMITH: Well, you know, based on 14 evidence in the record, that the Zyprexa and 15 Strattera patents passed all three doctrines of 16 interest to you in the United States, right? 17 PROFESSOR HOLBROOK: They passed one 18 as challenged in litigation. 19 MR. SMITH: You know that the Zyprexa 20 and Strattera patents at issue in this case were not 21 invalidated on the basis of any of the three 22 doctrines covered by your report, right? 23 PROFESSOR HOLBROOK: That is 24 technically correct. 25 MR. SMITH: And you know that the</p> <p>www.dianaburden.com</p>	<p>1 Zyprexa and Strattera patents failed only on utility 2 in Canada? 3 PROFESSOR HOLBROOK: I know that they 4 failed on utility in Canada. I believe that's the 5 case. The only part, I know they did fail on 6 utility. I'd have to go back and re-read the cases 7 to see. I don't recall offhand was there an 8 obviousness issue as well, but I do know they failed 9 on utility. 10 MR. SMITH: And you know that those 11 were only two of multiple patents that failed for 12 lack of utility in Canada? 13 PROFESSOR HOLBROOK: That's my 14 understanding. 15 MR. SMITH: Of that group that failed 16 for lack of utility in Canada, you're not aware of a 17 single patent that failed in the United States for 18 lack of utility or enablement or written description? 19 PROFESSOR HOLBROOK: I didn't look, so 20 I'm not aware of it. But I had no reason to be aware 21 of it. I never looked. 22 MR. SMITH: You didn't look, but you 23 do not have any awareness of such a case? 24 PROFESSOR HOLBROOK: I'm not, no. Not 25 aware of the case.</p> <p>www.dianaburden.com</p>

<p>1 MR. SMITH: Professor Holbrook, would 2 it surprise you to learn that of this group of 3 patents found to lack utility in Canada, none had 4 failed the utility or the enablement or the written 5 description requirements in the United States? 6 PROFESSOR HOLBROOK: I'd need to know 7 if they've been challenged on that basis in the 8 United States. 9 MR. LUZ: I'm sorry, I'm not quite 10 sure what group counsel is referring to. 11 THE PRESIDENT: You have to be more 12 specific, Mr. Smith. 13 MR. SMITH: I think it's best to ask 14 the question as a hypothetical because Professor 15 Holbrook is unfamiliar with the larger group. But 16 I'm referring only to cases in the record and 17 summarized by Professor Levin in his testimony 18 earlier today. 19 MR. LUZ: Professor Holbrook hasn't 20 testified in either of his expert reports with 21 respect to those statistics. 22 THE PRESIDENT: Being an expert in 23 this case, the hypothetical question is allowed. 24 MR. SMITH: Professor Holbrook, would 25 it surprise you to learn that a large group of</p> <p>www.dianaburden.com</p>	<p>1 patents found to lack utility in Canada were not 2 found in the United States to fail for either lack of 3 utility, lack of enablement or lack of written 4 description? 5 PROFESSOR HOLBROOK: Were they 6 challenged in the United States on that basis? 7 MR. SMITH: Regardless of whether they 8 were challenged -- 9 PROFESSOR HOLBROOK: That's crucial to 10 my decision. To say they have not been invalidated 11 on that basis when they've never been challenged on 12 that basis is a false comparison. 13 MR. SMITH: Assume that for the subset 14 that have been challenged on that basis, would it 15 surprise you that the outcomes would diverge in the 16 two jurisdictions? 17 PROFESSOR HOLBROOK: No. 18 MR. SMITH: Mr. President, no further 19 questions. 20 THE PRESIDENT: Mr. Luz, do you have 21 redirect? 22 MR. LUZ: Canada has no redirect, 23 Mr. President. Thank you. 24 THE PRESIDENT: Mr. Born has a 25 question.</p> <p>www.dianaburden.com</p>
<p>1557</p> <p>1 QUESTIONS BY THE ARBITRAL TRIBUNAL 2 MR. BORN: I'm a little confused about 3 your emphasis several times in the last 20 minutes 4 about the absence of litigation about a patent's 5 validity in the United States. I would have thought 6 that since a litigation is party-driven and since the 7 United States is, as I've heard in other testimony, a 8 fairly large and lucrative market, if parties, based 9 on some investigation, concluded that they were 10 unlikely to win, they wouldn't be bringing litigation 11 in the first instance; and, therefore, the absence of 12 litigation is, in fact, challenging a patent's 13 validity on one of the grounds you've mentioned is, 14 in fact, if not quite as good an indicator that the 15 high jumper passed the bar, still pretty good 16 evidence that she or he would pass the bar if they 17 ever ran the race? 18 PROFESSOR HOLBROOK: So the absence of 19 litigation, to me, doesn't tell us much because it 20 becomes a business decision as to whether to sue. Is 21 this cost-effective for the business? Are we willing 22 to risk losing the patent? So, in fact, they may not 23 assert the patent if they believe they won't clear 24 the bar, and if they believe there is a greater risk 25 that it's going to be invalidated. So the failure to</p> <p>www.dianaburden.com</p>	<p>1558</p> <p>1 challenge a patent or the failure to sue on a patent, 2 it's hard to read anything about the validity of that 3 patent based off of that decision. 4 MR. BORN: Thank you. 5 SIR DANIEL BETHLEHEM: Professor 6 Holbrook, I also have one very brief question of 7 clarification. In the last few minutes of testimony, 8 you've used slightly different formulations for, I 9 think, a single thought. Let me just read to you 10 from the record of your answer when Mr. Smith was 11 asking you about the height of the utility bar in 12 both Canada and the U.S. as regards Zyprexa and 13 Strattera. And you said -- and I'm quoting here from 14 18:01:08. You said, "Moreover, there is no 15 obligation that the laws be exactly the same. They 16 just have to be similar." 17 I'd like to know what you mean by 18 obligation, where you find this obligation. 19 PROFESSOR HOLBROOK: So the obligation 20 would be in the NAFTA requirement that patents be 21 useful. There's nothing that requires that that 22 line-drawing -- we talked about the timing issue of 23 when do we allow people to file, what type of -- 24 there's no evidence that that line-drawing isn't 25 subject to some discretion within the individual</p> <p>www.dianaburden.com</p>

