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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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1 (8:35 a.m. Thursday, 2 June 2016.) 08:35

2 DR. MICHAEL GILLEN, continued

3 THE PRESIDENT: Good morning, ladies and

4 gentlemen. We resume the hearing on Day 4. As

5 usual, are there any matters of an organizational or

6 administrative matter that the parties would like to

7 raise?

8 MS. CHEEK: Nothing from Claimant at this

9 time.

10 MR. SPELLISCY: Nothing from the

11 Respondent.

12 THE PRESIDENT: We saw that the parties

13 were conferring about the schedule. Is that still in

14 progress?

15 MS. CHEEK: It is still in progress,

16 Mr. President.

17 THE PRESIDENT: Thank you. Mr. Dearden,

18 please continue the cross-examination.

19 Good morning, Dr. Gillen.

20 DR. GILLEN: Good morning.

21 **CROSS-EXAMINATION ON BEHALF OF THE CLAIMANT,**

22 **continued**

23 MR. DEARDEN: Good morning, Dr. Gillen.

24 DR. GILLEN: Good morning.

25 MR. DEARDEN: Can you turn to tab 3 of

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1 the first volume, Exhibit C-414, please? It should 09:00

2 be a final action for Bayer on February 1, 2011.

3 DR. GILLEN: Yes, I see that.

4 MR. DEARDEN: Could you turn to page 3,

5 sir?

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

7 MR. DEARDEN: Under the heading Legal and

8 Administrative Considerations, "The claims are now

9 identified as non-compliant with section 2 of the

10 Patent Act. The claims were previously considered

11 defective for non-compliance with section 84 of the

12 Patent Rules, on the basis that the lack of proper

13 disclosure of a sound prediction implied a lack of

14 proper support for the claims."

15 Just as an aside, that would be a section

16 27(3) Patent Act disclosure issue?

17 DR. GILLEN: What I see here is a

18 reference to section 84 and section 2 of the Act.

19 MR. DEARDEN: But the disclosure

20 requirement would be 27(3)?

21 DR. GILLEN: It might be. I mean 27(3)

22 certainly is the section of the Patent Act that deals

23 with disclosure. It's a question of whether or not

24 disclosure of the sound prediction should be referred

25 to under 27(3) or under section 2.

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1 MR. DEARDEN: "Following current Office 09:02

2 practice, this objection is now presented as

3 non-compliance with section 2 of the Patent Act (lack

4 of utility). Reference in this regard is made to

5 17.03.03 of MOPOP, which came into force in

6 January 2009," and Chapter 17 is the Biotechnology

7 and Medicinal Inventions chapter?

8 DR. GILLEN: Yes, that's correct.

9 MR. DEARDEN: Just to finish that A)

10 section on page 3, "It should be noted that no

11 substantive change has been made to the basis of the

12 argument."

13 Is it fair to say that, when MOPOP is

14 amended, examiners have to follow those amendments as

15 this examiner is doing?

16 DR. GILLEN: Yes. MOPOP is a guide. As

17 I said yesterday, it's not an authority, but

18 examiners would follow the guidance in MOPOP, yes.

19 MR. DEARDEN: And if you could turn to

20 tab 4, sir, which is Exhibit C-415, this was an

21 appeal of that examiner's decision that we saw at

22 tab 3.

23 DR. GILLEN: Yes.

24 MR. DEARDEN: If you go to paragraph 8,

25 "The case was forwarded to the Patent Appeal Board on

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09:03

1 November 21, 2011 with a Summary of Reasons outlining
2 the outstanding defects. In the Summary of Reasons
3 the examiner stated that claims 1-11 lacked utility
4 but no longer put forward a separate issue with
5 respect to sufficiency. Our review is therefore
6 limited to issues relating to utility only."
7 And if you fast-forward to page 15,
8 paragraph 48 of tab 4, Exhibit 415, the
9 recommendation of the Board is to uphold the
10 rejection of the application. Correct?
11 DR. GILLEN: That's correct.
12 MR. DEARDEN: Sir, prior to the AZT
13 decision in 2002, you agree that there were no final
14 actions that rejected an application for lack of
15 utility under section 2 for failure to disclose a
16 factual basis and line of reasoning for the
17 prediction in the patent?
18 DR. GILLEN: I'm not aware of any.
19 MR. DEARDEN: And, prior to 2002 AZT
20 decision of the Supreme Court, are you aware of any
21 Patent Appeal Board decisions that dealt with the
22 issue of whether a rejected patent application failed
23 to disclose the factual basis and line of reasoning
24 in the patent?
25 DR. GILLEN: Certainly those terms

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1 wouldn't have been used prior to 2002, no.
2 MR. DEARDEN: What about a PAB decision
3 where the issue was before it where there was a
4 requirement from an examiner under appeal before the
5 PAB (Patent Appeal Board) that there had to be a
6 factual basis and a line of reasoning in the patent?
7 DR. GILLEN: There was a decision in the
8 late '90s -- I forget exactly what year, it might
9 have been 1995-- where there was an issue of the
10 applicant was trying to claim, I believe, monoclonal
11 antibodies for which there was no support, and the
12 Board ruled in that case that there was nothing upon
13 which to base the sound prediction.
14 MR. DEARDEN: You're talking about
15 decision 1206?
16 DR. GILLEN: That's correct.
17 MR. DEARDEN: I have some questions for
18 you on that later. So there is no Patent Appeal
19 Board decision prior to 2002 that dealt with the
20 issue of whether a rejected patent application failed
21 to disclose the factual basis and line of reasoning
22 in the patent?
23 DR. GILLEN: Not that I'm aware of.
24 MR. DEARDEN: And obviously if there was
25 no Patent Appeal Board decisions on that issue, there

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09:07

1 wouldn't be any Commissioner decisions either?
2 DR. GILLEN: That's correct.
3 MR. DEARDEN: Your First Report,
4 Dr. Gillen, paragraph 47, the first sentence of
5 paragraph 47 of your First Report says, "When the
6 MOPOP chapter on Description was updated in 2010 to
7 reflect recent jurisprudence on disclosure of the
8 basis for sound prediction, that update was
9 consistent with longstanding Patent Office practice."
10 You'll find MOPOP 2010, which is Exhibit
11 C-60, at tab 22 of your second volume, your white
12 binder.
13 DR. GILLEN: Yes, I have it.
14 MR. DEARDEN: If you'd turn to 9.04,
15 which should have a heading "Establishing utility"?
16 DR. GILLEN: Yes.
17 MR. DEARDEN: It has subheadings Sound
18 Prediction, Disclosure of the Factual Basis,
19 Disclosure of the Sound Line of Reasoning, which is
20 9.04.01b.
21 DR. GILLEN: Yes.
22 MR. DEARDEN: Without making you do this
23 from memory, when you're talking about recent
24 jurisprudence that MOPOP updated, would that be
25 what's footnoted, sir, in --

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1 DR. GILLEN: Paragraph 47.
2 MR. DEARDEN: I would say it would go
3 from footnotes 38 to 47 because footnote 38 is the
4 first footnote that I see under 9.04. The top of the
5 page is stamped 00043.
6 DR. GILLEN: 43, yes.
7 MR. DEARDEN: You see 9.04, Establishing
8 utility?
9 DR. GILLEN: Yes.
10 MR. DEARDEN: First paragraph has
11 footnote 38, and the last footnote that I see was 47.
12 DR. GILLEN: Yes.
13 MR. DEARDEN: Your eyes see that as well?
14 DR. GILLEN: 47 -- in section 9.04.01b?
15 MR. DEARDEN: Correct.
16 DR. GILLEN: I see 47, yes.
17 MR. DEARDEN: Right. So we go to the
18 footnotes at the back of tab 22, and I'm just getting
19 you to confirm that when you're talking about recent
20 jurisprudence that was used to update the MOPOP 2010,
21 I'm going to find that jurisprudence in footnotes
22 38-47?
23 DR. GILLEN: Yes.
24 MR. DEARDEN: In 9.04.01a, which is the
25 factual basis, footnote 44, "Any necessary facts that

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

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1 DR. GILLEN: Yes.
2 MR. DEARDEN: Tell me if I'm reading this
3 right. Decision issued. The hope is that by
4 March 31, 2010, 80 percent of applications that were
5 referred to the Board before 2008 would be dealt
6 with. Is that the standard that's being sought
7 there, or the commitment?
8 DR. GILLEN: Under Patent Appeal Board
9 patents and industrial designs?
10 MR. DEARDEN: Yes, then right underneath
11 that.
12 DR. GILLEN: Oh, the decision issued?
13 MR. DEARDEN: Yes. Decision issued, and
14 then the commitment, as I read it, is that the
15 Board's going to have 80 percent of applications that
16 were referred to it before 2008 completed.
17 DR. GILLEN: Yes, that was the
18 commitment.
19 MR. DEARDEN: Right. But they flunked.
20 DR. GILLEN: Yes, they did.
21 MR. DEARDEN: 34 percent.
22 DR. GILLEN: 34 percent.
23 MR. DEARDEN: But what I'm interested in
24 is the explanation which is "Changes in practice and
25 jurisprudence have imposed additional steps and time

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

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

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1 correct?
2 DR. GILLEN: It would have been a
3 decision that would be considered by the Office, but
4 relative to statutory subject matter it was more of a
5 minor issue.
6 MR. DEARDEN: But it was an issue?
7 DR. GILLEN: It was an issue, sure. The
8 Office would consider all jurisprudence coming out
9 and the effect it might have on Office practice.
10 MR. DEARDEN: And here, in Exhibit C-355,
11 your tab 2 there, Utility, albeit not No. 1 issue,
12 was a change in practice in jurisprudence that
13 imposed additional steps and time required, correct?
14 DR. GILLEN: I wouldn't say that there
15 was a change in Office practice with respect to
16 utility. As I said, the change in practice was how
17 to deal with patentable subject matter. The notion
18 of utility, certainly the AZT case gave the Office
19 the three-part test we talked about yesterday and
20 what I referred to as terminology to deal with a lack
21 of sound prediction. But I think the underlying
22 issues of utility, you know, didn't change from the
23 '90s into the 2000s.
24 MR. DEARDEN: Sir, can you find tab 28,
25 which is probably in your last binder. It is.

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

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

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1 might have given the Office guidance in how to pursue
2 certain objections under the Act and Rules.
3 MR. DEARDEN: So if a Federal Court case
4 or a Supreme Court of Canada case changed the law,
5 that would impact Patent Office practice, right?
6 DR. GILLEN: That's correct.
7 MR. DEARDEN: And Federal Court or
8 Supreme Court cases that changed the law will drive
9 an update of the MOPOP, correct?
10 DR. GILLEN: They would drive an update
11 of the MOPOP, correct.
12 MR. DEARDEN: Can we go to tab 5, Exhibit
13 C-412, Commissioner Decision 1303 in June 4, 2010.
14 DR. GILLEN: Yes, I see that.
15 MR. DEARDEN: Paragraph 8 under the
16 heading "Prosecution" at the bottom of the page.
17 DR. GILLEN: Yes, I see that.
18 MR. DEARDEN: So that application was
19 filed on March 2, 1989 under the provisions of the
20 Patent Act that read immediately before October 1,
21 1989, so an old Act patent. There were a total of
22 five Office actions issued during the prosecution,
23 the first being in 1992 and culminating in final
24 action dated June 19, 2006, right?
25 DR. GILLEN: Yes.

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1 MR. DEARDEN: Paragraph 9. "In the
2 Office Action February 22, 2005, an objection under
3 subsection 34(2) of the Patent Act was first raised,
4 it being subsequently reasserted and then appearing
5 in the Final Action. The objection under section 2
6 of the Patent Act was initially raised in an Office
7 Action dated September 26, 2005, (the 'pre-Final
8 Action'), and was reapplied in the Final Action."
9 So, sir, 13 years after the first Office
10 action, the examiner takes the position that utility
11 cannot be soundly predicted, correct?
12 DR. GILLEN: That's correct.
13 MR. DEARDEN: Paragraph 33 of
14 Commissioner Decision 1303, Exhibit C-412 --
15 DR. GILLEN: The same exhibit?
16 MR. DEARDEN: Same exhibit, paragraph
17 33 -- so flip a few pages -- should be under the
18 heading "There must be proper disclosure."
19 DR. GILLEN: I see that.
20 MR. DEARDEN: So "The concept that
21 untested embodiments may be patentable existed in
22 earlier case law (see Monsanto and Olin Mathieson)
23 but there was no articulated test for assessing the
24 soundness of a prediction until Wellcome."
25 DR. GILLEN: I see that.

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1 MR. DEARDEN: Which is AZT. You agree
2 with that statement, don't you?
3 DR. GILLEN: I agree that there was no
4 articulated test, but I don't agree that examiners
5 didn't look for the same kinds of information as AZT
6 asked for prior to AZT.
7 MR. DEARDEN: I didn't see that in
8 paragraph 33, what you just added there. For
9 clarity, you do agree there was no articulated test
10 for assessing the soundness of a prediction until
11 Wellcome AZT?
12 DR. GILLEN: Yes, there was no
13 articulated test.
14 MR. DEARDEN: Tab 6, exhibit R-381, is
15 the Commissioner decision 1206 that you referenced
16 earlier.
17 DR. GILLEN: Yes.
18 MR. DEARDEN: You do mention that in your
19 first -- or your second report, Dr. Gillen, at
20 paragraph 14 and 15, so if you could get your Second
21 Report, please.
22 DR. GILLEN: Yes, I have that.
23 MR. DEARDEN: Let me read the whole
24 paragraph. "Mr. Wilson states that, before 2002,
25 there 'was no basis in the Patent Act,

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1 Patent Rules or jurisprudence that would permit an
2 examiner to reject an application for failing to
3 disclose evidence of utility in the application at
4 the time of filing.' I disagree. In my experience,
5 since the Supreme Court decided the Monsanto case in
6 1979, patent examiners have applied the same
7 principle of disclosure in sound prediction cases as
8 they have more recently. While the terms 'factual
9 basis' and 'sound line of reasoning' were not
10 introduced until the Supreme Court of Canada's 2002
11 decision in AZT, applicants and examiners alike had
12 been including and looking for the same type of
13 information in the application."
14 Paragraph 15, "For example, the
15 disclosure relating to a sound prediction was at
16 issue in Commissioner's decision No. 1206," and
17 that's what you have before you at tab 6 of your
18 binder, correct?
19 DR. GILLEN: Yes.
20 MR. DEARDEN: And at paragraph 16 of your
21 Second Report, Dr. Gillen, you say, "While the
22 Commissioner refused to grant a patent containing
23 those claims on the basis of now 27(3) of the
24 Patent Act (which covers disclosure rather than
25 utility), it is clear that the examiner, the

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1 Patent Appeal Board, and the Commissioner all found
2 the patent invalid because of the failure to disclose
3 in the patent a factual basis for the sound
4 prediction as well as a sound line of reasoning."
5 DR. GILLEN: Yes.
6 MR. DEARDEN: Can we look at that
7 decision now? Let's go to the front page. At the
8 top there is topic codes. B20, B22 and C00.
9 DR. GILLEN: Yes, I see those.
10 MR. DEARDEN: And that is to indicate
11 what the subject matter of the decision is dealing
12 with?
13 DR. GILLEN: Yes, that's correct.
14 MR. DEARDEN: And what is the subject
15 matter code for utility?
16 DR. GILLEN: I don't know what the code
17 for utility is.
18 MR. DEARDEN: G00.
19 DR. GILLEN: G00, okay.
20 MR. DEARDEN: You're not going to agree
21 with me there?
22 DR. GILLEN: I will agree with you.
23 MR. DEARDEN: Okay. And B20 was
24 claims -- excessive width?
25 DR. GILLEN: Yes.

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1 MR. DEARDEN: B22, claims -- excessive
2 width -- not supported by disclosure, correct?
3 DR. GILLEN: Yes.
4 MR. DEARDEN: And C00 would be adequacy
5 or deficiency of description?
6 DR. GILLEN: Yes.
7 MR. DEARDEN: Then after the topic codes,
8 you see at the top of the decision -- what is that?
9 A summary of what the decision is when I see "Claims
10 rejected as being broader than disclosure"?
11 DR. GILLEN: Yes, it would be a
12 summary --
13 MR. DEARDEN: Or an abstract?
14 DR. GILLEN: Akin to an abstract.
15 MR. DEARDEN: Okay. So can you turn to
16 page 3 of the decision? That's the questions before
17 the Board.
18 DR. GILLEN: Yes, I see it.
19 MR. DEARDEN: Right after that print that
20 you can't read because it's so small, "The questions
21 before the Board are whether or not the specification
22 describes correctly and fully the preparation and the
23 properties of the hybridoma and the monoclonal
24 antibodies claimed in claims 84 and 85, and whether
25 or not such description is set out in such clear

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1 concise terms as to enable a person skilled in the
2 art to make and use the invention as required by
3 34(1) of the Patent Act".
4 So those are the issues, right?
5 DR. GILLEN: Yes.
6 MR. DEARDEN: And, sir, there is
7 discussion about Monsanto in this case, and it starts
8 at page 8, if you could flip to that. In the middle
9 of the page before the quote that you see, "In a
10 further argument, the Applicant urged the board to
11 follow, by analogy, the practice followed in the
12 chemical arts." And then Monsanto is cited in that
13 small print quote there, and then at the bottom of
14 that page -- and this is the Board reproducing
15 submissions from the applicant, and the this
16 submission is at pages 23 and 25 that they've
17 reproduced here in page 8 of their decision, the
18 page 25 submission was, "According to the Supreme
19 Court in the Monsanto decision referred to above, a
20 'sound prediction' is based on the capacity of the
21 person skilled in the art to foresee the properties
22 of a claimed product. Applicant has demonstrated
23 that techniques to produce monoclonal antibodies have
24 become tools generally available to a person skilled
25 in the art of hybridoma technology, in the same way

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

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1 referring the person skilled in the art to experiment
2 with the 'traditional techniques'. In summary, the
3 Board also finds that the description does not
4 include any clear references or description to enable
5 the person skilled in the art to make and use the
6 invention without considerable and protracted
7 experimentation."
8 So, sir, the Board's findings, you'll
9 agree, are not a sound prediction finding?
10 DR. GILLEN: Well, the Board's finding
11 here was there was lack of disclosure for methods as
12 well as the products produced by those methods,
13 hybridomas and monoclonal antibodies.
14 MR. DEARDEN: But you'll agree with me
15 the Board never made a finding about utility in this
16 invention, because they were finding there was no
17 invention, right?
18 DR. GILLEN: They found that, yes, that
19 there was no description of monoclonal antibodies or
20 methods for preparing those, so therefore there was
21 nothing upon which to base a prediction of utility
22 because those products had not actually been
23 prepared.
24 MR. DEARDEN: So what the applicant was
25 trying to do by using sound prediction in the

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1 chemical arts principles, but using them by analogy,
2 was he was trying to convince the Board that you
3 could predict the invention by using the Monsanto
4 analogy, right?
5 DR. GILLEN: I think that's what he was
6 trying to do. That was a more common occurrence with
7 biotechnology inventions, which is what this is,
8 where applicants would often claim very broadly,
9 where utility was not an issue because the compounds
10 were claimed almost in terms of their utility,
11 something like growth hormone, for example, and they
12 would try to use the sound prediction principle to
13 predict that they could do something or invent
14 something that they hadn't done. So there was a
15 tendency in the biotechnology arts to take the
16 principle of sound prediction for utility as it was
17 understood in Monsanto and apply that to predicting
18 inventions in other arts.
19 MR. DEARDEN: And, sir, you'll agree with
20 me that your statement in paragraph 16 is incorrect
21 by saying that the examiner, the Patent Appeal Board
22 and the Commissioner all found the patent invalid
23 because of failure to disclose in the patent the
24 factual basis for the sound prediction and sound line
25 of reasoning?

