IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN OF THE NORTH AMERICAN FREE TRADE AGREEMENT AND THE UNCITRAL ARBITRATION RULES (1976)

Case No. UNCT/14/2

ELI LILLY AND COMPANY
Claimant

vs.

GOVERNMENT OF CANADA
Respondent

MINUTES OF ARBITRATION
Washington, D.C.

Thursday, 2 June 2016

(Pages 952-1222)

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2 June 2016

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(8:35 a.m. Thursday, 2 June 2016.) 08:35

DR. MICHAEL GILLEN, continued

THE PRESIDENT: Good morning, ladies and gentlemen. We resume the hearing on Day 4. As usual, are there any matters of an organizational or administrative matter that the parties would like to raise?

MS. CHEEK: Nothing from Claimant at this time.

MR. SPELLISCY: Nothing from the Respondent.

THE PRESIDENT: We saw that the parties were conferring about the schedule. Is that still in progress?

MS. CHEEK: It is still in progress, Mr. President.

THE PRESIDENT: Thank you. Mr. Dearden, please continue the cross-examination.

Good morning, Dr. Gillen.

DR. GILLEN: Good morning.

CROSS-EXAMINATION ON BEHALF OF THE CLAIMANT, continued

MR. DEARDEN: Good morning, Dr. Gillen.

DR. GILLEN: Good morning.

MR. DEARDEN: Can you turn to tab 3 of

the first volume, Exhibit C-414, please? It should be a final action for Bayer on February 1, 2011. 09:00

DR. GILLEN: Yes, I see that.

MR. DEARDEN: Could you turn to page 3, sir?

DR. GILLEN: Yes, I'm on page 3.

MR. DEARDEN: Under the heading Legal and Administrative Considerations, "The claims are now identified as non-compliant with section 2 of the Patent Act. The claims were previously considered defective for non-compliance with section 84 of the Patent Rules, on the basis that the lack of proper disclosure of a sound prediction implied a lack of proper support for the claims."

Just as an aside, that would be a section 27(3) Patent Act disclosure issue?

DR. GILLEN: What I see here is a reference to section 84 and section 2 of the Act.

MR. DEARDEN: But the disclosure requirement would be 27(3)?

DR. GILLEN: It might be. I mean 27(3) certainly is the section of the Patent Act that deals with disclosure. It's a question of whether or not disclosure of the sound prediction should be referred to under 27(3) or under section 2.

MR. DEARDEN: "Following current Office practice, this objection is now presented as non-compliance with section 2 of the Patent Act (lack of utility). Reference in this regard is made to 17.03.03 of MOPOP, which came into force in January 2009," and Chapter 17 is the Biotechnology and Medicinal Inventions chapter? 09:02

DR. GILLEN: Yes, that's correct.

MR. DEARDEN: Just to finish that A) section on page 3, "It should be noted that no substantive change has been made to the basis of the argument."

Is it fair to say that, when MOPOP is amended, examiners have to follow those amendments as this examiner is doing?

DR. GILLEN: Yes. MOPOP is a guide. As I said yesterday, it's not an authority, but examiners would follow the guidance in MOPOP, yes.

MR. DEARDEN: And if you could turn to tab 4, sir, which is Exhibit C-415, this was an appeal of that examiner's decision that we saw at tab 3.

DR. GILLEN: Yes.

MR. DEARDEN: If you go to paragraph 8, "The case was forwarded to the Patent Appeal Board on

November 21, 2011 with a Summary of Reasons outlining the outstanding defects. In the Summary of Reasons the examiner stated that claims 1-11 lacked utility but no longer put forward a separate issue with respect to sufficiency. Our review is therefore limited to issues relating to utility only."

And if you fast-forward to page 15, paragraph 48 of tab 4, Exhibit 415, the recommendation of the Board is to uphold the rejection of the application. Correct?

DR. GILLEN: That's correct.

MR. DEARDEN: Sir, prior to the AZT decision in 2002, you agree that there were no final actions that rejected an application for lack of utility under section 2 for failure to disclose a factual basis and line of reasoning for the prediction in the patent?

DR. GILLEN: I'm not aware of any.

MR. DEARDEN: And, prior to 2002 AZT decision of the Supreme Court, are you aware of any Patent Appeal Board decisions that dealt with the issue of whether a rejected patent application failed to disclose the factual basis and line of reasoning in the patent?

DR. GILLEN: Certainly those terms

wouldn't have been used prior to 2002, no.

MR. DEARDEN: What about a PAB decision where the issue was before it where there was a requirement from an examiner under appeal before the PAB (Patent Appeal Board) that there had to be a factual basis and a line of reasoning in the patent?

DR. GILLEN: There was a decision in the late '90s -- I forget exactly what year, it might have been 1995-- where there was an issue of the applicant was trying to claim, I believe, monoclonal antibodies for which there was no support, and the Board ruled in that case that there was nothing upon which to base the sound prediction.

MR. DEARDEN: You're talking about decision 1206?

DR. GILLEN: That's correct.

MR. DEARDEN: I have some questions for you on that later. So there is no Patent Appeal Board decision prior to 2002 that dealt with the issue of whether a rejected patent application failed to disclose the factual basis and line of reasoning in the patent?

DR. GILLEN: Not that I'm aware of.

MR. DEARDEN: And obviously if there was no Patent Appeal Board decisions on that issue, there

wouldn't be any Commissioner decisions either?

DR. GILLEN: That's correct.

MR. DEARDEN: Your First Report, Dr. Gillen, paragraph 47, the first sentence of paragraph 47 of your First Report says, "When the MOPOP chapter on Description was updated in 2010 to reflect recent jurisprudence on disclosure of the basis for sound prediction, that update was consistent with longstanding Patent Office practice."

You'll find MOPOP 2010, which is Exhibit C-60, at tab 22 of your second volume, your white binder.

DR. GILLEN: Yes, I have it.

MR. DEARDEN: If you'd turn to 9.04, which should have a heading "Establishing utility"?

DR. GILLEN: Yes.

MR. DEARDEN: It has subheadings Sound Prediction, Disclosure of the Factual Basis, Disclosure of the Sound Line of Reasoning, which is 9.04.01b.

DR. GILLEN: Yes.

MR. DEARDEN: Without making you do this from memory, when you're talking about recent jurisprudence that MOPOP updated, would that be what's footnoted, sir, in --

DR. GILLEN: Paragraph 47.

MR. DEARDEN: I would say it would go from footnotes 38 to 47 because footnote 38 is the first footnote that I see under 9.04. The top of the page is stamped 00043.

DR. GILLEN: 43, yes.

MR. DEARDEN: You see 9.04, Establishing utility?

DR. GILLEN: Yes.

MR. DEARDEN: First paragraph has footnote 38, and the last footnote that I see was 47.

DR. GILLEN: Yes.

MR. DEARDEN: Your eyes see that as well?

DR. GILLEN: 47 -- in section 9.04.01b?

MR. DEARDEN: Correct.

DR. GILLEN: I see 47, yes.

MR. DEARDEN: Right. So we go to the footnotes at the back of tab 22, and I'm just getting you to confirm that when you're talking about recent jurisprudence that was used to update the MOPOP 2010, I'm going to find that jurisprudence in footnotes 38-47?

DR. GILLEN: Yes.

MR. DEARDEN: In 9.04.01a, which is the factual basis, footnote 44, "Any necessary facts that

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are not otherwise publicly available must be included in the description." So it must be in the patent, correct?
DR. GILLEN: Yes.
MR. DEARDEN: And footnote 44, those are the Raloxifene decisions?
DR. GILLEN: Yes. Eli Lilly v Apotex.
MR. DEARDEN: You can put that volume away and find volume 1 again, sir, if you could, please. Tab 2.
DR. GILLEN: Yes, I have it.
MR. DEARDEN: This is Canadian Intellectual Property Office client service standards extracts?
DR. GILLEN: Yes.
MR. DEARDEN: Can you turn to the one that is for 2009/2010, which is the second to last page of tab 2, Exhibit R-380.
DR. GILLEN: Appendix C?
MR. DEARDEN: Yes. It's entitled Appendix C, but there should be something handwritten in the right-hand corner.
DR. GILLEN: 2009/2010?
MR. DEARDEN: Right. So under the Patent Appeal Board -- you see that in the bottom?

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DR. GILLEN: Yes.
MR. DEARDEN: Tell me if I'm reading this right. Decision issued. The hope is that by March 31, 2010, 80 percent of applications that were referred to the Board before 2008 would be dealt with. Is that the standard that's being sought there, or the commitment?
DR. GILLEN: Under Patent Appeal Board patents and industrial designs?
MR. DEARDEN: Yes, then right underneath that.
DR. GILLEN: Oh, the decision issued?
MR. DEARDEN: Yes. Decision issued, and then the commitment, as I read it, is that the Board's going to have 80 percent of applications that were referred to it before 2008 completed.
DR. GILLEN: Yes, that was the commitment.
MR. DEARDEN: Right. But they flunked.
DR. GILLEN: Yes, they did.
MR. DEARDEN: 34 percent.
DR. GILLEN: 34 percent.
MR. DEARDEN: But what I'm interested in is the explanation which is "Changes in practice and jurisprudence have imposed additional steps and time

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required; further delays were encountered as high priority applications referred to the PAB after 2008 were reviewed."
So the changes in jurisprudence that is part of this explanation for not meeting the commitment would include decisions such as Raloxifene that came out dealing with the factual basis and line of reasoning being in the patent, amongst other decisions?
DR. GILLEN: Most of the work that went on in the 2000s with respect to Office practice had to do with patentable subject matter, not so much the utility issue. The Office struggled, especially the electrical division, with applications dealing with computer inventions and business methods, and throughout the 2000s the Office was looking at different ways in which those applications could be assessed to determine whether there was patentable subject matter or not. So the Office had what was called form and substance or contribution as one way in which this could be done. Inventive concept was another. In the Office today we use purposive construction. So a lot of the issues around patentable subject matter in the 2000s within patent branch and also at the PAB, the work was delayed as

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the Office struggled with how to deal with these kinds of applications and what kind of scheme should be used by examiners to determine if there was, indeed, patentable subject matter. This was outside of the issue of whether that subject matter would be new, useful or inventive. It was just was it patentable subject matter or not.
MR. DEARDEN: I understand, but you also said in your answer that most work was patentable subject matter, not so much utility. There were utility issues in play that were change in practices and jurisprudence issues, correct?
DR. GILLEN: Well, there are utility issues in play, yes. Whenever you're talking about patentable subject matter, a lot of matter which is not patentable subject matter is so because it doesn't have real world utility, so utility and patentable subject matter are linked together in that sense, and that's why, for example, Chapter 12 in the MOPOP is entitled "Statutory Subject Matter and Utility," because those two are linked together, yes.
MR. DEARDEN: I understand. But one of the changes in jurisprudence, amongst all of the other things you mentioned, was decisions such as the Raloxifene decisions that came out in 2008 and 2009,

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correct?
DR. GILLEN: It would have been a decision that would be considered by the Office, but relative to statutory subject matter it was more of a minor issue.
MR. DEARDEN: But it was an issue?
DR. GILLEN: It was an issue, sure. The Office would consider all jurisprudence coming out and the effect it might have on Office practice.
MR. DEARDEN: And here, in Exhibit C-355, your tab 2 there, Utility, albeit not No. 1 issue, was a change in practice in jurisprudence that imposed additional steps and time required, correct?
DR. GILLEN: I wouldn't say that there was a change in Office practice with respect to utility. As I said, the change in practice was how to deal with patentable subject matter. The notion of utility, certainly the AZT case gave the Office the three-part test we talked about yesterday and what I referred to as terminology to deal with a lack of sound prediction. But I think the underlying issues of utility, you know, didn't change from the '90s into the 2000s.
MR. DEARDEN: Sir, can you find tab 28, which is probably in your last binder. It is.

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Volume 4. So you should have at tab 28 a MOPOP update priority list?
DR. GILLEN: Yes.
MR. DEARDEN: And if we go down to Chapter 17 -- so you see the column in the left side?
DR. GILLEN: Yes.
MR. DEARDEN: So we've got Chapter 17 and Chapter 12 near the bottom. So for biotechnology -- and at this point you're leading that division, right?
DR. GILLEN: Yes.
MR. DEARDEN: 2005?
DR. GILLEN: No, not in 2005. I was there in 2006-2014.
MR. DEARDEN: I said 2005 because if you look at the top right-hand corner you see "Status 12-09-05"?
DR. GILLEN: Yes.
MR. DEARDEN: Biotechnology, the third bullet: "Sound prediction (interpretation and guidelines resulting from recent decisions)." So on the MOPOP update priority list was to update it for recent decisions regarding sound prediction, interpretation and guidelines?
DR. GILLEN: Yes, I see that.

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MR. DEARDEN: Do you know what the recent decisions are?
DR. GILLEN: I'm not sure what the recent decisions are that are referred to here. I would assume the AZT was one of them, although it's not so recent relative to -- well, this is a 2005 table, so I would assume that the AZT decision was one of those decisions.
MR. DEARDEN: Going to your second statement, paragraph 22, I'm looking at your last sentence in paragraph 22, Dr. Gillen, "In my experience there are two factors that drove updates to the MOPOP. 1, administrative changes (for example, amendments to the Patent Rules, including instructions on how to file a patent application); And, 2, a number of Federal Court cases that impacted Office practice."
So, sir, what number of Federal Court cases that impacted Office practice are you referring to?
DR. GILLEN: I'm not referring to any specific cases here, but just in general MOPOP would be updated if there was a change in practice of coming out of the Federal Court, or a number of decisions that impacted practice, or decisions that

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might have given the Office guidance in how to pursue certain objections under the Act and Rules.
MR. DEARDEN: So if a Federal Court case or a Supreme Court of Canada case changed the law, that would impact Patent Office practice, right?
DR. GILLEN: That's correct.
MR. DEARDEN: And Federal Court or Supreme Court cases that changed the law will drive an update of the MOPOP, correct?
DR. GILLEN: They would drive an update of the MOPOP, correct.
MR. DEARDEN: Can we go to tab 5, Exhibit C-412, Commissioner Decision 1303 in June 4, 2010.
DR. GILLEN: Yes, I see that.
MR. DEARDEN: Paragraph 8 under the heading "Prosecution" at the bottom of the page.
DR. GILLEN: Yes, I see that.
MR. DEARDEN: So that application was filed on March 2, 1989 under the provisions of the Patent Act that read immediately before October 1, 1989, so an old Act patent. There were a total of five Office actions issued during the prosecution, the first being in 1992 and culminating in final action dated June 19, 2006, right?
DR. GILLEN: Yes.

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MR. DEARDEN: Paragraph 9. "In the Office Action February 22, 2005, an objection under subsection 34(2) of the Patent Act was first raised, it being subsequently reasserted and then appearing in the Final Action. The objection under section 2 of the Patent Act was initially raised in an Office Action dated September 26, 2005, (the 'pre-Final Action'), and was reapplied in the Final Action."

So, sir, 13 years after the first Office action, the examiner takes the position that utility cannot be soundly predicted, correct?

DR. GILLEN: That's correct.

MR. DEARDEN: Paragraph 33 of Commissioner Decision 1303, Exhibit C-412 --

DR. GILLEN: The same exhibit?

MR. DEARDEN: Same exhibit, paragraph 33 -- so flip a few pages -- should be under the heading "There must be proper disclosure."

DR. GILLEN: I see that.

MR. DEARDEN: So "The concept that untested embodiments may be patentable existed in earlier case law (see Monsanto and Olin Mathieson) but there was no articulated test for assessing the soundness of a prediction until Wellcome."

DR. GILLEN: I see that.

MR. DEARDEN: Which is AZT. You agree with that statement, don't you?

DR. GILLEN: I agree that there was no articulated test, but I don't agree that examiners didn't look for the same kinds of information as AZT asked for prior to AZT.

MR. DEARDEN: I didn't see that in paragraph 33, what you just added there. For clarity, you do agree there was no articulated test for assessing the soundness of a prediction until Wellcome AZT?

DR. GILLEN: Yes, there was no articulated test.

MR. DEARDEN: Tab 6, exhibit R-381, is the Commissioner decision 1206 that you referenced earlier.

DR. GILLEN: Yes.

MR. DEARDEN: You do mention that in your first -- or your second report, Dr. Gillen, at paragraph 14 and 15, so if you could get your Second Report, please.

DR. GILLEN: Yes, I have that.

MR. DEARDEN: Let me read the whole paragraph. "Mr. Wilson states that, before 2002, there 'was no basis in the Patent Act,

Patent Rules or jurisprudence that would permit an examiner to reject an application for failing to disclose evidence of utility in the application at the time of filing.' I disagree. In my experience, since the Supreme Court decided the Monsanto case in 1979, patent examiners have applied the same principle of disclosure in sound prediction cases as they have more recently. While the terms 'factual basis' and 'sound line of reasoning' were not introduced until the Supreme Court of Canada's 2002 decision in AZT, applicants and examiners alike had been including and looking for the same type of information in the application."

Paragraph 15, "For example, the disclosure relating to a sound prediction was at issue in Commissioner's decision No. 1206," and that's what you have before you at tab 6 of your binder, correct?

DR. GILLEN: Yes.

MR. DEARDEN: And at paragraph 16 of your Second Report, Dr. Gillen, you say, "While the Commissioner refused to grant a patent containing those claims on the basis of now 27(3) of the Patent Act (which covers disclosure rather than utility), it is clear that the examiner, the

Patent Appeal Board, and the Commissioner all found the patent invalid because of the failure to disclose in the patent a factual basis for the sound prediction as well as a sound line of reasoning."

DR. GILLEN: Yes.

MR. DEARDEN: Can we look at that decision now? Let's go to the front page. At the top there is topic codes. B20, B22 and C00.

DR. GILLEN: Yes, I see those.

MR. DEARDEN: And that is to indicate what the subject matter of the decision is dealing with?

DR. GILLEN: Yes, that's correct.

MR. DEARDEN: And what is the subject matter code for utility?

DR. GILLEN: I don't know what the code for utility is.

MR. DEARDEN: G00.

DR. GILLEN: G00, okay.

MR. DEARDEN: You're not going to agree with me there?

DR. GILLEN: I will agree with you.

MR. DEARDEN: Okay. And B20 was claims -- excessive width?

DR. GILLEN: Yes.

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09:28 MR. DEARDEN: B22, claims -- excessive width -- not supported by disclosure, correct?
DR. GILLEN: Yes.
MR. DEARDEN: And C00 would be adequacy or deficiency of description?
DR. GILLEN: Yes.
MR. DEARDEN: Then after the topic codes, you see at the top of the decision -- what is that? A summary of what the decision is when I see "Claims rejected as being broader than disclosure"?
DR. GILLEN: Yes, it would be a summary --
MR. DEARDEN: Or an abstract?
DR. GILLEN: Akin to an abstract.
MR. DEARDEN: Okay. So can you turn to page 3 of the decision? That's the questions before the Board.
DR. GILLEN: Yes, I see it.
MR. DEARDEN: Right after that print that you can't read because it's so small, "The questions before the Board are whether or not the specification describes correctly and fully the preparation and the properties of the hybridoma and the monoclonal antibodies claimed in claims 84 and 85, and whether or not such description is set out in such clear

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09:30 concise terms as to enable a person skilled in the art to make and use the invention as required by 34(1) of the Patent Act".
So those are the issues, right?
DR. GILLEN: Yes.
MR. DEARDEN: And, sir, there is discussion about Monsanto in this case, and it starts at page 8, if you could flip to that. In the middle of the page before the quote that you see, "In a further argument, the Applicant urged the board to follow, by analogy, the practice followed in the chemical arts." And then Monsanto is cited in that small print quote there, and then at the bottom of that page -- and this is the Board reproducing submissions from the applicant, and the this submission is at pages 23 and 25 that they've reproduced here in page 8 of their decision, the page 25 submission was, "According to the Supreme Court in the Monsanto decision referred to above, a 'sound prediction' is based on the capacity of the person skilled in the art to foresee the properties of a claimed product. Applicant has demonstrated that techniques to produce monoclonal antibodies have become tools generally available to a person skilled in the art of hybridoma technology, in the same way

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09:31 the preparation of specific chemical compounds from a generic formula based on known processes is available to the person skilled in the art of chemical synthesis."
Then the Board talks about the Monsanto case at the bottom of page 8 and over on page 9. Look at the bottom of page 9. The Board finds that "In the present case, the Applicant does not show by examples or broad statements the steps that were successfully used to produce hybridomas secreting monoclonal antibodies which are capable of binding only with the specific antigen. Had any hybridoma and monoclonal antibody for certain antigens been prepared, then it would have been arguable that other hybridomas and monoclonal antibodies, which were claimed but unprepared or prepared but untested, could be allowable in view of the 'sound prediction' principle. In this case there's no consideration given by the disclosure to any monoclonal antibody so that there is nothing upon which to base a sound prediction. The Board finds that there is a lack of guidance in describing the core method to be used and the permissible modifications of that basic method for the specific antigens disclosed. Such deficiencies in guidance cannot be remedied by

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09:33 referring the person skilled in the art to experiment with the 'traditional techniques'. In summary, the Board also finds that the description does not include any clear references or description to enable the person skilled in the art to make and use the invention without considerable and protracted experimentation."
So, sir, the Board's findings, you'll agree, are not a sound prediction finding?
DR. GILLEN: Well, the Board's finding here was there was lack of disclosure for methods as well as the products produced by those methods, hybridomas and monoclonal antibodies.
MR. DEARDEN: But you'll agree with me the Board never made a finding about utility in this invention, because they were finding there was no invention, right?
DR. GILLEN: They found that, yes, that there was no description of monoclonal antibodies or methods for preparing those, so therefore there was nothing upon which to base a prediction of utility because those products had not actually been prepared.
MR. DEARDEN: So what the applicant was trying to do by using sound prediction in the

chemical arts principles, but using them by analogy, was he was trying to convince the Board that you could predict the invention by using the Monsanto analogy, right?

DR. GILLEN: I think that's what he was trying to do. That was a more common occurrence with biotechnology inventions, which is what this is, where applicants would often claim very broadly, where utility was not an issue because the compounds were claimed almost in terms of their utility, something like growth hormone, for example, and they would try to use the sound prediction principle to predict that they could do something or invent something that they hadn't done. So there was a tendency in the biotechnology arts to take the principle of sound prediction for utility as it was understood in Monsanto and apply that to predicting inventions in other arts.

MR. DEARDEN: And, sir, you'll agree with me that your statement in paragraph 16 is incorrect by saying that the examiner, the Patent Appeal Board and the Commissioner all found the patent invalid because of failure to disclose in the patent the factual basis for the sound prediction and sound line of reasoning?

DR. GILLEN: What I meant by that was the factual basis being the monoclonal antibodies themselves and processes for producing those.

MR. DEARDEN: But, sir, there's nothing in this decision at tab 6 where this Board makes a finding of invalidity because of failure to include a factual basis and the sound line of reasoning. Is that fair?

DR. GILLEN: I think what the Board was saying in this decision was there was no basis for predicting utility of products that hadn't been produced. The factual basis that I'm referring to was the monoclonal antibodies themselves and the support for those which was not found in the application.

MR. DEARDEN: I'm going to go at it again. You can't show me anywhere in this tab, R-381, this decision 1206, where that specific finding is made that you have in paragraph 16 of your statement?

DR. GILLEN: I can't find that exact finding, no, but that's my interpretation of that decision.

MR. DEARDEN: Fair enough.

MOPOP. Paragraph 6 of your first

statement. You set out in paragraph 6, sir, as chief at the Biotechnology division, certain duties which included -- and I'm looking more towards the bottom of paragraph 6 -- ensuring that examiners were following Patent Office practice. You see that?

DR. GILLEN: Yes, I do.

MR. DEARDEN: And that would include the Manual Of Patent Office Practice, the MOPOP?

DR. GILLEN: It would include MOPOP, office practice memos, and any other information from training sessions that examiners might have been subject to.

MR. DEARDEN: Turn to tab 15 of the binder, Exhibit C-449. It should be an extract from the CIPO website about MOPOP.

DR. GILLEN: Yes, from 2015. I see that.

MR. DEARDEN: So I want to know if you agree with the statements that I see in Exhibit C-449. "MOPOP is a guide for examiners, applicants, agents and the public in the operational procedures and examination practices of the Canadian Patent Office." Do you agree with that?

DR. GILLEN: Yes.

MR. DEARDEN: "Practices expressed in the MOPOP arise from the Office's interpretation of the

Patent Act, Patent Rules and jurisprudence as of the date each chapter came into effect."

DR. GILLEN: Yes.

MR. DEARDEN: "This manual is solely a guide and should not be considered to be a binding legal authority, in the event of any inconsistency between this guide and the applicable legislation, this legislation must be followed."

DR. GILLEN: That's correct.

MR. DEARDEN: "This manual is updated periodically to reflect changes to the statutory, regulatory and jurisprudential framework governing patents in Canada."

DR. GILLEN: Yes.

MR. DEARDEN: You agree with that?

DR. GILLEN: Yes.

MR. DEARDEN: And examiners will refer to MOPOP in Office actions and final actions, correct?

DR. GILLEN: They can, yes.

MR. DEARDEN: As we saw with Chris Evans doing that in the Bayer final action we looked at earlier in C-414, right?

DR. GILLEN: That's correct.

MR. DEARDEN: And the Patent Appeal Board will cite MOPOP in its decision?

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DR. GILLEN: It can, yes.
MR. DEARDEN: And the courts have cited MOPOP in their decisions?
DR. GILLEN: Yes.
MR. DEARDEN: And I have a couple of examples. Turn to tab 10, Exhibit R-151, paragraph 49, it should be on page 37 of that decision.
"While neither the Manual Of Patent Office Practice nor the paper and article just referred to are binding on me, I find them persuasive and, in the absence of persuasive evidence that would favor a different interpretation, I adopt the interpretation of 'issue' in the context of subsection 28(2) set out therein and urged on behalf of Bayer."
If you turn the page there's more glowing praise of MOPOP. I'm looking at paragraph 51, Dr. Gillen?
DR. GILLEN: Yes, I see.
MR. DEARDEN: "Much the same can be said here. The Act falls to be interpreted, used and applied by a broad range of individuals. As with the CEAA, the Canadian Environmental Assessment Act, it makes eminent sense that a document such as MOPOP was published to achieve a degree of uniformity in the

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interpretation of the Patent Act and the pronouncements of the Manual should therefore be treated with a reasonable degree of deference as an interpretive tool, to the extent that they are not inconsistent with the law."
So do you agree with the statement made in paragraph 51?
DR. GILLEN: Yes, I would.
MR. DEARDEN: Tab 11 should be R-150.
DR. GILLEN: The tab that begins with "Westlaw" at the top of the page?
MR. DEARDEN: Right. This is a Belzberg decision of Justice Shore, if you turn to paragraph 10.
DR. GILLEN: Yes, I see it.
MR. DEARDEN: And Justice Shore holds that "The MOPOP is a guideline prepared by the Patent Office outlining best practices for the Patent Office. Although it does not have the force of law, I regard the guideline as a useful interpretive tool."
DR. GILLEN: I see that.
MR. DEARDEN: Do you agree with it?
DR. GILLEN: I would.
MR. DEARDEN: And tab 12, Exhibit C-404,

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"How to become a registered patent agent ", and one of the references that you see on the other side of that page of tab 12 is the MOPOP.
DR. GILLEN: Yes, that is one of the things -- one of the manuals that somebody who wanted to become a patent agent would look to.
MR. DEARDEN: They'd have to study it to pass the exam, right, amongst other material?
DR. GILLEN: Among other material. I think certainly they would study the Act and Rules as well as MOPOP.
MR. DEARDEN: Paragraph 52 of your First Report, Dr. Gillen, if you could turn that up, please?
DR. GILLEN: I have it, yes.
MR. DEARDEN: I'm looking at about the middle of your paragraph where you say: "In this context, comments made by Mr. Wilson to the effect that utility was not an issue during the examination of the Canadian patent applications for olanzapine and atomoxetine are misleading. They ignore the nature of the examiner's review and the assumptions the examiner would have made based on the actual language of the olanzapine and atomoxetine applications."

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DR. GILLEN: I see that, yes.
MR. DEARDEN: First of all, you'll agree that there is nothing that we can find in the file wrappers for olanzapine -- which is tab 28 but you don't have to turn to it, it's Exhibit C-062, and the file wrapper for atomoxetine which is tab 7, C-068 -- there's nothing in there that demonstrates to us, shows us, that the examiner made any assumption in favor of Lilly in those two applications?
DR. GILLEN: There's nothing. I believe there's one report in one file and no reports in the other. And there's nothing in the file that would indicate that the examiner had an issue with utility, that is correct.
MR. DEARDEN: Sir, you didn't have any involvement with the prosecution of the olanzapine patent application?
DR. GILLEN: No, I did not.
MR. DEARDEN: And you had no involvement with the prosecution of the atomoxetine patent application?
DR. GILLEN: No, I did not.
MR. DEARDEN: And you had no direct involvement of the granting of the atomoxetine '735 patent?