<p>1 countries. So that bar may actually have some 2 variability between countries, and that's acceptable. 3 SIR DANIEL BETHLEHEM: So you are 4 addressing Article 1709(1) as a high-level 5 harmonization but not requiring exact similarity or 6 not requiring equivalence? 7 PROFESSOR HOLBROOK: Correct. 8 SIR DANIEL BETHLEHEM: Thank you. 9 THE PRESIDENT: Any followup questions 10 by the Claimant? 11 MR. SMITH: No, Mr. President. 12 THE PRESIDENT: By Respondent? 13 MR. LUZ: No, Mr. President. 14 THE PRESIDENT: Thank you for 15 testimony. You are now released as a witness and 16 excused. 17 May we now be clear who is on the menu 18 tomorrow? The first I have is No. 18, Mr. Erstling. 19 MS. CHEEK: That's correct. 20 THE PRESIDENT: Then No. 20, Mr. Reed. 21 MS. CHEEK: That's correct. 22 THE PRESIDENT: And that's where my 23 list stops unless you tell me -- also 24 Ms. Gonzalez-Carmona, she will only be on Monday. 25 MS. CHEEK: Correct. So the thought</p> <p>www.dianaburden.com</p>	<p>1 was to advance Mr. Thomas and Professor Gervais. 2 THE PRESIDENT: Also tomorrow? 3 MS. CHEEK: Yes. 4 THE PRESIDENT: What is the rolling 5 order tomorrow? Because that's a full program. 6 MS. CHEEK: The parties don't 7 anticipate it being a full program, but I will also 8 defer to counsel. 9 THE PRESIDENT: I have now sufficient 10 experience with lawyer minutes. So fine, I 11 understand it. Could you help me now, who is the 12 order now? So we have first Mr. Erstling, then we 13 have Mr. Reed, then we have Mr. Thomas, right? And 14 then we have Professor Gervais? 15 MR. SPELLISCY: Yes, that's right. 16 THE PRESIDENT: Gervais is the last 17 one tomorrow? 18 SIR DANIEL BETHLEHEM: Is it Erstling 19 and then Thomas? 20 MR. SPELLISCY: I think the original 21 schedule had been Erstling and then Thomas and then 22 Reed and then Gervais because they were all grouped 23 together. From our perspective, I think Mr. Erstling 24 and Mr. Reed engage more on the issues of the 25 Patent Cooperation Treaty. It doesn't really present</p> <p>www.dianaburden.com</p>
<p>1561</p> <p>1 to us any difficulty to have them heard back-to-back 2 if the Tribunal wants that, or we can stick with the 3 original schedule. I don't think it matters 4 particularly to us. 5 THE PRESIDENT: There is one further 6 question I have then. Monday we have a light 7 schedule, because we have only two experts left -- or 8 three experts. 9 MS. CHEEK: Three experts on Monday. 10 For which we need translation. 11 THE PRESIDENT: It's simultaneous 12 translation. 13 MS. CHEEK: Yes. 14 THE PRESIDENT: Then we'll see you all 15 tomorrow at 9:00. Have a good night. 16 (Hearing adjourned at 6:23 p.m.) 17 18 19 20 21 22 23 24 25</p> <p>www.dianaburden.com</p>	

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1341/17	1491/24	1261/11
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1317/1	1371/13	1403/7
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1437/10	1329/1	1508/10
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1348/19	1423/23	1504/13
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1326/13	1306/8	1371/20
1329/21	1306/13	1371/21
1346/12	1306/16	1422/1
1363/19	1358/11	1422/10
1364/4	1379/17	1533/22
1380/19	1388/9	shown [10]
1391/4	1389/20	1272/23
1445/22	1399/16	1292/12
1455/5	1409/4	1295/19
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1355/3 1355/8	1382/25	1413/25
1356/7	1385/12	1416/16
1357/19	1386/11	1416/18
1358/10	1387/2 1387/6	1421/9
1359/1 1359/1	1387/6	1433/25
1359/3 1359/5	1387/17	1436/22

T	1475/18	1526/5
that's..... [79]	1481/3	1526/17
1437/10	1483/25	1527/8
1442/6 1446/5	1484/3 1484/9	1528/19
1446/9	1487/18	1528/20
1448/23	1487/24	1528/20
1449/19	1490/15	1529/4 1535/7
1450/7 1451/2	1490/22	1536/11
1451/15	1491/17	1536/15
1452/7 1452/8	1492/18	1537/3 1538/4
1453/17	1495/24	1542/22
1454/11	1503/24	1543/16
1455/9	1505/3	1545/25
1455/25	1505/10	1549/2
1459/15	1506/4 1506/5	1550/15
1465/9 1466/8	1508/7	1552/24
1467/1	1511/17	1554/4
1468/12	1512/18	1554/13
1468/14	1514/25	1556/9 1559/2
1469/16	1517/18	1559/19
1469/18	1518/25	1559/21
1470/2	1520/14	1559/22
1471/24	1522/18	1560/5
1475/12	1524/14	1560/15

T	1271/9 1272/2	1467/5 1502/8
their [17]	1272/15	1509/21
1244/8 1253/8	1289/12	1509/22
1287/24	1290/5	1509/24
1303/20	1290/18	1512/3
1326/1 1332/2	1296/11	1528/24
1333/16	1307/18	1536/14
1333/18	1322/11	1545/19
1372/4 1382/4	1326/4	1561/1
1395/10	1329/25	themselves
1398/16	1337/6	[2] 1354/19
1441/16	1354/12	1424/1
1528/3 1528/9	1357/17	then [122]
1536/3	1358/2	1228/10
1551/10	1372/22	1228/11
them [46]	1388/8	1228/20
1228/6 1228/7	1388/12	1229/6
1228/17	1388/12	1231/17
1230/1 1234/8	1399/11	1238/2 1240/9
1236/17	1407/5	1241/8 1246/9
1236/18	1424/14	1251/2
1239/18	1441/14	1252/23
1248/23	1441/22	1253/3
1249/11	1446/4 1454/6	1260/18

T	1336/10	1390/22
then... [109]	1337/19	1391/25
1271/20	1342/9	1395/10
1273/7 1280/6	1342/18	1396/2 1398/8
1285/7	1347/15	1400/22
1286/14	1351/8	1402/14
1288/19	1351/14	1410/13
1289/1	1352/14	1410/25
1290/14	1355/4 1355/8	1411/18
1290/15	1357/9 1364/4	1412/13
1292/11	1364/8 1365/6	1415/1 1416/8
1301/17	1365/11	1423/1
1305/8 1306/2	1375/21	1427/12
1306/3	1377/10	1429/19
1310/22	1377/24	1442/1
1311/20	1378/1	1452/11
1316/4 1320/6	1378/13	1456/2
1324/20	1378/22	1466/17
1325/7	1380/4	1467/19
1325/15	1380/14	1467/19
1328/24	1385/15	1468/11
1334/6 1334/6	1387/25	1469/6
1335/20	1388/13	1472/15
1336/5	1388/15	1473/16

T	1560/13	1234/14
then..... [30]	1560/14	1235/6
1477/20	1560/19	1236/25
1477/23	1560/21	1237/3
1478/19	1560/21	1237/21
1478/22	1560/22	1238/5
1479/24	1561/6	1239/15
1480/9	1561/14	1240/10
1480/12	theoretical [1]	1240/22
1483/11	1285/6	1241/6
1484/12	theory [2]	1242/21
1484/15	1287/24	1243/9
1485/13	1552/11	1243/11
1489/5	therapeutic [1]	1255/7
1497/15	1351/19	1257/22
1508/2	therapeutically [1]	1258/6 1259/7
1510/21	1367/12	1260/13
1514/9	therapy [1]	1261/13
1527/22	1357/14	1263/8
1548/22	therapy' [1]	1263/15
1548/25	1366/1	1263/17
1549/10	there [239]	1264/5
1559/20	1228/12	1266/17
1560/12	1234/11	1267/4 1267/9