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1 DR. GILLEN: What I meant by that was the
2 factual basis being the monoclonal antibodies
3 themselves and processes for producing those.
4 MR. DEARDEN: But, sir, there's nothing
5 in this decision at tab 6 where this Board makes a
6 finding of invalidity because of failure to include a
7 factual basis and the sound line of reasoning. Is
8 that fair?
9 DR. GILLEN: I think what the Board was
10 saying in this decision was there was no basis for
11 predicting utility of products that hadn't been
12 produced. The factual basis that I'm referring to
13 was the monoclonal antibodies themselves and the
14 support for those which was not found in the
15 application.
16 MR. DEARDEN: I'm going to go at it
17 again. You can't show me anywhere in this tab,
18 R-381, this decision 1206, where that specific
19 finding is made that you have in paragraph 16 of your
20 statement?
21 DR. GILLEN: I can't find that exact
22 finding, no, but that's my interpretation of that
23 decision.
24 MR. DEARDEN: Fair enough.
25 MOPOP. Paragraph 6 of your first

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1 statement. You set out in paragraph 6, sir, as chief
2 at the Biotechnology division, certain duties which
3 included -- and I'm looking more towards the bottom
4 of paragraph 6 -- ensuring that examiners were
5 following Patent Office practice. You see that?
6 DR. GILLEN: Yes, I do.
7 MR. DEARDEN: And that would include the
8 Manual Of Patent Office Practice, the MOPOP?
9 DR. GILLEN: It would include MOPOP,
10 office practice memos, and any other information from
11 training sessions that examiners might have been
12 subject to.
13 MR. DEARDEN: Turn to tab 15 of the
14 binder, Exhibit C-449. It should be an extract from
15 the CIPO website about MOPOP.
16 DR. GILLEN: Yes, from 2015. I see that.
17 MR. DEARDEN: So I want to know if you
18 agree with the statements that I see in Exhibit
19 C-449. "MOPOP is a guide for examiners, applicants,
20 agents and the public in the operational procedures
21 and examination practices of the Canadian
22 Patent Office." Do you agree with that?
23 DR. GILLEN: Yes.
24 MR. DEARDEN: "Practices expressed in the
25 MOPOP arise from the Office's interpretation of the

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1 Patent Act, Patent Rules and jurisprudence as of the
2 date each chapter came into effect."
3 DR. GILLEN: Yes.
4 MR. DEARDEN: "This manual is solely a
5 guide and should not be considered to be a binding
6 legal authority, in the event of any inconsistency
7 between this guide and the applicable legislation,
8 this legislation must be followed."
9 DR. GILLEN: That's correct.
10 MR. DEARDEN: "This manual is updated
11 periodically to reflect changes to the statutory,
12 regulatory and jurisprudential framework governing
13 patents in Canada."
14 DR. GILLEN: Yes.
15 MR. DEARDEN: You agree with that?
16 DR. GILLEN: Yes.
17 MR. DEARDEN: And examiners will refer to
18 MOPOP in Office actions and final actions, correct?
19 DR. GILLEN: They can, yes.
20 MR. DEARDEN: As we saw with Chris Evans
21 doing that in the Bayer final action we looked at
22 earlier in C-414, right?
23 DR. GILLEN: That's correct.
24 MR. DEARDEN: And the Patent Appeal Board
25 will cite MOPOP in its decision?

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1 DR. GILLEN: It can, yes.
2 MR. DEARDEN: And the courts have cited
3 MOPOP in their decisions?
4 DR. GILLEN: Yes.
5 MR. DEARDEN: And I have a couple of
6 examples. Turn to tab 10, Exhibit R-151, paragraph
7 49, it should be on page 37 of that decision.
8 "While neither the Manual Of
9 Patent Office Practice nor the paper and article just
10 referred to are binding on me, I find them persuasive
11 and, in the absence of persuasive evidence that would
12 favor a different interpretation, I adopt the
13 interpretation of 'issue' in the context of
14 subsection 28(2) set out therein and urged on behalf
15 of Bayer."
16 If you turn the page there's more glowing
17 praise of MOPOP. I'm looking at paragraph 51,
18 Dr. Gillen?
19 DR. GILLEN: Yes, I see.
20 MR. DEARDEN: "Much the same can be said
21 here. The Act falls to be interpreted, used and
22 applied by a broad range of individuals. As with the
23 CEAA, the Canadian Environmental Assessment Act, it
24 makes eminent sense that a document such as MOPOP was
25 published to achieve a degree of uniformity in the

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1 interpretation of the Patent Act and the
2 pronouncements of the Manual should therefore be
3 treated with a reasonable degree of deference as an
4 interpretive tool, to the extent that they are not
5 inconsistent with the law."
6 So do you agree with the statement made
7 in paragraph 51?
8 DR. GILLEN: Yes, I would.
9 MR. DEARDEN: Tab 11 should be R-150.
10 DR. GILLEN: The tab that begins with
11 "Westlaw" at the top of the page?
12 MR. DEARDEN: Right. This is a Belzberg
13 decision of Justice Shore, if you turn to paragraph
14 10.
15 DR. GILLEN: Yes, I see it.
16 MR. DEARDEN: And Justice Shore holds
17 that "The MOPOP is a guideline prepared by the
18 Patent Office outlining best practices for the
19 Patent Office. Although it does not have the force
20 of law, I regard the guideline as a useful
21 interpretive tool."
22 DR. GILLEN: I see that.
23 MR. DEARDEN: Do you agree with it?
24 DR. GILLEN: I would.
25 MR. DEARDEN: And tab 12, Exhibit C-404,

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

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1 DR. GILLEN: I see that, yes.
2 MR. DEARDEN: First of all, you'll agree
3 that there is nothing that we can find in the file
4 wrappers for olanzapine -- which is tab 28 but you
5 don't have to turn to it, it's Exhibit C-062, and the
6 file wrapper for atomoxetine which is tab 7, C-068 --
7 there's nothing in there that demonstrates to us,
8 shows us, that the examiner made any assumption in
9 favor of Lilly in those two applications?
10 DR. GILLEN: There's nothing. I believe
11 there's one report in one file and no reports in the
12 other. And there's nothing in the file that would
13 indicate that the examiner had an issue with utility,
14 that is correct.
15 MR. DEARDEN: Sir, you didn't have any
16 involvement with the prosecution of the olanzapine
17 patent application?
18 DR. GILLEN: No, I did not.
19 MR. DEARDEN: And you had no involvement
20 with the prosecution of the atomoxetine patent
21 application?
22 DR. GILLEN: No, I did not.
23 MR. DEARDEN: And you had no direct
24 involvement of the granting of the atomoxetine '735
25 patent?

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

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1 the Office at that time.
2 So, for example, if an application
3 contained a statement that said, well, I predict that
4 this compound will cure cancer or something like
5 this, the examiner would look to the application to
6 determine what results and what experiments were done
7 that could support that statement, and what sort of
8 logic did the applicant have that took the applicant
9 from what had been done to their sound prediction --
10 or to the prediction.
11 MR. DEARDEN: Is it fair to say that the
12 changes that were made to the 2009 and 2010 MOPOPs
13 will not be found in the 1990 MOPOP?
14 DR. GILLEN: No, they would not be found
15 in the 1990 MOPOP. I think the chapter on utility in
16 the 1990 MOPOP would have been very bare bones.
17 Maybe only a few pages.
18 MR. DEARDEN: Right. Likewise for the
19 1996 MOPOP?
20 DR. GILLEN: Yes, that's correct.
21 MR. DEARDEN: And the 1998 MOPOP?
22 DR. GILLEN: That's correct.
23 MR. DEARDEN: So paragraph 32 says, "When
24 the MOPOP chapter on utility was updated in 2009 to
25 reflect recent jurisprudence, that update was

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

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1 decisions that were relevant prior to those dates.
2 MR. DEARDEN: In the 1990 MOPOP, it
3 didn't instruct examiners to reject applications that
4 did not include the factual basis and line of
5 reasoning for the prediction in the patent?
6 DR. GILLEN: No, I think in the 1990
7 MOPOP, as I recall, the only reference to utility was
8 that an invention had to be useful.
9 MR. DEARDEN: Not totally useless
10 actually?
11 DR. GILLEN: Not totally useless.
12 MR. DEARDEN: Some industrial value.
13 DR. GILLEN: Some industrial value.
14 MR. DEARDEN: And the same for the 1996
15 MOPOP. It did not instruct examiners to reject
16 applications that did not include the factual basis
17 and line of reasoning for the prediction in the
18 patent?
19 DR. GILLEN: No, those terms were not
20 used in the '96 MOPOP or in the '98 MOPOP. I think
21 the section on utility in those versions of MOPOP
22 simply referred to the invention being useful and for
23 its desired purpose, I believe is what's used in the
24 MOPOP.
25 MR. DEARDEN: Both of your answers that

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1 you've given me to the 1990 and 1996 MOPOP have start
2 off with "No," and I want the transcript when you
3 read it five years from now to be in no confusion.
4 You're agreeing with me?
5 DR. GILLEN: I'm agreeing that the terms
6 "factual basis" and "sound line" did not appear in
7 those versions of the MOPOP, yes.
8 MR. DEARDEN: And likewise for the '98
9 MOPOP?
10 DR. GILLEN: And likewise for the '98
11 MOPOP.
12 MR. DEARDEN: And it's only after the
13 Raloxifene decisions in 2008 and 2009 that examiners
14 get instructed by the 2009 MOPOP to require the
15 factual basis and line of reasoning for the
16 prediction to be in the patent?
17 DR. GILLEN: I think that's correct.
18 That's how the MOPOP laid out the guidance for
19 examiners but, prior to that decision, examiners were
20 looking for the factual basis and the sound line in
21 applications. Certainly after the AZT decision came
22 out, there was a question as to whether the third
23 part of that test, the disclosure requirement, was in
24 the application or not or whether it could be
25 provided at some later date.

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1 MR. DEARDEN: Why was there a discussion
2 about the third component of AZT, which is proper
3 disclosure?
4 DR. GILLEN: It wasn't a discussion
5 within the Office. The Office considered that
6 disclosure requirement that the factual basis and the
7 sound line had to be disclosed in the application at
8 the time of filing. But members of the patent
9 profession, for example, argued that that was not the
10 case and they disagreed with the Office's
11 interpretation of the AZT decision.
12 MR. DEARDEN: And did that happen around
13 the time AZT was issued?
14 DR. GILLEN: Well, it happened soon after
15 that, yes.
16 MR. DEARDEN: So the patent bar is saying
17 the third component of AZT, which is proper
18 disclosure, no footnote citation given by Justice
19 Binnie as to any authority for that, they took the
20 position with the Office that that did not mean the
21 factual basis and line of reasoning had to be in the
22 patent?
23 DR. GILLEN: Well, some members of the
24 profession did. Others felt it had to be in the
25 application at the time of filing, that an invention

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1 had to be complete, but there were other members of
2 the profession that took the position that the
3 disclosure could be made through other means or at a
4 later time, possibly in response to an Office action
5 from an examiner.
6 MR. DEARDEN: Okay. I just want to move
7 back to when I was talking to you about the 1990, '96
8 and '98 MOPOPs. Nowhere written in those editions of
9 MOPOP will I find an instruction to examiners to
10 reject applications that didn't include the factual
11 basis and line of reasoning for the prediction in the
12 patent.
13 DR. GILLEN: You won't find those
14 instructions in the MOPOP, no.
15 MR. DEARDEN: In those '90, '96 and '98
16 MOPOPs. I won't find it in those MOPOPs, correct?
17 DR. GILLEN: That's correct.
18 MR. DEARDEN: So, Dr. Gillen and
19 Mr. President, I'd ask that yesterday's transcript of
20 Dr. Gillen's testimony be provided to him. We have
21 copies. (Distributed)
22 Could you turn to page 921 of the
23 transcript, sir, line 17? See that paragraph?
24 DR. GILLEN: Yes.
25 MR. DEARDEN: It should be where you

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1 testified that "The examination is for compliance
2 with the Patent Act and the Patent Rules, so
3 inventions must be new, they must be non-obvious,
4 they must be useful, there must be patentable subject
5 matter and so forth."
6 DR. GILLEN: Yes.
7 MR. DEARDEN: So those requirements, sir,
8 of new, non-obvious and useful, those are separate
9 and distinct requirements for obtaining a patent?
10 DR. GILLEN: Yes, they are.
11 MR. DEARDEN: On page 927 of the
12 transcript you say at line 13 under the heading
13 "Post-filing evidence" that, "Post-filing evidence of
14 demonstrated utility that predates the filing date of
15 an application can be submitted to the Patent Office
16 to convince an examiner of the credibility of the
17 demonstrated utility. This is a rare thing." You
18 see that?
19 DR. GILLEN: That's correct.
20 MR. DEARDEN: So that legal requirement
21 regarding post-filing evidence comes from the 2002
22 AZT decision and not the Monsanto decision in 1979?
23 DR. GILLEN: Well, I'm referring here to
24 demonstrated utility, not to sound prediction, so
25 this would be for patent applications going back some

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1 years, back to Day 1, for example. So with respect
2 to demonstrated utility, you will look to the
3 application and you will see positive statements that
4 something has actually been made and tested and found
5 to do what it's supposed to do, what the applicant
6 says it will do.
7 Sometimes there are statements that
8 maybe, based on the examiner's knowledge of the
9 subject matter, seem a little -- it may be
10 surprising, shall we say, and so in some cases, and
11 this is a rare thing, the examiner may say gee,
12 that's remarkable that that compound did that, as you
13 say in your application, you know. Could I look at
14 some of the studies that you did just to convince
15 myself that something as incredible as what I've read
16 is actually, in fact, fact.
17 MR. DEARDEN: What I'm getting at, sir,
18 is you made the statement that "post-filing evidence
19 of demonstrated utility that predates the filing
20 date," so it's the "before the filing date" that I'm
21 focused on here, and AZT did decide that utility had
22 to be soundly predicted or demonstrated as of the
23 date of filing.
24 DR. GILLEN: Well, certainly that's what
25 AZT said but certainly as an examiner it was my

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1 understanding that inventions had to be complete at
2 the time that they were filed, so that you wouldn't
3 file a patent application for a compound whose
4 utility you didn't either have demonstrated or
5 soundly predicted. So I don't think -- certainly it
6 was my understanding and the practice that I was
7 taught that you wouldn't accept -- that you expected
8 that the utility of an invention would be disclosed
9 in the application at the time of filing, and not at
10 some later date.
11 MR. DEARDEN: But I'm not going to find
12 that in any of the 1990s MOPOPs, am I?
13 DR. GILLEN: You're not going to find
14 that statement in any of the MOPOPs, no.
15 MR. DEARDEN: Page 926. Do you have your
16 slide presentation with you?
17 DR. GILLEN: Yes, I do.
18 MR. DEARDEN: I think that what's on
19 page 926 matches slide 9.
20 DR. GILLEN: I have slide 9 here.
21 MR. DEARDEN: Looking at slide 9, the
22 second bullet, you have "The utility of inventions
23 that have not been fully tested at the time of filing
24 can be based on sound prediction. Monsanto 1979.
25 For a prediction to be sound a patent specification

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1 must disclose a factual basis and a sound line of
2 reasoning. Apotex, 2002."
3 That's the AZT decision, right?
4 DR. GILLEN: That's correct.
5 MR. DEARDEN: And you're saying that that
6 legal requirement that you're referring to in that
7 bullet -- or that requirement in that bullet comes
8 from AZT, not Monsanto. Right?
9 DR. GILLEN: Well, I think what I'm
10 saying there is that the principle of sound
11 prediction comes from Monsanto. The terms "factual
12 basis" and "sound line" come from the Apotex
13 decision.
14 MR. DEARDEN: Okay. And on page 928 of
15 your transcript, line 9, you say, "Evidence to
16 support the soundness of the predicted utility must
17 be disclosed in the application at the time of
18 filing."
19 Now, sir, that requirement is not going
20 to be found in Monsanto, correct?
21 DR. GILLEN: That will not be found in
22 Monsanto, no.
23 MR. DEARDEN: Speaking of Monsanto, we'll
24 give you a copy of the decision, which is C-61. In a
25 nutshell, Dr. Gillen, in Monsanto the Commissioner of

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1 Patents refused to grant a patent in respect of
2 claims for inhibiting premature vulcanization of
3 rubber, and the reason the examiner rejected those
4 claims was because they were too broad because only 3
5 out of 126 of the chemical compounds claimed had been
6 prepared.
7 DR. GILLEN: That's correct.
8 MR. DEARDEN: Then the Patent Appeal
9 Board affirmed the rejection of the application on
10 that basis?
11 DR. GILLEN: That's correct.
12 MR. DEARDEN: And the Federal Court of
13 Appeal upheld the refusal on the ground that the
14 disclosure in the application was not sufficient to
15 support the claim to such a broad range of new
16 compounds?
17 DR. GILLEN: That's correct.
18 MR. DEARDEN: The Supreme Court of Canada
19 decision that you have your hands on now, C-61,
20 reversed that finding, correct?
21 DR. GILLEN: That's correct.
22 MR. DEARDEN: Let's go to page 1113.
23 Unfortunately this is one that doesn't have paragraph
24 numbers, but the first full paragraph on that page?
25 DR. GILLEN: Yes.

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1 MR. DEARDEN: "With respect, I must say
2 that it appears to me that the Court below has
3 completely overlooked the rule that a patent
4 specification is addressed to a person 'skilled in
5 the art'. The Patent Appeal Board had before it
6 elaborate affidavits from persons skilled in the art,
7 one of whom described himself as a 'group leader
8 assigned to special synthesis problems in the field
9 of elastomers'. In this affidavit he explains in
10 detail with reference to authoritative scientific
11 publications that the knowledge and skill possessed
12 by chemists competent in this particular field of
13 endeavor would ensure that the directions contained
14 in the specifications would be adequate to enable
15 them to prepare all the described compounds although
16 specific directions were given for three or less."
17 So, sir, at that time evidence outside
18 the patent was allowed through those affidavits?
19 DR. GILLEN: Well, I'm not sure what was
20 in these affidavits, but certainly you can have some
21 evidence outside of what's in the patent application,
22 what the Patent Office would call common general
23 knowledge. So, for example, there are a number of --
24 if you're talking about organic chemistry, for
25 example, there would be a number of processes that

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1 would be well known to an organic chemist, so a
2 patent application wouldn't have to describe how to
3 make a salt from an acid and a base. You could
4 simply make that statement "I made the salt using
5 this acid and this base" without going into any
6 detail as to what process you used unless, of course,
7 the process itself was the basis of your invention.
8 So that's the kind of stuff that I
9 believe the court is referring to here.
10 MR. DEARDEN: Well, they do give us a
11 hint of what's in one of the affidavits because it
12 says "In this affidavit he explains in detail with
13 reference to authoritative scientific publications
14 that the knowledge and skilled possessed by chemists
15 competent in this particular field of endeavor would
16 ensure that the directions contained in the specs
17 would be adequate to enable them to prepare all the
18 described compounds although specific directions were
19 only given for three."
20 DR. GILLEN: Yes, that's correct. I
21 think what the court is saying -- or what the
22 affidavit there is saying is that one of skill in the
23 art, a chemist working in this area, based on what
24 was given in the application and that person's common
25 general knowledge of the subject matter, would have

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1 been able to practice the invention.
2 MR. DEARDEN: You'll agree that at the
3 time testing could be submitted by affidavit?
4 DR. GILLEN: To the Patent Office?
5 MR. DEARDEN: Yes, to the examiner.
6 DR. GILLEN: Are you asking me to show
7 demonstrated utility or sound prediction?
8 MR. DEARDEN: Say both.
9 DR. GILLEN: You could present something
10 to the patent examiner by way of argument. For
11 example, if the patent examiner was not convinced
12 that the so-called demonstrated utility or soundly
13 predicted utility that the applicant was relying upon
14 in their application, if the examiner didn't feel
15 that that demonstration or sound prediction was in
16 the application the examiner could accept some
17 communication from the applicant describing where in
18 the application that information is found or how the
19 application actually discloses the utility. But the
20 examiner wouldn't take, in the case of sound
21 prediction, would not accept results to show that the
22 prediction was, indeed, sound after the filing date.
23 MR. DEARDEN: Sir, when you say that the
24 applicant could present something to the examiner by
25 way of argument, argument could be in the form of

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1 affidavits, right?
2 DR. GILLEN: An argument could be in the
3 form of an affidavit, that's correct.
4 MR. DEARDEN: And that could deal with
5 testing?
6 DR. GILLEN: It could, yes.
7 MR. DEARDEN: Page 1114, so the next page
8 at the very bottom of Monsanto: "After this the
9 Board turned to the jurisprudence on such issues
10 ending with the recent Chancery Division decision in
11 Olin Mathieson v Biorex Labs and quoting from the
12 judgment itself the following: Where, then, is the
13 line to be drawn between a claim which goes beyond
14 the consideration and one which equiparates with it?
15 In my judgment this line was drawn properly by Sir
16 Lionel when he very helpfully stated in the words
17 quoted above that it depended upon whether it was
18 possible to make a sound prediction. If it is
19 possible for the patentee to make a sound prediction
20 and to frame a claim which does not go beyond the
21 limits within which the prediction remains sound,
22 then he is entitled to do so.
23 'This last paragraph puts succinctly what
24 we have been able to distill from the jurisprudence
25 discussed above' say the Board. As to this, I should

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1 say immediately that I am in full agreement with the
2 decision of Graham J in Olin Mathieson and find it
3 necessary to consider it more exhaustively."
4 So the Patent Office was aware of this
5 Olin Mathieson decision that the Monsanto court
6 adopted?
7 DR. GILLEN: That's my understanding,
8 yes.
9 MR. DEARDEN: And at the bottom there's
10 conclusions of Justice Graham that the court sets
11 out. I'm looking at the one at the very bottom of
12 the page. "From the point of view of the public and
13 the patentees it is desirable that research in the
14 drug or other fields, as the case may be, should
15 continue. In the drug field in particular research
16 in very expensive" -- is very -- it says "in" --
17 "very expensive and the number of 'winners' found is
18 only a minute proportion of those synthesized and
19 tested. Once a winner is found, however, it is very
20 common also to find that bodies more or less closely
21 related to it have the same or even greater
22 activity." And the court fully agrees with those
23 observations. I'm not reading the rest of that quote
24 there. And the Patent Office was not taking issue
25 with those conclusions, I take it?