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DR. GILLEN: No, I did not.
MR. DEARDEN: And you had no direct involvement in the granting of the olanzapine '113 patent?
DR. GILLEN: No, I did not.
MR. DEARDEN: In paragraph 26 of your first report, I'm looking at the last sentence of paragraph 26, sir, you say, "For reasons explained above and for the additional reasons I will give below, these changes to the MOPOP were not only unsurprising, but they were also consistent with longstanding Patent Office practice."
What year did that longstanding Office practice begin?
DR. GILLEN: I'm referring to my time as an examiner and how I was trained to examine, so from the late '80s in through the '90s and so forth. As I said before, examiners, when they were faced with a situation where the utility was based on a sound prediction, the examiner would look to the application to assess whether or not the prediction was, indeed, sound or not, so that's the longstanding practice that I'm referring to, the way that I was trained as an examiner, the way I trained examiners to work, and the way I understood practice to be in

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the Office at that time.
So, for example, if an application contained a statement that said, well, I predict that this compound will cure cancer or something like this, the examiner would look to the application to determine what results and what experiments were done that could support that statement, and what sort of logic did the applicant have that took the applicant from what had been done to their sound prediction -- or to the prediction.
MR. DEARDEN: Is it fair to say that the changes that were made to the 2009 and 2010 MOPOPs will not be found in the 1990 MOPOP?
DR. GILLEN: No, they would not be found in the 1990 MOPOP. I think the chapter on utility in the 1990 MOPOP would have been very bare bones. Maybe only a few pages.
MR. DEARDEN: Right. Likewise for the 1996 MOPOP?
DR. GILLEN: Yes, that's correct.
MR. DEARDEN: And the 1998 MOPOP?
DR. GILLEN: That's correct.
MR. DEARDEN: So paragraph 32 says, "When the MOPOP chapter on utility was updated in 2009 to reflect recent jurisprudence, that update was

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consistent with longstanding Patent Office practice."
Now, is the recent jurisprudence that you're referring to for the 2009 MOPOP update cases that were decided after the AZT decision in 2002?
DR. GILLEN: My understanding is that those updates to MOPOP in 2009/2010 are more reflective of the AZT decision. I don't think there are other decisions on utility that have gone into MOPOP. There may be. I wasn't drafting the chapters at the time, so my understanding was that those changes were based on the AZT decision.
MR. DEARDEN: Well, sir, the footnotes we looked at earlier dealt with, for instance, the Raloxifene decisions in 2008 and 2009.
DR. GILLEN: Yes. I agree.
MR. DEARDEN: So there are other decisions?
DR. GILLEN: There are other decisions, yes.
MR. DEARDEN: All I was interested in is that the recent jurisprudence you're referring to is a point after the AZT decision -- or including AZT and after.
DR. GILLEN: Yes. The manual that was prepared in 2009 or 2010 would certainly refer to any

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decisions that were relevant prior to those dates.
MR. DEARDEN: In the 1990 MOPOP, it didn't instruct examiners to reject applications that did not include the factual basis and line of reasoning for the prediction in the patent?
DR. GILLEN: No, I think in the 1990 MOPOP, as I recall, the only reference to utility was that an invention had to be useful.
MR. DEARDEN: Not totally useless actually?
DR. GILLEN: Not totally useless.
MR. DEARDEN: Some industrial value.
DR. GILLEN: Some industrial value.
MR. DEARDEN: And the same for the 1996 MOPOP. It did not instruct examiners to reject applications that did not include the factual basis and line of reasoning for the prediction in the patent?
DR. GILLEN: No, those terms were not used in the '96 MOPOP or in the '98 MOPOP. I think the section on utility in those versions of MOPOP simply referred to the invention being useful and for its desired purpose, I believe is what's used in the MOPOP.
MR. DEARDEN: Both of your answers that

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you've given me to the 1990 and 1996 MOPOP have start off with "No," and I want the transcript when you read it five years from now to be in no confusion. You're agreeing with me?

DR. GILLEN: I'm agreeing that the terms "factual basis" and "sound line" did not appear in those versions of the MOPOP, yes.

MR. DEARDEN: And likewise for the '98 MOPOP?

DR. GILLEN: And likewise for the '98 MOPOP.

MR. DEARDEN: And it's only after the Raloxifene decisions in 2008 and 2009 that examiners get instructed by the 2009 MOPOP to require the factual basis and line of reasoning for the prediction to be in the patent?

DR. GILLEN: I think that's correct. That's how the MOPOP laid out the guidance for examiners but, prior to that decision, examiners were looking for the factual basis and the sound line in applications. Certainly after the AZT decision came out, there was a question as to whether the third part of that test, the disclosure requirement, was in the application or not or whether it could be provided at some later date.

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MR. DEARDEN: Why was there a discussion about the third component of AZT, which is proper disclosure?

DR. GILLEN: It wasn't a discussion within the Office. The Office considered that disclosure requirement that the factual basis and the sound line had to be disclosed in the application at the time of filing. But members of the patent profession, for example, argued that that was not the case and they disagreed with the Office's interpretation of the AZT decision.

MR. DEARDEN: And did that happen around the time AZT was issued?

DR. GILLEN: Well, it happened soon after that, yes.

MR. DEARDEN: So the patent bar is saying the third component of AZT, which is proper disclosure, no footnote citation given by Justice Binnie as to any authority for that, they took the position with the Office that that did not mean the factual basis and line of reasoning had to be in the patent?

DR. GILLEN: Well, some members of the profession did. Others felt it had to be in the application at the time of filing, that an invention

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had to be complete, but there were other members of the profession that took the position that the disclosure could be made through other means or at a later time, possibly in response to an Office action from an examiner.

MR. DEARDEN: Okay. I just want to move back to when I was talking to you about the 1990, '96 and '98 MOPOPs. Nowhere written in those editions of MOPOP will I find an instruction to examiners to reject applications that didn't include the factual basis and line of reasoning for the prediction in the patent.

DR. GILLEN: You won't find those instructions in the MOPOP, no.

MR. DEARDEN: In those '90, '96 and '98 MOPOPs. I won't find it in those MOPOPs, correct?

DR. GILLEN: That's correct.

MR. DEARDEN: So, Dr. Gillen and Mr. President, I'd ask that yesterday's transcript of Dr. Gillen's testimony be provided to him. We have copies. (Distributed)

Could you turn to page 921 of the transcript, sir, line 17? See that paragraph?

DR. GILLEN: Yes.

MR. DEARDEN: It should be where you

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testified that "The examination is for compliance with the Patent Act and the Patent Rules, so inventions must be new, they must be non-obvious, they must be useful, there must be patentable subject matter and so forth."

DR. GILLEN: Yes.

MR. DEARDEN: So those requirements, sir, of new, non-obvious and useful, those are separate and distinct requirements for obtaining a patent?

DR. GILLEN: Yes, they are.

MR. DEARDEN: On page 927 of the transcript you say at line 13 under the heading "Post-filing evidence" that, "Post-filing evidence of demonstrated utility that predates the filing date of an application can be submitted to the Patent Office to convince an examiner of the credibility of the demonstrated utility. This is a rare thing." You see that?

DR. GILLEN: That's correct.

MR. DEARDEN: So that legal requirement regarding post-filing evidence comes from the 2002 AZT decision and not the Monsanto decision in 1979?

DR. GILLEN: Well, I'm referring here to demonstrated utility, not to sound prediction, so this would be for patent applications going back some

years, back to Day 1, for example. So with respect to demonstrated utility, you will look to the application and you will see positive statements that something has actually been made and tested and found to do what it's supposed to do, what the applicant says it will do.

Sometimes there are statements that maybe, based on the examiner's knowledge of the subject matter, seem a little -- it may be surprising, shall we say, and so in some cases, and this is a rare thing, the examiner may say gee, that's remarkable that that compound did that, as you say in your application, you know. Could I look at some of the studies that you did just to convince myself that something as incredible as what I've read is actually, in fact, fact.

MR. DEARDEN: What I'm getting at, sir, is you made the statement that "post-filing evidence of demonstrated utility that predates the filing date," so it's the "before the filing date" that I'm focused on here, and AZT did decide that utility had to be soundly predicted or demonstrated as of the date of filing.

DR. GILLEN: Well, certainly that's what AZT said but certainly as an examiner it was my

understanding that inventions had to be complete at the time that they were filed, so that you wouldn't file a patent application for a compound whose utility you didn't either have demonstrated or soundly predicted. So I don't think -- certainly it was my understanding and the practice that I was taught that you wouldn't accept -- that you expected that the utility of an invention would be disclosed in the application at the time of filing, and not at some later date.

MR. DEARDEN: But I'm not going to find that in any of the 1990s MOPOPs, am I?

DR. GILLEN: You're not going to find that statement in any of the MOPOPs, no.

MR. DEARDEN: Page 926. Do you have your slide presentation with you?

DR. GILLEN: Yes, I do.

MR. DEARDEN: I think that what's on page 926 matches slide 9.

DR. GILLEN: I have slide 9 here.

MR. DEARDEN: Looking at slide 9, the second bullet, you have "The utility of inventions that have not been fully tested at the time of filing can be based on sound prediction. Monsanto 1979. For a prediction to be sound a patent specification

must disclose a factual basis and a sound line of reasoning. Apotex, 2002."

That's the AZT decision, right?

DR. GILLEN: That's correct.

MR. DEARDEN: And you're saying that that legal requirement that you're referring to in that bullet -- or that requirement in that bullet comes from AZT, not Monsanto. Right?

DR. GILLEN: Well, I think what I'm saying there is that the principle of sound prediction comes from Monsanto. The terms "factual basis" and "sound line" come from the Apotex decision.

MR. DEARDEN: Okay. And on page 928 of your transcript, line 9, you say, "Evidence to support the soundness of the predicted utility must be disclosed in the application at the time of filing."

Now, sir, that requirement is not going to be found in Monsanto, correct?

DR. GILLEN: That will not be found in Monsanto, no.

MR. DEARDEN: Speaking of Monsanto, we'll give you a copy of the decision, which is C-61. In a nutshell, Dr. Gillen, in Monsanto the Commissioner of

Patents refused to grant a patent in respect of claims for inhibiting premature vulcanization of rubber, and the reason the examiner rejected those claims was because they were too broad because only 3 out of 126 of the chemical compounds claimed had been prepared.

DR. GILLEN: That's correct.

MR. DEARDEN: Then the Patent Appeal Board affirmed the rejection of the application on that basis?

DR. GILLEN: That's correct.

MR. DEARDEN: And the Federal Court of Appeal upheld the refusal on the ground that the disclosure in the application was not sufficient to support the claim to such a broad range of new compounds?

DR. GILLEN: That's correct.

MR. DEARDEN: The Supreme Court of Canada decision that you have your hands on now, C-61, reversed that finding, correct?

DR. GILLEN: That's correct.

MR. DEARDEN: Let's go to page 1113. Unfortunately this is one that doesn't have paragraph numbers, but the first full paragraph on that page?

DR. GILLEN: Yes.

MR. DEARDEN: "With respect, I must say that it appears to me that the Court below has completely overlooked the rule that a patent specification is addressed to a person 'skilled in the art'. The Patent Appeal Board had before it elaborate affidavits from persons skilled in the art, one of whom described himself as a 'group leader assigned to special synthesis problems in the field of elastomers'. In this affidavit he explains in detail with reference to authoritative scientific publications that the knowledge and skill possessed by chemists competent in this particular field of endeavor would ensure that the directions contained in the specifications would be adequate to enable them to prepare all the described compounds although specific directions were given for three or less."

So, sir, at that time evidence outside the patent was allowed through those affidavits?

DR. GILLEN: Well, I'm not sure what was in these affidavits, but certainly you can have some evidence outside of what's in the patent application, what the Patent Office would call common general knowledge. So, for example, there are a number of -- if you're talking about organic chemistry, for example, there would be a number of processes that

would be well known to an organic chemist, so a patent application wouldn't have to describe how to make a salt from an acid and a base. You could simply make that statement "I made the salt using this acid and this base" without going into any detail as to what process you used unless, of course, the process itself was the basis of your invention.

So that's the kind of stuff that I believe the court is referring to here.

MR. DEARDEN: Well, they do give us a hint of what's in one of the affidavits because it says "In this affidavit he explains in detail with reference to authoritative scientific publications that the knowledge and skilled possessed by chemists competent in this particular field of endeavor would ensure that the directions contained in the specs would be adequate to enable them to prepare all the described compounds although specific directions were only given for three."

DR. GILLEN: Yes, that's correct. I think what the court is saying -- or what the affidavit there is saying is that one of skill in the art, a chemist working in this area, based on what was given in the application and that person's common general knowledge of the subject matter, would have

been able to practice the invention.

MR. DEARDEN: You'll agree that at the time testing could be submitted by affidavit?

DR. GILLEN: To the Patent Office?

MR. DEARDEN: Yes, to the examiner.

DR. GILLEN: Are you asking me to show demonstrated utility or sound prediction?

MR. DEARDEN: Say both.

DR. GILLEN: You could present something to the patent examiner by way of argument. For example, if the patent examiner was not convinced that the so-called demonstrated utility or soundly predicted utility that the applicant was relying upon in their application, if the examiner didn't feel that that demonstration or sound prediction was in the application the examiner could accept some communication from the applicant describing where in the application that information is found or how the application actually discloses the utility. But the examiner wouldn't take, in the case of sound prediction, would not accept results to show that the prediction was, indeed, sound after the filing date.

MR. DEARDEN: Sir, when you say that the applicant could present something to the examiner by way of argument, argument could be in the form of

affidavits, right?

DR. GILLEN: An argument could be in the form of an affidavit, that's correct.

MR. DEARDEN: And that could deal with testing?

DR. GILLEN: It could, yes.

MR. DEARDEN: Page 1114, so the next page at the very bottom of Monsanto: "After this the Board turned to the jurisprudence on such issues ending with the recent Chancery Division decision in Olin Mathieson v Biorex Labs and quoting from the judgment itself the following: Where, then, is the line to be drawn between a claim which goes beyond the consideration and one which equiparates with it? In my judgment this line was drawn properly by Sir Lionel when he very helpfully stated in the words quoted above that it depended upon whether it was possible to make a sound prediction. If it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so.

'This last paragraph puts succinctly what we have been able to distill from the jurisprudence discussed above' say the Board. As to this, I should

say immediately that I am in full agreement with the decision of Graham J in Olin Mathieson and find it necessary to consider it more exhaustively."

So the Patent Office was aware of this Olin Mathieson decision that the Monsanto court adopted?

DR. GILLEN: That's my understanding, yes.

MR. DEARDEN: And at the bottom there's conclusions of Justice Graham that the court sets out. I'm looking at the one at the very bottom of the page. "From the point of view of the public and the patentees it is desirable that research in the drug or other fields, as the case may be, should continue. In the drug field in particular research in very expensive" -- is very -- it says "in" -- "very expensive and the number of 'winners' found is only a minute proportion of those synthesized and tested. Once a winner is found, however, it is very common also to find that bodies more or less closely related to it have the same or even greater activity." And the court fully agrees with those observations. I'm not reading the rest of that quote there. And the Patent Office was not taking issue with those conclusions, I take it?

DR. GILLEN: That would be my understanding. This is a case well before my time.

MR. DEARDEN: And, sir, on page 1119 the court deals with the Commissioner's refusal and says, "I have underlined by law to stress that this is not a matter of discretion: The Commissioner has to justify any refusal."

So the court looked at the section 42 of the Patent Act and said "Whenever the Commissioner is satisfied that the applicant is not by law entitled to be granted a patent he shall refuse the application and, by registered letter addressed to the applicant ...notify the applicant of such refusal and of the ground or reason therefor."

So Justice Pigeon underlines by law to stress that it's not a matter of discretion; the Commissioner has to justify any refusal, right?

DR. GILLEN: That's correct.

MR. DEARDEN: And what happened? So if you look at page 1121, middle of the page, "The Board say that they agree with the views of Graham J in that respect. However, they appear to me to reach exactly the opposite result. Graham J found valid the claim based on sound prediction. In the instant case, the Board, in spite of a complete absence of

any evidence of unsoundness of the prediction, deny the claims and would in the end limit them to the area of proved utility instead of allowing them to the extent of predicted utility. In my view this is contrary to s 42 of the Patent Act.

"Under that section the Commissioner is instructed to refuse the patent when 'satisfied that the applicant is not by law entitled' to it. Here what he has said in approving the decision of the Board is in effect 'I am not satisfied you are entitled to it'. In my opinion the Commissioner cannot refuse a patent because the inventor has not fully tested and proved it in all its claimed applications. This is what he has done in this case by refusing to allow claims 9 and 16 unless restricted to what had been tested and proved before the application was filed. If the inventors have claimed more than what they have invented and included substances which are devoid of utility, their claims will be open to attack. But in order to succeed, such attack will have to be supported by evidence of lack of utility. At present there is no such evidence and there is no evidence that the prediction of utility for every compound named is not sound and reasonable."

So what happened there, Dr. Gillen, is the burden was put on the Commissioner to have evidence of lack of utility before rejecting an application, correct?

DR. GILLEN: That would be one ground for rejecting an application for lack of utility, yes, if, in fact, there was evidence that the invention did not work.

MR. DEARDEN: No, but what I'm saying, burden, who -- is it for the patent applicant to prove there was utility, or was the burden on the Commissioner to have evidence of lack of utility and the Supreme Court has said it's on the Commissioner. Correct?

DR. GILLEN: Yes, the burden here would be on the Commissioner to show lack of utility.

MR. DEARDEN: And so that was for the benefit of -- the doctrine of sound prediction adopted by the Supreme Court was really for the benefit of the patentee, correct?

DR. GILLEN: Yes, I would agree with that.

MR. DEARDEN: Mr. President, could I maybe have five minutes to confer with my colleagues as to whether I have any other questions? Because

that does complete my binder.

THE PRESIDENT: Yes. (Pause).

Mr. Dearden?

MR. DEARDEN: I have no further questions. Thank you, Mr. President.

THE PRESIDENT: Thank you, Mr. Dearden. Any questions for redirect?

MS. ZEMAN: No questions on redirect.

THE PRESIDENT: There are a few questions from the Tribunal.

QUESTIONS BY THE ARBITRAL TRIBUNAL

SIR DANIEL BETHLEHEM: Thank you. I've got a number of questions simply for clarification.

We've been provided as part of the record with extracts of a number of the MOPOP publications. I think in the preambular parts of the 1990 MOPOP it indicates that MOPOP is a loose-leaf publication interleaved with updates, and describes a gray color paper for the interleaved updates. Can you clarify whether MOPOP is now still a loose-leaf publication or whether it is a bound volume without the interleaved updates?

DR. GILLEN: Actually the MOPOP today is electronic; it's not a paper MOPOP anymore. When I joined the Office it was a loose-leaf binder, like a

three-ring binder. Pages could be taken out or inserted, as the case may be, when amendments were made to the MOPOP. At some later date it did become more of a bound thing, but for the last several years it's now electronic so it makes making amendments to it even easier.

SIR DANIEL BETHLEHEM: Does that mean that it's updated on an ad hoc basis or whenever the view is taken that it needs to be updated? Because we are cited to -- whatever it is, the 2009 MOPOP, the 2010 MOPOP, rather than the 15th of January or the 16th of January MOPOP.

DR. GILLEN: Well, what's going on today in the Patent Office is there's a full-time person who is the manager of Office practice -- or practice manager, I'm not sure what her exact title is. There's also somebody who's in charge of training. There's a training team. So when a new court case would come out that would have some impact on Office practice that would necessitate an amendment to the MOPOP, for example, these people are going to get together with others in the Patent Office and make a decision as to what to do with it.

Now, whether or not they update the electronic version of MOPOP immediately or at some

later date when there's more jurisprudence perhaps, they often will have training sessions or Office memos or Office practice memos, many of which are published, in lieu of actually making amendments immediately to the MOPOP.

SIR DANIEL BETHLEHEM: We were taken by counsel for the Claimant in his cross-examination questions to you to a number of cases in which the MOPOP was cited by courts as a valuable interpretative guide. Insofar as the MOPOP would be cited to a court by counsel for either party, on what basis would the court be able to have confidence that what it was being cited to was the current updated version rather than yesterday's version which was going to be overtaken by tomorrow's version which may be significantly different?

DR. GILLEN: Well, I think the court would look to the date of the MOPOP and look to the most recent version of the MOPOP, if they were going to cite it. I think for the most part, when courts are citing MOPOP, I mean to some extent MOPOP is attempting to summarize and interpret some of the decisions of the court, so sometimes for the court it's easier to refer to the MOPOP where there's more of a summary of the jurisprudence rather than going

to the jurisprudence itself.

SIR DANIEL BETHLEHAM: What I'm wondering about, in a hypothetical, is we have Mr. Reddon or Mr. Dimock before a court, would they be able to come to a Patent Office and say: "Are you working on any updates. We want to put this before the court. We want to make sure we are putting before the court the current thinking of the Patent Office", or would it simply be whatever is on the website of the Patent Office?

DR. GILLEN: I don't recall the court ever coming to the Patent Office with those kinds of questions. I think the extent to which they relied upon the MOPOP would be based on the case and the subject matter and really up to the court as to whether they wanted to make a reference to MOPOP or refer directly to the jurisprudence.

SIR DANIEL BETHLEHEM: Right. We have evidence in Mr. Wilson's statement -- and it's not part of the paragraphs that you identify where you disagree with Mr. Wilson, so this is really just a point of clarification, if I may -- if there was a concern within the Patent Office or within the Department of Justice lawyers who were consulted on the updating of MOPOP arising out of a court decision

because, for example, they thought that the court decision was wrong, or they thought the court decision was imprecise, or because it was going to be very difficult to apply more broadly across the particular sector in which the decision was issued, how, if at all, would that be addressed?

Really what I'm trying to elicit from you is an explanation of whether the MOPOP would simply take the court judgment as given and introduce it into the MOPOP or whether there would be an analytical process that would interpret the judgment, make a decision not to reflect the judgment in the MOPOP because the law was not regarded as settled, or simply not to introduce it into the MOPOP because there was a disagreement with the outcome of the court case?

DR. GILLEN: All of those are possibilities. It really depends on the case. Some decisions are fairly straightforward, so they could be incorporated directly into the MOPOP. There are other decisions where the decision in the view of the Patent Office may not be as clear, and in those cases the Office would look to the decision and try to analyze and determine what it was the court was trying to tell the Office to do or not to do.

In those cases the Department of Justice might be consulted also for an opinion as to how far the decision went or what it actually meant or how it affected Office practice, so it would really depend on the case itself and how clear the decision was in the opinion of the Office.

As an example, there was a decision some years ago in the famous Harvard Mouse decision where it went back and forth about whether or not life forms like that should be patentable, and ultimately it was decided that they should not be patented, at least in Canada. There were statements in that decision with respect to fertilized eggs and other types of life forms that weren't a mouse, where the Office had to think about what they meant and maybe consult with the Department of Justice as to how far that decision would go with respect to life forms, or maybe even what a life form meant in terms of that decision.

So it really depends on how clear the decision is and how black and white it is whether or not a decision would be incorporated directly into training materials or MOPOP or practice notice, or whether there would be consultations at some point before the Office could finally take a position and

then that would become part of the training materials or go into the MOPOP.

SIR DANIEL BETHLEHEM: Would there be anything else apart from the court decisions and MOPOP to which the profession might have regard? For example, would there be Department of Justice guidelines, interpretations, publications which the profession would look to alongside the MOPOP to see how the Patent Office would work?

DR. GILLEN: I'm not aware of any Department of Justice guidelines sort of parallel to what the Patent Office would be doing with respect to Office practice.

SIR DANIEL BETHLEHEM: In light of what you just said, would it be overstating the matter or would it be a fair summation to say that to some extent there will be a, if you like, a professional dialogue between the Patent Office through the MOPOP and the courts through their judgment about what a particular principle should be, particularly in circumstances in which we were dealing with, as it were, innovation in the law?

DR. GILLEN: There is a little bit of a back and forth. I wouldn't say a dialogue or discussions but certainly with respect to patentable

subject matter, as I mentioned earlier, in the early 2000s the Office was looking at inventions related to computers and business methods, which was new subject matter for the Office, and trying to assess whether or not some of those inventions were, indeed, patentable subject matter or not. And so the Office developed certain practice with respect to those kinds of inventions. The practice that was developed by the Office was ultimately denied by the courts. The courts said no, that's not the way to go; you can't assess patentable subject matter in that way.

So in terms of a dialogue, the Office may have a position with respect to patentable subject matter or some other issue which ultimately the courts disagree with. So there's the back and forth that way. But there isn't sort of an ongoing dialogue, no.

SIR DANIEL BETHLEHEM: So the courts may disagree with it or the courts may agree with it on the basis that it's a valuable interpretative guideline?

DR. GILLEN: Exactly. We talked a few minutes ago about the Monsanto case, you know. The issue was whether or not those compounds should be patented and the Office said no and the Federal Court

of Appeal said no and the Supreme Court said yes, so there is back and forth on a number of these issues.

SIR DANIEL BETHLEHEM: It's your evidence that the MOPOP is sort of high-level guidance. Is there within the Office more granular guidance to the assessors in relation to any particular field, biotech or whatever, so that they've got something beyond the high-level guidance to turn to?

DR. GILLEN: No, there's no other manual that the examiners would use. They have MOPOP practice notices and Office memos and that sort of thing. And then on-the-job training, of course. When there are newer examiners they work with a senior examiner for the first two years that they're in the Office to learn how to examine an application, write a report and so forth.

SIR DANIEL BETHLEHEM: But there would be nothing along the lines of, for example, an internal annotation which says: We note the AZT case, it's reflected in paragraph whatever, be aware that this line of jurisprudence is developing or it changes the law previously?

There wouldn't be some touchstone to which an examiner would be able to go to get more of a granular feel for the law?

DR. GILLEN: No, there is not.

SIR DANIEL BETHLEHEM: Thank you very much.

THE PRESIDENT: Questions by Mr. Born.

MR. BORN: Just one question about slide 13 in your presentation, if you go to the last box on the page.

DR. GILLEN: Yes.

MR. BORN: If I understand what you're saying about post-filing evidence of utility, it is that post-filing evidence will not be accepted by the agency, and then, if I understand your reasoning, it is because an invention must be complete at the time it is filed.

I'm struggling, I guess, for the logic that connects those two statements because they seem to, at least to me, concern different things. Let's take, for example, an airplane. I invent an airplane. I build the airplane. I file the patent application and then I test it. The question of whether my invention is complete seems to be different from the question of whether I can submit evidence about how it works from after the filing date.

Can you help me on that difficulty that I

have?

DR. GILLEN: Yes, I think that analogy was actually used in one of the court cases with respect to a heavier-than-air flying machine, so an airplane, so if you've invented an airplane, for your invention to be complete at the time of filing, you would describe your airplane and enable one of skill in the art to make the airplane. For your invention to be complete you would either have flown the airplane and shown that it's useful for its intended purpose, or you would soundly predict that your airplane would fly and the prediction would be based on whatever facts you had disclosed in the application to show the examiner that, indeed, your prediction was sound. That's what we mean by the invention has to be complete at the time of filing.

So if you had made the airplane and never tested it and had no evidence that this would fly, you couldn't file your application and say well, I've invented an airplane, and then maybe five years later you send something to the Patent Office to show them that, indeed, your airplane does fly. The way it works is you have to have your invention complete at the time you file, so you can't have a hoped-for flying machine when you file your patent application

that later proves to be true, because if it isn't true, if it doesn't fly, then what you've given the public really is nothing at all.

MR. BORN: But if my disclosure explains how you make an airplane that, in fact, flies, I guess I'm struggling on why I haven't given the public something quite valuable.

DR. GILLEN: If you've described your airplane and you've described how to make it and you've described why you think it will fly, then that, to me, sounds like a sound prediction because you haven't actually flown the airplane yet, but if you can soundly predict that it will fly because you understand something about wings and air flow around wings and the whole concept of lift and so forth, then your application might be complete depending on what you've given the public. But if all you give the public is well, here's how you make this airplane and I hope it flies, that's really not an invention. You haven't completed the invention in the sense of having tested it and shown that it does work, or making statements that would soundly predict that it will, indeed, fly.

MR. BORN: Thank you.

THE PRESIDENT: Any follow-up questions?

Mr. Dearden? 10:33
MR. DEARDEN: Just one.
RE-CROSS EXAMINATION ON BEHALF OF THE CLAIMANT
MR. DEARDEN: Just following up on that, Dr. Gillen, the airplane example that Member Born just gave you, the date of the invention of that airplane or the date the invention is made is the date the airplane is built but not yet flown, correct?
DR. GILLEN: The date of the invention or the date of --
MR. DEARDEN: The date the invention is made, in the example that Member Born just gave you, would be the date that that airplane has been built and is sitting in the field but not yet flown, correct?
DR. GILLEN: No. I would say the date of invention is when you've built the airplane and based on -- and you've flown it or --
MR. DEARDEN: No, that's not my example, sir.
MR. SPELLISCY: Can he finish his answer there? I don't think he was done.
THE PRESIDENT: Okay. Could you please repeat your answer, and then finish it.

DR. GILLEN: The date the invention is complete is when -- the term that used to be used, or is used, is when it's reduced to practice. So, having just built something you call an airplane without having flown it or at least having described it in a way that you would predict it would fly, doesn't mean the invention is complete until you've at least done that. So I wouldn't say, just building the airplane and finishing the product, that the invention has been reduced to practice unless there's some indication, based on the wing design and so forth, that this airplane will actually fly. Or at least a prediction that it will. 10:34
MR. DEARDEN: Are you finished?
DR. GILLEN: Yes.
MR. DEARDEN: Sorry, I didn't mean to interrupt you. You can have constructive reduction to practice, correct?
DR. GILLEN: Yes.
MR. DEARDEN: Okay. Those are my questions, Mr. President.
THE PRESIDENT: Ms. Zeman, any follow-up questions from the Respondent?
MS. ZEMAN: No further questions.
THE PRESIDENT: Thank you, Dr. Gillen,

for testifying. You are now released as an expert in this case and excused. 10:35
DR. GILLEN: Thank you.
THE PRESIDENT: Recess 15 minutes.
(Recess taken)
RONALD E. DIMOCK
THE PRESIDENT: Mr. Dimock, good morning.
MR. DIMOCK: Good morning.
THE PRESIDENT: Could you please state your full name for the record?
MR. DIMOCK: My name is Ronald Edward Dimock.
THE PRESIDENT: Mr. Dimock, 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. DIMOCK: I understand.
THE PRESIDENT: Mr. Dimock, you appear here as an expert witness for the Respondent. You will appreciate that testifying, be it before a court or an arbitral tribunal, is a very serious matter. In that connection, the Tribunal expects you to give

the statement which is in front of you. 10:53
MR. DIMOCK: Thank you. I solemnly declare upon my honor and conscience that my statement will be in accordance with my sincere belief.
THE PRESIDENT: Thank you. Could you please go to your First Report which is dated January 26, 2015, page 60. Could you please confirm for the record that the signature appearing above your name is your signature?
MR. DIMOCK: Yes, it is.
THE PRESIDENT: Could you then please go to your second Expert Report, which is dated December 4, 2015. Could you please go through to page 40 and confirm for the record that the signature appearing above your name is your signature?
MR. DIMOCK: Yes, it is.
THE PRESIDENT: Are there any corrections you wish to make to either report?
MR. DIMOCK: No, there is none.
THE PRESIDENT: I see Mr. Johnston, you are doing the direct?
MR. JOHNSTON: Yes, President van den Berg. Mr. Dimock has prepared a presentation. However, we have had a logistical

10:54 issue in the printing of the slides, and so Mr. Dimock is ready to give his presentation and the PowerPoint is ready up on the screen, but we can't provide the slides at this moment. We're currently reprinting them. That would take I'm not sure exactly how many minutes but some time to do, so I'm in the Tribunal hands in terms of how we proceed.

