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

Tuesday, 31 May 2016 Washington DC, USA

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	334 1 APPEARANCES
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IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN	3 THE ARBITRAL TRIBUNAL:
OF THE NORTH AMERICAN FREE TRADE AGREEMENT AND THE UNCITRAL ARBITRATION RULES (1976)	4 PRESIDENT:
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Case No. UNCT/14/2	6 PROF. ALBERT JAN VAN DEN BERG HANOTIAU & VAN DEN BERG
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Tuesday, 31 May 2016	21 THE COURT REPORTERS:
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(1 uges 555 052)	25
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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	31 May 2016 INDEX ROBERT ALLEN ARMITAGE Direct Examination by Ms. Cheek	337	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	THE PRESIDENT: Good morning, ladies and gentlemen. I re-open the hearing for Day 2. As usual, a question to both sides. Are there any matters of an organizational or administrative nature you would like to raise? MS. CHEEK: Claimant does not have anything to raise at this point. MR. SPELLICSY: Respondent has nothing. THE PRESIDENT: Then we may proceed with the witness examination. ROBERT ALLEN ARMITAGE THE WITNESS: First we have Mr. Armitage. Could you please state your full name for the record? MR. ARMITAGE: Robert Allen Armitage. THE PRESIDENT: You are a fact witness appearing for the Claimant. If any question is unclear to you, either because of language or for any other reason, please do seek a clarification because, if you don't do so, the Tribunal will assume that you've understood the question and that your answer corresponds to the question. MR. ARMITAGE: Thank you. THE PRESIDENT: You will appreciate that testifying, be it before a court or an arbitral www.dianaburden.com	338 09:00
1 2 3 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	tribunal, is a very serious matter. In that respect, the Tribunal expects you to give the declaration, the text of which is in front of you. MR. ARMITAGE: Yes. I solemnly declare upon my honor and conscience that I shall speak the truth, the whole truth and nothing but the truth. THE PRESIDENT: Thank you. Mr. Armitage, I understand you have in front of you your witness statements? MR. ARMITAGE: I think I will shortly. THE PRESIDENT: Thank you. Could you go, please, to your first witness statement, which is dated September 27, 2014, to page 8? MR. ARMITAGE: Yes. THE PRESIDENT: And confirm for the record that the signature appearing above your name is your signature? MR. ARMITAGE: Yes, it is. THE PRESIDENT: Could you please go to your second witness statement, to page 17 that is dated September 11, 2015, and again confirm for the record that the signature appearing above your name is your signature? MR. ARMITAGE: Yes, it is. THE PRESIDENT: Is there any correction www.dianaburden.com	<b>339</b> 09:01	1 2 3 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	you would like to make to any of the statements? MR. ARMITAGE: In reviewing this statement, I discovered what I believe to be a typographical error in my first witness statement on page 6, Paragraph 21. It should refer to of the 36 jurisdictions rather than 35 jurisdictions, and I think that correct number, 36, appears in Paragraph 19 but unfortunately not in Paragraph 21. THE PRESIDENT: So noted. Is there any other correction you wish to make? MR. ARMITAGE: No. THE PRESIDENT: Thank you. Ms. Cheek, please proceed with the direct examination. MS. CHEEK: Thank you, Mr. President. DIRECT EXAMINATION ON BEHALF OF THE CLAIMANT MS. CHEEK: Mr. Armitage, behind tab 3 of your direct examination binder there are a few excerpts from Canada's Rejoinder, and at paragraphs 51 to 53 of Canada's Rejoinder, page 26 and 27, Canada argues and this is at the bottom of Paragraph 51 "The fact is that Claimant has enjoyed monopolies relating to these compounds for years before it filed applications for the patents at issue in these proceedings," and also at the end of Paragraph 53, Canada asserts "Claimant was www.dianaburden.com	<b>340</b> 09:02

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1	searching for another way to extend their monopoly	09:04	1	drafting practices were inconsistent in regard with	09:06
2	over different aspects of these compounds."		2	its earlier practices." And Canada cites to	
3	Mr. Armitage, did the Zyprexa and Strattera patents		3	Paragraph 11 of your first statement for this	
4	at issue in this case simply extend a pre-existing		4	proposition that your drafting practices for the	
5	patent monopoly, in your view?		5	'113 and '735 patents were inconsistent with earlier	
6	<b>MR. ARMITAGE:</b> In my view, they did not.		6	practices.	
7	For olanzapine, I think Canada is referring to an		7	Could you please turn to Paragraph 11 of	
8	earlier Canadian patent that actually issued before		8	your first statement?	
9	olanzapine itself had ever been synthesized. And		9	MR. ARMITAGE: I'm there.	
10	for atomoxetine, I believe Canada is referring to a		10	MS. CHEEK: And you've had a chance to	
11	Canadian patent that issued before Strattera's ADHD		11 12	review it?	
12	use had even been discovered. So at least in any			MR. ARMITAGE: Yes.	
13	practical sense, my view is that the Canadian		13	MS. CHEEK: Does Paragraph 11 of your	
14	monopolies for Zyprexa and Strattera can be traced		14 15	first statement "acknowledge that less data was	
15	back only to the filing of the patents actually at			included in the Strattera and Zyprexa patents than in other Lilly patents."	
16 17	issue in this Tribunal. I say that because it was the issuance of these patents that provided the		16 17	MR. ARMITAGE: No, it does not.	
18	economic justification for Lilly to proceed with the		18	MS. CHEEK: And does anything else in	
19	investment to develop Zyprexa for schizophrenia and		19	either of your statements support Canada's	
20	Strattera for ADHD.		20	assertion?	
20	MS. CHEEK: Thank you, Mr. Armitage. If		20	MR. ARMITAGE: Nothing that I'm aware of.	
22	you'd now turn to Canada's Rejoinder, paragraphs 57		22	MS. CHEEK: Mr. Armitage, if you can turn	
23	to 60 but in particular Paragraph 60 on page 29,		23	to paragraphs 154 and 155, which are actually at	
23	here Canada asserts the first sentence of		24	page 69 of Canada's Rejoinder, Canada here asserts	
24	Paragraph 60, "Claimant itself acknowledges that its		24	that if Canada had, in fact, dramatically changed	
25			25		
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1	its law on utility, that Lilly would have produced	09:07	1	routinely provided that kind of advice to Lilly.	09:08
2	documents during the document production phase of		2	And, in fact, I'm unaware of any more reliable way	
3	these proceedings and advised Lilly on this change.		3	in which to secure that advice than from the	
4	At the first sentence of Paragraph 154 they note		4	individuals who then actually filed and prosecuted	
5	that, had there been a major shift in Canadian law,		5	Lilly's Canadian patent applications.	
6	then Claimant should have had a significant number		6	In addition, Lilly's in-house foreign	
7	of documents reflecting comments and advice on the		7	patent law experts in Indianapolis would have	
8	allegedly new requirements, and then the first		8	routinely disseminated advice of this type to	
9	sentence at Paragraph 155 notes that Claimant did		9	Lilly's in-house patent lawyers.	
10	not produce or log in its privilege log any		10	MS. CHEEK: Mr. Armitage, would Lilly have	
11	responsive documents. And it is the case that no		11	received legal advice regarding the Canadian utility	
12	such documents were produced.		12	requirement at the time that it applied for the	
13	Mr. Armitage, would Lilly have received		13	Strattera and Zyprexa patents?	
14	legal advice regarding Canadian patent law at the		14	MR. ARMITAGE: Absolutely. If there had	
15	time that it applied for and received its Zyprexa		15	been material developments in the Canadian law on	
16	and Strattera patents?		16	utility, there would have been any number of	
17	MR. ARMITAGE: It most certainly would		17	communications back and forth between Lilly's	
18	have. Lilly maintained a network of patent agents		18	in-house patent attorneys and its Canadian patent	
19	whose responsibility it was to provide advice on		19	agents. However, on this particular issue I'd be	
20	matters of patent law and practice to keep Lilly		20	actually shocked if there were evidence that advice	
21	abreast of those developments. That global network		21	on Canadian utility law had been given during that	
22	included patent agents in each of the countries in		22	time frame, since it was so well understood that the	
23	which Lilly sought patents around the world, and in		23	threshold for meeting the Canadian utility	
24	the case of Canada included highly competent		24	requirement for pharmaceutical inventions was so	
25	Canadian patent agents located in Canada who		25	low.	
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1       MS. CHEEK: Thank you, Mr. Armitage.         2       Mr. President, I have no further questions         3       for Mr. Armitage at this time.         4       CROSS-EXAMINATION ON BEHALF OF THE RESPONDENT         5       MR. SPELLICSY: Good morning,         6       Mr. Armitage.         7       MR. ARMITAGE: Good morning.         8       MR. SPELLICSY: My name is Shane         9       Spelliscy, and I'm counsel for the Government of         10       Canada in this proceeding. I'm going to ask you a         11       few questions so I can understand the testimony you         12       have submitted on behalf of the Claimant.         13       As the Chair emphasized, if you don't         14       understand a question, it's important to let me         15       know. I'll do my best to rephrase it. It's very         16       important we understand each other. It's also         17       important, I would ask, that you answer my         18       questions. So in that sense, if the answer is a yes         19       or no, I would appreciate if you can start your         20       answer that way so we have a clear record. Then         21       I'ld om y best to allow you to add whatever context         22       that you think is necessary, though we	345 09:10	المتعاملات ويتعاقبه والمتعاملة المعمونية والمتعامل	<b>346</b> 9:11
1       MR. SPELLICSY: And you're not holding         2       yourself out as an expert in Canadian patent law         3       here?         4       MR. ARMITAGE: That is correct, yes.         5       MR. SPELLICSY: I think you spoke this         6       morning about it, and in Paragraph 7 of your witness         7       statement you say that you have maintained a general         8       familiarity with the patent laws of non U.S.         9       jurisdictions such as Canada. I think you were         10       explaining this morning that you have that         11       familiarity with Canadian law because you would be         12       briefed by Canadian lawyers and patent agents. Is         13       that right?         14       MR. SPELLICSY: In part. And you say         actually in Paragraph 5 that you received regular         reports "from attorneys in my office on litigation         risks across Eli Lilly's global patent portfolio as         well as on significant changes to patent law and         policy in each of Eli Lilly's major markets."         11       MR. ARMITAGE: Yes, that's correct. That         appears in my expert report or my witness         statement. Sorry.       MR. SPELLICSY: So that I understand,         then, Eli Lilly was constantly assessing the </td <td><b>347</b> 09:12</td> <td><ul> <li>Referentions whether within some particular the section to</li> </ul></td> <td><b>348</b> 99:13</td>	<b>347</b> 09:12	<ul> <li>Referentions whether within some particular the section to</li> </ul>	<b>348</b> 99:13

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1       patent law and policy in each of Lilly's major         2       markets."         3       MR. ARMITAGE: That's correct.         4       MR. SPELLICSY: So those briefings, then,         5       would have related to changes in patent law and how         6       they would affect Lilly's patents in those major         7       markets, correct?         8       MR. ARMITAGE: That would be correct, yes.         9       MR. SPELLICSY: I think you just we         10       touched on it there, you said in your first         11       statement and I'm looking at Paragraph 3 now, in         12       the first line, that you had "overall supervisory         13       responsibility for the company's patent litigation,         14       particularly the lawsuits that were material to the         15       company's business, both in the United States and         16       internationally." And I think you just confirmed         17       this, that you would receive appropriate briefings         18       on Canadian law when Eli Lilly was involved in a         19       patent litigation in Canada, correct?         20       MR. SPELLICSY: You would agree with me,         21       then, that when one of Eli Lilly's patents was         22       MR. SPELLICSY		1       involved, correct?         2       MR. ARMITAGE:       I don't believe that's what         3       I indicated in my report.         4       MR. SPELLICSY:       So is your testimony here         5       that when a patent was invalidated, you would not be         6       briefed by Canadian counsel on that decision?         7       MR. ARMITAGE:       I would not necessarily be         8       briefed by Canadian counsel when decisions would         9       come down. I would be briefed by individuals within         10       Lilly's organization who had responsibility for         11       those matters.         12       MR. SPELLISCY:         14       me relevant Canadian counsel, correct?         15       MR. ARMITAGE:         16       they'd been briefed, as a matter of fact, there         17       MR. SPELLISCY:         18       briefed by Canadian patent counsel.         19       MR. SPELLISCY:         10       briefed by Canadian patent counsel.         11       MR. SPELLISCY:         12       MR. SPELLISCY:         13       MR. SPELLISCY:         14       they'd been briefed, as a matter of fact, there         15       MR. SPELLISCY:	09:15
1       MR. ARMITAGE: Yes, that would necessarily         2       be the case because all of our Canadian litigation         3       matters were, in fact, handled by Canadian counsel.         4       MR. SPELLISCY: You would also be involved         5       in instructing well, if not directly local         6       counsel, at least indirectly on whether to pursue         7       appeals in Canadian courts, correct?         8       MR. ARMITAGE: I'm sorry, could you repeat         9       the question?         10       MR. SPELLISCY: You would be involved in         11       instructing, at least indirectly, counsel in Canada         12       MR. SPELLISCY: You would be involved in         13       instructing, at least indirectly, counsel in Canada         14       to pursue appeals in Canadian courts if Eli Lilly         15       lost one of its patents, correct?         14       MR. ARMITAGE: Just to be sure I can         15       answer that question in context, there may well have         16       been Canadian litigation matters that were of such a         17       consequence that I would not be briefed on those         18       matters on a regular basis or routinely, but when         19       you're talking about material matters in any <td< td=""><td></td><td>1 management, that would actually instruct counsel to pursue an appeal, correct? 3 MR. ARMITAGE: It would be the general counsel's responsibility to determine whether an appeal was appropriate, and if an appeal was appropriate whether it ought to be pursued. And in general there may have been situations where those were legal business decisions, but in many cases they would be legal decisions alone. MR. SPELLISCY: So ultimately the instruction to pursue appeal would come from your office? You may not personally have been briefed if it was a small matter, but on material matters ultimately the instruction would, in fact, come from you. Is that right? MR. ARMITAGE: When you say instruction would come from me, I think a better characterization would be certainly there weren't appeals that were taken that weren't authorized by me, and I use that in a sense that I may have done nothing more than received a recommendation and a justification and simply said this was an appropriate way to proceed. MR. SPELLISCY: So I understand, you're not saying you didn't review the grounds and make</td><td><b>352</b> 09:17</td></td<>		1 management, that would actually instruct counsel to pursue an appeal, correct? 3 MR. ARMITAGE: It would be the general counsel's responsibility to determine whether an appeal was appropriate, and if an appeal was appropriate whether it ought to be pursued. And in general there may have been situations where those were legal business decisions, but in many cases they would be legal decisions alone. MR. SPELLISCY: So ultimately the instruction to pursue appeal would come from your office? You may not personally have been briefed if it was a small matter, but on material matters ultimately the instruction would, in fact, come from you. Is that right? MR. ARMITAGE: When you say instruction would come from me, I think a better characterization would be certainly there weren't appeals that were taken that weren't authorized by me, and I use that in a sense that I may have done nothing more than received a recommendation and a justification and simply said this was an appropriate way to proceed. MR. SPELLISCY: So I understand, you're not saying you didn't review the grounds and make	<b>352</b> 09:17

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<ul> <li>your own decision on Canadian law. You're not</li> <li>qualified to do that. But you did authorize the</li> <li>filing of appeals. You would have seen that on</li> <li>material matters and authorized it, correct?</li> <li>MR. ARMITAGE: When you say I would have</li> <li>seen that, what is the "that"?</li> <li>MR. SPELLISCY: The request to file an</li> <li>appeal.</li> <li>MR. ARMITAGE: Okay. So just to be very</li> <li>clear about modus operandi here, there would be in</li> <li>some cases e-mails that would come to me that would</li> <li>describe a factual situation in a particular country</li> <li>and seek my authorization to take an action, and I</li> <li>would provide that authorization. In other</li> <li>circumstances where the matter was ongoing, there</li> <li>would be conferences with the particularly the</li> <li>Lilly attorneys responsible for those matters.</li> <li>Sometimes I might involve actually the foreign</li> <li>patent professionals who were responsible for those</li> <li>in-country, and so, one way or another, there would be</li> <li>either acquiescence or, in fact, I suppose in some</li> <li>cases direction, if indeed I decided that I wanted</li> <li>to take ultimate responsibility for the substance of</li> <li>that decision.</li> </ul>	09:19 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 24 25 14 15 14 15 14 15 14 15 16 17 16 17 17 18 19 10 17 18 19 10 17 18 19 19 10 10 10 10 10 10 10 10 10 10	<ul> <li>were going to take ultimate responsibility for the substance of that decision, I would assume that that would be a case where there was a material impact on Lilly's business or an important patent, correct?</li> <li>MR. ARMITAGE: Again, in my role as general counsel, there were only so many matters in which I could have enough in-depth involvement to say that I wanted to direct the decision that was being taken rather than simply be clear that this was an appropriate decision and have confidence in those who ultimately knew all the facts. There were particularly, in patent matters, issues in which I became deeply enough involved so that I would have made those decisions substantively, and those would have been typically on matters of most materiality to the company.</li> <li>MR. SPELLISCY: I think earlier you said and I'll just confirm that when Eli Lilly was involved in a domestic litigation which resulted in the invalidation of one of its patents, it would consider the implications for the validity of other patents in that same jurisdiction. Do you recall that?</li> </ul>	09:20
<ul> <li>question is clear, when you say domestic, are you referring to Canadian domestic?</li> <li>MR. SPELLISCY: Sure.</li> <li>MR. ARMITAGE: So just so I get the question clearly, because I was first hearing this as domestic obviously being a U.S. decision. If you could repeat it just so I get it clearly in mind.</li> <li>MR. SPELLISCY: I think we can do it in domestic as well, but when Lilly was involved in a Canadian litigation which resulted in the invalidation of one of its patents, Lilly would consider the implications of the validity of that for its other Canadian patents, correct?</li> <li>MR. ARMITAGE: You're asking me to speak on behalf of the company, and obviously I didn't have direct responsibility for those assessments.</li> <li>But in general, as developments occurred in Canadian patent law, Lilly needed, as they would in any jurisdiction, to take account of those developments in deciding how to proceed in the future to both litigate the patents and, more importantly, its ability to actually secure valid patents in any particular jurisdiction. So I don't believe there's anything unique about Canada here in the way Lilly</li> </ul>	355 09:21 1 2 3 4 5 6 7 8 9 9 10 11 12 13 14 15 16 17 18 16 17 18 19 20 21 22 23 24 10 12 12 12 12 12 12 12 12 12 12	<ul> <li>asked my question, first of all, domestic</li> <li>litigation. I assume this was a practice Lilly was</li> <li>doing in every jurisdiction. If it lost a patent in</li> <li>any jurisdiction, it would consider the implications</li> <li>of that decision for the other patents it held in</li> <li>that jurisdiction, correct?</li> <li>MR. ARMITAGE: Yes. And again, there's no</li> <li>general rule here. I mean there are situations in</li> <li>which you receive an adverse decision that, for</li> <li>example, you believe is wrong and won't be</li> <li>replicated and, therefore, the decision taken is no</li> <li>decision, that this anomaly need not affect our</li> <li>strategy or our practices.</li> <li>MR. SPELLISCY: I want to turn for a brief</li> <li>second to your second witness statement to</li> <li>understand the way Lilly thought about impacts of</li> <li>domestic law decisions on the patents. If you could</li> <li>turn to Paragraph 44. And in the last sentence you</li> <li>say " neither Lilly nor any other firm I'm aware</li> <li>of would put off the acquisition of a patent owned</li> <li>by another company until after someone brings</li> <li>litigation to challenge the validity of the patent."</li> </ul>	<b>356</b> 09:23

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2       MR. ARMITAGE: Second statement,         3       Paragraph 44. I apologize.         4       MR. SPELLISCY: That's okay.         5       MR. ARMITAGE: Yes, I see that.         6       MR. SPELLISCY: To be clear, while you         7       wouldn't necessarily put off the application, you         8       would certainly do your due diligence on the         9       applicable patent laws, correct?         10       MR. ARMITAGE: In any situation that I can         11       imagine where a patent would be of material value to         12       a transaction, there certainly would be some sort of         13       due diligence involved, yes.         14       MR. SPELLISCY: And so before any such         15       purchase, in doing that due diligence you would be         16       assessing the likely success of any invalidity         17       challenge to those patents, correct?         18       MR. ARMITAGE: As with any other asset         19       being acquired, we would do the appropriate level of         20       due diligence based on the potential value of the         21       MR. SPELLISCY: Right. And you would         22       MR. SPELLISCY: Right. And you would         23       asset being acquired, yes.         24 <td></td> <td><ul> <li>MR. SPELLISCY: Right, you would assess</li> <li>whether or not, if it was challenged on invalidity,</li> <li>that challenge might be successful, correct?</li> <li>MR. ARMITAGE: Well, I think, more to the</li> <li>point, what one would do if it were a patent asset</li> <li>as opposed to an asset of another type is make some</li> <li>assessment of whether, under the substantive</li> <li>requirements for patentability, that patent would</li> <li>contain patentable subject matter at least to the</li> <li>extent we were valuing the ability of that asset to</li> <li>affect competition in the marketplace. So you would</li> <li>do due diligence knowing, for example, that there's</li> <li>a possibility that patent would be litigated and, if</li> <li>litigated, would need to be defended.</li> <li>MR. SPELLISCY: And if you thought, in</li> <li>doing that due diligence, that there was a risk that</li> <li>the patent would affect the price that you were</li> <li>willing to pay for that patent, correct?</li> <li>MR. ARMITAGE: Well, in you're getting</li> <li>now into an area where you want my opinions and how</li> <li>to do market value assessments for intellectual</li> <li>property, which I'm a little reluctant to do, but</li> <li>let me just make this observation.</li> </ul></td> <td></td>		<ul> <li>MR. SPELLISCY: Right, you would assess</li> <li>whether or not, if it was challenged on invalidity,</li> <li>that challenge might be successful, correct?</li> <li>MR. ARMITAGE: Well, I think, more to the</li> <li>point, what one would do if it were a patent asset</li> <li>as opposed to an asset of another type is make some</li> <li>assessment of whether, under the substantive</li> <li>requirements for patentability, that patent would</li> <li>contain patentable subject matter at least to the</li> <li>extent we were valuing the ability of that asset to</li> <li>affect competition in the marketplace. So you would</li> <li>do due diligence knowing, for example, that there's</li> <li>a possibility that patent would be litigated and, if</li> <li>litigated, would need to be defended.</li> <li>MR. SPELLISCY: And if you thought, in</li> <li>doing that due diligence, that there was a risk that</li> <li>the patent would affect the price that you were</li> <li>willing to pay for that patent, correct?</li> <li>MR. ARMITAGE: Well, in you're getting</li> <li>now into an area where you want my opinions and how</li> <li>to do market value assessments for intellectual</li> <li>property, which I'm a little reluctant to do, but</li> <li>let me just make this observation.</li> </ul>	
1       By and large, these assets have a binary         2       character. If you buy a piece of property, either         3       you get a valid title or you don't. And if you're         4       going to build your business on the assumption that         5       you're going to have a valid title, then you         6       basically need to have assurance that you can defend         7       that title. So to a certain degree you have to, in         8       a due diligence assessment, make that binary         9       assessment, we're going to build a business on the         10       assumptions the patent is valid and can be enforced.         11       And then it's very difficult to get in a real world         12       economic negotiation some discount based on some         13       hypothetical probability that that patent might be         14       invalidated. So there's a real world context to         15       this that is sort of at a disconnect given the         16       binary nature of the acquisition of most assets.         17       I apologize if that doesn't make sense.         18       WR. SPELLISCY: Let me see if I         19       understand. If, in thinking about acquiring a         20       patent, Eli Lilly determined that there was a         21       significant risk	<b>359</b> 09:26	1       MR. ARMITAGE: Quite the contrary. It's a         2       binary decision, and I've been involved in these         3       binary decisions any number of times. Somebody at         4       the company comes to you and says we have the         5       potential to acquire a product that could be a         6       multi-million-dollar blockbuster. It's going to be         7       a viable business for us only if you can tell us         8       whether we can expect these patents to be valid, and         9       they need a yes or no answer. So if you look at the         10       patents and they look like you know, you look at         11       a patent based on your best understanding of the,         12       quote, domestic patent law of whatever country in         13       which this patent was issued; you make a         14       determination that this patent should be able to         15       survive any invalidity challenge; and you give the         16       business the answer yes.         17       On the other hand, you may see an asset         18       that clearly, on its face, isn't going to be able to         19       be defended or would be so problematic that it would         20       be irresponsible for the business to try to acquire         21       the asset an	360 09:28

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<ul> <li>of whether there are 500 or so that might survive,</li> <li>that typically isn't how our business works and it</li> <li>typically isn't how these decisions actually get</li> <li>made. That's why, at least in the pharmaceutical</li> <li>business, patents are really the bedrock asset on</li> <li>which you make the investment to develop</li> <li>pharmaceutical products.</li> <li>MR. SPELLISCY: Let me give it another</li> <li>shot at understanding. I think I get the binary</li> <li>nature now. If Eli Lilly was looking to acquire</li> <li>or if a business came to your office saying we've</li> <li>got a chance to acquire this patent, they would be</li> <li>looking for an answer from you as to do you think</li> <li>this would withstand a validity challenge if</li> <li>challenged, and if you looked at the patent laws of</li> <li>the jurisdiction and came to the conclusion that if</li> <li>would be irresponsible for the transaction to go</li> <li>mouting the answer, and so the record and the</li> <li>transcript is very confusing. I don't know if</li> <li>there's a way to use livenote more effectively or</li> </ul>	<b>361</b> 09:29	Mr. Spelliscy's asking the problem with the livenote, whether you are reading a answer? MS. CHEEK: My   restating of the witness' and does not have livenote and therefore THE PRESIDENT: speaking, so please proce MR. ARMITAGE: T question where my first re that I think what you resta of an overgeneralization a say something as categor wouldn't mind repeating yo help me. MR. SPELLISCY: understand is in the answ talking about they need a explained what would hap	er, so the witness has to stually what he just said. Is your problem with questions, or is your where you cannot see a question or reading an problem is with the nswers and the witness d so the witness is, I think we can hear who is eed, Mr. Spelliscy. There's actually a pending sponse was going to be te as my answer is a bit and that I didn't actually ical as you did. But if you	362 09:30
<ul> <li>And then you said, on the other hand, you may see an asset that clearly on its face isn't going to be able to be defended, or would be so problematic that it would be irresponsible for the business to try to acquire the asset and actually make the investment.</li> <li>And so I take it that was if it was a no answer. Is that correct?</li> <li>MR. ARMITAGE: Well, I think the fairest way to look at this is in my own practice, in my own experience and my own work for the company I've given yes and no answers, and typically those yes answers create the possibility that that transaction of that type will go forward, and a no answer makes it virtually impossible for that transaction to go forward, and so there are any number of situations, including some I recall at Lilly where we actually looked at a particular asset and explained to the business that there was actually no economic given the fact that we assessed there was no reasonable likelihood that you would be able to actually enforce a patent, and a patent was key to the valuation of the entire enterprise.</li> <li>MR. SPELLISCY: I think I understand now.</li> </ul>	<b>363</b> 09:31	statement, and I want to d You have it in the second relatively recent. So you w vice-president and genera until December 31, 2012, MR. ARMITAGE: T MR. SPELLISCY: Eli Lilly filed its first notice a claim to NAFTA arbitrati correct? MR. ARMITAGE: Y date, but if that's the date, correct. MR. SPELLISCY: was filed while you were so of Eli Lilly, correct? MR. ARMITAGE: A MR. SPELLISCY: some of the paragraphs in statement which you filed original Memorial. I want your comments regarding Canadian courts to invalid patents. If you could turn	paragraph, but it's were the senior Il counsel of Eli Lilly correct? 'hat's correct. So then you are aware that of intent to submit on on November 7, 2012, 'es. I do not recall the I accept that's You were assuming that it till the general counsel as I recall, yes. I want to look, then, at your first witness in support of Eli Lilly's to look first at with the decisions of the late Eli Lilly's olanzapine	<b>364</b> 09:33

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<ul> <li>go through some of your comments and then I'll ask</li> <li>you some questions.</li> <li>In Paragraph 13 in the last sentence you</li> <li>say, "The doctrine was especially egregious as</li> <li>applied to the '113 Patent." Just for clarity, the</li> <li>'113 patent was the patent for olanzapine, correct?</li> <li>MR. ARMITAGE: Correct.</li> <li>MR. SPELLISCY: In Paragraph 16 you say</li> <li>about halfway down that paragraph, "we were quite</li> <li>simply incredulous when, on remand, the trial judge</li> <li>invalidated our patent solely on the ground of</li> <li>inutility." Correct?</li> <li>MR. ARMITAGE: Correct.</li> <li>MR. SPELLISCY: You were incredulous</li> <li>because Eli Lilly's belief was that Canadian law had</li> <li>not been applied correctly to invalidate this</li> <li>patent, right?</li> <li>MR. ARMITAGE: I'm not sure that's a</li> <li>totally accurate statement of my incredulous.</li> <li>MR. SPELLISCY: You said in Paragraph 16,</li> <li>"We were incredulous when, on remand, the trial</li> <li>judge [in the olanzapine case] invalidated our</li> <li>patent solely on the ground of inutility."</li> </ul>	09:34	1 2 3 4 5 6 7 8 9 10 11 2 13 14 15 16 17 8 9 20 21 22 3 24 25	MR. ARMITAGE: That's correct. MR. SPELLISCY: Again, you were I'm trying to understand what you were incredulous about. Maybe let's look at that decision, and you can help me here. You've been handed a binder of documents. It's got the red cover on the front. If you can turn to Tab 1 in your binder, which for the record is Exhibit R-016, this is the decision of the Federal Court and the challenge to the '113 patent for olanzapine dated November 10, 2011. Do you see that? MR. ARMITAGE: Yes. MR. SPELLISCY: If we turn to page we're going to look just at the conclusion. If you turn to page 38 or Paragraph 273 the page numbers are in the very bottom, but they're a little hard to see because they're faint. Paragraph 273. MR. ARMITAGE: That's fine. MR. SPELLISCY: The Federal Court's conclusion here was as follows: "Lilly had a patent for olanzapine (the '687) that lasted from 1980 to 1997. But as the '687 patent neared expiry, it became important to Lilly to try to extend the patent protection for olanzapine. The '113 patent was clearly drafted with a view to justifying a www.dianaburden.com	09:35
fresh patent." I take it from your testimony this morning that you disagree with that part of the statement? MR. ARMITAGE: Well, there is a part of the statement that is incorrect that is correct. It did become important for Lilly in order to be able to develop olanzapine as a medicine to be able to secure patent protection on the molecule itself. I think what I stated earlier this morning is it's not fair to say we had protection for olanzapine that existed before olanzapine had even been synthesized chemically. It just simply didn't exist. And it's not in any practical sense. You had protection for a compound that, after it was synthesized, was a long hard road away from being able to be monopolized in the sense of there being any possible marketplace for it. MR. SPELLISCY: So your opinion was that the finding of the court that Lilly had a patent for olanzapine that lasted from 1980 to 1997, that finding was factually incorrect is what you're saying? MR. ARMITAGE: Whether it's factually correct or not, the truth of the matter is Lilly had a generic patent that included within the genus www.dianaburden.com	<b>367</b> 09:37	1 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 13 14 15 16 7 18 19 20 21 22 3 24 25	was olanzapine. Nonetheless, olanzapine had never been synthesized and when it did it became a separately patentable invention based on the discovery of properties of olanzapine that were unique relative to that genus, and so when you say we had a patent for olanzapine that began in 1980, olanzapine didn't begin its life until after that patent had issued in 1980 because it had never been made. MR. SPELLISCY: I think you just said that you do, you find this statement of fact the finding by the court incorrect, that olanzapine you didn't have a patent for olanzapine that started from 1980 because olanzapine hadn't been made. So you disagree with this finding of fact, correct? MR. ARMITAGE: Well, I think as I've tried to say two or three times, whether it's correct or not, it's a meaningless observation to the extent it's used to suggest that we had protection that we could have used in any practical sense beginning in 1980, for the two reasons I mentioned earlier. One, in 1980 the compound had never been synthesized; and, two, from the time it was synthesized after 1980, it was a long way from anybody being able to assert that patent in any www.dianaburden.com	368 09:38

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1       commercial environment because there was no possible         2       market for olanzapine until its development as a         3       medicine had been completed. So we had protection         4       without a possibility of protecting anything.         5       MR. SPELLISCY: Let's move on to second         6       sentence there that I just read out. "As the '687         7       patent neared expiry it became important to Lilly to         8       try to extend the patent protection for olanzapine."         9       Were you incredulous at that factual         10       statement or that finding of the court, sorry?         11       MR. ARMITAGE: Was I incredulous at that         12       statement? I think the answer to that is no, I was         13       actually incredulous with the holding of the court         14       in this case. But with respect to this particular         15       statement, it wasn't that the '687 patent was         16       nearing expiration that it became important for         11       that Lilly had done, the scientific work that Lilly         19       had done that satisfied them that, unlike other         2       compounds in this genus that basically had no         2       mearing appeared to have the ability to be an         2       effective a	369 09:40	<ul> <li>370</li> <li>incredulous with the holding in this case. Let's go</li> <li>a couple of sentences down. It says, "But the</li> <li>evidence just was not there in 1991 when the patent</li> <li>was filed. Novopharm has established that the</li> <li>patent's promise had not been demonstrated and could</li> <li>not have been soundly predicted on the basis of the</li> <li>evidence available to the inventors in 1991."</li> <li>So this was the holding you were</li> <li>incredulous with. Is that right?</li> <li>MR. ARNITAGE: Well, when you asked me</li> <li>what the holding was I was incredulous with, maybe I</li> <li>can answer that and that would maybe simplify this</li> <li>whole line of questioning.</li> <li>My understanding, when I was briefed on</li> <li>this opinion, is that there was no doubt that</li> <li>olanzapine had utility under the law of utility as</li> <li>well understood in any patent jurisdiction of which</li> <li>I'm aware, but that the court was actually doing, as</li> <li>is suggested in what you had read here, attempting</li> <li>to read in the patent a set of promises such that</li> <li>unless Lilly had actually been able to demonstrate</li> <li>what the court viewed as a promise, the compound</li> <li>that had utility, irrespective of how useful the</li> <li>compound actually was at that point as a medicine in</li> <li>www.dianaburden.com</li> </ul>
1       Canada.         2       So what I was incredulous about, in sum,         3       was that a utility requirement that would invalidate         4       a patent where it was clear the patent was useful.         5       MR. SPELLISCY: Let me ask you a few         6       questions to try and understand this. We had         7       earlier discussed how you had and you said in         8       your statement you had a general familiarity with         9       Canadian law and that you would have been briefed on         10       changes or significant developments in the Canadian         11       courts. And so what I don't understand this         12       decision was in 2011, correct?         13       MR. ARMITAGE: Correct.         14       MR. SPELLISCY: So, Mr. Armitage, clearly         15       by that point, 2011, you would have been aware that         16       Canadian courts were holding patentees to the         17       promises in their patents and were not considering         18       post-filing evidence, correct?         19       MR. ARMITAGE: Correct. If it helps, I'm         10       as incredulous today as I was when I read this about         11       the manner in which Canadian patent law operates         12       relative	<b>371</b> 09:42	372 <ol> <li>understand, Mr. Armitage, is your statement when you</li> <li>said "My understanding when I was briefed on this</li> <li>opinion is that there was no doubt that olanzapine</li> <li>had utility under the law of utility as well</li> <li>understood in any patent jurisdiction of which I am</li> <li>aware." But you would agree with me that the test</li> <li>that the court set out of the patent's promise on</li> <li>the basis of the evidence available to the</li> <li>inventors, you were aware in 2011 that that was</li> <li>Canadian law, right?</li> <li>MR. ARMITAGE: I was aware that there were</li> <li>decisions in Canadian patent law by 2011 that had</li> <li>set out the promise doctrine, that's correct, and I</li> <li>was aware that the promise doctrine was applied</li> <li>factually in each patent that came before the</li> <li>Canadian courts. And, as applied to Zyprexa, in my</li> <li>view for good reason I remain to this day</li> <li>incredulous that the doctrine of patent law.</li> <li>MR. SPELLISCY: Let's focus on the last</li> <li>part of what the court said in its decision, which</li> <li>is "could not have been soundly predicted on the</li> <li>basis of the evidence available to the inventors in</li> <li>1991."</li> </ol>

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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	the time the AZT decision was released in 2002, correct? MR. ARMITAGE: No. In 2002? MR. SPELLISCY: In 2002. MR. ARMITAGE: I believe I became general counsel in 2003. I'm sure I became general counsel in 2003. MR. SPELLISCY: You're right. So you were aware that the AZT decision was released essentially a month before you became general counsel, correct? MR. ARMITAGE: Well, if you're asking me am I aware now of that chronology, as you represented I am aware of that now, yes. MR. SPELLISCY: You weren't briefed on the AZT decision when you became senior vice-president and general counsel on January 1, 2003 on Canadian law? MR. ARMITAGE: I have no recollection whatsoever. I clearly was not briefed on January 1. MR. SPELLISCY: But sometime before 2011 you would have been briefed on the AZT decision, wouldn't you have? MR. ARMITAGE: Sometime before 2011, I would have been briefed at least generally on developments in Canadian patent law, and I don't www.dianaburden.com	373 09:45	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	have a specific recollection of whether that briefing would have gone into the details of individual decisions and holdings. MR. SPELLISCY: You did say, I think just now, that you were aware by 2011 that courts were looking for the promise of the patent. Is that right? MR. ARMITAGE: So when you say courts were looking to the promise of the patent, you mean courts were looking for the promise in a patent in order to apply the promise utility doctrine as a means of invalidating patents for lack of utility. Is that the context the question is asked because, if so, I had a general awareness of the promise utility doctrine. MR. SPELLISCY: You said, "I was aware that there were decisions in Canadian patent law by 2011 that had set out the promise doctrine." MR. SPELLISCY: So in 2011 when it was applied when that promise doctrine was applied to Lilly's olanzapine patent, you weren't incredulous or shocked by those doctrines existing, were you? MR. ARMITAGE: Yes. I think I've already testified to that effect. I mean from the very www.dianaburden.com	374 09:46
$\begin{array}{c}1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\9\\20\\21\\22\\324\\25\end{array}$	<ul> <li>beginning this idea that a utility under Canadian patent law would disregard utility in fact of inventions and go through the analytical analysis that's now done with the promise utility doctrine, I apologize if it's offensive, but I continue to find it incredulous.</li> <li>MR. SPELLISCY: But what I'm trying to understand is you knew the doctrine existed before 2011, correct?</li> <li>MR. ARMITAGE: I knew there were court decisions applying the doctrine, yes.</li> <li>MR. SPELLISCY: And your testimony earlier, I believe, was that one of the things you were incredulous at is not just the substance of the doctrine but that the doctrine was applied to the olanzapine patent, correct?</li> <li>MR. ARMITAGE: Absolutely. Absolutely. This was a patent where, unlike many patents on new chemical entities, Lilly actually had clinical data on this compound that actually was the basis of some excitement within the company. I was not there at the point, but as has been related to me, that after many, many years of failed efforts to develop an anti-psychotic medicine, they finally had a compound with the pharmacology and human clinical results</li> </ul>	<b>375</b> 09:48	1 2 3 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	that suggested that they could have a uniquely effective anti-psychotic medicine. MR. SPELLISCY: Let's turn to your comments on the decision invalidating Eli Lilly's patent concerning atomoxetine. We'll stay in your first statement and look to Paragraph 22, which is on page 6. We'll just clarify for the record. You say, "When Canada invalidated the '735 patent solely on the grounds of inutility in 2010, we found this development outrageous." The '735 patent is for atomoxetine, correct? MR. ARMITAGE: Correct. MR. SPELLISCY: The next page, the last sentence of the paragraph, you say, "It was inconceivable to us that the Canadian courts could fairly adjudicate the inutility issue without considering the most salient facts." Do you see that? MR. ARMITAGE: You're on Paragraph 22? MR. SPELLISCY: It's 22. MR. ARMITAGE: Yes, I see that. MR. SPELLISCY: You state after that what your view of the most salient facts are. "The clinical trial conducted at one of the world's best known research hospitals" which I assume you're www.dianaburden.com	<b>376</b> 09:49