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1 DR. GILLEN: That would be my
2 understanding. This is a case well before my time.
3 MR. DEARDEN: And, sir, on page 1119 the
4 court deals with the Commissioner's refusal and says,
5 "I have underlined by law to stress that this is not
6 a matter of discretion: The Commissioner has to
7 justify any refusal."
8 So the court looked at the section 42 of
9 the Patent Act and said "Whenever the Commissioner is
10 satisfied that the applicant is not by law entitled
11 to be granted a patent he shall refuse the
12 application and, by registered letter addressed to
13 the applicant ...notify the applicant of such refusal
14 and of the ground or reason therefor."
15 So Justice Pigeon underlines by law to
16 stress that it's not a matter of discretion; the
17 Commissioner has to justify any refusal, right?
18 DR. GILLEN: That's correct.
19 MR. DEARDEN: And what happened? So if
20 you look at page 1121, middle of the page, "The Board
21 say that they agree with the views of Graham J in
22 that respect. However, they appear to me to reach
23 exactly the opposite result. Graham J found valid
24 the claim based on sound prediction. In the instant
25 case, the Board, in spite of a complete absence of

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1 any evidence of unsoundness of the prediction, deny
2 the claims and would in the end limit them to the
3 area of proved utility instead of allowing them to
4 the extent of predicted utility. In my view this is
5 contrary to s 42 of the Patent Act.
6 "Under that section the Commissioner is
7 instructed to refuse the patent when 'satisfied that
8 the applicant is not by law entitled' to it. Here
9 what he has said in approving the decision of the
10 Board is in effect 'I am not satisfied you are
11 entitled to it'. In my opinion the Commissioner
12 cannot refuse a patent because the inventor has not
13 fully tested and proved it in all its claimed
14 applications. This is what he has done in this case
15 by refusing to allow claims 9 and 16 unless
16 restricted to what had been tested and proved before
17 the application was filed. If the inventors have
18 claimed more than what they have invented and
19 included substances which are devoid of utility,
20 their claims will be open to attack. But in order to
21 succeed, such attack will have to be supported by
22 evidence of lack of utility. At present there is no
23 such evidence and there is no evidence that the
24 prediction of utility for every compound named is not
25 sound and reasonable."

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1 So what happened there, Dr. Gillen, is
2 the burden was put on the Commissioner to have
3 evidence of lack of utility before rejecting an
4 application, correct?
5 DR. GILLEN: That would be one ground for
6 rejecting an application for lack of utility, yes,
7 if, in fact, there was evidence that the invention
8 did not work.
9 MR. DEARDEN: No, but what I'm saying,
10 burden, who -- is it for the patent applicant to
11 prove there was utility, or was the burden on the
12 Commissioner to have evidence of lack of utility and
13 the Supreme Court has said it's on the Commissioner.
14 Correct?
15 DR. GILLEN: Yes, the burden here would
16 be on the Commissioner to show lack of utility.
17 MR. DEARDEN: And so that was for the
18 benefit of -- the doctrine of sound prediction
19 adopted by the Supreme Court was really for the
20 benefit of the patentee, correct?
21 DR. GILLEN: Yes, I would agree with
22 that.
23 MR. DEARDEN: Mr. President, could I
24 maybe have five minutes to confer with my colleagues
25 as to whether I have any other questions? Because

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1 that does complete my binder.
2 THE PRESIDENT: Yes. (Pause).
3 Mr. Dearden?
4 MR. DEARDEN: I have no further
5 questions. Thank you, Mr. President.
6 THE PRESIDENT: Thank you, Mr. Dearden.
7 Any questions for redirect?
8 MS. ZEMAN: No questions on redirect.
9 THE PRESIDENT: There are a few questions
10 from the Tribunal.
11 **QUESTIONS BY THE ARBITRAL TRIBUNAL**
12 SIR DANIEL BETHLEHEM: Thank you. I've
13 got a number of questions simply for clarification.
14 We've been provided as part of the record
15 with extracts of a number of the MOPOP publications.
16 I think in the preambular parts of the 1990 MOPOP it
17 indicates that MOPOP is a loose-leaf publication
18 interleaved with updates, and describes a gray color
19 paper for the interleaved updates. Can you clarify
20 whether MOPOP is now still a loose-leaf publication
21 or whether it is a bound volume without the
22 interleaved updates?
23 DR. GILLEN: Actually the MOPOP today is
24 electronic; it's not a paper MOPOP anymore. When I
25 joined the Office it was a loose-leaf binder, like a

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1 three-ring binder. Pages could be taken out or
2 inserted, as the case may be, when amendments were
3 made to the MOPOP. At some later date it did become
4 more of a bound thing, but for the last several years
5 it's now electronic so it makes making amendments to
6 it even easier.
7 SIR DANIEL BETHLEHEM: Does that mean
8 that it's updated on an ad hoc basis or whenever the
9 view is taken that it needs to be updated? Because
10 we are cited to -- whatever it is, the 2009 MOPOP,
11 the 2010 MOPOP, rather than the 15th of January or
12 the 16th of January MOPOP.
13 DR. GILLEN: Well, what's going on today
14 in the Patent Office is there's a full-time person
15 who is the manager of Office practice -- or practice
16 manager, I'm not sure what her exact title is.
17 There's also somebody who's in charge of training.
18 There's a training team. So when a new court case
19 would come out that would have some impact on Office
20 practice that would necessitate an amendment to the
21 MOPOP, for example, these people are going to get
22 together with others in the Patent Office and make a
23 decision as to what to do with it.
24 Now, whether or not they update the
25 electronic version of MOPOP immediately or at some

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1 later date when there's more jurisprudence perhaps,
2 they often will have training sessions or Office
3 memos or Office practice memos, many of which are
4 published, in lieu of actually making amendments
5 immediately to the MOPOP.
6 SIR DANIEL BETHLEHEM: We were taken by
7 counsel for the Claimant in his cross-examination
8 questions to you to a number of cases in which the
9 MOPOP was cited by courts as a valuable
10 interpretative guide. Insofar as the MOPOP would be
11 cited to a court by counsel for either party, on what
12 basis would the court be able to have confidence that
13 what it was being cited to was the current updated
14 version rather than yesterday's version which was
15 going to be overtaken by tomorrow's version which may
16 be significantly different?
17 DR. GILLEN: Well, I think the court
18 would look to the date of the MOPOP and look to the
19 most recent version of the MOPOP, if they were going
20 to cite it. I think for the most part, when courts
21 are citing MOPOP, I mean to some extent MOPOP is
22 attempting to summarize and interpret some of the
23 decisions of the court, so sometimes for the court
24 it's easier to refer to the MOPOP where there's more
25 of a summary of the jurisprudence rather than going

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1 to the jurisprudence itself.
2 SIR DANIEL BETHLEHEM: What I'm wondering
3 about, in a hypothetical, is we have Mr. Reddon or
4 Mr. Dimock before a court, would they be able to come
5 to a Patent Office and say: "Are you working on any
6 updates. We want to put this before the court. We
7 want to make sure we are putting before the court the
8 current thinking of the Patent Office", or would it
9 simply be whatever is on the website of the
10 Patent Office?
11 DR. GILLEN: I don't recall the court
12 ever coming to the Patent Office with those kinds of
13 questions. I think the extent to which they relied
14 upon the MOPOP would be based on the case and the
15 subject matter and really up to the court as to
16 whether they wanted to make a reference to MOPOP or
17 refer directly to the jurisprudence.
18 SIR DANIEL BETHLEHEM: Right. We have
19 evidence in Mr. Wilson's statement -- and it's not
20 part of the paragraphs that you identify where you
21 disagree with Mr. Wilson, so this is really just a
22 point of clarification, if I may -- if there was a
23 concern within the Patent Office or within the
24 Department of Justice lawyers who were consulted on
25 the updating of MOPOP arising out of a court decision

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1 because, for example, they thought that the court
2 decision was wrong, or they thought the court
3 decision was imprecise, or because it was going to be
4 very difficult to apply more broadly across the
5 particular sector in which the decision was issued,
6 how, if at all, would that be addressed?
7 Really what I'm trying to elicit from you
8 is an explanation of whether the MOPOP would simply
9 take the court judgment as given and introduce it
10 into the MOPOP or whether there would be an
11 analytical process that would interpret the judgment,
12 make a decision not to reflect the judgment in the
13 MOPOP because the law was not regarded as settled, or
14 simply not to introduce it into the MOPOP because
15 there was a disagreement with the outcome of the
16 court case?
17 DR. GILLEN: All of those are
18 possibilities. It really depends on the case. Some
19 decisions are fairly straightforward, so they could
20 be incorporated directly into the MOPOP. There are
21 other decisions where the decision in the view of the
22 Patent Office may not be as clear, and in those cases
23 the Office would look to the decision and try to
24 analyze and determine what it was the court was
25 trying to tell the Office to do or not to do.

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1 In those cases the Department of Justice
2 might be consulted also for an opinion as to how far
3 the decision went or what it actually meant or how it
4 affected Office practice, so it would really depend
5 on the case itself and how clear the decision was in
6 the opinion of the Office.
7 As an example, there was a decision some
8 years ago in the famous Harvard Mouse decision where
9 it went back and forth about whether or not life
10 forms like that should be patentable, and ultimately
11 it was decided that they should not be patented, at
12 least in Canada. There were statements in that
13 decision with respect to fertilized eggs and other
14 types of life forms that weren't a mouse, where the
15 Office had to think about what they meant and maybe
16 consult with the Department of Justice as to how far
17 that decision would go with respect to life forms, or
18 maybe even what a life form meant in terms of that
19 decision.
20 So it really depends on how clear the
21 decision is and how black and white it is whether or
22 not a decision would be incorporated directly into
23 training materials or MOPOP or practice notice, or
24 whether there would be consultations at some point
25 before the Office could finally take a position and

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1 then that would become part of the training materials
2 or go into the MOPOP.
3 SIR DANIEL BETHLEHEM: Would there be
4 anything else apart from the court decisions and
5 MOPOP to which the profession might have regard? For
6 example, would there be Department of Justice
7 guidelines, interpretations, publications which the
8 profession would look to alongside the MOPOP to see
9 how the Patent Office would work?
10 DR. GILLEN: I'm not aware of any
11 Department of Justice guidelines sort of parallel to
12 what the Patent Office would be doing with respect to
13 Office practice.
14 SIR DANIEL BETHLEHEM: In light of what
15 you just said, would it be overstating the matter or
16 would it be a fair summation to say that to some
17 extent there will be a, if you like, a professional
18 dialogue between the Patent Office through the MOPOP
19 and the courts through their judgment about what a
20 particular principle should be, particularly in
21 circumstances in which we were dealing with, as it
22 were, innovation in the law?
23 DR. GILLEN: There is a little bit of a
24 back and forth. I wouldn't say a dialogue or
25 discussions but certainly with respect to patentable

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1 subject matter, as I mentioned earlier, in the early
2 2000s the Office was looking at inventions related to
3 computers and business methods, which was new subject
4 matter for the Office, and trying to assess whether
5 or not some of those inventions were, indeed,
6 patentable subject matter or not. And so the Office
7 developed certain practice with respect to those
8 kinds of inventions. The practice that was developed
9 by the Office was ultimately denied by the courts.
10 The courts said no, that's not the way to go; you
11 can't assess patentable subject matter in that way.
12 So in terms of a dialogue, the Office may
13 have a position with respect to patentable subject
14 matter or some other issue which ultimately the
15 courts disagree with. So there's the back and forth
16 that way. But there isn't sort of an ongoing
17 dialogue, no.
18 SIR DANIEL BETHLEHEM: So the courts may
19 disagree with it or the courts may agree with it on
20 the basis that it's a valuable interpretative
21 guideline?
22 DR. GILLEN: Exactly. We talked a few
23 minutes ago about the Monsanto case, you know. The
24 issue was whether or not those compounds should be
25 patented and the Office said no and the Federal Court

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1 of Appeal said no and the Supreme Court said yes, so
2 there is back and forth on a number of these issues.
3 SIR DANIEL BETHLEHEM: It's your evidence
4 that the MOPOP is sort of high-level guidance. Is
5 there within the Office more granular guidance to the
6 assessors in relation to any particular field,
7 biotech or whatever, so that they've got something
8 beyond the high-level guidance to turn to?
9 DR. GILLEN: No, there's no other manual
10 that the examiners would use. They have MOPOP
11 practice notices and Office memos and that sort of
12 thing. And then on-the-job training, of course.
13 When there are newer examiners they work with a
14 senior examiner for the first two years that they're
15 in the Office to learn how to examine an application,
16 write a report and so forth.
17 SIR DANIEL BETHLEHEM: But there would be
18 nothing along the lines of, for example, an internal
19 annotation which says: We note the AZT case, it's
20 reflected in paragraph whatever, be aware that this
21 line of jurisprudence is developing or it changes the
22 law previously?
23 There wouldn't be some touchstone to
24 which an examiner would be able to go to get more of
25 a granular feel for the law?

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1 DR. GILLEN: No, there is not.
2 SIR DANIEL BETHLEHEM: Thank you very
3 much.
4 THE PRESIDENT: Questions by Mr. Born.
5 MR. BORN: Just one question about slide
6 13 in your presentation, if you go to the last box on
7 the page.
8 DR. GILLEN: Yes.
9 MR. BORN: If I understand what you're
10 saying about post-filing evidence of utility, it is
11 that post-filing evidence will not be accepted by the
12 agency, and then, if I understand your reasoning, it
13 is because an invention must be complete at the time
14 it is filed.
15 I'm struggling, I guess, for the logic
16 that connects those two statements because they seem
17 to, at least to me, concern different things. Let's
18 take, for example, an airplane. I invent an
19 airplane. I build the airplane. I file the patent
20 application and then I test it. The question of
21 whether my invention is complete seems to be
22 different from the question of whether I can submit
23 evidence about how it works from after the filing
24 date.
25 Can you help me on that difficulty that I

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1 have?
2 DR. GILLEN: Yes, I think that analogy
3 was actually used in one of the court cases with
4 respect to a heavier-than-air flying machine, so an
5 airplane, so if you've invented an airplane, for your
6 invention to be complete at the time of filing, you
7 would describe your airplane and enable one of skill
8 in the art to make the airplane. For your invention
9 to be complete you would either have flown the
10 airplane and shown that it's useful for its intended
11 purpose, or you would soundly predict that your
12 airplane would fly and the prediction would be based
13 on whatever facts you had disclosed in the
14 application to show the examiner that, indeed, your
15 prediction was sound. That's what we mean by the
16 invention has to be complete at the time of filing.
17 So if you had made the airplane and never
18 tested it and had no evidence that this would fly,
19 you couldn't file your application and say well, I've
20 invented an airplane, and then maybe five years later
21 you send something to the Patent Office to show them
22 that, indeed, your airplane does fly. The way it
23 works is you have to have your invention complete at
24 the time you file, so you can't have a hoped-for
25 flying machine when you file your patent application

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1 that later proves to be true, because if it isn't
2 true, if it doesn't fly, then what you've given the
3 public really is nothing at all.
4 MR. BORN: But if my disclosure explains
5 how you make an airplane that, in fact, flies, I
6 guess I'm struggling on why I haven't given the
7 public something quite valuable.
8 DR. GILLEN: If you've described your
9 airplane and you've described how to make it and
10 you've described why you think it will fly, then
11 that, to me, sounds like a sound prediction because
12 you haven't actually flown the airplane yet, but if
13 you can soundly predict that it will fly because you
14 understand something about wings and air flow around
15 wings and the whole concept of lift and so forth,
16 then your application might be complete depending on
17 what you've given the public. But if all you give
18 the public is well, here's how you make this airplane
19 and I hope it flies, that's really not an invention.
20 You haven't completed the invention in the sense of
21 having tested it and shown that it does work, or
22 making statements that would soundly predict that it
23 will, indeed, fly.
24 MR. BORN: Thank you.
25 THE PRESIDENT: Any follow-up questions?

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1 Mr. Dearden?
2 MR. DEARDEN: Just one.
3 **RE-CROSS EXAMINATION ON BEHALF OF THE CLAIMANT**
4 MR. DEARDEN: Just following up on that,
5 Dr. Gillen, the airplane example that Member Born
6 just gave you, the date of the invention of that
7 airplane or the date the invention is made is the
8 date the airplane is built but not yet flown,
9 correct?
10 DR. GILLEN: The date of the invention or
11 the date of --
12 MR. DEARDEN: The date the invention is
13 made, in the example that Member Born just gave you,
14 would be the date that that airplane has been built
15 and is sitting in the field but not yet flown,
16 correct?
17 DR. GILLEN: No. I would say the date of
18 invention is when you've built the airplane and based
19 on -- and you've flown it or --
20 MR. DEARDEN: No, that's not my example,
21 sir.
22 MR. SPELLISCY: Can he finish his answer
23 there? I don't think he was done.
24 THE PRESIDENT: Okay. Could you please
25 repeat your answer, and then finish it.