T	1293/18	1339/1 1339/9
there... [211]	1296/10	1341/19
1267/14	1296/10	1341/20
1267/21	1298/4 1301/1	1342/12
1268/2 1268/7	1301/8	1343/2 1345/5
1270/24	1301/10	1350/7 1353/2
1271/1 1271/8	1302/13	1358/18
1271/19	1304/20	1359/20
1272/5	1306/11	1363/13
1272/14	1309/2	1363/24
1272/18	1309/17	1364/10
1273/14	1311/10	1365/2
1274/12	1312/8 1315/7	1366/13
1276/1	1316/7 1319/2	1368/4 1368/5
1277/10	1319/14	1368/10
1280/12	1319/25	1371/16
1280/19	1322/19	1372/21
1281/4 1284/9	1323/14	1375/12
1285/5	1328/14	1376/13
1285/20	1328/18	1381/2 1381/4
1286/2	1329/5	1388/4 1388/9
1286/11	1332/14	1388/11
1286/22	1336/8	1388/14
1286/22	1338/15	1390/8 1391/7

T	1418/20	1452/18
there..... [128]	1420/19	1455/4
1393/13	1421/17	1455/18
1393/14	1422/21	1456/1 1457/7
1394/6 1394/7	1423/23	1458/22
1395/20	1428/18	1465/3
1395/22	1429/14	1468/10
1395/23	1429/14	1468/13
1400/18	1429/15	1468/19
1402/4	1431/18	1475/7
1402/17	1432/5	1478/11
1404/8	1432/11	1478/22
1404/15	1433/12	1479/15
1407/6	1435/21	1481/14
1407/25	1437/15	1485/14
1408/4	1440/4	1485/23
1410/13	1440/13	1486/15
1410/17	1444/13	1486/18
1410/18	1445/4 1445/7	1486/21
1412/2	1449/16	1491/23
1412/23	1449/17	1492/4
1413/8	1450/16	1492/12
1413/22	1451/8 1451/9	1493/3 1493/7
1414/1 1416/8	1452/2	1493/14

T	1528/10	there's [96]
there.....	1529/15	1234/15
[52] 1494/11	1529/16	1234/25
1494/20	1538/16	1237/24
1498/16	1539/1 1540/2	1239/3
1502/15	1543/19	1240/24
1506/15	1544/19	1254/9 1272/8
1506/17	1544/21	1272/10
1508/17	1544/22	1272/14
1511/18	1544/23	1275/8
1512/4	1545/5 1545/8	1275/15
1512/16	1545/10	1275/22
1512/17	1545/21	1276/3
1512/18	1546/12	1280/14
1513/15	1547/16	1285/4 1285/6
1514/11	1547/20	1285/7
1516/2 1516/8	1547/24	1286/12
1518/2 1522/3	1548/18	1286/14
1523/7 1524/8	1549/23	1288/19
1525/12	1550/11	1292/6
1526/2	1553/1 1554/7	1292/20
1526/10	1557/24	1292/22
1527/22	1558/14	1297/20
1527/25	1561/5	1299/1

T	1382/18	1490/16
there's... [71]	1384/7 1384/9	1497/1
1304/24	1385/1 1388/6	1500/11
1305/25	1390/20	1504/6
1307/19	1396/10	1508/16
1312/4	1401/1 1402/2	1513/22
1317/17	1403/4 1403/9	1513/25
1319/17	1407/23	1524/2 1525/9
1320/10	1409/1	1526/7 1528/2
1322/5	1409/18	1528/18
1322/16	1410/23	1546/15
1322/17	1412/18	1547/21
1323/2	1414/7	1549/21
1323/12	1437/21	1558/21
1327/7 1327/9	1440/19	1558/24
1328/20	1440/22	thereafter [1]
1336/25	1453/23	1340/3
1341/21	1458/10	thereby [1]
1344/21	1468/1 1479/9	1351/24
1347/13	1486/12	therefor [1]
1349/14	1486/16	1503/2
1359/24	1486/20	therefore [15]
1366/5 1368/7	1487/18	1264/22
1371/11	1489/4 1489/8	1272/6

T	1256/25	1357/7
therefore...	1263/16	1357/10
[13] 1272/22	1272/21	1358/24
1275/14	1272/24	1359/18
1296/5	1273/17	1360/5
1297/15	1274/22	1360/12
1338/5	1276/5	1373/16
1343/13	1281/22	1373/25
1345/10	1287/25	1379/13
1382/4	1288/4 1290/1	1381/15
1432/25	1291/14	1383/1 1384/5
1438/4 1476/1	1296/8	1384/9 1388/7
1550/19	1296/21	1392/9 1394/3
1557/11	1298/24	1394/4
therein [1]	1302/21	1394/13
1438/20	1302/22	1396/7
thermodynami	1320/7	1396/24
cs [1] 1449/16	1320/21	1397/16
these [100]	1320/24	1399/12
1236/11	1339/13	1404/5
1245/9	1342/20	1422/23
1246/22	1343/14	1424/10
1251/19	1354/16	1429/4
1254/25	1356/24	1431/13

T	1516/22	1289/24
these... [43]	1517/10	1291/1
1436/23	1517/15	1297/10
1446/6 1446/8	1517/21	1297/15
1446/10	1517/22	1301/11
1446/16	1522/16	1303/23
1446/17	1526/23	1309/16
1446/25	1531/19	1322/22
1447/4	1535/2	1322/25
1447/11	1535/25	1328/6 1332/5
1451/5 1451/6	1543/13	1337/9
1453/21	1547/18	1337/10
1455/4 1456/9	1547/19	1337/11
1457/18	1550/18	1337/15
1457/19	1552/2 1552/7	1337/17
1461/1 1479/5	they [188]	1344/24
1490/14	1241/14	1348/15
1493/11	1242/12	1348/18
1504/4 1505/7	1251/22	1353/15
1505/14	1264/23	1354/12
1505/22	1275/2	1354/18
1506/1	1287/16	1354/19
1507/12	1287/17	1354/20
1513/19	1288/4	1356/19

T	1384/22	1440/4 1440/5
they... [155]	1386/6	1440/7
1357/6	1392/13	1441/20
1357/23	1392/25	1441/21
1357/25	1393/16	1445/6 1445/9
1358/2 1358/3	1393/17	1446/5 1446/8
1358/4 1358/8	1394/4 1394/5	1447/14
1358/9	1394/7 1394/8	1447/19
1358/12	1394/10	1447/19
1359/15	1394/11	1447/24
1360/20	1394/25	1447/24
1364/15	1395/10	1449/14
1370/18	1395/12	1453/4
1374/1 1374/7	1396/13	1453/14
1374/18	1398/1 1403/7	1463/3
1379/6	1403/18	1466/16
1380/22	1406/7	1466/17
1380/23	1406/14	1469/4
1380/24	1408/11	1476/20
1381/6 1381/7	1413/18	1479/4 1482/7
1381/7 1382/2	1413/18	1483/11
1382/3 1382/4	1415/23	1483/15
1382/19	1416/15	1489/4 1490/8
1384/17	1420/21	1491/20