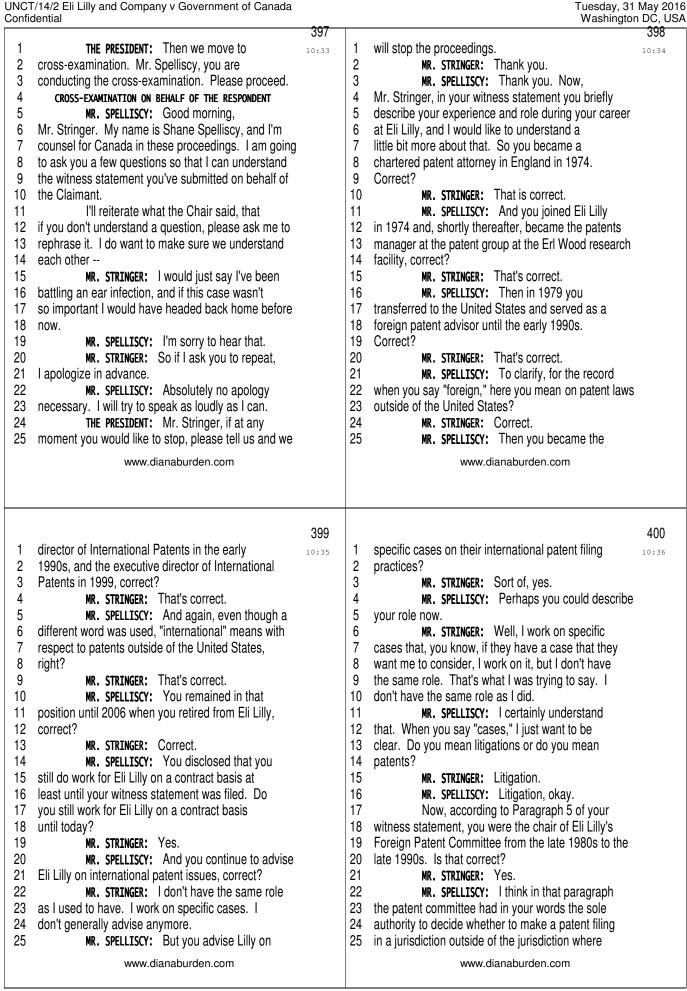
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1       referring to the MGH study?         2       MR. ARMITAGE: Right.         3       MR. SPELLISCY: "as well as the views         4       of Health Canada who had approved the drug as safe         5       and effective precisely because it was determined to         6       be useful in treating ADHD."         7       MR. ARMITAGE: Correct.         8       MR. SPELLISCY: So your concern or at         9       least one of your concerns as expressed in your         10       witness statement, was that the Canadian court's         11       decision was outrageous because in your view it did         12       not consider the right facts, right?         13       MR. ARMITAGE: When you say consider the         14       right facts, I think what's in Paragraph 22 is at         15       least my view that Canada didn't consider the         16       dispositive facts on the issue of whether or not         17       Strattera was useful to treat ADHD, which is the         19       work for a medicine of this type. So again, it goes         10       work for a medicine of this type. So again, it goes         10       work for a medicine of this the requirement to be         10       useful.         24       MR. SPELLISCY: And your concern was	2 8 9 1 1 1 1 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2	<ul> <li>MR. ARMITAGE: Without considering the</li> <li>dispositive evidence that Strattera was useful to</li> <li>treat ADHD in attempting to determine whether the</li> <li>requirement for utility was met. That was why,</li> <li>indeed, I think I used the intemperate word</li> <li>"outrageous" and again continued by saying I didn't</li> <li>believe that this could be part of a rational patent</li> <li>law.</li> <li>MR. SPELLISCY: The next paragraph,</li> <li>Paragraph 23 you say, you were "wholly perplexed by</li> <li>the court's decision." You see that?</li> <li>MR. ARMITAGE: Yes.</li> <li>MR. SPELLISCY: If we go to paragraph 24,</li> <li>you talk in the first line about the Strattera</li> <li>patent had been filed in Canada using the PCT</li> <li>process.</li> <li>MR. SPELLISCY: You continue later in that</li> <li>paragraph to say "That our patents would be held</li> </ul>	9:52
<ul> <li>decision. It's at Tab 3 of the binder you've been</li> <li>given, which is Exhibit R-027, for the record.</li> <li>This is the Federal court decision</li> <li>invalidating or the Federal court decision in the</li> <li>challenge to Eli Lilly's atomoxetine patent issued</li> <li>on September 14, 2010, correct?</li> <li>MR. ARMITAGE: Correct.</li> <li>MR. SPELLISCY: Let's turn to, again,</li> <li>page 31 in Paragraph 117. The Federal court says,</li> <li>"In a case involving a claimed sound prediction of</li> <li>utility, it is equally beyond debate that an</li> <li>additional disclosure obligation arises. According</li> <li>to Justice Binnie in AZT, above, this obligation is</li> <li>met by disclosing in the patent both the factual</li> <li>data on which the prediction is based and the line</li> <li>of reasoning followed to enable the prediction to be</li> <li>made. This requirement to disclose the basis of the</li> <li>prediction in the patent specification was said to</li> <li>be to some extent the <i>quid pro quo</i> the patentee</li> <li>offers in exchange for the patent monopoly."</li> <li>If we go to the next page in Paragraph 120</li> <li>the court says it follows the second sentence.</li> <li>"It follows inevitably from the authorities that to</li> <li>the extent that the '735 patent is based on a sound</li> <li>prediction from the MGH study, that atomoxetine is</li> </ul>	2 8 9 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 2 2 2 2	<ul> <li>useful in the treatment of ADHD, the patent fails</li> <li>for want of disclosure because some reference to</li> <li>those findings was required to be set out in the</li> <li>patent." You see that?</li> <li>MR. ARMITAGE: Yes.</li> <li>MR. SPELLISCY: Earlier you said as</li> <li>general counsel you had oversight of Lilly's</li> <li>responses to the cases brought by generic</li> <li>manufacturers in Canada against the Strattera and</li> <li>Zyprexa patents, correct?</li> <li>MR. SPELLISCY: You also had the</li> <li>responsibility for overseeing the case brought by</li> <li>generic manufacturers in Canada with respect to Eli</li> <li>Lilly's Raloxifene patent, correct?</li> <li>MR. ARMITAGE: Correct.</li> <li>MR. ARMITAGE: Correct.</li> <li>MR. SPELLISCY: What I'm not sure I</li> <li>understand is not once in your entire first</li> </ul>	<b>380</b> 9:56

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<ul> <li>Raloxifene decision at the Federal court. Do you see that?</li> <li>MR. ARMITAGE: I do, yes.</li> <li>MR. SPELLISCY: In the same paragraph, I think on the next page, quotes from the Federal Court of Appeal decision in the dispute over Raloxifene, correct? You see he's got 14 and 15 there?</li> <li>MR. ARMITAGE: Yes.</li> <li>MR. SPELLISCY: I want to look at those decisions. Let's turn to Tab 4 in your binder, which is Exhibit R-200 for the record. This is dated February 5, 2008. Again, if we turn to Paragraph 163 in this decision. It says, "The third criterion, however, is that of disclosure. It is clear that the '356 patent does not disclose the study described in the Hong Kong abstract. The patent does not disclose any more than Jordan did.</li> <li>The person skilled in the art was given, by way of disclosure, no more than such person already had.</li> <li>No hard coinage had been paid for the claimed monopoly. Thus, for lack of disclosure, there was no sound prediction."</li> <li>MR. ARMITAGE: Yes, I see you've read www.dianaburden.com</li> </ul>	09:57	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	<ul> <li>MR. SPELLISCY: Turn to Tab 5, which is Exhibit R-354, for the record. This is dated March 25, 2009, and it's the Federal Court of Appeal decision in Eli Lilly's appeal of the Raloxifene case, correct?</li> <li>MR. ARMITAGE: Correct. Well MS. CHEEK: Mr. President, just to be clear, neither of these opinions are opinions that Mr. Armitage covered in his witness statement. MR. SPELLISCY: I think that that's irrelevant because he's testified to the fact that he has supervisory charge of that. THE PRESIDENT: Overruled. Please proceed.</li> <li>MR. ARMITAGE: I'm sorry. Again, tab 5 is what?</li> <li>MR. SPELLISCY: The decision of the Federal Court of Appeal dated March 25, 2009 in Eli Lilly's appeal of the decision we just looked at in the Federal court in the Raloxifene case, correct?</li> <li>MR. ARMITAGE: I believe so, yes. MR. SPELLISCY: Let's turn to Paragraph 15 in this decision. The Federal court of Appeal active to fappeal says, "In my respectful view, the Federal court judge</li> </ul>	09:58
<ol> <li>proceeded on proper principle when he held, relying</li> <li>on AZT, that when a patent is based on a sound</li> <li>prediction, the disclosure must include the</li> <li>prediction. As the prediction was made sound by the</li> <li>Hong Kong study, this study had to be disclosed."</li> <li>Do you see that?</li> <li>MR. ARMITAGE: Yes.</li> <li>MR. SPELLISCY: Eli Lilly appealed to the</li> <li>Supreme Court of Canada, correct?</li> <li>MR. ARNITAGE: I believe that's correct,</li> <li>yes.</li> <li>MR. SPELLISCY: And the Supreme Court of</li> <li>Canada denied that leave to appeal. Is that right?</li> <li>MR. SPELLISCY: We can look at it if you</li> <li>want, if you don't recall, but yes, that is Tab 6.</li> <li>MR. SPELLISCY: My problem, then, is how I</li> <li>can understand your testimony, Mr. Armitage, because</li> <li>you have stated that the rule in the atomoxetine</li> <li>decision was wholly unexpected when that decision</li> <li>was rendered in 2010. But you testified that you</li> <li>were in charge of the Raloxifene case, so you were</li> <li>aware and had knowledge of a decision on the exact</li> </ol>	<b>383</b> 10:00	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	same grounds and reasoning even with respect to the Patent Cooperation Treaty on another one of Eli Lilly's patents that came out in 2008 and 2009. Is that right? MR. ARMITAGE: I'm sorry. You're pointing me to some paragraph in my first expert report? MR. SPELLISCY: Your first witness statement. MR. ARMITAGE: First witness statement. I apologize for that again. MR. SPELLISCY: We can go back to it again. The paragraph where you said we can look at several paragraphs here. Where you said in Paragraph 23 that you were wholly perplexed and in Paragraph 24 you say it was wholly unexpected. In Paragraph 25 you say this was a new requirement that never previously existed in Canadian law. What I'm trying to understand is how you could have testified to that to the Tribunal when you were aware, in 2008, that a Federal court had ruled on exactly the same grounds and that they were affirmed by the Federal Court of Appeal and Eli Lilly's application for leave was denied. MR. ARMITAGE: Okay. Let me try to explain that. As I understand the 2008 decisions on www.dianaburden.com	

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<ul> <li>Raloxifene, they go to a heightened disclosure</li> <li>standard, and this is a disclosure standard that,</li> <li>again, I find entirely perplexing. The issue on</li> <li>utility is whether the compound is useful in fact.</li> <li>That's traditionally how utility is decided. The</li> <li>compound Raloxifene was no more or less useful</li> <li>whether or not there was a disclosure of a reference</li> <li>study that was otherwise public made in the patent</li> <li>application itself. So with respect to Raloxifene,</li> <li>it's very difficult to decide other than in an</li> <li>arbitrary manner why this would be a requirement for</li> <li>demonstrating utility.</li> <li>In any event, with respect to atomoxetine,</li> <li>we would not have needed an enhanced disclosure of</li> <li>any kind because if we had conducted a clinical</li> <li>trial which we did in this case that we</li> <li>believe showed statistical significance, it should</li> <li>have been accepted without being disclosed in the</li> <li>Canadian patent application, actually not as a</li> <li>matter of sound prediction but as a matter of a</li> <li>demonstration that, in fact, Strattera had been</li> <li>shown to be effective to treat ADHD.</li> <li>This decision was lost only because the</li> <li>trial court judge did as Canadian trial court judges</li> <li>can do, made the extraordinary in my view</li> </ul>	385	9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	statement that for proving utility whether a compound works or not, I'm allowed not only to look at the promise that it will work but the promise that it will work long term for patients. And since it was, in effect, a short-term clinical trial and there were other issues that I think are reported in here about defects in the clinical trial, we're going to put you in the box of sound prediction. And by putting you in the box of sound prediction, if you don't actually disclose the study, you get the result in the Raloxifene case that, again, for reasons I just explained in this answer, are perplexing if the only issue is is this compound useful or not. Compounds only need to be novel, useful and non-obvious. These are two patents for which the compounds are novel, useful and non-obvious but nonetheless could not meet the Canadian requirement that they be useful. MR. SPELLISCY: Coming back to what you just said, so that I understand, your view here is that the Canadian court should have concluded on the facts before it that you had demonstrated utility based on this clinical study because as you said, it was actually not as a matter of prediction but as a matter of demonstration. You believe that the www.dianaburden.com	386
1       Canadian court got it wrong in that regard, correct?         2       MR. ARMITAGE: No. Only in small part.         3       The larger part of what I think was gotten wrong by         4       Canadian law was the fact that Health Canada         5       actually approved this compound as safe and         6       effective for the treatment of ADHD and, therefore,         7       there was no factual issue, no factual dispute no         8       possible factual dispute that this compound was, in         9       fact, useful. My problem again is this is simply         10       unprecedented, at least in my experience, among         11       patent laws in any jurisdiction.         12       MR. SPELLISCY: But you were aware by         13       2010, based on the AZT decision, or your briefings         14       of Canadian law that the Canadian courts were not         15       going to look to evidence post filing of the         16       application but were going to require that utility         17       be established at the date of the application,         18       correct? You were aware of that by 2010, right?         19       MR. ARMITAGE: Again, I had a general         10       awareness of what was going on in Canada at that         11       point. I'm not going to be able	387 10:05	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	unprecedented. MR. SPELLISCY: Give me one second. I thank you, Mr. Armitage, for your time this morning. I don't have any other questions. THE PRESIDENT: Ms. Cheek, any directions for redirect? MS. CHEEK: Mr. President, I have no questions for Mr. Armitage. Thank you. QUESTIONS BY THE ARBITRAL TRIBUNAL SIR DANIEL BETHLEHAM: Mr. Armitage, my name is Daniel Bethlehem. I have a number of questions. Forgive the questions, they may seem simplistic to you. I'm just trying to clarify things in my own mind from your evidence. You indicated in your testimony that olanzapine was one of a compound in a genus that was protected in the '687 patent. Is that correct? MR. ARMITAGE: I think that's largely correct. The way chemical patenting works is that all chemical compounds are characterized by individual chemical structures, and so what I understand Lilly did in the earlier patent was draw a structure that was more general in nature so that if you filled in the various blanks as to what that structure might have been, you could have arrived at www.dianaburden.com	<b>388</b> 10:06

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<ul> <li>olanzapine. So it was what's called a genus patent.</li> <li>The fact of the matter is that olanzapine could</li> <li>still be novel and patentable, which it was, novel</li> <li>and non-obvious even in Canada, for example, because</li> <li>it had the ability to frankly be clinically useful</li> <li>in ways other members of the genus were not.</li> <li>SIR DANIEL BETHLEHAM: I suppose what I'm</li> <li>trying to understand is that after the '687 patent</li> <li>was issued, my understanding from the testimony and</li> <li>from the documents to which we've been taken was</li> <li>that olanzapine was being marketed as a medicine</li> <li>known as Zyprexa. Is that correct?</li> <li>MR. ARMITAGE: Right. And so after</li> <li>olanzapine had been first synthesized, it was</li> <li>clinically developed and then ultimately put on the</li> <li>market I think somewhere in the mid to late 1990s.</li> <li>SIR DANIEL BETHLEHAM: So there was the</li> <li>original '687 patent, the genus patent, but then</li> <li>subsequently through development by Lilly,</li> <li>olanzapine was marketed as a medicine known as</li> <li>Zyprexa?</li> <li>MR. ARMITAGE: That's correct. After the</li> <li>Canadian patent had issued on the genus, olanzapine</li> <li>was actually made for the first time in a laboratory</li> <li>so it could be tested, and based on that testing,</li> </ul>	A successful the state of a second	<b>390</b> .0:09
1       it simply seeking regulatory approval? What further         2       development was required? My understanding was that         3       the drug was already being marketed.         4       MR. ARNITAGE: No, I don't think that's         5       the case. So I think olanzapine was synthesized in         6       rough-rough 1982, so it was a laboratory chemical.         7       Then there were animal studies and then human         8       studies and finally large-scale human studies. So I         9       think by about 1997, or thereabouts, Lilly was able         10       to file for regulatory approval. So the very first         11       regulatory approval of olanzapine came maybe         12       15 years after it was first synthesized and was, I         13       believe, for the treatment of schizophrenia. So         14       that olanzapine patent that we're talking about         15       that's at issue here is the Canadian patent on the         16       molecule and then protected that molecule from         17       SIR DANIEL BETHLEHAM: Thank you. I was         18       obviously misunderstanding the chronology of it, but         17       that's helpful to know.         18       You testified about the economic value of         19       patents in the context of the acqui		<b>392</b> .0:12

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<ul> <li>number of times the word "synthesized." So you</li> <li>synthesized out of the generic patent this specific</li> <li>patent or selection patent, as I understand it to be</li> <li>called. What is the process of synthesizing in your</li> <li>business?</li> <li>MR. ARMITAGE: I apologize for that</li> <li>because</li> <li>THE PRESIDENT: No, no. It's fine. We</li> <li>all have our own internal language.</li> <li>MR. ARMITAGE: It's a term of art chemists</li> <li>use. Basically they used to have chalkboards in</li> <li>their offices and they'd say I wonder if we can make</li> <li>a compound with this structure, I believe it could</li> <li>be a good medicinal compound. And they'll sit down</li> <li>and try to figure out a route to make it from</li> <li>simpler chemicals. So they'll take starting</li> <li>material chemicals, they'll run chemical reactions,</li> <li>and they'll be able to actually brew up this</li> <li>molecule that had never been made before.</li> <li>In this case in 1982, the world had never</li> <li>seen the molecule olanzapine until it was first</li> <li>synthesized, usually in small quantities. Then the</li> <li>synthesis is scaled up so you can do the testing and</li> <li>ultimately be able to formulate it as a medicine.</li> <li>THE PRESIDENT: Thank you. My second</li> </ul>	10:13	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>question concerns you had testified slightly earlier about Health Canada, that saying that the drug was safe. You remember that testimony?</li> <li>MR. ARMITAGE: Safe and effective, yes. THE PRESIDENT: Safe and effective. And then in almost the same sentence you said and therefore it was useful.</li> <li>MR. ARMITAGE: That's correct. THE PRESIDENT: So is it your testimony that once Health Canada has given this approval, if we may call it that way, safe and effective, that it is therefore also useful in the terms of Section 2 of the Patent Act?</li> <li>MR. ARMITAGE: Right. And so you can look at a regulatory approval for a medicine as sufficient to demonstrate it's useful but not necessary to demonstrate it's useful, and so usefulness, particularly in the international way in which that term utility is used, generally refers to some practical real-world value. And largely for many medicines for olanzapine, for example, as soon as we did the initial pharmacology testing, we knew the compound was useful. It had useful pharmacological properties. We could typically go ahead and seek a patent on that basis.</li> </ul>	10:14
1       But once you know a drug is safe and         2       effective in humans, it's hard to say that in a         3       patent sense, the drug can't even be useful.         4       THE PRESIDENT: Any followup questions?         5       Ms. Cheek?         6       MS. CHEEK: I have no followup questions,         7       Mr. President.         8       THE PRESIDENT: From matters arising from         9       the questions of the Tribunal.         10       MR. SPELLISCY: Nothing from Respondent.         11       THE PRESIDENT: Thank you, Mr. Armitage,         16       row excused and released as         18       witness.         14       We will have a recess until 10:30.         15       (Recess taken)         16       PETER GEORGE STRINGER         17       THE PRESIDENT: Good morning,         18       Mr. Stringer. Could you please state your full name         19       for the record?         20       MR. STRINGER: Peter George Stringer.         21       THE PRESIDENT: Mr. Stringer, you appear         23       a fact witness for the Claimant?         23       MR. STRINGER: Yes.         24       THE PRESIDENT: If any question is         25       u	<b>395</b> 10:15	3 4 5 6 7 8 9 10 11 2 3 4 15 16 7 8 9 10 11 22 23 24	reason, please do seek a clarification, because if you don't do so, the Tribunal assumes that you've understood the question and that your answer corresponds to the question. MR. STRINGER: Thanks for the warning! THE PRESIDENT: You will appreciate that testifying before a court or an arbitral tribunal is a very serious matter. In that connection the Tribunal expects you to make the declaration, the text of which is in front of you. MR. STRINGER: I solemnly declare upon my honor and conscience that I shall speak the truth, the whole truth, and nothing but the truth. THE PRESIDENT: Can you go to your witness statement which is dated September 25, 2014 and go to page 7? Could you confirm for the record that the signature appearing above your name is your signature? MR. STRINGER: Yes. I confirm. THE PRESIDENT: Is there any correction you wish to make to your witness statement? MR. STRINGER: No. THE PRESIDENT: Thank you. MR. BERENGAUT: Mr. President, we have no questions at this time. www.dianaburden.com	<b>396</b> 10:31



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<ul> <li>the initial patent was filed. Is that right?</li> <li>MR. STRINGER: Yes.</li> <li>MR. SPELLISCY: So throughout your career,</li> <li>then, you have been advising Eli Lilly on the</li> <li>filings of patents in Canada, correct?</li> <li>MR. STRINGER: Until 1999.</li> <li>MR. SPELLISCY: And after 1999, you</li> <li>remained the executive director of international</li> <li>patents, or you were there until 1999, correct? It</li> <li>says you remained in that position until 2006,</li> <li>doesn't it?</li> <li>MR. STRINGER: Yes, but the Foreign Patent</li> <li>Committee ceased to exist as such in 1999, so in the</li> <li>period from 1999 to 2006, I did not I no longer</li> <li>had direct responsibility for the filing of foreign</li> <li>patent applications. That's what I was trying to</li> <li>say.</li> <li>MR. STRINGER: Yes.</li> <li>MR. SPELLISCY: I see. But you were still</li> <li>the executive director of International Patents,</li> <li>right?</li> <li>MR. SPELLISCY: And so you were, even</li> <li>though outside of the Foreign Patent Committee, you</li> <li>were advising Lilly on the filing of patents</li> <li>internationally?</li> </ul>		6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. STRINGER: I think my role had changed somewhat. I think I was you know, I may have been consulted, but in terms of the Foreign Patent Committee, there was no longer a Foreign Patent Committee. So I'm struggling with your question. I'm sorry. Could you tell me what you want me to say? MR. SPELLISCY: I'm just trying to understand what your role was at Eli Lilly after 1999 when you were promoted to be executive director of International Patents. I had understood that you continued to advise in that period Eli Lilly on the filing of patents around the world. Is that not correct? MR. STRINGER: It's correct to some extent but not to the same extent as when I was chair of the Foreign Patent Committee. I spent a lot more time on litigation, foreign patent litigation, after 1999. My major focus was specific targets in the international area. We had a very serious challenge in connection with one of our products, and I was very heavily involved in that patent litigation. MR. STRINGER: Started about 1999. MR. SPELLISCY: When did that start? MR. STRINGER: Started about 1999. MR. SPELLISCY: Was that challenge in www.dianaburden.com	
1       Canada?         2       MR. STRINGER: It was a challenge in         3       Canada, actually, but we didn't we settled.         4       MR. SPELLISCY: Turn to Paragraph 27 of         5       your witness statement, Mr. Stringer, because I want         6       to understand something before we proceed on too         7       many questions.         8       You say, "A routine part of my job at         9       Lilly (and part of my role on the Foreign Patent         0       Committee) was to advise research and development         1       groups, and senior management, as to the prospects         2       of obtaining valid international patent protection.         1       was familiar with patent laws around the world,         1       including Canada." Then you go on to say "In the         1       1990s and early 2000s, I do not remember any         2       concerns vis-à-vis Canada's patent utility         7       requirements."         8       I guess I'm just trying to put some time         9       around that. So when you say the early 2000s, you         were just testifying that you were no longer         advising Lilly primarily on obtaining international         patents in the early 2000s. Or am I         misunderstanding?	<b>403</b> 10:40	2 3 4 5 6 7 8 9 10 11 12 13 14 15 6 7 18 9 20 21 22	decision, I didn't have the same role after 1999. But yes, I mean, I was the person at Lilly who was consulted on international patent matters. MR. SPELLISCY: So you were the person, then, at Lilly whose job it was up until 2006 to advise research and development groups and senior management as to the prospects of obtaining valid international patent protection outside of the U.S. That was your role in the 2006? MR. STRINGER: I wouldn't say I was "the" person, but it certainly was part of my responsibilities, yes. MR. SPELLISCY: I want to come back to the Foreign Patent Committee for a second. If you look at Paragraph 5 of your witness statement, you say that it was made up of heads of the various scientific research groups and senior patent personnel in the second sentence there. Do you see that? MR. STRINGER: Yes. MR. SPELLISCY: The Foreign Patent Committee did not include any patent lawyers from Canada, correct? MR. STRINGER: No.	<b>404</b> 10:42

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1	agents, correct?	10:43	1	MR. STRINGER: That's correct.	10:44
2	MR. STRINGER: That's correct.		2	MR. SPELLISCY: I want to turn to Tab	
3	MR. SPELLISCY: In Paragraph 10 of your		3	No. 1 in front of you in the book sorry, in the	
4	witness statement you write "As the Chair of the		4	binder. I think the legal profession keeps the	
5	Committee, it was ultimately my decision how widely		5	binder industry in business. Turn to Tab No. 1	
6	to file patent applications," in the first sentence.		6	there. This is Exhibit R-011, for the record.	
7	Do you see that?		7	MR. STRINGER: Okay.	
8	MR. STRINGER: Yes.		8	MR. SPELLISCY: It's a decision of the	
9	MR. SPELLISCY: You never went to a		9	Supreme Court of Canada in the case called	
10	Canadian law school, correct?		10	Consolboard v MacMillan Bloedel issued in 1981. Do	
11	MR. STRINGER: That's correct.		11	you see that?	
12	MR. SPELLISCY: You are not and have never		12	MR. STRINGER: Yes.	
13	been admitted to Canadian practice as lawyer in		13	MR. SPELLISCY: This decision was released	
14	Canada, right?		14	when you were a foreign patent agent for Eli Lilly	
15	<b>MR. STRINGER:</b> That's correct.		15	in the United States, correct?	
16	<b>MR. SPELLISCY:</b> You are not and have never		16	<b>MR. STRINGER:</b> Foreign patent advisor.	
17	been a Canadian patent attorney?		17	MR. SPELLISCY: Yes. Sorry. The other	
18	MR. STRINGER: Correct.		18	"A".	
19	MR. SPELLISCY: We just went to paragraph		19	MR. STRINGER: 1981, yes, I see it was.	
20	27 of your witness statement and we saw you said		20	MR. SPELLISCY: Do you recall being	
21	that "I was familiar with patent laws around the		21	briefed on this decision?	
22	•		22	MR. STRINGER: I don't think I ever have	
	world including Canada", so I take it, then, that				
23	you were familiar with Canadian law because you		23	been briefed on this, no.	
24	would receive briefings and advice from qualified		24	MR. SPELLISCY: You don't recall being	
25	Canadian lawyers, correct?		25	briefed on the decision when you were the chair of	
	www.dianaburden.com			www.dianaburden.com	
1 2 3 4 5 6 7 8 9 10 11 12	the Foreign Patent Committee from the 1980s to the 1990s? MR. STRINGER: I don't think I've heard of this case, but I don't think that you know, I don't remember, is the simple answer. MR. SPELLISCY: So you don't remember if you considered this case when, as the chair of the Foreign Patent Committee, you made the ultimate decision to file for a Canadian patent for olanzapine in 1991? MR. STRINGER: I just don't remember, no. MR. SPELLISCY: Just for the record, you	10:46	1 2 3 4 5 6 7 8 9 10 11 12	your binder now, which is, for the record, R-401. This is a decision of the Federal Court of Appeal in a case called Apotex v Wellcome Foundation, which was issued February 1, 1995. Are you there with me? MR. STRINGER: I'm sorry, I'm looking at the wrong one. Excuse me. MR. SPELLISCY: Tab 3. MR. STRINGER: Tab 3. Could you repeat that, please? MR. SPELLISCY: It's a case titled Apotex Inc. v Wellcome Foundation Ltd. et al. You can see it's issued February 1, 1995 in the italics right	10:47
13	don't recall that you were aware of this case when		12	above the first bold paragraph there.	
14	you made the ultimate decision to file for the		14	MR. STRINGER: I see, yes. Sorry.	
15	Canadian patent for atomoxetine on July 12, 1995.		15	MR. SPELLISCY: That's okay.	
16	Is that right?		16	So do you recall being briefed on this	
17	MR. STRINGER: I just don't remember.		17	decision while you were the chair of the Foreign	
18			18	Patent Committee?	
	What's troubling me is I do remember the case but,		10 19		
19	you know, I can't answer your specific questions.			MR. STRINGER: This 1995 decision?	
20	MR. SPELLISCY: But you don't recall if		20	MR. SPELLISCY: Yes.	
21	you remember the case from before or after you filed		21	MR. STRINGER: No.	
22	the patents for olanzapine and atomoxetine. Is that		22	MR. SPELLISCY: Have you seen this	
22 23	the patents for olanzapine and atomoxetine. Is that right?		23	decision before?	
22 23 24	the patents for olanzapine and atomoxetine. Is that right? MR. STRINGER: I don't recall.		23 24	decision before? MR. STRINGER: No.	
22 23	the patents for olanzapine and atomoxetine. Is that right?		23	decision before?	

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<ul> <li>February 1, 1995. In your witness statement I</li> <li>believe you attached the Foreign Patent Committee</li> <li>minutes as Appendix 2 to your witness statement,</li> <li>which was where the decision was made by the Foreign</li> <li>Patent Committee to file for the Strattera patent.</li> <li>It's also Exhibit C-89, but it is Appendix 2 to the</li> <li>witness statement. These are dated July 12, 1995,</li> <li>correct?</li> <li>MR. STRINGER: Yes. I'm sorry, yes.</li> <li>MR. SPELLISCY: So this Federal Court of</li> <li>Appeal decision was issued February 1, 1995, six</li> <li>months, five months before Eli Lilly applied for its</li> <li>patent that we just looked at, and you don't recall</li> <li>ever being briefed on this decision?</li> <li>MR. STRINGER: On this decision, no.</li> <li>MR. SPELLISCY: You say in Paragraph 8 of</li> <li>your witness statement, the first sentence, "Part of</li> <li>my responsibilities as chair of the Foreign Patent</li> <li>Committee was to monitor changes in patent law in</li> <li>the many national jurisdictions in which Lilly</li> <li>operated." Do you see that?</li> <li>MR. SPELLISCY: So I understand, then,</li> <li>that if there were significant and dramatic changes</li> <li>in the way Canada in the law in Canada, it would</li> </ul>	<b>409</b> 10:49	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	have been your responsibility to understand those changes and to brief senior Eli Lilly management on them, correct? MR. STRINGER: Yes. I mean, the expectation would be that our local patent attorney would advise us as to an important change in the law. MR. SPELLISCY: Right. Then you, in turn, would advise, as you said in Paragraph 27 of your witness statement, you would advise the research and development groups and senior management on those changes, correct? MR. STRINGER: Yes. MR. SPELLISCY: Let's turn to Tab No. 5 in your binder, which is R-004 for the record. It is the decision of the Supreme Court in 2002 in Apotex v Wellcome, another Apotex v Wellcome case. This one is commonly known as the AZT decision. Are you familiar with this decision? MR. STRINGER: Yes. MR. SPELLISCY: You were the executive director at International Patents at Lilly at the time, correct? MR. STRINGER: Correct. MR. SPELLISCY: In your witness statement www.dianaburden.com	410 10:51
1       you don't mention this decision, correct?         2       MR. STRINGER: I don't think so.         3       MR. SPELLISCY: I'd like to turn to what's         4       Tab No. 11 in your binder, which is a demonstrative         5       that we have prepared which lists in chronological         6       order all of the exhibits that Eli Lilly has         7       submitted in this arbitration. I'd like to go to         8       the bottom of page 14 here. In the very last line         9       you'll see a reference to the December 5, 2002         10       Apotex v Wellcome decision we were just looking at.         11       t was exhibited by the Claimant at C-213. It's the         12       same exhibit we looked at, just a different exhibit         13       number.         14       I want you to look at the next page,         15       page 15. You would agree with me, looking at this         16       list, that there is no evidence in the record of you         17       being briefed by Canadian counsel on this decision,         18       MR. SPELLISCY: I bink that the witness         19       MR. SPELLISCY: I think that the witness         10       MR. SPELLISCY: I think that the witness         11       MR. SPELLISCY: I think that the witness         12	<b>411</b> 10:52	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	briefings are in that record. THE PRESIDENT: You have already covered that area sufficiently, but he is not familiar with reviewing this index. MR. SPELLISCY: Do you recall, Mr. Stringer, briefing on this issue, on this decision, to senior management? MR. STRINGER: Do I recall excuse me. Do I recall briefing senior management? MR. SPELLISCY: Yes. MR. SPELLISCY: Yes. MR. SPELLISCY: You were the executive director still until 2006. In 2005 the Claimant has alleged there was a change, another dramatic change , in Canadian patent law. Do you recall providing any briefings to Eli Lilly senior management in 2005 as your role of executive director of International Patents on those changes? MR. STRINGER: No. MR. SPELLISCY: Let's move on. I want to turn to the process of Eli Lilly's Foreign Patent Committee itself and understand that a little bit more. MR. STRINGER: Are you finished with this? MR. SPELLISCY: Not wholly, but for now. www.dianaburden.com	<b>412</b> 10:54

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1You have annexed the Committee decisions2on atomoxetine and olanzapine to your statement, but3I also think that you explain in Paragraph 10 that4the minutes reflect really the decisions of the5Foreign Patent Committee, not the entirety of the6deliberations, correct?7MR. STRINGER: I'm sorry, could you repeat8that, please?9MR. SPELLISCY: I'm referencing the10appendices that you attached to your witness11statement, which are you say the minutes of the12Foreign Patent Committee meetings that approved the13foreign patent filings for atomoxetine and14olanzapine.15In Paragraph 10 in the last sentence of16your witness statement, you said, "The minutes of17our meetings tended to be short, simply recording18the outcome of our deliberations." Do you see that?19MR. STRINGER: Yes.20MR. STRINGER: That's correct.21MR. STRINGER: That's correct.22MR. SPELLISCY: The Foreign Patent23Committee did not draft the patents itself, right?www.dianaburden.com	1       MR. STRINGER: No.         2       MR. SPELLISCY: So as I understand it from         3       the first sentence in Paragraph 6 of your witness         4       statement, it was only after initial patent         5       statement, it was only after initial patent         6       the Foreign Patent Committee, correct?         7       MR. STRINGER: That's correct.         8       MR. SPELLISCY: In that same paragraph you         9       say in the second sentence that "Lilly drafted         0       patent applications with the goal of utilizing a         1       single patent description (sometimes referred to as         2       the disclosure) for use worldwide." Do you see         3       that?         4       MR. STRINGER: Whereabouts is that?         5       Sorry. Hang on, I'm sorry. Yes.         6       MR. SPELLISCY: The second sentence. Do         7       you see that?         8       MR. STRINGER: Yes.         9       MR. SPELLISCY: To confirm, my         10       understanding is Eli Lilly took that approach         11       because it was looking for the most efficient way to         12       file its applications worldwide. Isn't that right?         13       MR. STRINGER: Yes.	414
		<b>416</b> 10:59