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

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1 for testifying. You are now released as an expert in
2 this case and excused.
3 DR. GILLEN: Thank you.
4 THE PRESIDENT: Recess 15 minutes.
5 *(Recess taken)*
6 RONALD E. DIMOCK
7 THE PRESIDENT: Mr. Dimock, good morning.
8 MR. DIMOCK: Good morning.
9 THE PRESIDENT: Could you please state
10 your full name for the record?
11 MR. DIMOCK: My name is Ronald Edward
12 Dimock.
13 THE PRESIDENT: Mr. Dimock, if any
14 question is unclear to you, either because of
15 language or for any other reason, please do seek a
16 clarification because, if you don't do so, the
17 Tribunal will assume that you've understood the
18 question and that your answer corresponds to the
19 question.
20 MR. DIMOCK: I understand.
21 THE PRESIDENT: Mr. Dimock, you appear
22 here as an expert witness for the Respondent. You
23 will appreciate that testifying, be it before a court
24 or an arbitral tribunal, is a very serious matter.
25 In that connection, the Tribunal expects you to give

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1 the statement which is in front of you.
2 MR. DIMOCK: Thank you. I solemnly
3 declare upon my honor and conscience that my
4 statement will be in accordance with my sincere
5 belief.
6 THE PRESIDENT: Thank you. Could you
7 please go to your First Report which is dated
8 January 26, 2015, page 60. Could you please confirm
9 for the record that the signature appearing above
10 your name is your signature?
11 MR. DIMOCK: Yes, it is.
12 THE PRESIDENT: Could you then please go
13 to your second Expert Report, which is dated
14 December 4, 2015. Could you please go through to
15 page 40 and confirm for the record that the signature
16 appearing above your name is your signature?
17 MR. DIMOCK: Yes, it is.
18 THE PRESIDENT: Are there any corrections
19 you wish to make to either report?
20 MR. DIMOCK: No, there is none.
21 THE PRESIDENT: I see Mr. Johnston, you
22 are doing the direct?
23 MR. JOHNSTON: Yes, President
24 van den Berg. Mr. Dimock has prepared a
25 presentation. However, we have had a logistical

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1 issue in the printing of the slides, and so
 2 Mr. Dimock is ready to give his presentation and the
 3 PowerPoint is ready up on the screen, but we can't
 4 provide the slides at this moment. We're currently
 5 reprinting them. That would take I'm not sure
 6 exactly how many minutes but some time to do, so I'm
 7 in the Tribunal hands in terms of how we proceed.
 8 THE PRESIDENT: Mr. Dearden, do you have
 9 any problem in looking only electronically?
 10 MR. DEARDEN: In the interest of moving
 11 things along, Mr. President, my guess would be that
 12 you would want me to answer I have no problem.
 13 THE PRESIDENT: No, no. What we can do
 14 is we can quickly make one print-out for you so you
 15 have a hard copy, because you may be the same as me,
 16 in that I would like to make notes.
 17 MR. DEARDEN: Okay.
 18 THE PRESIDENT: Let's wait for a second
 19 until we have the hard copy.
 20 (Pause)
 21 THE PRESIDENT: Ms. Cheek?
 22 MS. CHEEK: Mr. President, we would just
 23 observe that in Mr. Dimock's presentation there are
 24 several demonstrative timelines, and there's no
 25 citations back to his original reports. The parties

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1 are agreed that the presentation that will be
 2 provided is solely a summary of material in the
 3 report, so our assumption would be that all of this
 4 material is, in fact, referenced in Mr. Dimock's
 5 reports, but we would appreciate some clarification
 6 in that regard.
 7 However, there's also a tab 2 and a tab 3
 8 which are additional materials that perhaps we could
 9 get some explanation of. I'm just really not sure
 10 what the tab 2 and tab 3 are. Perhaps they're not
 11 part of his presentation.
 12 THE PRESIDENT: Mr. Johnston, could we
 13 get an explanation from you on tabs 1, 2 and 3?
 14 MR. JOHNSTON: Yes. I can confirm that
 15 all of the cases represented on those timelines are,
 16 in fact, cases referred to in Mr. Dimock's expert
 17 reports. There's nothing going beyond his expert
 18 reports in his presentation. There is an interactive
 19 aspect of the slide show, and that is why we have
 20 these additional tabs 2 and 3 which bring up quotes
 21 from those decisions reflected on the timeline.
 22 In the context of the actual PowerPoint,
 23 it will appear on the screen, the same text. It's
 24 just for convenience it's included in a separate
 25 annex.

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1 THE PRESIDENT: And that applies to all
 2 three attachments, tabs 1, 2 and 3?
 3 MR. JOHNSTON: Yes. There are three
 4 timelines in the presentation, and so the annexes
 5 correspond to those timelines.
 6 MS. CHEEK: Mr. President, are the
 7 annexes, compendiums, behind tabs 2 and tab 3
 8 actually the exact same as the annexes already
 9 provided in Mr. Dimock's Expert Report? Because if
 10 not, then they appear to be new material.
 11 THE PRESIDENT: What I understood is that
 12 they all come from the expert reports. Is that a
 13 correct understanding, Mr. Johnston?
 14 MR. JOHNSTON: All of the cases referred
 15 to are relied upon by Mr. Dimock in his expert
 16 reports. I know that most or some of those quotes
 17 will be verbatim, identical to what appears in his
 18 Expert Report. It is possible that the quotes are
 19 not all fully reproduced in his expert reports; the
 20 cases are cited and relied upon.
 21 THE PRESIDENT: Okay.
 22 MS. CHEEK: Mr. President, I would note
 23 that Mr. Dimock has already provided to his Second
 24 Report an Annex B where he walks through a series of
 25 cases and provides various quotes. To the extent a

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1 quote that's behind tab 2 and tab 3 is identical to
 2 what he's provided in Annex B, we have no objection.
 3 To the extent he's providing additional material
 4 beyond Annex B, that needs to be provided through
 5 direct to the extent that it's responsive to new
 6 testimony that's come into the record.
 7 THE PRESIDENT: Ms. Cheek, I think we
 8 should wait until we have completed the presentation
 9 because what I understood is what these three
 10 timelines are is what will be shown on the PowerPoint
 11 presentation. Apparently it's an interactive
 12 timeline, as they call it, so let's wait, and maybe
 13 at the end of the presentation you can say "Wait a
 14 moment, this is not what is exactly in the record of
 15 Mr. Dimock's expert reports."
 16 MR. SPELLISCY: Mr. President, I would
 17 like to interject here. Yesterday we had Mr. Reddon
 18 give a presentation in which he referred at length to
 19 a case and cases that weren't even cited in his
 20 expert reports, and I had made a point to that point
 21 which was overruled by the President, I think.
 22 Here we actually are referring to cases
 23 that are cited in Mr. Dimock's expert reports, and we
 24 can't imagine that the simple fact that a citation
 25 may be different, or annex, is an objection,

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

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

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

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

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11:13

1 in effect.
 2 The patent bargain.
 3 Utility is required, just as the other
 4 four pillars of our patent bargain is based, and
 5 without it we do not have the hard coinage, as
 6 Justice Binnie has used that, adopting it from
 7 another case. You have to exchange for obtaining
 8 that monopoly.
 9 As we've heard, the Patent Act does not
 10 define "useful" or "utility" and consequently, as has
 11 been the case, the courts are to interpret and give
 12 meaning to the Patent Act.
 13 However, over the years, from my
 14 conducting cases and reading about them, utility is
 15 not considered in isolation. Even though there are
 16 the five pillars of a patent, a valid patent or a
 17 patentable invention, there is some overlapping and
 18 the courts have said that you can't pidgeon-hole some
 19 of the attacks.
 20 For example, overbreadth and inutility do
 21 overlap in some respects. You've heard, and I'll go
 22 over it in some detail when I look at some cases,
 23 overbreadth is where you claim more than what you
 24 invented or what you have disclosed. It's called
 25 covetous claiming: You are greedy or claiming more

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1 than you're entitled.
 2 The doctrine of sound prediction you've
 3 heard as part of the law of utility actually arose as
 4 a defense to overbreadth. What you've claimed is
 5 broader than the invention disclosed or made, and
 6 then you defend that claim based on sound prediction,
 7 that what you've disclosed has a factual basis and a
 8 good line of reasoning so that you can lay claim
 9 beyond the actual examples in the patent disclosure
 10 itself. Promises of utility are enforced through
 11 overbreadth, and I'll come to that when I look at
 12 some cases in a few moments.
 13 The patent bargain in relation to utility
 14 has three fundamental questions. What is the
 15 invention; was the invention actually made; and was
 16 the invention properly disclosed.
 17 You've heard about the "scintilla" or
 18 promise of utility, about reading the patent through
 19 the eyes and the mind of the person of skill in the
 20 art, that to make an invention you can either do so
 21 by demonstrating the utility or having a sound
 22 prediction made as of the filing date of the patent,
 23 and the disclosure for sound prediction requires a
 24 factual basis and a line of reasoning.
 25 What the Claimant's experts have

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1 indicated, as far as I can discern from the records
 2 and hearing them give evidence before the
 3 arbitration, is that the utility standard is only
 4 one -- and only one -- scintilla; it does not have a
 5 promise of utility standard; you don't read it
 6 through the eyes and the mind of a person of skill in
 7 the art -- although there may have been some
 8 concession on that. They're debating that the
 9 demonstration or sound prediction -- that's the two
 10 bases upon which you can prove utility -- they're I
 11 believe criticizing that that was a new point, that
 12 you had to do that as of the filing date, and,
 13 lastly, they're saying that the disclosure of a
 14 factual basis and line of reasoning is new.
 15 I say all those are old as of the dates
 16 that the patents were filed and NAFTA as well.
 17 The three fundamental questions of the
 18 patent bargain.
 19 The Claimant's experts say that as of
 20 2005 this promise standard was new. They also allege
 21 that reading the patent through the mind and eyes of
 22 a person of skill in the art was new as of 2005. My
 23 opinion, as I've indicated, is that these alleged
 24 changes have been part of our Canadian law since
 25 before the 1970s, and it's always been that the

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1 patentees are held to their side of the bargain. The
 2 promise secures the patent.
 3 Why does a patent applicant make a
 4 promise of utility when, according to Consolboard,
 5 there's no need to make reference to the utility or
 6 the novelty in the patent? Well, in some cases it is
 7 a necessity to satisfy another concept of law or an
 8 incentive, as the case may be, where there's a
 9 particular utility at the core of the invention, such
 10 as in the atomoxetine case where it was a new use.
 11 If you just claimed atomoxetine, that would have been
 12 an old molecule. You have to indicate why it's now
 13 new and inventive, or you indicate a new use for the
 14 treatment of attention deficit/hyperactivity
 15 disorder. And then selection inventions, where you
 16 take a very large genus of chemicals and realize
 17 through study and research that there's a certain
 18 smaller species which has an advanced or elevated or
 19 substantial improvements. Also, if there's a very
 20 clouded state of the art, you want to indicate some
 21 advantages in order to support your case that it's
 22 not obvious.
 23 I've indicated on this slide the three
 24 dates that I think I've heard are important in regard
 25 to promise of utility, and that is the filing date of

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1 the two patent applications, or the two patents in
 2 suit here, and the date of 2005, when they say that
 3 these two standards of utility came into being.
 4 THE PRESIDENT: May I stop you for one
 5 second for a discrete question? It is a Tribunal
 6 time question, don't worry.
 7 Concerning your understanding of
 8 Professor Siebrasse and what happened in 2005, what
 9 is the triggering event in 2005 according to your
 10 understanding?
 11 MR. DIMOCK: My understanding is that
 12 he's relying on three cases where the courts were
 13 asked to look for promises in the disclosure in order
 14 to assess whether or not that would render the patent
 15 invalid. That's my understanding of it.
 16 THE PRESIDENT: Maybe that can be
 17 explored later, the three decisions.
 18 MR. DIMOCK: Yes.
 19 THE PRESIDENT: Thank you. Please
 20 proceed.
 21 MR. DIMOCK: So what I've indicated on
 22 this slide is a timeline, and these cases and
 23 commentary I refer to in my two reports, and I
 24 thought it would be more demonstrative rather than
 25 having a long list, if we look at them in a timeline,

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1 as I've indicated here. I don't have time, nor will
 2 I go through each of these, but I just want to
 3 highlight some of the important ones.
 4 I'd like to take a look at the Donald
 5 Hill article which was in 1960. He's saying that
 6 there's one standard that you measure utility on the
 7 one hand, and a second on the other. If certain
 8 results are promised and they're inferred from the
 9 specification and these are not yielded by the
 10 embodiment of the claims, then the patent will fail.
 11 In the absence of a specific promise like that, then
 12 the courts do not seem to be overly anxious to strike
 13 down. That would appear to be the scintilla of
 14 utility, as opposed to the higher level of utility
 15 that is this other standard.
 16 THE PRESIDENT: Could you help me? Could
 17 you please pull up again what you just had on the
 18 slide in 1960? Where do we find that in tab 1, 2 or
 19 3, this text?
 20 MR. DIMOCK: You'll find that in tab 1.
 21 It's the third one down on the first page behind
 22 tab 1.
 23 THE PRESIDENT: Okay. Yes. I'm with
 24 you.
 25 MR. DIMOCK: I'll try and indicate as I

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1 go where you can actually find them.
 2 Then a year later, 1961, I'd like to talk
 3 about the New Process Screw case. We've heard
 4 something about that already. In that particular
 5 case there was a finding that the patent was invalid,
 6 and what was important there is two things. The
 7 first one, "...it was conclusively proved that if
 8 dies with the pitch angles referred to in the
 9 specification" -- and what the judge is referring to,
 10 "specification" here, is the disclosure. We heard
 11 yesterday some discussion about specification.
 12 In normal practice the specification is
 13 really the disclosure. There are two parts to a
 14 patent, the claims and the disclosure. Technically
 15 the specification is both the claims and the
 16 disclosure, but people invariably refer to the
 17 disclosure as the specification or vice versa.
 18 Sometimes they refer to the body of the specification
 19 as the disclosure. I'll try and point out where that
 20 occurs from time to time through some of these cases.
 21 Here in this case the judge concluded
 22 that there was a "failure of the promise of the
 23 patent which was fatal to it".
 24 Justice Thorson then also looked at the
 25 evidence of Mr. de Villiers, who was the inventor,

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1 and the inventor said if you used a certain angle you
 2 would roll a double-threaded screw, but it would not
 3 be a good one. It would be rough and not a
 4 commercial product. And reference to commercial
 5 product is in the disclosure only, it's not in the
 6 claim, so Justice Thorson said this statement was
 7 enough to destroy the patent. So that goes to the
 8 point that they were looking at the disclosure, not
 9 to the claims in looking for the promise of the
 10 patent.
 11 I'd like to then take a look at the next
 12 reference, Mr. Henderson's article, which refers to
 13 the New Process Screw case. Mr. Henderson was the
 14 editor and he wrote about these cases in his Reporter
 15 and he said "In the present case, it will be noted
 16 that in respect of one of the three patents in suit,
 17 the failure of the patentee to achieve a commercially
 18 good product" -- and that's the reference in the
 19 disclosure -- "in carrying out the disclosure
 20 rendered the patent invalid on the ground that the
 21 promise made in the specification was not
 22 fulfilled...".
 23 He then went on to say, "... in the
 24 absence of a promise or a representation of a
 25 specific usefulness, it is clear that only a limited

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1 degree of usefulness is required. If the patentee
2 makes a specific promise in the specification, the
3 promise must be fulfilled or the patent is
4 invalid..."

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

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

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

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1 that particular result is promised."
2 I'd like to jump a few years ahead -- a
3 couple of years -- to 1971, Bill Hayhurst. Bill
4 Hayhurst was a leading patent figure and wrote
5 extensively about patent law and was well read. Here
6 Mr. Hayhurst is saying, "In the introductory parts of
7 the specification" -- so that's the disclosure --
8 "one must be chary of promising advantages that are
9 not achieved by everything that falls within the
10 broadest claim." So there he is distinguishing
11 between the specification and the claim. "If you
12 make false promises you may get an invalid patent...
13 Since claims, to be valid, must not extend to useless
14 things, but must be confined to things which have the
15 utility promised by the disclosure, the agent should
16 be careful not to promise too much."
17 Again warning about putting too much in
18 the disclosure about promises, unless you absolutely
19 have to.

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

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1 it didn't meet the promise. The disclosure referred
2 to uniform distribution of these felts --

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

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

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

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

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

5 Then on the third promise, or the third
6 aspect of the bargain, has the invention been
7 disclosed, I'd just like to take a look at really two
8 things in my report or in my presentation, and that's
9 in 1971, if you turn to the timeline itself, Hayhurst
10 1971 on disclosure drafting. He says here, "Not only
11 must you instruct those skilled in the art. You must
12 also provide a disclosure which justifies the claims
13 you are making. You must include sufficient examples
14 to justify a sound prediction that everything falling
15 within the scope of the claims will have the promised
16 utility."

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

24 That concludes my presentation.
25 THE PRESIDENT: Thank you.

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

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

11 MR. JOHNSTON: Yes, that's correct.

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

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

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

25 THE PRESIDENT: Subject to your

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1 verification, we can proceed. Do you have further
2 questions to ask in direct?

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

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

7 **CROSS-EXAMINATION ON BEHALF OF THE CLAIMANT**

8 MR. DEARDEN: Good morning, Mr. Dimock.

9 MR. DIMOCK: Good morning, Mr. Dearden.

10 MR. DEARDEN: How are you doing?

11 MR. DIMOCK: I'm all right.

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

17 MR. DIMOCK: That's right.

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

20 MR. DIMOCK: Yes.

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

24 MR. DIMOCK: That's right.

25 MR. DEARDEN: And only Parliament can

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1 create requirements for obtaining a patent in Canada?
2 MR. DIMOCK: Yes. There's one exception.
3 Before the Parliament actually enacted obviousness
4 into the Patent Act, it was a judge-made law that, in
5 order to get a valid patent, the invention had to
6 be -- did not -- could not have been obvious, so
7 sometimes there's judge-made law like that but I
8 think, generally speaking, I agree with the statement
9 you gave to me.