T	1522/18	1551/2
they..... [71]	1529/2 1529/5	1553/17
1491/24	1531/23	1554/3 1554/5
1492/17	1531/24	1554/8 1556/5
1493/4 1494/8	1532/17	1556/7
1497/11	1533/23	1556/10
1497/13	1534/6 1536/8	1557/9
1500/23	1536/14	1557/10
1502/6 1502/7	1540/2 1540/3	1557/16
1502/9	1540/16	1557/22
1504/10	1542/5 1542/6	1557/23
1505/3	1542/6 1542/7	1557/23
1505/12	1542/9	1557/24
1505/13	1542/11	1558/15
1505/15	1542/14	1560/22
1505/18	1542/16	They'd [1]
1505/18	1542/21	1467/3
1508/3 1508/4	1544/18	they'll [1]
1509/25	1545/19	1486/11
1514/20	1546/1	they're [35]
1514/23	1546/16	1236/15
1514/24	1549/21	1288/3 1288/5
1515/9	1549/24	1290/2
1522/17	1550/22	1290/17

T	1514/18	1393/19
they're... [30]	1514/18	1394/12
1291/6	1517/19	1394/15
1300/19	1528/5 1541/4	1395/12
1300/20	1541/17	1398/2
1301/3	1541/18	1398/15
1348/20	1550/24	1399/23
1358/18	they've [3]	1413/22
1359/7	1398/17	1493/15
1360/14	1555/7	1493/16
1360/19	1556/11	things [25]
1371/13	thin [1]	1269/23
1381/14	1342/21	1275/6
1382/25	thing [20]	1287/20
1383/25	1255/13	1292/1
1388/5	1288/18	1302/15
1395/16	1288/20	1304/23
1408/14	1294/19	1309/16
1440/23	1305/20	1353/19
1446/13	1306/15	1359/5
1487/16	1325/9	1379/13
1495/20	1350/14	1383/1
1495/22	1353/14	1389/14
1500/24	1381/23	1389/16

T	1290/18	1326/22
things... [12]	1291/23	1328/8
1391/9 1393/5	1293/23	1329/10
1395/19	1294/13	1329/18
1395/22	1294/23	1330/8
1399/4 1407/7	1296/25	1332/10
1438/25	1299/1	1337/4
1441/15	1299/10	1346/19
1456/18	1299/12	1347/8
1497/23	1299/17	1347/20
1507/7	1303/9	1347/24
1532/25	1303/24	1348/1
think [161]	1304/10	1353/18
1229/6	1304/24	1354/4
1229/13	1308/23	1356/24
1232/22	1309/2	1357/2 1357/6
1246/7	1309/11	1358/6 1360/2
1251/13	1309/13	1364/10
1268/20	1309/16	1365/15
1270/21	1312/18	1371/8
1281/23	1316/21	1372/21
1284/16	1320/15	1375/17
1287/9 1288/1	1323/24	1383/25
1288/1 1290/8	1326/19	1385/9 1386/3

T	1401/15	1425/23
think... [97]	1402/17	1426/9
1386/17	1402/20	1428/21
1386/19	1403/1 1403/4	1430/4 1431/2
1387/4 1388/7	1403/10	1433/17
1390/20	1403/21	1434/9
1391/20	1404/25	1435/25
1391/21	1405/7	1436/21
1392/14	1405/10	1437/19
1394/3 1394/4	1405/10	1437/24
1394/6 1394/8	1405/13	1438/1
1394/19	1405/22	1439/20
1394/22	1405/25	1441/18
1396/19	1407/11	1445/2
1397/7 1397/8	1408/5 1410/5	1448/17
1397/10	1410/13	1466/10
1397/11	1410/17	1471/19
1397/13	1411/10	1471/22
1398/10	1411/12	1471/22
1398/11	1411/21	1473/11
1398/12	1413/20	1475/16
1399/4	1414/7 1415/5	1482/4
1400/13	1416/12	1482/24
1401/1 1401/2	1416/15	1484/8 1490/1

T	thinks [1]	those [97]
think..... [17]	1541/25	1230/6 1231/1
1496/2 1502/7	third [8]	1236/21
1524/16	1256/2	1236/24
1524/19	1256/10	1237/15
1526/15	1273/12	1247/2 1247/9
1530/18	1282/22	1247/21
1535/21	1299/10	1260/13
1536/15	1318/22	1260/17
1539/19	1326/11	1264/21
1542/3	1505/3	1273/18
1546/21	this [420]	1276/5
1548/3	THOMAS [10]	1282/11
1555/13	1225/10	1283/9
1558/9	1225/22	1284/10
1560/20	1228/23	1285/23
1560/23	1289/17	1287/7
1561/3	1330/12	1287/14
thinkers [1]	1364/6 1560/1	1291/8
1288/3	1560/13	1293/16
thinking [3]	1560/19	1302/7
1229/21	1560/21	1302/14
1267/13	thoroughly [1]	1302/25
1341/11	1343/14	1303/15

T	1441/24	1516/12
those... [72]	1445/13	1517/2
1306/5 1310/1	1446/22	1517/22
1311/3 1313/6	1448/1 1448/3	1529/1 1529/2
1316/16	1449/1 1450/9	1529/9
1317/13	1450/10	1529/13
1318/19	1450/23	1530/14
1348/12	1454/19	1532/1 1532/4
1354/24	1455/13	1535/7 1536/2
1358/4	1457/18	1539/4 1540/9
1362/14	1463/13	1546/1 1548/3
1363/23	1477/6 1477/9	1552/5
1364/7	1477/18	1552/14
1370/17	1477/21	1553/10
1372/20	1477/22	1554/10
1380/10	1477/25	1555/21
1385/8	1478/14	though [11]
1400/19	1484/13	1302/3 1318/2
1405/19	1484/24	1361/19
1413/11	1487/14	1368/6 1401/6
1416/15	1488/25	1402/15
1423/2	1498/18	1478/13
1424/25	1508/10	1491/21
1433/24	1510/7	1520/13

T	three [38]	1457/20
though... [2]	1231/11	1475/5
1522/17	1234/15	1505/22
1546/2	1234/18	1506/10
thought [9]	1244/22	1514/22
1246/1	1245/5 1245/9	1526/23
1336/23	1247/17	1551/22
1353/15	1247/21	1553/15
1373/19	1253/24	1553/21
1406/3 1542/6	1254/19	1561/8 1561/9
1557/5 1558/9	1266/23	threshold [7]
1559/25	1270/15	1291/15
thousands [5]	1288/6 1311/3	1386/4
1317/8	1311/9 1312/6	1386/18
1317/11	1312/25	1389/12
1322/10	1395/1 1410/1	1412/18
1322/10	1422/19	1455/25
1326/10	1436/23	1457/7
threat [3]	1440/14	threw [1]
1268/15	1440/15	1343/21
1268/16	1440/24	through [27]
1320/2	1447/3	1231/1 1269/6
threatened [1]	1447/11	1292/16
1321/15	1449/4	1293/16