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<ul> <li>countries, they would give you only a very short</li> <li>patent term, 15 years from filing, and the patents</li> <li>would be limited to processes. So we would not file</li> <li>there. So that's really what I'm talking about</li> <li>here, allowability of the types of invention.</li> <li>MR. SPELLISCY: And, to your knowledge,</li> <li>Eli Lilly filed patents for pharmaceutical products</li> <li>in Canada all the way up through when you retired in</li> <li>2006, correct?</li> <li>MR. SPELLISCY: One last set of questions</li> <li>here, and we may avoid going back to the binder at</li> <li>all.</li> <li>You state in Paragraph 6 of your witness</li> <li>statement in the last sentence on the page, I guess</li> <li>about four lines from the bottom, that it was only</li> <li>in the "later years" that Eli Lilly began using the</li> <li>PCT to file patent applications.</li> <li>MR. STRINGER: Yes. What happened was</li> <li>that in the early days of the PCT, Lilly didn't file</li> <li>through the PCT. We carried on we were concerned</li> <li>www.dianaburden.com</li> </ul>		t shout look of flouibility. Dut by 1005 Likink we	418
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onfider	แล	421		Washington	422 A
1 th	nank you.	11:08	1	MR. POSTLETHWAIT: Yes.	11:10
2	THE PRESIDENT: Then we will proceed with		2	MS. ZEMAN: Then you spent a bit of time	
	ne cross-examination.		3	in Indianapolis and in Italy?	
4	CROSS-EXAMINATION ON BEHALF OF THE RESPONDENT		4	MR. POSTLETHWAIT: Yes.	
5	MS. ZEMAN: Good morning,		5	MS. ZEMAN: In 1983 you were promoted to	
	Ir. Postlethwait. My name is Krista Zeman and I am		6	general manager of the Lilly affiliate in Argentina?	
	ounsel for Canada in this arbitration. A few		7	MR. POSTLETHWAIT: Yes.	
8 q	uestions for you this morning just to make sure		8	<b>MS. ZEMAN:</b> There you were responsible for	
	nat I understand a few aspects of your testimony.		9	all of Lilly's Argentina-based operations?	
	is very important that we understand each other,		10	MR. POSTLETHWAIT: Yes.	
	o if there's any question that I have that you		11	MS. ZEMAN: And you spent a substantial	
	on't understand, by all means let me know and I		12	portion of your time dealing with issues raised by	
	ill do my best to repeat it.		13	weak or uncertain patent protections in Argentina.	
4	MR. POSTLETHWAIT: Okay.		14	Is that right?	
5	MS. ZEMAN: I'd like to start by talking a		15	MR. POSTLETHWAIT: Could you the first	
16 bi	it about your background with Lilly. You started		16	part of your question. What was the first part of	
	rith the company in 1970. Is that right?		17	your question?	
18	MR. POSTLETHWAIT: Yes.		18	MS. ZEMAN: Yes. You spent a substantial	
19	MS. ZEMAN: As a staff engineer?		19	portion of your time dealing with issues raised by	
20	MR. POSTLETHWAIT: Yes.		20	weak or uncertain patent protection?	
21	MS. ZEMAN: Then you moved to Brazil in		21	MR. POSTLETHWAIT: I'm not sure that	
	974?		22	"substantial portion of my time" is applicable. I	
23	MR. POSTLETHWAIT: Yes.		23	did spend time on patents, but a substantial portion	
24	MS. ZEMAN: And you held various positions		24	of my time, I don't	
25 th	nere?		25	MS. ZEMAN: I was referring to	
	www.dianaburden.com			www.dianaburden.com	
1 0	arograph 01 of your statement where in the	423	4		424
	aragraph 21 of your statement where in the	<b>423</b>	1	MR. POSTLETHWAIT: Yes.	<b>424</b>
2 р	enultimate sentence there you say, "When I was the		2	MS. ZEMAN: And then you returned to	
2 p 3 g	enultimate sentence there you say, "When I was the eneral manager of Lilly's affiliates in Argentina		2 3	MS. ZEMAN: And then you returned to Indianapolis in 1988?	
2 p 3 g 4 a	enultimate sentence there you say, "When I was the eneral manager of Lilly's affiliates in Argentina nd Brazil, for example, I spent a substantial		2 3 4	MS. ZEMAN: And then you returned to Indianapolis in 1988? MR. POSTLETHWAIT: Yes.	
2 p 3 g 4 a 5 p	enultimate sentence there you say, "When I was the eneral manager of Lilly's affiliates in Argentina nd Brazil, for example, I spent a substantial ortion of my time dealing with issues raised by		2 3 4 5	MS. ZEMAN: And then you returned to Indianapolis in 1988? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And in 1994, you became	
2 p 3 g 4 a 5 p 6 th	enultimate sentence there you say, "When I was the eneral manager of Lilly's affiliates in Argentina nd Brazil, for example, I spent a substantial ortion of my time dealing with issues raised by nose countries' patent systems."		2 3 4 5 6	MS. ZEMAN: And then you returned to Indianapolis in 1988? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And in 1994, you became president of the Neuroscience Product Group. Is	
2 p 3 g 4 a 5 p 6 th 7	enultimate sentence there you say, "When I was the eneral manager of Lilly's affiliates in Argentina nd Brazil, for example, I spent a substantial ortion of my time dealing with issues raised by nose countries' patent systems." MR. POSTLETHWAIT: Okay. Yes. That's		2 3 4 5 6 7	MS. ZEMAN: And then you returned to Indianapolis in 1988? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And in 1994, you became president of the Neuroscience Product Group. Is that right?	
2 p 3 g 4 a 5 p 6 th 7 8 c	enultimate sentence there you say, "When I was the eneral manager of Lilly's affiliates in Argentina nd Brazil, for example, I spent a substantial ortion of my time dealing with issues raised by nose countries' patent systems." MR. POSTLETHWAIT: Okay. Yes. That's orrect. But there was balance I was running the		2 3 4 5 6 7 8	MS. ZEMAN: And then you returned to Indianapolis in 1988? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And in 1994, you became president of the Neuroscience Product Group. Is that right? MR. POSTLETHWAIT: That's correct.	
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2 pp 9 g 4 a pp 5 th 7 cr 8 a sp 6 th 7 a 9 sp 1 a 9 d 5 d 7 8 in 9 9	enultimate sentence there you say, "When I was the eneral manager of Lilly's affiliates in Argentina nd Brazil, for example, I spent a substantial ortion of my time dealing with issues raised by nose countries' patent systems." MR. POSTLETHWAIT: Okay. Yes. That's orrect. But there was balance I was running the ffiliate and so there was time, and important time, pent on patents, intellectual property. MS. ZEMAN: And Lilly closed its Argentina ffiliate in 1985. Is that right? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And inadequate patent rotection there was an important part of the ecision to close? MR. POSTLETHWAIT: Yes, it was an nportant part over there. MS. ZEMAN: After the Argentina affiliate		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	MS. ZEMAN: And then you returned to Indianapolis in 1988? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And in 1994, you became president of the Neuroscience Product Group. Is that right? MR. POSTLETHWAIT: That's correct. MS. ZEMAN: You held that position until you retired in 1999? MR. POSTLETHWAIT: Yes. MS. ZEMAN: I'd like to make sure that I understand the scope of your responsibilities as president of the Neuroscience Product Group. In that role you were responsible for planning and oversight of all of Lilly's neuroscience products? MR. POSTLETHWAIT: That is correct. MS. ZEMAN: Including Zyprexa? MR. POSTLETHWAIT: Including Zyprexa.	
2 pp 3 gg 4 a pf 5 ff 7 ca 5 ff 7 ca 9 a sp 0 sp 1 a 5 d 7 s 1 a 9 w 9 w	enultimate sentence there you say, "When I was the eneral manager of Lilly's affiliates in Argentina nd Brazil, for example, I spent a substantial ortion of my time dealing with issues raised by nose countries' patent systems." MR. POSTLETHWAIT: Okay. Yes. That's orrect. But there was balance I was running the ffiliate and so there was time, and important time, pent on patents, intellectual property. MS. ZEMAN: And Lilly closed its Argentina ffiliate in 1985. Is that right? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And inadequate patent rotection there was an important part of the ecision to close? MR. POSTLETHWAIT: Yes, it was an nportant part over there. MS. ZEMAN: After the Argentina affiliate vas closed, you moved back to Brazil to take the		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	MS. ZEMAN: And then you returned to Indianapolis in 1988? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And in 1994, you became president of the Neuroscience Product Group. Is that right? MR. POSTLETHWAIT: That's correct. MS. ZEMAN: You held that position until you retired in 1999? MR. POSTLETHWAIT: Yes. MS. ZEMAN: I'd like to make sure that I understand the scope of your responsibilities as president of the Neuroscience Product Group. In that role you were responsible for planning and oversight of all of Lilly's neuroscience products? MR. POSTLETHWAIT: That is correct. MS. ZEMAN: Including Zyprexa? MR. POSTLETHWAIT: Including Zyprexa. MS. ZEMAN: And part of that planning and	
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MS. ZEMAN: And as part of your plan for         launch and marketing and sales, an important part of         that plan was to ensure that your products were         appropriately protected by patents. Is that right?         MR. POSTLETHWAIT: That is correct.         MS. ZEMAN: And strong patent protection         was an important part of deciding where to launch         your products. Is that right?         MR. POSTLETHWAIT: Yes.         MS. ZEMAN: And you were particularly         attuned to patent issues because of your previous         experiences in Argentina and Brazil?         MR. POSTLETHWAIT: I was sensitive to         those issues, yes.         MS. ZEMAN: As the person with ultimate         oversight of the product launch, you were familiar         with the patent law systems of all the countries         where you would launch?         MR. POSTLETHWAIT: I was familiar with         them, yes. Not being a patent lawyer, of course, I         was not in-depth aware of those.         MS. ZEMAN: You had some general         familiarity?         MR. POSTLETHWAIT: Familiarity, yes.         MS. ZEMAN: Including in Canada?         www.dianaburden.com	11:12	$\begin{array}{c}1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\23\\14\\15\\16\\7\\18\\9\\0\\21\\22\\3\\4\\25\end{array}$	MR. POSTLETHWAIT: Including in Canada. MS. ZEMAN: And you worked closely with Lilly's legal team for this aspect of the product launch. Is that right? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And you expected them to monitor changes in the patent systems of launch countries? MR. POSTLETHWAIT: Yes. MS. ZEMAN: Including in Canada? MR. POSTLETHWAIT: Yes. MS. ZEMAN: Including in Canada? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And you expected them to keep informed about decisions of the Supreme Court of Canada related to patents? MR. POSTLETHWAIT: That's a bit specific. I did presume that they would be totally informed and very competent in this space and be attuned to any material changes, yes. MS. ZEMAN: And you expected your legal team to raise with you any issues they identified that might affect the products in your portfolio? MR. POSTLETHWAIT: Yes. MS. ZEMAN: For example, if Canada or another launch country changed its patent framework in a way that made it more difficult to protect your www.dianaburden.com	11:13
1       products, you expected to be informed about that?         2       MR. POSTLETHWAIT: Yes, I would have         3       expected that.         4       MS. ZEMAN: And if Canada or another         5       launch country fundamentally changed its approach to         6       a major patentability criterion, you expected to be         7       informed about that?         8       MR. POSTLETHWAIT: Your question is         9       regarding subsequent to filing of the patent, or         10       what?         11       MS. ZEMAN: Or during patent prosecution.         12       At both stages.         13       MR. POSTLETHWAIT: Yes, I would.         14       MS. ZEMAN: So I'd like to spend a bit of         15       time discussing Zyprexa specifically. The chemical         16       name of Zyprexa is olanzapine. Is that right?         17       MR. POSTLETHWAIT: Yes.         18       MS. ZEMAN: It is an anti-psychotic         19       medicine?         20       MR. POSTLETHWAIT: Yes.         21       MS. ZEMAN: For the treatment of         22       MR. POSTLETHWAIT: Yes.         23       MR. POSTLETHWAIT: Yes.         24       MS. ZEMAN: At Paragraph 19 of your	<b>427</b> 11:14	15 16 17 18 19 20 21 22	applied for was a selection patent. Is that right? MR. POSTLETHWAIT: Yes. MS. ZEMAN: I'd like to make sure I understand what that means. So olanzapine was part of a broader class of compounds. Is that right? MR. POSTLETHWAIT: Yes. Once again, I'm not a patent lawyer, but I know that olanzapine emerged from what was called a genus. MS. ZEMAN: And that genus had, as you say here, potential use in the treatment of central nervous system disorders? MR. POSTLETHWAIT: Yes. MS. ZEMAN: And Lilly held a patent in Canada for that broader class of compounds, is that right? MR. ARMITAGE: I believe that was the case, yes. MS. ZEMAN: That was the '687 patent in Canada? MR. POSTLETHWAIT: I'm not familiar with the number, but MS. ZEMAN: But it was granted in 1980? Does that sound about right? MR. POSTLETHWAIT: Yes. MS. ZEMAN: In Tab 1 of the binder with www.dianaburden.com	<b>428</b> 11:15

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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 3 24 25	<ul> <li>the red cover there is Exhibit R-292 for the record. This is Canadian patent '687. That was issued in 1980, you can see there on the right.</li> <li>At page 21 of the patent in line 13, which is about the middle of the page, the disclosure in this patent says, "As stated previously, the compounds of the invention have useful central nervous system activity." You see that?</li> <li>MR. POSTLETHWAIT: Yes.</li> <li>MS. ZEMAN: Then it discusses extensive testing in animal models. At the end it says, "These properties, coupled with their high therapeutic index, render them useful in the treatment of mild anxiety states and certain kinds of psychotic conditions such as schizophrenia and acute mania." You see that?</li> <li>MR. POSTLETHWAIT: Yes.</li> <li>MS. ZEMAN: So this disclosure is for the broader class of compounds in the genus. Is that ight?</li> <li>MR. POSTLETHWAIT: You're asking me questions that I think are for patent lawyers. Could you ask the question to me again to make sure lunderstand?</li> <li>MS. ZEMAN: This disclosure, if we take</li> <li>www.dianaburden.com</li> </ul>	<b>429</b> 11:16	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	<ul> <li>that the '687 patent is the patent number of the genus of compounds of which olanzapine is a part, is saying here that the general class has properties that render them useful in the treatment of mild anxiety states and certain kinds of psychotic conditions such as schizophrenia.</li> <li>MR. POSTLETHWAIT: And your question? MS. ZEMAN: My question is is that correct?</li> <li>MR. POSTLETHWAIT: Is that correct what the</li> <li>MS. ZEMAN: What this is saying</li> <li>MR. POSTLETHWAIT: Yes, that's correct.</li> <li>I'm sorry.</li> <li>MS. ZEMAN: The olanzapine selection patent application was filed in Canada in 1991. Is that correct?</li> <li>MR. POSTLETHWAIT: Yes.</li> <li>MS. ZEMAN: While the genus patent was still in effect?</li> <li>MR. POSTLETHWAIT: Yes.</li> <li>MS. ZEMAN: In your statement at Paragraph 29 you say in the second to last sentence that your patent attorneys had not flagged any issue with your Canadian patent application. Is that</li> </ul>	430
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	right? MR. POSTLETHWAIT: Yes. MS. ZEMAN: At Tab 2 of your binder is Exhibit C-64. This is a communication from applicant Lilly Industries Limited to the Canadian patent office. It's dated September 5, 1997. Do you see that? MR. POSTLETHWAIT: Yes. MS. ZEMAN: You were president of the Neuroscience Products Group at that time? MR. POSTLETHWAIT: Yes. MS. ZEMAN: The first sentence of the letter states that it is in reply to an official action dated April 1, 1997. You see that? MR. POSTLETHWAIT: Yes, I see that. MS. ZEMAN: In this communication on page 3 in the second to last paragraph Lilly asks for reconsideration of the examiner's rejection of the claims as being anticipated by the cited British patent specifications. Do you see that? MR. POSTLETHWAIT: I see that, yes. MS. ZEMAN: You were not informed that the patent office initially rejected the claims as being anticipated? MR. POSTLETHWAIT: I do not recall that I www.dianaburden.com	<b>431</b> 11:19	1 2 3 4 5 6 7 8 9 10 11 22 3 4 5 6 7 8 9 10 11 21 22 23 24 25	<ul> <li>was.</li> <li>MS. ZEMAN: Lilly states here in this paragraph that its claims are not anticipated because olanzapine is selected from the invention described in the other patent. Do you see that?</li> <li>MR. POSTLETHWAIT: I see that.</li> <li>MS. ZEMAN: And on page 4, in the second full paragraph yes, second full paragraph on that page in the middle Lilly says, "It is well settled in patent law that invention may be presented as a result of a new and useful selection among members of a broader close of substances." Do you see that?</li> <li>MR. POSTLETHWAIT: Yes.</li> <li>MS. ZEMAN: It is identifying the rules it views as applicable to selection patents?</li> <li>MR. POSTLETHWAIT: What</li> <li>MR. BERENGAUT: Objection.</li> <li>THE PRESIDENT: What's the objection?</li> <li>MR. BERENGAUT: There is no foundation in Mr. Postlethwait's statement for anything remotely qualifying him to answer a question about whether Lilly was here identifying the rules it believes are applicable to selection patents.</li> <li>THE PRESIDENT: Overruled.</li> <li>MS. ZEMAN: In the second sentence here in www.dianaburden.com</li> </ul>	<b>432</b> 11:20

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<ul> <li>2 invent</li> <li>3 memb</li> <li>4 partic</li> <li>5 may h</li> <li>6 purpo</li> <li>7 derive</li> <li>8 substance</li> <li>9 advar</li> <li>10</li> <li>11</li> <li>12</li> <li>13 paten</li> <li>14 special</li> <li>15 select</li> <li>16</li> <li>17</li> <li>18 saying</li> <li>19</li> <li>20 what in</li> <li>21</li> <li>22 that L</li> </ul>	ame paragraph Lilly states, "There may well be tion in the selection of one member (or a few pers) out of a number of substances for a ular purpose, even though others of this class have been used before, even perhaps for the same use, provided there is a special advantage to be ed from the use of the selected substance or ances and its selection constitutes a definite nee upon existing knowledge." You see that? MR. POSTLETHWAIT: I see that, yes. MS. ZEMAN: So to obtain a selection t in Canada, this is saying, there must be a al advantage to be derived from the use of the ted substance. MR. POSTLETHWAIT: Was that a question? MS. ZEMAN: Yes. That's what this is g? MR. POSTLETHWAIT: I don't know if that's it's saying. MS. ZEMAN: In this paragraph do you see illy is relying on Fox, Canadian Patent Law Practice, 4th Edition from 1969 as authority. MR. POSTLETHWAIT: Yes, I see that. MS. ZEMAN: Are you familiar with the www.dianaburden.com	<b>433</b> 11:22	1 2 3 4 5 6 7 8 9 10 11 25 21 22 23 24 25	Canadian patent lawyer scholar Fox? MR. POSTLETHWAIT: No. MS. ZEMAN: Lilly's agent MR. POSTLETHWAIT: Am I familiar with MS. ZEMAN: This is Lilly's agent representing to the Canadian patent office certain things, a response to an office action MR. POSTLETHWAIT: And your question is am I familiar with them? THE PRESIDENT: Wait. One at a time. Could you backtrack a little bit? First ask your question are you familiar with? MS. ZEMAN: The first question was are you familiar with the Canadian patent law scholar Fox? MR. POSTLETHWAIT: No. MS. ZEMAN: But it appears here that Lilly's patent agent in Canada was familiar with him. MR. POSTLETHWAIT: Is that a question or I don't understand if you're asking me a question or attesting to something that might appear logical or rational. I'm sorry. THE PRESIDENT: Ms. Zeman, could you ask a question, because if you state "But it appears here that Lilly's patent agent in Canada was familiar	<b>434</b> 11:23
<ul> <li>2 Pleas</li> <li>3 later.</li> <li>4</li> <li>5</li> <li>6 docur</li> <li>7 concluse</li> <li>8 paten</li> <li>9 invention</li> <li>10 exception</li> <li>11 from to exception</li> <li>12 adequities</li> <li>13 in the</li> <li>14</li> <li>15</li> <li>16</li> <li>17 this refine</li> <li>18</li> <li>19</li> <li>20 paten</li> <li>21 binde</li> <li>22 to flip</li> <li>23 numb</li> <li>24 have</li> </ul>	im" it's more argument than a question. e limit yourself to questions. Argument comes MS. ZEMAN: Okay. On page 6 one more question in this nent. In the first full paragraph Lilly's agent udes, "In applicant's view, therefore, tability of the compound of the present tion depends on proving that the compound has btional properties that could not be predicted the prior art, and this, it is believed, is uately established by evidence already included applicant's specification." You see that? MR. POSTLETHWAIT: I see that, yes. MS. ZEMAN: And you were not briefed on esponse to the Canadian patent office? MR. POSTLETHWAIT: Not to my recollection. MS. ZEMAN: Let's take a look at the t specification. It is at Tab 3 of your r. It is Exhibit R-030. On page 3 you have a couple of pages before they start being ered lines 17-19, the patent describes, "We now discovered a compound which possesses sing and unexpected properties by comparison www.dianaburden.com	<b>435</b> 11:24	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	<ul> <li>with flumezapine and other related compounds." Do you see that?</li> <li>MR. POSTLETHWAIT: I see that.</li> <li>MS. ZEMAN: Do you agree the word</li> <li>"surprising and unexpected properties" is the language of exceptional properties that cannot be predicted from the prior art?</li> <li>MR. BERENGAUT: Objection. Same objection. This is well outside the scope of Mr. Postlethwait's testimony, and now he's being asked to give an opinion about the technical patent language that's used in this particular patent.</li> <li>THE PRESIDENT: The questions should be limited to factual questions, not opinions. But what I understand the question to be is that it is limited to factual questions, whether he is familiar with this or not. So objection overruled.</li> <li>MS. ZEMAN: So my question was do you agree that "surprising and unexpected properties" is the language of exceptional properties that cannot be predicted from the prior art?</li> <li>MR. BERENGAUT: Same objection.</li> <li>MR. POSTLETHWAIT: I'm not a scientist, I can't</li> <li>THE PRESIDENT: First I have to rule on www.dianaburden.com</li> </ul>	<b>436</b> 11:25

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4 11	as abiastian. This time sustained because that is	437	4	them to be familiar with this	438
	ne objection. This time sustained, because that is	11:27	1	them to be familiar with this.	11:28
	n opinion question.		2	MS. ZEMAN: Thank you. I have no further	
3	MS. ZEMAN: You stated earlier that you		3	questions.	
4 e	xpected your patent attorneys to keep abreast of		4	THE PRESIDENT: That concludes your	
5 d	evelopments in Canadian patent law. Is that right?		5	cross-examination, Ms. Zeman? Thank you.	
6	MR. POSTLETHWAIT: Yes.		6	MR. BERENGAUT: No redirect.	
7	<b>MS. ZEMAN:</b> At Tab 4 of your binder is a		7	THE PRESIDENT: The Tribunal has no	
	ederal Court of Appeal decision from 1995, Exhibit		8	questions either. Thank you for testifying,	
	R-401, and it's dated February 1, 1995. You were		9	Mr. Postlethwait. You are now excused and released	
	ne president of the Neuroscience Product Group at		10	as a witness.	
	nis time?		11	MR. POSTLETHWAIT: Thank you.	
2	MR. POSTLETHWAIT: Yes.		12	<b>THE PRESIDENT:</b> Let's take 5 minutes and	
3	MS. ZEMAN: The olanzapine patent was in		13	you can reorganize.	
4 th	ne course of prosecution at this time?		14	(Recess taken)	
5	MR. POSTLETHWAIT: Is that a question?		15	ANNE NOBLES	
6 Y	es, I'm sorry.		16	THE PRESIDENT: Ms. Nobles, good morning.	
7	MS. ZEMAN: So you would have expected		17	MS. NOBLES: Good morning.	
	our patent attorneys to be aware of this decision?		18	THE PRESIDENT: Could you please state	
9	MR. POSTLETHWAIT: I'm sorry, the first		19	your full name for the record?	
	art of your question, did you say I did have or I		20	MS. NOBLES: Anne Nobles.	
	vould have expected, or what what was your		21	THE PRESIDENT: Ms. Nobles, you appear as	
	uestion?		22	a fact witness for the Claimant in this case?	
3	MS. ZEMAN: You would have expected your		23	MS. NOBLES: That's correct.	
4 р	atent attorneys to be familiar with this decision?		24	THE PRESIDENT: If any question is unclear	
5 <sup>'</sup>	MR. POSTLETHWAIT: I would have expected		25	to you, either because of language or for any other	
	www.dianaburden.com			www.dianaburden.com	
		420			440
1 rc	ason plasse do seek a clarification because if	439	1	NS NORIES: There is In Paragraph 21	
	eason, please do seek a clarification because, if	<b>439</b> 11:35	1	MS. NOBLES: There is. In Paragraph 21, I	
<u>2</u> y	ou don't do so, the Tribunal will assume that		2	mistakenly said that the Canadian patent application	
2 ye 3 ye	ou don't do so, the Tribunal will assume that ou've understood the question and that your answer		2 3	mistakenly said that the Canadian patent application was granted on December 1, 2002 when, in fact, it's	
2 yo 3 yo 1 co	ou don't do so, the Tribunal will assume that ou've understood the question and that your answer orresponds to the question.		2 3 4	mistakenly said that the Canadian patent application was granted on December 1, 2002 when, in fact, it's October 1, 2002.	
2 yi 3 yi 4 ci 5	ou don't do so, the Tribunal will assume that ou've understood the question and that your answer orresponds to the question. MS. NOBLES: Thank you.		2 3 4 5	mistakenly said that the Canadian patent application was granted on December 1, 2002 when, in fact, it's October 1, 2002. THE PRESIDENT: Any other correction?	
2 yr 3 yr 4 cr 5	ou don't do so, the Tribunal will assume that ou've understood the question and that your answer orresponds to the question. MS. NOBLES: Thank you. THE PRESIDENT: Ms. Nobles, you will		2 3 4 5 6	mistakenly said that the Canadian patent application was granted on December 1, 2002 when, in fact, it's October 1, 2002. THE PRESIDENT: Any other correction? MS. NOBLES: No.	
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2 yyy 3 4 5 5 7 3 9 0 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	ou don't do so, the Tribunal will assume that ou've understood the question and that your answer orresponds to the question. <b>MS. NOBLES:</b> Thank you. <b>THE PRESIDENT:</b> Ms. Nobles, you will ppreciate that testifying, be it before a court or n arbitral tribunal, is a very serious matter. In hat connection, the Tribunal expects you to give he statement which is in front of you. <b>MS. NOBLES:</b> I solemnly declare upon my onor and conscience that I shall speak the truth, he whole truth and nothing but the truth. <b>THE PRESIDENT:</b> Thank you, Ms. Nobles. Could you please go to your witness statement which is in front of you and go to page 7? Your witness tatement is dated September 25, 2014? <b>MS. NOBLES:</b> That's correct. <b>THE PRESIDENT:</b> Could you confirm for the ecord that the signature appearing above your name is your signature? <b>MS. NOBLES:</b> That is my signature. <b>THE PRESIDENT:</b> Thank you. Is there any		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>mistakenly said that the Canadian patent application was granted on December 1, 2002 when, in fact, it's October 1, 2002.</li> <li>THE PRESIDENT: Any other correction?</li> <li>MS. NOBLES: No.</li> <li>THE PRESIDENT: Thank you, Ms. Nobles.</li> <li>Mr. Berengaut, any question for direct?</li> <li>MR. BERENGAUT: No direct. Thank you,</li> <li>Mr. President.</li> <li>THE PRESIDENT: Ms. Zeman, you will conduct the cross-examination? Please proceed.</li> <li>CROSS-EXAMINATION ON BEHALF OF THE RESPONDENT</li> <li>MS. ZEMAN: Good morning.</li> <li>MS. ZEMAN: Good morning.</li> <li>MS. ZEMAN: My name is Krista Zeman. I am counsel for Canada and I will be asking you a few questions to make sure I understand a few aspects of your testimony this morning. It is important that we understand each other so, if there are any questions that you do not understand, please let me know and I will attempt to reframe it in a way that makes sense.</li> </ul>	11:36
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2       1990?         3       MS. NOBLES: That's correct.         4       MS. ZEMAN: And you were na         5       of the Strattera Product Launch Team         6       November 1999?         7       MS. NOBLES: That's correct.         8       MS. ZEMAN: And you were in         9       until mid 2003. Is that right?         10       MS. NOBLES: That's correct.         11       MS. NOBLES: That's correct.         12       vice-president Corporate Affairs. Is the         13       MS. NOBLES: That's correct.         14       MS. NOBLES: That's correct.         15       MS. NOBLES: That's correct.         16       MS. NOBLES: That's correct.         17       MS. NOBLES: That's correct.         18       MS. NOBLES: That's correct.         19       vice-president Corporate Affairs. Is the         10       MS. NOBLES: That's not correct.         18       MS. NOBLES: That's not correct.         19       until you retired in 2012. Is that right?         10       I moved into the job that eventually be         10       vice-president of Enterprise Risk Man         10       Chief Ethics and Compliance Officer.         11       MS. ZEMAN: So I'd like to un <td>med team leader in in that position</td> <td><ul> <li>responsibility for the molecule as it ended Phase II</li> <li>and oversaw the Phase III development, as well as</li> <li>the registration and eventual launch in the U.S.</li> <li>MS. ZEMAN: So</li> <li>MS. NOBLES: And other markets as well.</li> <li>MS. ZEMAN: And patent protection was an</li> <li>extremely important part of your launch strategy, as</li> <li>you stated in your witness statement. Is that</li> <li>right?</li> <li>MS. NOBLES: That's correct.</li> <li>MS. ZEMAN: And the patent attorney</li> <li>advises the product team about any issues that</li> <li>emerge in the prosecution of the patent. Is that</li> <li>right?</li> <li>MS. NOBLES: That's correct.</li> </ul></td>	med team leader in in that position	<ul> <li>responsibility for the molecule as it ended Phase II</li> <li>and oversaw the Phase III development, as well as</li> <li>the registration and eventual launch in the U.S.</li> <li>MS. ZEMAN: So</li> <li>MS. NOBLES: And other markets as well.</li> <li>MS. ZEMAN: And patent protection was an</li> <li>extremely important part of your launch strategy, as</li> <li>you stated in your witness statement. Is that</li> <li>right?</li> <li>MS. NOBLES: That's correct.</li> <li>MS. ZEMAN: And the patent attorney</li> <li>advises the product team about any issues that</li> <li>emerge in the prosecution of the patent. Is that</li> <li>right?</li> <li>MS. NOBLES: That's correct.</li> </ul>
www.dianaburden.c	om	www.dianaburden.com
1       well.         2       MS. ZEMAN: As the team lead         3       product team, your team advised you         4       issues?         5       MS. NOBLES: By that, do you         6       of the team would be working directly         7       lawyers and then would come to me?         8       MS. ZEMAN: Yes.         9       MS. NOBLES: Generally that         10       MS. ZEMAN: So patent prote         11       extremely important consideration in a         whether and how to launch Strattera s         13       a particular market. Is that right?         14       MS. NOBLES: That's correct.         15       MS. ZEMAN: So you expecter         16       attorney to be familiar with the patent         17       framework in each country in which you         18       aunching?         19       MS. NOBLES: That would be         20       would be the expert we would be rely         21       MS. ZEMAN: And you would         22       MS. NOBLES: That would be	der for the of these patent mean members with the was the case. ction was an determining specifically in d the patent law ou were correct. That ing on. expect them to Is that	<ul> <li>MS. ZEMAN: And you expected the patent attorneys to monitor developments in the patent law framework of your launch countries. Is that right?</li> <li>MS. NOBLES: The product team would not be setting the lawyers' responsibilities directly.</li> <li>That would be the legal division that would do that and the patent attorney. So I can't really speak to exactly how the patent attorney was directed by the legal division, but what I relied on and what our team relied on was the information from that lawyer assessing patents where that was appropriate, the probability or likelihood that we would get a patent, and so forth.</li> <li>MS. NOBLES: That's correct.</li> <li>MS. NOBLES: That's correct.</li> <li>MS. ZEMAN: And if there was a fundamental change that presented a potential risk to the validity of your patents, you would expect your patent attorney to advise you of that?</li> <li>MS. NOBLES: That's correct.</li> </ul>

NCT/14/2 Eli Lilly and Company v Government of Canada onfidential	445	Tuesday, 31 I Washington	DČ, U 446
1       responsibility for the launch of major products. Is         2       that right?         3       MS. NOBLES: As the vice-president for         4       Corporate Affairs, I obviously had global         5       responsibilities for corporate affairs, so I would         6       come in contact with information about products that         7       we were launching both in their initial markets and         8       subsequent markets, but I didn't have direct         9       responsibility for that any longer. My successor         10       MS. ZEMAN: You continued to follow         11       MS. NOBLES: Yes, in a general way,         12       because it was of great interest to me given my         13       ms. ZEMAN: So you would not have been         14       MS. ZEMAN: So you would not have been         15       because it was of great interest to me given my         16       previous responsibilities, as well as the new role         17       MS. NOBLES: Not run-of-the-mill kinds of         18       MS. NOBLES: Not run-of-the-mill kinds of         19       issues but if there are major issues it's possible a         12       team member would have come to me to talk about the         13       ms. ZEMAN: So if one of your patents was         14 <td< td=""><td>1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1</td><td>1       markets, you would be advised about that?         2       MS. NOBLES: If the product team felt that         3       it was important for me to specifically know about         4       that and felt they could draw on my expertise, they         5       certainly would have done that and I would have         6       expected them to do so.         7       MS. ZEMAN: And if there was a fundamental         8       change in the patent framework of one of your major         9       markets, would you have expected them to advise you         0       about that?         1       MS. NOBLES: I think it would depend on         1       how they assessed the change, but certainly if they         2       considered it a major change from the basis on which         4       we'd be proceeding previously, I think it's very         5       likely that they would have talked to me about that.         6       MS. ZEMAN: So you held this position         11       until 2005, is that correct?         7       MS. NOBLES: The Corporate Affairs role?         7       No, it was 2007.         8       NS. NOBLES: I was the Chief Ethics and         7       mother role, the name of which I cannot recall         1       right now.         23</td><td>11:42</td></td<>	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1       markets, you would be advised about that?         2       MS. NOBLES: If the product team felt that         3       it was important for me to specifically know about         4       that and felt they could draw on my expertise, they         5       certainly would have done that and I would have         6       expected them to do so.         7       MS. ZEMAN: And if there was a fundamental         8       change in the patent framework of one of your major         9       markets, would you have expected them to advise you         0       about that?         1       MS. NOBLES: I think it would depend on         1       how they assessed the change, but certainly if they         2       considered it a major change from the basis on which         4       we'd be proceeding previously, I think it's very         5       likely that they would have talked to me about that.         6       MS. ZEMAN: So you held this position         11       until 2005, is that correct?         7       MS. NOBLES: The Corporate Affairs role?         7       No, it was 2007.         8       NS. NOBLES: I was the Chief Ethics and         7       mother role, the name of which I cannot recall         1       right now.         23	11:42
1       promoted within that job to senior vice-president.         2       MS. ZEMAN: And, in that role, you would         3       have expected to be informed about invalidations of         3       patents?         5       MS. NOBLES: I think less so, because by         6       that point years had passed since my         7       responsibilities as product team leader, and         8       obviously in an ethics and compliance role I would         9       not have needed that information in order to do my         10       pb.         11       MS. ZEMAN: And so just to go back one job         12       time frame, when you were VP Corporate Affairs,         13       Lilly continued to file for patents in Canada, to         14       your knowledge. Is that right?         15       MS. NOBLES: You mean related to Strattera         16       specifically?         17       MS. ZEMAN: Other products.         18       MS. NOBLES: Other products? I would         19       assume so, but I wouldn't have had any direct         10       MS. ZEMAN: I'd like to turn now to         11       MS. ZEMAN: I'd like to turn now to         12       MS. NOBLES: That's correct.         18       MS. NOBLES: That's correct.      <	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	<ul> <li>treatment of attention deficit/hyperactivity</li> <li>disorder?</li> <li>MS. NOBLES: That's correct.</li> <li>MS. ZEMAN: And Lilly had previously held</li> <li>a patent for atomoxetine as an antidepressant agent</li> <li>in Canada since 1985?</li> <li>MS. NOBLES: I'm not familiar with that</li> <li>patent.</li> <li>MS. ZEMAN: But the ADHD patent was a new</li> <li>method of use patent. Is that right?</li> <li>MS. NOBLES: That's correct. That was my</li> <li>understanding.</li> <li>MS. ZEMAN: Lilly filed the Canadian</li> <li>patent application for the new use of atomoxetine in</li> <li>1996. Is that correct?</li> <li>MS. NOBLES: To the best of my</li> <li>recollection, that's correct, but I wasn't obviously</li> <li>on the product team when it was filed.</li> <li>MS. ZEMAN: Right. You joined the product</li> <li>team in 1999?</li> <li>MS. NOBLES: That's correct. At the end</li> <li>of 1999.</li> <li>MS. ZEMAN: And when you joined you</li> <li>received regular updates about the prosecution. Is</li> <li>that right?</li> </ul>	<b>448</b> 11:44

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<ul> <li>MS. NOBLES: Regular updates about patent issues in general, yes, and it would include that.</li> <li>MS. ZEMAN: And you can recall no patent-related concerns about Strattera in Canada. Is that right?</li> <li>MS. NOBLES: That's correct.</li> <li>MS. ZEMAN: You stated earlier that the patent attorney you worked with was responsible for advising the product team about any potential risks to the validity of the patent if and when it is granted. Is that correct?</li> <li>MS. NOBLES: That's correct.</li> <li>MS. ZEMAN: At Tab 3 of your binder, the one with the red cover, is Exhibit R-004 for the record, and it is the Supreme Court of Canada decision in Apotex Inc. v Wellcome Foundation Limited. Do you see that?</li> <li>MS. NOBLES: I do.</li> <li>www.dianaburden.com</li> </ul>	11:45       1         2       3         4       5         6       7         8       9         10       11         12       13         14       15         16       17         18       19         20       21         23       24         25       5	our Canadian patent for Strattera had been invalidated on the ground that it was not useful." Is that correct? MS. NOBLES: That's correct. MS. ZEMAN: I'd like to understand what you mean by that. At Tab 5 of your binder is Exhibit R-027, for the record. This is the decision of the Canadian Federal Court invalidating the Strattera patent. You see it's dated September 14, 2010? MS. NOBLES: Yes. MS. ZEMAN: And you were advised about this decision? MS. NOBLES: I don't recall being advised.	11:46
<ul> <li>surprised when you learned about the invalidation of this patent?</li> <li>MS. NOBLES: That's correct.</li> <li>MS. ZEMAN: At Tab 6 of your binder is</li> <li>Exhibit R-272. It is a decision of the U.S.</li> <li>District Court of New Jersey relating to the</li> <li>Strattera patent. You see it's dated August 12, 2010?</li> <li>MS. NOBLES: Yes, I do.</li> <li>MS. NOBLES: I was not.</li> <li>MS. NOBLES: I was not.</li> <li>MS. ZEMAN: At Tab 7 of your binder is</li> <li>Exhibit R-200. This is a decision of the Federal</li> <li>Court of Canada relating to Lilly's Canadian patent for Raloxifene. This is dated February 5, 2008. Is</li> <li>MS. NOBLES: That's correct. I don't</li> <li>See</li> <li>MS. ZEMAN: I think it's highlighted on</li> </ul>	451 11:47 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MS. CHEEK: Could I have a moment to confer with Respondent on that before we move to the next witness? I just note I believe the next witness is scheduled for a 20-minute presentation and two hours of cross, and so that doesn't break awkwardly over lunch I was wondering if we might take an earlier lunch today. THE PRESIDENT: I suggest we have first the presentation and then we break for lunch. Of	<b>452</b> 11:48

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(Recess taken)	403	1	the whole truth, and nothing but the truth.	404 11:57
2 MARCEL BRISEBOIS	11:50	2	THE PRESIDENT: Thank you. Mr. Brisebois,	11:57
3 THE PRESIDENT: Good morning,		3	could you go to your first witness statement. Go to	
Mr. Brisebois.		4	page 27. The first witness statement is dated	
5 MR. BRISEBOIS: Good morning.		5	January 26, 2015.	
THE PRESIDENT: Could you please state		6	MR. BRISEBOIS: Yes.	
		0 7		
7 your full name for the record?			THE PRESIDENT: Could you confirm for the	
MR. BRISEBOIS: My name is Marcel		8	record that the signature appearing above your name	
Brisebois.		9	is your signature?	
0 <b>THE PRESIDENT:</b> Mr. Brisebois, you appear		10	MR. BRISEBOIS: It's my signature.	
1 as a legal and fact witness for the Respondent. If		11	THE PRESIDENT: Then could you go to your	
2 any question is unclear to you, either because of			second witness statement dated December 7, 2015,	
3 language or for any other reason, please do seek a		13	page 19. Could you please confirm for the record	
4 clarification because, if you don't do so, the		14	that the signature appearing above your name is your	
5 Tribunal will assume that you've understood the		15	signature?	
6 question and that your answer corresponds to the		16	MR. BRISEBOIS: That's correct. This is	
7 question.		17	my signature.	
8 MR. BRISEBOIS: Sure.		18	THE PRESIDENT: Mr. Brisebois, you have	
9 <b>THE PRESIDENT:</b> Mr. Brisebois, you will		19	become very popular with my paralegal in light of	
0 appreciate that testifying, be it before a court or		20	all the corrections you have submitted to this	
an arbitral tribunal, is a very serious matter. In		21	Tribunal. We have a whole list of the corrections	
2 that connection, the Tribunal expects you to give		22	which have been submitted by letter of May 25, 2016.	
the statement which is in front of you.		23	No need to go over them now, but are there any other	
4 MR. BRISEBOIS: I solemnly declare upon my		24	corrections you wish to make?	
5 honor and conscience that I shall speak the truth,		24 25	MR. BRISEBOIS: Not that I'm aware of, no.	
o nonor and conscience that i shall speak the truth,		20	MK. DKISEDUIS: NOULINAUTIN AWARE OI, NO.	
THE DECTRENT. Thank you	455	1	allegedly caused by a shift in Canada's approach to	456
THE PRESIDENT: Thank you.	<b>455</b>	1	allegedly caused by a shift in Canada's approach to	<b>456</b>
MS. ZEMAN: No questions from the		1 2 2	utility. 2, to review Claimant's patent	
2 MS. ZEMAN: No questions from the 8 Respondent, but I believe you have a presentation to		3	utility. 2, to review Claimant's patent invalidation statistics and its conclusions with	
2 <b>MS. ZEMAN:</b> No questions from the 8 Respondent, but I believe you have a presentation to 9 give.		3 4	utility. 2, to review Claimant's patent invalidation statistics and its conclusions with respect to discrimination toward pharma patents,	
<ul> <li>MS. ZEMAN: No questions from the</li> <li>Respondent, but I believe you have a presentation to give.</li> <li>THE PRESIDENT: Ms. Zeman, already</li> </ul>		3 4 5	utility. 2, to review Claimant's patent invalidation statistics and its conclusions with respect to discrimination toward pharma patents, and, finally, to collect and consider evidence	
<ul> <li>MS. ZEMAN: No questions from the</li> <li>Respondent, but I believe you have a presentation to give.</li> <li>THE PRESIDENT: Ms. Zeman, already</li> <li>preempts me. That's okay.</li> </ul>		3 4 5 6	utility. 2, to review Claimant's patent invalidation statistics and its conclusions with respect to discrimination toward pharma patents, and, finally, to collect and consider evidence regarding Claimant's historic patent filing behavior	
<ul> <li>MS. ZEMAN: No questions from the</li> <li>Respondent, but I believe you have a presentation to give.</li> <li>THE PRESIDENT: Ms. Zeman, already</li> <li>preempts me. That's okay.</li> <li>MS. ZEMAN: My apologies!</li> </ul>		3 4 5 6 7	utility. 2, to review Claimant's patent invalidation statistics and its conclusions with respect to discrimination toward pharma patents, and, finally, to collect and consider evidence regarding Claimant's historic patent filing behavior relating to the compounds olanzapine, atomoxetine	
<ul> <li>MS. ZEMAN: No questions from the Respondent, but I believe you have a presentation to give.</li> <li>THE PRESIDENT: Ms. Zeman, already preempts me. That's okay.</li> <li>MS. ZEMAN: My apologies!</li> <li>THE PRESIDENT: I like proactive counsel.</li> </ul>		3 4 5 6 7 8	utility. 2, to review Claimant's patent invalidation statistics and its conclusions with respect to discrimination toward pharma patents, and, finally, to collect and consider evidence regarding Claimant's historic patent filing behavior relating to the compounds olanzapine, atomoxetine and Raloxifene.	
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2 fo 3 4 ar 5 qu 6 ac 7 w 8 9 sp 10 w 12 v 13 to 14 pr 15 re 16 be 17 ev 18 di 19 pr 20 21 hi 22 pr 23 24 u	recorded the challenged grounds and final outcomes or each challenged patent. MS. CHEEK: I'm very sorry, Mr. Brisebois nd Mr. President, but if I could just ask a uestion. Can we just confirm that Mr. Brisebois ctually does have notes in front of him, beyond that is actually being presented on this screen? MR. SPELLISCY: I believe he does have peaking notes, yes. THE PRESIDENT: Witnesses should testify vithout speaking notes. MR. SPELLISCY: We can certainly ask him o do so. It wasn't our understanding that for the resentation aspect of this that we were going to equire witnesses to memorize a presentation. We'd e happy to turn the speaking notes over. It may ven help the reporter later. But I certainly idn't understand that he couldn't script out his resentation in the same way that counsel do. Certainly he won't have any notes during is actual cross-examination, but for the resentation we had not understood that. THE PRESIDENT: The problem is you nderstood the rule normally for fact witnesses, no otes in direct examination? www.dianaburden.com		1 2 3 4 5 6 7 8 9 10 11 22 3 4 25	MR. SPELLISCY: No. I would say for these presentations we understood it differently. THE PRESIDENT: Let's first go for the basic rule. For fact witnesses there are no notes? MR. SPELLISCY: We would agree that for fact witnesses they shouldn't have notes during cross-examination. THE PRESIDENT: Now we get to the next one. Mr. Brisebois is a hybrid, if I may call it that way. MR. SPELLISCY: I would certainly think it would be unfair to allow experts to bring notes for their presentations and not Mr. Brisebois. THE PRESIDENT: Let's also go to the basic rule for experts. They may have notes for their presentation? MR. SPELLISCY: I would agree. MS. CHEEK: Actually our view was for their presentation all they were going to rely upon was their actual expert statements, as submitted to the Tribunal, and their PowerPoint presentation. THE PRESIDENT: But they may have notes for the PowerPoint presentation? MS. CHEEK: That was not our understanding but if that is your	12:03
3       th         4       5       pr         6       P       7         8       9       st         10       ha         11       in         12       is         13       th         14       fo         15       pa         16       fo         17       18       m         19       cc         20       m         21       22         23       al         24       no	THE PRESIDENT: This at least was the ribunal's but we should clarify it now. It's good hat you have raised it. MS. CHEEK: Our understanding was that all resentations would only be done through the owerPoint presentation without notes. THE PRESIDENT: I see. MR. SPELLISCY: I find it difficult to uggest that witnesses should try to or should ave been required to memorize their presentations in advance. We don't require that generally. This is a presentation. As I say, we'd be happy to share the notes. They're just his speaking notes. But for these presentations we certainly had and in our ast experience people have been able to bring notes or the presentation. THE PRESIDENT: Let me first confer with they colleagues about the experts in general. Then we ome back to Mr. Brisebois, who is somewhere in the hiddle. (The Tribunal conferred) THE PRESIDENT: The Tribunal is grateful lso to the Claimant that you have raised already ow this issue because the understanding of the ribunal was for experts in general, when they make www.dianaburden.com	<b>459</b> 12:04	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	a presentation, that they could also have speaking notes which we think is inherent to an expert and is also in accordance with the experience we have had in other cases. But fair enough, granted that this was an unclear point, we can clear it now at the beginning of the proceedings so also, when you now prepare your experts, if I may call it that way both sides then they are allowed to have speaking notes for their presentations. That's point 1. That's more the general rule on experts. No speaking notes obviously for direct for fact witnesses. Now the Tribunal has a question of Mr. Brisebois. Are you able to make your presentation of 25 minutes without your speaking notes? MR. BRISEBOIS: I can try but it won't be as clear as with my speaking notes. THE PRESIDENT: So you are capable of doing it? MR. BRISEBOIS: I mean I can try. I think I can do a presentation, yes. Will it be as clear as it will be with my notes? I don't think so. THE PRESIDENT: The alternative is that, www.dianaburden.com	<b>460</b> 12:06