THE PRESIDENT: Mr. Dearden, do you have any problem in looking only electronically?

MR. DEARDEN: In the interest of moving things along, Mr. President, my guess would be that you would want me to answer I have no problem.

THE PRESIDENT: No, no. What we can do is we can quickly make one print-out for you so you have a hard copy, because you may be the same as me, in that I would like to make notes.

MR. DEARDEN: Okay.

THE PRESIDENT: Let's wait for a second until we have the hard copy.

(Pause)

THE PRESIDENT: Ms. Cheek?

MS. CHEEK: Mr. President, we would just observe that in Mr. Dimock's presentation there are several demonstrative timelines, and there's no citations back to his original reports. The parties

11:03 are agreed that the presentation that will be provided is solely a summary of material in the report, so our assumption would be that all of this material is, in fact, referenced in Mr. Dimock's reports, but we would appreciate some clarification in that regard.

However, there's also a tab 2 and a tab 3 which are additional materials that perhaps we could get some explanation of. I'm just really not sure what the tab 2 and tab 3 are. Perhaps they're not part of his presentation.

THE PRESIDENT: Mr. Johnston, could we get an explanation from you on tabs 1, 2 and 3?

MR. JOHNSTON: Yes. I can confirm that all of the cases represented on those timelines are, in fact, cases referred to in Mr. Dimock's expert reports. There's nothing going beyond his expert reports in his presentation. There is an interactive aspect of the slide show, and that is why we have these additional tabs 2 and 3 which bring up quotes from those decisions reflected on the timeline.

In the context of the actual PowerPoint, it will appear on the screen, the same text. It's just for convenience it's included in a separate annex.

11:04 THE PRESIDENT: And that applies to all three attachments, tabs 1, 2 and 3?

MR. JOHNSTON: Yes. There are three timelines in the presentation, and so the annexes correspond to those timelines.

MS. CHEEK: Mr. President, are the annexes, compendiums, behind tabs 2 and tab 3 actually the exact same as the annexes already provided in Mr. Dimock's Expert Report? Because if not, then they appear to be new material.

THE PRESIDENT: What I understood is that they all come from the expert reports. Is that a correct understanding, Mr. Johnston?

MR. JOHNSTON: All of the cases referred to are relied upon by Mr. Dimock in his expert reports. I know that most or some of those quotes will be verbatim, identical to what appears in his Expert Report. It is possible that the quotes are not all fully reproduced in his expert reports; the cases are cited and relied upon.

THE PRESIDENT: Okay.

MS. CHEEK: Mr. President, I would note that Mr. Dimock has already provided to his Second Report an Annex B where he walks through a series of cases and provides various quotes. To the extent a

11:06 quote that's behind tab 2 and tab 3 is identical to what he's provided in Annex B, we have no objection. To the extent he's providing additional material beyond Annex B, that needs to be provided through direct to the extent that it's responsive to new testimony that's come into the record.

THE PRESIDENT: Ms. Cheek, I think we should wait until we have completed the presentation because what I understood is what these three timelines are is what will be shown on the PowerPoint presentation. Apparently it's an interactive timeline, as they call it, so let's wait, and maybe at the end of the presentation you can say "Wait a moment, this is not what is exactly in the record of Mr. Dimock's expert reports."

MR. SPELLISCY: Mr. President, I would like to interject here. Yesterday we had Mr. Reddon give a presentation in which he referred at length to a case and cases that weren't even cited in his expert reports, and I had made a point to that point which was overruled by the President, I think.

Here we actually are referring to cases that are cited in Mr. Dimock's expert reports, and we can't imagine that the simple fact that a citation may be different, or annex, is an objection,

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especially in light of what Mr. Reddon did yesterday. 11:07
THE PRESIDENT: Let's go ahead now. Let's move on and have the presentation on the basis that in any case, in this case, these presentations are cases referenced in the expert reports.
PRESENTATION BY MR. DIMOCK
MR. DIMOCK: Thank you.
The first slide gives an overview of my professional experience in relation to my testimony as an expert witness in this arbitration. My professional experience has been outlined in detail in my two expert reports. The first one of January 26th, in paragraphs 1-8 and the appendix A, contains my CV, and there's a further reference in my Second Report, Annex A, to a list of the patent cases involving pharmaceuticals upon which I've acted over the years.
I have now been practicing for 40 years, and I do mainly patent litigation in those 40 years. I was called to the Bar in 1976, and my first trial was in 1977, Xerox v IBM. My most recent trial finished two weeks ago, and that involved lottery tickets, so that was my 40th trial.
My early experience that's relevant, among other experience in this case, to the issues

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before you is that I acted as a junior lawyer with 11:09
Donald Sim on the Consolboard and Monsanto cases. I didn't appear as counsel in either of those cases, but I did work as a junior lawyer supporting him.
In the last 20 years I've acted for both the generic and innovator pharmaceutical manufacturers, and previously I've been retained by the Claimant's law firm, Gowlings, and by Mr. Reddon's law firm, McCarthy Tétrault, as an expert witness on patent and pharmaceutical litigation.
My presentation will cover three areas. I'll give you a summary of my mandate and conclusion. I'll then look at the patent bargain which has taken up part of this arbitration already, and I'll look at the three fundamental questions that relate to the patent bargain as they relate to this case.
My mandate was to look at the goals and structure of the Canadian patent system to put in context my opinion. I also looked at the olanzapine and atomoxetine court proceedings, and I was also asked to take a look at the alleged changes in the law of utility according to the Claimant's experts.
My opinion today, and in those two reports, is based on my own patent practice

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experience over these last 40 years and my historical 11:10
review of the legislation, case law and legal doctrine.
My conclusion ultimately is that the law which was applied in the two cases to invalidate the Claimant's two patents predates the NAFTA and the respective patent filing dates for those two drugs.
I'm not going to go over the olanzapine and atomoxetine cases, I've done that sufficiently and at length in my First Report, but I'll talk now about the patent bargain.
Very briefly, patent rights are a narrow exception to the free trade principle against monopolies, and we know that there's a general preference to have unfettered competition, and monopolies do put fetters on competition and put restrictions. Thus, in order to get monopoly of a patent, you must enter into a bargain with the state, and in this case the state would give a time-limited monopoly in exchange for a disclosure of certain types of advances made in the state of the knowledge or in the art, as we understand it to be, and what must be exchanged in that bargain for that limited monopoly, time-limited monopoly.
The Patent Act, as you've heard, requires

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there to be patentable subject matter; that the 11:12
subject matter have novelty, or be new; that it have inventiveness or, as we've heard it, not to be obvious; that it have utility or usefulness, as is said in the Act, useful; and it must have a sufficient disclosure as well.
That bargain is made at the time that the application for patent is filed. Not later, not before.
The key date for the start of the monopoly is when that patent application is filed because monopoly in Canada will extend for 20 years out from that filing date, and that patent bargain is always subject to review by the courts.
When patents are granted they are presumed to be valid, but that presumption disappears as soon as there's any evidence that's led in the court, such as the Federal Court, where that evidence contradicts the validity of the patent, in which case the presumption, as I said, disappears and the person attacking the validity then has the onus to prove invalidity on a balance of probabilities.
The invalidation means that the patent is void ab initio and, in effect, under the Patent Act would have had no effect and would never have issued

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in effect.

The patent bargain.

Utility is required, just as the other four pillars of our patent bargain is based, and without it we do not have the hard coinage, as Justice Binnie has used that, adopting it from another case. You have to exchange for obtaining that monopoly.

As we've heard, the Patent Act does not define "useful" or "utility" and consequently, as has been the case, the courts are to interpret and give meaning to the Patent Act.

However, over the years, from my conducting cases and reading about them, utility is not considered in isolation. Even though there are the five pillars of a patent, a valid patent or a patentable invention, there is some overlapping and the courts have said that you can't pidgeon-hole some of the attacks.

For example, overbreadth and inutility do overlap in some respects. You've heard, and I'll go over it in some detail when I look at some cases, overbreadth is where you claim more than what you invented or what you have disclosed. It's called covetous claiming: You are greedy or claiming more

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than you're entitled.

The doctrine of sound prediction you've heard as part of the law of utility actually arose as a defense to overbreadth. What you've claimed is broader than the invention disclosed or made, and then you defend that claim based on sound prediction, that what you've disclosed has a factual basis and a good line of reasoning so that you can lay claim beyond the actual examples in the patent disclosure itself. Promises of utility are enforced through overbreadth, and I'll come to that when I look at some cases in a few moments.

The patent bargain in relation to utility has three fundamental questions. What is the invention; was the invention actually made; and was the invention properly disclosed.

You've heard about the "scintilla" or promise of utility, about reading the patent through the eyes and the mind of the person of skill in the art, that to make an invention you can either do so by demonstrating the utility or having a sound prediction made as of the filing date of the patent, and the disclosure for sound prediction requires a factual basis and a line of reasoning.

What the Claimant's experts have

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indicated, as far as I can discern from the records and hearing them give evidence before the arbitration, is that the utility standard is only one -- and only one -- scintilla; it does not have a promise of utility standard; you don't read it through the eyes and the mind of a person of skill in the art -- although there may have been some concession on that. They're debating that the demonstration or sound prediction -- that's the two bases upon which you can prove utility -- they're I believe criticizing that that was a new point, that you had to do that as of the filing date, and, lastly, they're saying that the disclosure of a factual basis and line of reasoning is new.

I say all those are old as of the dates that the patents were filed and NAFTA as well.

The three fundamental questions of the patent bargain.

The Claimant's experts say that as of 2005 this promise standard was new. They also allege that reading the patent through the mind and eyes of a person of skill in the art was new as of 2005. My opinion, as I've indicated, is that these alleged changes have been part of our Canadian law since before the 1970s, and it's always been that the

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patentees are held to their side of the bargain. The promise secures the patent.

Why does a patent applicant make a promise of utility when, according to Consolboard, there's no need to make reference to the utility or the novelty in the patent? Well, in some cases it is a necessity to satisfy another concept of law or an incentive, as the case may be, where there's a particular utility at the core of the invention, such as in the atomoxetine case where it was a new use. If you just claimed atomoxetine, that would have been an old molecule. You have to indicate why it's now new and inventive, or you indicate a new use for the treatment of attention deficit/hyperactivity disorder. And then selection inventions, where you take a very large genus of chemicals and realize through study and research that there's a certain smaller species which has an advanced or elevated or substantial improvements. Also, if there's a very clouded state of the art, you want to indicate some advantages in order to support your case that it's not obvious.

I've indicated on this slide the three dates that I think I've heard are important in regard to promise of utility, and that is the filing date of

11:18

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the two patent applications, or the two patents in suit here, and the date of 2005, when they say that these two standards of utility came into being.

THE PRESIDENT: May I stop you for one second for a discrete question? It is a Tribunal time question, don't worry.

Concerning your understanding of Professor Siebrasse and what happened in 2005, what is the triggering event in 2005 according to your understanding?

MR. DIMOCK: My understanding is that he's relying on three cases where the courts were asked to look for promises in the disclosure in order to assess whether or not that would render the patent invalid. That's my understanding of it.

THE PRESIDENT: Maybe that can be explored later, the three decisions.

MR. DIMOCK: Yes.

THE PRESIDENT: Thank you. Please proceed.

MR. DIMOCK: So what I've indicated on this slide is a timeline, and these cases and commentary I refer to in my two reports, and I thought it would be more demonstrative rather than having a long list, if we look at them in a timeline,

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as I've indicated here. I don't have time, nor will I go through each of these, but I just want to highlight some of the important ones.

I'd like to take a look at the Donald Hill article which was in 1960. He's saying that there's one standard that you measure utility on the one hand, and a second on the other. If certain results are promised and they're inferred from the specification and these are not yielded by the embodiment of the claims, then the patent will fail. In the absence of a specific promise like that, then the courts do not seem to be overly anxious to strike down. That would appear to be the scintilla of utility, as opposed to the higher level of utility that is this other standard.

THE PRESIDENT: Could you help me? Could you please pull up again what you just had on the slide in 1960? Where do we find that in tab 1, 2 or 3, this text?

MR. DIMOCK: You'll find that in tab 1. It's the third one down on the first page behind tab 1.

THE PRESIDENT: Okay. Yes. I'm with you.

MR. DIMOCK: I'll try and indicate as I

11:23

go where you can actually find them.

Then a year later, 1961, I'd like to talk about the New Process Screw case. We've heard something about that already. In that particular case there was a finding that the patent was invalid, and what was important there is two things. The first one, "...it was conclusively proved that if dies with the pitch angles referred to in the specification" -- and what the judge is referring to, "specification" here, is the disclosure. We heard yesterday some discussion about specification.

In normal practice the specification is really the disclosure. There are two parts to a patent, the claims and the disclosure. Technically the specification is both the claims and the disclosure, but people invariably refer to the disclosure as the specification or vice versa. Sometimes they refer to the body of the specification as the disclosure. I'll try and point out where that occurs from time to time through some of these cases.

Here in this case the judge concluded that there was a "failure of the promise of the patent which was fatal to it".

Justice Thorson then also looked at the evidence of Mr. de Villiers, who was the inventor,

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and the inventor said if you used a certain angle you would roll a double-threaded screw, but it would not be a good one. It would be rough and not a commercial product. And reference to commercial product is in the disclosure only, it's not in the claim, so Justice Thorson said this statement was enough to destroy the patent. So that goes to the point that they were looking at the disclosure, not to the claims in looking for the promise of the patent.

I'd like to then take a look at the next reference, Mr. Henderson's article, which refers to the New Process Screw case. Mr. Henderson was the editor and he wrote about these cases in his Reporter and he said "In the present case, it will be noted that in respect of one of the three patents in suit, the failure of the patentee to achieve a commercially good product" -- and that's the reference in the disclosure -- "in carrying out the disclosure rendered the patent invalid on the ground that the promise made in the specification was not fulfilled...."

He then went on to say, "... in the absence of a promise or a representation of a specific usefulness, it is clear that only a limited

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degree of usefulness is required. If the patentee makes a specific promise in the specification, the promise must be fulfilled or the patent is invalid..." 11:26

So that's in 1961, Mr. Henderson, the managing partner of Gowlings for many years and one of Canada's leading patent lawyers, making that statement.

I'd like to turn now to the Fox statement in 1969, and it's the second paragraph, and you'll see that in the third page of the annex. "The plea of non-utility based on a failure to produce the promised results of a specification is similar to, and cannot always be separated from, the plea of false representation, or failure of consideration as it is sometimes called. It necessarily involves a construction of the specification in order to ascertain what the ordinary workman would apprehend by its disclosure."

So here specification is used as a disclosure, and you use a person of skill in the art, mind and eyes as to what that means. "It is, therefore, of the utmost importance to decide whether the specification makes a promise of a result and whether the ordinary workman would understand that

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that particular result is promised." 11:27

I'd like to jump a few years ahead -- a couple of years -- to 1971, Bill Hayhurst. Bill Hayhurst was a leading patent figure and wrote extensively about patent law and was well read. Here Mr. Hayhurst is saying, "In the introductory parts of the specification" -- so that's the disclosure -- "one must be chary of promising advantages that are not achieved by everything that falls within the broadest claim." So there he is distinguishing between the specification and the claim. "If you make false promises you may get an invalid patent... Since claims, to be valid, must not extend to useless things, but must be confined to things which have the utility promised by the disclosure, the agent should be careful not to promise too much."

Again warning about putting too much in the disclosure about promises, unless you absolutely have to.

I'd like to turn to the Consolboard v MacMillan Bloedel case, not the Supreme Court of Canada but the trial division, to indicate here that Justice Collier -- and this is the case I worked on with Mr. Sim -- Justice Collier held the patent to be invalid, one of the patents invalid on the basis that

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it didn't meet the promise. The disclosure referred to uniform distribution of these felts -- 11:28

THE PRESIDENT: You're almost out of time, I understand. I'll give you three more minutes.

MR. DIMOCK: I'd like to jump ahead to MacOdrum, 1995, where he says that "the level of utility is not high [in general]. However, the situation is different where some specific utility is promised by the disclosure". And that's in 1995.

So I've tried to indicate that over the years one did look to the disclosure to see whether there was a promise, and there were two levels of utility.

The next part of the bargain is has the invention been made, and I'd like to skip right down to the last paragraph on that page. Post-filing evidence cited by the Claimant's experts deals with operability, and yes, evidence is adduced about commercial success of an invention. That's to show that it does work or doesn't work. But it's not useful, it's not used, it cannot be used to show that the person who made an invention had a sound prediction at the time that the application was filed. It doesn't follow that if it works now that

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you knew that it worked then, and I've got some timelines indicated there in my report that show how the disclosure had to be -- the invention had to be made prior to the application for patent. 11:30

Then on the third promise, or the third aspect of the bargain, has the invention been disclosed, I'd just like to take a look at really two things in my report or in my presentation, and that's in 1971, if you turn to the timeline itself, Hayhurst 1971 on disclosure drafting. He says here, "Not only must you instruct those skilled in the art. You must also provide a disclosure which justifies the claims you are making. You must include sufficient examples to justify a sound prediction that everything falling within the scope of the claims will have the promised utility."

So it's been known for many years that you had to have a disclosure in order to support your claims, whether they be based on sound prediction or on demonstration. But with sound prediction you must have a factual basis, as we've heard, and a line of reasoning, and that must be disclosed in the disclosure.

That concludes my presentation.

THE PRESIDENT: Thank you.

MR. DEARDEN: Mr. President, I stand to be corrected by my friend across, but I don't recollect Mr. Dimock's presentation referring to anything in tabs 2 and 3 of his binder. If I'm incorrect -- 11:32

THE PRESIDENT: My understanding is those are what would have happened, if you look at the second timeline, that is tab 2, that's what I understand it to be, and the third timeline, the last slide, is tab 3. Is that correct?

MR. JOHNSTON: Yes, that's correct.

THE PRESIDENT: That was my understanding. So it's in the presentation, except that all lawyers have difficulties with counting estimated time.

MR. DEARDEN: What I would ask for confirmation on, for instance, in tab 2 is, looking at the summary of the Christiani v Rice decision on the first page, is that verbatim out of one of his expert reports? I didn't recall it was, but I may be wrong.

MR. JOHNSTON: The case is certainly cited in Mr. Dimock's expert reports. I will have to verify the exact language cited.

THE PRESIDENT: Subject to your

verification, we can proceed. Do you have further questions to ask in direct? 11:33

MR. JOHNSTON: I don't have any questions in direct examination.

THE PRESIDENT: Then we can move on to cross-examination.

CROSS-EXAMINATION ON BEHALF OF THE CLAIMANT

MR. DEARDEN: Good morning, Mr. Dimock.

MR. DIMOCK: Good morning, Mr. Dearden.

MR. DEARDEN: How are you doing?

MR. DIMOCK: I'm all right.

MR. DEARDEN: I think we can have common agreement on the initial questions I'm going to ask you about the patent system being rooted in legislation. There's no common law right to a patent in Canada, correct?

MR. DIMOCK: That's right.

MR. DEARDEN: And the Canadian patent system is entirely rooted in legislation?

MR. DIMOCK: Yes.

MR. DEARDEN: And an inventor gets a patent according to the terms of the Patent Act? No more, no less?

MR. DIMOCK: That's right.

MR. DEARDEN: And only Parliament can

create requirements for obtaining a patent in Canada? 11:37

MR. DIMOCK: Yes. There's one exception. Before the Parliament actually enacted obviousness into the Patent Act, it was a judge-made law that, in order to get a valid patent, the invention had to be -- did not -- could not have been obvious, so sometimes there's judge-made law like that but I think, generally speaking, I agree with the statement you gave to me.

MR. DEARDEN: So your position is that the obviousness requirement prior to it being legislated into the Patent Act was a judge-made patent requirement?

MR. DIMOCK: Yes.

MR. DEARDEN: The granting of a patent is akin to a contract between the Crown and the inventor?

MR. DIMOCK: Yes.

MR. DEARDEN: Can you turn up tab 15 of volume 3, which is Exhibit C-05, which should be the Patent Act, Mr. Dimock.

MR. DIMOCK: Yes, that's what I have.

MR. DEARDEN: So three of the requirements that I'm going to deal with here, if you go to section 2 which defines Invention, so the

requirement that an invention be new we find in section 2 of the Patent Act? 11:39

MR. DIMOCK: Yes.

MR. DEARDEN: And the requirement that an invention be useful, we find that in section 2 of the Patent Act?

MR. DIMOCK: Yes. Under the definition of Invention, yes.

MR. DEARDEN: Then if you flip over to section 28.3, this is what you just referred to as the legislative version of the non-obvious requirement?

MR. DIMOCK: What page is that again?

MR. DEARDEN: I have it at page 36.

MR. DIMOCK: Yes, that's right.

MR. DEARDEN: And there are certain patentability requirements that there can't be any conflation, correct?

MR. DIMOCK: I'm sorry, I don't understand the question.

MR. DEARDEN: Okay. Why don't you turn to tab 16.

MR. DIMOCK: Of that same volume?

MR. DEARDEN: Yes. It's in volume 3. So it's Exhibit C-35.

11:40 MR. DIMOCK: Is that the Pfizer case?
MR. DEARDEN: Pfizer v Ranbaxy Labs.
MR. DIMOCK: Yes.
MR. DEARDEN: This case deals with the relationship between section 2 and section 27(3) which is the disclosure requirement of the Act, right?
MR. DIMOCK: I should know so. I was involved in that case.
MR. DEARDEN: You were counsel.
MR. DIMOCK: Yes.
MR. DEARDEN: Did you win or lose?
MR. DIMOCK: We lost at the appeal. We won at trial -- or we won at the hearing. I guess he who has the last laugh...
MR. DEARDEN: I'm not laughing. Sometimes losing happens, right.
MR. DIMOCK: And if you can take advantage of losing to win another case, that's even better.
MR. DEARDEN: Paragraph 56, Mr. Dimock.
MR. DIMOCK: Yes.
MR. DEARDEN: This again is with respect to the relationship between section 2 and 27(3), so in that case the Court of Appeal held the application

11:41 judge was wrong in interpreting the disclosure requirement of 27(3) of the Act as requiring the patentee back up his invention by data. By doing so, he confused the requirements --
MR. DIMOCK: Sorry, where are you reading from again?
MR. DEARDEN: 56.
MR. DIMOCK: Yes.
MR. DEARDEN: Do you have that, Mr. Dimock?
MR. DIMOCK: Yes, I do now.
MR. DEARDEN: It's on page 24. So, second sentence, "By so doing, he confused the requirements that an invention be new, useful and non-obvious with the requirement under subsection 27(3) that the specification disclose the 'use' to which the inventor conceived the invention could be put:" And cites Consolboard.
MR. DIMOCK: Yes.
MR. DEARDEN: "Whether or not a patentee has obtained enough data to substantiate its invention is, in my view, an irrelevant consideration with respect to the application of subsection 27(3). An analysis thereunder is concerned with the sufficiency of the disclosure, not the sufficiency of

11:42 the data underlying the invention. Allowing Ranbaxy to attack the utility, novelty and/or obviousness of the 546 patent through the disclosure requirement unduly broadens the scope of the inventor's obligation under 27(3) and disregard the purposes of the provision."
Paragraph 57. "While it's true that 27(3) requires the inventor to 'correctly and fully describe' his invention, this provision is concerned with ensuring that the patentee provide the information needed by the person skilled in the art to use the invention as successfully as the patentee."
And at paragraph 59 the Court of Appeal holds, "Only two questions are relevant for the purposes of 27(3) of the Act. What is the invention? How does it work?: See Consolboard...In the case of selection patents, answering the question 'What is the invention?' involves disclosing the advantages conferred by the selection. If the patent specification (disclosure and claims) answers these questions, the inventor has held his part of the bargain."
So the court there is saying the requirements of section 27(3) are not the same as the

11:44 requirements of section 2, correct?
MR. DIMOCK: I don't know whether you can put it simply like that, but they were looking at the requirements of section 27(3) in those paragraphs that you were reading to me.
MR. DEARDEN: Well, why do you say -- I mean the Court of Appeal is saying the applications judge was confused about the requirements that the invention be new, useful and non-obvious with the requirement of 27(3). That seems pretty straightforward to me that they are different requirements.
MR. DIMOCK: 27(3) does deal with what must be in a disclosure ordinarily, and it's been said -- and I think it's the Consolboard case and others thereafter as well -- that the patentee is obligated to describe his or her invention sufficiently well so that any member of the public that's interested and has a practical use for the invention could make the same successful use of the invention after the patent expires.
MR. DEARDEN: I'll run at this one more time, Mr. Dimock. Do you agree that the requirements of section 2 for new and useful, as well as 28.3 for obvious, are separate requirements from

11:45 subsection 27(3), according to this paragraph 53 of the Court of Appeal's decision?

MR. DIMOCK: That is one interpretation you could give to it, yes.

MR. DEARDEN: Do you agree with that interpretation?

MR. DIMOCK: I didn't agree with the decision. No, I did not.

MR. DEARDEN: Once you received it, sir --

MR. DIMOCK: I had to agree with it, yes.

MR. DEARDEN: Tab 17 of the same binder should be Exhibit C-544, Genpharm v Proctor & Gamble, another one of your cases. That you won?

MR. DIMOCK: We won this time.

MR. DEARDEN: You won.

MR. DIMOCK: Yes.

MR. DEARDEN: Paragraph 47. Do you have that, sir? It's right at the bottom of page 12 of 13.

MR. DIMOCK: Yes, I see that.

MR. DEARDEN: So "As counsel for P&G has pointed out" -- that would be you.

MR. DIMOCK: It was, indeed.

MR. DEARDEN: So, "As [Ron Dimock] has

11:46 pointed out, sound prediction and obviousness are considerations with different perspectives. Sound prediction is relied upon by an inventor to justify patent claims whose utility is not actually demonstrated but can be soundly predicted from information and expertise that is available. Obviousness is relied upon by a potential competitor of the patentee who argues that what is claimed in the patent is something that a skilled technician keeping up with the state of the art and common general knowledge would be able to come to directly and without difficulty in the absence of the solution taught by the patent. These are different concepts and they are not to be conflated. The doctrine of sound prediction has no application to the doctrine of obviousness."

In light of the fact that you made that submission, I'm assuming that you embrace that paragraph 47 wholeheartedly?

MR. DIMOCK: At the time I did, yes, and I still do today.

MR. DEARDEN: Do you have your first statement, Mr. Dimock?

MR. DIMOCK: I do.

MR. DEARDEN: Paragraph 7 of your first

11:48 statement.

MR. DIMOCK: The bottom of page 3 of my report?

MR. DEARDEN: Paragraph 70 of the First Report. Sorry, did you say page 3 or page 20?

MR. DIMOCK: I have page 3 of my copy.

MR. DEARDEN: Paragraph 70.

MR. DIMOCK: Oh. I heard 7, sorry. I apologize. I now have paragraph 70. That's at page 20.

MR. DEARDEN: Yes.

So in that paragraph you say "Consolboard and the promise of the patent were inextricably linked together long before 2005. One example of a court decision around the time of the application dates of the olanzapine and atomoxetine patents was Mobil Oil v Hercules Canada." And in paragraph 71 you say, "In Mobil Oil, the validity of patent in suit was challenged on utility grounds for failing to meet the utility promised in the patent," and then you give a quote from Justice Wetston's decision.

Mobil Oil is tab 19 of volume 3, if you could turn it up, sir. Can you turn to page 513?

MR. DIMOCK: I have it.

MR. DEARDEN: So you see paragraph B, the

11:50 second paragraph there, "The defendant argues that the only teaching in the patent to assist the addressee in what he is not to do, is found in the table test results at page 6 of the patent. Counsel argues that the invention's promise of enhanced adhesion is only achieved when a bond strength measurement of at least 250 grams an inch with no metal lift-off is obtained. Since the inter parties tests show that the Hercules film did not reach this level, he submits that there can be no infringement. Further, he relies on the evidence of Mr. Seguin that, in his experience with Hercules film, the typical range of bond strengths is from 100 grams an inch to about 200 grams an inch, also below 250 grams an inch."

Then Justice Wetston holds, "I cannot accept the defendant's argument on this point. The data presented in the patent does not define the promise of the patent. It is merely provided as an example of the enhanced adhesion which may be achieved using the subject film, as compared with a film of homopolymer polypropylene. If it was intended that the invention relate to a film with at least 250 grams per inch bond strength, it would be so claimed. Such is not the case, and I see no

reason to construe the patent as limiting the inventor's intention in this way."

So, Mr. Dimock, Justice Wetston did not accept the argument of counsel that the statement in the disclosure of a bond strength measurement of at least 250 grams per inch was going to define the promise because that was not in the claims, correct?

MR. DIMOCK: I think what he was saying is that that was an example given, and that what he did decide, construing the disclosure, was the promise that was given was not an adhesion level that high but that it be an enhanced adhesion, and he concluded that the claims met the enhanced adhesion as he interpreted it to be and, therefore, the claim satisfied the promise of a disclosure of the patent that there be enhanced adhesion. He concluded that there was not a promise that the adhesion had to be 250 grams per inch.

MR. DEARDEN: Where do I see Justice Wetston saying there was a promise of enhanced adhesion? A promise?

MR. DIMOCK: Well, counsel was arguing that.

MR. DEARDEN: No, Counsel was arguing that there was --

MR. DIMOCK: The invention --

THE PRESIDENT: Hold on a second. One at a time.

MR. DEARDEN: Go ahead, Mr. Dimock. Sorry.

MR. DIMOCK: In that sentence, the second sentence after letter b, "Counsel argues that the invention's promise of enhanced adhesion..." so counsel was saying that there is a promise of enhanced adhesion. The question is at what level. And what Justice Wetston decided was that that level was not as high as 250 grams per inch. He did conclude that the promise of enhanced adhesion was, indeed, effected by the claims as drafted and embodiment of those claims.

MR. DEARDEN: Where did Justice Wetston use the word "promise" of enhanced adhesion, as opposed to the claims only claimed enhanced adhesion as opposed to counsel arguing that there was a promise of bond strength of 250 grams per inch? Justice Wetston made no findings of promise, did he? What he did do was he rejected the counsel trying to argue a statement out of the disclosure for 250 grams an inch was a promise that the patentee should have been held to, and he rejected that because that

wasn't in the claims. Agreed?