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

14 MR. DIMOCK: Yes.

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

18 MR. DIMOCK: Yes.

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

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

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

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

3 MR. DIMOCK: Yes.

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

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

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

13 MR. DIMOCK: What page is that again?

14 MR. DEARDEN: I have it at page 36.

15 MR. DIMOCK: Yes, that's right.

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

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

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

23 MR. DIMOCK: Of that same volume?

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

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

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

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1 the data underlying the invention. Allowing Ranbaxy
 2 to attack the utility, novelty and/or obviousness of
 3 the 546 patent through the disclosure requirement
 4 unduly broadens the scope of the inventor's
 5 obligation under 27(3) and disregard the purposes of
 6 the provision."
 7 Paragraph 57. "While it's true that
 8 27(3) requires the inventor to 'correctly and fully
 9 describe' his invention, this provision is concerned
 10 with ensuring that the patentee provide the
 11 information needed by the person skilled in the art
 12 to use the invention as successfully as the
 13 patentee."
 14 And at paragraph 59 the Court of Appeal
 15 holds, "Only two questions are relevant for the
 16 purposes of 27(3) of the Act. What is the invention?
 17 How does it work?: See Consolboard...In the case of
 18 selection patents, answering the question 'What is
 19 the invention?' involves disclosing the advantages
 20 conferred by the selection. If the patent
 21 specification (disclosure and claims) answers these
 22 questions, the inventor has held his part of the
 23 bargain."
 24 So the court there is saying the
 25 requirements of section 27(3) are not the same as the

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

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1 subsection 27(3), according to this paragraph 53 of
2 the Court of Appeal's decision?
3 MR. DIMOCK: That is one interpretation
4 you could give to it, yes.
5 MR. DEARDEN: Do you agree with that
6 interpretation?
7 MR. DIMOCK: I didn't agree with the
8 decision. No, I did not.
9 MR. DEARDEN: Once you received it,
10 sir --
11 MR. DIMOCK: I had to agree with it, yes.
12 MR. DEARDEN: Tab 17 of the same binder
13 should be Exhibit C-544, Genpharm v Proctor & Gamble,
14 another one of your cases. That you won?
15 MR. DIMOCK: We won this time.
16 MR. DEARDEN: You won.
17 MR. DIMOCK: Yes.
18 MR. DEARDEN: Paragraph 47. Do you have
19 that, sir? It's right at the bottom of page 12 of
20 13.
21 MR. DIMOCK: Yes, I see that.
22 MR. DEARDEN: So "As counsel for P&G has
23 pointed out" -- that would be you.
24 MR. DIMOCK: It was, indeed.
25 MR. DEARDEN: So, "As [Ron Dimock] has

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1 pointed out, sound prediction and obviousness are
2 considerations with different perspectives. Sound
3 prediction is relied upon by an inventor to justify
4 patent claims whose utility is not actually
5 demonstrated but can be soundly predicted from
6 information and expertise that is available.
7 Obviousness is relied upon by a potential competitor
8 of the patentee who argues that what is claimed in
9 the patent is something that a skilled technician
10 keeping up with the state of the art and common
11 general knowledge would be able to come to directly
12 and without difficulty in the absence of the solution
13 taught by the patent. These are different concepts
14 and they are not to be conflated. The doctrine of
15 sound prediction has no application to the doctrine
16 of obviousness."
17 In light of the fact that you made that
18 submission, I'm assuming that you embrace that
19 paragraph 47 wholeheartedly?
20 MR. DIMOCK: At the time I did, yes, and
21 I still do today.
22 MR. DEARDEN: Do you have your first
23 statement, Mr. Dimock?
24 MR. DIMOCK: I do.
25 MR. DEARDEN: Paragraph 7 of your first

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1 statement.
2 MR. DIMOCK: The bottom of page 3 of my
3 report?
4 MR. DEARDEN: Paragraph 70 of the First
5 Report. Sorry, did you say page 3 or page 20?
6 MR. DIMOCK: I have page 3 of my copy.
7 MR. DEARDEN: Paragraph 70.
8 MR. DIMOCK: Oh. I heard 7, sorry. I
9 apologize. I now have paragraph 70. That's at
10 page 20.
11 MR. DEARDEN: Yes.
12 So in that paragraph you say "Consolboard
13 and the promise of the patent were inextricably
14 linked together long before 2005. One example of a
15 court decision around the time of the application
16 dates of the olanzapine and atomoxetine patents was
17 Mobil Oil v Hercules Canada." And in paragraph 71
18 you say, "In Mobil Oil, the validity of patent in
19 suit was challenged on utility grounds for failing to
20 meet the utility promised in the patent," and then
21 you give a quote from Justice Wetston's decision.
22 Mobil Oil is tab 19 of volume 3, if you
23 could turn it up, sir. Can you turn to page 513?
24 MR. DIMOCK: I have it.
25 MR. DEARDEN: So you see paragraph B, the

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1 second paragraph there, "The defendant argues that
2 the only teaching in the patent to assist the
3 addressee in what he is not to do, is found in the
4 table test results at page 6 of the patent. Counsel
5 argues that the invention's promise of enhanced
6 adhesion is only achieved when a bond strength
7 measurement of at least 250 grams an inch with no
8 metal lift-off is obtained. Since the inter parties
9 tests show that the Hercules film did not reach this
10 level, he submits that there can be no infringement.
11 Further, he relies on the evidence of Mr. Seguin
12 that, in his experience with Hercules film, the
13 typical range of bond strengths is from 100 grams an
14 inch to about 200 grams an inch, also below 250 grams
15 an inch."
16 Then Justice Wetston holds, "I cannot
17 accept the defendant's argument on this point. The
18 data presented in the patent does not define the
19 promise of the patent. It is merely provided as an
20 example of the enhanced adhesion which may be
21 achieved using the subject film, as compared with a
22 film of homopolymer polypropylene. If it was
23 intended that the invention relate to a film with at
24 least 250 grams per inch bond strength, it would be
25 so claimed. Such is not the case, and I see no

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1 reason to construe the patent as limiting the
2 inventor's intention in this way."
3 So, Mr. Dimock, Justice Wetston did not
4 accept the argument of counsel that the statement in
5 the disclosure of a bond strength measurement of at
6 least 250 grams per inch was going to define the
7 promise because that was not in the claims, correct?
8 MR. DIMOCK: I think what he was saying
9 is that that was an example given, and that what he
10 did decide, construing the disclosure, was the
11 promise that was given was not an adhesion level that
12 high but that it be an enhanced adhesion, and he
13 concluded that the claims met the enhanced adhesion
14 as he interpreted it to be and, therefore, the claim
15 satisfied the promise of a disclosure of the patent
16 that there be enhanced adhesion. He concluded that
17 there was not a promise that the adhesion had to be
18 250 grams per inch.
19 MR. DEARDEN: Where do I see
20 Justice Wetston saying there was a promise of
21 enhanced adhesion? A promise?
22 MR. DIMOCK: Well, counsel was arguing
23 that.
24 MR. DEARDEN: No, Counsel was arguing
25 that there was --

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1 MR. DIMOCK: The invention --
2 THE PRESIDENT: Hold on a second. One at
3 a time.
4 MR. DEARDEN: Go ahead, Mr. Dimock.
5 Sorry.
6 MR. DIMOCK: In that sentence, the second
7 sentence after letter b, "Counsel argues that the
8 invention's promise of enhanced adhesion..." so
9 counsel was saying that there is a promise of
10 enhanced adhesion. The question is at what level.
11 And what Justice Wetston decided was that that level
12 was not as high as 250 grams per inch. He did
13 conclude that the promise of enhanced adhesion was,
14 indeed, effected by the claims as drafted and
15 embodiment of those claims.
16 MR. DEARDEN: Where did Justice Wetston
17 use the word "promise" of enhanced adhesion, as
18 opposed to the claims only claimed enhanced adhesion
19 as opposed to counsel arguing that there was a
20 promise of bond strength of 250 grams per inch?
21 Justice Wetston made no findings of promise, did he?
22 What he did do was he rejected the counsel trying to
23 argue a statement out of the disclosure for 250 grams
24 an inch was a promise that the patentee should have
25 been held to, and he rejected that because that

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1 wasn't in the claims. Agreed?
2 MR. DIMOCK: You had a lot in that
3 question. My reading of the case was that he did
4 cite MacMillan Bloedel v Consolboard with regard to a
5 promise of utility, and I understood through the
6 evidence and his analysis of it that there was an
7 argument made about the promise being as high as
8 250 grams per inch, and I just can't put my finger on
9 the particular sentence in Justice Wetston's reasons
10 where he dismisses the argument or dismisses the
11 attack, but the discussion, it seemed to me, was
12 surrounding a promise and whether or not it was a
13 promise of enhanced adhesion or a promise of enhanced
14 adhesion at the level of 250 grams per inch.
15 MR. DEARDEN: That definitely is on
16 page 513 out of the mouth of counsel who argued that
17 there was a promise of enhanced adhesion of 250 grams
18 per inch in the disclosure, and he rejected it.
19 Justice Wetston rejected that.
20 MR. DIMOCK: Yes, he did.
21 MR. DEARDEN: Okay. Got that. And the
22 enhanced adhesion, Mr. Dimock, was in the claims,
23 right?
24 MR. DIMOCK: Yes.
25 MR. DEARDEN: The 250 grams per inch was

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1 in the disclosure?
2 MR. DIMOCK: That's correct.
3 MR. DEARDEN: When you first were
4 answering my question about what Justice Wetston said
5 about the example given, that's the 250 grams per
6 inch adhesion, that example is in the disclosure, not
7 the claims. Correct?
8 MR. DIMOCK: The claims did not recite an
9 enhanced adhesion of 250 grams per inch. There was
10 an example given with that enhanced adhesion, but he
11 said that was not a promise made.
12 MR. DEARDEN: Where does Justice Wetston
13 say that is not a "promise" made?
14 MR. DIMOCK: He dismissed the argument.
15 The argument was that that was a promise and he
16 dismissed it.
17 MR. DEARDEN: You agree with me he
18 doesn't use the words you just used on page 513,
19 correct?
20 MR. DIMOCK: On 5 --
21 MR. DEARDEN: 13. The quote I just read
22 to you.
23 MR. DIMOCK: I did not recite it verbatim
24 from Justice Wetston's decision, no.
25 MR. DEARDEN: So, Mr. Dimock, if a

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1 defendant advanced this argument today that you could
2 look to the disclosure for a bond strength of at
3 least 250 grams per inch with no metal lift-off
4 obtained, would the court find that to be a promise
5 that had to be met by the patentee today?
6 MR. DIMOCK: No, it would not.
7 MR. DEARDEN: It would not?
8 MR. DIMOCK: No. Based on the court's
9 interpretation of the patent at that time, the
10 interpretation would be no different today.
11 MR. DEARDEN: So an adhesion strength of
12 250 grams per inch would not be seen as a promise
13 that the patentee would be held to if that was
14 litigated in Federal Court today, according to your
15 evidence?
16 MR. DIMOCK: That's my opinion, yes.
17 MR. DEARDEN: Your second statement,
18 Mr. Dimock, if you could turn to paragraph 75,
19 please.
20 MR. DIMOCK: On page 21?
21 MR. DEARDEN: Yes. You say, "Their
22 views, in my opinion, are far from correct. The
23 courts are not 'scouring the patents for promises',
24 as both Professor Siebrasse and Reddon seemingly
25 state. Rather it is the parties in pharmaceutical

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1 litigation -- and not the courts -- that are now
2 placing promises that are made in the patents front
3 and center before the courts."
4 Mr. Dimock, what happened that caused the
5 parties to now place promises made in the patents
6 front and center?
7 MR. DIMOCK: Up until 1995 we had no
8 pharmaceutical litigation to speak of, and it took a
9 number of years for both the pharmaceutical and the
10 generic side of the industry to understand the proper
11 procedures. And then it took a case where a patent
12 was held invalid for not fulfilling the promise that
13 one would, as counsel, try to run that same argument
14 in your own case, and so there were attempts to
15 invalidate a patent on old law that was now being
16 used in the pharmaceutical field in a way that was
17 succeeding.
18 MR. DEARDEN: You're saying it took a
19 case where a patent was held invalid for not
20 fulfilling the promise that one would as counsel try
21 to run that same argument in your own case. What
22 case are you referring to?
23 MR. DIMOCK: When I read up on -- I can't
24 give you the recitation of that case but my point was
25 that, when a case succeeds and you read about it, you

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1 then try to adapt it to your own cases that you have
2 in your own files, so that you have that practice.
3 My comment here was really to the point that
4 Messrs. Reddon and Siebrasse were suggesting that it
5 was the court's undertaking to scour the patents for
6 promises when, in fact, it was counsel who were
7 asking the courts to interpret the disclosures of the
8 patents before the courts in their cases, with the
9 intention that the courts would find promises made in
10 those disclosures that could not be met by the
11 claims.
12 MR. DEARDEN: My question, sir, on your
13 paragraph 75 of your Second Report, is what happened
14 that caused the parties in pharmaceutical litigation
15 to now start placing promises made in the patents
16 front and center before the courts. I have as your
17 answer "It took a case where a patent was held
18 invalid for not fulfilling the promise that one would
19 as counsel try to run that same argument in your own
20 case," and I'm trying to identify what case triggered
21 this placing of promises front and center before the
22 courts.
23 MR. DIMOCK: As I understand,
24 Mr. Siebrasse did mention some cases as of 2005, I
25 believe. That's what I'm referring to.

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1 MR. DEARDEN: So those three cases,
2 that's what you're referring to? Okay.
3 Prior to 2005, how many patents were
4 invalidated for lack of utility for failure to
5 soundly predict or demonstrate a promise construed
6 from the disclosure of the patent?
7 MR. DIMOCK: I can think of four -- or I
8 can think of three. The New Process Screw, the
9 Consolboard at the trial division --
10 MR. DEARDEN: Before Justice Collier?
11 MR. DIMOCK: Yes. And then the case that
12 I also lost, the Amfac case where the Court of Appeal
13 upheld the decision of Justice Strayer when Justice
14 Strayer interpreted the disclosure of the patent to
15 make French fry cuts, that the disclosure promised a
16 level of utility such that the outside cuts would be
17 separated at the knife, not downstream, and because
18 the claim did not meet that utility, that the claim
19 did not have the feature such that the outside slabs
20 could be separated at the knife and, therefore, did
21 not satisfy that promise of utility, they held it
22 invalid on the basis of claims broader than the
23 invention disclosed. As I said, overbreadth and
24 utility sometimes do overlap and that was one case
25 that the argument could have been made that the

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1 patent was invalid, not only for claims broader than
2 the inventions disclosed but also for inutility,
3 since the claim could not meet the promise of utility
4 of separation at the knife plate.
5 MR. DEARDEN: But, in fact, in Amfac the
6 only argument that was made was overbreadth --
7 MR. DIMOCK: That's correct -- yes and --
8 I'm sorry, I didn't mean to interrupt you.
9 THE PRESIDENT: Could you repeat your
10 question?
11 MR. DEARDEN: Yes. So in Amfac the only
12 argument that was made was overbreadth.
13 MR. DIMOCK: That's right. There were
14 discussions at the Court of Appeal as to whether it
15 was made by inutility, but the end result was that it
16 was claims broader than the invention disclosed.
17 MR. DEARDEN: And the decision was an
18 overbreadth decision?
19 MR. DIMOCK: That's correct.
20 MR. DEARDEN: And that -- what do I call
21 it, French fry maker?
22 MR. DIMOCK: Yes. You can call it a very
23 successful French fry maker.
24 MR. DEARDEN: It worked?
25 MR. DIMOCK: It worked.

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1 MR. DEARDEN: It just didn't --
2 MR. DIMOCK: It didn't work for the
3 promise of utility made. And it was held invalid
4 because, even though it did work, it didn't meet the
5 promise.
6 MR. DEARDEN: Other claims were upheld?
7 MR. DIMOCK: Other claims were not
8 alleged to be invalid for overbreadth because those
9 other claims did have the means by which the potatoes
10 could be separated, the outside slabs could be
11 separated at the knife plate.
12 MR. DEARDEN: So the question I posed to
13 you was, prior to 2005, how many patents were
14 invalidated for lack of utility for failure to
15 soundly predict or demonstrate a promise construed
16 from the disclosure of the patent, and you've given
17 me three cases, New Process Screw, Consolboard and
18 Amfac, and in none of those cases, Mr. Dimock, was
19 there an analysis of a demonstration or sound
20 prediction, correct?
21 MR. DIMOCK: In none of those three cases
22 was there an issue of sound prediction, that's right.
23 MR. DEARDEN: And was there an issue that
24 the demonstration had to be as of the date of filing
25 in those three cases?

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1 MR. DIMOCK: Not that I recall in the
2 Amfac case, and not what I could discern from reading
3 the reasons for judgment in either New Process, nor
4 Consolboard trial division. And, based on also my
5 recollection, having worked on Consolboard.
6 MR. DEARDEN: Can you turn to paragraph
7 44 of your first statement, please? Now we are
8 moving into the area of Patent Medicines (Notice of
9 Compliance) decisions.
10 MR. DIMOCK: Paragraph 44 is on page 12?
11 MR. DEARDEN: It is page 12. "The
12 proceedings under the Patented Medicines (Notice of
13 Compliance) regulations do not resolve issues as to
14 whether a listed patent is actually invalid or not
15 infringed as between the parties or as against the
16 world. Rather, the proceedings are limited to
17 determining whether an allegation of non-infringement
18 or invalidity justifies the issuance of an NOC" --
19 which is Notice of Compliance, right?
20 MR. DIMOCK: That's right, yes. Some
21 call it NOC.
22 MR. DEARDEN: That's a terrible acronym.
23 "Notice of Compliance by a Minister of Health for a
24 particular generic pharmaceutical product. A
25 decision that an allegation of invalidity is

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1 justified may lead to a Notice of Compliance being
2 issued but does not render the patent invalid under
3 section 60 of the Patent Act. Rather the patent
4 remains valid and can be asserted against the generic
5 in a subsequent patent infringement action or be
6 involved again with other generics in separate
7 proceedings under the Patented Medicines (Notice of
8 Compliance) regulation. This has become a reality in
9 some disputes."
10 Firstly, sir, when Justice Hughes issued
11 his decision in Raloxifene in 2008 -- and it's at
12 tab 4, C-115 if you need to look at it, but I think
13 you're quite familiar with it, when he issued his
14 decision in that Patented Medicine (Notice of
15 Compliance) proceeding, there was no determination by
16 the Federal courts about the validity of Lilly's
17 Raloxifene patent, correct? He didn't invalidate
18 that patent?
19 MR. DIMOCK: He did not invalidate the
20 patent. He said that Lilly didn't satisfy its onus
21 to show that the allegation was not justified.
22 MR. DEARDEN: I'm just going to rephrase
23 that to make sure the record is clear. Justice
24 Hughes in the Raloxifene decision did not invalidate
25 that patent. There could be then a subsequent action

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1 by Lilly for infringement of the generic who obtained
2 the Notice of Compliance to sell its generic version
3 of Raloxifene.
4 MR. DIMOCK: Pursuant to the regulations
5 and the interpretation of those regulations by the
6 courts, Justice Hughes did not have the jurisdiction
7 to invalidate in that hearing. But there are now
8 some cases under PM(NOC) proceedings where they're
9 almost having them as a hybrid, trials and hearings,
10 but I believe that was not one of them.
11 MR. DEARDEN: That wasn't one of them.
12 MR. DIMOCK: That was not one of them, I
13 believe.
14 MR. DEARDEN: Decisions in these Patent
15 Medicine (Notice of Compliance) proceedings are
16 precedents in patent infringement and impeachment
17 actions, right?
18 MR. DIMOCK: Yes.
19 MR. DEARDEN: For instance, Supreme Court
20 of Canada's decision in Sanofi Plavix, as we call it,
21 R-013, tab 21, and Pfizer v Novopharm which is
22 tab 14, R-197, those two Supreme Court of Canada
23 decisions were dealing with Notice of Compliance
24 applications, yet they are judicially cited and
25 considered by the courts like over a hundred times,

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1 right?
2 MR. DIMOCK: I don't know whether over a
3 hundred times, but they are cited. Our patent law
4 over the last 10 to 15 years has been driven by
5 pharmaceutical cases, whether they be PM(NOC)
6 hearings or whether they be trials. It's a very
7 active part of litigation. And yes, you're right,
8 even though it's a decision from a judge in a PM(NOC)
9 hearing, it is his or her view of the law which you
10 can apply in any type of case.
11 MR. DEARDEN: And when it comes from the
12 Supreme Court of Canada, that law is going to be
13 cited by counsel in their factums and it's going to
14 be cited by judges who are making decisions on those
15 issues that are dealt with by those Supreme Court
16 decisions, right?
17 MR. DIMOCK: Yes.
18 MR. DEARDEN: And we find PM(NOC)
19 decisions are cited by Patent Office examiners in
20 Office actions?
21 MR. DIMOCK: I can't point to one in
22 particular, but I can't imagine that that's not the
23 case.
24 MR. DEARDEN: Well, they're in MOPOP,
25 right?

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1 MR. DIMOCK: I've heard that, yes.
2 MR. DEARDEN: You mean you don't have
3 MOPOP as a reference tool like right --
4 MR. DIMOCK: No, I don't use MOPOP as a
5 source of authority in any case I've argued. If I've
6 ever referred to MOPOP, it's to perhaps about
7 procedures in the Patent Office, but I've been very
8 reluctant to use MOPOP as a source of law in any case
9 I argued. I could stand to be corrected, but that's
10 my recollection of the cases I have argued.
11 MR. DEARDEN: And I'm not doubting your
12 recollection, sir, but you were in the room when I
13 was cross-examining Dr. Gillen this morning?
14 MR. DIMOCK: I certainly was.
15 MR. DEARDEN: And you heard my reference
16 to two Federal Court cases --
17 MR. DIMOCK: Yes, Justice Shore's case
18 and --
19 THE PRESIDENT: Can you let Mr. Dearden
20 finish?
21 MR. DEARDEN: Go ahead, Justice Shore's
22 decision and Justice Gibson's decision?
23 MR. DIMOCK: That's right.
24 MR. DEARDEN: In those two cases. So the
25 courts cite MOPOP from time to time.