	7/14/2 Eli Lilly and Company v Government of Canada dential			Tuesday, 31 Washingtoi	n DČ, U
1 2 3 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 12 2 10 11 12 10 10 11 12 10 10 11 12 10 10 11 12 10 10 11 12 10 11 11 12 11 11 12 11 11 12 11 11 11 11	if you feel uncomfortable in doing this and in view of clarity, if you can make the copy available of your speaking notes to the parties, especially to the Claimant, during the break so you can go over these speaking notes, would that resolve your concerns, Ms. Cheek? MS. CHEEK: That actually raises our other expectation, which was that, given these are effectively demonstratives, that copies would be distributed in advance of the presentation as with our opening oral argument. So we had been wondering where our copy was of the PowerPoint presentation and certainly, if Mr. Brisebois is going to testify with notes, we would expect to have a copy of that in its entirety. THE PRESIDENT: Now you're raising a compound question, if I may call it that way, Ms. Cheek. Let's first deal with his speaking notes. So he will hand over the speaking notes, and that alleviates your concerns because during the break you can review them? MS. CHEEK: If that is the case, then what I would suggest is that Respondent provide us with a copy now. At the beginning of his presentation is when I would like to see the copy, not at the end. www.dianaburden.com	<b>46</b> 12:07	1 2 3 4 5 6 7 8 9 10 11 22 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 32 4 25	THE PRESIDENT: Okay. MS. CHEEK: They can either pass that out now and he can proceed. If they don't have it ready then let's take an early lunch break so they can give it us to when he begins his testimony. MR. SPELLISCY: I'm confused as to what we are talking about. Is this the PowerPoint presentation? THE PRESIDENT: No. That's the reason I raised it as compound. I come to the second question. Two issues came up. Let's deal with this issue first and then I will come back on the issue of the PowerPoint yesterday. Can the speaking notes of Mr. Brisebois be made available now? MR. BRISEBOIS: I can provide them, because there's some handwriting on it. THE PRESIDENT: That looks very general. MR. BRISEBOIS: But yes, I can. THE PRESIDENT: Can it be copied now on the copy machine outside? We will wait two minutes and then we will continue, because I would like to have the presentation concluded before the lunch, also in light of the situation that your side, Ms. Cheek, should have a possibility to review the	462
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	speaking notes prior to the commencing the cross-examination, which you can do conveniently during the lunch. MS. CHEEK: Thank you, Mr. President. THE PRESIDENT: Then we get to No. 2, because you had two questions in one observation, which was about the PowerPoint. If I understood it correctly, you were looking for an electronic copy of the PowerPoint of yesterday of the opening statement? Or the PowerPoint that we see here now on the screen? MS. CHEEK: Well, it looks like maybe the Tribunal has copies of his presentation, and Claimant has no copy of this presentation. That is my confusion. MR. SPELLISCY: My paralegals have stepped out. My understanding from them was that they did hand a copy to the Claimant. MS. CHEEK: We have no copy of what is being presented. No hard copy. THE PRESIDENT: This is a logistical issue	<b>463</b> 12:09	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	have no hard copy of what is being presented. THE PRESIDENT: We proceeded on the assumption that you had a copy because each time it has been handed out, but apparently it has been overlooked. Can the Claimant be handed a copy? MR. SPELLISCY: As soon as one of my paralegals comes back, I'm sure they can. I don't know where they are. THE PRESIDENT: Whilst we're talking about these copies, have the electronic versions of the opening statements been exchanged yesterday? MS. CHEEK: No, they have not. THE PRESIDENT: It would be helpful. Also the Tribunal would like to have them. MS. CHEEK: We'd be pleased to provide that. THE PRESIDENT: Thank you. And also for the Respondent. MR. SPELLISCY: I actually have a point of clarification, too, while we're talking on this, which is about Dr. Gillen, who is THE PRESIDENT: Let's first finish with	<b>464</b> 12:10

22 issue. MS. CHEEK: We'd be pleased to receive an 23 24 electronic copy of the opening statement of 25 Respondent, but in this instance our concern is we

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THE PRESIDENT: Let's first finish with

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the version of your opening statement of yesterday.
 MR. SPELLISCY: Yes, we will provide that.
 THE PRESIDENT: Now move on to next

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1       subject.         2       MR. SPELLISCY: I guess I'd like         3       clarification on the status of Dr. Gillen's         4       presentation as well on the issue of speaking notes         5       because, again, I think we have the disparity and         6       I'd like clarity as well that, if experts are coming         7       up with speaking notes, that we'd be able to get a         8       copy of those speaking notes as well, because I         9       think we have a situation here where the Claimant         10       has presented an expert in Dr. Levin and, styled as         11       an expert report, Mr. Wilson, and our responding         12       witnesses, Dr. Gillen and Dr. Brisebois, are being         13       asked to turn over speaking notes.         14       It also like to know whether we should be         15       then it's not an issue, but if they do, I'd like to         16       see it. I'd also like to know whether we should be         17       informing Dr. Gillen that if he's going to have         18       speaking notes he has to be prepared, or what the         19       notes, and I assume that those speaking notes would         10       notes, and I assume that those speaking notes. With regards         10       to Mr. Gillen, any witness that has	<ul> <li>that witness is going to speak from speaking notes,</li> <li>those should be shared with the other side. I think</li> <li>that's a coherent approach.</li> <li>THE PRESIDENT: Wait a moment. So you</li> <li>accept that Mr. Gillen has speaking notes? Because</li> <li>he is a witness, he is not an expert.</li> <li>MS. CHEEK: In the same regard that</li> <li>Mr. Brisebois has speaking notes, and, as</li> <li>I understand it, you have determined that, as long</li> <li>as he shares those notes with us, that he can use</li> <li>them. And Mr. Gillen would be in the same category.</li> <li>THE PRESIDENT: Exactly. Is that</li> <li>acceptable to the Respondent?</li> <li>MR. SPELLISCY: I'm not sure that it is.</li> <li>Dr. Wilson, or Mr. Wilson, is then in the same</li> <li>category? Because he's been sequestered as well.</li> <li>MS. CHEEK: That's correct. Those three</li> <li>witnesses, Mr. Wilson, Mr. Brisebois and Mr. Gillen,</li> <li>because they've been sequestered and, therefore, are</li> <li>quasi fact witnesses, shall we say, given the</li> <li>default rule that they would not have any speaking</li> <li>notes, if it's been determined they may have</li> <li>speaking notes, those speaking notes need to be</li> <li>shared with the other party at the beginning of</li> <li>their presentation.</li> </ul>	466
1       THE PRESIDENT: The determination, at         2       least as a practical solution as regards         3       Mr. Brisebois, was that since he has speaking notes         4       and he was already starting this, he gives a copy to         5       your side so you can study it during the lunch         6       break. But with Dr. Gillen, we don't know yet         7       whether that should be the case.         8       MS. CHEEK: Maybe Respondent can let us         9       know if Mr. Gillen intends to speak with speaking         10       notes, but if he does intend to speak with speaking         11       notes, then I think the same rule would apply. The         12       sequestered witnesses need to provide those notes         13       since they're testifying as quasi fact witnesses.         14       THE PRESIDENT: Do you have a problem that         15       he has speaking notes, Mr. Gillen?         16       MS. CHEEK: I think if we are going to         17       have one of our quasi fact witnesses have speaking         18       notes, then I have no objection to being consistent         19       in that regard.         10       THE PRESIDENT: Then for both, and you         19       agree also for Mr. Dimock? But he is not a true         10	1       THE PRESIDENT:       l agree. So is it clear         2       now, Mr. Spelliscy? We have now the speaking notes         3       of Mr. Brisebois, and Dr. Gillen, when he testifies         4       and gives his presentation, may also have speaking         5       notes on the condition that the speaking notes are         6       shared with the Claimant and the Tribunal.         7       MR. SPELLISCY:         8       Mr. Wilson.         9       THE PRESIDENT:         9       THE PRESIDENT:         10       MS. CHEEK:         11       COPRECT:         12       THE PRESIDENT:         13       and speaking notes shared with the Respondent and         14       the Tribunal.         15       MS. CHEEK:         16       presentation.         17       THE PRESIDENT:         18       assue.         19       MR. SPELLISCY:         11       THE PRESIDENT:         12       THE PRESIDENT:         13       notes on the claification.         14       the Tribunal.         15       MS. CHEEK:         16       presentation.         17       THE PRESIDENT:	<b>468</b> 12:15

4 second a static second a la factura da seconda e a la seconda e seconda e seconda e seconda e seconda e se	<b>469</b> 12:16	Washington DC, USA 470 1 large PowerPoint version but I'm assuming it is the 12:18
<ul> <li>20 minutes.</li> <li>THE PRESIDENT: That's what I thought but</li> <li>I saw 25. Further agreement of the parties. All</li> <li>right.</li> <li>MR. SPELLISCY: I'm asking one of our</li> <li>paralegals to come over. He did leave two copies of</li> <li>the PowerPoint presentation for Claimant.</li> <li>THE PRESIDENT: Let's check that everybody</li> <li>is literally on the same page. Ms. Cheek, your</li> <li>side, you have a document which is captioned</li> <li>"Summary of Witness Statements of Marcel Brisebois",</li> <li>and I show it here to you?</li> <li>MS. CHEEK: Yes, Claimant has a copy of</li> <li>the Summary of Witness Statements of Marcel</li> <li>Brisebois, the speaking notes version.</li> <li>THE PRESIDENT: You have the PowerPoint,</li> <li>the large PowerPoint, and then you have the version</li> <li>with it's probably the same but then the speaking</li> <li>notes are below it?</li> </ul>		<ul> <li>same as the speaking notes version, if Respondent</li> <li>can confirm.</li> <li>MR. BRISEBOIS: One difference. The last</li> <li>slide doesn't exist in the final version.</li> <li>THE PRESIDENT: How come that the Claimant</li> <li>has not received the original PowerPoint without the</li> <li>notes?</li> <li>MR. SPELLISCY: They have received it.</li> <li>They have received two copies. I think perhaps on</li> <li>the five-minute break they gathered it up.</li> <li>MS. CHEEK: With my sincere apologies,</li> <li>they've been discovered at Claimant's table.</li> <li>THE PRESIDENT: So now we have resolved</li> <li>everything. Mr. Brisebois, could you please start</li> <li>again your presentation. This time it's 20 minutes.</li> <li>MR. BRISEBOIS: Yes.</li> <li>In this matter I was asked to review</li> <li>Claimant's allegation regarding the spike in the</li> <li>invalidations for pharma patents on utility grounds,</li> <li>allegedly caused by a shift in Canada's approach to</li> <li>utility. Also to review Claimant's patent</li> <li>invalidation statistics and its conclusions with</li> <li>respect to discrimination toward pharmaceutical</li> </ul>
24 notes are below it? 25 MS. CHEEK: Correct. We do not have the		<ul><li>24 respect to discrimination toward pharmaceutical</li><li>25 patents, and, finally, to collect and consider</li></ul>
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	12:19	<ul> <li>472</li> <li>represent the 1980-2004 period and the dark purple</li> <li>bars represent the 2005-2014 period. As you can</li> <li>see, the number of challenges in the post 2005</li> <li>period increased and is observed for all</li> <li>requirements, including the non-obviousness and</li> <li>novelty, utility and sufficiency of disclosure.</li> <li>Therefore, it's not surprising that the absolute</li> <li>number of invalidity findings including those on</li> <li>utility grounds has so increased in the post-2005</li> <li>period.</li> <li>I also found that PM(NOC) cases represent</li> <li>the vast majority of all pharma patent challenges.</li> <li>And with regard to PM(NOC) proceedings it must be</li> <li>remembered that an adverse finding in a PM(NOC) case</li> <li>does not invalidate a patent. The patentee still</li> <li>can enforce his patent rights against generic</li> <li>companies, and PM(NOC) proceedings are available</li> <li>exclusively to the pharma sector.</li> <li>So this graphic represents a timeline of</li> <li>the pharma patent challenges. The PM(NOC)</li> <li>proceedings are represented by the light purple and</li> <li>the bars. You can see an increase of the total</li> <li>number of validity challenges per year from 2004</li> <li>onward, and that PM(NOC) cases contributed</li> <li>substantially to this increase in pharma patent</li> <li>www.dianaburden.com</li> </ul>

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1       litigation.         2       83 percent of the patent challenges were         3       under PM(NOC) proceedings in the post-2005 period.         4       So, therefore, it's incorrect to refer to the 23         5       invalidations on utility grounds when only five         6       pharma patents were actually invalidated for lack of         7       utility under an impeachment action in the 2005-2014         8       period.         9       I also found that about half of the pharma         10       patents that lost a utility challenge had other         11       problems as well. In other words, about half of         12       these patents would have been found invalid anyway         13       had they not been challenged for lack of utility.         14       I also produced a timeline of total         15       validity challenges and total invalidity findings         16       tor each main ground to determine if the spike of         17       findings of lack of utility that began in 2005 is         18       unique to the utility requirement. So these two         19       graphs show that challenges and invalidity findings         20       on other grounds peaked around the same time.         21       On your left on figure 1 you can see the         22 </td <td>12:22</td> <td><ul> <li>corresponding finding of invalidity that all peak</li> <li>around the same time.</li> <li>In orange you also observe a spike for</li> <li>cases where utility was not challenged, so</li> <li>supporting that the utility challenges did not drive</li> <li>the challenges on other grounds. So these graphs</li> <li>support that the observed increase in findings of a</li> <li>lack of utility is not related to an event specific</li> <li>to the utility requirement, such as an alleged shift</li> <li>in the interpretation of the utility criteria by the</li> <li>Canadian courts.</li> <li>I will turn now to the review of</li> <li>Claimant's patent invalidation statistics, and its</li> <li>conclusions with respect to discrimination toward</li> <li>pharma patents. For this section of my second</li> <li>statement, I updated the pharmaceutical case list.</li> <li>I reviewed the case list relied on by Dr. Levin, and</li> <li>for the non-pharma post-2005 cases I relied on</li> <li>Appendix C of Dr. Levin's expert report. As only</li> <li>one patent was challenged on utility grounds in each</li> <li>case, I counted my outcomes based on an individual</li> <li>patent challenge basis, except for two cases,</li> <li>Eurocopter and Uponor, two non-pharma cases which</li> <li>had opposite utility findings for distinct</li> <li>embodiments in a single patent.</li> </ul></td> <td>12:24</td>	12:22	<ul> <li>corresponding finding of invalidity that all peak</li> <li>around the same time.</li> <li>In orange you also observe a spike for</li> <li>cases where utility was not challenged, so</li> <li>supporting that the utility challenges did not drive</li> <li>the challenges on other grounds. So these graphs</li> <li>support that the observed increase in findings of a</li> <li>lack of utility is not related to an event specific</li> <li>to the utility requirement, such as an alleged shift</li> <li>in the interpretation of the utility criteria by the</li> <li>Canadian courts.</li> <li>I will turn now to the review of</li> <li>Claimant's patent invalidation statistics, and its</li> <li>conclusions with respect to discrimination toward</li> <li>pharma patents. For this section of my second</li> <li>statement, I updated the pharmaceutical case list.</li> <li>I reviewed the case list relied on by Dr. Levin, and</li> <li>for the non-pharma post-2005 cases I relied on</li> <li>Appendix C of Dr. Levin's expert report. As only</li> <li>one patent was challenged on utility grounds in each</li> <li>case, I counted my outcomes based on an individual</li> <li>patent challenge basis, except for two cases,</li> <li>Eurocopter and Uponor, two non-pharma cases which</li> <li>had opposite utility findings for distinct</li> <li>embodiments in a single patent.</li> </ul>	12:24
So following the review of the dataset relied on by Dr. Levin, one of my observations was that the data counts court judgments rather than individual patent challenges. I consider this to be inappropriate because the data set includes cases wherein multiple pharma patents were challenged on the same grounds, and that only one outcome is counted if you count court judgments rather than patent challenges. So this example illustrates the difference in counting outcomes based on the core judgments, or on individual patent challenges. So for this particular decision, 2009 FCA 1102, two pharma patents were challenged for lack of utility. One patent, a '453 patent, was found useful and the other one, '492, was found to lack utility. So based on the basis of an individual patent challenge, I counted two different outcomes. One patent held invalid and one patent held valid. According to Appendix C of Dr. Levin's report, Claimants counted only one outcome, the invalidity finding, and the other outcome was not taken into account in the analysis relied on by Dr. Levin. When you repeat this same methodology in several cases it affects the observed rates of invalidity. In the context of this example, I www.dianaburden.com	<b>475</b> 12:25	<ul> <li>obtained an invalidity rate of 33 percent, and</li> <li>counting for judgments will lead to a rate of</li> <li>66 percent.</li> <li>So I consider outcomes based on each</li> <li>individual patent challenge reflects more accurately</li> <li>the outcomes of cases dealing with multiple pharma</li> <li>patent challenges on the same grounds.</li> <li>I also found there are discrepancies and</li> <li>inaccuracies in the data relied on by Dr. Levin.</li> <li>The most significant one is the treatment of Bell</li> <li>Helicopter versus Eurocopter. This is a case where</li> <li>two different embodiments of a landing gear were</li> <li>challenged for lack of utility. So the first</li> <li>embodiment is the landing gear with a forward offset</li> <li>cross-piece. One was held useful, the one with the</li> <li>forward offset cross-piece, and one was held to lack</li> <li>utility, the one with the backward offset</li> <li>cross-piece. So in my opinion, counting this case</li> <li>exclusively as a case where a non-pharma patent was</li> <li>held valid on utility grounds, as Claimant did in</li> <li>Appendix C to Dr. Levin's report, is not an accurate</li> <li>reflection of the outcomes of this case. I</li> <li>considered that counting this case as a non-pharma</li> </ul>	

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<ul> <li>patent, that both won and lost a utility challenge,</li> <li>is a more accurate reflection of the outcomes of</li> <li>this case.</li> <li>I also found that the data relied on by</li> <li>Dr. Levin is biased by PM(NOC) cases. I considered</li> <li>that PM(NOC) cases should not be included in any</li> <li>statistical analysis regarding the difference of</li> <li>invalidity rates between pharma and non-pharma</li> <li>sectors for at least three main reasons.</li> <li>First, like I said previously, PM(NOC)</li> <li>proceedings do not invalidate a pharma patent.</li> <li>2, there is an interim problem of double</li> <li>counting associated with the inclusion of PM(NOC)</li> <li>proceedings, because the same pharma patent can be</li> <li>challenged in one or more PM(NOC) proceedings and</li> <li>subsequently challenged in an impeachment action.</li> <li>In my view recording the same outcome more than one</li> <li>time for the same patent is problematic. Also, the</li> <li>only invalidations that are equally comparable</li> <li>between the pharma and non-pharma sectors are</li> <li>invalidation under impeachment actions.</li> <li>So I reproduced Claimant's analysis with</li> <li>an updated and corrected data set, and I found there</li> <li>is no statistical evidence of discrimination towards</li> <li>pharma patents. And this is true whether or not I</li> </ul>	12:28	<ul> <li>include PM(NOC) proceedings in my analysis.</li> <li>I also produced additional analyses.</li> <li>First I looked whether there was a difference in</li> <li>overall invalidity rates before and after 2005. A</li> <li>finding of invalidity on a single ground is</li> <li>sufficient to invalidate a patent. Therefore if</li> <li>utility-based invalidation rates increased with</li> <li>statistical significance after 2005, but the rates</li> <li>of invalidation on other grounds remain stable</li> <li>before and after 2005, one would expect to see a</li> <li>significant increase in overall patent invalidation</li> <li>rates for pharma patents. This is not the case.</li> <li>I also looked at the utility based</li> <li>invalidity rates for two specific cases, AZT in 2002</li> <li>and Raloxifene in 2008. These two cases were</li> <li>identified by the Claimant as a decision where</li> <li>important changes were made to the rules about the</li> <li>utility-based invalidity rates for pharma patents</li> <li>before and after any of these two cases.</li> <li>Finally, I collected and considered</li> <li>evidence regarding Claimant's historic patent filing</li> <li>behavior relating to the compounds olanzapine,</li> <li>atomoxetine and Raloxifene. So I retrieved the</li> </ul>	12:29
<ul> <li>application related to these three compounds and I</li> <li>found that there were multiple patent applications</li> <li>that were filed for new therapeutic uses for at</li> <li>least three compounds considering the 1990 and 2004</li> <li>period, 16 for olanzapine, 12 for atomoxetine and 68</li> <li>for Raloxifene.</li> <li>I reviewed the applications to identify</li> <li>the presence of experimental data relevant to the</li> <li>claimed therapeutic use, and I found that about half</li> <li>of Claimant's patent applications contained at least</li> <li>some reference to experimental data specifically</li> <li>relevant to the claimed therapeutic use. I also</li> <li>determined the status of each patent application,</li> <li>meaning whether it was still in prosecution before</li> <li>the Canadian patent office, whether it was dead, or</li> <li>whether it became a patent, and what I found is that</li> <li>94 percent of these patent applications are dead.</li> <li>Unlike abandoned applications that could be</li> <li>reinstated under certain conditions, dead</li> <li>applications in perspective, I compared it to</li> <li>Claimant's percentage of dead applications for all</li> <li>applications filed in the same field of invention,</li> <li>and to the percentage of dead applications for</li> </ul>	<b>479</b> 12:31	<ul> <li>applications filed in the same field of invention by</li> <li>any applicant during the same time period. The</li> <li>field of invention was based on classification code</li> <li>that was shared by 95 percent of all applications</li> <li>that I reviewed.</li> <li>As can be seen here on this graph, the</li> <li>average percentage of dead applications filed by the</li> <li>Claimant in the field of therapeutic use of</li> <li>compounds of the same broad category of olanzapin</li> <li>atomoxetine and Raloxifene during the 1990 and 200</li> <li>period is 86 percent. This is lower than what I</li> <li>observed for the application covering the new uses</li> <li>of the three compounds, but higher than 64 percent</li> <li>which is the percentage of dead applications among</li> <li>all applications filed in the same field of</li> <li>inventions during the same time period.</li> <li>This concludes my presentation. Thank yof</li> <li>for your time.</li> <li>THE PRESIDENT: Thank you. Mr. Spelliscy,</li> <li>or Ms. Zeman, that also concludes the direct</li> <li>examination, because you have five minutes left, I</li> <li>understand.</li> <li>MS. ZEMAN: That does conclude our direct</li> <li>examination.</li> <li>THE PRESIDENT: Then we break now for</li> <li>www.dianaburden.com</li> </ul>	e, 4

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<ul> <li>lunch. We resume at 1:30. Dr. Brisebois, you are</li> <li>under testimony. It means you are not allowed to</li> <li>discuss this case with anyone during your testimony,</li> <li>but you are free to, of course, have your lunch.</li> <li>Thank you. Resume at 1:30.</li> <li><i>(Recess taken)</i></li> <li>THE PRESIDENT: Ms. Cheek, you are</li> <li>conducting the cross-examination?</li> <li>MS. CHEEK: I will be conducting the</li> <li>cross-examination of Mr. Brisebois.</li> <li>THE PRESIDENT: Please proceed. And</li> <li>you've had a certain time to review the speaking</li> <li>notes?</li> <li>MS. CHEEK: We have. Thank you.</li> <li><i>CROSS-EXAMINATION</i></li> <li>MS. CHEEK: Good afternoon, Mr. Brisebois.</li> <li>MR. BRISEBOIS: Good afternoon.</li> <li>MS. CHEEK: I'd like to start just by</li> <li>asking you a few questions about your background.</li> <li>After receiving your doctorate you went to work for</li> <li>the Canadian Intellectual Property Office as a</li> <li>patent examiner. Is that correct?</li> <li>MR. BRISEBOIS: That's correct.</li> <li>MS. CHEEK: Then in December 2013, after</li> <li>this arbitration commenced, you were seconded to</li> <li>www.dianaburden.com</li> </ul>	12:33	Industry Canada. Is that correct?         MR. BRISEBOIS: That's correct.         MS. CHEEK: And there at Industry Canada         you were assigned to the strategic policy sector.         Is that right?         MR. BRISEBOIS: That's correct.         MS. CHEEK: And there your title was         senior policy analyst and strategic policy advisor.         Is that right?         MR. BRISEBOIS: I think it was senior         analyst, yeah.         MS. CHEEK: So I assume by its name, if         you were a policy analyst in the strategic policy         sector at Industry Canada, that that meant you         formed strategic policies for Canadian industry. Is         that right?         MR. BRISEBOIS: I mean I participated in         the work done there, yeah.         MS. CHEEK: And I believe, is it correct         that you also a notable part of your job was to         be advising on matters specific to this arbitration?         MS. CHEEK: So Mr. Brisebois, you're         familiar with patent validity challenges brought         under Canada's Patented Medicines (Notice of         www.dianaburden.com	01:34
<ol> <li>Compliance) Regulations, right?</li> <li>MR. BRISEBOIS: I'm familiar with it.</li> <li>MS. CHEEK: In your second statement</li> <li>and if you could turn to your second statement at</li> <li>Paragraph 3 your second statement should be</li> <li>before you.</li> <li>MR. BRISEBOIS: I missed the page, sorry.</li> <li>MS. CHEEK: Paragraph 3 of your second</li> <li>statement.</li> <li>MR. BRISEBOIS: Yes.</li> <li>MS. CHEEK: At Paragraph 3 of your second</li> <li>statement, you say that the data set analyzed by</li> <li>Professor Levin is I believe the words used here</li> <li>are afflicted with at least three flaws. Is that</li> <li>right?</li> <li>MR. BRISEBOIS: That's right.</li> <li>MS. CHEEK: And one of those flaws is the</li> <li>inclusion of the PM(NOC) cases. Is that right?</li> <li>MS. CHEEK: Now, Mr. Brisebois, are you</li> <li>aware that PM(NOC) proceedings apply the same</li> <li>utility law as infringement cases?</li> <li>MR. BRISEBOIS: Yes.</li> <li>MS. CHEEK: And are you aware that PM(NOC)</li> <li>decisions are cited as precedent in subsequent</li> <li>www.dianaburden.com</li> </ol>	<b>483</b> 01:35	<ul> <li>patent case, both pharma cases and in other sectors?</li> <li>MR. BRISEBOIS: Yes, they're not binding,</li> <li>but they are cited, yes.</li> <li>MS. CHEEK: And PM(NOC) cases are relied</li> <li>upon by the Canadian patent office as well, as</li> <li>reflected in the MOPOP. Is that right?</li> <li>MR. BRISEBOIS: I'm not sure about that,</li> <li>but could be right, yes.</li> <li>MS. CHEEK: Perhaps if you could turn to</li> <li>Tab 7 of the binder. This is C-351, and this is the</li> <li>chapter of the MOPOP on biotechnology, Chapter 17.</li> <li>Do you see that?</li> <li>MR. BRISEBOIS: Yes. Can you tell me</li> <li>which date is that?</li> <li>MS. CHEEK: This is the 2009 MOPOP. Just</li> <li>to familiarize ourselves with the document, if you</li> <li>turn to page 17-9, there you can see this is the</li> <li>January 2009 edition of the MOPOP. At the bottom of</li> <li>page 17-9, there's the Section 17.03 on utilities.</li> <li>Do you see that?</li> <li>MR. BRISEBOIS: Yes, I do.</li> <li>MS. CHEEK: And then if we keep flipping</li> <li>to page 17-12, here at 17.03.02a there's a section</li> <li>discussing factual basis. Do you see that?</li> <li>MR. BRISEBOIS: Yes, I do.</li> <li>WWW.dianaburden.com</li> </ul>	<b>484</b> 01:37

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<ul> <li>MS. CHEEK: A little more than halfway</li> <li>down there is a statement that says, "As was noted</li> <li>in the case of Pfizer v Apotex, however, 'utility</li> <li>and sound prediction are questions of fact that must</li> <li>obviously be supported." Do you see that?</li> <li>MR. BRISEBOIS: Yes, I do.</li> <li>MS. CHEEK: There's a footnote 20 there,</li> <li>correct?</li> <li>MR. BRISEBOIS: Sorry, a what?</li> <li>MS. CHEEK: A footnote 20 to that</li> <li>sentence.</li> <li>MR. BRISEBOIS: Yes.</li> <li>MS. CHEEK: Let's look at footnote 20.</li> <li>I'm sorry. That's on page 17-49 of the MOPOP before</li> <li>you.</li> <li>MR. BRISEBOIS: Okay.</li> <li>MS. CHEEK: Footnote 14 the Pfizer Canada</li> <li>v Apotex case, here the cite is 2007 FCA 135, and I</li> <li>assume that's familiar to you as a PM(NOC) case?</li> <li>MR. BRISEBOIS: I'm sorry, you said</li> <li>footnote 20?</li> <li>MS. CHEEK: 20, yes, on page 17-49. I'll</li> <li>give you a moment to look at footnote 20.</li> <li>MR. BRISEBOIS: Okay.</li> <li>MS. CHEEK: And the cite here is 2007 FCA</li> </ul>		2 3 4 5 6 7 8 9 10 11 12 13 14 15 6 7 8 9 21 22 23	<ul> <li>195. So is that familiar to you as a PM(NOC) case? MR. BRISEBOIS: Let me check in my case list.</li> <li>MS. CHEEK: Mr. Brisebois, if I could assist, it might help you to look at line 17 of Annex B to your First Report. MR. BRISEBOIS: Okay. Okay, yes, PM(NOC). MS. CHEEK: And if we can turn back to the substantive discussion of MOPOP to page 17-13, here at 17.03.02c, Proper Disclosure, do you see that provision? MR. BRISEBOIS: Yes, I do. MS. CHEEK: It says: "The requirement for proper disclosure means that the person skilled in the art has to, throughout the specification interpreted in view of their common general knowledge, be provided with sufficient information to understand the basis of the sound prediction." At the end of that sentence there's a footnote 21. Is that right? MR. BRISEBOIS: Yes. MS. CHEEK: If we could flip back to the footnote, I'll give you a moment to look at footnote 21, which is on page 17-49. MR. BRISEBOIS: Okay.</li> </ul>	486 01:40
	<b>487</b> 01:42	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 7 18 9 20 1 22 23	·	<b>488</b> 01:45

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MS. CHEEK: So Mr. Brisebois, I'd like to         go back to Paragraph 3 of your second statement.         We've looked at this paragraph before, and here you         discuss the three flaws with Professor Levin's data         set, correct?         MR. BRISEBOIS: Correct.         MS. CHEEK: And one of those flaws is the         use of cases instead of patents to measure patent         invalidation rates. Is that right?         MR. BRISEBOIS: That's right.         MS. CHEEK: Mr. Brisebois, if I could         direct your attention to behind tab 1 of the binder,         this is Brisebois cross-examination demonstrative 1,         and I'll give you a moment to familiarize yourself         with it. I'll walk you through it as well, and the         Tribunal as well as Respondent.         Table 1 at the top is listed "Corrections         to Levin's Table No. 1." For the record, that's         Professor Levin's Table No. 1, which is actually         titled in Professor Levin's Report "Patent cases in         the post-2005 period involving a decided challenge         on grounds of utility."         So this table 1 is counting patent cases         deciding utility challenges. Is that right?         MR. BRISEBOIS: Yes.	01:47	1       MS. CHEEK: Then table 2 is your table,       a         2       which you've titled "Patents involving a decided         3       challenge on grounds of utility post-2005." Is that         4       right?         5       MR. BRISEBOIS: Yes, that's right.         6       MS. CHEEK: And in your chart, table 2,         7       you counted challenged patents rather than court         8       decisions, right?         9       MR. BRISEBOIS: Right.         10       MS. CHEEK: And for the record, both your         11       table 1, corrections to Professor Levin's table 1,         12       and your table 2 have been updated to reflect your         13       errata that were submitted prior to the hearing. Is         14       that correct?         15       MR. BRISEBOIS: Yes.         16       MS. CHEEK: So, Mr. Brisebois, when you         17       count patents, your second table, rather than         18       decisions, the first table, that does not change the         19       number of invalidations on grounds of utility for         19       pharmaceutical patents, correct? That number stays         21       MR. BRISEBOIS: That's correct.         22       MS. CHEEK: And when you count patents         under your table	D1:49
<ul> <li>non-pharma patents. That stays at 2. Is that</li> <li>correct?</li> <li>MR. BRISEBOIS: Yes, it's correct.</li> <li>MS. CHEEK: It also does not change the</li> <li>number of non-pharmaceutical patents that survive a</li> <li>utility challenge. That remains at 8, correct?</li> <li>MR. BRISEBOIS: That's correct.</li> <li>MS. CHEEK: But when you look at</li> <li>pharmaceutical patents that survive the utility</li> <li>challenge then your number changed, right?</li> <li>MR. BRISEBOIS: The number changed but the</li> <li>first one is not my number.</li> <li>MS. CHEEK: Correct. So your</li> <li>correction so let me just phrase the question,</li> <li>Mr. Brisebois, so the record would be clear. When</li> <li>you counted patents in your table 2 you found 49</li> <li>patents, whereas in Professor Levin's table No. 1</li> <li>there would only be 42 patents found valid on</li> <li>utility in the pharmaceutical sector. Is that</li> <li>right?</li> <li>MR. BRISEBOIS: That's correct.</li> <li>MS. CHEEK: So the change there is from 42</li> <li>to 49?</li> <li>MR. BRISEBOIS: That's correct.</li> <li>MS. CHEEK: So just quickly eyeballing the</li> <li>www.dianaburden.com</li> </ul>	<b>491</b> 01:50	1. waatta in talala 1. Duafaasay Laudula talala 00	<b>492</b> D1:52

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1 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 3 14 15 16 17 18 9 21 22 3 4 25	correct? MR. BRISEBOIS: Correct. MS. CHEEK: And this is the Canadian Federal Court's decision in the Cefaclor case? MR. BRISEBOIS: I believe so. MS. CHEEK: Do you recall that Cefaclor is a single pharmaceutical product? It's an antibiotic? MR. BRISEBOIS: Okay. But the patents in play, at issue, were not all about this particular compound. They were also patents for the process of making it, and I can't remember all the details but there's other patents in play in there. MS. CHEEK: So this decision in line 72 did relate to a single product. That's right? MR. BRISEBOIS: I'd have to see the patent per se. MS. CHEEK: So, Mr. Brisebois, this same case, this same decision, Lilly v Apotex, 2009 FC 991, you code that same case also in line 73. Is that right? MR. BRISEBOIS: Yes, for other patents. MS. CHEEK: And it appears in line 74. MR. BRISEBOIS: Yes. MS. CHEEK: And line 75? www.dianaburden.com	<b>493</b> 01:54	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	MR. BRISEBOIS: Yeah, but I did some corrections for these cases. MS. CHEEK: Yes. So I think your corrections still coded lines 72 through 76 green. Would you like to check that? MR. BRISEBOIS: Oh, yes. Yes, you're correct. MS. CHEEK: And green means that a utility challenge was won by the patent owner according to your coding, so here in this case Lilly prevailed. Is that right? MR. BRISEBOIS: Yes. MS. CHEEK: I would note, in case the Tribunal doesn't have a corrected version before them, that your correction to the record was that in lines 78 and 79 you no longer coded those green, correct? MR. BRISEBOIS: Correct. MS. CHEEK: If we could go back to demonstrative 1, the tables that were behind tab 1. MR. BRISEBOIS: Yes. MS. CHEEK: To refresh our memory, the	<b>494</b> 01:56
1 2 3	table I'm sorry. I said that backwards. So the only difference between the two charts is that there's 42 utility findings in table	<b>495</b> 01:57	1 2 3	MS. CHEEK: If you could turn to page 4 in your binder, this is the Eurocopter decision. MR. BORN: Tab 4?	<b>496</b> 02:00
6 4 5 6 7 8 9 10 11 12 13	1 that counts decisions, and there's 49 utility findings in table 2 that counts patents. Is that right? MR. BRISEBOIS: Yes. MS. CHEEK: And so these five entries we just looked at for your chart in a single case, lines 72, 73, 74, 75, 76, those five cases account for five of the seven differences between those two? MR. BRISEBOIS: Yes, they are part of it. MS. CHEEK: Mr. Brisebois, if we could		4 5 6 7 8 9 10 11 12 13	MS. CHEEK: Tab 4, yes. Just to be clear, Mr. Brisebois, Eurocopter, you count this case twice in each of the tables in your second statement. You count it once as a non-pharma case with a finding of validity, and then you also count it a second time as a non-pharma case with a finding of invalidity. Is that right? MR. BRISEBOIS: Yes, to acknowledge that two different outcomes or two different embodiments that were claimed in the patent received different	

- 14 rulings with regard to utility.
- MS. CHEEK: If you could turn to
  Paragraph 456 of the Eurocopter decision, it's on
  page 146, so it's near the end, Mr. Brisebois, at
  Paragraph 456 the court says, "In the final
- Paragraph 456 the court says, "In the finalanalysis, the court finds that Eurocopter is
- 20 entitled to punitive damages as a result of the
- 21 infringement by Bell of the '787 patent and the
- 22 deliberate and outrageous conduct of Bell in this
- 23 case." Do you see that?
  - MR. BRISEBOIS: Uh-huh.
    - MS. CHEEK: So the court found

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case.

14 turn to your second statement at Paragraph 8.

MR. BRISEBOIS: Yes.

20 down or so, "I have counted this case as one in

a utility-based validity challenge." Is that right?