MR. DIMOCK: You had a lot in that question. My reading of the case was that he did cite MacMillan Bloedel v Consolboard with regard to a promise of utility, and I understood through the evidence and his analysis of it that there was an argument made about the promise being as high as 250 grams per inch, and I just can't put my finger on the particular sentence in Justice Wetston's reasons where he dismisses the argument or dismisses the attack, but the discussion, it seemed to me, was surrounding a promise and whether or not it was a promise of enhanced adhesion or a promise of enhanced adhesion at the level of 250 grams per inch.

MR. DEARDEN: That definitely is on page 513 out of the mouth of counsel who argued that there was a promise of enhanced adhesion of 250 grams per inch in the disclosure, and he rejected it. Justice Wetston rejected that.

MR. DIMOCK: Yes, he did.

MR. DEARDEN: Okay. Got that. And the enhanced adhesion, Mr. Dimock, was in the claims, right?

MR. DIMOCK: Yes.

MR. DEARDEN: The 250 grams per inch was

in the disclosure?

MR. DIMOCK: That's correct.

MR. DEARDEN: When you first were answering my question about what Justice Wetston said about the example given, that's the 250 grams per inch adhesion, that example is in the disclosure, not the claims. Correct?

MR. DIMOCK: The claims did not recite an enhanced adhesion of 250 grams per inch. There was an example given with that enhanced adhesion, but he said that was not a promise made.

MR. DEARDEN: Where does Justice Wetston say that is not a "promise" made?

MR. DIMOCK: He dismissed the argument. The argument was that that was a promise and he dismissed it.

MR. DEARDEN: You agree with me he doesn't use the words you just used on page 513, correct?

MR. DIMOCK: On 5 --

MR. DEARDEN: 13. The quote I just read to you.

MR. DIMOCK: I did not recite it verbatim from Justice Wetston's decision, no.

MR. DEARDEN: So, Mr. Dimock, if a

defendant advanced this argument today that you could look to the disclosure for a bond strength of at least 250 grams per inch with no metal lift-off obtained, would the court find that to be a promise that had to be met by the patentee today? 11:58

MR. DIMOCK: No, it would not.

MR. DEARDEN: It would not?

MR. DIMOCK: No. Based on the court's interpretation of the patent at that time, the interpretation would be no different today.

MR. DEARDEN: So an adhesion strength of 250 grams per inch would not be seen as a promise that the patentee would be held to if that was litigated in Federal Court today, according to your evidence?

MR. DIMOCK: That's my opinion, yes.

MR. DEARDEN: Your second statement, Mr. Dimock, if you could turn to paragraph 75, please.

MR. DIMOCK: On page 21?

MR. DEARDEN: Yes. You say, "Their views, in my opinion, are far from correct. The courts are not 'scouring the patents for promises', as both Professor Siebrasse and Reddon seemingly state. Rather it is the parties in pharmaceutical

litigation -- and not the courts -- that are now placing promises that are made in the patents front and center before the courts." 12:00

Mr. Dimock, what happened that caused the parties to now place promises made in the patents front and center?

MR. DIMOCK: Up until 1995 we had no pharmaceutical litigation to speak of, and it took a number of years for both the pharmaceutical and the generic side of the industry to understand the proper procedures. And then it took a case where a patent was held invalid for not fulfilling the promise that one would, as counsel, try to run that same argument in your own case, and so there were attempts to invalidate a patent on old law that was now being used in the pharmaceutical field in a way that was succeeding.

MR. DEARDEN: You're saying it took a case where a patent was held invalid for not fulfilling the promise that one would as counsel try to run that same argument in your own case. What case are you referring to?

MR. DIMOCK: When I read up on -- I can't give you the recitation of that case but my point was that, when a case succeeds and you read about it, you

then try to adapt it to your own cases that you have in your own files, so that you have that practice. My comment here was really to the point that Messrs. Reddon and Siebrasse were suggesting that it was the court's undertaking to scour the patents for promises when, in fact, it was counsel who were asking the courts to interpret the disclosures of the patents before the courts in their cases, with the intention that the courts would find promises made in those disclosures that could not be met by the claims. 12:01

MR. DEARDEN: My question, sir, on your paragraph 75 of your Second Report, is what happened that caused the parties in pharmaceutical litigation to now start placing promises made in the patents front and center before the courts. I have as your answer "It took a case where a patent was held invalid for not fulfilling the promise that one would as counsel try to run that same argument in your own case," and I'm trying to identify what case triggered this placing of promises front and center before the courts.

MR. DIMOCK: As I understand, Mr. Siebrasse did mention some cases as of 2005, I believe. That's what I'm referring to.

MR. DEARDEN: So those three cases, that's what you're referring to? Okay. 12:03

Prior to 2005, how many patents were invalidated for lack of utility for failure to soundly predict or demonstrate a promise construed from the disclosure of the patent?

MR. DIMOCK: I can think of four -- or I can think of three. The New Process Screw, the Consolboard at the trial division --

MR. DEARDEN: Before Justice Collier?

MR. DIMOCK: Yes. And then the case that I also lost, the Amfac case where the Court of Appeal upheld the decision of Justice Strayer when Justice Strayer interpreted the disclosure of the patent to make French fry cuts, that the disclosure promised a level of utility such that the outside cuts would be separated at the knife, not downstream, and because the claim did not meet that utility, that the claim did not have the feature such that the outside slabs could be separated at the knife and, therefore, did not satisfy that promise of utility, they held it invalid on the basis of claims broader than the invention disclosed. As I said, overbreadth and utility sometimes do overlap and that was one case that the argument could have been made that the

patent was invalid, not only for claims broader than the inventions disclosed but also for inutility, since the claim could not meet the promise of utility of separation at the knife plate. 12:05

MR. DEARDEN: But, in fact, in Amfac the only argument that was made was overbreadth --

MR. DIMOCK: That's correct -- yes and -- I'm sorry, I didn't mean to interrupt you.

THE PRESIDENT: Could you repeat your question?

MR. DEARDEN: Yes. So in Amfac the only argument that was made was overbreadth.

MR. DIMOCK: That's right. There were discussions at the Court of Appeal as to whether it was made by inutility, but the end result was that it was claims broader than the invention disclosed.

MR. DEARDEN: And the decision was an overbreadth decision?

MR. DIMOCK: That's correct.

MR. DEARDEN: And that -- what do I call it, French fry maker?

MR. DIMOCK: Yes. You can call it a very successful French fry maker.

MR. DEARDEN: It worked?

MR. DIMOCK: It worked.

MR. DEARDEN: It just didn't -- 12:06

MR. DIMOCK: It didn't work for the promise of utility made. And it was held invalid because, even though it did work, it didn't meet the promise.

MR. DEARDEN: Other claims were upheld?

MR. DIMOCK: Other claims were not alleged to be invalid for overbreadth because those other claims did have the means by which the potatoes could be separated, the outside slabs could be separated at the knife plate.

MR. DEARDEN: So the question I posed to you was, prior to 2005, how many patents were invalidated for lack of utility for failure to soundly predict or demonstrate a promise construed from the disclosure of the patent, and you've given me three cases, New Process Screw, Consolboard and Amfac, and in none of those cases, Mr. Dimock, was there an analysis of a demonstration or sound prediction, correct?

MR. DIMOCK: In none of those three cases was there an issue of sound prediction, that's right.

MR. DEARDEN: And was there an issue that the demonstration had to be as of the date of filing in those three cases?

MR. DIMOCK: Not that I recall in the Amfac case, and not what I could discern from reading the reasons for judgment in either New Process, nor Consolboard trial division. And, based on also my recollection, having worked on Consolboard. 12:08

MR. DEARDEN: Can you turn to paragraph 44 of your first statement, please? Now we are moving into the area of Patent Medicines (Notice of Compliance) decisions.

MR. DIMOCK: Paragraph 44 is on page 12?

MR. DEARDEN: It is page 12. "The proceedings under the Patented Medicines (Notice of Compliance) regulations do not resolve issues as to whether a listed patent is actually invalid or not infringed as between the parties or as against the world. Rather, the proceedings are limited to determining whether an allegation of non-infringement or invalidity justifies the issuance of an NOC" -- which is Notice of Compliance, right?

MR. DIMOCK: That's right, yes. Some call it NOC.

MR. DEARDEN: That's a terrible acronym. "Notice of Compliance by a Minister of Health for a particular generic pharmaceutical product. A decision that an allegation of invalidity is

justified may lead to a Notice of Compliance being issued but does not render the patent invalid under section 60 of the Patent Act. Rather the patent remains valid and can be asserted against the generic in a subsequent patent infringement action or be involved again with other generics in separate proceedings under the Patented Medicines (Notice of Compliance) regulation. This has become a reality in some disputes." 12:10

Firstly, sir, when Justice Hughes issued his decision in Raloxifene in 2008 -- and it's at tab 4, C-115 if you need to look at it, but I think you're quite familiar with it, when he issued his decision in that Patented Medicine (Notice of Compliance) proceeding, there was no determination by the Federal courts about the validity of Lilly's Raloxifene patent, correct? He didn't invalidate that patent?

MR. DIMOCK: He did not invalidate the patent. He said that Lilly didn't satisfy its onus to show that the allegation was not justified.

MR. DEARDEN: I'm just going to rephrase that to make sure the record is clear. Justice Hughes in the Raloxifene decision did not invalidate that patent. There could be then a subsequent action

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by Lilly for infringement of the generic who obtained the Notice of Compliance to sell its generic version of Raloxifene. 12:11

MR. DIMOCK: Pursuant to the regulations and the interpretation of those regulations by the courts, Justice Hughes did not have the jurisdiction to invalidate in that hearing. But there are now some cases under PM(NOC) proceedings where they're almost having them as a hybrid, trials and hearings, but I believe that was not one of them.

MR. DEARDEN: That wasn't one of them.

MR. DIMOCK: That was not one of them, I believe.

MR. DEARDEN: Decisions in these Patent Medicine (Notice of Compliance) proceedings are precedents in patent infringement and impeachment actions, right?

MR. DIMOCK: Yes.

MR. DEARDEN: For instance, Supreme Court of Canada's decision in Sanofi Plavix, as we call it, R-013, tab 21, and Pfizer v Novopharm which is tab 14, R-197, those two Supreme Court of Canada decisions were dealing with Notice of Compliance applications, yet they are judicially cited and considered by the courts like over a hundred times,

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right? 12:13

MR. DIMOCK: I don't know whether over a hundred times, but they are cited. Our patent law over the last 10 to 15 years has been driven by pharmaceutical cases, whether they be PM(NOC) hearings or whether they be trials. It's a very active part of litigation. And yes, you're right, even though it's a decision from a judge in a PM(NOC) hearing, it is his or her view of the law which you can apply in any type of case.

MR. DEARDEN: And when it comes from the Supreme Court of Canada, that law is going to be cited by counsel in their factums and it's going to be cited by judges who are making decisions on those issues that are dealt with by those Supreme Court decisions, right?

MR. DIMOCK: Yes.

MR. DEARDEN: And we find PM(NOC) decisions are cited by Patent Office examiners in Office actions?

MR. DIMOCK: I can't point to one in particular, but I can't imagine that that's not the case.

MR. DEARDEN: Well, they're in MOPOP, right?

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MR. DIMOCK: I've heard that, yes. 12:14

MR. DEARDEN: You mean you don't have MOPOP as a reference tool like right --

MR. DIMOCK: No, I don't use MOPOP as a source of authority in any case I've argued. If I've ever referred to MOPOP, it's to perhaps about procedures in the Patent Office, but I've been very reluctant to use MOPOP as a source of law in any case I argued. I could stand to be corrected, but that's my recollection of the cases I have argued.

MR. DEARDEN: And I'm not doubting your recollection, sir, but you were in the room when I was cross-examining Dr. Gillen this morning?

MR. DIMOCK: I certainly was.

MR. DEARDEN: And you heard my reference to two Federal Court cases --

MR. DIMOCK: Yes, Justice Shore's case and --

THE PRESIDENT: Can you let Mr. Dearden finish?

MR. DEARDEN: Go ahead, Justice Shore's decision and Justice Gibson's decision?

MR. DIMOCK: That's right.

MR. DEARDEN: In those two cases. So the courts cite MOPOP from time to time.

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MR. DIMOCK: I don't know whether from time to time. It depends on the type of issue that's before the court. As I said, it would be my practice, if I ever did cite MOPOP, it would be in relation to the practice in the Patent Office as opposed to being an authority of substantive patent law or of patent litigation practice. 12:16

MR. DEARDEN: But you have cited MOPOP in your Second Report at page 27, haven't you?

MR. DIMOCK: Second Report, page 27. Yes, I did --

MR. DEARDEN: You did. Mr. Dimock, you did rely on MOPOP in paragraph 97 of your second Expert Report, didn't you?

MR. DIMOCK: I did put that in there, yes.

MR. DEARDEN: Paragraph 158 of your First Report?

MR. DIMOCK: Page 46?

MR. DEARDEN: Yes. The last very long sentence that starts, "Although there are more reported decisions in recent years about the issues of utility concerning pharmaceuticals than any other subject matter, that is explained by the large volume of pharmaceutical cases in the Federal Court due to

Patented Medicine (Notice of Compliance) Regulations, not that pharmaceutical inventions are treated differently under the law of utility." 12:17

So, Mr. Dimock, the Patented Medicines (Notice of Compliance) Regulations come into force in 1993, correct?

MR. DIMOCK: Yes.

MR. DEARDEN: And, as of 1993, a generic could serve a notice of allegation on a pharmaceutical patentee alleging it was not infringing the patent and/or the patent was invalid, right?

MR. DIMOCK: Yes, the so-called second person could make either/or both of those allegations.

MR. DEARDEN: And the so-called second person is the generic?

MR. DIMOCK: Yes.

MR. DEARDEN: Then in response the pharmaceutical patentee would typically file a notice of application in the Federal Court seeking an order that prohibits the Minister of Health from issuing a Notice of Compliance to the generic, right?

MR. DIMOCK: You said "typically"?

MR. DEARDEN: You think all the time?

MR. DIMOCK: Likely, but I don't want to say absolutely. But typically? Fair enough. 12:18

MR. DEARDEN: But that's the process?

MR. DIMOCK: Fair enough.

MR. DEARDEN: You get a notice of allegation from the generic. You want to stop them going on the market and getting an NOC. You file a notice of application in Federal Court and you ask for an order prohibiting the Minister of Health from issuing a Notice of Compliance to that generic?

MR. DIMOCK: Yes.

MR. DEARDEN: So, from 1993 to 2004, there isn't a single Patented Medicines (Notice of Compliance) case that decided that a pharmaceutical patent lacked utility, right? Not one. Zero.

MR. DIMOCK: I believe you are right. As I said -- well, I've answered your question. That's all I have to do.

MR. DEARDEN: Paragraphs 142 and 143 of your Second Report.

MR. DIMOCK: On page 38? I'm reading paragraph 142.

MR. DEARDEN: "As I noted...PM(NOC) decisions are not the end of the road for patentees and generics alike. A subsequent trial on the merits

of the patent's infringement and invalidity can come to the avail of either side. Prior PM(NOC) proceedings do not create or abolish any rights of action between the parties, nor are they adjudicative or binding on subsequent actions for infringement and validity. In this regard, PM(NOC) proceedings are favorable to innovator litigants as they have 'a second chance' through a patent infringement action." 12:21

Sir, when an innovative pharmaceutical company has failed to obtain an order prohibiting the Minister of Health from issuing a Notice of Compliance to the generic on the ground that the patent lacked utility, you'll agree that an innovator company has never been successful in the subsequent infringement action? Whereas lack of utility -- so the order doesn't go in the NOC proceeding because the patent was found to lack utility, action is brought for infringement subsequently by the pharma patentee and never has there been a successful action when the patent was found to lack utility at the NOC stage -- or the PM(NOC) stage. Right?

MR. DIMOCK: I'm not aware of any.

MR. DEARDEN: That's not much of a second chance, is it, when you lose on utility at the PM(NOC) proceeding?

MR. DIMOCK: If the generic succeeds at the PM(NOC) hearing, it is likely to get a Notice of Compliance within a matter of days, and there's no appeal that can be taken by the pharmaceutical company that was the patentee. On the other hand, if the patentee succeeds in getting a prohibition order, the generic can appeal that decision. The reason why the patentee cannot appeal is the Court of Appeal has said it is academic. Once the compliance is issued and the generic is on the market, they really can't pull it back. 12:23

Then at the trial there is an opportunity for both sides to delve more deeply into any of the issues before the court because in the case on infringement or impeachment, as the case may be, there's discovery, which one doesn't have in a PM(NOC) hearing, so there is a greater second chance to delve into things in the trial of an infringement action or a trial of an impeachment action. So I don't know that I can agree with you to say that it's not much of a second chance.

MR. DEARDEN: I appreciate that there is a second proceeding available to a pharma patentee who loses the application for the prohibition order in the PM(NOC) proceedings, but when it comes to

losing that PM(NOC) proceeding because the patent was found to lack utility, there has never been a second chance in terms of the pharma patentee winning the infringement action when it lost on utility in the PM(NOC) proceeding, right? 12:25

MR. DIMOCK: As I said, I'm not aware of a case where it's been reversed, no.

MR. DEARDEN: That's binder 1.

MR. DIMOCK: How many do you have?

MR. DEARDEN: 3.

MR. DIMOCK: It's like being in a dentist chair. How many more minutes?

MR. DEARDEN: I have four hours.

MR. DIMOCK: I have all the time.

MR. DEARDEN: Keep going, Mr. President?

THE PRESIDENT: If you're moving to a new subject matter and you cannot complete it in five minutes...

MR. DEARDEN: I'm sorry. I thought we were breaking at 1.

THE PRESIDENT: 12:30. Maybe there's a new agreement between the parties.

MR. DEARDEN: None that I'm aware of.

THE PRESIDENT: Okay. 12:30. If we break now, then we will recommence at 1:25. What I

assume is that you are now going into a new area which takes more than three minutes? 12:26

MR. DEARDEN: Yes.

THE PRESIDENT: Fair assumption.

Mr. Dimock, you are under testimony and are not allowed to discuss this case with anyone.

MR. DIMOCK: I understand.

THE PRESIDENT: Recess until 1:25.

(Recess taken)

MS. CHEEK: As a preliminary matter, I want to report that the parties are continuing to confer on the schedule and Canada is confirming the availability of some of their witnesses, but we would expect that by the coffee break we would have a proposal to the Tribunal which will accelerate the schedule and have us not running until next Thursday. But we need to confirm some witness availability.

THE PRESIDENT: Or there are two alternatives that the Tribunal was thinking. One is that Saturday is actually a free Saturday, at least a non-hearing day, or the day prior to the closing statements. So there are two alternatives which may also be considered. Or accelerate. So what you were considering is that you finish on Wednesday?

MS. CHEEK: Or even Tuesday. We will

continue to confer and we will keep the Tribunal's proposals in mind. 01:28

THE PRESIDENT: But that is on the basis that we also continue on Saturday?

MS. CHEEK: Yes, probably an abbreviated day on Saturday.

THE PRESIDENT: Then this also raises a question for Mr. Dearden and your estimate -- I know it's a non-binding estimate -- for your cross-examination?

MR. DEARDEN: It feels like two and a half hours.

THE PRESIDENT: More? Or including what we have already had?

MR. DEARDEN: More, yes. I had four. I think I'm on track.

THE PRESIDENT: You are at 48 minutes.

MR. DEARDEN: We may finish by the break.

THE PRESIDENT: It's okay. Please continue.

MR. DEARDEN: Mr. Dimock, all set?

MR. DIMOCK: Yes.

MR. DEARDEN: Can we go back to Consolboard, which is in volume 3, tab 18.

MR. DIMOCK: Yes, I have it.

MR. DEARDEN: This morning during your presentation, as I recall, Mr. Dimock, you said several times that the specification is understood to mean the disclosure of the patent. 01:30

MR. DIMOCK: Not always, Mr. Dearden. Under the Patent Act the specification is defined to include the disclosure and the claims. However, in normal parlance between patent lawyers, people tend to use specification to mean disclosure, or that the disclosure is the body of the specification or that the specification is, indeed, the disclosure, but never would the specification be the claims only. I think that's what I was trying to say.

MR. DEARDEN: If you look at paragraph 26 of Consolboard, we have the Supreme Court of Canada telling us exactly what specification means, don't we? Paragraph 26, which is a long paragraph. The part I'm looking at is right at the bottom of the page above paragraph 27. You see that?

MR. DIMOCK: I'm sorry. I'm having a hard time trying to find paragraph numbers.

THE PRESIDENT: You are quoting from the Consolboard in R-011? That has numbers.

MR. DEARDEN: C-118 is the one I thought was in our binder.

01:32 THE PRESIDENT: I'm working always on the same copy because --

MR. DEARDEN: There's no paragraph numbers. Page 520, and it will be the paragraph that starts "In essence." I'll read it in.

"In essence, what is called for in the specification (which includes both the 'disclosure', i.e. the descriptive portion of the patent application, and the 'claims') is a description of the invention and the method of producing or constructing it, coupled with the claim or claims which state those novel features in which the applicant wants an exclusive right. The specifications must define the precise and exact extent of the exclusive property and privilege claimed."

So, Consolboard, the Supreme Court of Canada is saying the specification includes the disclosure and the claims, correct?

MR. DIMOCK: In that paragraph, yes.

MR. DEARDEN: And in your presentation binder, tab 1 -- so after the end of slide 21 -- you have some extracts from cases and commentators, and if you go to the third page of those extracts, Mr. Dimock, you should be finding the 1978

01:34 Consolboard v MacMillan Bloedel at the bottom.

MR. DIMOCK: Yes, that's the Federal Court decision.

MR. DEARDEN: That's Justice Collier, who we spoke of this morning?

MR. DIMOCK: Yes.

MR. DEARDEN: And you've extracted paragraph 164 as that first paragraph, and then the Fox citation is found at paragraph 169.

MR. DIMOCK: I believe that's right.

MR. DEARDEN: I'm only interested in paragraph 164, the first paragraph that you have on that extract. It reads "One of the essentials in both these patents is that a uniform map be laid down by the felting process or the apparatus described. Various expressions are used in patent '232, one finds in column 1 'uniform distribution', in column 2 'substantially uniform thickness' and 'uniform deposition'. There are many other similar phrases throughout both patents. The requirement of uniformity is specifically set out in each of the claims in suit."

So you agree, Mr. Dimock, that the trial judge, Justice Collier, found that the requirement of uniformity is specifically set out in each of the

01:35 claims in suit?

MR. DIMOCK: That's what he said.

MR. DEARDEN: The Monsanto decision should be at tab 1 of volume 1, it should be C-61, and your First Report, paragraph 139. Let's go to it first.

MR. DIMOCK: Mr. Dearden, I don't want to complain, but I'm having a hard time hearing when you refer to numbers.

MR. DEARDEN: Okay. We should be at page 41 of your first part, paragraph 139.

MR. DIMOCK: I'm there.

MR. DEARDEN: "The trial court decision referred to by Professor Siebrasse is a decision by Justice Hughes, my former law partner, concerning the drug Raloxifene in Eli Lilly v Apotex. As in the Monsanto case, one of the questions before Justice Hughes was 'whether the disclosure in the patent was adequate to tell a person skilled in the art how to practice the invention or whether it discloses enough so that a person skilled in the art could "soundly predict" that it would work'."

And in your footnote 162 in that paragraph you cite to Justice Hughes' Raloxifene decision at R-200. Right?

01:37 MR. DIMOCK: Yes.

MR. DEARDEN: You'll agree that the Monsanto decision of the Supreme Court of Canada does not make a finding that the factual basis and line of reasoning for sound prediction of utility must be disclosed in the patent?

MR. DIMOCK: Impliedly, it did. Monsanto had before it, the Supreme Court of Canada had in the patent application, reference to three examples to support the claim for 126 chemicals. That was the factual basis. And the common general knowledge, which was as of the date of the patent application gave the basis, the reasoning, for being able to claim all 126 chemicals. So it didn't use the very words that are found in Justice Binnie's decision in the AZT. However, that's the inference you draw from reading the case and knowing the facts of it.

MR. DEARDEN: And it didn't use the very words found in Justice Hughes' 2008 Raloxifene decision either, correct? That's Monsanto. Did not use the very words used by Justice Hughes?

MR. DIMOCK: I've never done a side-by-side comparison.

MR. DEARDEN: Is my statement fair, though?

01:39

MR. DIMOCK: Yes, I accept that. If you say so, Mr. Dearden, I accept it.

MR. DEARDEN: You know, we could be out of here by 2:00 if you keep doing that!

MR. DIMOCK: I don't plan to.

MR. DEARDEN: Do you agree that the Monsanto decision did not find that in cases of sound prediction of utility there is a heightened or an enhanced disclosure requirement on the patentee?

MR. DIMOCK: Well, the word "enhanced", I believe, has this origin. Every patent disclosure, whether it be for sound prediction or one that was demonstrated utility or what-have-you, requires sufficient disclosure so as to permit another to make and use the invention after the monopoly expires. And I mentioned that earlier this morning.

When they talk about "enhanced" disclosure I believe what they're talking about is the disclosure of the factual basis upon which the sound prediction is based, and either the reasoning for that is to be found in the common general knowledge possessed by chemists, as the case may be, or whether or not it's explicitly stated, as was the case in AZT, where it was a certain phenomenon which they drew upon as the basis, or as the reasoning. So

01:41

I believe when you refer to an "enhanced" disclosure it's referring to going beyond just telling you how to make it. It's telling you why, if you make it and make all the compounds, they will have usefulness because of the factual basis, in that case in Monsanto three examples. And the common general knowledge, the reasoning, will make you conclude that you can make all 26 and they would work.

MR. DEARDEN: Enhanced or heightened disclosure has been decided to be -- it's a phrase, they're not my phrases, they're Federal Court of Appeal phrases -- that you have to have the factual basis and the line of reasoning in the patent, right?

MR. DIMOCK: Yes.

MR. DEARDEN: So that's what I'm referring to as "heightened" or "enhanced" disclosure requirement, that in cases of sound prediction, you have to have the factual basis and line of reasoning in the patent, and I'm not going to find that anywhere in Monsanto, am I?

MR. DIMOCK: You asked me that question a few moments ago, and I said you won't find those explicit words, but you do find it impliedly by knowing what it is that the case was all about.

MR. DEARDEN: Monsanto made no finding

01:43

that factual basis had to be disclosed. Agree?

MR. DIMOCK: They accepted the fact that the three examples given and what was said by the two experts about the common general knowledge was sufficient to make the sound prediction.

MR. DEARDEN: I'll ask it again. Agree or disagree. Monsanto made no finding that the factual basis had to be disclosed?

MR. DIMOCK: It didn't make that explicit finding. Yes, it did not. But, you know, and we've gone back and forth on this now three times, but I'm saying impliedly you understand that to be the case.

MR. DEARDEN: Let's just go to AZT for a second. It's at tab 2 of volume 1, Supreme Court of Canada decision in 2002.

MR. DIMOCK: Yes.

MR. DEARDEN: I'm going to take you to paragraph 70.

MR. DIMOCK: That's on page 186?

MR. DEARDEN: Yes, of the SCR report. Paragraph 70 contains the tripartite test for sound prediction, right?

MR. DIMOCK: Yes.

MR. DEARDEN: Let me put it on the record.

01:44

"The doctrine of sound prediction has three components. Firstly, as here, there must be a factual basis for the prediction. In Monsanto and Burton Parsons, the factual basis was supplied by the tested compounds, but other factual underpinnings, depending on the nature of the invention, may suffice. Secondly, the inventor must have, at the date of the patent application an articulable and 'sound' line of reasoning from which the desired result can be inferred from the factual basis. In Monsanto and Burton Parsons, the line of reasoning was grounded in the known 'architecture of chemical compounds' but other line of reasoning, again depending on the subject matter, may be legitimate. Thirdly, there must be proper disclosure. Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practiced."

And there's a citation to Dr. Fox.

"It is generally not necessary for an inventor provide a theory of why the invention works. Practical readers merely want to know that it does work and how to work it. In this sort of case, however, the sound prediction is to some extent the

quid pro quo the applicant offers in exchange for the patent monopoly. Precise disclosure requirements in this regard do not arise for decision in this case because both the underlying facts (the test data) and the line of reasoning (the chain terminator effect) were in fact disclosed, and disclosure in this respect did not become an issue between the parties. I therefore say no more about it." 01:46

You'll agree that Monsanto did not create that tripartite test that I see in paragraph 70 of Justice Binnie's decision in AZT?

MR. DIMOCK: If I could answer your question this way, it did not articulate the tripartite test that Justice Binnie has done, but what you see here in Justice Binnie's articulation of the law is that Monsanto had the sound basis and Monsanto had the line of reasoning he cites for both the Monsanto case, and he said that there must be proper disclosure. And, as I indicated in my presentation and in my two reports, it's understood that you must have claims that are fairly based on the disclosure. Fairly based on the disclosure. And those words have meaning in that the disclosure must give you the basis upon which to allow you to claim the claims on a sound prediction.

So "fairly based on the disclosure" implies that there is a need for a proper disclosure. 01:48

MR. DEARDEN: At paragraph 136 of your First Report --

MR. DIMOCK: I have it.

MR. DEARDEN: -- you're saying "In its reasons, the Supreme Court in Monsanto emphasized that a sound prediction must not go beyond the consideration provided by the disclosure. The court quoted the following passage from the British case Olin Mathieson, and held that the last sentence, which refers to whether a claim is fairly based on the disclosure, captures 'what is meant by a sound prediction':".

The Supreme Court of Canada adopted the Olin Mathieson case as part of Canadian law in Monsanto, correct?

MR. DIMOCK: That's fair. It adopted that aspect of it. There was an obviousness part of Olin Mathieson but, insofar as the fairly based claim aspect of the case, they adopted that statement, which I believe Justice Graham took from Lionel Hill's submissions.

MR. DEARDEN: And he was counsel for plaintiff, Sir Lionel?

MR. DIMOCK: Yes. 01:50

MR. DEARDEN: While we have your paragraph 136 open and that quote from Olin Mathieson, which I'm going to go to next, you see where you have underlined the very last lines that are underlined, "but if, when attacked, he survives this risk successfully, then his claim does not go beyond the consideration given by his disclosure, his claim is fairly based on such disclosure in these respects, and is valid."

The "when attacked" is at trial, correct?

MR. DIMOCK: That would appear to be the case, yes.

MR. DEARDEN: So Olin Mathieson is at tab 3, C-461, the decision of Justice Graham in 1970, the High Court.

MR. DIMOCK: Yes.

MR. DEARDEN: You deal with this decision at paragraph 119 of your Second Report.