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1 MR. DIMOCK: I don't know whether from
2 time to time. It depends on the type of issue that's
3 before the court. As I said, it would be my
4 practice, if I ever did cite MOPOP, it would be in
5 relation to the practice in the Patent Office as
6 opposed to being an authority of substantive patent
7 law or of patent litigation practice.
8 MR. DEARDEN: But you have cited MOPOP in
9 your Second Report at page 27, haven't you?
10 MR. DIMOCK: Second Report, page 27.
11 Yes, I did --
12 MR. DEARDEN: You did. Mr. Dimock, you
13 did rely on MOPOP in paragraph 97 of your second
14 Expert Report, didn't you?
15 MR. DIMOCK: I did put that in there,
16 yes.
17 MR. DEARDEN: Paragraph 158 of your First
18 Report?
19 MR. DIMOCK: Page 46?
20 MR. DEARDEN: Yes. The last very long
21 sentence that starts, "Although there are more
22 reported decisions in recent years about the issues
23 of utility concerning pharmaceuticals than any other
24 subject matter, that is explained by the large volume
25 of pharmaceutical cases in the Federal Court due to

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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

1 Patented Medicine (Notice of Compliance) Regulations,
2 not that pharmaceutical inventions are treated
3 differently under the law of utility."
4 So, Mr. Dimock, the Patented Medicines
5 (Notice of Compliance) Regulations come into force in
6 1993, correct?
7 MR. DIMOCK: Yes.
8 MR. DEARDEN: And, as of 1993, a generic
9 could serve a notice of allegation on a
10 pharmaceutical patentee alleging it was not
11 infringing the patent and/or the patent was invalid,
12 right?
13 MR. DIMOCK: Yes, the so-called second
14 person could make either/or both of those
15 allegations.
16 MR. DEARDEN: And the so-called second
17 person is the generic?
18 MR. DIMOCK: Yes.
19 MR. DEARDEN: Then in response the
20 pharmaceutical patentee would typically file a notice
21 of application in the Federal Court seeking an order
22 that prohibits the Minister of Health from issuing a
23 Notice of Compliance to the generic, right?
24 MR. DIMOCK: You said "typically"?
25 MR. DEARDEN: You think all the time?

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1 MR. DIMOCK: Likely, but I don't want to
2 say absolutely. But typically? Fair enough.
3 MR. DEARDEN: But that's the process?
4 MR. DIMOCK: Fair enough.
5 MR. DEARDEN: You get a notice of
6 allegation from the generic. You want to stop them
7 going on the market and getting an NOC. You file a
8 notice of application in Federal Court and you ask
9 for an order prohibiting the Minister of Health from
10 issuing a Notice of Compliance to that generic?
11 MR. DIMOCK: Yes.
12 MR. DEARDEN: So, from 1993 to 2004,
13 there isn't a single Patented Medicines (Notice of
14 Compliance) case that decided that a pharmaceutical
15 patent lacked utility, right? Not one. Zero.
16 MR. DIMOCK: I believe you are right. As
17 I said -- well, I've answered your question. That's
18 all I have to do.
19 MR. DEARDEN: Paragraphs 142 and 143 of
20 your Second Report.
21 MR. DIMOCK: On page 38? I'm reading
22 paragraph 142.
23 MR. DEARDEN: "As I noted...PM(NOC)
24 decisions are not the end of the road for patentees
25 and generics alike. A subsequent trial on the merits

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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

1 of the patent's infringement and invalidity can come
2 to the avail of either side. Prior PM(NOC)
3 proceedings do not create or abolish any rights of
4 action between the parties, nor are they adjudicative
5 or binding on subsequent actions for infringement and
6 validity. In this regard, PM(NOC) proceedings are
7 favorable to innovator litigants as they have 'a
8 second chance' through a patent infringement action."
9 Sir, when an innovative pharmaceutical
10 company has failed to obtain an order prohibiting the
11 Minister of Health from issuing a Notice of
12 Compliance to the generic on the ground that the
13 patent lacked utility, you'll agree that an innovator
14 company has never been successful in the subsequent
15 infringement action? Whereas lack of utility -- so
16 the order doesn't go in the NOC proceeding because
17 the patent was found to lack utility, action is
18 brought for infringement subsequently by the pharma
19 patentee and never has there been a successful action
20 when the patent was found to lack utility at the NOC
21 stage -- or the PM(NOC) stage. Right?
22 MR. DIMOCK: I'm not aware of any.
23 MR. DEARDEN: That's not much of a second
24 chance, is it, when you lose on utility at the
25 PM(NOC) proceeding?

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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

1 MR. DIMOCK: If the generic succeeds at
2 the PM(NOC) hearing, it is likely to get a Notice of
3 Compliance within a matter of days, and there's no
4 appeal that can be taken by the pharmaceutical
5 company that was the patentee. On the other hand, if
6 the patentee succeeds in getting a prohibition order,
7 the generic can appeal that decision. The reason why
8 the patentee cannot appeal is the Court of Appeal has
9 said it is academic. Once the compliance is issued
10 and the generic is on the market, they really can't
11 pull it back.
12 Then at the trial there is an opportunity
13 for both sides to delve more deeply into any of the
14 issues before the court because in the case on
15 infringement or impeachment, as the case may be,
16 there's discovery, which one doesn't have in a
17 PM(NOC) hearing, so there is a greater second chance
18 to delve into things in the trial of an infringement
19 action or a trial of an impeachment action. So I
20 don't know that I can agree with you to say that it's
21 not much of a second chance.
22 MR. DEARDEN: I appreciate that there is
23 a second proceeding available to a pharma patentee
24 who loses the application for the prohibition order
25 in the PM(NOC) proceedings, but when it comes to

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1:2:25

1 losing that PM(NOC) proceeding because the patent was
2 found to lack utility, there has never been a second
3 chance in terms of the pharma patentee winning the
4 infringement action when it lost on utility in the
5 PM(NOC) proceeding, right?
6 MR. DIMOCK: As I said, I'm not aware of
7 a case where it's been reversed, no.
8 MR. DEARDEN: That's binder 1.
9 MR. DIMOCK: How many do you have?
10 MR. DEARDEN: 3.
11 MR. DIMOCK: It's like being in a dentist
12 chair. How many more minutes?
13 MR. DEARDEN: I have four hours.
14 MR. DIMOCK: I have all the time.
15 MR. DEARDEN: Keep going, Mr. President?
16 THE PRESIDENT: If you're moving to a new
17 subject matter and you cannot complete it in five
18 minutes...
19 MR. DEARDEN: I'm sorry. I thought we
20 were breaking at 1.
21 THE PRESIDENT: 12:30. Maybe there's a
22 new agreement between the parties.
23 MR. DEARDEN: None that I'm aware of.
24 THE PRESIDENT: Okay. 12:30. If we
25 break now, then we will recommence at 1:25. What I

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1:2:26

1 assume is that you are now going into a new area
2 which takes more than three minutes?
3 MR. DEARDEN: Yes.
4 THE PRESIDENT: Fair assumption.
5 Mr. Dimock, you are under testimony and
6 are not allowed to discuss this case with anyone.
7 MR. DIMOCK: I understand.
8 THE PRESIDENT: Recess until 1:25.
9 *(Recess taken)*
10 MS. CHEEK: As a preliminary matter, I
11 want to report that the parties are continuing to
12 confer on the schedule and Canada is confirming the
13 availability of some of their witnesses, but we would
14 expect that by the coffee break we would have a
15 proposal to the Tribunal which will accelerate the
16 schedule and have us not running until next Thursday.
17 But we need to confirm some witness availability.
18 THE PRESIDENT: Or there are two
19 alternatives that the Tribunal was thinking. One is
20 that Saturday is actually a free Saturday, at least a
21 non-hearing day, or the day prior to the closing
22 statements. So there are two alternatives which may
23 also be considered. Or accelerate. So what you were
24 considering is that you finish on Wednesday?
25 MS. CHEEK: Or even Tuesday. We will

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01:28

1 continue to confer and we will keep the Tribunal's
2 proposals in mind.
3 THE PRESIDENT: But that is on the basis
4 that we also continue on Saturday?
5 MS. CHEEK: Yes, probably an abbreviated
6 day on Saturday.
7 THE PRESIDENT: Then this also raises a
8 question for Mr. Dearden and your estimate -- I know
9 it's a non-binding estimate -- for your
10 cross-examination?
11 MR. DEARDEN: It feels like two and a
12 half hours.
13 THE PRESIDENT: More? Or including what
14 we have already had?
15 MR. DEARDEN: More, yes. I had four. I
16 think I'm on track.
17 THE PRESIDENT: You are at 48 minutes.
18 MR. DEARDEN: We may finish by the break.
19 THE PRESIDENT: It's okay. Please
20 continue.
21 MR. DEARDEN: Mr. Dimock, all set?
22 MR. DIMOCK: Yes.
23 MR. DEARDEN: Can we go back to
24 Consolboard, which is in volume 3, tab 18.
25 MR. DIMOCK: Yes, I have it.

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01:30

1 MR. DEARDEN: This morning during your
2 presentation, as I recall, Mr. Dimock, you said
3 several times that the specification is understood to
4 mean the disclosure of the patent.
5 MR. DIMOCK: Not always, Mr. Dearden.
6 Under the Patent Act the specification is defined to
7 include the disclosure and the claims. However, in
8 normal parlance between patent lawyers, people tend
9 to use specification to mean disclosure, or that the
10 disclosure is the body of the specification or that
11 the specification is, indeed, the disclosure, but
12 never would the specification be the claims only. I
13 think that's what I was trying to say.
14 MR. DEARDEN: If you look at paragraph 26
15 of Consolboard, we have the Supreme Court of Canada
16 telling us exactly what specification means, don't
17 we? Paragraph 26, which is a long paragraph. The
18 part I'm looking at is right at the bottom of the
19 page above paragraph 27. You see that?
20 MR. DIMOCK: I'm sorry. I'm having a
21 hard time trying to find paragraph numbers.
22 THE PRESIDENT: You are quoting from the
23 Consolboard in R-011? That has numbers.
24 MR. DEARDEN: C-118 is the one I thought
25 was in our binder.

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01:32

1 THE PRESIDENT: I'm working always on the
2 same copy because --
3 MR. DEARDEN: There's no paragraph
4 numbers. Page 520, and it will be the paragraph that
5 starts "In essence." I'll read it in.
6 "In essence, what is called for in the
7 specification (which includes both the 'disclosure',
8 i.e. the descriptive portion of the patent
9 application, and the 'claims') is a description of
10 the invention and the method of producing or
11 constructing it, coupled with the claim or claims
12 which state those novel features in which the
13 applicant wants an exclusive right. The
14 specifications must define the precise and exact
15 extent of the exclusive property and privilege
16 claimed."
17 So, Consolboard, the Supreme Court of
18 Canada is saying the specification includes the
19 disclosure and the claims, correct?
20 MR. DIMOCK: In that paragraph, yes.
21 MR. DEARDEN: And in your presentation
22 binder, tab 1 -- so after the end of slide 21 -- you
23 have some extracts from cases and commentators, and
24 if you go to the third page of those extracts,
25 Mr. Dimock, you should be finding the 1978

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01:34

1 Consolboard v MacMillan Bloedel at the bottom.
2 MR. DIMOCK: Yes, that's the Federal
3 Court decision.
4 MR. DEARDEN: That's Justice Collier, who
5 we spoke of this morning?
6 MR. DIMOCK: Yes.
7 MR. DEARDEN: And you've extracted
8 paragraph 164 as that first paragraph, and then the
9 Fox citation is found at paragraph 169.
10 MR. DIMOCK: I believe that's right.
11 MR. DEARDEN: I'm only interested in
12 paragraph 164, the first paragraph that you have on
13 that extract. It reads "One of the essentials in
14 both these patents is that a uniform map be laid down
15 by the felting process or the apparatus described.
16 Various expressions are used in patent '232, one
17 finds in column 1 'uniform distribution', in column 2
18 'substantially uniform thickness' and 'uniform
19 deposition'. There are many other similar phrases
20 throughout both patents. The requirement of
21 uniformity is specifically set out in each of the
22 claims in suit."
23 So you agree, Mr. Dimock, that the trial
24 judge, Justice Collier, found that the requirement of
25 uniformity is specifically set out in each of the

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01:35

1 claims in suit?
2 MR. DIMOCK: That's what he said.
3 MR. DEARDEN: The Monsanto decision
4 should be at tab 1 of volume 1, it should be C-61,
5 and your First Report, paragraph 139. Let's go to it
6 first.
7 MR. DIMOCK: Mr. Dearden, I don't want to
8 complain, but I'm having a hard time hearing when you
9 refer to numbers.
10 MR. DEARDEN: Okay. We should be at
11 page 41 of your first part, paragraph 139.
12 MR. DIMOCK: I'm there.
13 MR. DEARDEN: "The trial court decision
14 referred to by Professor Siebrasse is a decision by
15 Justice Hughes, my former law partner, concerning the
16 drug Raloxifene in Eli Lilly v Apotex. As in the
17 Monsanto case, one of the questions before Justice
18 Hughes was 'whether the disclosure in the patent was
19 adequate to tell a person skilled in the art how to
20 practice the invention or whether it discloses enough
21 so that a person skilled in the art could "soundly
22 predict" that it would work'.
23 And in your footnote 162 in that
24 paragraph you cite to Justice Hughes' Raloxifene
25 decision at R-200. Right?

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01:37

1 MR. DIMOCK: Yes.
2 MR. DEARDEN: You'll agree that the
3 Monsanto decision of the Supreme Court of Canada does
4 not make a finding that the factual basis and line of
5 reasoning for sound prediction of utility must be
6 disclosed in the patent?
7 MR. DIMOCK: Impliedly, it did. Monsanto
8 had before it, the Supreme Court of Canada had in the
9 patent application, reference to three examples to
10 support the claim for 126 chemicals. That was the
11 factual basis. And the common general knowledge,
12 which was as of the date of the patent application
13 gave the basis, the reasoning, for being able to
14 claim all 126 chemicals. So it didn't use the very
15 words that are found in Justice Binnie's decision in
16 the AZT. However, that's the inference you draw from
17 reading the case and knowing the facts of it.
18 MR. DEARDEN: And it didn't use the very
19 words found in Justice Hughes' 2008 Raloxifene
20 decision either, correct? That's Monsanto. Did not
21 use the very words used by Justice Hughes?
22 MR. DIMOCK: I've never done a
23 side-by-side comparison.
24 MR. DEARDEN: Is my statement fair,
25 though?

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01:39

1 MR. DIMOCK: Yes, I accept that. If you
2 say so, Mr. Dearden, I accept it.
3 MR. DEARDEN: You know, we could be out
4 of here by 2:00 if you keep doing that!
5 MR. DIMOCK: I don't plan to.
6 MR. DEARDEN: Do you agree that the
7 Monsanto decision did not find that in cases of sound
8 prediction of utility there is a heightened or an
9 enhanced disclosure requirement on the patentee?
10 MR. DIMOCK: Well, the word "enhanced", I
11 believe, has this origin. Every patent disclosure,
12 whether it be for sound prediction or one that was
13 demonstrated utility or what-have-you, requires
14 sufficient disclosure so as to permit another to make
15 and use the invention after the monopoly expires.
16 And I mentioned that earlier this morning.
17 When they talk about "enhanced"
18 disclosure I believe what they're talking about is
19 the disclosure of the factual basis upon which the
20 sound prediction is based, and either the reasoning
21 for that is to be found in the common general
22 knowledge possessed by chemists, as the case may be,
23 or whether or not it's explicitly stated, as was the
24 case in AZT, where it was a certain phenomenon which
25 they drew upon as the basis, or as the reasoning. So

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01:41

1 I believe when you refer to an "enhanced" disclosure
2 it's referring to going beyond just telling you how
3 to make it. It's telling you why, if you make it and
4 make all the compounds, they will have usefulness
5 because of the factual basis, in that case in
6 Monsanto three examples. And the common general
7 knowledge, the reasoning, will make you conclude that
8 you can make all 26 and they would work.
9 MR. DEARDEN: Enhanced or heightened
10 disclosure has been decided to be -- it's a phrase,
11 they're not my phrases, they're Federal Court of
12 Appeal phrases -- that you have to have the factual
13 basis and the line of reasoning in the patent, right?
14 MR. DIMOCK: Yes.
15 MR. DEARDEN: So that's what I'm
16 referring to as "heightened" or "enhanced" disclosure
17 requirement, that in cases of sound prediction, you
18 have to have the factual basis and line of reasoning
19 in the patent, and I'm not going to find that
20 anywhere in Monsanto, am I?
21 MR. DIMOCK: You asked me that question a
22 few moments ago, and I said you won't find those
23 explicit words, but you do find it impliedly by
24 knowing what it is that the case was all about.
25 MR. DEARDEN: Monsanto made no finding

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01:43

1 that factual basis had to be disclosed. Agree?
2 MR. DIMOCK: They accepted the fact that
3 the three examples given and what was said by the two
4 experts about the common general knowledge was
5 sufficient to make the sound prediction.
6 MR. DEARDEN: I'll ask it again. Agree
7 or disagree. Monsanto made no finding that the
8 factual basis had to be disclosed?
9 MR. DIMOCK: It didn't make that explicit
10 finding. Yes, it did not. But, you know, and we've
11 gone back and forth on this now three times, but I'm
12 saying impliedly you understand that to be the case.
13 MR. DEARDEN: Let's just go to AZT for a
14 second. It's at tab 2 of volume 1, Supreme Court of
15 Canada decision in 2002.
16 MR. DIMOCK: Yes.
17 MR. DEARDEN: I'm going to take you to
18 paragraph 70.
19 MR. DIMOCK: That's on page 186?
20 MR. DEARDEN: Yes, of the SCR report.
21 Paragraph 70 contains the tripartite test for sound
22 prediction, right?
23 MR. DIMOCK: Yes.
24 MR. DEARDEN: Let me put it on the
25 record.

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01:44

1 "The doctrine of sound prediction has
2 three components. Firstly, as here, there must be a
3 factual basis for the prediction. In Monsanto and
4 Burton Parsons, the factual basis was supplied by the
5 tested compounds, but other factual underpinnings,
6 depending on the nature of the invention, may
7 suffice. Secondly, the inventor must have, at the
8 date of the patent application an articulable and
9 'sound' line of reasoning from which the desired
10 result can be inferred from the factual basis. In
11 Monsanto and Burton Parsons, the line of reasoning
12 was grounded in the known 'architecture of chemical
13 compounds' but other line of reasoning, again
14 depending on the subject matter, may be legitimate.
15 Thirdly, there must be proper disclosure. Normally,
16 it is sufficient if the specification provides a
17 full, clear and exact description of the nature of
18 the invention and the manner in which it can be
19 practiced."
20 And there's a citation to Dr. Fox.
21 "It is generally not necessary for an
22 inventor provide a theory of why the invention works.
23 Practical readers merely want to know that it does
24 work and how to work it. In this sort of case,
25 however, the sound prediction is to some extent the

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1 *quid pro quo* the applicant offers in exchange for the
2 patent monopoly. Precise disclosure requirements in
3 this regard do not arise for decision in this case
4 because both the underlying facts (the test data) and
5 the line of reasoning (the chain terminator effect)
6 were in fact disclosed, and disclosure in this
7 respect did not become an issue between the parties.
8 I therefore say no more about it."
9 You'll agree that Monsanto did not create
10 that tripartite test that I see in paragraph 70 of
11 Justice Binnie's decision in AZT?
12 MR. DIMOCK: If I could answer your
13 question this way, it did not articulate the
14 tripartite test that Justice Binnie has done, but
15 what you see here in Justice Binnie's articulation of
16 the law is that Monsanto had the sound basis and
17 Monsanto had the line of reasoning he cites for both
18 the Monsanto case, and he said that there must be
19 proper disclosure. And, as I indicated in my
20 presentation and in my two reports, it's understood
21 that you must have claims that are fairly based on
22 the disclosure. Fairly based on the disclosure. And
23 those words have meaning in that the disclosure must
24 give you the basis upon which to allow you to claim
25 the claims on a sound prediction.