17 Eurocopter decision. Is that right?

MS. CHEEK: And here you discuss the

MS. CHEEK: And you say, about halfway

MR. BRISEBOIS: That's right. It was the

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MR. BRISEBOIS: That's correct.

which a non-pharmaceutical patent both won and lost

most accurate way of reflecting the outcomes of the

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<ul> <li>infringement and awarded punitive damages in this</li> <li>case. Is that right?</li> <li>MR. BRISEBOIS: Yes.</li> <li>MS. CHEEK: Yet nevertheless you coded</li> <li>this case as both a win for the patent holder and a</li> <li>loss?</li> <li>MR. BRISEBOIS: No. What I said is that I</li> <li>coded this as both a won and lost utility challenge</li> <li>on the grounds of utility, so not as a loss or a</li> <li>win, since what I was coding was for the challenge</li> <li>and the outcomes, and there was an outcome which is</li> <li>invalidity on the grounds of utility for one of the</li> <li>embodiments, so that's why I coded that way.</li> <li>The fact that the infringer was infringing</li> <li>the valid claim has no relevance to what I was</li> <li>doing, and to acknowledge that there was a finding</li> <li>of lack of utility for a non-pharma patent in my</li> <li>opinion should be acknowledged and in any</li> <li>statistical analysis to see if there's any</li> <li>statistically significant difference between</li> <li>invalidity rates on the basis of utility between</li> <li>pharma and non-pharma sectors. Because the fact</li> <li>that this infringer was infringing that one doesn't</li> <li>mean anyone elsewhere could have infringed the other</li> <li>invalidated claims, and it doesn't mean that in the</li> </ul>	49/ 02:02	<ul> <li>future, now that this claim is out, that people are</li> <li>allowed to produce and market this second</li> <li>embodiment. So there was a true finding of</li> <li>invalidity on grounds of utility for that case.</li> <li>MS. CHEEK: Mr. Brisebois, are you aware</li> <li>that the embodiment that was found to be infringed</li> <li>was the only commercialized embodiment of this</li> <li>invention?</li> <li>MR. BRISEBOIS: Yes, but, again, this has</li> <li>no bearing on the outcomes of the case, whether or</li> <li>not a finding of invalidity on utility grounds was</li> <li>found, so</li> <li>MS. CHEEK: In layman's terms, given that</li> <li>there was a finding that Eurocopter was entitled to</li> <li>punitive damages because of Bell's infringement of</li> <li>its patent, would you say that Eurocopter won this</li> <li>case?</li> <li>MR. BRISEBOIS: No. They won the</li> <li>infringement portion of it but they lost on the</li> <li>utility findings with regard to one of the two</li> <li>embodiments.</li> <li>MS. CHEEK: And they were able to protect</li> <li>the embodiment that they commercialized because it</li> <li>was found to be useful?</li> <li>MR. BRISEBOIS: Yes, but they won't be</li> <li>www.dianaburden.com</li> </ul>	<b>490</b> 02:03
<ul> <li>able to defend and then protect the second embodiment for the future.</li> <li>MS. CHEEK: Are you aware of any plans they had to commercialize the second embodiment?</li> <li>MR. BRISEBOIS: Again, not part of my work. Same as I never distinguished the outcomes based on the commercial value of the claims. It was with regard to whether or not a finding of invalidity was present or not. So if we want to look at the impact and the impact is being invalid, I think this should be acknowledged that one of the embodiments had been found invalid for lack of utility.</li> <li>MS. CHEEK: So, despite the fact that the commercial embodiment was found infringed and it was found that it had utility, you code this case both as a finding of validity and as a finding of invalidity?</li> <li>MS. CHEEK: With regards to utility, yes.</li> <li>MS. CHEEK: With regards to utility. If we could now turn to the Uponor case, which is at Tab 10 of your binder, I direct your attention to the operative part of this judgment which is on page 93.</li> </ul>	<b>499</b> 02:04	1       MR. BRISEBOIS: Yes.         2       MS. CHEEK: You coded this case the same         3       way you code Eurocopter, is that right, as both a         4       finding of validity and a finding of invalidity?         5       MR. BRISEBOIS: That's correct.         6       MS. CHEEK: At Paragraph 2 on page 93, you         7       see that claim 16, 17, 25, 26 and 27 of the '376         8       patent were found valid and infringed by Pexcor and         9       Heatlink, correct?         10       MR. BRISEBOIS: Yes. I also see that many         11       claims in Paragraph 1 were found invalid, and I         12       believe many of these were found invalid for lack of         11       MS. CHEEK: That's with regard to the         12       claims.         16       MR. BRISEBOIS: That's right. That claims         17       an embodiment of an invention.         18       MS. CHEEK: So in paragraph 4, you see,         19       Mr. Brisebois, it says "Pexcor and Heatlink are         19       enjoined from manufacturing, using, offering for         19       sale and/or selling to others for their use the         20       apparatus of the heating polymer material that         21       infringes the '376 patent." You see that?	<b>500</b> 02:06

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<ul> <li>says here that the plaintiff is entitled to damages</li> <li>as a result of Pexcor and Heatlink's infringement?</li> <li>MR. BRISEBOIS: Yes.</li> <li>MS. CHEEK: And in paragraphs 7 and 8 it</li> <li>says the plaintiff is entitled to pre-judgment</li> <li>interest on that damages award, correct?</li> <li>MR. BRISEBOIS: 7 and 8?</li> <li>MS. CHEEK: Yes.</li> <li>MS. CHEEK: Yes.</li> <li>MS. CHEEK: So, again, even though in this</li> <li>case, Uponor v Heatlink, there is a finding of</li> <li>infringement, and damages are awarded, you code this</li> <li>both as a finding of inutility and a finding of</li> <li>utility. Is that right?</li> <li>MR. BRISEBOIS: That's correct, because I</li> <li>was not coding infringement outcomes, and the party</li> <li>lost his monopoly over many of the scope of the</li> <li>claims with regard to particular embodiments, what</li> <li>is particular invention. So he cannot anymore</li> <li>enforce these patent rights with regard to these</li> <li>claims.</li> <li>MS. CHEEK: But surely they can enforce</li> <li>their patent rights for the commercially valuable</li> <li>claims that were upheld and found infringed,</li> <li>correct?</li> </ul>	02:07	1       MR. BRISEBOIS: Commercially valuable for         2       this particular infringer, and at this particular         3       time, who knows, next year, for anybody else trying         4       to infringe any other part of this patent.         5       MS. CHEEK: In theory, because you don't         6       know anything about the other claims.         7       MR. BRISEBOIS: But it's never theory. At         8       the end of the day they lost claims because they         9       were held invalid for lack of utility.         10       MS. CHEEK: You do see that on the claims,         11       the commercially valuable claims, that the defendant         12       was enjoined from manufacturing, using, offering for         13       sale and/or selling to others the use of that         14       apparatus that was at issue and contention in this         15       case between these two parties, correct?         16       MR. BRISEBOIS: Yes.         17       MS. CHEEK: So, Mr. Brisebois, could we         18       turn to your first statement at Paragraph 41?         19       MR. BRISEBOIS: Yes.         20       MS. CHEEK: In Paragraph 41,         21       MR. BRISEBOIS: Correct.         22       MS. CHEEK: And you define the term	02:08
<ul> <li>"secondary patent" in Paragraph 41. You say, "I use</li> <li>'secondary patent' to describe a patent directed to</li> <li>modified forms of that base compound, or to a new</li> <li>medical use of a known drug." Is that correct?</li> <li>MR. BRISEBOIS: Yes.</li> <li>MS. CHEEK: Now, Mr. Brisebois, you would</li> <li>agree that Canadian patent law doesn't make a</li> <li>distinction between primary and secondary patents in</li> <li>terms of their patentability criteria, right?</li> <li>MR. BRISEBOIS: No. Yes, I agree.</li> <li>MS. CHEEK: Now, Mr. Brisebois, you</li> <li>characterized the atomoxetine '735 patent as a</li> <li>secondary patent. Is that correct?</li> <li>MR. BRISEBOIS: That's correct, because it</li> <li>was falling in the category of new therapeutic use.</li> <li>MS. CHEEK: Mr. Brisebois, what known drug</li> <li>or known medicine was already on the market at the</li> <li>time that the '735 patent was filed?</li> <li>MR. BRISEBOIS: I don't know.</li> <li>MS. CHEEK: There was no known drug</li> <li>already on the market for the atomoxetine compound,</li> <li>correct?</li> <li>MR. BRISEBOIS: Possibly. It doesn't</li> <li>matter with regard to how I classified a patent.</li> <li>MS. CHEEK: You say here that it's for a</li> <li>www.dianaburden.com</li> </ul>	<b>503</b> 02:10	<ul> <li>new use of a known drug, and I take "drug" to mean a medicine that's being offered to patients, correct?</li> <li>MR. BRISEBOIS: No. What I meant is a known drug as a molecule, so I guess this isn't precise to say known-drug. It should have been known molecule, or patented molecule.</li> <li>MS. CHEEK: Are you aware, Mr. Brisebois, that Strattera, the drug, the known drug that's protected by the '735 patent, was the very first human treatment ever developed and approved using the compound atomoxetine?</li> <li>MR. BRISEBOIS: I believe you, but it was not the first patent that protected that molecule.</li> <li>MS. CHEEK: Mr. Brisebois, you also say that you consider selection patents as secondary patents. This is also at Paragraph 41, since they involve a member of an already patented class of compounds. Is that right?</li> <li>MR. BRISEBOIS: That's correct.</li> <li>MS. CHEEK: And on that basis you've characterized Zyprexa, the '113 patent, as a secondary patent?</li> <li>MR. BRISEBOIS: Yes.</li> <li>MS. CHEEK: So are you aware that the olanzapine compound itself was never even www.dianaburden.com</li> </ul>	<b>504</b> 02:12

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<ul> <li>synthesized until two years after the genus patent</li> <li>was issued?</li> <li>MR. BRISEBOIS: I think I read about this,</li> <li>yeah.</li> <li>MS. CHEEK: And are you aware that</li> <li>Zyprexa so the invention protected by the '113</li> <li>patent was the very first human treatment that</li> <li>was ever developed and approved to use the compound</li> <li>olanzapine?</li> <li>MR. BRISEBOIS: Okay, but it doesn't</li> <li>change the fact that the molecule was previously</li> <li>protected by the genus patent, although it was not</li> <li>synthesized.</li> <li>MS. CHEEK: Your focus is on the molecule,</li> <li>not on the approved drug?</li> <li>MR. BRISEBOIS: My focus is on whether it</li> <li>was patented.</li> <li>MS. CHEEK: Mr. Brisebois, if we could</li> <li>turn to Paragraph 62 of your statement.</li> <li>MR. BRISEBOIS: The first one?</li> <li>MS. CHEEK: Yes, I believe the first one.</li> <li>Here you note that Claimant filed 12 patent</li> <li>applications for atomoxetine between 1992 and 2004.</li> <li>Is that right?</li> <li>MR. BRISEBOIS: That's right.</li> </ul>	505       MS. CHEEK: Mr. Brisebois, you know that         2       research takes place before a scientist applies for         3       a patent, correct?         4       MR. BRISEBOIS: They should, yes.         5       MS. CHEEK: And did you have any personal         6       knowledge of any of the Lilly scientists who were         7       working on atomoxetine in the 1990s?         8       MR. BRISEBOIS: No.         9       MS. CHEEK: Did you have access to any of         10       Lilly's reports or studies on their research for         11       atomoxetine in the 1990s?         12       MR. BRISEBOIS: No. I only base my         13       observation on what I saw in the patents         14       application, sorry. Patent applications.         15       MS. CHEEK: So, beyond what's in the         16       patent applications, you have no insight into the         17       research and development taking place of atomoxetine         18       inside Lilly laboratories. Correct?         19       MR. BRISEBOIS: That's correct.         20       MS. CHEEK: If we could turn to Tab 8,         21       which is C-384, for your own reference,         22       MR. BRISEBOIS: Sure.	<b>506</b> 02:15
25 MK. BKISEBUIS: I hat s right. www.dianaburden.com	25 MK. BKISEBUIS: Sure. www.dianaburden.com	
<ul> <li>MS. CHEEK: Mr. Brisebois, in your Annex E</li> <li>to your First Report, if you could turn to the page</li> <li>with the atomoxetine patents, which is page 3,</li> <li>you've coded them in green, and on line 4 there is a</li> <li>patent 2,304,657 for conduct disorder where you say</li> <li>there was no data pertinent to the therapeutic use.</li> <li>Is that right?</li> <li>MR. BRISEBOIS: That's correct.</li> <li>MS. CHEEK: This is the same patent,</li> <li>patent 2,304,657, that is behind tab 8?</li> <li>MR. BRISEBOIS: Yes.</li> <li>MS. CHEEK: So you've criticized this</li> <li>patent for including no data that was pertinent to</li> <li>therapeutic use. Is that right?</li> <li>MR. BRISEBOIS: No. I just observed that</li> <li>there was no relevant experimental data to the</li> <li>specific therapeutic use claimed.</li> <li>MS. CHEEK: Are you aware that by the time</li> <li>this patent, the 2,304,657 patent, was filed in</li> <li>1998, that Lilly had spent close to two decades</li> <li>researching the atomoxetine compound?</li> <li>MR. BRISEBOIS: Okay, but was it on the</li> <li>treatment of conduct disorder?</li> <li>MS. CHEEK: Are you aware that the</li> <li>scientist who's listed as the inventor who</li> </ul>	<ul> <li>507</li> <li><sup>02:17</sup></li> <li>1 discovered actually let me back up,</li> <li>Mr. Brisebois.</li> <li>3 This patent application that we're looking</li> <li>4 at, patent application 2,304,657, that is for a</li> <li>5 norepinephrine reuptake inhibitor that's used to</li> <li>6 treat conduct disorder, correct?</li> <li>MR. BRISEBOIS: That's the abstract?</li> <li>8 MS. CHEEK: I am reading from the</li> <li>9 abstract, yes, and line 54 on the front of the</li> <li>10 patent which says "Treatment of conduct disorder".</li> <li>11 MR. BRISEBOIS: I observe that the claim</li> <li>12 includes the use of atomoxetine as a norepinephrine</li> <li>13 reuptake inhibitor.</li> <li>14 MS. CHEEK: Very good. And you're looking</li> <li>15 to the claims of this patent and the claims of this</li> <li>16 patent are on page 13. Is that right?</li> <li>17 MR. BRISEBOIS: That's correct.</li> <li>18 MS. CHEEK: So, looking back at the front</li> <li>19 of the patent, Mr. Brisebois, you'll see that</li> <li>20 there's two inventors listed, John Harrison</li> <li>21 Ligenstein and Eli Lilly and Company. Is that</li> <li>22 right?</li> <li>23 MR. BRISEBOIS: Are these the same person</li> <li>24 or</li> </ul>	<b>508</b> 02:19

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1       listed at line 72 on the front of the patent.         2       MR. BRISEBOIS: Yeah, okay. Yeah.         3       MS. CHEEK: Are you aware that John         4       Heiligenstein was one of the inventors of the '735         5       patent atomoxetine for the treatment of ADHD?         6       MR. BRISEBOIS: I didn't know.         7       MS. CHEEK: Do you have any personal         8       knowledge of the research that Dr. Heiligenstein was         9       performing before he filed this patent before you?         10       MR. BRISEBOIS: No, because I only looked         11       at what was disclosed in the patent application.         12       MS. CHEEK: So you weren't privy to any         13       internal scientific research or other information         14       that Lilly might have relied upon when it decided to         15       file this patent, correct?         16       MR. BRISEBOIS: That's correct. It could         17       be the reason why this patent did not include         18       experimental data relevant to the therapeutic use,         19       but I did not assess the reason or I was just         10       looking whether or not it was containing this         19       specific data for the claimed therapeutic use.         11		MR. BRISEBOIS: That's correct. I was         just finding it interesting that some patents did         include experimental data and some did not.         MS. CHEEK: So again, Mr. Brisebois, but         you're not familiar at all with the lines of         research on atomoxetine that Lilly was conducting in         the 1990s, correct?         MR. BRISEBOIS: That's correct.         MS. CHEEK: I think we've now         established and in fact, it's established in your         chart that there were multiple patents filed         related to the compound atomoxetine. Is that right?         MR. BRISEBOIS: That's right.         MR. BRISEBOIS: That's right.         MR. BRISEBOIS: No, not precisely.         MR. BRISEBOIS: No, not precisely.         MR. BRISEBOIS: No, not precisely.         MS. CHEEK: So you're not privy to the         reasons why Lilly might decline to commercialize a         particular patented use, correct?         MR. BRISEBOIS: That's correct.         MS. CHEEK: Mr. Brisebois, you've said         that you're not privy to all of the research that         was being done on the atomoxetine patent at Lilly?         MR. BRISEBOIS: Correct.         www.dianaburden.com	02:22
1       MS. CHEEK: And the same can be said for         2       all the research that had been done related to         3       olanzapine at Lilly, correct?         4       MR. BRISEBOIS: Correct. Except for what         5       is disclosed in the patent application.         6       MS. CHEEK: And it's also true that you         7       have no personal knowledge of all of the research         8       that Lilly was doing on Raloxifene prior to filing         9       these patents. Is that correct?         10       MR. BRISEBOIS: That's correct.         11       MS. CHEEK: So, Mr. Brisebois, to confirm,         12       when you made statements in your witness statement         13       about Lilly's patents that were filed for         14       atomoxetine, olanzapine and Raloxifene, you did that         15       solely based on reading what happened to be in the         16       patent applications and not based at all on any         17       knowledge of the broader research that Lilly was         18       doing on those compounds at the time. Is that         19       mR. BRISEBOIS: For the olanzapine, I also         10       MR. BRISEBOIS: For the olanzapine, I also         10       oked at a list of clinical trials performed for         10		1       NS. CHEEK: I have no further questions.         2       Thank you, Mr. Brisebois.         3       THE PRESIDENT: Thank you, Ms. Cheek. Any         4       redirect?         5       MR. SPELLISCY: Just give us a moment to         6       confer.         7       THE PRESIDENT: Yes.         8       MS. ZEMAN: There will be no questions         9       from the Respondent.         10       THE PRESIDENT: Thank you. No questions         11       from the Tribunal either. Mr. Brisebois, thank you         12       for testifying. You are now released and excused as         13       a witness.         14       MR. BRISEBOIS: Thank you.         15       THE PRESIDENT: I suggest five minutes         16       change-over for Professor Siebrasse.         17       MS. CHEEK: Very good. Thank you.         18       (Recess taken)         19       PROFESSOR NORMAN SIEBRASSE         20       THE PRESIDENT: Good afternoon. Could you         21       please state your full name for the record?         22       PROFESSOR SIEBRASSE: Professor Norman         23       Siebrasse.         24       THE PRESIDENT: Professor Siebrasse, you         25       appear as a	<b>512</b> 02:26

1 PROFESSOR SIEBR		513		Washingtor THE PRESIDENT: Could you then go to your	514
<ul> <li>to you, either because of</li> <li>reason, please do seek a</li> <li>you don't do so, the Tribu</li> <li>you've understood the quest</li> <li><b>PROFESSOR SIEBR</b></li> <li><b>THE PRESIDENT:</b></li> <li>appreciate that testifying,</li> <li>an arbitral tribunal, is a ve</li> <li>in this connection the Tribu</li> <li>the statement which is in</li> <li><b>PROFESSOR SIEBR</b></li> <li>upon my honor and consister</li> <li>be in accordance with my</li> <li><b>THE PRESIDENT:</b></li> <li>please go to your first Exp</li> <li><b>PROFESSOR SIEBR</b></li> <li><b>THE PRESIDENT:</b></li> <li>September 29, 2014, and</li> <li>the signature appearing a</li> <li>signature?</li> <li>Signature.</li> </ul>	anal will assume that lestion and that your answer ion. ASSE: Yes, I understand. Professor, you will be it before a court or ery serious matter, and bunal requests you to make front of you. ASSE: I solemnly declare cience that my statement will y sincere belief. Thank you. Could you pert Report. ASSE: Yes. To page 31, and it's dated i confirm for the record that		2 3 4 5 6 7 8 9 10 11 2 13 14 15 6 7 8 9 10 11 2 23 24 25 23 24 25	second Expert Report and go to page 36, and that is dated September 10, 2015, and again confirm for the record that the signature appearing above your name is your signature? PROFESSOR SIEBRASSE: Yes, that is my signature. THE PRESIDENT: Is there any correction you wish to make to either report? PROFESSOR SIEBRASSE: Yes. I have an errata sheet. THE PRESIDENT: The errata sheet is there, but is there anything in addition to the errata sheet? PROFESSOR SIEBRASSE: No. THE PRESIDENT: Ms. Cheek or Ms. Wagner, who is conducting the direct examination? MS. CHEEK: Ms. Wagner will be directing Professor Siebrasse. Thank you. To clarify, we were going to propose that Professor Siebrasse present his presentation in the first instance, and then we do have some direct questions for him that will follow his presentation. THE PRESIDENT: Five minutes? MS. CHEEK: Of direct? Probably a bit www.dianaburden.com	
<ul> <li>5 speaking notes?</li> <li>6 MS. CHEEK: He</li> <li>7 THE PRESIDENT:</li> <li>8 please proceed. Actually</li> <li>9 counsel for the Claimant,</li> <li>10 MS. WAGNER: Pla</li> <li>11 PRESENTATION BY F</li> <li>12 PROFESSOR SIEBR</li> <li>13 qualifications, I'm Norman</li> <li>14 Law at the University of N</li> <li>15 held for 23 years. I teach</li> <li>16 commercial law, remedie</li> <li>17 research generally is on 0</li> <li>18 remedies, and the interse</li> <li>19 property and commercial</li> <li>20 I've written som</li> <li>21 at issue in this arbitration</li> <li>22 here were written before</li> <li>23 this matter, and the third</li> <li>24 and I'll confirm that I had</li> <li>25 relationship with Lilly.</li> </ul>	And the Professor has no does not. Professor Siebrasse, you are in the hands of not in my hands. ease go ahead. ^ <b>PROFESSOR SIEBRASSE</b> <b>ASSE:</b> My background and n Siebrasse, Professor of Jew Brunswick, a post I've n in the areas of IP law, s and competition law. My Canadian patent law, patent ection of intellectual law. ne articles on the matters . The first two listed I was retained by Lilly in was written subsequently,	<b>515</b> 02:36	$\begin{array}{c}1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\23\\14\\15\\16\\7\\18\\9\\20\\21\\22\\23\\24\\25\end{array}$	Turning, then, to the substantive overview, first I'll start with the utility requirements under prior law when Lilly's patents were filed and granted. At the time the standard for utility was very low. It was normal to say "a slight amount" or "very little will do." Since 2005 it's become normal for the courts to say a "mere scintilla" of utility is required. No one has ever suggested this is any different; it all reflects the same standard. Post-filing evidence was always admissible to establish utility, and in particular two kinds of post-filing evidence were commonly used. One is commercial success so the fact that the product was sold in the marketplace was considered evidence of utility. And also use by the defendant. If the defendant was actually infringing, this would be considered also proof that the invention was useful on the view the infringer would not infringe something useless, or couldn't really infringe something useless. The rationale for this under prior law was that proof today that the invention works is proof that it would have worked yesterday. So for example, if the Wright brothers build an airplane, www.dianaburden.com	<b>516</b> 02:38

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<ul> <li>they park it in the field on Day 1. Day 2, they</li> <li>write down a patent application that perfectly</li> <li>describes that particular airplane. They file their</li> <li>patent application and the next day they come back</li> <li>and actually fly the airplane, the fact that the</li> <li>airplane flew on Day 3 is evidence that that</li> <li>airplane that same airplane would have worked,</li> <li>would have flown on Day 1.</li> <li>Utility was assessed as of the filing</li> <li>date. What this means is that it's the very plane</li> <li>that was parked in the field and described in the</li> <li>application that had to fly and not some</li> <li>subsequently improved version.</li> <li>On to the third aspect of the law we're</li> <li>concerned with, sound prediction. As you've heard I</li> <li>believe the past couple of days, a patent can claim</li> <li>a broad class of compounds called a genus or a</li> <li>single compound sometimes referred to as a species.</li> <li>It's not possible to test all the compounds in a</li> <li>broad genus, and the utility of the tested compounds</li> <li>under prior law is said to be demonstrated. The</li> <li>utility of the untested compounds can be established</li> <li>on the basis of sound prediction.</li> <li>Evidence from outside the patent was</li> <li>admissible to establish sound prediction, so this is</li> </ul>	02:39	<ul> <li>a quote from Olin Mathieson, a UK case, but it is</li> <li>one that was accepted into Canadian law by Monsanto</li> <li>in '78. It's clear from that case the works relied</li> <li>on to establish the sound prediction were outside</li> <li>the patent.</li> <li>So, in summary, the bar was low,</li> <li>post-filing evidence was admissible to establish</li> <li>utility, sound prediction could be established on</li> <li>the basis of all the evidence. So when were</li> <li>inventions held to lack utility? Not very often.</li> <li>And it was primarily in the case or only in the case</li> <li>of inoperable inventions death ray, perpetual</li> <li>motion, the snow blower in Wandscheer, the Supreme</li> <li>Court of Canada decision, that really didn't throw</li> <li>snow, or inoperable species within a claim.</li> <li>Turning now to the current law of utility</li> <li>when Lilly's patents were revoked, in 2002 and</li> <li>I'm going chronologically through the changes in</li> <li>2002 in the AZT decision, the Supreme Court of</li> <li>Canada held that after-the-fact evidence cannot be</li> <li>used to establish utility. And, in particular, the</li> <li>claim was to AZT for the treatment of HIV Aids, and</li> <li>the Federal Court, the trial court, and the Court of</li> <li>Appeal said yes, of course it's useful, it's</li> <li>actually being used to treat people with HIV Aids.</li> </ul>	02:40
<ul> <li>And the Supreme Court of Canada said that fact that</li> <li>it's actually being used cannot be considered.</li> <li>So how do we know the law changed? First,</li> <li>there are no prior decisions excluding post-filing</li> <li>evidence of utility. The Supreme Court itself did</li> <li>not cite any prior case law supporting this rule</li> <li>excluding post-filing evidence. Canada doesn't even</li> <li>cite any prior case law excluding post-filing</li> <li>evidence of utility. And the Supreme Court reversed</li> <li>both the AZT decision and it reversed the Court of</li> <li>Appeal decision in AZT, and overruled the prior</li> <li>Court of Appeal decision in Ciba-Geigy.</li> <li>Also there was subsequent clarification</li> <li>required as to the scope of this rule. I believe</li> <li>you heard that a patent filed in Canada can claim</li> <li>priority to a prior, subsequent or foreign</li> <li>application, and the question was well, does</li> <li>after-the-fact mean after the priority date or after</li> <li>the filing date. Subsequent to AZT the Court of</li> <li>Appeal clarified, interpreting AZT, that this meant</li> <li>post filing. If this had been a long-established</li> <li>rule; that clarification shouldn't have been</li> <li>necessary.</li> <li>Most clearly, I suppose, patents for</li> <li>commercially successful products are now often held</li> </ul>	<b>519</b> 02:41	<ul> <li>to lack patentable utility. Prior to AZT no</li> <li>commercially successful product was ever held to</li> <li>lack patentable utility.</li> <li>Next on the standard for utility, now we</li> <li>have a bifurcated standard for utility. You can</li> <li>have an invention which would otherwise be valid,</li> <li>that is would have a scintilla of utility, and can</li> <li>nonetheless promise more for the invention than is</li> <li>required by the Act so as to render the patent</li> <li>invalid. So this promise of the patent, promise</li> <li>doctrine, I call it here, or promise of the patent,</li> <li>may result, as the courts have said, in an elevated</li> <li>standard for utility that's an exception to the Act.</li> <li>So it represents a standard above the scintilla that</li> <li>would otherwise be required.</li> <li>The promise of the patent is determined by</li> <li>a detailed examination of statements in the</li> <li>disclosure. Anastrozole is a good example of this.</li> <li>62 paragraphs, a quarter of the decision, dedicated</li> <li>type of analysis of the disclosure to determine the</li> <li>promise was not seen under prior law.</li> <li>Now, it may seem intuitive that a patentee</li> <li>should not be able to obtain a patent on the basis</li> <li>of misrepresentations, and the Patent Act but</li> </ul>	<b>520</b> 02:43

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<ul> <li>that's not well, in my opinion that's not the</li> <li>rationale for the promise of the patent doctrine</li> <li>because the Patent Act has always policed untrue</li> <li>statements under Section 53 we've had an</li> <li>equivalent to Section 53 in almost the same wording</li> <li>ever since the Confederation and a patent is void</li> <li>if any material allegation is untrue and the</li> <li>admission is willfully made for the purpose of</li> <li>misleading.</li> <li>This is distinct from the promise of the</li> <li>patent. In particular, under Section 53, any</li> <li>statement must be false in fact. It must actually</li> <li>be false.</li> <li>Under the promise of the patent, a</li> <li>statement of promise may be true in fact and, yet,</li> <li>the patent will be held to not have met the promise</li> <li>because it could not have been proven to have been</li> <li>true as of the filing date. 53 must actually be</li> <li>false. Also 53 has an intent requirement,</li> <li>willfulness, not under the promise, and also</li> <li>materiality requirement, which we don't see under</li> <li>the promise of the patent.</li> <li>The fact of this distinction is</li> <li>illustrated by the first decision on olanzapine, in</li> <li>www.dianaburden.com</li> </ul>	02:44	<ul> <li>on the basis of Section 53, and the court dismissed</li> <li>that attack both on the basis that there was no</li> <li>intent but also that the generic had not persuaded</li> <li>me that Lilly had made any false statements.</li> <li>And it was the same patent that was</li> <li>nonetheless held invalid for failure to satisfy the</li> <li>promise.</li> <li>So how do we know the law has changed?</li> <li>Prior to 2005 no Canadian court ever held a patent</li> <li>invalid for failure to satisfy an elevated standard</li> <li>of utility derived from the disclosure. Consolboard</li> <li>itself emphasized a low bar, did not apply an</li> <li>elevated standard for utility, and Consolboard was</li> <li>never cited as supporting a bifurcated or elevated</li> <li>standard prior to 2005.</li> <li>The third aspect of the law that we're</li> <li>considering is that the additional disclosure</li> <li>requirement for sound prediction so now it's</li> <li>clear law that only evidence in the patent itself</li> <li>can be used in support of sound prediction, this was</li> <li>established by the Raloxifene decision in</li> <li>interpreting the AZT decision. But, on the other</li> <li>hand, it's equally clear law that evidence outside</li> <li>the patent can be used to demonstrate utility, and</li> <li>so the courts say that the disclosure requirements</li> </ul>	322 02:45
<ul> <li>for sound prediction are more onerous than to</li> <li>demonstrate utility. They might say enhanced or</li> <li>additional disclosure requirements.</li> <li>There is no basis in the Act for this</li> <li>distinction. Utility, the word "useful", only</li> <li>appears once. There's no statutory basis for this.</li> <li>How do we know the law changed? No sound</li> <li>prediction decision prior to Raloxifene ever refused</li> <li>to consider evidence from outside the patent. No</li> <li>court has ever cited any decision prior to AZT as</li> <li>authority for the rule. And, in fact, prior sound</li> <li>prediction cases like Olin Mathieson and Ciba-Geigy</li> <li>admitted evidence from outside the patent.</li> <li>In addition details of the rule are still</li> <li>being debated by the courts, does it apply in all</li> <li>sound prediction cases, as usually thought, or some</li> <li>courts have suggested that no, it only applies in</li> <li>new use cases such as atomoxetine in this context.</li> <li>These changes have had particular impact</li> <li>on pharmaceutical patents essentially because, as a</li> <li>practical matter, pharmaceuticals have to be</li> <li>patented before any large scale clinical trials,</li> <li>otherwise there's a risk of anticipating your own</li> <li>patent by having clinical trials and the nature of</li> <li>the invention becomes public, in which case you</li> </ul>	<b>523</b> 02:46	1       can't get a patent.         2       Also, of course, the pharmaceutical         3       companies don't want to invest in expensive clinical         4       trials before they actually have the patent. So the         5       problem is, if we have an elevated standard for         6       disclosure under the promise of the patent, as in         7       atomoxetine, a requirement to establish clinical         8       efficacy in the longer term, you really need longer         9       term clinical trials to establish this, but those         10       very trials that are needed to establish the higher         11       elevated standard are excluded by this rule against         12       after-the-fact evidence. This means utility of a         13       commercially successful product cannot always be         14       demonstrated.         15       This means that the ability to establish         16       utility based on sound prediction is much more         17       important, even for commercially successful         18       pharmaceuticals. It was never used previously for         19       commercially successful pharmaceuticals because         20       utility would be demonstrated. That sound         19       prediction is now important but we now have this	<b>524</b> 02:48

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Confid 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	evidence, in particular commercial success/regulatory approval, would have established validity under old law but the elevated standard to which they were held could not be proven at the time of filing. So for those reasons my conclusion is that there has been a sea change in the Canadian law of utility that has made it interact, made it substantially more difficult to establish utility and substantially easier to challenge patents on that basis. Thank you. <b>DIRECT EXAMINATION ON BEHALF OF THE CLAIMANT</b> MS. WAGNER: Good afternoon, Professor Siebrasse. Members of the Tribunal, I'm not sure you're aware that a hard copy of Professor Siebrasse's presentation slides are at Tab 4 of our direct examination binder. Professor Siebrasse, you don't have to speak too quickly. I think the court reporter might be having some difficulty, although she has said nothing! I'm primarily going to be referring to Tab 18 of the direct examination binder, which is the Second Report of Mr. Dimock. The cases that I	<b>525</b> 02:49	1 2 3 4 5 6 7 8 9 10 11 12 13 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 9 20 21 22 23 24 25	examination binder. You may or may not need to refer to them, but they're there if you need them. So at Tab 18, the Second Report of Mr. Dimock, at Paragraph 33 of that report, Mr. Dimock claims "There are several other cases and legal commentary not mentioned in my First Report which show that Consolboard was cited as authority for promised utility." And he gives a date range between 1981 and 2005. Then, at paragraphs 38-40 of that report, Mr. Dimock references in particular three cases. Feherguard, which is at Tab 5 of the direct examination materials and is Exhibit R-360; Almecon, which is at Tab 6 of the materials and is Exhibit C-230, and the Goldfarb case at Tab 7, R-187. With respect to those cases, what is your response to his assertion? <b>PROFESSOR SIEBRASSE:</b> Mr. Dimock says "These cases cite Consolboard as authority for the promised standard of utility." These cases cite the particular passage from Consolboard that's controversial, but they don't cite it for the promised standard of utility. Almecon/Goldfarb says what I take from this is that the patent must work,	02:50
25	will be referencing are also within the direct www.dianaburden.com		25	and Almecon similarly just takes from it that the www.dianaburden.com	
1 2 3 4 5 6 7 8 9 10 11 22 3 4 5 6 7 8 9 10 11 12 13 14 15 16 7 8 9 20 21 22 23 24 25	patent has to work. Feherguard was a case in which the claimed invention didn't work because the claim didn't specify its nuts and bolts that were needed to make it operable, so it was a simple case of inoperability. In none of these cases was there an elevated standard of utility or a standard derived from the disclosure. <b>NS. WAGNER:</b> At Paragraph 40 of his Second Report again, this is at Tab 18 Mr. Dimock also quotes the 1995 treatise of Donald MacOdrum, and that is at Tab 8 of the direct examination binder, R-361, and he states that this text considered Consolboard as authority for the promise standard prior to 2005. What is your response to this assertion? <b>PROFESSOR SIEBRASSE:</b> So Mr. Dimock at Paragraph 40 cites Mr. MacOdrum as saying where some specific utility is promised, the patentee must meet that, and then notes that Mr. MacOdrum cited the Consolboard decision with the implication, I suppose, I would take, that Mr. MacOdrum cited Consolboard for that proposition. But Mr. MacOdrum cited Consolboard for this basic utility requirement. He had three bulleted points, cited Consolboard in the first bulleted point along with www.dianaburden.com	<b>527</b> 02:52	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	cases like the Death Ray case and the Perpetual Motion case, so he didn't cite it for the promise of the patent in the sense of a bifurcated standard. The cases which Mr. MacOdrum did cite in the section Mr. MacOdrum did indeed refer to a promised utility. In that section he cited some UK cases and three Canadian cases. I believe the only Canadian case I haven't discussed previously is the TRW case. Let me take a look. Which tab is Mr. MacOdrum? MS. WAGNER: It's at Tab 8. PROFESSOR SIEBRASSE: The only other case is TRW, and in that case it was a patent for claim to a produced article, and the produced article included compressor blades and turbine blades, and the claimed method worked to produce turbine blades. So it's simply a matter of inoperability. And none of the cases cited by MacOdrum none of the Canadian cases, I'm sorry, cited by Mr. MacOdrum use an elevated standard derived from the disclosure. THE PRESIDENT: Can you please help me, in the MacOdrum treatise, where can we find the three bullets you just referred to? www.dianaburden.com	<b>528</b> 02:53

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1 <b>PROFESSOR SIEBRASSE:</b> That's page 1, which2is about the fourth physical page of that tab. The3one that says Chapter 5, Utility. And if you look4at the second paragraph under Introduction, "There5are three broad ways " 1, 2, 3. If you look6above it, utility, he's got an introduction and7general comments but it's 5.2, 3 and 4 correspond to8those bullet points 1, 2, 3.9 <b>NS. WAGNER:</b> Professor Siebrasse, at10Paragraph 26 of Mr. Dimock's Second Report, he11refers to a number of cases also listed in Annex B12to his report, which is at page 45 of his report.13 <b>PROFESSOR SIEBRASSE:</b> Yes.14 <b>NS. WAGNER:</b> These are cases which he16indicates exemplify the promise of the patent16analysis. Some of these are new to his Second17Report and you've not addressed these previously,18and so I'm going to ask you to respond briefly to19Mr. Dimock's assertion with respect to each of these20cases, and each are in your direct examination21binder. The first case is listed in Annex B that22you have not responded to, the Wandscheer case,23which is also at Tab 10 of the direct examination24binder and is Exhibit C-259.25 <b>PROFESSOR SIEBRASSE:</b> Yes. This case, the34www.dianaburden.com	<b>529</b> 02:55	discussed in to the trial de says really in the Supreme It was the sn invention did to mean the inoperable. 3 Supreme Co Supreme Co MS. 2 have not disc decision, whi and is R-359 C decision, the issue at trial. 3 utility addres appealed, an pointed out in process wou was unconte mat. It was h	WAGNER: The next listed decision you cussed is the Consolboard trial division ch is included in the binder at Tab 11	530 02:57
1       and R-375.         2       PROFESSOR SIEBRASSE: The Corning Glass         3       case really applies a very low standard of utility.         4       The invention was fiber optic cable, fiber optic         5       cable defined to include impurities up to         6       .1 percent, and there was uncontested evidence that         7       cables with that degree of impurity would not be         8       commercially successful, and the trial judge said         9       well, that doesn't matter, commercial utility isn't         10       the success. There's no evidence that it doesn't         1       have some degree some utility, commercial or         0       otherwise, and upheld the validity.         13       MS. WAGNER: The last case I'll ask you to         14       comment on is the Wellcome Foundation v Apotex.         15       This is actually not the AZT case; it's a different         16       Wellcome case. It's at Tab 13 of the direct         17       materials and C-41 is the exhibit.         18       PROFESSOR SIEBRASSE: Yes. As I stated in         19       my First Report, the courts often have to look to         20       the disclosure to find out what the invention is         20       good for. This is particularly in the case true for	<b>531</b> 02:58	for the produ law, that clain considered u were useful, disclosure to good for. It's case becaus statements in arguably at le intermediates very superion products wer properties, a whether or n satisfied. Statements. establishing have any gen regarding the <b>PRO</b>	because the claim was to intermediates ction of end products. Under Canadian in to the intermediates would only be seful if the end products themselves and the court was looking to the see well, what are the end products evident that this is not a promise e there were actually a number of in the disclosure that today would be, east, considered to be promises, so the swere said to have yields that were to other processes, and the end e said to have very high antibacterial ind today there would be a debate as to bot those were promises that had to be the patent was not held to any of those They were not even considered in the utility. WAGNER: Professor Siebrasse, do you heral reaction to Mr. Dimock's assertion ese cases and what they exemplify? FESSOR SIEBRASSE: Yes. As I said in I report, but one of my reports, the mere www.dianaburden.com	532 02:59

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<ul> <li>use of the word "promise" doesn't indicate the promise doctrine. Promise of the patent is look to the disclosure for an elevated standard. The courts and all that Mr. MacOdrum has done taken a bunch of examples where the court use word "promise" in the utility context. Yes, the courts often use the word "promise" in the utility context and, as these very cases illustrate, the used it simply to mean what is the patent good MS. WAGNER: Professor Siebrasse, I'll you to now turn to Paragraph 54 of Mr. Dimock Second Report. At this Paragraph Mr. Dimock contends that the overbreadth jurisprudence, including several cases he did not address in h First Report, demonstrates that the current law promised utility is not new. How would you rest to that assertion with respect to these new case</li> <li>PROFESSOR SIEBRASSE: Overbreadth jurisprudence, invented. By the nature of overbreadth, it's not that your claim, if it's too broad, would overlap with some other ground of invalidity. For examif I invent the spoked wheel but I claimed the wheel, my invention would be too broad. I've claimed more than I actually invented. But it w www.dianaburden.com</li> </ul>	e here is es the y y for. ask c's s spond es? ust ctually rmal nple,	<ul> <li>also be anticipated because the wheel was not new.</li> <li>Only the spoked wheel was.</li> <li>So overbreadth can overlap with any of the</li> <li>other grounds of invalidity; it can overlap with</li> <li>utility, or anticipation or obviousness. Prior to</li> <li>2005, whenever overbreadth overlapped with utility,</li> <li>it overlapped with the scintilla branch because that</li> <li>was the only branch there was. Since 2005 it's</li> <li>possible that overbreadth could overlap with either</li> <li>of the branches of utility.</li> <li>MS. WAGNER: Professor Siebrasse, if you</li> <li>can now turn to Paragraph 91 of Mr. Dimock's Second</li> <li>Report.</li> <li>PROFESSOR SIEBRASSE: Yes.</li> <li>MS. WAGNER: In this paragraph Mr. Dimock</li> <li>has stated that in characterizing the bar on</li> <li>post-filing evidence as new, you've ignored the</li> <li>jurisprudence on this point that was developed under</li> <li>Canada's first-to-invent regime. What is your</li> <li>response to this assertion?</li> <li>PROFESSOR SIEBRASSE: Well, I didn't deal</li> <li>with that jurisprudence in my Second Report because</li> <li>first off these are inventorship cases, not utility</li> <li>attacks as such, and there are lots of utility cases</li> <li>to deal with, but, more importantly, the First</li> </ul>	534 03:02
<ol> <li>Report, to my mind on its face, simply didn't</li> <li>address Mr. Dimock's point.</li> <li>Mr. Dimock says, and I agree, that the</li> <li>test for whether the invention was made, as he</li> <li>it, under these inventorship disputes was wheth</li> <li>not it was reduced to a definite and practical fo</li> <li>That says nothing about testing. So the Wright</li> <li>brothers' airplane that's sitting in the field is</li> <li>not a mere idea floating through somebody's b</li> <li>It's definite and practical. That says nothing</li> <li>about whether it had to be tested.</li> <li>In his Second Report Mr. Dimock has</li> <li>it clear that he views that part of this reducing t</li> <li>definite and practical form is that not only must</li> <li>exist but it must have been tested, in effect, an</li> <li>this is incorrect as a matter of law. In fact, the</li> <li>very case cited by Mr. Dimock in his First Repord</li> <li>Christiani v Rice, a leading Supreme Court of C</li> <li>decision on this case from the 1930s, I believed</li> <li>the very paragraph cited by Mr. Dimock, there's</li> <li>contrast drawn between when the invention was</li> <li>reduced to a definite and practical shape at this</li> <li>date, only tested at a later date, and the Privy</li> <li>Council in that case, accepted by the Supreme</li> </ol>	e puts her or orm. t rain. s made to t it d ort, Canada , in s a as s e Court,	<ul> <li>practical form is when it's written down in a manner</li> <li>that allows some third party to implement it, and</li> <li>not when it was tested. So definite and practical</li> <li>shape, on the one hand, means more than an idea</li> <li>floating through someone's brain, but less than</li> <li>testing.</li> <li>MS. WAGNER: And, Professor Siebrasse, at</li> <li>Paragraph 98 of his report, Mr. Dimock raises in</li> <li>this context a decision in 2001, Goldfarb, which is</li> <li>also in the materials at Tab 7 and is R-187. Can</li> <li>you comment specifically on that case?</li> <li>PROFESSOR SIEBRASSE: Yes. Mr. Dimock on</li> <li>page 28 quotes a little section from Goldfarb and</li> <li>underlines the words "at that date." I don't know</li> <li>if it's really worth turning to the tab but, if you</li> <li>do turn to the Goldfarb case, you'll see that that</li> <li>passage is excerpted from a discussion of general</li> <li>principles of law, and the general thrust of the</li> <li>discussion as a whole is that failed experiments are</li> <li>not considered to establish that the invention was</li> <li>made, and on the facts that's what happened at the</li> <li>earliest date. The court held that's a failed</li> <li>experiment. So really the decision as a whole says</li> <li>failed experiment is not an invention. That's</li> <li>nothing new.</li> </ul>	<b>536</b> 03:04