MR. DIMOCK: I have it.

MR. DEARDEN: "The Court concluded that based on the skilled person's reading of the disclosure alone, the patent description provided more than ample support for basing a sound prediction of the stated utility. It reached this conclusion in

light of the following: (a) the processes used to make ten different example compounds belonging to the claimed class were described in the specification itself (reproduced in the reported decision): (b) compounds with similar 'base' structures were previously disclosed in the competitors' patents and known to have therapeutic activity; and (c) the skilled person's expectations based on the common general knowledge and understanding in what was described as a 'well-worked field'." Okay? 01:52

You cite for the (b) and (c) basis, for the conclusion you say was reached by Justice Graham, (b) and (c) you cite page 168 of the decision in footnotes 130 and 131. Right?

MR. DIMOCK: That's what the report says.

MR. DEARDEN: We're going to go there. Let's go to page 168 of Olin Mathieson, which is tab 3, C-461.

MR. DIMOCK: And I see, just before you go there, Mr. Dearden, that it looks as though I had the wrong page, because 168 is the submission of John Whitford.

MR. DEARDEN: Right, who was counsel for the plaintiffs, and Sir Lionel is actually counsel for the defendants. So we both got it wrong.

01:54 MR. DIMOCK: We both got it wrong.
MR. DEARDEN: But he was counsel.
MR. DIMOCK: He was counsel.
MR. DEARDEN: So what we see on page 168, though, Mr. Dimock, is you do find there your (b) and (c) basis for what you say the conclusion reached by the judge was. The 119(b) of your second Expert Report I find reference to at line 35, which is "Of the cited prior art three particular disclosures, two in the Journal of Organic Chemistry by Nathan Smith and one patent specification, do show [that] group in the '2' position and the same kind of basic structure as the ones claimed in the patent in suit," and if you go up to line 25, your paragraph 119(c) contains the part about work the field.
But that's not what Justice Graham used to conclude -- it wasn't the basis for Justice Graham's conclusion at all, was it?
MR. DIMOCK: No. Those were submissions made.
MR. DEARDEN: Right. So let's go to pages 195, 196. Firstly, the issue that was before Justice Graham at trial was whether there was a sound prediction that the claimed compounds that were untested at the time of trial were useful. Right?

01:56 MR. DIMOCK: That's right.
MR. DEARDEN: There was no issue as to the sound prediction at the time of filing, which was 1956, right?
MR. DIMOCK: I don't understand what you mean by that.
MR. DEARDEN: Well, first of all, you agree that the patent was filed in 1956? You can believe me on that?
MR. DIMOCK: I'll believe you on that.
MR. DEARDEN: Was there any issue in Olin Mathieson that the sound prediction had to be at the time of the filing of that patent, which was 1956? And I put it to you that it wasn't an issue.
MR. DIMOCK: I don't recall now that particular issue being dealt with by Justice Graham. The issue is whether or not the ten examples and the common general knowledge and the understanding of the chemistry relating to these types of chemicals would be enough to say that the claim to this large class was fairly based on the disclosure.
MR. DEARDEN: On page 193 of Justice Graham's decision at the bottom, Justice Graham states in his reasons, "There are certain other matters dealt with in the evidence bearing on the

01:58 questions of obviousness, width of claim and consideration which in my judgment are of importance and support the view that the claim here is fairly based on the disclosure in the specification."
And he has four of them in round brackets, right? Parentheses. The first one, No. 1, one of the pieces of evidence that he relies on is this Robson and Stacey Recent Advances in Pharmacology which you see under the formula in the middle of the page. You see that? Right after the --
MR. DIMOCK: Yes, I see that.
MR. DEARDEN: And Robson and Stacey's work was done in 1962, correct?
MR. DIMOCK: He cites from it as the 1962 publication, that's right.
MR. DEARDEN: Right. And the judge also references of importance the commercial success. "It may be as well to mention here that the figures of sales of [the compounds], both worldwide and in the United Kingdom, are shown in the bundle 'Confidential documents'. While it is not necessary to mention the actual figures in this judgment, it is obvious that both drugs have been very successful. This bundle also contains details of the work by SKF on the

01:59 substitution of CF3 in various compounds prior to 1955."
Your eyes may be better than I mean, Mr. Dimock. Is that a 3 or a 2? CF?
MR. DIMOCK: It's a 3. I must say, I'm having a hard time reading the small print because of the light -- I shed a shadow on the page so I'm having a hard time, but I'll do my best. But it is a 3.
MR. DEARDEN: So you can't see and I can't speak loud enough. We're doing really well!
"The evidence showed this was not a selected list and supports the conclusion, referred to by Dr. Gordon, that they had no reason to think in 1955 that CF3 was likely to enhance activity. This work is unpublished."
So that's No. 1 of the important considerations by Justice Graham in arriving at his conclusion, and if you flip the page to page 195, No. 3 is "The CF3 substitution in the '2' position for virtually any given basic side chain confers the highest known activity. See the evidence of Dr. Simkins commenting on Sexton 1963 edition page 447. Nothing has happened since to throw doubt on this statement."

No. 4 is: "All CF3 substituted...bodies which the plaintiffs have made and tested show therapeutic activity. The defendants have not given evidence that they have found any such body which does not have therapeutic activity."

And here's what Justice Graham says: "(3) and (4) above are of great importance because it seems right, and I so hold, that the plaintiffs are entitled to rely on the fact that it appears to be correct that the CF3 substitution confers higher activity than any other substitution with any given side chain. They do not say or promise this in their specification, their promise being more modest, namely, that the compounds are therapeutically active. But if it be true, and it appears to be so from works such as those of Sexton, [which is 1963] and Robson and Stacey [1962] subsequent to the date of the patent, that such enhanced activity is obtained by the use of the CF3 substitution, then it is clear that the plaintiffs have, in fact, 'contributed, and indeed contributed considerably, to the common stock of human knowledge' by their invention, even if the promise in their specification can, as a matter of the words be said to guarantee nothing more than the therapeutic activity which is

said to be the characteristic of all phenothiazines."

Am I saying that right?

MR. DIMOCK: Yes, that's it.

MR. DEARDEN: "In my judgment it is what the patentee has actually achieved and not what he has promised (provided, of course, his promise is not false) which matters from the point of view of consideration and subject-matter in the sense of inventive merit.

"Having regard to the relevant principles and evidence referred to above, in my judgment the claims of the patent in suit have not been shown by the defendants to be invalid on the ground that they are not fairly based on the disclosure in the specification."

So, Mr. Dimock, there is post-filing evidence and evidence that is not in the patent that Justice Graham found to be of great importance, correct?

MR. DIMOCK: You are right. I believe that he found it to be important to say that the prediction was correct, that because it did give rise to this, that you couldn't say that the sound prediction was unsound or false. I don't know that he meant to say that you could rely on all this

post-filing evidence to say that at the time you filed that the inventors had a sound prediction, it turned out that the prediction was correct.

MR. DEARDEN: That's correct, but there's no doubt as a fact that Justice Graham relied on post-filing evidence and evidence also that was not in the patent, right?

MR. DIMOCK: For the reasons I gave, yes.

MR. DEARDEN: I'm not sure what you mean by that, so I want it to be clear. The patent is filed in 1956, item No. 3 and 4 are of great importance. On page 195 we have reference to a 1963 work. We have reference to a 1962 work. We have reference, sir, without a doubt to post-filing evidence and evidence that's not in the disclosure, correct?

MR. DIMOCK: Yes. I've agreed with you on that.

MR. DEARDEN: Okay. So when you say in paragraph 119 of your Second Report that the court concluded that based on the skilled person's reading of the disclosure alone the patent description provided more than ample support for basing a sound prediction of the stated utility, that statement is not accurate, correct?

MR. DIMOCK: I'm sorry, where are you reading from?

MR. DEARDEN: Your second statement, paragraph 119, first line, "The court concluded that, based on the skilled person's reading of the disclosure alone, the patent description provided more than ample support for basing a sound prediction of the stated utility," and the "disclosure alone" part isn't accurate, is it?

MR. DIMOCK: It's the disclosure for basing a sound prediction. It turned out with the post-filing evidence that the evidence showed that it was not wrong, that it was right, but I believe that the disclosure itself was sufficient to say that the prediction was sound. That's what he meant when he said the claims were fairly based on the disclosure.

MR. DEARDEN: That description doesn't say that, does it, Mr. Dimock?

MR. DIMOCK: It doesn't say it in those words. I'm just reading it as a practicing patent lawyer.

MR. DEARDEN: Now let's move to factual basis and line of reasoning in the patent. So we've gone through AZT, paragraph 70, the tripartite test, and the third component of that which is tab 2,

C-213. It's just simply proper disclosure. Thirdly, there must be proper disclosure, right. 02:08

MR. DIMOCK: I recall our discussion about that before we broke for lunch, yes.

MR. DEARDEN: And Justice Binnie doesn't have any case law cite or textbook or commentator for the third component of his tripartite test; it just simply says: "Thirdly, there must be proper disclosure."

MR. DIMOCK: That's right.

MR. DEARDEN: And it's your opinion that AZT did not change the law in Canada?

MR. DIMOCK: It articulated it and elaborated on it, but it didn't change it.

MR. DEARDEN: What was the elaboration?

MR. DIMOCK: Justice Binnie's reasons elaborated on and the three -- I'm sorry.

MR. DEARDEN: No. Go ahead.

MR. DIMOCK: And the three-part test, as you call it, was the articulation of what I believe the law to have been since Monsanto.

MR. DEARDEN: Anything else to add when I ask you, you know, what he elaborated on? Because it is a long decision.

MR. DIMOCK: I can't at this moment in

this chair do that for you. 02:10

MR. DEARDEN: And you'll agree that there's nowhere in the AZT decision that Justice Binnie states that the proper disclosure component, third component of the test, must be in the patent?

MR. DIMOCK: When you say a "proper disclosure," that means a disclosure in the patent. It can't mean anything else but that.

MR. DEARDEN: Well, there was some considerable debate about that point after this decision, wasn't there?

THE PRESIDENT: May I ask a question? A couple of questions before, Mr. Dearden, you asked whether Justice Binnie gave any authority for his third proposition in paragraph 70 of the AZT judgment. You remember that question?

MR. DEARDEN: Yes, after the words --

THE PRESIDENT: I'm conscious that you are not the witness or the expert but I wondered whether what follows after that, which starts with "Normally" -- maybe I should ask not you but I should ask the expert, Mr. Dimock. You see "Normally" and then it has Fox, and it apparently deals with disclosure. "In this sort of case, however, the

sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly. Precise disclosure requirements in this regard do not arise for decision in this case..." and then he concludes with the words "I therefore say no more about it." 02:11

Mr. Dimock, how do I have to consider all these musings, if I may call them that, by the judge?

MR. DIMOCK: When I answered Mr. Dearden's question, he said -- and there was no judicial authority given for the third part, that there must be a proper disclosure, I was thinking of what Justice Binnie did for the first two parts. He referred to Monsanto and Burton Parsons for the first two, and then he said "Thirdly, there must be proper disclosure. Period." Then he goes on to describe it.

Yes, he does go on to talk about the need for a disclosure and that's what I said earlier today, that normally it is sufficient if the specification provides a fault. You have to teach the person of skill in the art how to make the invention and it's not generally necessary for an inventor to provide a theory, and then he says "Precise disclosure requirements do not arise for

decision in this case." So when he quotes Fox there he's quoting Fox for the purpose of having a disclosure showing you how to make it, but what he goes on to say is -- I believe the inference to be drawn is that in this case there was, indeed, a proper disclosure because there was the underlying test data, and there was a line of reasoning, the chain terminator, that was the phenomenon I referred earlier, so the authority or the basis upon which he said he didn't have to go into any more detail was the fact that in this case the patent agents for Wellcome had included in their disclosure the factual basis and the line of reasoning, and my position has been that it's understood that you have to have in your disclosure, in regards to sound prediction, something which allows the claims to be fairly based. 02:13

I said earlier today how Mr. William Hayhurst had said that you've got to include in your disclosure examples sufficient enough to say that your claims are fairly based on the disclosure.

That's a long-winded response to your question. Sorry.

THE PRESIDENT: Okay. Thank you. Mr. Dearden, please proceed.

MR. DEARDEN: Still looking at paragraph

70 of AZT, Mr. Dimock, the three-part test paragraph of AZT.

MR. DIMOCK: Yes.

MR. DEARDEN: The issue, or the debate, as I referred to earlier, is where Justice Binnie, after he has the *quid pro quo* sentence, says: "Precise disclosure requirements in this regard do not arise for decision in this case." So there became later on a debate of what the precise disclosure requirements were that constitute the third component of this test, right?

MR. DIMOCK: I believe that what you take from this case, as did Justice Hughes and others, is that in this application -- and it was not debated by the parties in the Supreme Court -- there was indeed a factual basis and a line of reasoning, and he said in this case the disclosure requirements are met. It is a proper disclosure.

But I don't think what Justice Binnie wanted to do was to draw a hard line because of the fact that the parties had agreed before him that in this case, at least, there had been a disclosure of the factual basis and a line of reasoning, and he said that there should be some sort of proper disclosure.

MR. DEARDEN: And the scope of the proper disclosure requirements have been left to be decided another day, is that fair? Where he says "I say no more", it's been left to be decided another day?

MR. DIMOCK: He said "I therefore say no more about it." Whether or not he was implying that it's going to be further debated, I don't know. I don't take that inference.

MR. DEARDEN: So you don't think that the issue has been left to another day when a judge says "Precise disclosure requirements in this regard do not arise for decision in this case... I therefore say no more about it"?

MR. DIMOCK: I took from that that the proper disclosure would be constituted by, as he said, the factual basis, the underlying facts, the test data and the line of reasoning, the chain terminator, phenomenon, just as in Monsanto one had the three examples and the common general knowledge with regard to the chemistry in that area of chemical compounds, would say that the prediction was sound that you could claim 126.

MR. DEARDEN: Are you going to agree with me that the first decision to interpret the third component of the tripartite test that we see in

paragraph 70 was Justice Hughes' decision?

MR. DIMOCK: I'm trying to run through the cases but it may be that it was Justice Hughes' decision in Raloxifene that first looked at that issue, as you referred to it.

MR. DEARDEN: Let's turn to paragraph 140 of your First Report.

MR. DIMOCK: I have that.

MR. DEARDEN: You say in paragraph 140, "On first blush, Raloxifene appears to be somewhat controversial, in that Justice Hughes concluded that Eli Lilly had a factual basis and sound line of reasoning prior to its Canadian filing date, but that the patent specification did not adequately support such a prediction, therefore justifying the allegation of invalidity raised by Apotex. However, on a careful reading of the case, it becomes apparent that Raloxifene was well considered and reasoned, and follows the same principles applied more than 25 years prior in Monsanto."

MR. DIMOCK: Yes.

MR. DEARDEN: So why, Mr. Dimock, why would Justice Hughes' decision be somewhat controversial?

MR. DIMOCK: Because when you first read

it, you wonder about how he arrived at it, but then you look closely at it, and Justice Hughes has written many decisions about this, about patent law; he's got the textbooks; and so he understands it. So you have to then say well, what was he getting at. And, as I understand it, for the Eli Lilly patent to have a basis for a sound prediction included some rat studies, as they're referred to, and he made the point that if the rat studies were sufficient to provide a sound basis, to make a sound prediction, those studies were no better than a piece of prior art called Jordan. And if the rat studies were the equivalent of the Jordan prior art in terms of what they disclosed, he was saying that if you accept that the rat studies is the sound basis, then the Jordan renders it obvious, but he didn't think that Jordan did render it obvious, he didn't think that the rat studies did give a sound prediction, and one that would have was the Hong Kong study that was not included, and he said that, as a result, what Eli Lilly was giving the public was no more than Jordan, a piece of prior art, and therefore it was not living up to its bargain of advancing the art.

MR. DEARDEN: So your answer to my question why would Justice Hughes' decision be

somewhat controversial is because, when you first read it, you wonder how he arrived at it? 02:22

MR. DIMOCK: That's how I use "controversial." Maybe it would have been better if I used a different wording, but it's not the easiest decision to understand really until you break it down like I did after some study, that he was equating the rat studies to a piece of prior art.

Now, it did receive a lot of press, I'll say that.

MR. DEARDEN: Justice Hughes' Raloxifene decision received a lot of press from the --

MR. DIMOCK: When I mean press --

THE PRESIDENT: Wait, wait. He's not finished with the question.

MR. DEARDEN: I think I know what you meant. I didn't expect it to be on the front page of the Globe and Mail, right? You're talking about within the Patent Bar, that decision received a lot of commentary.

MR. DIMOCK: I don't know whether it immediately received written commentary. There may have been blogs about it, but I don't read blogs. But certainly there was discussion amongst patent lawyers about that decision, yes.

MR. DEARDEN: You said it did receive a lot of press. 02:23

MR. DIMOCK: And I was about to explain that, and I interrupted you --

MR. DEARDEN: Go ahead.

MR. DIMOCK: What I meant by press, I don't mean printed publications, I meant discussion, really. Probably internal discussions in firms and among lawyers.

MR. DEARDEN: And was the discussion amongst other things because Lilly had a factual basis, they had a sound line of reason, and they couldn't use it?

MR. DIMOCK: No. No.

MR. DEARDEN: Okay. What was it?

MR. DIMOCK: It was the -- what I found is understanding the decision, which only became clear once I appreciated that what Justice Hughes was doing was equating the rat studies to this Jordan piece of prior art, and that as a result it was either invalid for being obvious or there was no sound prediction because you weren't giving anything more than the Jordan piece of prior art. That's where you have to read it closely to come away with that understanding.

MR. DEARDEN: I'm still on the "lot of press." You're not serious in saying understanding the decision received a lot of press? 02:25

MR. DIMOCK: No.

MR. DEARDEN: Surely you'll admit, Mr. Dimock, that some of that press, as you refer to it, would have been that Lilly proved it but they couldn't use it because the Hong Kong study wasn't in the patent. Can you give me that much?

MR. DIMOCK: I don't want to debate with you. I'm here to answer your questions. The press, as I referred to it, was that Justice Hughes had invalidated the patent with a thorough review of the law that he inferred from Justice Binnie's decision, and was able to come to the conclusion that, despite the fact that the Eli Lilly had based the sound prediction on the rat studies, the rat studies were no better than the piece of prior art, so as I said -- and I don't want to repeat myself but I will to conclude it -- it's either invalid for being obvious or invalid for not having a sound line of reasoning for a prediction of utility.

MR. DEARDEN: Eli Lilly didn't base their prediction on the rat studies. Justice Hughes made them be restricted to the rat studies because they

were in the patent, and wouldn't let them use the evidence outside the patent, which was the Hong Kong study, correct? 02:27

MR. DIMOCK: That's right because, as I understood it, your claims have to be based on your disclosure, and if you don't have it in your disclosure you can't say it's fairly based on something that's not there.

MR. DEARDEN: Do you have to disclose evidence in the patent to show that the patent is non-obvious?

MR. DIMOCK: No.

MR. DEARDEN: Let's go to Raloxifene. It's at tab 4, justice Hughes' decision, c-115, paragraph 163. So Justice Hughes in prior paragraphs has dealt with the tripartite test in AZT, which you'll find at paragraph 160, and he gets to the third criteria of that test in paragraph 163. Do you have that?

MR. DIMOCK: I have it. That's page 469 of the report.

MR. DEARDEN: Yes. Paragraph 163. "The third criteria 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. The person skilled in the art was given, by way of disclosure, no more than such person already had. No 'hard coinage' has been paid for the claimed monopoly. Thus, for lack of disclosure, there was no sound prediction..

Eli Lilly argues that there is no need for such disclosure. First, it argues that the Hong Kong abstract was already public by the time the Canadian filing was made and that was sufficient disclosure to satisfy the third element of the AZT requirements. I disagree. A considered reading of paragraph 70 of the AZT decision leads to the conclusion that the disclosure must be in the patent, not elsewhere. The public should not be left to scour the world's publications in the hope of finding something more to supplement or complete a patent disclosure. As the Supreme Court said at paragraph 70, the *quid pro quo* offered in exchange for the monopoly is disclosure. It must be in the patent."

Mr. Dimock, I don't recollect seeing any case prior to this decision of Justice Hughes in 2008 that required a patentee to disclose the factual basis and line of reasoning for sound prediction of utility in the patent. Do you recall any between AZT

in 2002 and this decision in 2008?

MR. DIMOCK: Oh, between 2002 and 2008, as far as I know, there were no cases on point. I stand to be corrected, but I don't recall any.

MR. DEARDEN: Paragraph 138 of your First Report.

MR. DIMOCK: I have it, yes.

MR. DEARDEN: You say, "Likewise, Professor Siebrasse's statement that the 'heightened disclosure requirement for utility based on sound prediction was introduced by the trial courts in 2008' based on 'the third part of the test for sound prediction set out by the Supreme Court in Wellcome/AZT' is simply contrary to my understanding and experience in litigation and reading patent cases."

Are you agreeing or disagreeing that the Raloxifene decision imposed a heightened disclosure requirement in sound prediction cases?

MR. DIMOCK: It was the use of the words "heightened disclosure requirement," and I think I described what I understood that to mean. It goes beyond just saying how to make the invention. It's the proper disclosure of a factual basis and a line of reasoning, and I took that from Monsanto, and I

had a case in the 1980s Cabot v a numbered company on an earplug where we did discuss Monsanto and the line and the sound prediction, but as far as I can recall there were no sound prediction cases in that period.

MR. DEARDEN: Let's go to the Federal Court of Appeal decision of Raloxifene, which you'll find at tab 35, C-119, paragraph 14, Mr. Dimock. The Federal Court of Appeal decision in Raloxifene.

MR. DIMOCK: I have that.

MR. DEARDEN: The court holds "The decision of the Supreme Court in AZT is particularly significant to the disposition" --

MR. DIMOCK: I'm sorry, hold --

MR. DEARDEN: Paragraph 14.

MR. DIMOCK: On page 6?

MR. DEARDEN: Page 6, yes. Do we have the same copy of the case?

MR. DIMOCK: Behind tab 5 at page 6, paragraph 14, "The decision of the Supreme Court in AZT"?

MR. DEARDEN: Yes.

MR. DIMOCK: I'm there.

MR. DEARDEN: I'll start over.

Paragraph 14, "The decision of the Supreme Court in AZT is particularly significant to

the disposition of this appeal. According to AZT, the requirements of sound prediction are three-fold: There must be a factual basis for the prediction; the inventor must have at the date of the patent application an articulable and sound line of reasoning from which the derived result can be inferred from the factual basis; and third, there must be proper disclosure." (citing paragraph 70 of AZT).

"As was said in that case: 'the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly'. In sound prediction cases there is a heightened obligation to disclose the underlying facts and the line of reasoning for inventions that comprise the prediction."

Paragraph 15. "In my respectful view, the Federal Court judge proceeded on proper principle when he held, relying on AZT, that when a patent is based on a sound prediction, the disclosure must include the prediction. As the prediction was made sound by the Hong Kong study, this study had to be disclosed."

Firstly, Mr. Dimock, you don't take issue with the Court of Appeal saying that Justice Hughes

relied on AZT in making the decision that he made? 02:35
MR. DIMOCK: I don't take issue with that.
MR. DEARDEN: And this is the first Federal Court of Appeal decision to decide that in sound prediction of utility cases there is a heightened obligation to disclose the underlying facts and the line of reasoning for the invention that comprises the prediction?
MR. DIMOCK: That is the first Federal Court of Appeal case after AZT, yes.
MR. DEARDEN: Mr. Dimock, there were some unresolved legal issues that arose, or legal issues that arose after AZT was decided that was the subject of a number of Federal Court cases as to what that paragraph 70 and the third component meant. One of those issues, sir, was what's the cut-off date for the evidence of the factual basis and the line of reasoning for the prediction.
So what application are we talking about? Are we talking a priority date application or the subsequent Canadian filing date application, right? That was an issue that had to be resolved.
MR. DIMOCK: There was -- as I recall, there was a case or two on that, yes.

MR. DEARDEN: I'm going to take you to them. And there was another issue, and that is whether the proper disclosure requirement only applies to new use patents, and that issue remains unresolved to today. Agreed? 02:36
MR. DIMOCK: I don't agree that it remains unresolved. In my view the requirements of a factual basis, a line of reasoning and proper disclosure applies to any patent which relies on a sound prediction to support its claimed utility at the time of filing.
MR. DEARDEN: That wasn't the question I put to you, Mr. Dimock, so let me just repeat it. There's an unresolved issue whether the proper disclosure requirement only applies to new use patents, and that issue is definitely unresolved today, isn't it?
MR. DIMOCK: Justice Rennie did refer to that, and there's some other judges who thought that that may not be, indeed, the case.
MR. DEARDEN: The score is 2-2. Justice Rennie, justice Annis, it only applies that proper disclosure requirement, the heightened disclosure obligation, only applies to new use. Score two goals for them. Justice Barnes and Justice Zinn, it

applies to all patents. 2-2. Unresolved, right? 02:38
MR. DIMOCK: You've cited the cases that are on point, yes.
MR. DEARDEN: And that's unresolved today. We have Justice Zinn issuing a decision just a couple of months ago siding with Justice Barnes that the disclosure requirements applies to all patents, not just new use patents.
MR. DIMOCK: And with that I agree.
MR. DEARDEN: Okay. So let's go to the cut-off date cases --
MR. DIMOCK: I mean I agree with Justice Zinn and Justice Barnes but, anyway, that's what I said when I agreed. Not with what you just said, but I agree with them.
MR. DEARDEN: I thought we were coming to common ground!
MR. DIMOCK: Well, my goal -- or my job is to answer your questions, and when your questions are fair, I agree with you. When I think that they're not, I will not agree.
MR. DEARDEN: I was just joking, by the way.
MR. DIMOCK: I know. But I'm not.
MR. DEARDEN: So, cut-off date. Is it

the priority date or the Canadian filing date? 02:39
Obviously if it's the Canadian filing date you can rely on more evidence for your factual basis because you get typically -- what, an extra year of possible evidence?
MR. DIMOCK: If you file firstly in another country such as the one we're in today --
MR. DEARDEN: U.S.
MR. DIMOCK: -- under the Patent Cooperation Treaty you have a year within which to file in Canada.
MR. DEARDEN: Right. So that's a pretty significant issue, isn't it, to get the extra year of possible evidence that you could say you had the factual basis.
MR. DIMOCK: If your disclosure that you file in Canada a year later is the same disclosure, it makes no difference.
MR. DEARDEN: Right. I'm saying if you had the evidence in that time period, you don't get knocked out because it's a priority date, and it's something happening in between priority dates --
MR. DIMOCK: I don't know then you could rely on the priority if you've added to your Canadian application.

MR. DEARDEN: There's no addition. Anyway, let me go to the first case.
THE PRESIDENT: Could you please slow down a little bit between the answer and the questions. Take some more time, otherwise the court reporter cannot keep up with you.
MR. DEARDEN: So the first decision is a ramipril decision that you'll find, Exhibit C-209. It should be same volume, tab 6, C-209, paragraph 159. Here Justice Mactavish is dealing with the third component, the proper disclosure component of the tripartite AZT test. At 161 Justice Mactavish quotes Justice Binnie saying, "Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practiced."
Paragraph 162, "Before turning to consider the sufficiency of the disclosure in this case, it is once again necessary to address the appropriate date for the determination of this question.
163. I will return to this question in relation to my analysis of the sufficiency issue under subsection 34(1) of the old Patent Act.

However, for the purpose of addressing the third element of the Wellcome test for sound prediction it is clear that the date to be used is either the priority date or the Canadian filing date. There is nothing in the Wellcome decision that would suggest that the date of issue should be used.
164. As noted earlier, Wellcome is less clear as to whether it is the priority date or the Canadian filing date that is to be used in relation to the test for sound prediction. However, as for the reasons cited above, I have concluded that it is the date of the Canadian filing that should be used. It does not make any sense that the first two elements of the test for sound prediction be determined as of one date, and the third element as of another date -- that is, the date of issue -- nor is there any suggestion in Wellcome that this should be the case. Accordingly, I intend to assess the sufficiency of the disclosure in the '206 patent as of October 20, 1981," which is the Canadian filing date.
So there were issues left unresolved by AZT and Justice Mactavish has decided that it's going to be the filing date, Canadian filing date, correct?
MR. DIMOCK: Yes. She does that.

MR. DEARDEN: Now, this decision is a 2005 decision. So three years after AZT, three years before Justice Hughes' decision. And Justice Mactavish in this ramipril decision here at tab 5, Exhibit C-209, she didn't require the factual basis and line of reasoning for the sound prediction to be in the patent, did she?
MR. DIMOCK: I'm sorry, you referred me to --
MR. DEARDEN: It's okay. I'll repeat. 2005 decision, right, this --
MR. DIMOCK: The Justice Mactavish decision is 2005, yes.
MR. DEARDEN: We call it ramipril. It's fair for me to say that in this decision, three years after AZT, three years before Justice Hughes' decision in Raloxifene, that Justice Mactavish did not require the factual basis and line of reasoning for sound prediction to be in the patent.
MR. DIMOCK: I don't know where you draw that.
MR. DEARDEN: Well, I don't see it. Do you see it? Do you see her making that finding in this decision, sir?
MR. DIMOCK: I thought that she was just

addressing the question as to when the proper disclosure should be taken, is it in the priority date or the Canadian filing date. That's the issue I thought was before her.
MR. DEARDEN: But it's a sound prediction case. So if AZT decided that the proper disclosure for the third component of the test had to be in the patent, then why is Justice Mactavish not insisting that the factual basis and line of reasoning be in the patent in the sound prediction case she's deciding?
MR. DIMOCK: It has to be in the patent. The disclosure is in the patent, and the disclosure that's required -- she does refer -- I think you did indicate to paragraph 159 of her decision to the third element of the tripartite test. I thought that's what she was dealing with, not with numbers 1 and 2.
MR. DEARDEN: The proper disclosure that Justice Mactavish is referring to in paragraph 139 is the third component, and there is, of course, a requirement in section 27(3) of the Patent Act for disclosure, and that's what she's referring to in paragraph 163 of this decision.
MR. DIMOCK: I don't read it that way.

MR. DEARDEN: Well, what is today's section number for subsection 34(1) of the old Patent Act? It's 27(3), right? 02:47

MR. DIMOCK: Yes.

MR. DEARDEN: And that's what she says she's --

MR. DIMOCK: Are you referring to --

THE PRESIDENT: Wait.