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01:48

1 So "fairly based on the disclosure"
2 implies that there is a need for a proper disclosure.
3 MR. DEARDEN: At paragraph 136 of your
4 First Report --
5 MR. DIMOCK: I have it.
6 MR. DEARDEN: -- you're saying "In its
7 reasons, the Supreme Court in Monsanto emphasized
8 that a sound prediction must not go beyond the
9 consideration provided by the disclosure. The court
10 quoted the following passage from the British case
11 Olin Mathieson, and held that the last sentence,
12 which refers to whether a claim is fairly based on
13 the disclosure, captures 'what is meant by a sound
14 prediction':".
15 The Supreme Court of Canada adopted the
16 Olin Mathieson case as part of Canadian law in
17 Monsanto, correct?
18 MR. DIMOCK: That's fair. It adopted
19 that aspect of it. There was an obviousness part of
20 Olin Mathieson but, insofar as the fairly based claim
21 aspect of the case, they adopted that statement,
22 which I believe Justice Graham took from Lionel
23 Hill's submissions.
24 MR. DEARDEN: And he was counsel for
25 plaintiff, Sir Lionel?

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01:50

1 MR. DIMOCK: Yes.
2 MR. DEARDEN: While we have your
3 paragraph 136 open and that quote from
4 Olin Mathieson, which I'm going to go to next, you
5 see where you have underlined the very last lines
6 that are underlined, "but if, when attacked, he
7 survives this risk successfully, then his claim does
8 not go beyond the consideration given by his
9 disclosure, his claim is fairly based on such
10 disclosure in these respects, and is valid."
11 The "when attacked" is at trial, correct?
12 MR. DIMOCK: That would appear to be the
13 case, yes.
14 MR. DEARDEN: So Olin Mathieson is at
15 tab 3, C-461, the decision of Justice Graham in 1970,
16 the High Court.
17 MR. DIMOCK: Yes.
18 MR. DEARDEN: You deal with this decision
19 at paragraph 119 of your Second Report.
20 MR. DIMOCK: I have it.
21 MR. DEARDEN: "The Court concluded that
22 based on the skilled person's reading of the
23 disclosure alone, the patent description provided
24 more than ample support for basing a sound prediction
25 of the stated utility. It reached this conclusion in

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01:52

1 light of the following: (a) the processes used to
2 make ten different example compounds belonging to the
3 claimed class were described in the specification
4 itself (reproduced in the reported decision): (b)
5 compounds with similar 'base' structures were
6 previously disclosed in the competitors' patents and
7 known to have therapeutic activity; and (c) the
8 skilled person's expectations based on the common
9 general knowledge and understanding in what was
10 described as a 'well-worked field'." Okay?
11 You cite for the (b) and (c) basis, for
12 the conclusion you say was reached by Justice Graham,
13 (b) and (c) you cite page 168 of the decision in
14 footnotes 130 and 131. Right?
15 MR. DIMOCK: That's what the report says.
16 MR. DEARDEN: We're going to go there.
17 Let's go to page 168 of Olin Mathieson, which is tab
18 3, C-461.
19 MR. DIMOCK: And I see, just before you
20 go there, Mr. Dearden, that it looks as though I had
21 the wrong page, because 168 is the submission of John
22 Whitford.
23 MR. DEARDEN: Right, who was counsel for
24 the plaintiffs, and Sir Lionel is actually counsel
25 for the defendants. So we both got it wrong.

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01:54

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

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01:56

1 MR. DIMOCK: That's right.
2 MR. DEARDEN: There was no issue as to
3 the sound prediction at the time of filing, which was
4 1956, right?
5 MR. DIMOCK: I don't understand what you
6 mean by that.
7 MR. DEARDEN: Well, first of all, you
8 agree that the patent was filed in 1956? You can
9 believe me on that?
10 MR. DIMOCK: I'll believe you on that.
11 MR. DEARDEN: Was there any issue in
12 Olin Mathieson that the sound prediction had to be at
13 the time of the filing of that patent, which was
14 1956? And I put it to you that it wasn't an issue.
15 MR. DIMOCK: I don't recall now that
16 particular issue being dealt with by Justice Graham.
17 The issue is whether or not the ten examples and the
18 common general knowledge and the understanding of the
19 chemistry relating to these types of chemicals would
20 be enough to say that the claim to this large class
21 was fairly based on the disclosure.
22 MR. DEARDEN: On page 193 of Justice
23 Graham's decision at the bottom, Justice Graham
24 states in his reasons, "There are certain other
25 matters dealt with in the evidence bearing on the

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01:58

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

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01:59

1 substitution of CF3 in various compounds prior to
2 1955."
3 Your eyes may be better than I mean,
4 Mr. Dimock. Is that a 3 or a 2? CF?
5 MR. DIMOCK: It's a 3. I must say, I'm
6 having a hard time reading the small print because of
7 the light -- I shed a shadow on the page so I'm
8 having a hard time, but I'll do my best. But it is a
9 3.
10 MR. DEARDEN: So you can't see and I
11 can't speak loud enough. We're doing really well!
12 "The evidence showed this was not a
13 selected list and supports the conclusion, referred
14 to by Dr. Gordon, that they had no reason to think in
15 1955 that CF3 was likely to enhance activity. This
16 work is unpublished."
17 So that's No. 1 of the important
18 considerations by Justice Graham in arriving at his
19 conclusion, and if you flip the page to page 195,
20 No. 3 is "The CF3 substitution in the '2' position
21 for virtually any given basic side chain confers the
22 highest known activity. See the evidence of
23 Dr. Simkins commenting on Sexton 1963 edition
24 page 447. Nothing has happened since to throw doubt
25 on this statement."

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02:01

1 No. 4 is: "All CF3 substituted...bodies
2 which the plaintiffs have made and tested show
3 therapeutic activity. The defendants have not given
4 evidence that they have found any such body which
5 does not have therapeutic activity."
6 And here's what Justice Graham says:
7 "(3) and (4) above are of great importance because it
8 seems right, and I so hold, that the plaintiffs are
9 entitled to rely on the fact that it appears to be
10 correct that the CF3 substitution confers higher
11 activity than any other substitution with any given
12 side chain. They do not say or promise this in their
13 specification, their promise being more modest,
14 namely, that the compounds are therapeutically
15 active. But if it be true, and it appears to be so
16 from works such as those of Sexton, [which is 1963]
17 and Robson and Stacey [1962] subsequent to the date
18 of the patent, that such enhanced activity is
19 obtained by the use of the CF3 substitution, then it
20 is clear that the plaintiffs have, in fact,
21 'contributed, and indeed contributed considerably, to
22 the common stock of human knowledge' by their
23 invention, even if the promise in their specification
24 can, as a matter of the words be said to guarantee
25 nothing more than the therapeutic activity which is

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1 said to be the characteristic of all phenothiazines."
2 Am I saying that right?
3 MR. DIMOCK: Yes, that's it.
4 MR. DEARDEN: "In my judgment it is what
5 the patentee has actually achieved and not what he
6 has promised (provided, of course, his promise is not
7 false) which matters from the point of view of
8 consideration and subject-matter in the sense of
9 inventive merit.
10 "Having regard to the relevant principles
11 and evidence referred to above, in my judgment the
12 claims of the patent in suit have not been shown by
13 the defendants to be invalid on the ground that they
14 are not fairly based on the disclosure in the
15 specification."
16 So, Mr. Dimock, there is post-filing
17 evidence and evidence that is not in the patent that
18 Justice Graham found to be of great importance,
19 correct?
20 MR. DIMOCK: You are right. I believe
21 that he found it to be important to say that the
22 prediction was correct, that because it did give rise
23 to this, that you couldn't say that the sound
24 prediction was unsound or false. I don't know that
25 he meant to say that you could rely on all this

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1 post-filing evidence to say that at the time you
2 filed that the inventors had a sound prediction, it
3 turned out that the prediction was correct.
4 MR. DEARDEN: That's correct, but there's
5 no doubt as a fact that Justice Graham relied on
6 post-filing evidence and evidence also that was not
7 in the patent, right?
8 MR. DIMOCK: For the reasons I gave, yes.
9 MR. DEARDEN: I'm not sure what you mean
10 by that, so I want it to be clear. The patent is
11 filed in 1956, item No. 3 and 4 are of great
12 importance. On page 195 we have reference to a 1963
13 work. We have reference to a 1962 work. We have
14 reference, sir, without a doubt to post-filing
15 evidence and evidence that's not in the disclosure,
16 correct?
17 MR. DIMOCK: Yes. I've agreed with you
18 on that.
19 MR. DEARDEN: Okay. So when you say in
20 paragraph 119 of your Second Report that the court
21 concluded that based on the skilled person's reading
22 of the disclosure alone the patent description
23 provided more than ample support for basing a sound
24 prediction of the stated utility, that statement is
25 not accurate, correct?

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1 MR. DIMOCK: I'm sorry, where are you
2 reading from?
3 MR. DEARDEN: Your second statement,
4 paragraph 119, first line, "The court concluded that,
5 based on the skilled person's reading of the
6 disclosure alone, the patent description provided
7 more than ample support for basing a sound prediction
8 of the stated utility," and the "disclosure alone"
9 part isn't accurate, is it?
10 MR. DIMOCK: It's the disclosure for
11 basing a sound prediction. It turned out with the
12 post-filing evidence that the evidence showed that it
13 was not wrong, that it was right, but I believe that
14 the disclosure itself was sufficient to say that the
15 prediction was sound. That's what he meant when he
16 said the claims were fairly based on the disclosure.
17 MR. DEARDEN: That description doesn't
18 say that, does it, Mr. Dimock?
19 MR. DIMOCK: It doesn't say it in those
20 words. I'm just reading it as a practicing patent
21 lawyer.
22 MR. DEARDEN: Now let's move to factual
23 basis and line of reasoning in the patent. So we've
24 gone through AZT, paragraph 70, the tripartite test,
25 and the third component of that which is tab 2,

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1 C-213. It's just simply proper disclosure. Thirdly,
2 there must be proper disclosure, right.
3 MR. DIMOCK: I recall our discussion
4 about that before we broke for lunch, yes.
5 MR. DEARDEN: And Justice Binnie doesn't
6 have any case law cite or textbook or commentator for
7 the third component of his tripartite test; it just
8 simply says: "Thirdly, there must be proper
9 disclosure."
10 MR. DIMOCK: That's right.
11 MR. DEARDEN: And it's your opinion that
12 AZT did not change the law in Canada?
13 MR. DIMOCK: It articulated it and
14 elaborated on it, but it didn't change it.
15 MR. DEARDEN: What was the elaboration?
16 MR. DIMOCK: Justice Binnie's reasons
17 elaborated on and the three -- I'm sorry.
18 MR. DEARDEN: No. Go ahead.
19 MR. DIMOCK: And the three-part test, as
20 you call it, was the articulation of what I believe
21 the law to have been since Monsanto.
22 MR. DEARDEN: Anything else to add when I
23 ask you, you know, what he elaborated on? Because it
24 is a long decision.
25 MR. DIMOCK: I can't at this moment in

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1 this chair do that for you.
2 MR. DEARDEN: And you'll agree that
3 there's nowhere in the AZT decision that
4 Justice Binnie states that the proper disclosure
5 component, third component of the test, must be in
6 the patent?
7 MR. DIMOCK: When you say a "proper
8 disclosure," that means a disclosure in the patent.
9 It can't mean anything else but that.
10 MR. DEARDEN: Well, there was some
11 considerable debate about that point after this
12 decision, wasn't there?
13 THE PRESIDENT: May I ask a question? A
14 couple of questions before, Mr. Dearden, you asked
15 whether Justice Binnie gave any authority for his
16 third proposition in paragraph 70 of the AZT
17 judgment. You remember that question?
18 MR. DEARDEN: Yes, after the words --
19 THE PRESIDENT: I'm conscious that you
20 are not the witness or the expert but I wondered
21 whether what follows after that, which starts with
22 "Normally" -- maybe I should ask not you but I should
23 ask the expert, Mr. Dimock. You see "Normally" and
24 then it has Fox, and it apparently deals with
25 disclosure. "In this sort of case, however, the

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1 sound prediction is to some extent the *quid pro quo*
2 the applicant offers in exchange for the patent
3 monopoly. Precise disclosure requirements in this
4 regard do not arise for decision in this case..." and
5 then he concludes with the words "I therefore say no
6 more about it."
7 Mr. Dimock, how do I have to consider all
8 these musings, if I may call them that, by the judge?
9 MR. DIMOCK: When I answered
10 Mr. Dearden's question, he said -- and there was no
11 judicial authority given for the third part, that
12 there must be a proper disclosure, I was thinking of
13 what Justice Binnie did for the first two parts. He
14 referred to Monsanto and Burton Parsons for the first
15 two, and then he said "Thirdly, there must be proper
16 disclosure. Period." Then he goes on to describe
17 it.
18 Yes, he does go on to talk about the need
19 for a disclosure and that's what I said earlier
20 today, that normally it is sufficient if the
21 specification provides a fault. You have to teach
22 the person of skill in the art how to make the
23 invention and it's not generally necessary for an
24 inventor to provide a theory, and then he says
25 "Precise disclosure requirements do not arise for

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1 decision in this case." So when he quotes Fox there
2 he's quoting Fox for the purpose of having a
3 disclosure showing you how to make it, but what he
4 goes on to say is -- I believe the inference to be
5 drawn is that in this case there was, indeed, a
6 proper disclosure because there was the underlying
7 test data, and there was a line of reasoning, the
8 chain terminator, that was the phenomenon I referred
9 earlier, so the authority or the basis upon which he
10 said he didn't have to go into any more detail was
11 the fact that in this case the patent agents for
12 Wellcome had included in their disclosure the factual
13 basis and the line of reasoning, and my position has
14 been that it's understood that you have to have in
15 your disclosure, in regards to sound prediction,
16 something which allows the claims to be fairly based.
17 I said earlier today how Mr. William
18 Hayhurst had said that you've got to include in your
19 disclosure examples sufficient enough to say that
20 your claims are fairly based on the disclosure.
21 That's a long-winded response to your
22 question. Sorry.
23 THE PRESIDENT: Okay. Thank you.
24 Mr. Dearden, please proceed.
25 MR. DEARDEN: Still looking at paragraph

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1 70 of AZT, Mr. Dimock, the three-part test paragraph
2 of AZT.
3 MR. DIMOCK: Yes.
4 MR. DEARDEN: The issue, or the debate,
5 as I referred to earlier, is where Justice Binnie,
6 after he has the *quid pro quo* sentence, says:
7 "Precise disclosure requirements in this regard do
8 not arise for decision in this case." So there
9 became later on a debate of what the precise
10 disclosure requirements were that constitute the
11 third component of this test, right?
12 MR. DIMOCK: I believe that what you take
13 from this case, as did Justice Hughes and others, is
14 that in this application -- and it was not debated by
15 the parties in the Supreme Court -- there was indeed
16 a factual basis and a line of reasoning, and he said
17 in this case the disclosure requirements are met. It
18 is a proper disclosure.
19 But I don't think what Justice Binnie
20 wanted to do was to draw a hard line because of the
21 fact that the parties had agreed before him that in
22 this case, at least, there had been a disclosure of
23 the factual basis and a line of reasoning, and he
24 said that there should be some sort of proper
25 disclosure.

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1 MR. DEARDEN: And the scope of the proper
2 disclosure requirements have been left to be decided
3 another day, is that fair? Where he says "I say no
4 more", it's been left to be decided another day?
5 MR. DIMOCK: He said "I therefore say no
6 more about it." Whether or not he was implying that
7 it's going to be further debated, I don't know. I
8 don't take that inference.
9 MR. DEARDEN: So you don't think that the
10 issue has been left to another day when a judge says
11 "Precise disclosure requirements in this regard do
12 not arise for decision in this case... I therefore
13 say no more about it"?
14 MR. DIMOCK: I took from that that the
15 proper disclosure would be constituted by, as he
16 said, the factual basis, the underlying facts, the
17 test data and the line of reasoning, the chain
18 terminator, phenomenon, just as in Monsanto one had
19 the three examples and the common general knowledge
20 with regard to the chemistry in that area of chemical
21 compounds, would say that the prediction was sound
22 that you could claim 126.
23 MR. DEARDEN: Are you going to agree with
24 me that the first decision to interpret the third
25 component of the tripartite test that we see in

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1 paragraph 70 was Justice Hughes' decision?
2 MR. DIMOCK: I'm trying to run through
3 the cases but it may be that it was Justice Hughes'
4 decision in Raloxifene that first looked at that
5 issue, as you referred to it.
6 MR. DEARDEN: Let's turn to paragraph 140
7 of your First Report.
8 MR. DIMOCK: I have that.
9 MR. DEARDEN: You say in paragraph 140,
10 "On first blush, Raloxifene appears to be somewhat
11 controversial, in that Justice Hughes concluded that
12 Eli Lilly had a factual basis and sound line of
13 reasoning prior to its Canadian filing date, but that
14 the patent specification did not adequately support
15 such a prediction, therefore justifying the
16 allegation of invalidity raised by Apotex. However,
17 on a careful reading of the case, it becomes apparent
18 that Raloxifene was well considered and reasoned, and
19 follows the same principles applied more than
20 25 years prior in Monsanto."
21 MR. DIMOCK: Yes.
22 MR. DEARDEN: So why, Mr. Dimock, why
23 would Justice Hughes' decision be somewhat
24 controversial?
25 MR. DIMOCK: Because when you first read

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1 it, you wonder about how he arrived at it, but then
2 you look closely at it, and Justice Hughes has
3 written many decisions about this, about patent law;
4 he's got the textbooks; and so he understands it. So
5 you have to then say well, what was he getting at.
6 And, as I understand it, for the Eli Lilly patent to
7 have a basis for a sound prediction included some rat
8 studies, as they're referred to, and he made the
9 point that if the rat studies were sufficient to
10 provide a sound basis, to make a sound prediction,
11 those studies were no better than a piece of prior
12 art called Jordan. And if the rat studies were the
13 equivalent of the Jordan prior art in terms of what
14 they disclosed, he was saying that if you accept that
15 the rat studies is the sound basis, then the Jordan
16 renders it obvious, but he didn't think that Jordan
17 did render it obvious, he didn't think that the rat
18 studies did give a sound prediction, and one that
19 would have been the Hong Kong study that was not
20 included, and he said that, as a result, what Eli
21 Lilly was giving the public was no more than Jordan,
22 a piece of prior art, and therefore it was not living
23 up to its bargain of advancing the art.
24 MR. DEARDEN: So your answer to my
25 question why would Justice Hughes' decision be

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1 somewhat controversial is because, when you first
2 read it, you wonder how he arrived at it?
3 MR. DIMOCK: That's how I use
4 "controversial." Maybe it would have been better if
5 I used a different wording, but it's not the easiest
6 decision to understand really until you break it down
7 like I did after some study, that he was equating the
8 rat studies to a piece of prior art.
9 Now, it did receive a lot of press, I'll
10 say that.
11 MR. DEARDEN: Justice Hughes' Raloxifene
12 decision received a lot of press from the --
13 MR. DIMOCK: When I mean press --
14 THE PRESIDENT: Wait, wait. He's not
15 finished with the question.
16 MR. DEARDEN: I think I know what you
17 meant. I didn't expect it to be on the front page of
18 the Globe and Mail, right? You're talking about
19 within the Patent Bar, that decision received a lot
20 of commentary.
21 MR. DIMOCK: I don't know whether it
22 immediately received written commentary. There may
23 have been blogs about it, but I don't read blogs.
24 But certainly there was discussion amongst patent
25 lawyers about that decision, yes.