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Image: Missing Wagner:Can you turn now toparagraphs 124 and 125 of Mr. Dimock's SecondReport? In these paragraphs Mr. Dimock asserts thatrecent legal commentary draws a link between theheightened disclosure requirement for soundprediction and the Supreme Court of Canada'sdecision in the 1979 Monsanto case. And he cites inparticular articles that are written byCarol Hitchman and Adrian Zahl. Just for referencethe Hitchman article is Tab 14 and is R-366. TheZahl article is Tab 14 and is R-310. Can yourespond to this?PROFESSOR SIEBRASSE: Yes. Ms. Hitchmansays the need for proper disclosure certainly wasraised in the Monsanto case, but the question iswhat does that mean. She's quoted some words, thosewords are actually from Monsanto, but those wordswords are actually from Monsanto, but those wordsfrom Olin Mathieson that were quoted by the SupremeCourt in Monsanto.So rather than trying to interpret whatthese commentators have said in these brief remarks,if we go to Olin Mathieson, Olin Mathieson tells uswhat that phrase means. What it means is that the		1 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 3 14 5 10 10 10 10 10 10 10 10 10 10 10 10 10	prediction must be sound, based on the specification and all the surrounding circumstances, and based on all the evidence. And, if we look at Olin Mathieson itself, there was no disclosure of any factual basis in the patent. MS. WAGNER: Thank you, Professor Siebrasse. Those are my direct questions. Thank you. THE PRESIDENT: Thank you. Mr. Johnston, are you conducting the cross-examination? MR. JOHNSTON: Yes, I will be, President van den Berg. If it's possible to take a brief break of five minutes before we begin, or the afternoon break? THE PRESIDENT: That's fine. Five minutes' break. Professor Siebrasse, you are under testimony. It means you are not allowed to discuss this case with anyone. Break for five minutes. ( <i>Recess taken</i> ) THE PRESIDENT: Mr. Johnson, please proceed with the cross-examination. MR. JOHNSTON: Thank you, President van den Berg.	538 03:07
1       CROSS-EXAMINATION ON BEHALF OF THE RESPONDENT         2       MR. JOHNSTON: Professor Siebrasse, I'll         3       be asking you some questions this afternoon about         4       your expert reports. If I'm not clear in how I ask         5       the question, please do let me know, and I'll be         6       able to rephrase it so we can understand each other.         7       Professor Siebrasse, you've submitted two         8       expert reports in this proceeding. Do you consider         9       your role as an expert witness to address matters         10       PROFESSOR SIEBRASSE: Yes, of course.         11       PROFESSOR SIEBRASSE: Yes, of course.         12       MR. JOHNSTON: And to assist the Tribunal         13       in understanding the matters falling within the         14       scope of your reports?         15       PROFESSOR SIEBRASSE: Yes.         16       MR. JOHNSTON: And part of your mandate in         17       preparing those reports is to describe the law of         18       utility in Canada, both at the time that Lilly's         19       Strattera and Zyprexa patents were filed and         20       granted?         21       PROFESSOR SIEBRASSE: Yes.         22       MR. JOHNSTON: You mentioned in your <td><b>539</b> 03:14</td> <td>1 2 3 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 9 20 21 22 23 24 25 23 24 25 25 25 25 25 25 25 25 25 25</td> <td>the third, and I wonder if you could please provide the date at which you were retained by Eli Lilly? PROFESSOR SIEBRASSE: Well, I don't have notes, but I believe it was June of 2013. But I mean, I don't have notes in front of me. That's my best recollection. MR. JOHNSTON: And your opinion in this case concerns alleged changes in Canadian patent law in 2002, 2005 and 2008, referring to the elements of the PROFESSOR SIEBRASSE: Yes. I should maybe clarify that the second article might have been published after that date, but it was completed, and I did check on this in October of 2012. That is when I submitted the second article for publication, final version. MR. JOHNSTON: In your expert reports you refer to a period of prior law? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: And so prior law would refer to the time when none of the alleged changes were part of Canadian law? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: So prior law is prior to 2002?</td> <td><b>540</b> 03:15</td>	<b>539</b> 03:14	1 2 3 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 9 20 21 22 23 24 25 23 24 25 25 25 25 25 25 25 25 25 25	the third, and I wonder if you could please provide the date at which you were retained by Eli Lilly? PROFESSOR SIEBRASSE: Well, I don't have notes, but I believe it was June of 2013. But I mean, I don't have notes in front of me. That's my best recollection. MR. JOHNSTON: And your opinion in this case concerns alleged changes in Canadian patent law in 2002, 2005 and 2008, referring to the elements of the PROFESSOR SIEBRASSE: Yes. I should maybe clarify that the second article might have been published after that date, but it was completed, and I did check on this in October of 2012. That is when I submitted the second article for publication, final version. MR. JOHNSTON: In your expert reports you refer to a period of prior law? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: And so prior law would refer to the time when none of the alleged changes were part of Canadian law? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: So prior law is prior to 2002?	<b>540</b> 03:15

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PROFESSOR SIEBRASSE: Yes.	03:16	1	the Bar, that's correct.	03:17
<b>MR. JOHNSTON:</b> To the AZT decision?		2	MR. JOHNSTON: You're a law professor at	
PROFESSOR SIEBRASSE: Yes.		3	the University of New Brunswick?	
MR. JOHNSTON: You obtained your Law		4	PROFESSOR SIEBRASSE: Yes.	
degree in 1991?		5	MR. JOHNSTON: And you say in your Expert	
PROFESSOR SIEBRASSE: That's right.		6	Report that your academic research focuses on patent	
MR. JOHNSTON: And when were you called to		7	law?	
the Bar?		8	PROFESSOR SIEBRASSE: Yes.	
PROFESSOR SIEBRASSE: I'm not a member of		9	MR. JOHNSTON: In particular	
the Bar. Not called to the Bar.		10	pharmaceutical patent law?	
MR. JOHNSTON: So you're not a member of		11	PROFESSOR SIEBRASSE: Well, yes. Yes,	
2 any Canadian law society?		12	that's right.	
B <b>PROFESSOR SIEBRASSE:</b> That's correct.		13		
			<b>MR. JOHNSTON:</b> You began teaching at the	
MR. JOHNSTON: So you have never litigated		14	University of New Brunswick in 1993?	
a patent case?		15	PROFESSOR SIEBRASSE: Yes.	
6 <b>PROFESSOR SIEBRASSE:</b> That's correct		16	MR. JOHNSTON: You did not start teaching	
well, I did consult for Apotex on a damages case, as		17	intellectual property law until 1995?	
is stated in my First Report.		18	<b>PROFESSOR SIEBRASSE:</b> I can't remember the	
MR. JOHNSTON: You're not able to provide		19	exact date, but I know I didn't teach intellectual	
) legal advice in the context of a patent case in		20	property law from the very first time I arrived, no,	
Canada?		21	that's correct.	
2 <b>PROFESSOR SIEBRASSE:</b> Right, yes.		22	MR. JOHNSTON: Perhaps, actually, as we're	
3 MR. JOHNSTON: Because you're not called		23	discussing your background, it would be useful to	
to the bar?		24	pull up your CV, which is in your first expert	
5 PROFESSOR SIEBRASSE: I'm not called to		25	report. It follows at the very end of your report	
www.dianaburden.com			www.dianaburden.com	
·	543			544
in attachment A and	<b>543</b> 03:18	1	MR. JOHNSTON: So it's fair to say that	
PROFESSOR SIEBRASSE: Yes, I have it.		2	patent law was not the focus of your teaching in the	
<b>PROFESSOR SIEBRASSE:</b> Yes, I have it. <b>MR. JOHNSTON:</b> You've got it there. So		2 3	patent law was not the focus of your teaching in the 1990s?	
<b>PROFESSOR SIEBRASSE:</b> Yes, I have it. MR. JOHNSTON: You've got it there. So I'm looking at		2 3 4	patent law was not the focus of your teaching in the 1990s? PROFESSOR SIEBRASSE: Well, it's still not	
<b>PROFESSOR SIEBRASSE:</b> Yes, I have it. <b>MR. JOHNSTON:</b> You've got it there. So		2 3	patent law was not the focus of your teaching in the 1990s? <b>PROFESSOR SIEBRASSE:</b> Well, it's still not the focus of my teaching. We teach I teach four	
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<ol> <li>perhaps I should have said in my overview that those</li> <li>are my current research interests. When I first</li> <li>started at UNB I was teaching, it was really hard to</li> <li>teach real estate law and I was associated with some</li> <li>kind of center for real estate and so for the '90s I</li> <li>had a variety of interest and the focus on IP and</li> <li>patents in particular did start around 1995.</li> <li>MR. JOHNSTON: So in the 1990s you did not</li> </ol>			546 03:22
<ul> <li>9 have any publications at all on patent law?</li> <li>10 PROFESSOR SIEBRASSE: Well, that's not</li> <li>11 quite true, I don't think. Let me see here. Yes,</li> <li>12 no, that's right. Yes.</li> <li>13 MR. JOHNSTON: Your first publication on</li> <li>14 patent law was actually in 2004, I understand from</li> <li>15 your CV?</li> <li>PROFESSOR SIEBRASSE: That's not quite</li> <li>17 right. The 2001 publication property rights theory,</li> <li>18 the limits of copyright, while it's about the</li> <li>19 limits idea/expression dichotomy in copyright, it</li> <li>10 really goes into why there's a distinction between</li> <li>11 copyright and patent, so it did substantially engage</li> <li>12 with patent law. But let me see after that. Then</li> <li>13 it would be the 2004, yes.</li> </ul>	9 1 1 1 1 1 1 1 1 1 1 1 1 2 2 2 2 2 2 2	<ul> <li>prediction.</li> <li>PROFESSOR SIEBRASSE: Yes. That's fair.</li> <li>MR. JOHNSTON: This is seven years after</li> <li>you say that the Federal Court introduced the</li> <li>promise standard.</li> <li>PROFESSOR SIEBRASSE: Uh-huh.</li> <li>MR. JOHNSTON: And ten years after you say</li> <li>the Supreme Court of Canada changed the rule</li> <li>regarding evidence to establish utility.</li> <li>After 2005, the issue of whether the</li> <li>promise standard was part of Canadian law, that was</li> <li>being actively litigated in Canadian courts, wasn't</li> <li>it?</li> <li>PROFESSOR SIEBRASSE: Yes.</li> <li>MR. JOHNSTON: So arguments were being</li> </ul>	
24       MR. JOHNSTON: You'd agree that during the         25       1990s, patent law was neither the focus of your         www.dianaburden.com		<ul> <li>made that Consolboard did or did not stand for the</li> <li>promise standard of utility.</li> <li>www.dianaburden.com</li> </ul>	
	547		548
1 <b>PROFESSOR SIEBRASSE:</b> Well, no, not2really. I mean I'm not sure that Canadian courts3have really ever engaged with the question of4whether or not Consolboard stands for the promise5utility doctrine. The courts have cited Consolboard6for that proposition but, that I can think of, no7court has ever done an analysis of Consolboard.8They just say: Promise of the patent, cite9Consolboard.10MR. JOHNSTON: But the parties were11arguing about the meaning of Consolboard presumably12after 2005 in Canadian courts?13PROFESSOR SIEBRASSE: Well, I'm not sure14the I mean if what you're saying is the Canadian15courtes were citing Consolboard for the promise of16the patent analysis starting in 2005, yes, that's17correct. I mean the degree to which you know,18the early cases on the promise analysis was I19think the first one was it was either a motion to20strike or a discovery motion. It was one of many21issues, so it certainly wasn't the central issue in	03:23 2 4 4 4 4 4 4 4 4 4 4 4 4 4	PROFESSOR SIEBRASSE:       Sometimes I do,         sometimes I don't.       It depends how deeply I want to         go into the decision.       MR. JOHNSTON:       You don't know whether the         issue of what Consolboard meant was being put before       the courts after 2005 by the parties?         PROFESSOR SIEBRASSE:       Well, in the         nefazadone case now, that was the first well,         I mean obviously starting in nefazadone they must         have put it to the court in the sense that the court         cited it.       I mean it was a prothonotary which a case         management judge initially cited I believe in         nefazadone so clearly the parties put Consolboard to         her, but I mean did they debate it with her back and         forth? It was a motion to strike.         There were a lot         of issues. I mean, sure, they were citing it to         they were citing Consolboard on that issue. It         wasn't the major issue in the case.         MR.       JOHNSTON:         Take that case, for         example.       You haven't reviewed the written pleadings         of the parties in that case?         PROFESSOR SIEBRASSE:       Yes, I did review	03:24

	7/14/2 Eli Lilly and Company v Government of Canada dential			Tuesday, 31 Washingtoi	n DĆ USA
001111		549		Washington	550
1	patent law?	03:25	1	damages papers.	03:27
2	PROFESSOR SIEBRASSE: Yes.		2	MR. JOHNSTON: You would agree that not	
3	MR. JOHNSTON: And to investigate the		3	every inutility decision can be attributed to the	
4	legal history of the issue?		4	promise utility doctrine?	
5	PROFESSOR SIEBRASSE: Yes. Well, I		5	<b>PROFESSOR SIEBRASSE:</b> Currently you mean	
6	believe so, yes.		6	or ever?	
7	<b>MR. JOHNSTON:</b> And it is now the case that		7	MR. JOHNSTON: Currently in Canadian law.	
8	brand pharmaceutical companies cite your papers in		8	<b>PROFESSOR SIEBRASSE:</b> There are probably	
9	their submission to Canadian courts?		9	two decisions that expressly apply scintilla	
10	PROFESSOR SIEBRASSE: Well, I think		10	standard, and there are a few other decisions I	
11			11		
12	everybody cites my submissions. I mean I know		12	mean the promise is so entrenched now that the	
	Apotex has cited my submissions, both leave			patentees rarely, so far as you can tell from the	
13	applications and so yes, I mean, I understand the		13	cases, rarely even argue for a scintilla standard	
14	brands do but I know that the generics do as well.		14	because a promise will almost always be found. I	
15	MR. JOHNSTON: Your view is that both the		15	think there are about two cases that expressly say	
16	brands and the generics cite your papers on the		16	there's no promise and there's a scintilla. And	
17	promise utility doctrine?		17	there are a handful of others that have a very low	
18	PROFESSOR SIEBRASSE: No. Not on the I		18	promise that maybe the promise actually corresponds	
19	mean I don't know of a generic citing my promise		19	to scintilla.	
20	paper. I know in the Plavix appeal, so it was		20	MR. JOHNSTON: There's certainly other	
21	Apotex Apotex was granted leave to appeal in the		21	reasons in the law that a patent could be found to	
22	Plavix decision and I know I've looked at their		22	lack utility. For example, would you agree if an	
23	leave application and I believe they do cite my		23	invention is completely inoperable, an inutility	
24	promise doctrine paper, but without notes in front		24	finding would be possible?	
25	of me I can't be sure. Mostly the generics cite my		25	PROFESSOR SIEBRASSE: Yes, absolutely.	
	www.dianaburden.com			www.dianaburden.com	
		551			552
1	MR. JOHNSTON: For example, if the patent	<b>551</b> 03:28	1	that time an English court could have had the final	<b>552</b> 03:29
1 2	is held to a specific claimed utility, that could		2	say in any Canadian patent dispute.	
1 2 3	is held to a specific claimed utility, that could lead to an inutility decision, which would not be		2 3	say in any Canadian patent dispute. <b>PROFESSOR SIEBRASSE:</b> Yes, and they	
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1       UK case on the same issue is I think Norton and         2       Gregory, a different case. So the Privy Council         3       doesn't apply UK law when it hears appeals on         4       Canadian patent cases.         5       MR. JOHNSTON: Could you turn up in volume         6       1, tab 16? This is Exhibit R-476. These are         7       excerpts from your patent law blog which is called         8       Sufficient Description. On page 2 there's a blog         9       entry from February 11, 2011. Around the middle of         10       the page on page 2, we're talking here about rules         11       governing the scope of the claim. In the middle,         12       "In contrast to Canadian law where it is in         13       principle enough to show that one embodiment within         14       the claim lacks utility" that's a situation of a         15       claim covering an inoperable species?         16       PROFESSOR SIEBRASSE: Yes.         17       MR. JOHNSTON: Then you begin this next         paragraph, "The UK did at one time have the same         19       rule as Canada. It should be no surprise that we         adopted this rule from English law."       1         11       PROFESSOR SIEBRASSE: Uh-huh.         12       PROFESSOR SIEBRA	553 03:30	11 12 13 14 15 16 17 18 19 20 21	explained how it came to us. It came to us from Mineral Separation. MR. JOHNSTON: The doctrine of sound prediction was developed in English law and received into Canadian law? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: And the Supreme Court of Canada, in its 2008 decision in Sanofi, described an English case from 1930 In re IG Farbenindustrie. It was described as the locus classicus on the doctrine of selection patents? PROFESSOR SIEBRASSE: Yes, although yes, that's right. MR. JOHNSTON: So it's fair to say, even in recent years, the Supreme Court has relied heavily on UK law in a number of important decisions? PROFESSOR SIEBRASSE: Well, it has relied on UK law, yes. MR. JOHNSTON: In the Patent Act, Professor Siebrasse, the utility requirement is set out in Section 2 the definition of invention. That's right? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: And that definition is that www.dianaburden.com	<b>554</b> 03:31
1       inventions must be new and useful.         2       PROFESSOR SIEBRASSE: Yes.         3       MR. JOHNSTON: The Act does not define         4       what "useful" means.         5       PROFESSOR SIEBRASSE: That's right. Well,         6       not beyond that, yes.         7       MR. JOHNSTON: It does not specify any         8       particular meaning in the Act for the word "useful"?         9       PROFESSOR SIEBRASSE: That's right.         10       MR. JOHNSTON: It does not say that         11       "useful" is a high bar?         12       PROFESSOR SIEBRASSE: No.         13       MR. JOHNSTON: It does not say that it is         14       "useful" is a high bar?         15       PROFESSOR SIEBRASSE: No.         16       MR. JOHNSTON: It does not say that it is         17       PROFESSOR SIEBRASSE: No.         18       a low bar?         15       PROFESSOR SIEBRASSE: No. Not in the Act.         16       MR. JOHNSTON: Would you agree that it is         17       left to the courts to interpret what the word         18       "useful" means in the Patent Act?         19       PROFESSOR SIEBRASSE: Yes. They         10       interpreted it a hundred years ago as meaning very	<b>555</b>	15 16 17 18 19 20 21 22 23	PROFESSOR SIEBRASSE: That's right. That's correct. MR. JOHNSTON: And if an invention does not achieve the particular utility claimed, it will be invalid for lack of utility. PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: So certainly part of the meaning of utility in Canadian law is that you must deliver the claimed utility? PROFESSOR SIEBRASSE: The claimed invention must be operable, must have utility, yes. MR. JOHNSTON: The utility as claimed. PROFESSOR SIEBRASSE: Well, strictly the claims define the invention. That's what the Patent Act says. That's what the courts have always said. So if you define the invention and I'll use New Process Screw as an example, since it's discussed extensively, the claim is defined as a die capable of rolling only double threads, so you've defined your invention in that way, and it's actually wholly incapable of rolling double threads, that it's inoperable, the claimed invention is inoperable whether or not it rolls single threads or tiple threads or faster-than-light travel, yes. MR. JOHNSTON: And if in that case the www.dianaburden.com	556 03:33

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<ul> <li>Claimant said it would roll strong threads or thin</li> <li>threads or thick threads, whatever it is that the</li> <li>claim says, the invention must operate for that's</li> <li>what it must do.</li> <li>PROFESSOR SIEBRASSE: Yes.</li> <li>MR. JOHNSTON: In New Process Screw</li> <li>perhaps we should turn up the case since we were</li> <li>just talking about it this is volume 1, tab 8,</li> <li>R-162 at page 46 in the middle, so this decision in</li> <li>New Process Screw, just above the middle of the page</li> <li>it says, "He also said that dies with a pitch angle</li> <li>of 22 degrees would roll a double-threaded No. 18</li> <li>screw, but it would not be a good one but would be</li> <li>rough and not a good commercial product."</li> <li>Did the claims in New Process Screw make</li> <li>any reference to the need to be a good commercial</li> <li>product?</li> <li>PROFESSOR SIEBRASSE: No, but it did say</li> <li>"capable of only rolling double threaded screws,"</li> <li>and the actual promise language, which is about a</li> <li>quarter of the way to the bottom, was "Thus, it was</li> <li>conclusively proved that dies at the specified</li> <li>angles would not produce No. 18 double-threaded</li> <li>screws. Thus there was a failure of the promise</li> <li>www.dianaburden.com</li> </ul>	03:34	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	<ul> <li>double-threaded screws, so that's the failure of the promise.</li> <li>MR. JOHNSTON: But if we go back up to right after the sentence I read, not a good commercial product, the court says, "This statement was enough in itself to destroy the patent."</li> <li>PROFESSOR SIEBRASSE: It might be that the court was saying, you know, very little doesn't necessarily mean zero. It means very little. Mostly when it's very little, no scintilla, it means wholly inoperable. But it's quite possible the court was saying well, the fact that it's not good is enough in itself to say it doesn't have a scintilla of utility. In fact, the patent itself does refer to commercial results, but I know that because I've read the patent itself. That phrase the court never looked in the patent. That phrase sin't in the case. If it were deriving this from the patent presumably the court would have said well, today the court would have certainly said: Commercial results, you said it in the disclosure, that's the promise.</li> <li>MR. JOHNSTON: The term "commercial results" was in the patent.</li> <li>MRESSOR SIEBRASSE: In the disclosure, total suits "was in the patent.</li> </ul>	03:36
1       yes.         2       MR. JOHNSTON: In the disclosure. And the         3       patent was before the court.         4       PROFESSOR SIEBRASSE: Yes.         5       MR. JOHNSTON: And the court says this         6       statement alone would be enough to destroy the         7       patent?         8       PROFESSOR SIEBRASSE: Well, yes, "it would         9       be rough and not a good one." This could well be         10       taken as saying it didn't have a scintilla of         11       utility just on a scintilla standard.         12       MR. JOHNSTON: You were discussing in your         13       direct testimony the treatise by Donald MacOdrum in         1995?       PROFESSOR SIEBRASSE: Yes.         16       MR. JOHNSTON: It's included in your         17       direct binder. You identified that Mr. MacOdrum had         18       set out a category of cases referring to promise         19       utility.         20       PROFESSOR SIEBRASSE: Yes.         21       MR. JOHNSTON: And he included the New         22       PROFESSOR SIEBRASSE: Yes.         23       PROFESSOR SIEBRASSE: Yes. Well, that's         24       right. I mean Mr. MacOdrum, he has New Process         25	<b>559</b> 03:38	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	clear enough well, clear enough. It would appear that Mr. MacOdrum is not drawing any distinction between statements made by I shouldn't say that. The English cases he's lumped together in that section, the English cases where there are statements in the disclosure, with the Canadian cases where the New Process Screw statement and claim I mean Mr. MacOdrum is really quite clear where his excerpt starts off with the definition of the claim "capable of only rolling double threads." TRW that's the one that was inoperable for compressor and Feherguard, yes. MR. JOHNSTON: So does he include this case in his section on promise utility? PROFESSOR SIEBRASSE: Right, but the promise in this case was in the claims. MR. JOHNSTON: And Mr. MacOdrum, you say, appears not to be distinguishing between the English  THE PRESIDENT: One at a time, and can you please repeat the last question? MR. JOHNSTON: What you're saying is that Donald MacOdrum is not distinguishing in his chapter. He's putting in English false promise www.dianaburden.com	<b>560</b> 03:39

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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 7 18 90 21 22 23 24 25 24 25 24 25 24 25 24 25 25 26 26 27 26 27 26 27 26 27 26 27 26 27 27 27 27 27 27 27 27 27 27	cases, and he's also putting in cases like New Process Screw, which you regard as being a case where the promise was derived from the claims. That's a fair statement of what's contained in Donald MacOdrum's section on promised utility. <b>PROFESSOR SIEBRASSE:</b> Well, there are both kinds of cases in here. We don't really know; they're teaching materials. We don't know what he was saying about them. <b>MR. JOHNSTON:</b> You state in your expert report this is your first expert report at page 21, Paragraph 72, footnote 98, you identify here that the first decisions trial level decisions adopting the requirement that utility be assessed by reference to the promise of the patent. Is that correct? <b>PROFESSOR SIEBRASSE:</b> Yes. <b>MR. JOHNSTON:</b> And so these cases are listed in footnote 98. Do you recall which of these was the first case to be decided? <b>PROFESSOR SIEBRASSE:</b> I believe it was the first one listed, but I'm not entirely sure. <b>MR. JOHNSTON:</b> In any case, these three cases are your understanding of the origin of the application of the promise standard in 2005? www.dianaburden.com	<b>561</b> 03:40	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: In your first expert report, Professor Siebrasse, at page 21, Paragraph 72, if you could turn that up, please. PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: Perhaps you're already there, you write that the promise of the patent began in 2005 and had no basis in prior case law or the Act? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: If you could please turn up volume 1, tab 3, C-205, at page 22. PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: This is your 2013 paper entitled "False Doctrine of False Promise." PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: You write here on page 22, "The promise of the patent played no significant role in Canadian patent law until 2005. There were only two cases of which I am aware that considered a heightened utility requirement based on the promise of the specification, and one more which arguably did so." Now, your footnote 91 points to the bottom of the page and states, "The clearest support for www.dianaburden.com	<b>562</b> 03:41
1 2 3 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 12 3 4 5 6 7 8 9 10 11 12 3 14 15 6 7 8 9 10 11 12 3 14 5 6 7 8 9 10 11 12 3 14 5 6 7 8 9 10 11 12 3 14 5 6 7 8 9 10 11 12 3 14 5 6 7 8 9 10 11 12 3 14 5 6 7 8 9 10 11 12 3 14 5 6 7 8 9 10 11 12 3 14 5 16 7 8 9 10 11 12 3 14 5 16 7 8 9 10 11 12 3 14 15 16 17 10 10 11 12 3 14 11 12 3 14 11 12 11 11 12 11 11 12 11 11 11 12 11 11	the promise of the patent doctrine was in Wellcome Foundation v Apotex, 1991." If you go down in the paragraph you state, "MacKay J. held that the utility was only as intermediates in making useful end products." You further note, "In his analysis MacKay J. did examine the specification itself, and the Court of Appeal in affirming, remarked at 154 that 'the utility of a patent must ultimately be judged against its promise the exercise requires that the specification be carefully construed to determine exactly what that promise is'." This is what you wrote in your paper? PROFESSOR SIEBRASSE: Yes, that's right. MR. JOHNSTON: Earlier today you affirmed that you understood your role as an expert witness is to provide the Tribunal with an impartial perspective on the matters falling within the scope of your Expert Report. Is that right? MR. JOHNSTON: And part of that mandate was to describe the law of utility both at the time that Lilly's Strattera and Zyprexa patents were field and granted. They were filed in 1991 and 1996. Is that right? PROFESSOR SIEBRASSE: Yes.	<b>563</b> 03:43	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	MR. JOHNSTON: This Wellcome v Apotex decision, the trial decision was rendered in 1991. The Federal Court of Appeal decision was rendered in 1995. Is that right? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: You've described these cases as the clearest support for the promise doctrine in Canadian law in your paper. PROFESSOR SIEBRASSE: Yes, the clearest support. I didn't say they are clear support. The point of this was that the doctrine is new. So I was saying here even if you look for any case you know, this is the closest you're going to find. I wasn't saying these are promise cases; I was saying these are the closest you're going to find. So even if you're I also say see Corning Glass, which is the case which really had no scintilla of utility, so I wasn't saying these were promise cases. I'm saying this is as close as you're going to get, and they're, in fact, not promise cases. WR. JOHNSTON: You did say they were cases you were aware of where the court considered a heightened utility requirement based on the promise of the specification. That's what you said in your paragraph on page 22. www.dianaburden.com	<b>564</b> 03:44

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1 <b>PROFESSOR SIEBRASSE:</b> Well, in the2footnote I say the clearest support was in Wellcome.3To the extent that there's any error, it's in this4false promise article and not in my evidence,5meaning in this article it was focusing on, as I6say, the real emergence, and I read these cases7enough in fact, I have to say that there are a8couple of other there's an error in the footnote9where he said that "the utility was only as10intermediates in making useful end products, without11any promise that the intermediates would themselves12be therapeutically useful." Now that's true, but13also he looked for the utility of the end product14itself which is also required. So15MR. JOHNSTON: And he did look for that in16the disclosure of the patent?17PROFESSOR SIEBRASSE: Yes, for what the18end products are good for, yes.19MR. JOHNSTON: Which was held to be part20of the claimed utility of the invention in that21case. The production of intermediates22PROFESSOR SIEBRASSE: No.23MR. JOHNSTON: that would produce end24products having a certain utility.25PROFESSOR SIEBRASSE: Well, as a matter of26www.dianaburden.com	<b>565</b> 03:45	2 c c ir 3 ir 4 b 5 t c f f f f f f f f f f f f f f f f f f	Canadian law, if you have a process for producing ompounds, even if the process is new or the netermediates are new, the final product also has to be useful. It's not enough that it simply operate o produce the final product. The final product has o be useful. So the final product also had to have tility, which the court said was therapeutic value or potentiating properties or one other. Antibacterial properties, I think. MR. JOHNSTON: Professor Siebrasse, in our direct testimony today you referred to this ase and you said that it's not a promise case. PROFESSOR SIEBRASSE: That's right. MR. JOHNSTON: And that today, on the acts of this case, there would be a debate about what the promise is. PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: That's how you know the law tas changed. Is that right? PROFESSOR SIEBRASSE: Yes. But the debate yould not be over these issues raised here. It yould be over the statements that the process has a ery much higher yield markedly superior ields to the other known processes; that the end products would have very high antibacterial www.dianaburden.com	<b>566</b> 03:46
<ul> <li>properties. Those are the statements in the</li> <li>disclosure that today would be considered to be</li> <li>promise statements, not the statements I'm referring</li> <li>to in the footnote.</li> <li>MR. JOHNSTON: If you could turn up in</li> <li>your first volume, tab 1, this is the trial decision</li> <li>in Wellcome v Apotex from 1991. It's Exhibit C-41.</li> <li>If you could please turn to page 347g, here the</li> <li>judge writes, just toward h: "The utility of the</li> <li>inventions was characterized quite differently by</li> <li>the two learned counsel, as might be expected."</li> <li>That's what the trial judge wrote in that decision.</li> <li>You see that that's what the trial judge</li> <li>wrote?</li> <li>PROFESSOR SIEBRASSE: Yes.</li> <li>MR. JOHNSTON: And you recognize that, in</li> <li>this case, both parties called expert evidence</li> <li>interpreting certain words in the disclosure for the</li> <li>purpose of the utility analysis. Is that your</li> <li>recollection of the case?</li> <li>PROFESSOR SIEBRASSE: Well, certainly this</li> <li>is chemical compounds and trial judges in Canada are</li> <li>not normally chemists, and so certainly words like</li> <li>"benzylpyrimidines" would have expert evidence as to</li> <li>www.dianaburden.com</li> </ul>	<b>567</b> 03:48	3       d         4       5       kc         5       kc       p         6       7       e         9       10       "I         11       12       a         12       13       a         14       15       C         17       18       tl         19       ju       ju         21       tl       fa         23       ir       ir	MR. JOHNSTON: So there was expert evidence on the proper interpretation of the lisclosure in this case? PROFESSOR SIEBRASSE: I mean, I'm not boking at it I don't see it right there on the bage, but I don't doubt there would have been expert evidence on things like what does "benzylpyrimidine" mean. MR. JOHNSTON: Is that because the word benzylpyrimidine" would have been in the claims ather than the disclosure? PROFESSOR SIEBRASSE: It's because patents are addressed to a person skilled in the art and so, is I've explained, trial judges in Canada and even Court of Appeal judges typically don't have a cience background, and the role of the experts in my patent case is to educate the judge as to what he terms mean, because the judge typically won't e there will be some terms, of course, that the udge is familiar with, ordinary English words, but here will be many terms that the judge is not amiliar with, and those words might appear anywhere in the specification. That is the claims as well as he disclosure. MR. JOHNSTON: Would it surprise you that www.dianaburden.com	<b>568</b> 03:50

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<ul> <li>in this case there was competing expert evidence on the meaning of the word "chemotherapeutic activity" which was found in the disclosure and not in the claims?</li> <li>PROFESSOR SIEBRASSE: No, it wouldn't surprise me.</li> <li>MR. JOHNSTON: This case was appealed, as you've noted in your paper, and the Federal Court of Appeal affirmed the trial judge. I think it's worth pulling up the Federal Court of Appeal decision at Tab 15. This is R-401 at 154g.</li> <li>So here the Federal Court of Appeal</li></ul>	569 03:51 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 24 25	<ul> <li>valuable end products, and the question was well,</li> <li>what are those end products good for, and so the</li> <li>processes themselves, by looking at the chemical</li> <li>definition of the intermediate and reading the</li> <li>processes, the end products have to be useful but</li> <li>you can't tell from the claim what the end products</li> <li>are useful for, so the trial judge looked at the</li> <li>disclosure to say, well, what's it useful for, and</li> <li>it's true that the parties disagreed on the standard</li> <li>for utility, but neither of them made a promise of</li> <li>the patent argument. The generic argued that</li> <li>therapeutic utility was required, and I forget what</li> <li>the patentee argued.</li> <li>But the trial judge went through the</li> <li>patent to see what are the stated uses for the end</li> <li>products, which were therapeutic utility,</li> <li>potentiating, which means it enhances the utility of</li> <li>other products, and antibacterial compounds. As</li> <li>long as these end products had any of these</li> <li>products, then it was useful.</li> <li>MR. JOHNSTON: If we go back you</li> <li>needn't turn it up again, but in your tab 3 paper,</li> <li>Doctrine of False Promise, you said you'd also refer</li> </ul>	570 03:52
1       PROFESSOR SIEBRASSE: Yes.         2       MR. JOHNSTON: So you had also cited this         3       case as an example considered as a case where the         4       court considered a heightened utility requirement         5       based on the promise of the specification. You         6       cited it for this purpose in that paper.         7       PROFESSOR SIEBRASSE: Yes. I mean, can we         8       turn to the actual case?         9       MR. JOHNSTON: Sure. It's tab 13, R-375.         10       PROFESSOR SIEBRASSE: So the statements in         11       that case that I was referring to so what I was         12       referring to in my direct is page 19 at the bottom         13       of the very long paragraph where the court said         14       sorry, the top this says "A person skilled in the         15       art must be taken to have known that the presence of         16       certain impurities such as iron would render the         17       waveguide [fiber optic cable] useless for long         18       distance transmission" but there wasn't any evidence         19       as to whether it would render it useless for any         19       purpose. At the end it says well, there's no         19       evidence that would render it useless for any	571 03:54 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 24 25 10 11 12 13 14 15 10 10 11 12 10 11 12 10 11 12 10 11 12 10 10 11 12 10 10 10 10 10 10 10 10 10 10	<ul> <li>at the bottom of the page. The court states in the middle of the second to last paragraph, "But neither in the disclosures nor in the claims in question does the patent describe a specific use for its optical waveguide nor does it promise any specific result with respect to practical transmission, distance or rates of attenuation." That's what the court said.</li> <li><b>PROFESSOR SIEBRASSE:</b> Right. That's what I would have been referring to when I said "see also."</li> <li><b>MR. JOHNSTON:</b> This is why you would cite that case as further authority as a situation in which the court considered a heightened utility requirement based on the promise of the specification, as you stated in your earlier paper.</li> <li><b>PROFESSOR SIEBRASSE:</b> Well, that's what I stated in the paper. This is the sentence that we're looking at, so that's the sentence in question. Now, there weren't any such heightened requirements and, if there had been, would the court have said we're going to hold you to it? We don't know, right?</li> </ul>	<b>572</b> 03:55

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<ul> <li>very low standard of utility, so this was clearly</li> <li>not a case in which the patentee was held to a</li> <li>higher standard of utility based on statements from</li> <li>the disclosure. You know, trial judges say all</li> <li>sorts of things and usually they're pretty good and</li> <li>get the law pretty right, but not every obiter</li> <li>statement can be taken as a reflection of the law.</li> <li>That's why I said "see also" with respect to this</li> <li>because it is clearly not a promise case.</li> <li>MR. JOHNSTON: Let's turn back to Tab 3,</li> <li>C-205. This is still the footnote that we're on</li> <li>where you're citing these cases in your false</li> <li>promise paper. Footnote 92 here is a different</li> <li>footnote. We were looking at 91 before. 92, you</li> <li>distinguish, here this is a case where, you say, the</li> <li>court arguably considered a heightened utility</li> <li>requirement based on the promise of the</li> <li>specification, and you cite to Mobil Oil</li> <li>1995 decision, and lower down in that footnote you</li> <li>state that "In context this is a matter of claims</li> <li>construction, though it could also be taken as a</li> <li>modest interpretation of the promise of the patent</li> <li>by Wetston J." You did not mention this case at all</li> <li>in your first Expert Report.</li> <li>PROFESSOR SIEBRASSE: I believe you. I</li> </ul>	<b>573</b> 03:57	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 7 18 9 20 21 22 23 24	mean I don't have a specific recollection. MR. JOHNSTON: Mr. Dimock cited it in his first Expert Report, and you responded to Mr. Dimock on this case in your second Expert Report. You said that it is, if anything, contrary to the promise of the patent. That's at page 2, Paragraph 6 of your second Expert Report. You did not state any qualifications in that report like the ones that I just read in your 2013 paper. PROFESSOR SIEBRASSE: Yes. I mean I've read these cases more carefully now than I did for this false promise article. The point of the false promise article was I was looking as I say on the following page at the real emergence. Prior to that it was is there any I didn't want somebody to come back and say you missed this case and you missed that case, and so I said maybe this one, maybe that one. That wasn't the focus of my report sorry not my report, my article. My focus was this is new, here's the real emergence, and went on from that. So these cases I've simply read them more carefully now. MR. JOHNSTON: To recall again the language which you've reiterated today from your www.dianaburden.com	574 03:58
<ul> <li>first Expert Report is that, prior to 2005, the</li> <li>promise of the patent had no basis in prior case law</li> <li>or the Act. That's your view.</li> <li>PROFESSOR SIEBRASSE: Yes.</li> <li>MR. JOHNSTON: Please turn up tab 4,</li> <li>C-206, page 11. This is your 2012 paper entitled</li> <li>"Must the factual basis for sound prediction be</li> <li>disclosed in the patent?"</li> <li>At page 11, footnote 30, you write that</li> <li>"This doctrine has had a long but sporadic history</li> <li>in Anglo-Canadian patent law but it has recently</li> <li>become a much more important feature of Canadian</li> <li>patent law."</li> <li>PROFESSOR SIEBRASSE: Uh-huh.</li> <li>MR. JOHNSTON: And if you could turn up</li> <li>tab 34, this is R-498 at page 132 at the bottom,</li> <li>this is your 2011 in review article, and at page 132</li> <li>at the bottom you're making reference here to the</li> <li>promise doctrine and the requirement to disclose the</li> <li>factual basis for a sound prediction, and you write</li> <li>near the bottom of that last paragraph before the</li> <li>conclusion, "The problem is compounded because both</li> <li>doctrines are recent, at least in their prominence."</li> <li>And if I can ask you to flip up to one</li> <li>more document, tab 3, this is back to your false</li> </ul>	<b>575</b> 03:59	2 3 4 5 6 7 8 9 10 11 12 13 14 15 6 7 18 9 20 21 22 23	doctrine of false promise paper, C-205, page 3 at the top, you write midway through the first paragraph, "Even in Canada the doctrine was almost entirely quiescent for decades." That's what you wrote. <b>PROFESSOR SIEBRASSE:</b> Yes. Well, let's start with the first one. It does have a long but sporadic history in Anglo-Canadian patent law. It had a very long history in UK patent law and by the time I was writing this it was also part of Canadian patent law. And the other one I think you were saying something about at least in its prominence well, I wasn't going to debate how new is it. That wasn't the point. It was a review article. So that wasn't the point there to argue that absolutely this is new and so on. So then we've got quiescent, almost entirely quiescent. The fact is there are no cases citing an elevated standard for utility derived from the disclosure. There aren't any. I don't cite any. I mean you've pointed to me saying well, almost you say "almost entirely quiescent." Doesn't that mean that it must have been actually there but you haven't pointed there are no cases where they've actually applied an elevated standard. Even the TMP, Corning and Mobil Oil all www.dianaburden.com	<b>576</b> 04:01