MR. DIMOCK: Sorry. I apologize. I was just responding to your -- you say 34 is now 27. I remember it as section 36, so even before that.

MR. DEARDEN: In paragraph 163 Justice Mactavish says she will return to the question in relation to her analysis of the sufficiency issue under subsection 34(1), which today is subsection 27(3). Correct?

MR. DIMOCK: That's my understanding.

MR. DEARDEN: And that's disclosure about how to make and use the invention.

MR. DIMOCK: Yes.

MR. DEARDEN: Right. Nowhere in this decision, which is dealing with sound prediction, is there any analysis of whether the factual basis is in the patent, has been disclosed in the patent. Correct? Is that fair?

MR. DIMOCK: I must be missing, or misunderstanding your question. As I understood the case -- and I haven't read this one for a long time -- what she was asked here is what is the date to be used. Is it the priority date or the Canadian filing date. And all that you read to me, as I understand it, was her conclusion that it was the Canadian filing date, not the priority date. But I'd have to read the whole case to put it in proper context, I'm sorry. 02:48

MR. DEARDEN: Well, we all can read it, too, so we'll deal with that in argument.

MR. DIMOCK: Sure.

MR. DEARDEN: Now, this decision gets appealed to the Court of Appeal at tab 7 of your second volume. At paragraph 30 Chief Justice Richard, who is a master of brevity --

MR. DIMOCK: He was your partner.

MR. DEARDEN: He sure was. He was my man.

He says, "I'm in agreement with Justice Mactavish that the relevant date is the Canadian filing date, in this case October 20, 1981. It is the time which is most reasonable in achieving consistency in the application of the three

components of the Wellcome test." 02:50

So that's the first Court of Appeal decision to decide that the relevant date is the Canadian filing date?

MR. DIMOCK: That's right.

MR. DEARDEN: And then at tab 8 of your volume 2 you have Exhibit C-250, which is the decision of Justice Heneghan in Pfizer v Minister of Health, the quinapril case. To go through this very quickly, if you turn up paragraphs 77 and 78, this also was a 2005 decision, Justice Heneghan in paragraph 77 says: "As a preliminary matter, the parties dispute the date of the invention for the '330 Patent. Pfizer argues the date is June 18, 1980; Apotex submits the relevant date is October 3, 1980, that is the priority date. In this regard, Apotex argues that as of June 18, 1980, the inventors had only 'conceived' of a single member of the purported invented class of compounds , had no basis to extrapolate different stereoisomers to various classes of compounds and to bulky compounds , and were unable to predict antihypertensive properties of the claimed compounds.

78. In my opinion, these arguments are sound. I note that the inventors themselves referred

to June 18, 1980 as the date on which they 'conceived' of an idea that would 'probably' be useful as an ACE inhibitor. I'm not persuaded that a 'conceived' idea is synonymous with an invention. I conclude that the appropriate date for the date of invention is October 3, 1980, the priority date of the '330 patent." 02:52

That got appealed in the next tab, and Justice Henaghan was overturned. If you go to tab 9, C-250, paragraph 153, a decision of Justice Nadon. Do you have that?

MR. DIMOCK: Page 58?

MR. DEARDEN: Yes. The Court of Appeal says "In any event, Pfizer points, correctly in my view, to this Court's recent decision in Aventis v Apotex [which is ramipril which we just looked at] which held that the relevant date for assessing the soundness of a prediction was the Canadian filing date, in this case September 30, 1981. Contrary to Apotex's notice of allegation and to Justice Heneghan's finding, the relevant date is not the priority date which, in this case, is October 3, 1980. Further, in its notice of allegation... Apotex refers to testing of quinapril that showed the compound reduced blood pressure in rats. The results

of those tests were received on December 8, 1980 well before the Canadian filing date. Accordingly, even if some testing were required to establish a sound prediction, such testing was conducted in this case." 02:54

So the cut-off date, Canadian filing date, right?

MR. DIMOCK: That's what this Court of Appeal said, yes.

MR. DEARDEN: And the Court of Appeal also relied on these rat tests that were received after the priority date but before the Canadian filing date, right. See that?

MR. DIMOCK: Yes, I see the reference to the rat tests.

MR. DEARDEN: And those tests come in between the priority date and the Canadian filing date, right?

MR. DIMOCK: That would appear to be the case.

MR. DEARDEN: Were they in the Canadian patent that was filed September 30, 1981?

MR. DIMOCK: I don't recall that they were. However -- and I don't know that you can rely on them unless they were in the Canadian filing application -- unless they were in the Canadian

application as filed on the Canadian filing date. 02:56

MR. DEARDEN: You haven't reviewed the patent 1,341,330 to see if those rat studies tests that were done after the priority date were actually put in the Canadian --

MR. DIMOCK: I have not.

MR. DEARDEN: You haven't. And is it fair to say they weren't in the Canadian patent as filed?

MR. DIMOCK: That would be my -- if they were trying to rely on the priority date, then that would be added matter, and you'd have some debate as to whether or not you could rely on the priority date. So my inference from what you've told me is that they were likely not in the Canadian patent as filed but, as I said on a few occasions where I don't know for certain, I stand to be corrected.

MR. DEARDEN: Can we go to the Supreme Court of Canada's decision in Pfizer sildenafil, which is the Viagra decision at tab 14. I just wanted to finish off the loop on heightened or enhanced disclosure before. Volume 3, tab 14, Exhibit C-197, Supreme Court of Canada decision from 2012.

MR. DIMOCK: I have that.

MR. DEARDEN: Do I have you at paragraph 36? I didn't give you a paragraph, did I? 02:58

MR. DIMOCK: You did not, but I have now just turned up paragraph 36 on page 640.

MR. DEARDEN: Correct. That's the sound prediction part of this judgment, and in paragraph 37 Justice LeBel holds "For a patent to be valid, the invention it purports to protect must be useful. This requirement of utility comes from the definition of 'invention' in section 2 of the Act, which requires that the purported invention be 'new and useful'. Sound prediction is a concept that becomes relevant only when an invention's utility cannot actually be demonstrated by way of tests or experiments, but can nevertheless be successfully predicted." And he cites AZT. "The lack of certainty that comes from predicting rather than demonstrating an invention's utility has led some courts to conclude that there is a 'heightened' or 'enhanced' disclosure requirement in cases in which a claim of utility is based on sound prediction: See Eli Lilly v Apotex", which is the Raloxifene case, right?

MR. DIMOCK: Yes.

MR. DEARDEN: "Teva submits that this

heightened requirement was not met in this case", and at paragraph 38, at the bottom, that last sentence of that paragraph, Justice LeBel holds "The fact that Pfizer did not disclose that the tested compound was sildenafil goes to the issue of disclosure of the invention, not to that of disclosure of the invention's utility." 02:59

MR. DIMOCK: Yes, that's what Justice LeBel said and concluded.

MR. DEARDEN: Then in paragraph 39 Justice LeBel says "That the invention must be useful as of the date of claim or as of the time of filing is consistent with this Court's comments in AZT" and he reproduces Justice Binnie's paragraph 56 that utility required for section 2 must, as of the priority date, either be demonstrated or be a sound prediction.

In paragraph 40, "Nothing in this passage should suggest that utility is a disclosure requirement; all it says is that 'the utility required for patentability must, as of the priority date, either be demonstrated or be a sound prediction'. Utility can be demonstrated by, for example, conducting tests, but this does not mean that there is a separate requirement for the

disclosure of utility. In fact, there is no requirement whatsoever in 27(3) to disclose the utility of the invention:" Citing Consolboard at page 521 and Justice Dickson: "I am further of the opinion that 36(1) [now 27(3)] does not impose upon a patentee the obligation of establishing the utility of the invention."

Paragraph 41. "In any event, Pfizer disclosed the utility of sildenafil by disclosing the tests had been conducted. Sildenafil was found to be useful before the priority date, which means the requirement in AZT is met. Further, 'evidence as to utility may be found in the reception of the invention by the public. Enthusiastic reception by those to whom it is directed will tend to indicate that the invention is useful'."

So Justice LeBel has stated in paragraph 41 that commercial success can be considered as evidence of utility. Agree?

MR. DIMOCK: There's no doubt about that, Mr. Dearden, that one way of disproving utility is to show that the patent doesn't work, and one way of showing that it has utility -- in certain circumstances where I'm talking about operability, then you can rely on the success of the invention so

long as it's embodied in a commercially successful product.

MR. DEARDEN: There's no distinction like you make in your report, sir, in what Justice LeBel says in paragraph 41. Would you agree with that?

MR. DIMOCK: I took these paragraphs of Justice LeBel to be obiter dicta because he said "since sound prediction is not an issue the question of whether there is enhanced or heightened disclosure requirement with respect to sound prediction does not arise in this case and need not be addressed. I will now turn to the issue at the heart of this appeal whether patent '446 meets the requirements of section 27(3) of the Act."

So I don't believe that Justice LeBel was attempting to state the law in the last couple of paragraphs you read to me. He was certainly reciting the law that he understood, generally speaking, but I don't think you can take what he said here as the law as enunciated by the Supreme Court of Canada because it was an obiter.

MR. DEARDEN: Mr. President, would this be an appropriate time to take a break?

THE PRESIDENT: Yes, a 15-minute break. Mr. Dimock, you know what it means. You are under

testimony.

MR. DIMOCK: Yes.

(Recess taken)

THE PRESIDENT: We resume the hearing. Mr. Dimock, can you bear with us for a moment, because the parties have agreed on scheduling for the remaining days of the hearing.

Ms. Cheek, could you talk on behalf of both parties? Because we've already discussed it outside.

MS. CHEEK: Yes. The parties have agreed that we will adjourn for both Saturday and Sunday. We anticipate completing witness testimony on Monday. The expectation is that the Tribunal will get us their questions at the end of the day on Monday, if other questions don't come before. We would adjourn on Tuesday, and then we will do our closing arguments on Wednesday.

THE PRESIDENT: Mr. Spelliscy?

MR. SPELLISCY: Yes. This is the agreement.

THE PRESIDENT: Your proposal for the parties still factors in the possibility that the Tribunal may ask questions of the experts?

MS. CHEEK: It does, and we're prepared

to alter the schedule if needed to ensure the Tribunal's questions are answered, so we in no way wish to rush the process.

THE PRESIDENT: Thank you. Mr. Dearden, please continue the cross-examination.

MR. DEARDEN: Thank you, Mr. President:

Mr. Dimock, your second report, paragraph 95.

MR. DIMOCK: I have that.

MR. DEARDEN: You say in paragraph 94 -- actually go to 95: "Here the Court cited a number of the cases I referenced at paragraphs 92-95 of my First Report, as well as others, in which judges were asked to consider when an invention has been made. Repeatedly, they emphasized that an invention was not reduced to a definite and practical shape (i.e. was not made) if its utility had not been established."

In paragraph 96 you say, "This arose in the case of Control Data v Senstar, in which I was trial counsel for Control Data. In its judgment, the Court explained that to make an invention, the inventor had to have done enough work to establish utility or 'the workability of the invention'."

And you have a quote which I'll read into the record from Control Data, paragraph 137. "...an

apparatus or device is reduced to practice when it is assembled, adjusted and used. It can be an experiment; it need not be a commercial use, ...[and that] reduction to practice is the testing of the invention to demonstrate utility but not mechanical perfection. The operative means must merely accomplish the desired result. Improvements obvious to the skilled workman to increase its practical efficiency or perfect its operation may still be made to an invention already reduced to practice. Thus, commercial feasibility is not necessarily relevant to the question of 'reduction to practice' so long as the experimental equipment proves the workability of the invention. It does not have to be mechanically perfect."

03:30

Can you turn to the decision, Mr. Dimock, at tab 23, which is volume 4 of your binders Exhibit R-364, paragraph 137. Do you have paragraph 137, sir?

MR. DIMOCK: I do.

MR. DEARDEN: Your paragraph 96 quoted from paragraph 137 stopped at "mechanically perfect," but there's more to that paragraph. The additional part of that paragraph reads, "Further, I quote from Euth...: 'It follows that actual reduction to

practice is not the only competent evidence of perfection and adaptation to use, but the inventor's act in filing an allowable application is to be regarded in law as such an efficient and crowning step as to give it the standing of an invention so perfected and adapted'."

03:32

So the crowning step is the act of filing an allowable application, correct?

MR. DIMOCK: That is the crowning step. I should say, Mr. Dearden, that in that case Justice Cullen was asked to decide whether the invention was reduced to practice -- that's an American term -- and he said that he understood the difference to be between our reduction to a definite and practical shape and reduction to practice in the United States is that in the United States it has to be a diligent reduction to practice, but according to that U.S. case the crowning step was the filing, yes.

MR. DEARDEN: And the court adopted that, right?

MR. DIMOCK: The court cited from that, yes.

MR. DEARDEN: Can you turn to paragraph 106 of your First Report, which should be referencing Ciba-Geigy?

MR. DIMOCK: I'm at page 30?

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MR. DEARDEN: Yes. So paragraph 106 of your First Report says: "The only case that I'm aware of that may be construed as relying on post-filing evidence in support of demonstrating or soundly predicting utility at the time of filing is the Ciba-Geigy v Commissioner of Patents case, a decision cited by Professor Siebrasse. Notably, and as mentioned in his report, the Patent Office refused to consider post-filing evidence when an objection arose concerning the soundness of the predicted utility, and rejected the application. The decision of the Patent Office was later overturned by the Federal Court of Appeal."

Ciba-Geigy is at tab 24, Exhibit C-44, volume 4 of the binder.

MR. DIMOCK: I have it.

MR. DEARDEN: Can you go to page 75, tab 24? At the top of the page, the Federal Court of Appeal, Chief Justice Thurlow, says "There is no longer any issue as to the size of the class of the amines or as to the utility claimed for them. Nor is there any issue as to the first or second of the processes claimed. What was considered objectionable about the others by the Patent Appeal Board was that

they were speculative and had not been invented at the time when the application for patent was filed."

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Then he has a long quote from the Board, and I'm going down to the bottom of the page, second to last paragraph, "Recognizing the insufficiency of the disclosure, the applicant, on October 23, 1972, submitted five new examples illustrating five of the six missing processes. We do not believe, however, that the applicant should be permitted to retain claims on the basis of something done after the event, and not part of the original disclosure."

So the Patent Appeal Board holds, on that basis, "we consider the examiner's objection was justified" with respect to the claims that they say there.

If you turn the page to page 76, the second paragraph, "On the appeal what was before the court consisted only of the Patent Office file, including the application, specification, correspondence between the examiner and the applicant, amendments, representations and the decisions of the Patent Appeal Board and the commissioner. Also included were descriptions of the five examples of the carrying out of the processes (c) to (g) inclusive which had been submitted to the

examiner for his information in the hope of persuading him that the processes were not mere speculation but would, in fact, work and which are referred to in the foregoing excerpts from the board's reasons." 03:38

At the bottom of that page the Chief Justice holds, "In this context the use by the author of the word 'possible' does not appear to me to support the view that what was being asserted was speculation. But even assuming that the reactions or methods identified as (c) to (g) inclusive had not in fact been carried out or tested before the application was filed, the board appears to have been satisfied by the examples subsequently submitted and to have found that the amines referred to in the specification can, in fact, be produced by the application of the methods to materials of the kinds defined. It seems to me to follow that if indeed what is in the patent specification was mere speculation or prediction, the speculation or prediction having turned out to be true, ought to be considered to have been well founded at the time it was made. Even at the time it was made it's not improbable that it would have been considered well founded."

And if you go over to page 78, the second paragraph or the first full paragraph, "What remains is the question whether the position taken by the Board that the applicant should not be permitted to retain claims on the basis of something done after the filing of the application and not part of the original disclosure should be upheld. In effect, this objection is that the subject-matter of process claims (c) to (g) had not yet been invented when the application was filed. This objection, as well, appears to me to be met by the decision of Pigeon J in the Monsanto case. There, after discussing the decision of Justice Graham in Olin Mathieson, and the limits within which a patent claim embraced untested substances may be valid, Pigeon J held" and he quotes from that decision, and over to paragraph 79: 03:39

"In the present case the question of the soundness of the prediction having been put to rest, the only question left is the first, that of utility in respect of some area covered. As to this there is, in my view, nothing in the record which shows or tends to show that the processes will not work to produce the amines which are said to have the novel pharmacological usefulness referred to earlier in these reasons, a matter as to which no reason is

raised." 03:41

In conclusion, we see on page 80, the Chief Justice says "On the material in the record I am of the opinion that the commissioner's conclusion that the process claims in question should be rejected based as it is on the reasons of the Patent Appeal Board is not sustainable in law and should not be allowed to stand. I would allow the appeal, set aside the decision and refer the matter back to the Commissioner of Patents to proceed with the appellant's application '368 on the basis that the claims for the processes identified at (c), (d), (e), (f) and (g) and for the new amines described in the specification, when produced by said processes, are not open to objection or rejection on the grounds that the processes are speculative or that they had not been carried out prior to the filing of the appellant's application for a patent."

So the Federal Court of Appeal in Ciba-Geigy upheld the claims on the basis of sound prediction, Mr. Dimock?

MR. DIMOCK: They did.

MR. DEARDEN: And post-filing evidence of five examples that was not in the patent and were done after the application was filed was allowed?

MR. DIMOCK: The Court of Appeal did refer to those five pieces to show that the prediction did eventually turn out to be correct, but I submit not that the prediction had been made as found when it was filed, although because what Justice Thurlow said at page 77 where he said even at the time it was made it is not improbable that it would have been considered well founded, so he made the finding that without these other pieces he would have considered based on the disclosure that at that time the prediction was sound, that there was a factual basis and a line of reasoning -- 03:42

MR. DEARDEN: But he point blank held, at page 77, "It seems to me to follow that if indeed what is in the patent specification was mere speculation or prediction, the speculation or prediction having turned out to be true, ought to be considered to have been well founded at the time it was made."

MR. DIMOCK: And Justice Binnie looked at that and concluded that the case could not stand for that but, if it did, it should not be followed.

MR. DEARDEN: Right. So as of 1982, which is the decision of the Federal Court of Appeal, Mr. Justice Binnie, not deciding until 2002, this was

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the law, right? Ciba-Geigy was the law? 03:44
MR. DIMOCK: Ciba-Geigy presented a difficulty in that it was Justice Thurlow who had said that, based on what he had seen, having it turned out to be true, was considered to have been well founded at the time it was made. He was saying that yes, the prediction turned out to be correct by these later pieces, but he also said that even that proves that the prediction was correct but it didn't, in my view, and based on what he said and what Justice Binnie said later, it didn't say that the inventors knew that their prediction was sound and had made such a sound prediction at the time of filing.
MR. DEARDEN: Mr. Dimock, you keep going back to AZT in -- what is it, back to the future? AZT in 2002. I'm talking about this point in time. 1982. The Federal Court of Appeal said post-filing evidence could be considered, correct?
MR. DIMOCK: Not for the purpose of showing that, at the time that the application was filed, that the inventors had made a sound prediction based on a factual basis and a line of reasoning.
MR. DEARDEN: He said "It seems to me to follow that if, indeed, what is in the patent

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specification was mere speculation or prediction, 03:46
speculation or prediction, having turned out to be true, ought to be considered to have been well founded at the time it was made."
So the issue was patentability, right?
MR. DIMOCK: Yes, this was an application still pending, so this was a question of patentability, and what I take from that is he was saying that the fact that the prediction was correct can be considered on the point of whether or not it works but not to the point that, at the time the application was filed, the inventors knew that it had soundly predicted.
MR. DEARDEN: The issue that was before the Commissioner of Patents was an issue of patentability, correct?
MR. DIMOCK: Yes.
MR. DEARDEN: Okay. Got overturned by the Federal Court of Appeal in Ciba-Geigy, correct?
MR. DIMOCK: The Patent Appeal Board decision, yes, was overturned.
MR. BORN: Mr. Dimock, I'm not understanding exactly what you say the post-filing evidence wasn't considered relevant to establishing. You acknowledge, if I understood your interchange,

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that post-filing evidence was admitted and was 03:47
relevant to demonstrating that a prediction turned out to be accurate.
MR. DIMOCK: Yes, that's right.
MR. BORN: But you're saying that that evidence didn't itself show that there had been a prediction?
MR. DIMOCK: That there had been a prediction that was soundly based at the time the application was filed, that's right. You have to look at the disclosure and, as Justice Thurlow said, in that next line, even at the time it was made it is not improbable that it would have been considered well founded. So what Justice Thurlow was saying, put those pieces aside, that the prediction that was made at the time of filing was soundly based, and it was properly disclosed, that the subsequent -- and I say from that, then the subsequent proof of the success of the prediction was just to show that yes, indeed, the prediction had been right.
MR. BORN: In your view, is that a relevant issue, then? Are you saying the only real question here is whether, at the time that it was made, the prediction was soundly based, ergo, the fact that it turned out to be right subsequently is

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irrelevant? 03:49
MR. DIMOCK: That's right.
MR. BORN: Then why does he talk about it?
MR. DIMOCK: I think he's talked about it to show that it did turn out to be correct had the later evidence -- and I made mention of this in my report -- had this later evidence shown that the prediction was incorrect, that would be relevant, but not relevant to the point as to whether or not the inventor knew that the prediction was sound at the time, and disclosed that understanding.
MR. BORN: Thank you.
MR. DEARDEN: Mr. Dimock, I put it to you, sir, that the issue before the Board is what we see on page 75 where the Chief Justice quotes what the Board said in its reasons in that first passage that we see quoted there. "We have come to the conclusion that the methods are standard methods known to the skilled chemist. This is confirmed by the amendment of October '72 showing that variants (c), (d), (e), (f), (g) can be used to prepare desired compounds. What concerns us, however, is whether at beginning of 1970 (the priority date of the application) it can properly be said that the

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inventor had made the invention claimed or whether, on the contrary at that time the processes (as distinct from the products) were speculative."

Then they deal with the fact that five new examples, as you see at the bottom, were provided by the applicants of post-filing evidence, not in the patent itself, that illustrated that they worked and that was accepted. The Board got overturned, correct?

MR. DIMOCK: That's what it says, that's right. It's the logic of it, Mr. Dearden, that I quarrel with and what Justice Binnie had said in his report, but I've already made my point.

MR. DEARDEN: Can we go to the Federal Court of Appeal decision in AZT, which is at tab 25 of the same volume, Exhibit C-117, paragraph 50.

MR. DIMOCK: Paragraph 50 at page?

MR. DEARDEN: 83. This is the decision that got appealed to Justice Binnie in the AZT 2002 decision. Start with paragraph 50.

"In my view, this Court's decision in Ciba-Geigy stands for the proposition that even where an invention constitutes a speculation as of the priority date claimed in the patent, the patent will not be invalid if it turns out that the speculation

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is valid at the time the patent is attacked." And that means at trial, right?

MR. DIMOCK: That's right.

MR. DEARDEN: "In Ciba-Geigy, this Court held that 'if indeed what is in the patent speculation was mere speculation or prediction, the speculation or prediction having turned out to be true, ought to be considered to have been well founded at the time it was made'. Similarly, in Ciba-Geigy, this Court rejected the proposition that a patent applicant 'should not be permitted to retain claims on the basis of something done after the filing of the application and not part of the original disclosure'.

51. "In other words, so long as the inventor can demonstrate utility or a sound prediction at the time a patent is attacked" -- and again, Mr. Dimock, that's at trial, right?

MR. DIMOCK: Yes.

MR. DEARDEN: -- "the patent will not fail for lack of utility. The time at which usefulness is to be established is when required by the Commissioner of Patents or in court proceedings when the validity of the patent is challenged on that ground. The Commissioner may require a patent's

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utility to be demonstrated pursuant to section 38 of the Act, which permits the Commissioner to require an applicant to 'furnish specimens of the ingredients [of a composition of matter], and of the composition, sufficient in quantity for the purpose of experiment'."

52. "To conclude that the evidence of actual utility subsequent to a patent's priority date may not be introduced to demonstrate that an invention meets the requirements of the Patent Act would produce illogical results. For instance, suppose that on December 10, 1903, Wilbur and Orville Wright obtained a patent for an airplane, and that by that date, neither brother had successfully flown the plane or could be said to have a 'sound prediction' that a machine heavier than air could fly. Suppose further that one week later, the Wright brothers managed to successfully fly their plane. If the Wright brothers' patent was later attacked, and if uncontradicted expert testimony was provided by the attackers to demonstrate that by December 10, 1903, machines heavier than air could not fly, would their patent be invalid even though all would concede that by the time the attack was brought, such machines could fly? In my view, to so conclude would require

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the Court to close its eyes to continuing scientific advancements, and would disentitle patentees to rely on the instinctive sparks that so often engender great discoveries. In Dr. Rideout's words, one of the co-inventors of AZT, combinations of 'instinct and intuition [and] gut reaction' supported by actual evidence of utility at the time the patent is attacked, would not be sufficient to support a patent.

53. The decisions cited by A&N in support of the proposition that all pharmaceuticals must invariably be tested on living human beings prior to the priority date claimed in a patent are not applicable to the instant appeal. Firstly, as the trial judge held, the decisions deal with the notion of 'sound prediction', a doctrine that applies only to cases in which a few claimed compounds are tested but many are untested even at the time when the patent is attacked. Such testing requirements simply do not apply where, at the time the patent is attacked, there is evidence of actual utility (i.e. that the pharmaceutical does what the patent promises). Where such utility is demonstrated, there is no need to fall back on the 'sound prediction' doctrine and the experiments that are required to

make such predictions. Since A&N do not dispute that AZT is indeed useful to treat HIV, the '277 patent meets the 'actual utility' test."

So 18 years after Ciba-Geigy the Federal Court of Appeal again allows and upholds that post-filing evidence can be relied on to establish utility. Agreed?

MR. DIMOCK: Justice Sexton here makes that point, yes.

MR. DEARDEN: Tell me if you agree with the next point, paragraph 54. "Finally, if the Court in Ciba-Geigy intended to hold that a higher standard of utility is required for pharmaceutical inventions, as opposed to other inventions" --

MR. DIMOCK: I'm sorry, where are you reading?

MR. DEARDEN: Paragraph 54 of the AZT Federal Court of Appeal decision in the year 2000. "... if the court in Ciba-Geigy intended to hold that a higher standard of utility is required for pharmaceutical inventions, as opposed to other inventions, this may be explained by the fact the decision in Ciba-Geigy preceded the establishment of Canada's international treaty obligations under NAFTA and TRIPS. Both of these agreements, which have been

incorporated into domestic law, prohibit discrimination based on field of technology. Thus, this Court may not hold pharmaceutical inventions to a higher standard of utility than it does other classes of inventions."

Do you take exception to that? Agree with it? Neutral?

MR. DIMOCK: I disagreed with Justice Sexton's reasoning and logic when it came out.

MR. DEARDEN: What, on NAFTA? That's what I'm talking about.

MR. DIMOCK: You didn't ask me whether I agree with what he had said earlier, just whether or not that's what he said. It turned out that his -- well, that's what I was trying to say.

MR. DEARDEN: What I thought I asked you, going back to the issue of post-filing evidence in AZT that we're looking at here at tab 25, is that 18 years after Ciba-Geigy, the Federal Court of Appeal confirmed that post-filing evidence can be relied upon to establish utility, and you agreed with me that that's what the decision has held.

MR. DIMOCK: That's what Justice Sexton seemed to be saying. It's not whether I agree with it but that's what he seemed to be saying. He used

the example of the Orville Wright planes, and I think there's some problems with that but, in any event that's what he said.

MR. DEARDEN: Seemed to be saying, Mr. Dimock, or he point blank held that?

MR. DIMOCK: I'm not going to quarrel with you. That's what he said.

MR. DEARDEN: That's what he said. Okay.

Tab 26 should be the Cochlear v Cosem decision of Joyal in 1995. Do you have that?

MR. DIMOCK: Yes.

MR. DEARDEN: Exhibit C-228.

MR. BORN: Actually, before you go to that case, did that decision in AZT, the Court of Appeal decision, surprise you?

MR. DIMOCK: It did, just on the logic of -- well, what was said by Justice Binnie in the appeal that went to the Supreme Court of Canada was that what Justice Sexton and the Court of Appeal was seeming to approve was that you could apply for a patent on mere predictions and good hunches, and if it turned out that you were right, when it was being attacked, you'd have a valid patent notwithstanding.

That was the logic that I thought was not sound when it was delivered by Justice Sexton and

subsequently that logic was said to not be in accordance with the Patent Act and the requirements for making the sound prediction, and so it was Justice Binnie's decision and the entirety of the Supreme Court of Canada which said that that logic should not be accepted.

MR. BORN: My question wasn't so much directed at whether you thought the logic was sound but, instead, whether you thought it was a departure from what the law hitherto had been.

MR. DIMOCK: I see. Ciba-Geigy, I thought, didn't stand for that proposition but, according to Justice Sexton, he interpreted it to be that way, that he --

MR. BORN: Just to push you a little bit further if I can, did you, therefore, A, regard the Court of Appeal's admission of post-filing evidence as a change from prior law or, B, did you regard it as consistent with prior law?

MR. DIMOCK: In some respects it did mirror what Justice Thurlow said in Ciba-Geigy, but the logic again didn't make sense, just as Justice Thurlow's logic didn't make sense. Whether it was simply upholding the law, I didn't take it that way. I thought that he was giving reasons for making that

law and I didn't find that to be sound. 04:02

MR. BORN: Thank you.

MR. DEARDEN: Before we deal with the Cochlear case, can we go back to Justice Binnie's AZT at tab --

MR. DIMOCK: Where do we find that again?

MR. DEARDEN: Tab 2, volume 1. C-213.

MR. DIMOCK: I have the case, yes.

MR. DEARDEN: Can you turn to paragraph 79?

MR. DIMOCK: Yes.

MR. DEARDEN: So Justice Binnie says "The 'after-the-fact' validation theory was accepted by the Federal Court of Appeal at paragraph 51" -- which we've just gone through, right?

MR. DIMOCK: Yes.