T	thumb [1]	1272/16
through... [23]	1366/22	1282/21
1294/20	Thursday [2]	1284/19
1295/7	1365/5 1365/7	1296/9
1311/14	thus [5]	1296/25
1311/16	1330/18	1297/5 1297/7
1312/7 1325/7	1380/5 1380/8	1297/18
1333/15	1455/23	1304/7
1350/14	1455/24	1305/21
1365/5 1422/1	tidal [2]	1313/5
1422/3	1349/11	1317/13
1423/21	1349/18	1318/15
1436/18	tide [2]	1335/10
1437/3	1349/12	1335/12
1440/19	1349/15	1335/23
1440/21	tied [2]	1336/1
1446/18	1447/20	1339/11
1446/22	1448/2	1353/9
1451/17	time [68]	1360/25
1457/19	1229/17	1367/9
1485/25	1253/17	1367/20
1521/14	1264/12	1369/7 1374/3
1534/10	1265/8 1268/5	1374/8
throughout [1]	1269/8	1374/10
1232/20		

T	1493/17	1410/23
time... [36]	1496/4 1500/6	1479/15
1374/12	1520/11	1496/24
1374/20	1520/13	1557/3
1375/2 1379/4	1528/8 1540/2	timing [9]
1379/9 1382/3	1541/8	1313/14
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1380/21	1411/19	1444/13
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1460/20	1513/13	1541/13
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1465/3 1470/8	1518/2 1518/3	1542/1 1542/3
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1479/2	1525/17	1543/9 1544/4
1482/13	1525/20	1544/7
1482/14	1525/22	1544/19
1482/17	1525/24	1544/22
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1334/10	1240/20	1277/11
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1366/19	1401/5	1429/14
1366/25	1402/18	1432/14
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1522/12	1237/15	1281/2 1286/4
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1551/14	1241/4	1296/9
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1357/25	1416/6 1427/7	1482/15
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1363/18	1428/24	1490/7
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1369/3	1433/14	1516/7
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1375/17	1437/14	1532/16
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1380/22	1440/4 1440/5	1533/16
1384/24	1441/20	1533/22
1387/14	1450/6 1450/6	1536/8
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1391/25	1451/1	1539/4 1540/2
1395/14	1458/18	1540/3
1398/15	1458/22	1540/13
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1550/19	1247/5	1291/13
1553/1	1249/18	1293/20
1553/20	1251/14	1294/5 1294/6
1554/11	1252/25	1294/7
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1556/8 1557/9	1255/7	1296/20
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1382/19	1264/3 1264/5	1312/6
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1228/3 1231/2	1275/2	1321/9
1233/5 1233/8	1276/19	1323/17
1233/14	1283/20	1326/20
1233/20	1284/17	1328/11
1235/2	1285/3	1331/8 1334/7
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1347/7	1382/25	1415/8 1415/8
1348/22	1384/10	1415/16
1349/12	1385/7	1423/10
1351/1 1353/9	1386/22	1426/23
1353/15	1387/21	1427/7
1354/2 1354/9	1393/3	1427/19
1354/15	1394/25	1427/19
1357/10	1396/15	1428/21
1358/4 1358/4	1397/5 1398/4	1429/6
1359/7	1398/19	1430/16
1359/11	1399/7	1431/3
1359/12	1399/22	1431/12
1359/21	1400/12	1432/1 1433/8
1360/17	1401/5	1433/22
1365/10	1403/19	1433/25
1369/6	1405/17	1434/9 1435/3
1369/10	1406/17	1435/25
1370/16	1406/20	1437/14
1371/12	1406/21	1438/1 1438/6

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1438/8	1469/5	1524/3
1439/25	1469/16	1524/12
1445/11	1471/21	1525/11
1446/5	1473/8	1525/21
1449/20	1476/21	1528/7
1451/1 1451/6	1477/14	1534/24
1454/1 1454/4	1482/21	1536/15
1454/17	1483/1	1539/7
1454/17	1484/11	1539/18
1456/21	1486/24	1540/17
1459/15	1489/21	1540/21
1459/17	1490/2	1543/9 1544/6
1459/20	1490/12	1547/9
1464/23	1490/16	1548/14
1465/19	1495/19	1548/22
1466/8 1466/9	1497/2	1550/1
1466/17	1497/21	1550/22
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1560/4	1298/12	1321/19
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1271/20	1402/8	1323/17
1274/4	1402/10	1324/18
1287/10	1402/19	1325/17
1303/21	1407/16	1326/17
1304/21	1409/7	1326/21
1324/9	when [91]	1327/2
1327/23	1240/24	1333/16
1347/15	1253/12	1333/20
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1407/10	1285/14	1334/20
1408/16	1285/16	1336/6
1409/4	1286/23	1338/19
1413/10	1288/14	1340/2
1528/22	1288/15	1343/21
1528/22	1289/23	1352/16
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what's the [1]	1295/16	1357/24
1540/9	1306/5	1360/13
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1374/13	1500/23	1252/18
1382/7	1501/9 1505/8	1254/2
1383/25	1505/12	1254/16
1384/6	1512/17	1275/17
1384/11	1513/15	1281/18
1386/10	1513/15	1284/10
1393/18	1517/19	1285/15
1394/7	1520/3	1287/7
1394/14	1525/11	1288/15
1395/8 1398/2	1526/16	1292/23
1399/21	1527/2 1535/1	1292/25
1400/6 1405/9	1540/1 1541/6	1293/8 1295/4
1405/15	1541/16	1295/18
1406/23	1541/19	1299/13
1407/22	1544/6	1300/6 1301/9
1409/24	1556/11	1302/5
1420/19	1558/10	1305/19
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1422/24	where [107]	1312/4
1425/2 1438/9	1237/21	1319/25
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1323/10	1380/6	1445/16
1324/1 1328/6	1381/17	1447/13
1328/15	1386/12	1449/18
1337/1	1386/20	1449/19
1343/21	1386/23	1451/9
1347/12	1387/10	1453/23
1347/14	1387/19	1454/1
1351/15	1387/22	1465/21
1355/8	1388/11	1473/1 1481/8
1355/22	1389/6 1390/6	1481/19
1356/7	1393/14	1485/12
1356/10	1396/3 1396/6	1492/13
1356/12	1400/16	1492/24
1356/16	1401/23	1494/20
1357/9	1403/18	1498/13
1357/20	1403/22	1499/16
1360/8	1407/1	1502/23
1368/10	1409/15	1506/7
1368/16	1411/17	1508/21
1376/19	1421/22	1512/8
1377/4	1424/6	1521/19
1377/15	1424/15	1529/17