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<ul> <li>have upheld the validity of standard. None of them</li> <li>actually applied an elevated standard. So you can</li> <li>say, look, Corning, they said no utility was</li> <li>promised. Maybe that was there. Well, it wasn't a</li> <li>case that applied an elevated standard based on the</li> <li>disclosure. On the contrary, it applied a scintilla</li> <li>requirement.</li> <li>MR. JOHNSTON: Professor Siebrasse, in</li> <li>these three papers you've described the promise</li> <li>doctrine as having a long but sporadic history in</li> <li>Canadian law, recently becoming a much more</li> <li>important feature, being recent at least in their</li> <li>prominence, and being almost entirely quiescent for</li> <li>decades. But in your expert report you said that</li> <li>the promise doctrine has no basis in prior case law</li> <li>or the Act.</li> <li>PROFESSOR SIEBRASSE: Yes, and it has no</li> <li>basis in prior case law or the Act. I mean, as I</li> <li>said, you've pointed me to this statement here, this</li> <li>statement there, in my reports, but there isn't a</li> <li>case there are no cases that apply an elevated</li> <li>standard. Certainly the Act hasn't changed and</li> <li>there are no cases applying an elevated standard for</li> <li>utility based on the disclosure.</li> <li>MR. JOHNSTON: Professor Siebrasse, I want</li> </ul>	5781to go through a few of the treatises that we've been2discussing that have been mentioned so far in the3proceedings. If you could turn up, please, tab 9.4This is R-163. This is volume 1, tab 9. This is5Dr. Fox's 1969 treatise, Canadian Patent Law and6Practice. You're familiar with this treatise?7PROFESSOR SIEBRASSE: Yes.8MR. JOHNSTON: And would you say that this9treatise is still regularly cited in Canadian10courts?11PROFESSOR SIEBRASSE: Well, I don't doubt12it's still cited. I'm not sure exactly how13regularly.14MR. JOHNSTON: The Supreme Court has on15multiple occasions affirmatively cited Dr. Fox's1969 treatise.1969 treatise.17PROFESSOR SIEBRASSE: Yes.18MR. JOHNSTON: Do you consider this19treatise to be an authoritative text on Canadian20patent law at the time that it was written?21PROFESSOR SIEBRASSE: Well, it was the22only text. I mean are you asking me for my23assessment of the quality of this? It's certainly a24very well known text and regularly cited by the25courts.
1       MR. JOHNSTON: As a legal scholar, if you         2       were looking for a statement of the law, a point of         3       Canadian law in the late 1960s, what is the first         4       text that you would reach for on your shelf in the         5       Ibirary?         6       PROFESSOR SIEBRASSE: The first text I'd         7       look for would be Fox, but I must say I was told a         8       number of years ago by a practitioner I can't         9       remember who at some conference, he said about         10       Fox, you know, always read the footnotes. So         11       rest and the state of the utility chapter, as         12       MR. JOHNSTON: If you could please turn up         13       page 150 it's actually the utility chapter, as         14       you can see. On page 150 there's a section, Utility         15       as Specified. Dr. Fox includes a quote, "If when         16       used in accordance with the directions contained in         17       the"         18       PROFESSOR SIEBRASSE: Sorry?         19       THE PRESIDENT: Professor, are you there?         10       pROFESSOR SIEBRASSE: Yes, I have the page         10w.       MR. JOHNSTON: "If when used in accordance         10       with the directions co	580 1 the patent law." If you'll turn up to page 152, 2 there is a section entitled Promised Results, so we can look there to see what Dr. Fox was saying about promised results. 5 Over the page at 153, in that section 6 still, in the last paragraph Dr. Fox states: "Cases of this type are of importance in that a distinction must be drawn between them and those cases where the specification contains no promise of results. In the latter case no particular quantum of utility is necessary; and a mere scintilla of utility is sufficient for validity. But in those cases of patents that are based upon a promise of results contained in the specification it is not sufficient that the patent be useful for a part only of the result, or for that result only in a manner inferior to that claimed." 18 You see that Dr. Fox wrote these passages. 19 Please turn up 10 <b>PROFESSOR SIEBRASSE:</b> Do I get a chance to respond to those? 21 <b>THE PRESIDENT:</b> Yes. But the question was whether you saw them. 22 <b>THE PRESIDENT:</b> Yes, I saw them. 23 whether you saw them. 24 <b>PROFESSOR SIEBRASSE:</b> Yes, I saw them. 25 <b>THE PRESIDENT:</b> If you would like to www.dianaburden.com

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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	expound on that, I think you can do it via redirect. PROFESSOR SIEBRASSE: Okay. MR. JOHNSTON: Please turn up tab 8. This is R-162. THE PRESIDENT: Mr. Johnson, one thing, I think the professor has a point. Cross-examination is asking questions and not taking us through the documents in order to show to the court or the Tribunal this matter what the document says. We can read ourselves the document. MR. JOHNSTON: Certainly. My apologies professor van den Berg. I wanted to cover three documents here and then to put a question to Professor Siebrasse. THE PRESIDENT: If this is to lay a foundation, fine, go ahead. MR. JOHNSTON: Yes. So in Tab 8 this is R-162. This is the New Process Screw case? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: This is a head note to the case. It's an editorial note. Gordon Henderson was the editor of The Reporter that this is published in. Are you familiar with him? PROFESSOR SIEBRASSE: Yes. www.dianaburden.com	581 04:08	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	MR. JOHNSTON: You know he was a Canadian patent practitioner in the mid to late 20th century? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: He was a managing partner of Gowling Lafleur Henderson, Claimant's counsel. Page 34, near the top, this editorial note states, "These findings illustrate the different senses in which utility has been used in patent law. It has been used in the sense of quantum of usefulness." then lower in the paragraph, "However, commercial utility may become a requirement as in the present case, if it is found by the court to be part of the promise. If the specification promises a commercial advantage over the prior art, then commercial utility would be a requisite." You read that in the editorial note? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: Last document, tab 7 at this is R-160. This is Donald Hill's article entitled Claim Inutility. Are you familiar with Donald Hill. PROFESSOR SIEBRASSE: I can't say I mean I'm familiar now that I've read this article. I can't say that I was familiar with him before. MR. JOHNSTON: You know that he was a www.dianaburden.com	582
1 2 3 4 5 6 7 8 9 10 11 22 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	practitioner? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: Of Canadian patent law? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: At page 188 in the middle, Mr. Hill writes "Where, however, the patentee has promised in his specification results of a certain kind or order, and these are not yielded when the invention is put into practice, the patent of course will be invalid. This is so obvious that it hardly needs stating." You see that comment? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: Now, Mr. Dimock cited these three practitioners' publications in his first Expert Report, and you responded to them in your second Expert Report. Is that right? PROFESSOR SIEBRASSE: Well, I imagine I did. I mean if you're MR. JOHNSTON: If we could go to your second Expert Report, page 16, Paragraph 40. PROFESSOR SIEBRASSE: Yes. MR. SPELLISCY: You write that "Mr. Dimock cites three commentators as supporting the view that the promise of the patent was part of Canadian law." www.dianaburden.com	583 04:11	1 2 3 4 5 6 7 8 9 10 11 22 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 3 24 25	You're referring here to Dr. Fox, Mr. Henderson and Mr. Hill. PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: You dismiss the views of these three leading practitioners in a single three-sentence paragraph of your report, stating that, "The only law cited by these commentators is the old English false promise doctrine which, as noted, did not form part of Canadian law." Is that right? PROFESSOR SIEBRASSE: Yes, that's what the sentence says. MR. JOHNSTON: You do note in footnote 53 that Dr. Fox did cite two Canadian cases in his section on promised results, but that you disagree with his citation of those cases as authority for the proposition? MR. JOHNSTON: This is not, unfortunately in the binder, but if we could pull up on the screen the first Expert Report of Mr. Dimock at page 19, Paragraph 69, this immediately follows those last three practitioners' views that we just reviewed, but Mr. Dimock actually referred to a fourth practitioner's views on the promise standard, which www.dianaburden.com	<b>584</b> 04:12

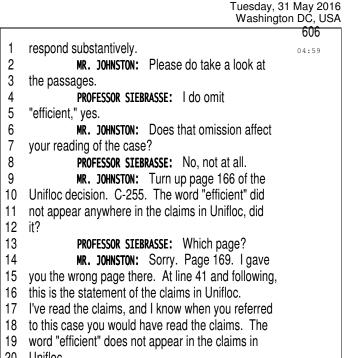
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<ul> <li>you did not address in your responding expert</li> <li>report. This is a passage taken from an article by</li> <li>William Hayhurst, if we could pull up the article,</li> <li>tab 10, R-164. The passage quoted is at page 73.</li> <li>So the passage quoted by Mr. Dimock in his</li> <li>Expert Report is first of all, I should say this</li> <li>article was published in 1970 by William Hayhurst.</li> <li>"In the introductory parts of the specification, one</li> <li>must be chary of promising advantages that are not</li> <li>achieved by everything that falls within the</li> <li>broadest claim. If you make false promises, you may</li> <li>get an invalid patent."</li> <li>There's an endnote or footnote 12,</li> <li>and Mr. Hayhurst cites this is now on page 84 if</li> <li>we follow footnote 12 Mr. Hayhurst cites Raleigh</li> <li>v Miller, which is an English case, and he cites</li> <li>Hoechst v Gilbert, which is a Canadian case, right?</li> <li>PROFESSOR SIEBRASSE: Yes.</li> <li>MR. JOHNSTON: Decided in 1965.</li> <li>He's citing these authorities for the</li> <li>proposition if you make false promises you get an</li> <li>invalid patent?</li> <li>PROFESSOR SIEBRASSE: Well, it's not</li> <li>exactly what he said, I don't think oh yes,</li> <li>that's right.</li> </ul>	04:13	1 2 3 4 5 6 7 8 9 10 11 25 6 7 8 9 10 11 12 13 14 15 16 17 18 9 20 21 22 23 24 25	MR. JOHNSTON: And you did not respond to this passage from Mr. Hayhurst's article or to the authority that he relies upon in your expert reports. Is that right? PROFESSOR SIEBRASSE: Well, I can't specifically remember having done so. No, I wouldn't. MR. JOHNSTON: I'd like to take you to the Supreme Court's Consolboard decision at Tab 2. This is C-118. This is the 1981 Consolboard decision. If you could turn up page 525 this is the much discussed passage where Consolboard turns to the utility requirement. The key passage states, "There is a helpful discussion in Halsbury's Laws of England on the meaning of 'not useful' in patent law. It means that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do." And lower down the page the court states "Canadian law is to the same effect." Professor Siebrasse, would you agree that, on its face, Consolboard quoted with approval the passage from Halsbury? www.dianaburden.com	04:15
1       PROFESSOR SIEBRASSE: Consolboard quoted         2       with approval the passage. I disagree with the         3       implication from the highlight that the words         4       "Canadian law are to the same effect" implies that         5       "Canadian law are to the same effect" implies that         6       "MR. JOHNSTON: In the passage quoted by         7       the Supreme Court that I read earlier now, there         8       are which is the meaning of "not useful" in         9       patent law and, following from there, there are two         10       parts to that sentence, that "the invention will not         11       work either in the sense that it will not operate at         12       all or, more broadly, that it will not do what the         13       specification promises that it will do."         14       You'd agree there's an "or" connecting two         15       parts of the sentence there?         16       PROFESSOR SIEBRASSE: I agree the word         17       "or" appears in the sentence, yes.         18       MR. JOHNSTON: The first branch says that         19       the invention will not operate at all.         10       PROFESSOR SIEBRASSE: I agree those are         11       the words written there, yes.         12	<b>587</b> 04:17	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	are the words. MR. JOHNSTON: Now, you've said that a bifurcated utility standard is new in Canadian law since 2005 but you would agree that on the plain reading of these words on their face, there is a bifurcated statement here about what "not useful" means in Canadian patent law. PROFESSOR SIEBRASSE: No, I disagree. MR. JOHNSTON: In substance, would you agree that the quoted passage from Halsbury did rely in part on old English false promise cases that held patentees to promises made in the disclosure? PROFESSOR SIEBRASSE: Halsbury does footnote such cases, yes. MR. JOHNSTON: And the leading Canadian practitioners of the day like Dr. Fox, publishing in the years preceding Consolboard, did consider the promise standard to be part of Canadian law. PROFESSOR SIEBRASSE: Well, that's not clear to me. They quote the Canadian cases. They say you should worry about this. Whether they considered it part of Canadian law they may have but it's not clear to me that they did. MR. JOHNSTON: Your view is that this passage in Consolboard cannot reasonably be www.dianaburden.com	588 04:18

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<ul> <li>interpreted as acknowledging the existence of the</li> <li>promise doctrine in prior law?</li> <li>PROFESSOR SIEBRASSE: Well, this one</li> <li>sentence out of the whole decision could be read as</li> <li>supporting that, yes, and that's how the current</li> <li>Canadian courts read that and they're not being</li> <li>ridiculous in reading it, but you have to read the</li> <li>whole decision. And certainly my position is that</li> <li>the decision as a whole cannot reasonably be read as</li> <li>importing this doctrine into Canadian law.</li> <li>MR. JOHNSTON: In your second Expert</li> <li>Report at page 7, footnote 15, you write,</li> <li>"Mr. Dimock states that Consolboard is the leading</li> <li>authority on the standard of an invention's utility</li> <li>(Dimock report at Paragraph 61). That is not</li> <li>correct. It is now cited for the promise doctrine,</li> <li>but it was rarely cited for utility prior to 2005."</li> <li>That was your expert opinion?</li> <li>PROFESSOR SIEBRASSE: Yes.</li> <li>MR. JOHNSTON: In your report. Earlier</li> <li>today actually if I could ask you to please turn</li> <li>up tab 41, this is R-360. It's the 1994 Feherguard</li> <li>case that you did mention in your direct testimony</li> <li>earlier today. R-360, page 6, Paragraph 23.</li> <li>You referred to this case and to two other</li> </ul>		1cases in your direct testimony saying that, yes,2they did cite Consolboard, but they did not endorse3a bifurcated standard for utility. You said that4you read these cases as simply saying that the5patent must work?6PROFESSOR SIEBRASSE: Yes.7MR. JOHNSTON: That was your testimony8earlier today. So at Paragraph 23, the Federal9Court in Feherguard states, "In patent law, a patent10is not useful if the invention will not work, either11in the sense that it will not operate at all or,12more broadly, that it will not do what the13specification promises that it will do." And it14cites to Consolboard for that proposition.15Would you agree that what the court has16reproduced there is the full bifurcated passage from17Consolboard that we were discussing earlier?18PROFESSOR SIEBRASSE: I agree that it is19referencing the passage that we were discussing20earlier. I do not agree that it represents a21bifurcated standard, particularly as applied in22Feherguard.23MR. JOHNSTON: Could you please turn up24tab 25? This is C-230. It's the Almecon decision.25Tab 26. I'm sorry. I've given you badwww.dianaburden.com	04:22
<ul> <li>instructions. On page 98 at Paragraph 45, again, we</li> <li>see the court says "Mr. Justice Dickson, as he then</li> <li>was, in the same matter [referring to Consolboard]</li> <li>when it came before the Supreme Court of Canada</li> <li>wrote by reference to the third edition of Halsbury</li> <li>that" and then he repeats the same passage from</li> <li>Consolboard that we've been discussing, that the</li> <li>invention will not work either in the sense that it</li> <li>will not operate at all or, more broadly, that it</li> <li>will not do what the specification promises that it</li> <li>will do.</li> <li>PROFESSOR SIEBRASSE: You're asking me if</li> <li>those words appear in the text?</li> <li>MR. JOHNSTON: Yes.</li> <li>PROFESSOR SIEBRASSE: Yes, they do. If</li> <li>you look at paragraphs 47 and 48, you'll see how the</li> <li>court interpreted it. I mean can I say more, or</li> <li>do we have to wait for redirect?</li> <li>THE PRESIDENT: Please expound.</li> <li>PROFESSOR SIEBRASSE: If you look at</li> <li>Paragraph 47, they quote this passage, and then they</li> <li>say counsel for the inventor urged it simply "did</li> <li>not work." 48. "It was a commercial success." "On</li> </ul>		<ul> <li>utility and, B, citing that very passage as simply</li> <li>standing for a unitary operability standard.</li> <li>Feherguard is to the same effect.</li> <li>Goldfarb is to the same effect. I mean yes, they</li> <li>say these words, but these cases show that, prior to</li> <li>2005, the courts did not interpret these words as</li> <li>adopting a bifurcated standard. It worked.</li> <li>MR. JOHNSTON: So your view of these</li> <li>cases, Feherguard, Almecon and Goldfarb, all of</li> <li>which you acknowledge reproduce the bifurcated</li> <li>language of Consolboard, you say do es not mean that</li> <li>these courts were recognizing a bifurcated standard</li> <li>of utility?</li> <li>PROFESSOR SIEBRASSE: As I stated in my</li> <li>response to your question about Consolboard, that</li> <li>statement does not state a bifurcated standard.</li> <li>Now, I could expound unless we have to wait for</li> <li>redirect, but I do not agree that that statement</li> <li>states a bifurcated standard in Consolboard, the principle</li> <li>in Consolboard, was reproduced in these cases prior</li> <li>to 2005</li> </ul>	<b>592</b> 04:25

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MR. JOHNSTON: Despite what you have said         in your second expert report, that it was rarely         cited for utility prior to 2005.         PROFESSOR SIEBRASSE: Consolboard was         cited for roughly 100 cases. To my knowledge, this         passage was cited in six of them, four of which are         in the record. That's why I say "rarely." I didn't         say "never;" I said "rarely."         MR. JOHNSTON: Could you please turn up         tab 19. This is R-489. This is your 2003 paper         entitled "A remedial benefit-based approach to the         innocent-user problem in the patenting of higher         life forms." This paper, as I understand it, is not         about the utility standard.         PROFESSOR SIEBRASSE: Right.         MR. JOHNSTON: However, you do address the         issue of utility at page 95. In the middle of the         page you write, "As the Supreme Court has affirmed,         lack of utility means that the invention will not         work, either in the sense that it will not operate         at all or, more broadly, that it will not do what         the specification promises that it will do the         practical usefulness of the invention does not         matter, nor does its commercial utility"         www.dianaburden.com	04:26	1 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 13 14 5 16 17 18 19 20 1 22 23 24 25	This is what you wrote in your 2003 paper? <b>PROFESSOR SIEBRASSE:</b> Yes, I wrote those words, but the Supreme Court those words, the court's decision does not mean a bifurcated standard. You've focused on this. I mean you've got we had the Supreme Court of Canada Consolboard decision, about 30 pages. We focused to one page, comments on utility, where the case was primarily about disclosure. In fact, the passage cited most commonly from Consolboard is the passage stating that patents, we should not be too astute or technical in construction of the specification or claims, but we've glossed over that part which was really the most important holding in the case. We focused on one small section on utility and, in fact, on one sentence and, you know, half a dozen words. If maybe on redirect I'll have a chance to read the case in context, but I certainly don't deny that these words appear in the case. What I do deny is that, when read in context, the Supreme Court should have been taken to endorse a bifurcated standard of utility with those words. THE PRESIDENT: Mr. Johnson, how many more minutes do you estimate your cross will last? www.dianaburden.com	04:27
1       MR. JOHNSTON: There are still a number of         2       topics to cover in the cross.         3       THE PRESIDENT: Would it be an appropriate         4       moment to break for ten minutes? I'm conscious         5       about the court reporters. Finish your line of         6       questioning and then, when you find a moment, you         7       break.         8       MR. JOHNSTON: Thank you.         9       Just to conclude on this point,         9       Professor Siebrasse, you have quoted from         10       Consolboard in your 2003 paper. It is the only         11       useful" in Canadian patent law in 2003. Is that         11       right?         15       PROFESSOR SIEBRASSE: Yes.         16       MR. JOHNSTON: And that is two years         17       before you say that the promise utility doctrine was         18       first recognized by Canadian courts         19       PROFESSOR SIEBRASSE: Well, I'm telling         10       you this passage does not state the promise utility         11       doctrine.         12       MR. JOHNSTON: Consolboard was your go-to         13       authority for a statement of the law of utility in         14       2003?         15	<b>595</b> 04:29	1 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 13 14 15 16 17 18 19 20 21 22 3 24 25	cited. I mean, go-to? You know, I've said that the cases rarely cited Consolboard. That is correct. It was almost always cited for disclosure. It was cited six times for this particular passage. As you've pointed out, this whole article really is nothing to do with utility. I mean presumably it's the one that I landed on, but I mean I don't know that that has really any significance at all. MR. JOHNSTON: I'm done with this line of questioning. THE PRESIDENT: Ten minutes' break. Professor Siebrasse, you are still under testimony. You know what it means. Thank you. <i>(Recess taken)</i> THE PRESIDENT: Mr. Johnson, please proceed with the cross-examination. MR. JOHNSTON: Professor Siebrasse, before the break we were going through the language of Consolboard and the times that it's been reproduced, and I just want to ask one sort of last brief line of questions on that topic before we move on. Now, you have recognized that the language itself of Consolboard is bifurcated language, two parts of the sentence, and you've recognized that that language has been reproduced prior to 2005 in www.dianaburden.com	<b>596</b> 04:30

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<ul> <li>view from your expe</li> <li>understand you to be</li> <li>passage from Conse</li> <li>bifurcated standard,</li> <li>means that the inver</li> <li>correct?</li> <li>PROFESSOR 9</li> <li>the language is bifur</li> <li>an "or" in the senten</li> <li>THE PRESID</li> <li>elaborate, because y</li> <li>point, so we better d</li> <li>PROFESSOR 9</li> <li>Consolboard?</li> <li>MR. JOHNSTO</li> <li>report, I believe my 9</li> <li>from Halsbury's, the</li> <li>I'll point out the footr</li> <li>Consolboard. There</li> <li>cited in the footnotes</li> <li>simple inoperability.</li> <li>suggestion cases, w</li> <li>patent, and one line</li> </ul>	e saying that you understand that iboard not to stand for a but you think that it only ition must work. Is that <b>SIEBRASSE:</b> I did not agree that cated. I agreed that there is ce. I could happily elaborate. <b>STT:</b> Would you please you come back each time on this eal with it now. <b>SIEBRASSE:</b> Which tab is <b>STEBRASSE:</b> Which tab is <b>STEBRASSE:</b> As I noted in my Second Report, this passage footnotes to that passage iotes aren't reproduced in are three lines of authority is to Consolboard. One line is	04:45	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 9 20 21 22 23 24 25	utility, and this line of cases is best illustrated by and I'm not 100 percent sure it was cited in Halsbury's, but what I call the red dye case, which was a patent for a chemical for dying compounds red. And the defendant said well, there's been no commercial success; nobody is using this dye in the marketplace. And the court said there was a suggestion of this argument that to be useful, to warrant a monopoly, it had to actually be better than what had gone before and commercial acceptance was the test. And the court said no, that can't be right because this red dye, maybe it's just not a fashionable color of red this year. It's enough that the patent does what the specification promises, which means it's enough that it works to dye the clothes red. And that's this language, that it's enough that it does what the specification promises that we see now. That's really the origin of that language is in the rejection of the comparative utility cases. The false suggestion cases. And that's not a bifurcated standard. It's a lower standard. It's not saying that you have to meet any purpose; it's saying it's enough that it works. Commercial success is not www.dianaburden.com	04:46
<ul> <li>in the context of Correpresent a bifurcate rejection of comparation operability.</li> <li>THE PRESIDI</li> <li>explanation?</li> <li>PROFESSOR 9</li> <li>my explanation of th that particular phrase rejection.</li> <li>Tribunal question.</li> <li>MR. JOHNSTO 15</li> <li>the language again of we have turned up min reading this sente when you say that the must work. I see that sentence. But is it n 21</li> <li>this sentence reads comes after the "or"</li> <li>PROFESSOR 9</li> <li>the cases that estab</li> </ul>	<ul> <li>ENT: Does that complete your</li> <li>EIEBRASSE: It doesn't complete e entire Consolboard, but of a and whether it's bifurcated.</li> <li>ENT: Thank you. This was a</li> <li>N: If we could just bring up n the screen, C-118, the passage ow at 525, Professor Siebrasse, nce, I understand what you mean is says that the invention, it it in the first half of the ot true that your reading of but the entire second half, what</li> </ul>	<b>599</b> 04:48	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	promises, and that was a rejection of comparative utility. MR. JOHNSTON: You've also said that the subsequent cases that reproduce this language, these were not cases, in your view, in which a promise standard was being applied. It was simply that the invention worked in those cases. PROFESSOR SIEBRASSE: Right. We saw Almecon, it worked. If we actually look at Goldfarb, the judge quotes this, and the judge I can't remember if it was he or she says what I take from this is that it must work. MR. JOHNSTON: You'd agree, Professor Siebrasse, that just because a case only engages half of a rule, it doesn't mean that the other half isn't there. PROFESSOR SIEBRASSE: Well, what I'm saying about this passage specifically is the origin was in the cases rejecting comparative utility. That's what that passage meant, is that you don't have to be better than what went before; you merely have to dye clothes red. What the specification promises is it will dye clothes red, it does dye clothes red, it does not have to be better than what went before. That's	600 04:49

JNCT/14/2 Eli Lilly and Company v Government of Canada Confidential	Tuesday, 31 Washingtor	n DČ, US
<ul> <li>where that phrase originates.</li> <li>MR. JOHNSTON: I understand your view that you've explained about this passage. If you'll, just as a hypothetical, assume that the reading of this passage, that it, in fact, does stand for a bifurcated standard of utility. Imagine that that were to be true.</li> <li>PROFESSOR SIEBRASSE: Yes.</li> <li>MR. JOHNSTON: The fact that that passage in its entirety was cited in a case that only engaged half of the passage PROFESSOR SIEBRASSE: Which hypothetical case is this?</li> <li>MR. JOHNSTON: Let's imagine this is a bifurcated standard and the first half means that it works, and the second half is the promise utility standard. The bifurcated standard. Imagine that to be true. You've said in cases like Goldfarb and Almecon on the facts these were not promise cases, they are cases where just it wouldn't work. Or that was the sentence</li> <li>PROFESSOR SIEBRASSE: Yes. So just as in Corning Glass, the fact that the judge says well there were no promises, I mean it wasn't at issue, so I agree strictly those would be obiter I mean.</li> </ul>	601         04:51       1       I will say Goldfarb, if you take a look at it,         2       quotes that passage and then says "What I take from         3       this is that it must work." And they held it did         4       work, but clearly the court was reading that passage         5       as simply standing for the proposition "It must         6       work." Maybe they were thinking "or must satisfy         7       any elevated promises but I'm not going to mention         8       that because it's not at issue." I mean maybe they         9       were.         10       MR. JOHNSTON: My question,         11       Professor Siebrasse, is if there's a case where a         12       rule with two parts is enunciated but the facts of         13       the case only engage one part, but the court quotes         14       two parts of the rule, does that mean that the court         15       is saying that only half of that rule is there?         16       Just because the facts of a case only engage half of         17       a rule, does that mean we have to read what the         18       court reproduces as only meaning the half that         19       applies to the facts of the case?         20       PROFESSOR SIEBRASE: Well, you know, this         1 <t< th=""><th>602 04:52</th></t<>	602 04:52
<ul> <li>see it the test of utility or usefulness reflects</li> <li>the notion that what is patented will work."</li> <li>Now, is it possible that the court you</li> <li>know, I suppose it's possible, as I just said, that</li> <li>the court was thinking or, of course, you know,</li> <li>there's a second part, which is an elevated</li> <li>standard, and I quoted the whole thing but only one</li> <li>part is relevant. I mean conceivably, but on its</li> <li>face that's not what the court is saying.</li> <li>MR. JOHNSTON: I'll move on now from this</li> <li>topic. If I could ask you to turn up the very last</li> <li>tab in volume 2, which is I'm sorry. If I could</li> <li>first take you to your first Expert Report, page 22,</li> <li>footnote 102, here at footnote 102 you're discussing</li> <li>the case of Unifloc Reagents. To put it in context,</li> <li>you see it, in Consolboard, this was another case</li> <li>cited by Supreme Court of Canada in Consolboard,</li> <li>Unifloc Reagents. You explain in your footnote 102</li> <li>that this case "was cited for the proposition that</li> <li>if when used in accordance with the directions</li> <li>contained in the specification the promised results</li> <li>are obtained, the invention is useful in the sense</li> <li>in which that term is used in patent law."</li> <li>And you say, "On the facts, the question</li> <li>in Unifloc was purely one of operability, the</li> </ul>	603 04:541decision implicates neither the promise of the patent doctrine, nor comparative utility." 3 Is that right?4PROFESSOR SIEBRASSE: That's what I say there.6MR. JOHNSTON: And in your second Expert Report at page 11, Paragraph 30, you write 8 Consolboard takes this sentence from the Unifloc 9 case, and again in the Unifloc case the use of the 10 words "promised results" did not signal the 11 application of the promise of the patent or any similar analysis. The utility attack in Unifloc was 13 based on the fact that the disclosure of the 14 invention stated that a material that was used to 15 make the invention (a flocculating gel) functioned 16 because it used cellulose membranes when in fact the 17 membranes were made of starch. The court held that 18 the misdescription was irrelevant since it did not 19 affect the utility of the invention. By following 20 the directions contained in the specification and 21 using the specified materials, a gel is produced and 21 that gel is a flocculating gel." 23 24 25 25 26 26 26 27 27 28 28 28 29 20	<b>604</b> 04:56



		605			606
1	<b>MR. JOHNSTON:</b> So the utility that the	04:57	1	respond substantively.	04:59
2	invention had to have in that case was that, by		2	MR. JOHNSTON: Please do take a look at	
3	following the directions contained in the		3	the passages.	
			4	PROFESSOR SIEBRASSE: I do omit	
4	specification and using the specified materials, it				
5	had to produce a gel, and that gel had to be a		5	"efficient," yes.	
6	flocculating gel.		6	<b>MR. JOHNSTON:</b> Does that omission affect	
7	PROFESSOR SIEBRASSE: Yes. I mean can I		7	your reading of the case?	
8	respond substantively? You've read me the words in		8	<b>PROFESSOR SIEBRASSE:</b> No, not at all.	
9	my report and I agree you've read me the words.		9	MR. JOHNSTON: Turn up page 166 of the	
10	MR. JOHNSTON: We're going to go to		10	Unifloc decision. C-255. The word "efficient" did	
11	Unifloc right now. Perhaps we could just do that.		11	not appear anywhere in the claims in Unifloc, did	
12	Please turn up the final tab in volume 2, tab 42,		12	it?	
13	C-255, page 184. Around line 45, line 48, the last		13	PROFESSOR SIEBRASSE: Which page?	
14	sentence there, "By following the directions		14	MR. JOHNSTON: Sorry. Page 169. I gave	
15	contained in the specification and using the		15	you the wrong page there. At line 41 and following,	
16	specified materials a gel is produced and that gel		16	this is the statement of the claims in Unifloc.	
17	is an efficient flocculating agent."		17	I've read the claims, and I know when you referred	
18	So I take it this is the passage that you		18	to this case you would have read the claims. The	
19	were aiming to reproduce in your expert report, but		19	word "efficient" does not appear in the claims in	
20	there's a slight difference in the language. Your		20	Unifloc.	
21	expert report omits the word "efficient flocculating		21	PROFESSOR SIEBRASSE: Right.	
22	agent." Is that right?		22	<b>MR. JOHNSTON:</b> The word "efficient" does	
23	PROFESSOR SIEBRASSE: I'm not sure that I		23	appear at a number of places in the disclosure in	
24	actually quote the passage. The word "efficient"		24	Unifloc. Is that correct?	
25	does not I hate to say "yes" without a chance to		25	PROFESSOR SIEBRASSE:   can't recall	
25	does not Thate to say yes without a chance to		20	<b>FRUFEJJUR JIEDRAJJE.</b> I GATTITEGAN	
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		607			608
1	specifically, but I don't doubt it.	<b>607</b>	1	what happens here.	608
2	MR. JOHNSTON: I could take you to		2	MR. JOHNSTON: I'm having difficulty	
2 3	MR. JOHNSTON: I could take you to PROFESSOR SIEBRASSE: You don't need to.		2 3	MR. JOHNSTON: I'm having difficulty understanding, Professor Siebrasse, because before I	
2 3 4	MR. JOHNSTON: I could take you to PROFESSOR SIEBRASSE: You don't need to. I'm willing to accept it, at least for the point of		2 3 4	MR. JOHNSTON: I'm having difficulty understanding, Professor Siebrasse, because before I put the passage as quoted in your expert report to	
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<ul> <li>explaining the mechanism of why the board was an improvement. So that was really the issue. The court said you have to explain why your invention works. That was the issue in Consolboard. Do you have to explain why your invention works.</li> <li>I'll point out on page 525, Canadian law is to the same effect. That's not talking about I mean it's referring to the passage above but this is the passage citing Unifloc. Here is what the court is telling us, Canadian law is to the same effect.</li> <li>Unifloc, if you look at the passage we just looked at, there was a misstatement in the specification, so it's a flocculating agent, a flocculating agent is something you add to wastewater that causes the suspended particles to drop out of solution so the water is clean. So you add the flocculating agent and the specification said that the flocculating agents are made of cellulose. They're cellulose bubbles. The truth was they were made of starch, not cellulose. The defendant said it's misdescription. You haven't described the invention. You said cellulose, it was actually starch. That's exactly parallel to Consolboard, where the court said you haven't told</li> </ul>	<ul> <li>us how the invention works.</li> <li>Unifloc, the court said it doesn't matter</li> <li>if the bubbles are starch or cellulose. It doesn't</li> <li>matter that they've told us something wrong about</li> <li>how the invention works. What matters is that it</li> <li>works. That's why this word "efficient" the</li> <li>whole utility attack had nothing to do with the</li> <li>standard of utility, right? It was accepted that it</li> <li>was actually an efficient flocculating agent. That</li> <li>wasn't the debate. The debate was as to whether or</li> <li>not this misstatement was relevant, and the court</li> <li>said it's not relevant because the thing works.</li> <li>That's what Canadian law is to the same effect.</li> <li>The paragraph begins "Canadian law is to</li> <li>the same effect." It ends, that paragraph after</li> <li>Unifloc, saying "is not obliged to extol the effect</li> <li>or advantage of discovery if he describes his</li> <li>invention so as to produce it." That's what we're</li> <li>talking about. Unifloc says errors in your</li> <li>description don't matter, the thing works, that's</li> <li>all that matters. That's what Unifloc stands for.</li> <li>That's what Canadian law is to the same effect as</li> <li>which was, after all, the point directly at issue in</li> <li>Consolboard.</li> </ul>	610 05:04
1       MR. JOHNSTON: So in your view in Unifloc,         2       the fact that the court says "by following the         3       directions contained in the specification and using         4       the specified materials a gel is produced and that         5       gel is an efficient flocculating agent," and that         6       word "efficient" came from the disclosure not from         7       the claims, that does not mean that this patent had         8       to deliver that this invention had to deliver an         9       efficient flocculating agent for utility.         10       PROFESSOR SIEBRASSE: Absolutely. I mean         11       there's nothing in that discussion I mean the         12       word "efficient" no doubt appears in the         13       specification. A Canadian court today would say,         14       oh, the word "efficient." There would be an express         15       statement. You said "efficient." There would be a         16       debate. Is that a promise. Did you really you         17       know, there are statements in the disclosure that it         18       was efficient. I believe you. But a Canadian court         19       today, we'd have expert evidence on well, they said         20       efficient. Was that a real promise? Was it a mere         21	<ul> <li>fact was it was an efficient flocculating agent.</li> <li>The only attack was this misdescription and they</li> <li>said look, it works, you know. It works super well.</li> <li>It works. That wasn't the point.</li> <li>MR. JOHNSTON: So the patent specification</li> <li>said this is an efficient flocculating agent, and</li> <li>that is the utility that the invention delivered in</li> <li>this case on the facts?</li> <li>PROFESSOR SIEBRASSE: Well, I don't doubt</li> <li>that it may well have said that. I mean I should</li> <li>say I think this is clear enough, that simply</li> <li>because it says this is an efficient flocculating</li> <li>agent, even in modern Canadian law, does not mean</li> <li>that that statement would necessarily be taken as a</li> <li>promise, right? In current Canadian law you would</li> <li>still look at that statement and there would be a</li> <li>debate, is that a promise or is that not a promise.</li> <li>So we can't simply look at the specification. You</li> <li>know certainly today in Canadian law you don't say</li> <li>oh, well, it says these words, that must be a</li> <li>promise.</li> <li>There's a debate over it. There was no</li> <li>such debate. So the mere fact that it says that,</li> <li>even in modern Canadian law, does not imply that</li> <li>would be a promise. You have to have that debate.</li> </ul>	612 05:06

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$\begin{array}{c}1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\23\\14\\15\\16\\7\\18\\9\\21\\22\\23\\24\\25\end{array}$	They did not have that debate. And the court never even referred to the specification or the disclosure in coming up with this "efficient" word. The fact was it was efficient. It wasn't a dispute. The dispute was over something totally different. THE PRESIDENT: Professor, could you help me? Can we go back to basics for one second? Very elementary. Can I ask you an elementary question now, because I thought I understood it but maybe I'm wrong. The promise utility, where do we find it? In the claim or in the disclosure? PROFESSOR SIEBRASSE: Well, in current Canadian law? THE PRESIDENT: First of all, what was the law, in your submission, prior to 2002? That doesn't exist actually? PROFESSOR SIEBRASSE: That's right. THE PRESIDENT: But utility, where should that be stated prior to 2002? PROFESSOR SIEBRASSE: There's no requirement to state utility anywhere in the patent, so that was stated in Consolboard, if the utility would be obvious to a skilled person. So	613 05:07	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 7 18 90 21 22 23 24 25 25 25 25 25 25 25 25 25 25	Consolboard in particular, it was a board, they didn't have to say "It's useful for building things." I don't believe there was any actual statement in Consolboard. So the utility strictly doesn't have to be stated anywhere. But the problem is if you have, for example, a new chemical compound and a person reads it and looks at the patent and says it's a chemical compound, I can make it, but you don't know what it's good for, well, it may cure cancer but if nobody knows that it's not useful. So if the utility would not be obvious to a skilled person from reading the entire patent, then you would have to state it somewhere. THE PRESIDENT: "Somewhere?" What do you mean? Under the claim or under the disclosure? PROFESSOR SIEBRASSE: If you're claiming a compound per se, so this compound has never existed before, it has to be useful in order to get a patent on it, in that case you would never state the utility in the claim because if you did state the compound for treating X or for doing X, you would be restricted to that use. If you're claiming a compound per se, you would state the utility in the disclosure.	614 05:08
1 2 3 4 5 6 7 8 9 10 11 23 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 9 20 21 22 23 24 25	THE PRESIDENT: You are free to state it in either part. Is that what you're saying? PROFESSOR SIEBRASSE: As a practical matter you're not free because, if you state it in the claim, then the limit of your monopoly is restricted to that use. But you could write it in the claim, then the limit of your monopoly is restricted to that use. But you could write it in the restricted to that use. But you could write it in the value of the president of the time of the time to use. PROFESSOR SIEBRASSE: That's right. THE PRESIDENT: And in this case in the thifloc case, it was stated in the disclosure. "fficient Unifloc?" PROFESSOR SIEBRASSE: Yes. I mean I'm not sure there was ever actually a dispute as to what it as useful for, so it's possible that it would have been obvious to a person skilled in the art what it as good for, but I believe it was stated in the disclosure. THE PRESIDENT: Can you please go to page 184 again? You were taken to this passage, where you see in the margin No. 45. You see first to judge is lamenting about the waste of time. PROFESSOR SIEBRASSE: Yes.	<b>615</b> 05:10	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	THE PRESIDENT: "An enormous amount of time was, as I think, wasted in taking evidence upon the question whether the membranes enveloping the granules of starch were, as the patentee said they were, cellulose or, as the Defendants said they were, starch. If the patentees had misdescribed them, this misdescription did not seem to me to matter or to affect the utility of the invention described in the specification." So there's two things, as far as I read this misdescription does not seem to matter to me, or to affect the utility of the invention described in the specification. And then comes, "By following the directions contained in the specification and using the specified materials a gel is produced and that gel is an efficient locculating agent." So is that not directed to utility as found in what is here called the specification, which is the disclosure, I understand? <b>PROFESSOR SIEBRASSE:</b> Yes, well, the disclosure in this case, it being a chemical fompound, it would be normal to have it disclosed in the disclosure, so yes, it's referred to that utility in the disclosure, and it's common for the www.dianaburden.com	<b>616</b> 05:11