MR. DEARDEN: Then in paragraph 81 of Justice Binnie's AZT decision, he says, "The Federal Court of Appeal was concerned that patents based on 'instinct and intuition (and) gut reaction' might be invalidated in a case where the ignorance that passed at the time for 'sound prediction' turned out to be wrong and the inventor eventually vindicated. An example was given of a hypothetical patent on the Wright brothers' airplane. Perhaps all the 'experts'

thought it would not fly, but it did. Would it not be illogical, it was asked, to invalidate a hypothetical patent for a heavier-than-air flying machine because scientific opinion in the pre-flight era was wrong? 04:04

82. The hypothetical Wright brothers' patent relates to a new and useful product, rather than (as here) to a new use for an old product, but all the same it illustrates, I think, the flaw in the Glaxo/Wellcome argument. The mere idea of a 'heavier-than-air flying machine' is no more patentable than would be 'anything that grows hair on bald men'. The patent (even in this improbable scenario) would have to teach precisely how the machine could be made to fly. Section 34(1)(b) of the Patent Act requires the applicant to set out in the specification 'the method of constructing, making... or using a machine... in such full, clear, concise and exact terms as to enable any person skilled in the art... to make, construct... or use it'. This means the Wright brothers' hypothetical patent would have to describe, amongst other things, how to design an air foil that creates 'lift' by reducing the air pressure on upper surface of the wing as the air rushes over it, as well as a suitable

airborne method of forward locomotion. If the essentials of the heavier-than-air flying machine were set out with sufficient precision to allow the reader actually to make a flying machine that flies, it is hard to accept the 'hypothetical' that experts would continue to insist, after it had flown, that the prediction was unsound. (Of course, if the prediction turned out to be wrong, the patent would be struck down for inutility. Leonardo da Vinci's elegant drawings showed exactly how to make a 'bird man' machine but it never could, would or did sustain a person in flight.)'" 04:05

That passage about Justice Binnie finding it hard to accept a hypothetical that experts would continue to insist, after it had flown, that the prediction was unsound turned out to be pretty wrong, didn't it, because generics have experts all the time saying that, you know, drugs that have flown, safe and effective approved drugs, so they've flown -- that any expert would actually question. And they do that all the time, right?

MR. DIMOCK: Sorry, maybe it's the lateness of the day. I don't understand your question.

MR. DEARDEN: I understand. The top

paragraph there before paragraph 83, I'm looking at that passage that Justice Binnie says "If the essentials of the heavier-than-air flying machine were set out with sufficient precision to allow the reader actually to make a flying machine that flies, it is hard to accept the 'hypothetical' that experts would continue to insist, after it had flown, that the prediction was unsound." So all the drugs that have been invalidated post AZT, they give a description about how to make those drugs fly, and the experts put on by the generics most definitely insist, notwithstanding Justice Binnie thinking they never would, they continue to insist after it had flown that the prediction was unsound. 04:07

That's the name of the game now, isn't it, Mr. Dimock?

MR. DIMOCK: I wouldn't call it a game.

MR. DEARDEN: It's an expression. That's what's going on now, right?

MR. DIMOCK: We're talking about situations where applications are being made hoping that, as was said, perhaps the patent was filed too soon, that there's not sufficient work done to make any prediction of its utility sound so that you are giving to the public its part of the bargain, the

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quid pro quo as Justice Binnie said, and, you know, in order to get this monopoly that you've got to give something up and it can't be just a mere prediction. It's got to be a sound prediction and the disclosure has to give the facts and the basis for it. So I cannot agree with you. 04:08

MR. DEARDEN: Mr. Dimock, in sound prediction cases post AZT, safe and effective drugs -- so they actually work, they're being consumed by thousands of patients, they're being sold and the generics want to sell a generic version of that very same drug, those drugs actually work, the generics are putting on experts, questioning or saying that the prediction was unsound. Agreed?

MR. DIMOCK: Yes, that's happening, and there are many patents where there is a prediction that turns out not to be correct. That's why you have these safeguards, these -- you know, you have to get past a certain --

MR. DEARDEN: Those are inoperability cases, right?

MR. DIMOCK: Well, if you can show that your prediction was wrong, that if you predict that a particular drug X would treat disease Y and it turns out it doesn't, then why should you be able to get a

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patent if your hunch turned out to be right? You have to be able to give more as part of the bargain to the government to get the monopoly. And I defer to the reasons for judgment of Justice Binnie to explain the basis for that. I'm just giving a very shorthand view of it. 04:10

MR. DEARDEN: Olanzapine worked, correct? Blockbuster drug called Zyprexa.

MR. DIMOCK: It did work for schizophrenia, yes.

MR. DEARDEN: And atomoxetine worked for ADHD, treatment of ADHD? Strattera.

MR. DIMOCK: Your client's witnesses have put that evidence forward.

MR. DEARDEN: You don't dispute it?

MR. DIMOCK: I don't dispute it.

MR. SPELLISCY: I think there's a question of expertise on whether or not Mr. Dimock knows that they worked.

THE PRESIDENT: Sustained.

MR. DEARDEN: And Mr. Justice Binnie's prediction in paragraph 82 in AZT that "it is hard to accept the 'hypothetical' that experts would continue to insist after it had flown that the prediction was unsound", turned out to be an unsound prediction,

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didn't it? 04:12

MR. DIMOCK: We're dealing with different situations here. It turned out, as I recall, the Wright brothers had several unsuccessful flights. They didn't succeed with their first airplane. So that's my point.

MR. DEARDEN: The guy that invented the light bulb first didn't either and Thomas Edison improved on his patent and takes all the credit today for the light bulb.

MR. DIMOCK: However, he did demonstrate its utility, that light shone from the bulb.

MR. DEARDEN: All right. Cochlear, tab 26 in your binder, but don't open it yet because I'm going to your paragraph 103 of your Second Report, Mr. Dimock.

MR. DIMOCK: I have that at page 29.

MR. DEARDEN: You say in paragraph 103 "In his reference to Cochlear v Cosem Professor Siebrasse cites the following excerpt from the case. '...[the] utility of a patent may be proven by the reception received from the public i.e. its commercial success' and continued in the very next sentence to state expressly that utility 'is" -- and the word "also" should be there -- "to be judged at

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the date of the making of the invention, in light of the knowledge existing at the time'." 04:13

Now, that passage doesn't stop where you've got the quotation mark there, so let's go to the case.

MR. DIMOCK: I just wanted to -- you said that I wanted to put "also" in there. I wanted to put "also" in there just because otherwise the statement without the word "also" I took to be misleading.

MR. DEARDEN: "Also" is -- I'm not agreeing on your "misleading" but the word "also" should be there and that's why I read it into the passage, but the passage also should include more words. So let's go to Cochlear. Where did that quote come from, Mr. Dimock, of Cochlear? Page 35?

MR. BORN: Page 35.

MR. DEARDEN: Page 35 under the heading "Utility."

MR. DIMOCK: Yes, I have it.

THE PRESIDENT: To be clear, you are quoting here from paragraph 58 of the second Siebrasse report?

MR. DIMOCK: Yes, that's right.

THE PRESIDENT: And you quoted him or you

quoted directly from the original decision?
MR. DIMOCK: I was taking it from his report.
THE PRESIDENT: Which I call then a secondary quote. Maybe you are familiar with law publications. They copy simply the footnotes of the previous author, and you see the same error serially quoted. What I learned from my mentor was always go back to the source, the original one, so that's what Mr. Dearden is now doing actually.
MR. DEARDEN: That's what I'm doing. Let's look at Utility, page 35, paragraphs (c) and (d) of the decision. Justice Joyal finds "The utility of a patent may be proven by the reception received from the public, i.e. its commercial success... Utility is also to be judged at the date of the making of the invention, in light of the knowledge existing at that time:" Cites Dr. Fox at page 160 and concludes, "In light of its commercial success, there can be little doubt as to the utility of the Cochlear prosthesis." Right?
MR. DIMOCK: You've read it correctly.
MR. DEARDEN: And what does the Fox say? 163, tab 27. Let's go to Fox, page 160, under the heading "Time for decision."

MR. DIMOCK: I have that.
MR. DEARDEN: So Dr. Fox says, "Utility is to be judged at the date of the making of the invention and in the light of the knowledge existing at that time. It is, therefore, a relative quality, and the decision as to its existence depends upon the presence or absence of practical utility at the time the invention was made" and he cites the Tubeless case and quotes Justice Byrne. "'I can quite understand that an invention may be held useful when applied to a subject-matter not known at the date of the invention, if the original description permits such an application; but I cannot think that an inventor, having patented something which he says will work in relation to one form of object, or with one set of constituents, can be allowed to say it is true my invention will not so work, but it will work when altered by a subsequently discovered material or device'."
So what Dr. Fox has quoted there is that utility can't be established by showing utility of a different version of the claimed invention. It can't be a subsequently improved version of the invention to establish the utility. You're stuck with the invention as it was filed?

MR. DIMOCK: Yes. And as he said at the outset, utility is to be judged at the date of the making of the invention and in light of the knowledge existing at that time, and that's the point you've got at the time of the application or the time of making the invention or at the time of filing, that you either have to have a demonstration of utility or a sound prediction.
MR. DEARDEN: What the invention is that is being referred to as being made is the invention that you put down in your patent application, not some improved or different version of what your claimed invention was, right?
MR. DIMOCK: I'm sorry. I didn't quite catch the question.
MR. DEARDEN: Utility isn't allowed to be established by showing the utility of a different version of the claimed invention.
MR. DIMOCK: That's right. You've got -- you want to deal with the invention as disclosed and whatever promises are made and the claims in suit.
MR. DEARDEN: Utility has to be known, not tested. Agreed?
MR. DIMOCK: If you know by just having made the device, for example, that it was obvious

that it would have the utility, then you don't have to test it. But if it is not so obvious that what you've made has the utility, then you've got to test it. And that's what the Proctor & Gamble and Bristol Myers case stands for in the Court of Appeal, where the case was asked to decide whether there was a prior inventor, whether he knew or used the invention before the inventor of the Bounce dryer sheet, and the court said that when the prior inventor responded that it was a good try but no success, what they were saying is that to know the invention is to know its utility.
MR. DEARDEN: While we have Fox open, can you go to page 159? Under the heading "Infringement" as evidence Dr. Fox writes, "It is also strong evidence of utility of an invention if a patent thereon has been infringed or if an attempt to infringe has been made. As Justice Astbury observed in Turner v Bowman: '...the best evidence of its utility... is the fact that the defendants... have thought fit to use the machine which is alleged in the Particulars of Breaches as an infringement'."
So Dr. Fox wrote that in his 4th Edition in 1969, but that statement is no longer true today, is it, Mr. Dimock?

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MR. DIMOCK: No, I don't -- I think it's still applicable today because you can defend an infringement case by saying that what you've described doesn't work at all, that it's inoperable, and what the patentee would say in response, well, if you'd copied my invention, how can you say it doesn't work? I don't think it's anything more than that.

MR. DEARDEN: So your evidence is infringement today is evidence -- strong evidence -- of the utility of the invention if a patent has been infringed or if there's an attempt to infringe?

MR. DIMOCK: If the court concludes that there's infringement, therefore the infringing activity comes within the scope of the claims, and there's an argument made by the defendant infringer that the claim is just inoperable, then it might not work.

But you have to also consider this, Mr. Dearden, that a claim has a certain breadth, and it may be that one part of it doesn't work and the part that the infringer is working does work. The fact that part of it doesn't work can invalidate that claim, so I'm probably drawing out an exception to your point.

MR. DEARDEN: I only want to understand

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your evidence. Your opinion is that Dr. Fox's statement at page 159 about infringement as evidence is that today a patentee can -- well, let me make the quote. "It is also strong evidence of the utility of an invention if a patent thereon has been infringed or if an attempt to infringe has been made." So that argument can still be made today?

MR. DIMOCK: Yes, it's like the argument it hardly lies in the mouth of the defendant to denigrate that which he has chosen to copy.

MR. DEARDEN: But that evidence is admissible as strong evidence of utility today.

MR. DIMOCK: On the issue of operability, not on some of the other issues that we've talked about.

MR. DEARDEN: Mr. Dimock, can you cite a case decided prior to 2002 that invalidated a patent for a commercially useful invention because the patentee could not demonstrate or soundly predict the utility at the date of filing? Let me say that again, because I see you writing it down.

MR. DIMOCK: I don't have your transcript.

MR. DEARDEN: These are really handy. Can you cite a case decided prior to 2002 that

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invalidated a patent for a commercially useful invention because the patentee could not demonstrate or soundly predict the utility at the date of filing?

MR. DIMOCK: As I said, there are so few sound prediction cases, and so right now at this time in this chair, I can't think of any.

MR. DEARDEN: So zero. Fair?

MR. DIMOCK: None that I can think of right now.

MR. DEARDEN: Okay, none. Can you cite a decision prior to 2002 in which the court did not allow the patentee to rely on post-filing evidence to prove utility?

MR. DIMOCK: A case before 2002 where the court --

MR. DEARDEN: Did not allow the patentee to rely on post-filing evidence to prove utility?

MR. DIMOCK: Well, the case I had in the mid-80s, the Cabot case, there was an allegation that the claims were broader than the invention disclosed because the Claimants went beyond the examples and the court held that the disclosure was sufficient. So no, I can't think of any right now. But in that case we didn't have to rely on evidence afterwards and I don't know that I would have put any in because

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I don't believe you can. I put in evidence based on what was in the disclosure.

MR. DEARDEN: Do you agree, Mr. Dimock, that the first time a drug that was approved by Health Canada as safe and effective was found to lack utility was after the 2002 AZT decision? The first time a drug that was approved by Health Canada as safe and effective was found to lack utility was after the 2002 AZT decision. Agree?

MR. DIMOCK: I can't think of any right now, and I presume you're asking me these questions because you know the answer.

MR. DEARDEN: I do.

Switching topics now, you haven't acted for Apotex, but you've litigated against Apotex?

MR. DIMOCK: That's correct.

MR. DEARDEN: And Apotex is the largest generic manufacturer in Canada?

MR. DIMOCK: Yes.

MR. DEARDEN: And Apotex is a prolific pharmaceutical patent litigant in Canada, correct?

MR. DIMOCK: Yes.

MR. DEARDEN: Half the cases in the four binders at your feet seem to be Apotex cases.

MR. DIMOCK: I was just trying to -- I

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wasn't trying to avoid your question. I was just trying to make sure I was answering correctly. But yes, you're right.

MR. DEARDEN: You did. And Apotex has been very ably represented by the Goodmans law firm, has it not?

MR. DIMOCK: Yes.

MR. DEARDEN: And that team of lawyers is led by Harry Radomski.

MR. DIMOCK: Yes.

MR. DEARDEN: And he has senior back-up with Andrew Brodkin, amongst others at that Goodmans firm?

MR. DIMOCK: Among others, yes.

MR. DEARDEN: And both of them are reputable and extremely experienced patent counsel?

MR. DIMOCK: Yes.

MR. DEARDEN: We call them frequent flyers in the Federal courts, right?

MR. DIMOCK: As I said years ago when some of my clients could not get trial dates because the pharmaceutical cases were jumping the queue, that the pharmaceutical cases were choking the court.

MR. DEARDEN: Just as an aside, Mr. Dimock, because I was trying to figure out from

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looking at your CV in the cases you listed that you've litigated, from 2005 until today, how many pharmaceutical patent cases have you litigated that involved the issue of sound prediction of utility? So from '05 to now, have you had the opportunity to litigate any cases where the issue was sound prediction of utility?

MR. DIMOCK: I did work for Ranbaxy against Pfizer. That's the case you referred to. Proctor & Gamble and Genpharm.

MR. DEARDEN: Those are all before 2005.

MR. DIMOCK: Yes.

MR. DEARDEN: I'm talking from 2005 to now. I figured out what ones you were involved in before but, from 2005 to date, have you done any pharmaceutical patent litigation that involved the issue of sound prediction of utility?

MR. DIMOCK: No.

MR. DEARDEN: And from, again, 2005 to now, how many pharmaceutical patent cases have you litigated that involve the issue of whether the promise of utility derived from the disclosure was demonstrated or soundly predicted at the date of filing?

MR. DIMOCK: None.

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MR. DEARDEN: Sir, can you turn to tab 28, Exhibit C-53? What you should have there is a written representations made by the defendant Apotex in the Bristol Myers case. Is that what you have there?

MR. DIMOCK: Yes.

MR. DEARDEN: And these were written representations with respect to an issue being argued before Justice Tremblay-Lamer. Can you turn to 15? There's a heading there, "Change in law: The Wellcome decision." See that?

MR. DIMOCK: Yes.

MR. DEARDEN: Paragraph 15 reads, "At the time of the above discovery, the governing law relating to sound prediction was the Federal Court of Appeal's decision in Apotex v Wellcome Foundation" -- so that's our AZT case, right?

MR. DIMOCK: Yes.

MR. DEARDEN: "Pursuant to this decision, BMS did not need to establish a sound basis for predicting utility as at the filing date of the '436 patent because nefazodone had eventually been shown to have antidepressant activity, precisely as counsel for Apotex had indicated on discovery.

Paragraph 16. "The law changed following

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the decision of the Supreme Court of Canada in December 2002 in Wellcome. The Court rejected the proposition that speculation as to utility, even if subsequently confirmed, is sufficient to justify the grant of the patent."

Mr. Dimock, you agree with the submissions of counsel for Apotex, that the law was changed by AZT?

MR. DIMOCK: I disagree.

MR. DEARDEN: Then go to tab 29. You should have there Exhibit C-532, which is a decision of Madam Justice Tremblay-Lamer. Go to paragraph 30.

MR. DIMOCK: I have that at the bottom of page 12.

MR. DEARDEN: Right. Justice Tremblay-Lamer holds: "Apotex argues, however, that Mr. Radomski's statement was not so much an admission as it was an agreement as to the current state of the law as it existed in February of 2003."

MR. DIMOCK: 2002.

MR. DEARDEN: 2, sorry. "Mr. Radomski had indicated at that time that there was no issue with respect to the sound prediction of nefazodone because" -- and Madam Justice Tremblay-Lamer italicized "because -- "nefazodone had, subsequent to

the filing of the '436 Patent, been made, clinically tested and was successful. Under the governing law of the time, as established in Apotex v Wellcome Foundation" -- the Federal Court of Appeal's AZT decision, correct? That's what she's referring to there, is the Federal Court of Appeal decision in AZT that we have talked about a few minutes ago?

MR. DIMOCK: That's what she's referring to, not to the Supreme Court of Canada decision.

MR. DEARDEN: No, the Federal Court of Appeal one, so "Under the governing law at the time, as established by [AZT Federal Court of Appeal], that was enough -- all that was required was for an inventor to demonstrate utility or sound prediction at the time a patent was attacked. Apotex points out, however, that the law changed subsequent to Mr. Radomski's statement. In December of 2002, the Supreme Court of Canada in Apotex v Wellcome Foundation 2002 SCC 77... directed that either actual utility or sound basis for predicting utility was required as of the filing date of the patent. As such, Apotex argues that the statement made by Mr. Radomski in February of 2002 was obviously no longer applicable: The fact that nefazodone had been shown to eventually have utility as an antidepressant

no longer necessarily meant that the '436 Patent was immune to attack based on lack of sound prediction as of the filing date.

Paragraph 32. "While I agree that it would have been preferable if Apotex had formally withdrawn its statement in light of the change of the law, I find that the amendments made by Apotex to paragraph 21 in July of 2004 sufficiently demonstrated that lack of sound prediction with respect to nefazodone and nefazodone hydrochloride was a live issue. The amendment to paragraph 21 parallelled the change of law with respect to sound prediction: It alleged that even if one of the compounds of the '436 Patent was eventually shown to have the utility promised, there was a lack of sound prediction at the time of filing."

I'm not going to read the rest of paragraph 31, but paragraph 32: "I find that given the change of law regarding lack of sound prediction, and given the modifications made by Apotex to paragraph 21 subsequent to that change, it cannot be said that the amendment sought by Apotex on the current motion constitute a radical departure from Apotex's prior pleadings."

Do you agree with Justice Tremblay-Lamer

the law was changed by AZT 2002 Supreme Court of Canada?

MR. DIMOCK: Before I answer that, Mr. Dearden, was not this decision of Madam Justice Tremblay-Lamer not appealed and she was criticized?

MR. DEARDEN: She was criticized by giving the amendment to Apotex so late in the day in the trial. So she allowed --

MR. SPELLISCY: Sorry, is that testimony from Mr. Dearden, or is that a question?

THE PRESIDENT: No, sorry. First of all, it's Mr. Dimock who asked the question to the examiner, if I may call it that way. Reverse of roles, and he answered, so I will allow the question both ways!

MR. DIMOCK: I guess I should have said a statement. It was appealed.

MR. DEARDEN: My last document Mr. Dimock is the next tab, tab 30, which is Exhibit C-375. Do you know, sir, Apotex's position about the arbitrariness of Canada's law of utility?

MR. DIMOCK: Do I know its position?

MR. DEARDEN: Yes.

MR. DIMOCK: I guess I don't understand what you mean by that.

MR. DEARDEN: Do you know what their view is of the current state of the law of utility in Canada as being arbitrary or non-arbitrary? Do you know?

MR. DIMOCK: The only time I've read what they say is in court proceedings. I'm not aware of any printed publications that they've made as to what their position is, so only what they argue, and like any good law firm -- and they are a very good law firm -- they argue the case as they see it to advance the interests of their client.

MR. DEARDEN: And they do so as officers of the court?

MR. DIMOCK: We all do, yes.

MR. DEARDEN: Yes, we do. So the document you have at tab 30 of the binder is a notice of application for leave to appeal of Apotex in the Plavix case.

MR. DIMOCK: And I won't ask this as a question, I'll make it as a statement in answer to your question. Yes, this case did go on appeal and leave was granted by the Supreme Court of Canada, and the day before the hearing was to take place Apotex and Sanofi settled and there was no appeal.

MR. DEARDEN: There was no decision of

04:42 the Supreme Court of Canada, that's absolutely correct, but what I'm asking you to look at in this notice of application, where, indeed, leave was granted, is one of the submissions made to obtain leave of the Supreme Court is at paragraph 14 under the heading "The proposed appeal raises questions of urgent national interest." Do you have that? So page 4 of the notice is where you'll see heading C, "The proposed appeal raises questions of urgent national interest." Tab 30.

MR. DIMOCK: I'm at tab 30.

MR. DEARDEN: It's only like two pages in. You look like you're deeper.

MR. DIMOCK: Okay. I was looking at a page much later on in the tab.

MR. DEARDEN: So you have paragraph 14 now?

MR. DIMOCK: Yes, I do. Page 4, yes.

MR. DEARDEN: Right. So here's what Apotex had to say to the Supreme Court of Canada. "It is well understood that a Canadian patent will be invalid for want of utility if its invention does not do what the patent promises it will do. However, this Court has never guided the lower courts in how they are to identify or characterize the limits of a

04:44 patent's promise and how the promised utility relates to the inventive concept of the claims of the patent. Without this guidance, the lower Courts have created and applied a hopeless tangle of contradictory approaches to these questions. The situation is now a 'free-for-all' in which the outcome of cases depends upon the particular judge or panel hearing the dispute, rather than on legal authority. The outcome of cases (particularly cases like the present case, where the stakes to the parties are counted in the hundreds of millions of dollars) must not be determined so arbitrarily. The proposed appeal raises this intolerable confusion for resolution."

And Apotex succeeded in getting the Supreme Court of Canada to give them leave to appeal the Federal Court of Appeal's decision in Plavix, correct?

MR. DIMOCK: That's correct.

MR. DEARDEN: Mr. Dimock, that completes my questions, sir. Thank you.

Mr. President, that completes my questions.

THE PRESIDENT: Thank you.

MR. SPELLISCY: Can we have five minutes?

THE PRESIDENT: Five minutes granted.

04:45 Mr. Dimock, you know what it means. You're still under testimony.

(Recess taken)

THE PRESIDENT: Mr. Johnston, please proceed with the redirect.

REDIRECT EXAMINATION ON BEHALF OF THE RESPONDENT

MR. JOHNSTON: Thank you, President van den Berg.

Mr. Dimock, quite early in your cross-examination you were asked about the Mobil Oil case, and Mr. Dearden put it to you -- this is at 11:55:08 on today's transcript -- he put it to you, "Justice Wetston made no findings of promise, did he?" And in your response at 11:55:32 in the transcript, you said: "I just can't put my finger on the particular sentence in Justice Wetston's reasons." You were taken to page 513 of the decision, though you were not given an opportunity to look at that decision in full.

The quoted portion -- the portion of your Expert Report which was at issue in Mr. Dearden's questions was in your first Expert Report at paragraph 70 and 71 where you draw the link between Consolboard and Mobil Oil, and if I could direct you to paragraphs 70 and 71 of your first Expert Report,

04:56 I wonder if, in reviewing these paragraphs, there's anything more you'd like to add in respect to this issue?

MR. DIMOCK: Yes. I was curious myself about the passage I was trying to recall in answering Mr. Dearden, and I didn't want to interrupt his line of questioning this afternoon, but I had found what I was looking for, and that's at page 508 of the Canadian Patent Reporter, and it's at letter B.

THE PRESIDENT: Could you help me with the tab, and which volume number?

MR. DIMOCK: Yes. It's tab 19 in volume 3.

THE PRESIDENT: Thank you.

MR. DIMOCK: This was the decision of Justice Wetston that Mr. Dearden took me to this morning, and he directed my attention particularly to paragraphs on page 513, but it's page 508 that I had in mind when I was trying to answer his questions, and here Justice Wetston -- and if you go back to page 507 Justice Wetston says, "In order to be an invention worthy of protection, the patent must disclose and claim an invention which works, that is, which achieves the promise it sets out." And then in the second paragraph on page 508 here's what Justice

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Wetston said. "The patent specification promises an oriented polypropylene film substrate having enhanced adhesion to a metallized coating. The evidence indicates that this was indeed achieved..." and then he goes on to say something about the bond strength of 90 grams per inch. He concludes, "Therefore the patent is not valid for inutility."

So yes, he was asked, or he did look to the specification to see whether or not there was a promise, and he found that there was a promise of enhanced adhesion, and that was met by the claims.

MR. JOHNSTON: Thank you.

You were also asked now towards the end of your cross-examination regarding a Bristol Myers case, this was at tab 28 of your cross-examination binders, you were taken to written representations by Apotex in this BMS case, then at tab 29 you were taken to the decision of Justice Tremblay-Lamer in that case, and then you indicated in your response to Mr. Dearden that you had understood this matter to have been appealed, and so I wanted to give you the opportunity -- I'd like to bring up that appeal which was not provided to you in your cross-examination binder.

If we could pull up C-545, please,

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paragraph 23, this is where that issue was discussed by the Federal Court of Appeal. This is C-545, page 10, paragraph 23, if you'd like to take a minute to look at that.

MS. CHEEK: Mr. Johnston, if you could also give us a moment to get that exhibit?

THE PRESIDENT: Mr. Dimock, do you need a hard copy?

MR. DIMOCK: I am myopic, so I have a hard time seeing small print.

THE PRESIDENT: Mr. Johnston, could you please provide a hard copy to Mr. Dimock?

MR. JOHNSTON: Yes, that will require a minute to go print a hard copy.

THE PRESIDENT: You don't have a hard copy here available?

MR. JOHNSTON: One moment.

THE PRESIDENT: Maybe the Tribunal has a hard copy. (Handed)

MR. DIMOCK: I've read that paragraph, and I believe I've got the context of it, yes.

MR. JOHNSTON: Based on that, is there anything more you'd like to add in response to Mr. Dearden's questions?

MR. DIMOCK: What I think the Court of

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Appeal was saying, if I understand it correctly, in the time I've had to look at it -- although I do remember something about the case and the appeal, they waited very long afterwards to say that there was a change in the law; that it was something, if they wanted to make the amendments that they did, they should have done so a lot sooner, and that militated against their abilities to amend now.

MR. JOHNSTON: Mr. Dimock, you made reference in one of your responses to a case you had worked on, the Proctor & Gamble case. Am I right this is the 1979 Proctor & Gamble case you were referring to?

MR. DIMOCK: Yes, it was.

MR. JOHNSTON: Just for clarity of the record to confirm that is Exhibit R-183, the case you were referring to, and it's the case relied upon in your Expert Report?

MR. DIMOCK: I believe that's the number, that's right. It's a decision of the -- you say 1979 Proctor & Gamble? And the one I was referring to was the decision of Proctor & Gamble v Unilever in 1995.

MR. JOHNSTON: That's the decision you were referring to in your response?

MR. DIMOCK: Yes.

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MR. JOHNSTON: If that is Exhibit R-172. Just one more question, Mr. Dimock. You were asked how many pharmaceutical cases have you litigated where the issue of demonstration or sound prediction of utility were at issue. I'd like to ask how many cases outside of the pharmaceutical field, or to what extent have you litigated other cases raising these types of issues?

MR. DIMOCK: I was involved as a junior lawyer in Monsanto, which was sound prediction. And I was counsel for Cabot in the case that I referred to earlier that was sound prediction, and I think the chart that I had this morning, Has the Invention Support for Prediction Been Disclosed, and that was the decision of Cabot v 318602 Ontario Ltd, a decision of Justice Cullen -- no Justice Rouleau in 1988. And that was a sound prediction case.

So I was involved in two of them, the Consolboard case in the Court of Appeal and the Supreme Court of Canada -- that is to say I was not counsel but I helped prepare the brief for those and I was counsel on Cabot and the numbered company.

MR. JOHNSTON: Have you recently been involved in any cases involving issues of the promise of the patent?

MR. DIMOCK: Yes. The one I just finished two weeks ago, I brought an impeachment action on behalf of a company called Pollard v Scientific Games over a lottery ticket, and throughout the disclosure of the patent belonging to Scientific Games they had made a promise that, by using the particular design and construction of the lottery ticket, the lottery system would somehow be protected from fraud by customers through what we called in the trial bar code security. And because the claim, we argued, could not satisfy that utility of bar code security, that that was, therefore, an invalid claim and therefore the patent should be impeached. I'm waiting for that decision.

There was also a case involving sound prediction -- not sound prediction but promise, and the case I acted on behalf of Dow Chemical v Nova, a Court of Appeal is still under reserve with that decision. We argued that appeal in December. We were acting as Respondent to an attack against the Dow patent by Nova saying that a promise made in the disclosure could not be met and we were arguing that there was no such promise made in the disclosure.

MR. JOHNSTON: Thank you. I have no further questions.

THE PRESIDENT: Application for recross?

MR. DEARDEN: None, Mr. President.

THE PRESIDENT: Mr. Born has a question.

QUESTIONS BY THE ARBITRAL TRIBUNAL

MR. BORN: Just one question. Going back to the Mobil Oil case, which we talked about briefly, and the reference that you were taken regarding the promise of the patent.

MR. DIMOCK: Yes.

MR. BORN: That promise -- and this, I think, is tab 19 in your third bundle.