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where..... [4]	1313/21	1436/7
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1545/13	1326/6	1438/19
1558/18	1326/13	1440/19
1559/22	1335/12	1443/24
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1293/17	1355/5 1359/9	1447/13
1439/3	1360/11	1449/20
1439/23	1362/12	1452/5 1452/5
1499/23	1364/13	1458/23
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1403/17	1365/25	1461/16
whether [69]	1368/5	1468/19
1229/15	1369/15	1472/5
1255/17	1371/16	1473/13
1265/6	1373/21	1479/1 1504/7
1266/13	1383/13	1526/13
1267/14	1393/18	1526/18
1274/3	1400/15	1532/12
1274/18	1400/18	1535/16
1298/11	1405/8	1541/5 1542/6
1300/23	1405/10	1544/23
1300/25	1406/3	1548/4

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1549/16	1273/22	1302/20
1551/20	1275/6 1275/8	1303/2
1553/5	1278/14	1304/25
1553/10	1278/14	1305/25
1556/7	1279/17	1314/8
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1231/4 1231/8	1281/23	1324/15
1234/10	1281/25	1325/20
1241/9	1282/13	1327/25
1242/21	1283/11	1328/21
1243/14	1284/8	1328/25
1243/20	1284/25	1329/19
1244/21	1286/6	1330/11
1245/7 1246/5	1290/22	1330/16
1251/10	1292/1	1340/24
1254/13	1292/19	1341/14
1255/8	1293/13	1342/6
1255/22	1295/21	1342/10
1262/10	1295/23	1342/17
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which... [104]	1390/12	1447/4 1449/5
1346/24	1391/13	1450/6
1347/9	1391/17	1451/12
1348/24	1391/23	1452/23
1349/7	1394/19	1452/24
1349/11	1395/24	1453/17
1349/17	1396/13	1463/1
1349/25	1397/19	1464/14
1350/7 1350/9	1402/4 1407/7	1465/6
1351/10	1409/5	1467/13
1351/17	1413/10	1469/20
1352/23	1413/14	1469/22
1354/20	1415/2 1418/2	1472/24
1355/24	1418/8	1474/4
1356/25	1419/21	1477/13
1357/13	1420/1 1423/4	1478/8
1359/2 1359/2	1423/24	1479/19
1360/5	1423/25	1486/3 1488/2
1366/23	1426/13	1489/9 1491/2
1368/20	1427/2	1491/3
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1381/12	1433/8 1434/4	1496/14
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1502/14	1366/13	1408/1
1508/20	1520/11	1408/13
1510/7	whimsy [1]	1408/14
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1511/12	white [2]	1434/19
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1514/4 1516/2	whittle [1]	1448/20
1523/12	1398/9	1527/1
1524/7	who [27]	1541/25
1525/10	1228/11	1559/17
1525/23	1241/13	1560/11
1526/3 1526/7	1241/15	who's [1]
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1530/14	1281/17	Whoever [1]
1545/13	1287/18	1502/24
1551/24	1287/21	whole [12]
1552/20	1288/8	1325/8
1553/5	1303/19	1341/14
1561/10	1358/11	1350/14
while [6]	1368/11	1354/19
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1394/14	1360/24	will [89]
1395/2	1378/3	1228/9
1395/19	1380/24	1228/13
1395/23	1380/24	1228/18
1398/2	1392/10	1228/18
1440/11	1399/22	1229/14
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1305/20	1404/17	1230/15
whose [1]	1406/14	1230/19
1550/5	1407/2	1270/5
why [31]	1409/14	1270/10
1245/17	1430/10	1278/15
1246/11	1454/24	1279/9
1256/24	1522/18	1279/14
1262/13	1526/5 1549/2	1279/21
1284/4	wide [1]	1281/11
1291/10	1232/24	1281/16
1292/19	widely [2]	1283/10
1293/10	1281/23	1287/20
1298/4	1453/12	1288/8
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1290/19	1427/23	1480/22
1294/25	1431/8	1484/13
1295/2 1297/5	1432/10	1489/10
1297/19	1437/20	1491/24
1319/3	1441/24	1497/13
1321/25	1442/23	1497/15
1323/7	1443/5	1497/24
1324/23	1448/16	1508/22
1326/6 1351/3	1449/12	1520/8
1351/22	1449/13	1521/10
1359/8	1449/14	1521/10
1362/14	1449/16	1521/12
1363/5	1451/14	1548/17
1363/12	1454/1 1458/1	1559/24
1364/16	1458/2	1560/7
1371/22	1465/23	WILLARD [1]
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1408/8	1471/11	1552/14
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1557/21	1237/15	1279/4 1417/1
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1224/12	1347/19	1431/1
wilmerhale.co	1412/6	1431/23
m [1] 1224/13	1484/24	1433/6 1441/8
Wilson [2]	1528/12	1442/16
1464/4 1464/6	1532/8	1458/18
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1557/10	1558/25	witnesses [10]
windfall [1]	without [11]	1228/16
1446/1	1293/7	1286/5
wish [3]	1297/20	1300/14
1229/12	1330/23	1306/14
1280/13	1367/16	1363/20
1418/21	1387/5 1450/2	1363/23
withdraw [1]	1452/6 1473/8	1364/5 1364/8
1272/1	1486/24	1364/9 1365/6
withdrawing	1511/18	woman [1]
[1] 1271/14	1519/25	1344/15
withdrawn [1]	withstand [1]	won [1]
1271/11	1326/6	1243/20
within [12]	witness [12]	won't [4]

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1350/25	1500/15	work [46]
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1473/18	1501/10	1285/18
1557/23	1501/10	1285/25
wonder [2]	1501/19	1287/25
1288/10	1501/22	1288/19
1288/11	1501/24	1291/12
wondering [1]	1502/23	1291/17
1385/6	1503/4	1292/10
word [28]	1533/20	1293/20
1256/17	words [14]	1294/25
1275/1 1286/7	1267/12	1295/2 1298/7
1286/9	1291/24	1301/1
1286/15	1301/19	1302/12
1294/23	1330/19	1335/10
1309/5	1346/21	1339/4
1320/16	1348/12	1357/18
1347/14	1370/18	1357/21
1348/5 1348/7	1372/21	1358/11
1398/10	1391/12	1361/3
1398/14	1405/7 1405/9	1367/13
1434/1 1440/5	1422/25	1371/23