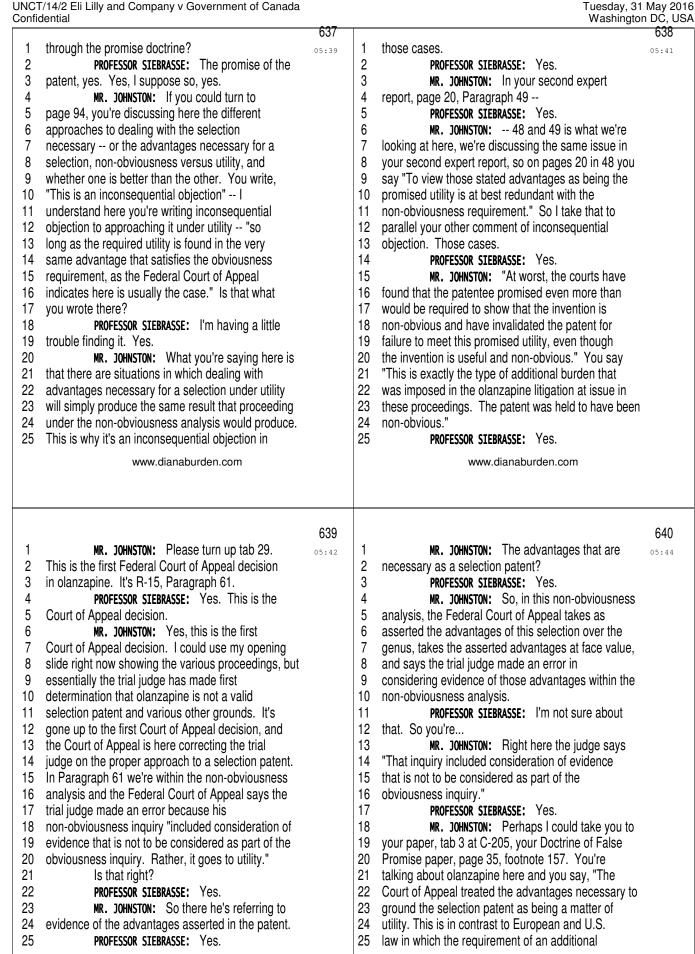
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<ul> <li>courts to say when they're referring to the utility,</li> <li>just the simple utility, they'll say the promised</li> <li>utility, the utility stated in the disclosure, the</li> <li>purpose for which it is useful, so those simply</li> <li>refer to the utility stated in the disclosure. So</li> <li>yes, the utility in this case was stated in the</li> <li>disclosure. But that doesn't mean that the degree</li> <li>of utility was imported from the disclosure today</li> <li>in Canadian law it says "efficient flocculating gel"</li> <li>and, as I said, we'd have a debate, okay, is that</li> <li>actually a promise. And then there would have been</li> <li>a debate, is it efficient? We would have had expert</li> <li>evidence on how efficient would a skilled person</li> <li>have understood efficiency to be. We'd have a</li> <li>debate as to whether it met that standard. Here</li> <li>really the fact that it was efficient meant that it</li> <li>more than satisfied the utility standard.</li> <li>THE PRESIDENT: Okay.</li> <li>MR. JOHNSTON: Professor Siebrasse, you</li> <li>would agree that in a patent trial, courts will be</li> <li>interpreting the patent for many different purposes?</li> <li>PROFESSOR SIEBRASSE: Yes.</li> <li>MR. JOHNSTON: They might have to construe</li> <li>the claims?</li> </ul>	<b>617</b> 05:12	MR. JOHNST courts should alway disclosure? PROFESSOR strictly the rule is that paramount. If the w there's no need to h If the words are amile the disclosure to intre- be the black letter la MR. JOHNST before you can know actually ambiguous, disclosure to unders ought to be interpre- PROFESSOR would be the case. sometimes. Someti- there's no need to h MR. JOHNST have to do is identify invention for the nor PROFESSOR	<b>ON:</b> Wouldn't you say that even v if a word in the claims is you'd have to look at the stand how the claim language ted to know if it is ambiguous? <b>SIEBRASSE:</b> Yes, often that I say "often" at least maybe mes the word is plain enough,	618 05:13
<ul> <li>They often do identify the inventive concept. They</li> <li>may look to the disclosure, although it's not always</li> <li>necessary to do so.</li> <li>MR. JOHNSTON: Your view is that it's</li> <li>generally necessary to do so?</li> <li>PROFESSOR SIEBRASSE: No. I wouldn't say</li> <li>that it's generally necessary to do so. I mean the</li> <li>leading case on that, which I think was Sanofi</li> <li>adopting this windsurfer Pozzoli test, but it says,</li> <li>as one of the steps, identify the inventive concept</li> <li>or, if that cannot be done, construe the claims. So</li> <li>it's a step but it's an alternative step which may</li> <li>or may not be necessary.</li> <li>MR. JOHNSTON: Tab 16, R-476, page 80, the</li> <li>middle of the page. This is an excerpt again from</li> <li>your blog where you write, "The '764 patent is one</li> <li>more example showing that it is generally necessary</li> <li>to have recourse to the disclosure to construe the</li> <li>inventive concept, not only in the case of a per se</li> <li>compound claim."</li> <li>PROFESSOR SIEBRASSE: Yes, generally, you</li> <li>know, in the particular context well, certainly</li> <li>in the context of a compound claim it will be</li> <li>generally necessary. I mean, is it generally</li> <li>necessary in all kinds of inventive concepts, I mean</li> </ul>	<b>619</b> 05:14	well, as I said, the b determine the inven claim. Certainly ofte inventive concept determine the inven not strictly necessar obviousness determ necessary. Even w concept is part of th not necessary to loc that is often done. MR. JOHNST discussion, you've s looking to the disclo the patent. PROFESSOR MR. JOHNST use of the disclosurr if I've got your positi PROFESSOR MR. JOHNST R-488, page 7, para Court of Appeal's de and at Paragraph 15	it overstated. Yes, it's lack letter law is that you tive concept or construe the en the courts will look to the or look to the disclosure to tive concept. As I said, it's y at all as part of an ination, and it's not strictly hen identifying the inventive e obviousness analysis, it's ik to the disclosure, although <b>ON:</b> Just to situate this aid what's new in 2005 is courts sure to identify promises of <b>SIEBRASSE:</b> Yes. <b>ON:</b> And that you consider this e antithetical to its purpose, on correct? <b>SIEBRASSE:</b> Yes, yes. <b>ON:</b> If you can turn up tab 18, graph 19, this is the Federal ecision in Feherguard in 1995, Of the court says, "The patent as a ww.dianaburden.com	620 05:16

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whole, and not only the claims, must be considered         when assessing the utility of an invention" You         consider this to be a correct statement of the law         in 1995?         PROFESSOR SIEBRASSE: Yes.         MR. JOHNSTON: If you could please turn up         tab 15, R-401 at 154g, this is a passage we looked         at earlier. It's the Federal Court of Appeal in         Wellcome v Apotex saying that "Since the utility of         a patent must ultimately be judged against its         promise, the exercise requires that the         specification be carefully construed to determine         exactly what that promise is."         Mow, here you understand the court in         using the word "specification" to be referring to         the disclosure?         PROFESSOR SIEBRASSE: Yes.         MR. JOHNSTON: Just to be clear, is this         the case we discussed earlier that you described as         the clearest support for the promise of the patent         doctrine?         PROFESSOR SIEBRASSE: Yes.         MR. JOHNSTON: If you could turn up your         first Expert Report at page 14, Paragraph 48, here         you're discussing the Latanoprost case which         www.dianaburden.com	621         05:18         1       involved a patent that claimed a compound for the         2       treatment of glaucoma. The patent came before two         3       different panels of the Federal Court of Appeal and         4       you are highly critical of the second Federal Court         5       of Appeal panel as interpreting treatment of         6       glaucoma to require the treatment of a chronic         7       condition. You consider this an extremely         8       aggressive application of the false promise         9       doctrine. Is that a fair statement of your position         10       on this case?         11 <b>PROFESSOR SIEBRASSE:</b> Well, I don't know         12       that in this report I characterize it. I say it's a         13       striking illustration because of the contrast and so         14       on. I say it may vary between different courts.         15       I'm afraid I'm losing you a little bit here. You've         16       read me three different passages from three         17       different things, and I'm trying to hold this all in         18       my mind. Or are you just wanting me to confirm that         19       it says these words?         20       MR. JOHNSTON: If you can confirm for me         1	622 05:19
<ul> <li>Federal Court of Appeal interpreted that language to mean chronic treatment of glaucoma?</li> <li>PROFESSOR SIEBRASSE: Yes. Well, I don't</li> <li>know they interpreted that language. They construed</li> <li>the patent as promising chronic treatment, but I'm</li> <li>not sure that it was a matter of them</li> <li>MR. JOHNSTON: But in this case the</li> <li>language they were talking about was in the claims, and that's what the court was interpreting</li> <li>PROFESSOR SIEBRASSE: I'm not sure</li> <li>MR. JOHNSTON: In arriving at that promise</li> <li></li> <li>PROFESSOR SIEBRASSE: It was</li> <li>THE PRESIDENT: Hold on.</li> <li>MR. JOHNSTON: In the Latanoprost case was</li> <li>it not that the Court of Appeal was interpreting the</li> <li>meaning of those words in the claims in arriving at</li> <li>its understanding of the promise of the patent?</li> <li>PROFESSOR SIEBRASSE: I don't believe so.</li> <li>I believe it was interpreting the disclosure.</li> <li>MR. JOHNSTON: If you could, please, turn</li> <li>up tab 3, C-205, page 43, at the bottom you're</li> <li>discussing that Federal Court of Appeal decision in</li> <li>Latanoprost, and you write, "Thus, treatment was</li> <li>construed as chronic treatment due to the chronic</li> </ul>	<ul><li>2 the Court of Appeal made no reference whatsoever to</li><li>3 the disclosure."</li></ul>	<b>624</b> 05:23

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	<ul> <li>established its vie</li> <li>without making ar</li> <li>description and w</li> <li>have argued is im</li> <li>information. It is it</li> <li>this as a very agg</li> <li>doctrine."</li> <li>MS. WAGN</li> <li>interrupt, but we h</li> <li>We're missing models</li> <li>to follow along.</li> <li>THE PRES</li> <li>the tabs in in Tame</li> <li>missing.</li> <li>THE PRES</li> <li>replaced. Do you</li> <li>MS. WAGN</li> <li>bundle. There's a</li> <li>MS. WAGN</li> <li>tabs that are missing</li> <li>can see, and it loop</li> </ul>	626 ails to show that the FCA w of the promise of the patent by reference to what is said in the ithout taking into account what I portant factual context for these reasons that I regard ressive use of the false promise IER: Mr. President, I'm sorry to have an incomplete tab for Tab 16. Ist pages of the tab so we're unable SIDENT: You don't have page 32? IER: No. We don't have many of ab 16 many of the pages are SIDENT: Maybe the bundle can be have an extra bundle? (Handed) IER: Thank you. SIDENT: Return the incomplete
1       page 28 and no further within the tab.         2       THE PRESIDENT: There are many more, I can         3       promise you!         4       MS. WAGNER: I'm well aware of that.         5       Thank you.         6       THE PRESIDENT: It goes to 43.         7       You have them now?         8       MS. WAGNER: We have them now. Thank you.         9       THE PRESIDENT: Mr. Johnson, please         10       MR. JOHNSTON: Page 32 of Tab 16.         11       MR. JOHNSTON: Page 32 of Tab 16.         12       Professor Siebrasse, your view is this is a case         13       where the Federal Court of Appeal should have looked         14       at the language of the disclosure?         15       PROFESSOR SIEBRASSE: This case is best         16       understood by contrast with the subsequent Plavix         17       decision the Court of Appeal, where in the Plavix         18       decision the Court of Appeal reaffirmed the promise         19       of the patent analysis but at the same time said         20       there must be an explicit promise. And I would say         21       Isee well, I certainly see that case and it's         22       probably often thought to be a reaction to         23       Latanopros	<ul> <li>2 patent doctrine we</li> <li>3 disclosure and loc</li> <li>4 if you're going to f</li> <li>5 As I've</li> <li>6 abandoned entire</li> <li>7 false promise doc</li> <li>8 valid patent, it sho</li> <li>9 the patent itself, s</li> <li>10 that they read the</li> <li>11 skilled person and</li> <li>12 chronic treatment</li> <li>13 promise. That's r</li> <li>14 weren't in there.</li> <li>15 doctrine, well, at I</li> <li>16 a promise when ti</li> <li>17 opposed to this hi</li> <li>18 MR. JOHN</li> <li>19 is that you have d</li> <li>20 doctrine as cases</li> <li>21 against a promise</li> <li>22 disclosure of the p</li> <li>23 that you've writter</li> <li>24 very clear that you</li> <li>25 of Appeal as havi</li> </ul>	said here I've argued it should be ly, but if we're going to retain the trine to strike down an otherwise buld be with more attention to o my criticism of Latanoprost is disclosure through the eyes of a d concluded that it promised a even though there was no explicit eally the point, that the words So if we've got the promise east you should only be held to here are actually words in there as

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<ul> <li>patent, so I don't understand how yo</li> <li>this to be an example of the promise</li> <li>doctrine as you have defined it.</li> <li>PROFESSOR SIEBRASSE: May</li> <li>new doctrine that they just make up</li> <li>whole cloth, and that would also be j</li> <li>mean, as I stated, Plavix subsequent</li> <li>should be an explicit promise.</li> <li>MR. JOHNSTON: You have of</li> <li>your expert report as an example of</li> <li>utility doctrine.</li> <li>PROFESSOR SIEBRASSE: Yes.</li> <li>MR. JOHNSTON: But you wo</li> <li>the case, in fact, does not meet the you have defined the promise utility</li> <li>PROFESSOR SIEBRASSE: Well</li> <li>reading the disclosure through the e</li> <li>person. It was reading the disclosure</li> <li>yes of a skilled person. It was I r</li> <li>Mr. Dimock's report makes the point</li> <li>is interpreted by construing the discl</li> <li>the eyes of a skilled person. That's</li> <li>in Latanoprost. My point here is not</li> <li>not read the disclosure to determine</li> <li>A promise being found y</li> </ul>	e utility be it's a whole promises out of problematic. I tly said that it ited this case in the promise uld agree that way in which doctrine. , no, it was yes of a skilled through the nean that the promise osure through what happened that they did the promise. you know, the	<ul> <li>point is that there weren't words in there. It</li> <li>wasn't the explicit words. But they read the</li> <li>promise. They construed the promise by reading the</li> <li>disclosure through the eyes of a skilled person.</li> <li>They did that. And the fact that the word "chronic"</li> <li>isn't in there, that was the focus of my criticism.</li> <li>But nonetheless, that court construed the promise by</li> <li>reading the disclosure through the eyes of a skilled</li> <li>person.</li> <li>MR. JOHNSTON: By reading the claims in</li> <li>that case through the eyes of a skilled person?</li> <li>PROFESSOR SIEBRASSE: I don't believe so.</li> <li>I believe it was the disclosure. But I mean</li> <li>MR. JOHNSTON: We just had you look at a</li> <li>passage in your writing where you said that you</li> <li>wrote, "the Court of Appeal made no reference</li> <li>whatsoever to the disclosure." That's what you</li> <li>wrote in your paper.</li> <li>PROFESSOR SIEBRASSE: What I meant there</li> <li>is that they didn't there weren't explicit words</li> <li>in there. They certainly talked about the</li> <li>disclosure.</li> <li>MR. JOHNSTON: And the words they were</li> <li>interpreting were "treatment" and "glaucoma"?</li> <li>PROFESSOR SIEBRASSE: Yes.</li> <li>www.dianaburden.com</li> </ul>	
1       MR. JOHNSTON: And those weights         2       both in the claims in Latanoprost?         3       PROFESSOR SIEBRASSE: Well         4       in the claims, but my recollection of the that they were construing it from the         6       MR. JOHNSTON: You state in         7       reports that courts will scour the disc         8       determine what specific promises have         9       would you agree that there have beed         11       checkrine?         12       PROFESSOR SIEBRASSE: Well         13       that the promise utility doctrine is inf         14       unprincipled, but there have been m         15       applications of it, yes.         16       MR. JOHNSTON: So, given th         17       believe that the manner in which it h         18       by at least some Canadian judges ha         19       PROFESSOR SIEBRASSE: Well         20       sometimes. I mean this is the point,         21       to know until you get a judge to sit d         22       actually go through it. I'm certainly r         23       that the promise is always construed         high promise.       Sometimes it is const         24       alow promise.         25       a low promise. <td>, they do appear the case is disclosure. n your expert closure to ve been made, but en moderate and e utility , my view is nerently oderate ne doctrine, you as been applied s been moderate? , yes, that it's hard own and not saying i to be a very rued to be quite</td> <td>1       MR. JOHNSTON: You've described the         2       practice of construing the promise as subjective and         3       arbitrary, and in part of that description you say         4       that it involves a fine grammatical parsing and         5       hair-splitting of the specification. If you'd turn         6       to your section expert report at page 17,         7       Paragraph 42, you present the Anastrozole decision         8       as such fine hair-splitting.         9       PROFESSOR SIEBRASSE: Yes. I don't say         10       hair-splitting in that one but yes, it's a good         11       today as an example of a 62 paragraph analysis of         11       the promise. Elsewhere, Professor Siebrasse, you         11       have described this decision as a significant         12       MR. JOHNSTON: You mentioned it again         13       today as an example of a 62 paragraph analysis of         14       the promise. Elsewhere, Professor Siebrasse, you         15       have described this decision as a significant         16       advance in developing a coherent jurisprudence that         17       is consistent with general principles of claim         18       construction and statutory interpretation.         19       PROFESSOR SIEBRASSE: Yes.</td> <td><b>632</b> 05:33</td>	, they do appear the case is disclosure. n your expert closure to ve been made, but en moderate and e utility , my view is nerently oderate ne doctrine, you as been applied s been moderate? , yes, that it's hard own and not saying i to be a very rued to be quite	1       MR. JOHNSTON: You've described the         2       practice of construing the promise as subjective and         3       arbitrary, and in part of that description you say         4       that it involves a fine grammatical parsing and         5       hair-splitting of the specification. If you'd turn         6       to your section expert report at page 17,         7       Paragraph 42, you present the Anastrozole decision         8       as such fine hair-splitting.         9       PROFESSOR SIEBRASSE: Yes. I don't say         10       hair-splitting in that one but yes, it's a good         11       today as an example of a 62 paragraph analysis of         11       the promise. Elsewhere, Professor Siebrasse, you         11       have described this decision as a significant         12       MR. JOHNSTON: You mentioned it again         13       today as an example of a 62 paragraph analysis of         14       the promise. Elsewhere, Professor Siebrasse, you         15       have described this decision as a significant         16       advance in developing a coherent jurisprudence that         17       is consistent with general principles of claim         18       construction and statutory interpretation.         19       PROFESSOR SIEBRASSE: Yes.	<b>632</b> 05:33

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<ul> <li>arbitrary and hair-splitting kinds of distinctions,</li> <li>even with the principled that was Justice Rennie,</li> <li>who is now in the Court of Appeal, and even with a</li> <li>good judge and a principled approach you still end</li> <li>up with these unprincipled hair-splitting decisions</li> <li>because the promise doctrine is inherently</li> <li>arbitrary, and the reason for that is the claims</li> <li>define the invention. Patentees know they must be</li> <li>very precise. The disclosure describes the</li> <li>invention. They're supposed to say everything they</li> <li>know about the invention, and there's attention</li> <li>there. They're construing the disclosure to define</li> <li>the level of utility when the disclosure is not</li> <li>meant for that and, in fact, the purpose of the</li> <li>disclosure requiring the patentee to say everything</li> <li>they know as the courts have recognized long ago,</li> <li>it's almost antithetical to this point of defining</li> <li>the invention. So Justice Rennie did make a big</li> <li>advance, and even with that big advance we're still</li> <li>ending up with this very fine parsing.</li> <li>MR. JOHNSTON: I appreciate that your</li> <li>position is that the whole enterprise is flawed of</li> <li>looking to the disclosure, but you're saying that,</li> <li>given that enterprise, an approach which you hold</li> <li>out as the example of fine grammatical parsing and</li> </ul>	633 05:35	15 16 17 18 19 20 21 22 23	hair-splitting is, in fact, a principled approach that is consistent with principles of statutory PROFESSOR SIEBRASSE: Well, his approach is principled THE PRESIDENT: Sorry. Let him finish the question. MR. JOHNSTON: Consistent with principles of statutory interpretation. PROFESSOR SIEBRASSE: Yes, yes. The principles are sound principles. I mean, they're applying the same principles that are applied to claim construction. The problem is that, even applying those sound principles, it's fine to apply them to claim construction because the claims define the invention and parties have known for over 100 years that they have to be very precise in defining the claims, but to apply that very same principle, which is the best approach to construction we can do, to apply it to the disclosure which was never meant to define for this purpose, that results in arbitrary results. I mean it is the best approach we can have. It's consistent with claim construction approach. But, when applied to construing the promise in the disclosure, it gives unsatisfactory results.	634 05:36
1       MR. JOHNSTON: Claimant's patent for         2       olanzapine was a selection patent. That's right?         3       PROFESSOR SIEBRASSE: Yes.         4       MR. JOHNSTON: And you'd agree that, for a         5       selection patent, the selection must have a special         6       advantage compared with the genus.         7       PROFESSOR SIEBRASSE: Yes. It's usually         8       special advantage or absence of disadvantage and         9       generally unexpected properties. Some unexpected         10       MR. JOHNSTON: To be clear, that         12       requirement for a selection patent is something         13       that's longstanding for those patents in Canadian         14       law         15       PROFESSOR SIEBRASSE: Yes.         16       MR. JOHNSTON: traced to this 1930         17       IG Farbenindustrie case in the UK.         18       PROFESSOR SIEBRASSE: Yes.         19       MR. JOHNSTON: Not being a valid selection         10       patent is not an independent ground of invalidity         11       under the Patent Act.         12       PROFESSOR SIEBRASSE: That's right.         13       MR. JOHNSTON: So the requirements for a         14       So the requirements for a	<b>635</b> 05:37	14 15 16 17 18 19 20 21 22 23 24	PROFESSOR SIEBRASSE: That's well MR. JOHNSTON: Or through the requirements of patentability, I should say. PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: And in Europe, an the United States, I know you've written that selection patent issues are often dealt with under non-obviousness? PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: And in Canada they're primarily dealt with through utility instead? PROFESSOR SIEBRASSE: Well, I'm not sure it's primarily. They're dealt with both as a matter of obviousness and utility and, in fact, we shouldn't forget anticipation. There are also anticipation aspects. MR. JOHNSTON: In tab 16, R-476, at 93 at the top, you say, "In Canadian law, in contrast, the unexpected advantages are also, and primarily, treated as a matter of utility." So you're talking here about the approach to selection patents in Canada. PROFESSOR SIEBRASSE: Yes. MR. JOHNSTON: And the way in which they're treated as a matter of utility in Canada is www.dianaburden.com	<b>636</b> 05:38



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advantage is considered to be a matter of obviousness." <b>PROFESSOR SIEBRASSE:</b> Yes, I think that's wrong. I mean if I can go back to the <b>MR. JOHNSTON:</b> Sorry, what's wrong? <b>PROFESSOR SIEBRASSE:</b> Well, the advantages necessary to ground selection patents as a matter of utility. <b>MR. JOHNSTON:</b> The statement in your paper at footnote 157? <b>PROFESSOR SIEBRASSE:</b> Yeah. I mean if we can go back to the Court of Appeal decision, so generally speaking for selection patents, you have a prior genus, which in this case was the '687 patent. All the compounds of the prior genus have certain properties. To have a valid selection you have to have unexpected properties over the genus. So at Paragraph 13, the trial judge identified the '113 patent's advantages over the '687 patent and over other anti-psychotics. So he determined the advantages, and then the advantages over other antipsychotics in a second list. So when I read the passage you were just reading to me, I take it the court was saying that www.dianaburden.com		<ul> <li>first list of advantages over the genus is what was</li> <li>relevant to selection patents, and the trial judge</li> <li>erred because the trial judge bundled it all</li> <li>together and he considered the list of advantages</li> <li>over the genus but he also considered the promised</li> <li>advantages over all other anti-psychotic drugs, and</li> <li>as a matter of selection patents it's not necessary</li> <li>to be better than all other anti-psychotics. It's</li> <li>just necessary to be better than the genus.</li> <li>So that's how I read that passage.</li> <li>MR. JOHNSTON: Professor Siebrasse, you</li> <li>would accept that the Federal Court of Appeal's</li> <li>approach to the non-obviousness analysis in its</li> <li>first olanzapine decision that we were looking at at</li> <li>R-15, the Federal Court of Appeal did not consider</li> <li>any evidence of whether the advantages actually</li> <li>existed. It simply looked at the language of the</li> <li>patent.</li> <li>PROFESSOR SIEBRASSE: Well, I'm not sure.</li> <li>I mean it's a relatively we don't know what</li> <li>they they had all the record before them. We</li> <li>don't really know what they considered.</li> <li>MR. JOHNSTON: So the analysis is in that</li> <li>section in R-15 between Paragraph 54 and ending at</li> <li>Paragraph 64, and there is no assessment of the</li> </ul>	
<ul> <li>evidence of advantages in that section of the judgment.</li> <li>PROFESSOR SIEBRASSE: Well, it's pretty</li> <li>clear law that, like any invention, a selection</li> <li>patent has to be non-obvious. It has to be</li> <li>inventive. That's right in the Act. And a</li> <li>selection patent has to have advantages over the</li> <li>other compounds in the genus. And if the selection</li> <li>patent doesn't actually have the advantages, then</li> <li>it's not an invention. The invention must be new,</li> <li>useful and non-obvious. So to suggest that the</li> <li>Court of Appeal simply took these advantages at face</li> <li>value is I mean, I can't read it that way because</li> <li>the invention has to be inventive.</li> <li>MR. JOHNSTON: Which would mean in this</li> <li>context it has to have the advantages?</li> <li>PROFESSOR SIEBRASSE: Yes, and the court</li> <li>held it was non-obvious, so it's a pretty short</li> <li>inference that it has to have the it has to be</li> <li>non-obvious. That means it has to have the</li> <li>advantages. The court held it was non-obvious.</li> <li>They had the record before them. I take them to be</li> <li>saying it had the advantages, the specific ones over</li> </ul>		<ul> <li>Court of Appeal to be saying that on the record</li> <li>there was sufficient evidence establishing</li> <li>advantages over the genus to support a selection</li> <li>patent.</li> <li>PROFESSOR SIEBRASSE: That's what I take</li> <li>them to be saying, yes. I mean they held it was</li> <li>non-obvious, and they also held that a selection</li> <li>patent like any other has to be non-obvious, so I</li> <li>have to interpret them that way.</li> <li>MR. JOHNSTON: The passage I took you to</li> <li>in Paragraph 61 indicates that the Federal Court of</li> <li>Appeal found error in the trial judge's</li> <li>considered as part of the obviousness inquiry.</li> <li>Rather, it goes to utility. So isn't this, rather,</li> <li>that the Federal Court of Appeal is telling the</li> <li>trial judge that you ought to be doing this under a</li> <li>different heading?</li> <li>PROFESSOR SIEBRASSE: Well, that's not how</li> <li>I read it. I read it as saying the trial judge</li> <li>considered the question of is it a valid selection</li> <li>patent. Is it a valid selection patent as a single</li> <li>question and that, as the court said, tainted his</li> </ul>	<b>644</b>

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MR. JOHNSTON:       I said so isn't this,         rather, that the Federal Court of Appeal is telling         the trial judge that you ought to be doing this         under a different heading?         PROFESSOR SIEBRASSE:       Oh, okay. No. So I         see it as saying, look, the problem was you         considered all of these advantages the advantages         over the genus and the advantages over all the other         compounds all at the same time, mushed it all         together, what you have to do is separate them out.         The obviousness stuff is all the         advantages over the genus, and the utility stuff is         any promise under the current promise doctrine, all         the promises, and the court found in this case that         you promised advantages over other known         anti-psychotics.         And the court, as I read it, is         relevant to obviousness is the advantages over the         genus, and you made a mistake by taking those         promises which are relevant to utility and requiring         as a matter of obviousness so we have advantages         tha here's the genus, is useful, advantages over         the genus is this useful, advantages over all other         compounds, and you put the bar too high for         obviousness, because you imported those promises <td>05:52</td> <td><ul> <li>into the obviousness analysis, and the bar is lower,</li> <li>that is, advantage over the genus. So that's how I</li> <li>read this.</li> <li>MR. JOHNSTON: Let's just take a look at</li> <li>the trial judge's findings of fact in the first</li> <li>instance. If you could please turn up tab 30, R-16,</li> <li>Paragraph 260, these are the trial judge's findings</li> <li>of fact. "More particularly the evidence does not</li> <li>support a prediction that the alleged advantages of</li> <li>olanzapine over two '687 compounds, flumezapine and</li> <li>ethyl olanzapine, are substantial. To the extent</li> <li>they existed at all their magnitude was</li> <li>insignificant. In addition, there is no evidence</li> <li>that olanzapine was superior to any other compounds</li> <li>in the '687 class in respect of the characteristics</li> <li>described in the '113 patent. The comparisons did</li> <li>not relate to the class as a whole, and I have no</li> <li>evidence that any advantage was peculiar to</li> <li>olanzapine."</li> <li>I'll just continue because this next</li> <li>paragraph is relevant also. "None of the</li> <li>comparisons in the '113 patent was supported by</li> <li>evidence suggesting that olanzapine was a peculiar</li> <li>or special member of the '687 class. I have no</li> <li>information about any of the other '687 members'</li> </ul></td> <td>05:53</td>	05:52	<ul> <li>into the obviousness analysis, and the bar is lower,</li> <li>that is, advantage over the genus. So that's how I</li> <li>read this.</li> <li>MR. JOHNSTON: Let's just take a look at</li> <li>the trial judge's findings of fact in the first</li> <li>instance. If you could please turn up tab 30, R-16,</li> <li>Paragraph 260, these are the trial judge's findings</li> <li>of fact. "More particularly the evidence does not</li> <li>support a prediction that the alleged advantages of</li> <li>olanzapine over two '687 compounds, flumezapine and</li> <li>ethyl olanzapine, are substantial. To the extent</li> <li>they existed at all their magnitude was</li> <li>insignificant. In addition, there is no evidence</li> <li>that olanzapine was superior to any other compounds</li> <li>in the '687 class in respect of the characteristics</li> <li>described in the '113 patent. The comparisons did</li> <li>not relate to the class as a whole, and I have no</li> <li>evidence that any advantage was peculiar to</li> <li>olanzapine."</li> <li>I'll just continue because this next</li> <li>paragraph is relevant also. "None of the</li> <li>comparisons in the '113 patent was supported by</li> <li>evidence suggesting that olanzapine was a peculiar</li> <li>or special member of the '687 class. I have no</li> <li>information about any of the other '687 members'</li> </ul>	05:53
<ul> <li>properties in respect of efficacy, liver enzymes,</li> <li>CPK, cholesterol or anything else. I do not know</li> <li>flumezapine's tendency, if any, to raise cholesterol</li> <li>or ethyl olanzapine's liability, if any, in respect</li> <li>of liver enzymes or CPK. There is no evidence</li> <li>before me indicating whether only a small number of</li> <li>unselected compounds possess the same alleged</li> <li>advantages as olanzapine, or whether a larger number</li> <li>of them does."</li> <li>So those were the trial judge's findings</li> <li>of fact regarding the evidence of alleged</li> <li>advantages?</li> <li><b>PROFESSOR SIEBRASSE:</b> Yes, well, the trial</li> <li>judge made a number of other findings as well that I</li> <li>see aren't actually in the binder, but the two</li> <li>compounds that were part of the genus were ethyl I'm</li> <li>sorry, what we were looking at? Flumezapine and</li> <li>ethyl olanzapine, those were the known compounds</li> <li>that were part of the genus. Those had been and</li> <li>this is as I say, it's not in these paragraphs</li> <li>but Lilly had started it is in the trial</li> <li>decision, just not in the paragraphs we have in</li> <li>front of us.</li> </ul>	<b>647</b> 05:55	<ul> <li>decision?</li> <li>PROFESSOR SIEBRASSE: I don't have the</li> <li>entire decision, no. I have Paragraph 114 and on.</li> <li>MR. JOHNSTON: I apologize. You should</li> <li>have the entire decision there.</li> <li>PROFESSOR SIEBRASSE: But in the earlier</li> <li>decision Lilly had actually started testing</li> <li>flumezapine and ethyl olanzapine and they had been</li> <li>told to stop by the FDA because of side effects. I</li> <li>believe CPK, which I believe is a kind of jerking</li> <li>no, CPK is a liver enzyme, so one of them had</li> <li>increased liver enzymes. The other had I think</li> <li>it was some kind of motion side effect. Anyway,</li> <li>both of those compounds earlier the judge sets that</li> <li>out, that Lilly had actually been required to stop</li> <li>by the FDA because of those side effects, so this is</li> <li>confusing.</li> <li>Again, as I say, this is in particular why</li> <li>it's important that the Court of Appeal had the</li> <li>whole trial record before it. You know, the trial</li> <li>judge here also did say that the compounds are</li> <li>inventive and non-obvious, which are synonyms. It's</li> <li>not possible. So the trial judge says that. The</li> <li>trial judge also says some other things. The Court</li> <li>of Appeal had the whole record. I don't have the</li> </ul>	648 05:56

1         whole record. I haven't read the whole record and a an invertice. It nust be invertice. It must be invertice it is dovious, and they held it wasn't obvious.         1         precisely an application of the test which caused states and it the four-year-old data data precised.         5           4         advantages. For us it's obvious, and they held it wasn't obvious.         1         the EVEXABUT: You have two minutes left?         7         This is what you wrote about the trial it for the analysis in understandable that the FCA would not it.         6           9         find a natural moment, then well stop.         This is what you wrote about the trial it precises assesses: Yes. So the trial it precises in the precises assesses: Yes. So the trial it precises assesses: Yes. So the trial it precises and the analy and that she it the apprecises in the precises assesses: Yes. So the trial it precises and the analy and that she it is the obvious mess?         1         1           11         Maximum apprecises in the precises and the analy and that she it is it and that she and analy and the analy and that and the analy and you it is it and that she and you it approving as and the apprecises assess if a trans on about the trial is the obvious. There is a substantial advantage over the 25 prior class. That is, his do dowise interes?         1         1         1         1         1         1         1         1         1         1         1         1         1         1         1         1         1	UNCT/14/2 Eli Lilly and Company v Gove Confidential	ernment of Canada		Tuesday, 31 Washingtoi	May 2016 n DC, USA
1       in the genus and, yet, that's non-obvious. That's       06:01         2       why the obviousness requirement applies because,         3       forgetting about selection patents, any patent has         4       to be non-obvious over the prior art. You have a         5       genus, it treats schizophrenia with side         7       effects. That was known. You can't get a patent         8       for that. And you're suggesting to me, as         9       l understand it, that the Court of Appeal said well,         10       that's okay, it's inventive anyway. And it's just         11       not l just can't read the case that way.         12       MR. JOHNSTON:         14       THE PRESIDENT:         15       overnight you cannot discuss this case with anyone.         16       overnight you cannot discuss this case with anyone.         17       We'll see each other tomorrow at 9:00, and         18       we will continue the cross-examination.         19       (The hearing was adjourned at 6:03 p.m.)	<ul> <li>so I have to go back to the pretty so an invention must be inventive. It advantages. For us it's obvious, a wasn't obvious.</li> <li>THE PRESIDENT: You hav for today. You can take a coupler but finish this line of questioning a gind a natural moment, then we'll so MR. JOHNSTON: Thank yo If you could please turn If you could please turn Again, your blog excerpts. This is at the bottom, and here you're writt trial judge's findings in the olanzapt the very end of that last paragraph the findings and you write, "In other evidence was that flumezapine"</li></ul>	whole record and simple syllogism, must have the and they held it re two minutes left minutes longer, nd, when you top. u. up tab 16 again. R-476, page 57, ting about the bine case. At n you summarize er words, the so another st as promising as se you to , you write here, he FC decision, ne patent exactly riments to show advantage over the irned on	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	the EWCA to reject the IG Farbenindustrie rules as unsound. Nonetheless, in light of the four-year-old decision in Sanofi Supreme Court approving those rules, it is understandable that the FCA would not choose to revisit them here." This is what you wrote about the trial judge's findings of fact on your blog? <b>PROFESSOR SIEBRASSE:</b> Yes. So the trial judge you can read it that way, and that's the way the way you've just read it, and that's what I was saying in my blog, but the point is that so why does a selection why is this relevant to obviousness? We have a genus of all these prior compounds that are all known to treat schizophrenia but they have side effects. If you pull one out of that genus and you say, hey, look, it treats schizophrenia with all sorts of side effects, anybody's going to say well, duh, yeah, of course it does they all do. That's obvious. So what you're, as I understand it, trying to suggest to me is that the Court of Appeal held that you can pick one compound out of a genus and it has exactly the same properties as everything else	06:00
www.dianaburden.com	<ul> <li>why the obviousness requirement</li> <li>forgetting about selection patents,</li> <li>to be non-obvious over the prior al</li> <li>genus, it treats schizophrenia with</li> <li>you pull one out, it treats schizoph</li> <li>effects. That was known. You can</li> <li>for that. And you're suggesting to</li> <li>I understand it, that the Court of A</li> <li>that's okay, it's inventive anyway.</li> <li>not I just can't read the case tha</li> <li>MR. JOHNSTON: I think that</li> <li>for me to end my questions today.</li> <li>THE PRESIDENT: Professor</li> <li>are still under testimony, which me</li> <li>overnight you cannot discuss this</li> <li>We'll see each other tor</li> <li>we will continue the cross-examinat</li> <li>(The hearing was adjourned at</li> <li>22</li> <li>23</li> <li>24</li> <li>25</li> </ul>	bvious. That's 06:01 applies because, any patent has rt. You have a side effects, renia with side n't get a patent me, as ppeal said well, And it's just t way. at's a good place or Siebrasse, you eans that case with anyone. norrow at 9:00, and ation. : 6:03 p.m.)			

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<b>5</b>	62 [3] 505/19	495/10
<b>51 [1]</b> 340/21	520/19 632/13	<b>75 [2]</b> 493/25
<b>525 [3]</b> 586/12	64 [3] 431/4	495/10
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<b>526 [1]</b> 597/16	64 percent [1]	494/4 495/10
<b>53 [9]</b> 340/19	480/13	<b>78 [2]</b> 492/12
340/25 521/4	651 [1] 333/24	494/16
521/5 521/11	66 percent [1]	<b>79 [1]</b> 494/16
521/18 521/19	476/3	<b>8</b>
522/1 584/13	68 [1] 479/5	<b>80 [1]</b> 619/14
<b>54 [3]</b> 508/9	69 [2] 342/24	<b>83 percent [1]</b>
533/11 642/24	584/22	473/2
<b>57 [2]</b> 341/22	6:03 p.m [1]	<b>84 [1]</b> 585/14
649/12	651/19	<b>86 percent [1]</b>
<b>6</b> <b>6-10 [1]</b> 544/18 <b>60 [3]</b> 341/23 341/23 341/25 <b>61 [4]</b> 589/15 639/3 639/15 644/11 <b>613.233.1781</b> <b>[1]</b> 335/17	<b>7</b> <b>71 [1]</b> 492/2 <b>72 [9]</b> 492/21 492/23 493/14 494/4 495/10 509/1 561/12 562/4 649/20 <b>73 [3]</b> 493/20 495/10 585/4 <b>74 [2]</b> 493/23	480/11 <b>89 [1]</b> 409/6 <b>9</b> <b>91 [3]</b> 534/12 562/24 573/14 <b>92 [2]</b> 573/13 573/14 <b>93 [3]</b> 499/25 500/6 636/17

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