MR. DIMOCK: I have that, Mr. Born, yes.

MR. BORN: That promise, if I understand correctly, was in the claims? I'm looking at page 493.

MR. DIMOCK: Yes. There was a promise of, as Justice Wetston said, the patent specification promises such and such, an enhanced adhesion. The claims also had enhanced adhesion as an element of it.

MR. BORN: When I looked on page 493, I see that in the claims. Is that right?

MR. DIMOCK: Yes. The promise that was made in the disclosure of enhanced adhesion carried on into the claim, that's right.

MR. BORN: I guess what I'm struggling with is when I get to page 513 -- and you'll help me on this if I'm wrong -- when I get to page 513, which was the focus of your cross-examination testimony, the defendant's argument there was that the promise was not the enhanced adhesion that we saw in the claim but, instead, a particular level. The 250 I don't know, grams per inch or something.

MR. DIMOCK: They were suggesting that not only was there a promise of enhanced adhesion but a promise of enhanced adhesion at a particular level.

MR. BORN: Right, and that particular level promise came from the disclosure, not the claims.

MR. DIMOCK: That's correct.

MR. BORN: And the court said we don't find that promise.

MR. DIMOCK: That's correct.

MR. BORN: Okay. Thank you.

THE PRESIDENT: I have one question, Mr. Dimock, a discrete question concerning your first Expert Report, paragraph 78. Although we have to be cautious regarding law firm newsletters, in paragraph 78 you cite a newsletter of your law firm, I understand it to be, is that correct, of 1987?

MR. DIMOCK: That's correct.

THE PRESIDENT: Congratulations that you could find it still after so many years. But more seriously --

MR. DIMOCK: My wife accuses me of being a pack rat.

THE PRESIDENT: Okay. You're not the only one!

But what you say right there is about dangers of including object clauses in patents, and that follows the Amfac decision, 1986. Could you please elaborate on what is the danger -- or was the danger, because I have a compound question, a second question, is the danger still there today? First, answer the first question what was the danger, and then...

MR. DIMOCK: The danger is still there, so I answered the second question first. The danger is still there. And the danger I was trying to make our clients aware of was the same danger that Mr. Hayhurst wrote about to which I referred in paragraph 79, and that is he also said earlier you don't lard up your disclosure with a lot of promises because, if you do, you might have to meet those promises in the claim, so beware. Only make a

promise when you have to. And what I was saying in that newsletter is that avoid -- because you don't have to describe utility of your invention in the ordinary course, as I said earlier today, there are occasions when you have to talk about the utility for a new use patent or a sound prediction or what-have-you, but what I was saying here, unless you have to refer to utility, avoid that because if you are reckless in how you give the objectives and the promises in the patent, your claims could go from a much larger scope down to a very small scope and, therefore, not be able to capture as many infringements as you'd like. That's what I was suggesting.

05:13

THE PRESIDENT: But could you be more specific what is the danger if you include --

MR. DIMOCK: The danger is that the court -- for example, if a patent had these objectives that were considered by the court to be promises, just as in Amfac, I was faced with a disclosure where not only was the invention a good one to throw the potato against a grid of knives to get long slender cuts, but the patent went on to say that a further utility and a promise that we make if you adopt our invention, you're going to separate the

potatoes at the knife and, therefore, your claims are going to be narrowed, and because we had a very broad claim, 16, it was held invalid. So what I was saying is unless you have to, for whatever reason, include promises, don't do so because if you do you're going to be held to them, and your claim may be held to be invalid.

05:15

THE PRESIDENT: Thank you. Any follow-up questions?

MR. DEARDEN: No, Mr. President.

MR. JOHNSTON: None.

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

Changeover of five minutes for the next expert, Mr. Levin.

(Recess taken)

BRUCE LEVIN

THE PRESIDENT: Before we proceed with the examination of Professor Levin, there is one question on which the Tribunal would like clarification. It's a small question and it concerns the Expert Report of Mr. Siebrasse. Without going into a formal recall of Professor Siebrasse, we wondered whether footnote 98 of the First Report has

the correct citation.

05:21

SIR DANIEL BETHLEHEM: It's simply a question of clarification. We've been having a lot of references back to the three cases in 2005, and a number of the witnesses have gone back to Professor Siebrasse's report. In footnote 98, which refers to paragraph 72, we see a reference to the three cases. I think our concern about the correctness of the citation relates to the first one, Bristol-Myers Squibb v Apotex 2005, which is referenced as C-190, but when you pull up C-190, that doesn't seem to be the correct case, so we would just like a technical clarification at some point from you, please.

MS. CHEEK: I would suggest we will get you an answer to that question, but we go ahead and proceed with Professor Levin.

SIR DANIEL BETHLEHEM: Yes.

THE PRESIDENT: If you can give it to us tomorrow morning, that's fine, or you can send it by e-mail.

MS. CHEEK: We will plan to do that.

MR. SPELLISCY: This may actually come up in the cross-examination, so I'm not sure if we can break to get a clarification quickly.

THE PRESIDENT: This footnote?

MR. SPELLISCY: The dates of the relevant cases, I think.

05:22

THE PRESIDENT: These three relevant cases?

MR. SPELLISCY: These three.

SIR DANIEL BETHLEHEM: So are you proposing that we do break or we don't break?

MR. SPELLISCY: If we can get an answer on it quickly. We can confer with our colleagues.

THE PRESIDENT: Then maybe it's useful that we resolve it now, because it's relatively easy, I think, to check.

MS. CHEEK: I can confirm now that the correct exhibit cite --

THE PRESIDENT: C-190 is the correct exhibit cite?

MS. CHEEK: The correct exhibit cite is actually C-520, which I suppose we also could submit as an amended C-190. I just think there was some kind of clerical error that we caught later.

THE PRESIDENT: It can all happen. We are all human beings. There's no problem.

MR. SPELLISCY: This is what we had understood was the correct cite.

THE PRESIDENT: Then we're all on the

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same page again. Thank you.
Good afternoon, Professor Levin.
PROFESSOR LEVIN: Good afternoon.
THE PRESIDENT: Could you please state your name for the record?
PROFESSOR LEVIN: Bruce Levin.
THE PRESIDENT: Professor Levin, you appear as an expert witness for the Claimant in this case.
PROFESSOR LEVIN: Yes, Mr. President.
THE PRESIDENT: If any question is unclear to you, either because of language or for any other reason, please do seek a clarification because, if you don't do so, the Tribunal will assume that you've understood the question and that your answer corresponds to the question.
PROFESSOR LEVIN: Yes.
THE PRESIDENT: Professor Levin, you will appreciate that testifying, be it before a court or an arbitral tribunal, is a very serious matter. In that connection, the Tribunal requests you to give the statement which is in front of you.
PROFESSOR LEVIN: Yes. I solemnly declare, upon my honor and conscience, that my statement will be in accordance with my sincere

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belief.
THE PRESIDENT: Thank you.
Professor Levin, could you please go to your Report to page 14? Your report is dated December 7, 2015.
PROFESSOR LEVIN: Yes.
THE PRESIDENT: And confirm for the record that the signature appearing above your name is your signature?
PROFESSOR LEVIN: I so confirm.
THE PRESIDENT: We have your correction errata sheet. Are there any other corrections you wish to make to your report?
PROFESSOR LEVIN: No, Mr. President.
THE PRESIDENT: Thank you. Then, Ms. Cheek?
MS. CHEEK: Thank you, Mr. President. Mr. Smith will be conducting the direct examination of Professor Levin.
THE PRESIDENT: Thank you. Mr. Smith, please proceed.
MR. SMITH: Thank you.
Professor Levin, the President referred to the errata sheet that you had submitted. Could you please turn to that page? I'm sorry, I

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apologize. We will deal with the errata after your presentation. If you would, please proceed to your presentation.
PROFESSOR LEVIN: Thank you.
PRESENTATION BY PROFESSOR LEVIN
Good afternoon, I am a tenured professor of Biostatistics at Columbia University in their School of Public Health in New York City. I was Chair of the Department of Biostatistics from 2000 through 2011. I have some Honors, and I just want to say I have performed similar disproportionate impact analyses in other legal disputes such as employment and housing discrimination cases. I'd like to add that this is my first consultation with Eli Lilly and Company.
I was asked by counsel for Eli Lilly to do the following, which was to assess the statistical significance of certain differences in the proportions of patent lawsuits in which courts sustained validity challenges on grounds of utility or on other grounds comparing the pharmaceutical sector with non-pharmaceutical sectors, both from 2005 onward, which I'd like to refer to as the post-2005 period, and from 1980 through the end of 2004, which I'd like to refer to as the pre-2005

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period.
The graphic on the right-hand side of this slide represents the question that was posed to me upon first contact by counsel. They presented these pie charts showing the 40 percent of pharmaceutical cases that had been held invalid in the pharmaceutical cases as compared to none in the non-pharmaceutical cases, and this was put to me as whether that was statistically significant.
I'd like to summarize my conclusions. After the analysis I did I concluded that post-2005, there is a statistically significant difference in invalidation rates based on lack of utility between pharmaceutical and non-pharmaceutical sectors in Canada.
Prior, pre-2005, there is no significant difference across sectors. On grounds other than utility, there is no significant difference between the invalidation rates. And the above findings are consistent with the view that Canada's utility requirement has had a disproportionate impact on the pharmaceutical sector since 2005.
The data that I was presented for analysis consisted of a spreadsheet listing all patent invalidity decisions issued by Canada's

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Federal courts between January 1, 1980 and, at the time, August 10, 2015. I'd like to emphasize that that was the entire census, all the cases that had been so decided. There were 234 cases in the spreadsheet.

Of those, 17 were not challenged on either grounds of utility or obviousness or novelty or sufficiency or any combination of those, so I removed those 17 cases from analysis and focused on those 217 which did involve at least one such challenge. There were 129 cases post-2005 and 88 cases pre-2005 among those 217 that I studied.

The analysis consisted of cross-classifying the cases that involved a challenge on grounds of utility. Table 1 before you shows that cross-classification. In the post-2005 period 39.7 percent, almost 40 percent of the pharmaceutical cases that were challenged on grounds of utility were held invalid, whereas in the non-pharmaceutical sector, none of the eight were held invalid on those grounds.

In the lower right-hand corner of the slide you'll notice P equals 0.0245. In statistics this is known as the P-value, and it indicates statistical significance. In a moment I'd like to

explain in more detail what I mean by "statistical significance", but let me just say here that when the P-value is less than .05, we will refer to that as "statistically significant", and would lead to a rejection of the null hypothesis.

So what do I mean by the null hypothesis and how do we test it?

The null hypothesis states that the positive difference that we observe in the proportions of pharmaceutical versus non-pharmaceutical cases with a finding of inutility in the post-2005 period is due merely to chance. The word "chance" is there. I will define what I mean by "chance" momentarily.

In distinction to the null hypothesis, the alternative hypothesis states that the observed difference in proportions is due not to chance but to substantive reasons. Specifically, that Canadian utility law has had a disproportionate impact on the pharmaceutical sector since 2005.

The question that the words above, referring to "chance" and "null hypothesis" results in a question: How frequently would we see inutility proportions between the two sectors, pharmaceutical and non-pharmaceutical, differ by at least as much as

we actually have observed in these cases by chance alone?

The answer to that question is the P-value. So on the previous slide, when it said P equals .0245, what it meant was that, by chance, we would expect a separation of those two invalidity proportions by that much, or even more so, only 2.45 percent of the time.

I've prepared a graphical display to portray, hopefully concretely, what we mean by chance. This is an illustration of what we call an urn model. In front of you there's notionally an urn in which I've put 71 chips colored green and colored red, 71 because I was studying 71 cases involving grounds of utility challenges. 46 of the chips are green reflecting that, in the actual data, there were 46 cases held valid, and 25 chips are red, reflecting the fact that, again, among those 71 there were 25 holdings in total of invalidity on utility grounds.

Now, the particular separation of these chips on the basis of whether they are pharmaceutical cases or non-pharmaceutical cases is one way we could split this urn full of chips, but it is only one of many ways, and if by "chance" what we mean is that we should consider other ways, in fact, all of the ways

that we could possibly split this urn into two groups reflecting the number of pharmaceutical cases and non-pharmaceutical cases, in fact randomly -- that being the meaning of "chance" -- how often would we find the observed results.

So on the next slide I've notionally imagined drawing, or withdrawing, eight chips from the urn at random and without replacement. Close your eyes, don't look at the colors, withdraw eight chips at random. Strictly speaking, that means all possible subsets of eight chips would be equally likely because it's at random.

Question: What color would these withdrawn chips be, likely? And on the next slide we see that, in fact, what we observed was all of the eight chips were green, referring to the fact that all of the non-pharmaceutical sectors were held as valid. How likely is that? And the answer to that is the P-value. So on the next slide we see, having withdrawn eight random chips, all being green, the likelihood of that is only 2 1/2 percent -- less than 2 1/2 percent of the time.

Because that proportion, that probability, is less than 5 percent, we say that the result is "statistically significant" and gives us

grounds to reject the null hypothesis in favor of the alternative hypothesis.

So to summarize my conclusions from table 1, post-2005 we saw a 39.7 percentage point difference in pharmaceutical versus non-pharmaceutical utility-based invalidation rates, that percentage point difference being clearly the difference between 39.7 and 0. That difference is statistically significant. Its P-value is .0245. So, as I said, we reject the null in favor of the alternative.

I was next asked to consider the similar analysis pre-2005, so these are different cases; there were 27 cases pre-2005, also deciding a challenge on grounds of utility. If you notice two things, first of all, the numbers of cases were substantially smaller. In the lower right-hand corner we see P equals 1.0. Since that's greater than .05, we find no statistical significance.

The second thing you'll notice is that, again, while the numbers are small, there is an 8.3 percentage point difference; however, in the opposite direction to the hypothesized direction under the alternative hypothesis. We might call that 0 minus 8.3 percent, a minus 8.3 percentage point difference.

As a caveat, I do not make much of the result in this table for the simple reason that the numbers are so small, so I neither conclude to accept the null hypothesis nor to reject it. The numbers are too small. We call such a situation a low power situation, "power" meaning the likelihood that, even if there were a true difference under the alternative, the chance that we would declare it as statistically significant is quite low.

So I will summarize what I just said. A minus 8.3 percent difference, sometimes we say that's a difference in direction opposite to that specified by the alternative hypothesis. We do not reject the null hypothesis in this case. This difference is not statistically significant.

Next, I was asked to consider in table 3, the same analysis back to the post-2005 period, this time where cases were decided based on challenges other than utility, specifically in this table on grounds of non-obviousness or novelty. Here what we see are more substantial numbers in the marginal totals. In the lower right-hand corner we see P equals .593 so, again, we find no statistical significance to this difference.

The distinct difference between this and

the previous slide is, when we look at the actual invalidity proportions, they're very, very close. There's only a 0.2 percent difference between the 41.1 percent difference in pharmaceutical cases found invalid on other grounds versus the 40.9 percent invalidation proportion in non-pharmaceutical cases.

So here we have greater confidence when we reject the null hypothesis -- when we don't reject the null hypothesis to understand the reason, the reason being that there's only a trivial difference in the proportions themselves.

I'd like to add while I don't have a slide for this, I also repeated the analysis, including grounds of sufficiency. So when we have non-obvious or novelty or sufficiency or any combinations of those grounds, the results were substantively the same. There was no significant difference.

So to summarize table 3, post-2005 there was a 0.2 percentage point difference in invalidation rates across the pharmaceutical and non-pharmaceutical sectors on grounds other than utility, whether that be including or excluding sufficiency. That difference arising from two very close proportions, roughly 41 percent. That

difference is not statistically significant. And that brings me essentially to the end of my key findings.

Just to recap, post-2005, that 39.7 percent difference in the proportion of utility-based invalidations is statistically significant. Before 2005, the 8.3 percentage point difference in the opposite direction to that specified by the alternative was not statistically significant. And post-2005, the small, 0.2 percentage point difference in the proportions of invalidations on other grounds between pharma and non-pharma sectors was not statistically significant.

These three bullets are consistent with the Claimant's view that Canadian utility law has had a disproportionate impact on the pharmaceutical sector since 2005.

Thank you.

MR. SMITH: Thank you, Professor Levin.

DIRECT EXAMINATION ON BEHALF OF CLAIMANT

MR. SMITH: The errata referred to earlier I believe are reproduced on demonstrative slide 1. Could you please pull up that slide. That is at tab 3.

MR. BORN: 3? Or 4.

MR. SMITH: Thank you. Tab 4. 05:42
PROFESSOR LEVIN: Yes.
MR. SMITH: Professor Levin, could you please explain the changes that are shown on demonstrative slide 1?
PROFESSOR LEVIN: Yes. There were four errata that were identified. I'd like to begin, if I may, with the second line. This is the Pfizer Canada Inc. v Canada case, alternately referred to in Dr. Brisebois' report as Apotex v Pfizer. This is the only case involving a challenge on utility grounds. The correct coding is not useful. I'd like to be very clear. The only error that was involved was a typographical error that appeared in Appendix C in my original report, but it was coded correctly in my analysis. So the tables that we've been looking at did not have any influence of this printed typographical error.
Then the first line and the third line represent coding errors for grounds of sufficiency, one not useful, the other useful in the pharmaceutical sector on top and non-pharmaceutical sector on line 3. These did not affect our comparisons on grounds of utility, clearly because the coding error was in the sufficiency column. And

then the fourth line, similarly, was coding errors on grounds of non-obviousness and novelty. 05:44
MR. SMITH: Professor Levin, do these errata have any effect on the conclusions you just summarized?
PROFESSOR LEVIN: No, they do not. The statistical significance of table 1 remains because none of these cases, including Apotex v Pfizer, were in error on utility grounds. Nor did the other analyses, table 2 and table 3, remain not statistically significant.
MR. SMITH: Are you familiar with the second witness statement of Dr. Marcel Brisebois?
PROFESSOR LEVIN: Yes, I've reviewed it.
MR. SMITH: In that statement Dr. Brisebois suggests at paragraph 10 that after you submitted your report, additional Canadian cases have been decided and published that should be considered. What, if anything, did you do in response to this comment?
PROFESSOR LEVIN: I requested an updated database, which would include not only these corrections of errata but also the additional more recent cases since my report, and on the next demonstrative slide we see what those cases are.

There were nine cases in total. You'll notice that 05:45
two of those cases were not challenged on grounds of utility, so for the utility analysis there were seven additional cases which I included in my reanalysis.
MR. SMITH: How, if at all, did your conclusions change as a result of analyzing this updated dataset that is shown on demonstrative slide 2?
PROFESSOR LEVIN: They did not change at all. The table 1 remains statistically significant. The other two tables remain statistically not significant. On the next demonstrative slide I have an updated table referred to here as table 1A. What you see is the seven additional cases in the lower right-hand corner. Now there are 78 cases, 69 of which were pharmaceutical, nine of which were non-pharmaceutical. There was an additional case in the interim in the non-pharmaceutical sector. When we look at the proportions found invalid on utility grounds, we find, if anything, the proportion has increased a bit. It's now 40.6 percent, almost 41 percent, whereas in the non-pharmaceutical sector the percentage is still zero. Zero out of 9 this time.
The increase in the proportion slightly

and the increase in the sample size has caused the 05:47
P-value to become smaller, meaning there's a bit more statistical significance than previously. The P-value is now .014 approximately, meaning that there's only a 1.4 probability one would find this kind of split by chance alone.
MR. SMITH: So those updated findings with respect to utility appear on table 1A and demonstrative slide 3.
Next, could you please discuss any changes in what appeared as table 2 in your report, based on your analysis of the updated dataset?
PROFESSOR LEVIN: Yes. On the next demonstrative there's absolutely no difference in my original table 2 because, as I said, the corrections and the updated cases all occurred after 2005. So table 2 remains the same.
MR. SMITH: Finally, could we please turn to demonstrative slide 5, and would you please discuss any changes to your conclusions in table 3 from your original report?
PROFESSOR LEVIN: Yes. Table 3A is the only one that had some additional changes to it based on the errata and the additional cases but not substantive changes. That is to say, the proportions

are still not as close as they were but still certainly within the realm of chance. The P-value on the lower right-hand corner is still not statistically significant. 05:48

MR. SMITH: In his second statement, Dr. Brisebois suggests at paragraphs 20-26 that your dataset should have excluded what are referred to as PM(NOC) cases and counted only actions for infringement or impeachment.

PROFESSOR LEVIN: Yes.

MR. SMITH: What, if anything, did you do in response to that statement?

PROFESSOR LEVIN: Well, I asked for a revised dataset which would now exclude the PM(NOC) decisions and redid the analysis. On the next demonstrative, updated table 1B, it contains actions only. You see that the sample numbers -- I should say the universe numbers here are drastically smaller and still -- I should say notwithstanding the proportion of invalid cases in the pharmaceutical sector held invalid on utility grounds -- has, if anything, continued to increase. There's now almost 43 percent of the cases among the 14 held invalid still versus 0 percent among the non-pharmaceutical cases.

You'll see that the P-value, being less than 5 percent, is still significantly significant. And a comment that I'd like to draw the Tribunal's attention to is that when we have markedly reduced marginal totals such as we have here and, yet, we still have statistically significant difference, it arises because of the large substantive difference in the proportions of invalidity. 05:50

MR. SMITH: In his second statement Dr. Brisebois also suggests at paragraph 17 that the dataset should have been compiled by counting patents rather than individual cases. What, if anything, did you do in response to that statement?

PROFESSOR LEVIN: I asked for a new dataset in which the unit of analysis was patents, because I wanted to see if the findings held up on the basis of patents. I do want to point out, before we discuss the results, that there is an important distinction that should be kept clearly in mind, which is what is the unit of analysis. I was asked to consider the difference in proportion of patent lawsuits, cases, and what are the invalidity proportions on a case basis. I call that the unit of analysis.

Here, we're changing the question. We're

now asking whether there's a difference in the proportion of patents held valid or invalid. And owing to the fact that you can have several patents under consideration in a single case, one has to deal with the issue of the clustering of the unit of analysis within the case. So there are methods of addressing that. But, nevertheless, on the next slide we see what the result was following Canada's own approach, which was to ignore the clustering of patents within cases, and simply looking at the comparison of invalidity proportions without worrying about whether, when we withdraw individual patents from the urn, they're splitting up individual patents from the same case. 05:52

What we see is 36.8 percent invalid in pharmaceutical sectors versus that same 0 out of 9 in non-pharmaceutical sector. You see in the lower right-hand corner that the P-value is still about .02 and, therefore, still statistically significant.

MR. SMITH: Next, Dr. Brisebois suggests that three individual cases were miscoded. What, if anything, did you do in response to Dr. Brisebois' proposed correction to the Pfizer v Canada case discussed at paragraph 9 of his report?

PROFESSOR LEVIN: Once again, I requested

the specific particular cases and modified the analysis to reflect Dr. Brisebois' suggestions. On the next slide we continued to deal at the unit of analysis of patent, because that's what Dr. Brisebois was using, and I added Bayer v Apotex and removed the Wenzel case and, yet again, what we see is the difference persists. It's a large proportional percentage point difference, 36.4 versus 0. The P-value is still below 5 percent, so those two modifications did not alter the conclusion of statistical significance. 05:53

MR. SMITH: Professor Levin, for the record I asked you about the Pfizer v Canada case in paragraph 9 of Dr. Brisebois' report. Did you make reference to that case earlier in your presentation in your errata?

PROFESSOR LEVIN: Yes, I did. That was the case on the second line of the demonstrative. That was the case that merely was a typographical error but which was correctly analyzed in my table.

MR. SMITH: In your summary of updated table 1D on demonstrative slide 8, you just referred to the other two cases to which Dr. Brisebois suggested that corrections be made, and those cases are Wenzel Downhole Tools and Bayer v Apotex

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discussed at paragraphs 7 and 10 of his Second Report. Is that correct? 05:55

PROFESSOR LEVIN: Yes, it is.

MR. SMITH: Finally, Dr. Brisebois suggests at paragraph 8 of his report that cases such as Eurocopter, cases with split outcomes across claims within a single patent, should be coded both as a win and as a loss for the innovator. In other words, counted twice. What, if anything, did you do in response to Dr. Brisebois' statement regarding these split claims cases?

PROFESSOR LEVIN: Well, I was asked to do the calculation, even though initially I strongly objected to doing that for the simple reason that in my opinion, the approach Dr. Brisebois has taken here is entirely statistically invalid. It's invalid and inconsistent, in fact. It's invalid because it violates a fundamental statistical rule, which is that when you're classifying units such as we are here as either valid or invalid, the classification system must be mutually exclusive and exhaustive. That means that every patent, if that is your unit, must be classifiable as one or the other, not both.

I understand the rationale Dr. Brisebois took, which was to somehow reflect the different

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claims clustered within given patents in Eurocopter, but that's an inconsistent approach. Inconsistent because he could have, but did not, enumerate all the individual claims, shifting the unit of analysis down to the level of claims clustered within patents. He could have asked what was the proportion of all claims held invalid, but he did not do that. Nor did I. 05:56

You have to decide on your unit of analysis. If you're talking about claims, well, go do that analysis. If you're talking about patents, however, you can't all of a sudden clone a patent and call it both valid and invalid. Obviously, for example, if you look at the total number in the margin of the table, you'd get the wrong number of patents. So this is not a statistically valid approach.

MR. SMITH: Nonetheless, did you perform the analysis as suggested by Dr. Brisebois using his coding, coding you consider improper for these split claims cases?

PROFESSOR LEVIN: Yes, I did.

MR. SMITH: What were the results?

PROFESSOR LEVIN: The difference was not statistically significant at that point. I looked at

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various versions of this, looking at the corrections, looking at the patents. All of them with that inappropriate coding scheme resulted in a loss of statistical significance. 05:58

MR. SMITH: Professor Levin, could you please summarize your overall findings in response to Dr. Brisebois' statements?

PROFESSOR LEVIN: Yes. In my opinion, the variations in the data, the variation in the approach, whether it be patent or case, removing the PM(NOC) cases, with the sole exception of what I consider to be an entirely invalid statistical approach, all of those results confirm the statistical significance of the difference between pharmaceutical and non-pharmaceutical proportions of invalid cases, or patents for that matter, post-2005.

The other findings in my table 2 and table 3 also remain unchanged. I want to point out that that is not a foregone conclusion. That is to say, if we assume that we'd always get the same result, that's not generally the case. The fact that we did get the same result, as I said with the exception of the inappropriate tact, actually bolsters confidence in the robustness of the statistically significant finding or the lack thereof

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in tables 2 and 3. 05:59

MR. SMITH: Thank you. Mr. President, that concludes our direct examination.

THE PRESIDENT: I think we will continue, then, the cross-examination tomorrow, unless you have not a long cross-examination?

MR. SPELLISCY: I think the cross-examination will be longer than negative five seconds. So I would suggest it's probably going to be a bit longer than we would want to do tonight. I think it's best to wait until tomorrow, which puts us slightly behind our optimistic schedule, but maybe we can make up some more ground tomorrow.

THE PRESIDENT: I cannot leave tonight without knowing how you have calculated the P-value. What's the formula?

PROFESSOR LEVIN: It's a formula that involves three so-called binomial coefficients. When you want to calculate, if we could go back to the urn --

THE PRESIDENT: I know how you calculate if you roll two dice and you know that the dice are fair, the null hypothesis.

PROFESSOR LEVIN: Yes.

THE PRESIDENT: Then I see then if you

get two times 6 you get 36, then I think it is then you get a 2.8 percentage because you diverge -- you divide by 36 and the calculation goes on. So there I understand the calculation of the P-value. But how do you calculate it here? What is the formula?

PROFESSOR LEVIN: Yes. The formula was introduced by Sir Ronald Fisher, the father of biostatistics in his book called The Design of Experiments.

Looking at the demonstrative slide here, we see the red and the green chips. Now we're going to withdraw eight at random. So how many ways are there of withdrawing a certain number of green chips? For example, let's ask ourselves all the green chips --

THE PRESIDENT: May I cut you short here, with all due respect. In this case what is the formula you used to arrive at -- and if you go to slide -- and actually for your main finding, if you go to slide 6, table 1.

PROFESSOR LEVIN: Yes.

THE PRESIDENT: You see here this. What is the underlying formula, so how you get to the number?

PROFESSOR LEVIN: Yes. It's a product of

two binomial coefficients divided by a third binomial coefficient. A binomial coefficient counts the number of ways you could withdraw these chips from the urn. So the formula is 25 -- choose 25 whose value is 1. That first 25 is from the bottom margin. The second 25 is from the first row. You multiply that by 46, choose 38, the so-called binomial coefficient, 46 from the bottom row and 38 from the top row. And that's a very large number. The way you calculate a binomial coefficient is you multiply 46 times 45 times 44 for 38 factors and divide by 38 factors. Calculators can do this quite readily. And then, finally, you divide by the total 71, choose 63.

THE PRESIDENT: I suggest tomorrow we have drawing board and you take us through the calculation.

PROFESSOR LEVIN: I'd be happy to.

THE PRESIDENT: Does the name Pierre-Simon Laplace tell you something?

PROFESSOR LEVIN: I know Laplace very well. I'm not following your reference.

THE PRESIDENT: Because you said that the P-values were invented or developed by -- and then you used a name. But my understanding is -- but please correct me if I'm wrong -- that Pierre-Simon

Laplace was the original inventor of the P-value, is that correct? In 1770, I think it was.

PROFESSOR LEVIN: Yes, I was referring to Sir Ronald Fisher as the inventor of the so-called Fisher Exact Test, which is exactly what I've used here. That P-value is the result of applying Fisher's Exact Test.

THE PRESIDENT: So you don't use Laplace's method?

PROFESSOR LEVIN: Laplace was talking about an entirely different mathematical problem, that of predicting whether the sun will rise the next day.

THE PRESIDENT: Let's wait for that tomorrow. Can't wait! Thank you so much.

You're under testimony, Professor Levin. That means that you are not allowed to discuss this case with anyone.

PROFESSOR LEVIN: Yes.

THE PRESIDENT: We will see each other tomorrow at 9:00.

(Hearing adjourned at 6:05 p.m.)

DR. GILLEN:

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MR. DIMOCK:
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MR. JOHNSTON:
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SIR DANIEL BETHLEHAM: [1] 1011/1

SIR DANIEL BETHLEHEM: [13] 1008/11 1009/6 1010/5 1011/17 1014/2 1014/13 1015/17 1016/2 1016/16 1017/1 1194/1 1194/16 1195/5

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