W	1297/24	1391/4 1391/6
work... [24]	1360/21	1453/21
1379/17	1377/18	1454/11
1384/2	1379/22	1454/12
1384/18	1382/20	1469/21
1387/6 1398/5	1388/25	1494/24
1446/1 1449/9	1389/19	works [12]
1449/12	workable [6]	1255/17
1450/18	1292/9	1292/12
1453/16	1298/12	1300/25
1456/12	1360/20	1305/8
1463/11	1385/17	1314/23
1482/14	1387/17	1389/21
1482/15	1388/10	1394/9 1397/1
1522/17	worked [8]	1449/21
1531/18	1305/11	1454/25
1539/25	1358/8	1480/5
1540/4 1540/5	1369/21	1513/20
1541/10	1372/7 1373/7	world [10]
1541/14	1374/11	1285/7 1288/2
1541/15	1374/17	1293/16
1541/17	1456/13	1356/20
1545/13	working [8]	1364/14
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1445/3 1451/8	1249/21	1272/2
worldwide [1]	1249/24	1272/18
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worms [1]	1250/9 1253/7	1273/23
1341/14	1253/10	1273/24
worried [1]	1253/17	1274/11
1457/11	1253/19	1274/12
worse [2]	1253/20	1274/16
1397/14	1258/11	1282/6 1283/7
1485/18	1260/5	1283/23
would [243]	1260/11	1288/11
1229/1	1260/18	1292/23
1232/21	1260/20	1296/18
1233/10	1263/8 1263/9	1302/5 1302/6
1233/12	1263/18	1303/12
1233/16	1264/6	1303/16
1233/23	1264/14	1305/11
1238/14	1267/8	1309/19
1239/4 1239/6	1267/17	1327/23
1240/14	1267/25	1327/24
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would... [178]	1364/7	1399/22
1328/7 1329/2	1364/20	1400/1 1401/8
1329/10	1364/22	1401/16
1331/22	1364/25	1401/16
1332/7 1339/6	1366/4	1402/8
1339/12	1367/21	1402/15
1347/17	1369/20	1403/5
1348/3 1348/4	1372/5 1373/5	1403/11
1348/22	1373/22	1404/2
1349/1 1349/6	1374/1	1405/13
1349/12	1374/21	1405/17
1349/17	1375/3	1405/17
1352/7	1379/17	1406/13
1353/10	1380/24	1406/14
1355/3 1357/7	1383/16	1407/3 1407/4
1357/11	1385/23	1440/22
1358/22	1391/24	1441/18
1359/16	1392/6	1443/24
1361/5	1393/19	1445/12
1361/11	1395/3 1397/5	1446/3
1361/15	1397/13	1449/10
1362/20	1397/20	1450/11
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1453/21	1477/24	1517/15
1457/4	1478/6	1517/21
1458/20	1478/10	1517/22
1461/13	1478/12	1521/1
1466/12	1478/14	1525/13
1466/16	1478/23	1527/24
1466/17	1482/18	1528/10
1468/11	1483/5	1530/16
1471/18	1483/11	1530/18
1471/19	1483/14	1532/17
1471/20	1484/25	1533/25
1471/22	1485/14	1534/11
1471/22	1485/15	1534/20
1471/22	1486/23	1534/20
1472/25	1488/2 1490/1	1535/1 1535/2
1473/16	1492/9	1535/17
1474/12	1492/10	1535/22
1474/13	1494/8	1535/24
1474/14	1496/18	1535/25
1476/15	1496/21	1536/13
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1541/10	1328/12	1272/8
1541/15	1335/6	1309/12
1543/17	1338/25	1310/19
1545/18	1387/12	1320/11
1549/4	1401/19	1321/19
1549/20	1401/24	1337/22
1550/23	1515/18	1345/4
1552/2 1552/5	1534/23	1349/23
1552/14	1539/16	1375/22
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1555/1	Wow [1]	1399/22
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1556/14	wrangling [1]	1465/21
1556/15	1346/7	1468/17
1557/5	wrap [4]	1469/9
1557/16	1297/2 1297/8	1470/11
1558/20	1297/10	1507/23
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1343/6	1295/16	1344/13
1359/13	1298/20	1345/5
1526/25	1299/7	1345/22
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1319/9	1299/21	1380/20
1339/12	1301/22	1382/13
1350/17	1302/11	1390/16
1353/1 1407/4	1303/6	1390/25
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1407/13	1316/22	1412/14
1439/11	1318/5 1332/8	1412/20
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1251/13	1334/2 1334/7	1432/3
1251/15	1334/8	1446/23
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1451/22	1514/14	1283/1
1455/5 1455/8	1516/9	1284/13
1455/20	1516/16	1305/12
1456/3 1456/3	1516/23	1382/18
1456/8	1517/11	1407/3
1457/15	1517/17	1411/19
1479/14	1526/23	1412/16
1479/15	1543/22	1490/17
1493/12	1544/11	1498/5 1507/3
1502/2 1502/4	1544/13	1507/9
1503/23	1544/21	1507/20
1504/1 1504/7	1544/24	wrote [18]
1505/8 1506/2	1545/16	1306/17
1506/11	1545/19	1319/5 1322/2
1507/6	1545/23	1324/18
1507/13	1546/10	1326/17
1507/23	1549/17	1334/24
1508/5	1551/3	1335/24
1508/22	1551/24	1350/10
1509/3 1509/7	1552/23	1352/16
1509/8	1554/18	1374/14

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1452/20	1317/9	1378/2 1398/3
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1515/20	1326/11	1419/6
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1519/8	1427/13	1456/13
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Yale [1]	1282/19	1231/15
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yeah [4]	1284/10	1231/24
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1348/9	1289/14	1232/11
1390/11	1289/15	1232/25
1406/13	1293/6 1303/8	1233/17
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1235/12	1243/22	1252/16
1235/15	1244/11	1253/2 1253/5
1235/18	1244/19	1253/21
1235/22	1245/1	1255/10
1236/1 1236/5	1245/12	1255/19
1236/10	1245/19	1256/3
1236/20	1245/23	1256/15
1236/24	1246/7 1246/8	1257/4
1237/9	1246/14	1257/18
1237/19	1246/18	1257/24
1238/16	1246/21	1258/2 1258/5
1238/20	1247/23	1259/3
1238/23	1247/25	1259/10
1239/13	1248/9	1259/13
1240/5 1240/8	1248/13	1259/16
1240/13	1249/10	1259/21
1240/16	1250/4 1250/8	1260/1
1241/24	1250/17	1260/16
1242/2 1242/8	1250/21	1260/23

Y	1280/11	1319/15
yes..... [218]	1280/22	1319/22
1261/1 1261/4	1281/16	1320/5
1262/14	1303/9	1320/14
1263/13	1303/25	1320/18
1264/10	1306/14	1325/13
1264/14	1307/22	1325/22
1265/19	1308/2 1308/7	1326/23
1266/1	1308/10	1331/23
1268/21	1309/25	1332/15
1269/2	1310/5	1332/20
1269/22	1310/12	1333/12
1270/22	1310/21	1335/13
1273/25	1311/2	1337/16
1274/10	1314/22	1340/12
1274/20	1315/11	1340/21
1274/25	1316/1 1316/8	1340/22
1276/9	1316/13	1342/11
1276/16	1316/18	1343/1
1276/22	1317/10	1343/25
1279/5	1317/15	1344/5
1279/19	1317/19	1347/11
1279/25	1317/24	1349/22
1280/5	1318/7	1350/12

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yes..... [145]	1399/3	1459/16
1351/13	1403/21	1460/3 1460/6
1352/12	1403/24	1460/10
1355/7	1412/3	1460/13
1361/23	1412/10	1460/17
1365/15	1414/15	1460/21
1366/12	1414/21	1461/24
1367/3	1415/14	1462/20
1367/25	1415/18	1463/12
1372/15	1416/11	1465/25
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1375/9	1426/16	1467/2 1468/8
1375/20	1426/20	1469/17
1376/12	1427/20	1469/20
1376/16	1429/23	1474/10
1378/4	1430/7	1474/16
1378/11	1431/11	1475/2
1378/21	1431/15	1475/16
1379/7 1380/7	1432/9	1476/3
1383/16	1434/17	1476/14
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1393/23	1437/12	1480/12
1393/24	1439/7	1480/20

Y	1513/12	1536/23
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1485/22	1516/14	1538/1 1538/8
1486/11	1516/20	1538/12
1487/13	1517/1	1542/23
1488/7	1518/21	1543/7
1488/11	1520/15	1543/12
1488/18	1520/20	1544/14
1488/22	1520/24	1546/6
1491/7	1521/18	1550/14
1491/11	1522/5 1523/2	1550/17
1493/14	1523/5 1527/7	1550/23
1494/18	1527/12	1551/19
1496/4	1530/7	1552/18
1498/18	1530/21	1560/3
1502/11	1532/20	1560/15
1502/18	1532/21	1561/13
1504/10	1532/22	yesterday [13]
1504/25	1534/15	1228/12
1505/5	1534/18	1229/11
1505/24	1534/25	1231/4
1510/25	1535/11	1244/18
1512/7 1513/1	1535/14	1244/21

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[8] 1251/25	1274/14	1424/6
1255/6 1255/6	1356/17	1426/10
1265/11	1385/6 1403/2	1426/20
1268/19	1403/22	1433/23
1268/23	1428/20	1435/25
1277/19	1429/19	1451/19
1363/18	1432/17	1474/18
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1318/22	1476/11	you're [100]
1387/6	1488/4 1536/8	1233/22
1387/18	1539/18	1247/5 1249/8
1416/8 1445/5	you'll [21]	1249/23
1445/6	1230/22	1256/21
1457/14	1270/24	1259/1 1260/9
1503/17	1319/10	1260/10
1532/3	1368/14	1268/13
you [1150]	1386/22	1275/11
you'd [20]	1392/25	1276/1 1276/2
1233/1 1233/6	1407/19	1276/3 1277/2
1236/21	1409/9 1420/6	1283/23
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you're... [82]	1389/16	1480/7
1306/6	1396/16	1480/10
1308/20	1396/20	1481/8
1308/23	1396/21	1485/13
1314/9 1315/9	1399/19	1488/3
1315/17	1401/12	1490/15
1315/21	1401/24	1491/8
1323/17	1402/17	1493/13
1328/11	1405/22	1494/23
1337/2 1347/7	1408/15	1495/16
1349/12	1409/13	1498/13
1350/17	1412/5 1426/4	1507/22
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1357/20	1437/15	1509/13
1357/21	1438/24	1515/16
1360/11	1445/13	1518/5 1522/3
1360/16	1454/16	1522/20
1363/7	1454/23	1523/9 1524/3
1376/14	1457/11	1524/4 1524/4
1386/15	1462/18	1525/2
1386/23	1473/1	1527/21
1387/21	1477/12	1536/3
1389/8	1478/19	1541/22

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1547/10	1389/23	1533/7 1551/8
1547/16	1393/5	1552/16
1551/13	1396/17	1557/13
1554/16	1398/8	1558/8
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1232/19	1404/22	1230/23
1232/23	1410/22	1230/24
1255/18	1417/20	1231/4 1231/5
1264/5	1422/16	1231/17
1279/10	1425/24	1232/20
1283/12	1429/10	1232/20
1287/9 1288/3	1429/11	1234/5
1291/20	1442/20	1235/21
1308/24	1466/7	1235/24
1309/7 1334/7	1475/20	1237/7 1237/7
1361/1 1368/4	1480/9 1481/1	1239/22
1376/10	1490/23	1241/20
1377/17	1500/16	1242/3 1242/7
1385/15	1505/22	1243/14
1386/25	1505/25	1244/13
1388/23	1519/4	1244/14

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your... [276]	1258/23	1281/13
1244/20	1259/6	1284/12
1244/22	1259/18	1286/21
1245/2	1260/3 1260/9	1291/17
1245/13	1262/12	1291/20
1247/12	1263/6	1292/4
1248/20	1263/10	1293/24
1249/15	1264/7	1298/2
1250/5	1265/10	1298/23
1250/15	1265/14	1300/9
1250/16	1265/18	1300/22
1250/22	1266/2	1300/25
1251/3	1266/23	1301/18
1251/12	1268/19	1301/21
1251/16	1268/25	1301/22
1251/25	1269/18	1302/21
1252/5	1276/10	1302/24
1252/14	1278/25	1305/13
1252/17	1279/10	1307/17
1253/7	1279/24	1307/23
1253/18	1280/4 1280/4	1308/4 1309/5
1253/25	1280/7	1309/22
1255/1 1256/5	1280/10	1309/24

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1311/5	1329/22	1366/23
1311/12	1332/9	1369/7 1371/9
1311/23	1332/12	1374/14
1312/2	1333/10	1375/7 1376/6
1312/16	1333/24	1376/8
1312/20	1335/10	1376/14
1313/6	1336/1 1336/6	1376/17
1313/13	1340/11	1381/3
1313/13	1340/25	1385/16
1314/13	1346/19	1386/13
1316/6	1347/20	1386/15
1319/13	1349/5	1387/24
1319/18	1349/21	1388/19
1319/20	1350/9	1391/11
1320/23	1353/16	1391/16
1320/25	1353/22	1392/1 1392/2
1322/1	1357/12	1392/3
1324/14	1357/15	1392/15
1326/21	1364/25	1398/10
1328/6	1365/6	1398/13
1329/16	1365/14	1398/20

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1402/5 1404/7	1427/1	1460/23
1405/4 1405/5	1428/17	1461/19
1405/6	1429/18	1461/20
1407/20	1429/19	1462/3 1462/4
1407/22	1429/21	1462/17
1408/15	1430/11	1465/15
1409/15	1432/16	1465/16
1411/25	1433/6 1434/2	1465/20
1412/16	1434/3	1466/1
1412/17	1435/19	1466/11
1414/12	1436/1	1467/10
1414/13	1442/12	1467/21
1416/9	1442/21	1468/22
1417/11	1443/8	1469/18
1417/21	1443/13	1469/24
1418/7	1443/13	1470/4
1418/12	1443/20	1470/19
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1418/17	1444/6	1471/12
1418/17	1458/17	1472/1 1472/9
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