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1 MR. DEARDEN: You said it did receive a
2 lot of press.
3 MR. DIMOCK: And I was about to explain
4 that, and I interrupted you --
5 MR. DEARDEN: Go ahead.
6 MR. DIMOCK: What I meant by press, I
7 don't mean printed publications, I meant discussion,
8 really. Probably internal discussions in firms and
9 among lawyers.
10 MR. DEARDEN: And was the discussion
11 amongst other things because Lilly had a factual
12 basis, they had a sound line of reason, and they
13 couldn't use it?
14 MR. DIMOCK: No. No.
15 MR. DEARDEN: Okay. What was it?
16 MR. DIMOCK: It was the -- what I found
17 is understanding the decision, which only became
18 clear once I appreciated that what Justice Hughes was
19 doing was equating the rat studies to this Jordan
20 piece of prior art, and that as a result it was
21 either invalid for being obvious or there was no
22 sound prediction because you weren't giving anything
23 more than the Jordan piece of prior art. That's
24 where you have to read it closely to come away with
25 that understanding.

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1 MR. DEARDEN: I'm still on the "lot of
2 press." You're not serious in saying understanding
3 the decision received a lot of press?
4 MR. DIMOCK: No.
5 MR. DEARDEN: Surely you'll admit,
6 Mr. Dimock, that some of that press, as you refer to
7 it, would have been that Lilly proved it but they
8 couldn't use it because the Hong Kong study wasn't in
9 the patent. Can you give me that much?
10 MR. DIMOCK: I don't want to debate with
11 you. I'm here to answer your questions. The press,
12 as I referred to it, was that Justice Hughes had
13 invalidated the patent with a thorough review of the
14 law that he inferred from Justice Binnie's decision,
15 and was able to come to the conclusion that, despite
16 the fact that the Eli Lilly had based the sound
17 prediction on the rat studies, the rat studies were
18 no better than the piece of prior art, so as I
19 said -- and I don't want to repeat myself but I will
20 to conclude it -- it's either invalid for being
21 obvious or invalid for not having a sound line of
22 reasoning for a prediction of utility.
23 MR. DEARDEN: Eli Lilly didn't base their
24 prediction on the rat studies. Justice Hughes made
25 them be restricted to the rat studies because they

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1 were in the patent, and wouldn't let them use the
2 evidence outside the patent, which was the Hong Kong
3 study, correct?
4 MR. DIMOCK: That's right because, as I
5 understood it, your claims have to be based on your
6 disclosure, and if you don't have it in your
7 disclosure you can't say it's fairly based on
8 something that's not there.
9 MR. DEARDEN: Do you have to disclose
10 evidence in the patent to show that the patent is
11 non-obvious?
12 MR. DIMOCK: No.
13 MR. DEARDEN: Let's go to Raloxifene.
14 It's at tab 4, justice Hughes' decision, c-115,
15 paragraph 163. So Justice Hughes in prior paragraphs
16 has dealt with the tripartite test in AZT, which
17 you'll find at paragraph 160, and he gets to the
18 third criteria of that test in paragraph 163. Do you
19 have that?
20 MR. DIMOCK: I have it. That's page 469
21 of the report.
22 MR. DEARDEN: Yes. Paragraph 163. "The
23 third criteria however is that of disclosure. It is
24 clear that the '356 patent does not disclose the
25 study described in the Hong Kong abstract. The

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1 patent does not disclose any more than Jordan did.
2 The person skilled in the art was given, by way of
3 disclosure, no more than such person already had. No
4 'hard coinage' has been paid for the claimed
5 monopoly. Thus, for lack of disclosure, there was no
6 sound prediction.
7 Eli Lilly argues that there is no need
8 for such disclosure. First, it argues that the Hong
9 Kong abstract was already public by the time the
10 Canadian filing was made and that was sufficient
11 disclosure to satisfy the third element of the AZT
12 requirements. I disagree. A considered reading of
13 paragraph 70 of the AZT decision leads to the
14 conclusion that the disclosure must be in the patent,
15 not elsewhere. The public should not be left to
16 scour the world's publications in the hope of finding
17 something more to supplement or complete a patent
18 disclosure. As the Supreme Court said at paragraph
19 70, the *quid pro quo* offered in exchange for the
20 monopoly is disclosure. It must be in the patent."
21 Mr. Dimock, I don't recollect seeing any
22 case prior to this decision of Justice Hughes in 2008
23 that required a patentee to disclose the factual
24 basis and line of reasoning for sound prediction of
25 utility in the patent. Do you recall any between AZT

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1 in 2002 and this decision in 2008?
2 MR. DIMOCK: Oh, between 2002 and 2008,
3 as far as I know, there were no cases on point. I
4 stand to be corrected, but I don't recall any.
5 MR. DEARDEN: Paragraph 138 of your First
6 Report.
7 MR. DIMOCK: I have it, yes.
8 MR. DEARDEN: You say, "Likewise,
9 Professor Siebrasse's statement that the 'heightened
10 disclosure requirement for utility based on sound
11 prediction was introduced by the trial courts in
12 2008' based on 'the third part of the test for sound
13 prediction set out by the Supreme Court in
14 Wellcome/AZT' is simply contrary to my understanding
15 and experience in litigation and reading patent
16 cases."
17 Are you agreeing or disagreeing that the
18 Raloxifene decision imposed a heightened disclosure
19 requirement in sound prediction cases?
20 MR. DIMOCK: It was the use of the words
21 "heightened disclosure requirement," and I think I
22 described what I understood that to mean. It goes
23 beyond just saying how to make the invention. It's
24 the proper disclosure of a factual basis and a line
25 of reasoning, and I took that from Monsanto, and I

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1 had a case in the 1980s Cabot v a numbered company on
2 an earplug where we did discuss Monsanto and the line
3 and the sound prediction, but as far as I can recall
4 there were no sound prediction cases in that period.
5 MR. DEARDEN: Let's go to the Federal
6 Court of Appeal decision of Raloxifene, which you'll
7 find at tab 35, C-119, paragraph 14, Mr. Dimock. The
8 Federal Court of Appeal decision in Raloxifene.
9 MR. DIMOCK: I have that.
10 MR. DEARDEN: The court holds "The
11 decision of the Supreme Court in AZT is particularly
12 significant to the disposition" --
13 MR. DIMOCK: I'm sorry, hold --
14 MR. DEARDEN: Paragraph 14.
15 MR. DIMOCK: On page 6?
16 MR. DEARDEN: Page 6, yes. Do we have
17 the same copy of the case?
18 MR. DIMOCK: Behind tab 5 at page 6,
19 paragraph 14, "The decision of the Supreme Court in
20 AZT"?
21 MR. DEARDEN: Yes.
22 MR. DIMOCK: I'm there.
23 MR. DEARDEN: I'll start over.
24 Paragraph 14, "The decision of the
25 Supreme Court in AZT is particularly significant to

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1 the disposition of this appeal. According to AZT,
2 the requirements of sound prediction are three-fold:
3 There must be a factual basis for the prediction; the
4 inventor must have at the date of the patent
5 application an articulable and sound line of
6 reasoning from which the derived result can be
7 inferred from the factual basis; and third, there
8 must be proper disclosure." (citing paragraph 70 of
9 AZT).
10 "As was said in that case: 'the sound
11 prediction is to some extent the *quid pro quo* the
12 applicant offers in exchange for the patent
13 monopoly'. In sound prediction cases there is a
14 heightened obligation to disclose the underlying
15 facts and the line of reasoning for inventions that
16 comprise the prediction."
17 Paragraph 15. "In my respectful view,
18 the Federal Court judge proceeded on proper principle
19 when he held, relying on AZT, that when a patent is
20 based on a sound prediction, the disclosure must
21 include the prediction. As the prediction was made
22 sound by the Hong Kong study, this study had to be
23 disclosed."
24 Firstly, Mr. Dimock, you don't take issue
25 with the Court of Appeal saying that Justice Hughes

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1 relied on AZT in making the decision that he made?
 2 MR. DIMOCK: I don't take issue with
 3 that.
 4 MR. DEARDEN: And this is the first
 5 Federal Court of Appeal decision to decide that in
 6 sound prediction of utility cases there is a
 7 heightened obligation to disclose the underlying
 8 facts and the line of reasoning for the invention
 9 that comprises the prediction?
 10 MR. DIMOCK: That is the first Federal
 11 Court of Appeal case after AZT, yes.
 12 MR. DEARDEN: Mr. Dimock, there were some
 13 unresolved legal issues that arose, or legal issues
 14 that arose after AZT was decided that was the subject
 15 of a number of Federal Court cases as to what that
 16 paragraph 70 and the third component meant. One of
 17 those issues, sir, was what's the cut-off date for
 18 the evidence of the factual basis and the line of
 19 reasoning for the prediction.
 20 So what application are we talking about?
 21 Are we talking a priority date application or the
 22 subsequent Canadian filing date application, right?
 23 That was an issue that had to be resolved.
 24 MR. DIMOCK: There was -- as I recall,
 25 there was a case or two on that, yes.

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

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1 applies to all patents. 2-2. Unresolved, right?
 2 MR. DIMOCK: You've cited the cases that
 3 are on point, yes.
 4 MR. DEARDEN: And that's unresolved
 5 today. We have Justice Zinn issuing a decision just
 6 a couple of months ago siding with Justice Barnes
 7 that the disclosure requirements applies to all
 8 patents, not just new use patents.
 9 MR. DIMOCK: And with that I agree.
 10 MR. DEARDEN: Okay. So let's go to the
 11 cut-off date cases --
 12 MR. DIMOCK: I mean I agree with
 13 Justice Zinn and Justice Barnes but, anyway, that's
 14 what I said when I agreed. Not with what you just
 15 said, but I agree with them.
 16 MR. DEARDEN: I thought we were coming to
 17 common ground!
 18 MR. DIMOCK: Well, my goal -- or my job
 19 is to answer your questions, and when your questions
 20 are fair, I agree with you. When I think that
 21 they're not, I will not agree.
 22 MR. DEARDEN: I was just joking, by the
 23 way.
 24 MR. DIMOCK: I know. But I'm not.
 25 MR. DEARDEN: So, cut-off date. Is it

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1 the priority date or the Canadian filing date?
 2 Obviously if it's the Canadian filing date you can
 3 rely on more evidence for your factual basis because
 4 you get typically -- what, an extra year of possible
 5 evidence?
 6 MR. DIMOCK: If you file firstly in
 7 another country such as the one we're in today --
 8 MR. DEARDEN: U.S.
 9 MR. DIMOCK: -- under the
 10 Patent Cooperation Treaty you have a year within
 11 which to file in Canada.
 12 MR. DEARDEN: Right. So that's a pretty
 13 significant issue, isn't it, to get the extra year of
 14 possible evidence that you could say you had the
 15 factual basis.
 16 MR. DIMOCK: If your disclosure that you
 17 file in Canada a year later is the same disclosure,
 18 it makes no difference.
 19 MR. DEARDEN: Right. I'm saying if you
 20 had the evidence in that time period, you don't get
 21 knocked out because it's a priority date, and it's
 22 something happening in between priority dates --
 23 MR. DIMOCK: I don't know then you could
 24 rely on the priority if you've added to your Canadian
 25 application.

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

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

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1 MR. DEARDEN: Now, this decision is a
2 2005 decision. So three years after AZT, three years
3 before Justice Hughes' decision. And
4 Justice Mactavish in this ramipril decision here at
5 tab 5, Exhibit C-209, she didn't require the factual
6 basis and line of reasoning for the sound prediction
7 to be in the patent, did she?
8 MR. DIMOCK: I'm sorry, you referred me
9 to --
10 MR. DEARDEN: It's okay. I'll repeat.
11 2005 decision, right, this --
12 MR. DIMOCK: The Justice Mactavish
13 decision is 2005, yes.
14 MR. DEARDEN: We call it ramipril. It's
15 fair for me to say that in this decision, three years
16 after AZT, three years before Justice Hughes'
17 decision in Raloxifene, that Justice Mactavish did
18 not require the factual basis and line of reasoning
19 for sound prediction to be in the patent.
20 MR. DIMOCK: I don't know where you draw
21 that.
22 MR. DEARDEN: Well, I don't see it. Do
23 you see it? Do you see her making that finding in
24 this decision, sir?
25 MR. DIMOCK: I thought that she was just

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

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1 MR. DEARDEN: Well, what is today's
2 section number for subsection 34(1) of the old
3 Patent Act? It's 27(3), right?
4 MR. DIMOCK: Yes.
5 MR. DEARDEN: And that's what she says
6 she's --
7 MR. DIMOCK: Are you referring to --
8 THE PRESIDENT: Wait.
9 MR. DIMOCK: Sorry. I apologize. I was
10 just responding to your -- you say 34 is now 27. I
11 remember it as section 36, so even before that.
12 MR. DEARDEN: In paragraph 163
13 Justice Mactavish says she will return to the
14 question in relation to her analysis of the
15 sufficiency issue under subsection 34(1), which today
16 is subsection 27(3). Correct?
17 MR. DIMOCK: That's my understanding.
18 MR. DEARDEN: And that's disclosure about
19 how to make and use the invention.
20 MR. DIMOCK: Yes.
21 MR. DEARDEN: Right. Nowhere in this
22 decision, which is dealing with sound prediction, is
23 there any analysis of whether the factual basis is in
24 the patent, has been disclosed in the patent.
25 Correct? Is that fair?

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1 MR. DIMOCK: I must be missing, or
2 misunderstanding your question. As I understood the
3 case -- and I haven't read this one for a long
4 time -- what she was asked here is what is the date
5 to be used. Is it the priority date or the Canadian
6 filing date. And all that you read to me, as
7 I understand it, was her conclusion that it was the
8 Canadian filing date, not the priority date. But I'd
9 have to read the whole case to put it in proper
10 context, I'm sorry.
11 MR. DEARDEN: Well, we all can read it,
12 too, so we'll deal with that in argument.
13 MR. DIMOCK: Sure.
14 MR. DEARDEN: Now, this decision gets
15 appealed to the Court of Appeal at tab 7 of your
16 second volume. At paragraph 30 Chief Justice
17 Richard, who is a master of brevity --
18 MR. DIMOCK: He was your partner.
19 MR. DEARDEN: He sure was. He was my
20 man.
21 He says, "I'm in agreement with
22 Justice Mactavish that the relevant date is the
23 Canadian filing date, in this case October 20, 1981.
24 It is the time which is most reasonable in achieving
25 consistency in the application of the three

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1 components of the Wellcome test."
2 So that's the first Court of Appeal
3 decision to decide that the relevant date is the
4 Canadian filing date?
5 MR. DIMOCK: That's right.
6 MR. DEARDEN: And then at tab 8 of your
7 volume 2 you have Exhibit C-250, which is the
8 decision of Justice Heneghan in Pfizer v Minister of
9 Health, the quinapril case. To go through this very
10 quickly, if you turn up paragraphs 77 and 78, this
11 also was a 2005 decision, Justice Heneghan in
12 paragraph 77 says: "As a preliminary matter, the
13 parties dispute the date of the invention for the
14 '330 Patent. Pfizer argues the date is June 18,
15 1980; Apotex submits the relevant date is October 3,
16 1980, that is the priority date. In this regard,
17 Apotex argues that as of June 18, 1980, the inventors
18 had only 'conceived' of a single member of the
19 purported invented class of compounds, had no basis
20 to extrapolate different stereoisomers to various
21 classes of compounds and to bulky compounds, and were
22 unable to predict antihypertensive properties of the
23 claimed compounds.
24 78. In my opinion, these arguments are
25 sound. I note that the inventors themselves referred

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1 to June 18, 1980 as the date on which they
2 'conceived' of an idea that would 'probably' be
3 useful as an ACE inhibitor. I'm not persuaded that a
4 'conceived' idea is synonymous with an invention. I
5 conclude that the appropriate date for the date of
6 invention is October 3, 1980, the priority date of
7 the '330 patent."
8 That got appealed in the next tab, and
9 Justice Heneghan was overturned. If you go to tab 9,
10 C-250, paragraph 153, a decision of Justice Nadon.
11 Do you have that?
12 MR. DIMOCK: Page 58?
13 MR. DEARDEN: Yes. The Court of Appeal
14 says "In any event, Pfizer points, correctly in my
15 view, to this Court's recent decision in Aventis v
16 Apotex [which is ramipril which we just looked at]
17 which held that the relevant date for assessing the
18 soundness of a prediction was the Canadian filing
19 date, in this case September 30, 1981. Contrary to
20 Apotex's notice of allegation and to Justice
21 Heneghan's finding, the relevant date is not the
22 priority date which, in this case, is October 3,
23 1980. Further, in its notice of allegation... Apotex
24 refers to testing of quinapril that showed the
25 compound reduced blood pressure in rats. The results

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1 of those tests were received on December 8, 1980 well
2 before the Canadian filing date. Accordingly, even
3 if some testing were required to establish a sound
4 prediction, such testing was conducted in this case."
5 So the cut-off date, Canadian filing
6 date, right?
7 MR. DIMOCK: That's what this Court of
8 Appeal said, yes.
9 MR. DEARDEN: And the Court of Appeal
10 also relied on these rat tests that were received
11 after the priority date but before the Canadian
12 filing date, right. See that?
13 MR. DIMOCK: Yes, I see the reference to
14 the rat tests.
15 MR. DEARDEN: And those tests come in
16 between the priority date and the Canadian filing
17 date, right?
18 MR. DIMOCK: That would appear to be the
19 case.
20 MR. DEARDEN: Were they in the Canadian
21 patent that was filed September 30, 1981?
22 MR. DIMOCK: I don't recall that they
23 were. However -- and I don't know that you can rely
24 on them unless they were in the Canadian filing
25 application -- unless they were in the Canadian

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1 application as filed on the Canadian filing date.
2 MR. DEARDEN: You haven't reviewed the
3 patent 1,341,330 to see if those rat studies tests
4 that were done after the priority date were actually
5 put in the Canadian --
6 MR. DIMOCK: I have not.
7 MR. DEARDEN: You haven't. And is it
8 fair to say they weren't in the Canadian patent as
9 filed?
10 MR. DIMOCK: That would be my -- if they
11 were trying to rely on the priority date, then that
12 would be added matter, and you'd have some debate as
13 to whether or not you could rely on the priority
14 date. So my inference from what you've told me is
15 that they were likely not in the Canadian patent as
16 filed but, as I said on a few occasions where I don't
17 know for certain, I stand to be corrected.
18 MR. DEARDEN: Can we go to the Supreme
19 Court of Canada's decision in Pfizer sildenafil,
20 which is the Viagra decision at tab 14. I just
21 wanted to finish off the loop on heightened or
22 enhanced disclosure before. Volume 3, tab 14,
23 Exhibit C-197, Supreme Court of Canada decision from
24 2012.
25 MR. DIMOCK: I have that.

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1 MR. DEARDEN: Do I have you at paragraph
2 36? I didn't give you a paragraph, did I?
3 MR. DIMOCK: You did not, but I have now
4 just turned up paragraph 36 on page 640.
5 MR. DEARDEN: Correct. That's the sound
6 prediction part of this judgment, and in paragraph 37
7 Justice LeBel holds "For a patent to be valid, the
8 invention it purports to protect must be useful.
9 This requirement of utility comes from the definition
10 of 'invention' in section 2 of the Act, which
11 requires that the purported invention be 'new and
12 useful'. Sound prediction is a concept that becomes
13 relevant only when an invention's utility cannot
14 actually be demonstrated by way of tests or
15 experiments, but can nevertheless be successfully
16 predicted." And he cites AZT. "The lack of
17 certainty that comes from predicting rather than
18 demonstrating an invention's utility has led some
19 courts to conclude that there is a 'heightened' or
20 'enhanced' disclosure requirement in cases in which a
21 claim of utility is based on sound prediction: See
22 Eli Lilly v Apotex", which is the Raloxifene case,
23 right?
24 MR. DIMOCK: Yes.
25 MR. DEARDEN: "Teva submits that this

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1 heightened requirement was not met in this case", and
2 at paragraph 38, at the bottom, that last sentence of
3 that paragraph, Justice LeBel holds "The fact that
4 Pfizer did not disclose that the tested compound was
5 sildenafil goes to the issue of disclosure of the
6 invention, not to that of disclosure of the
7 invention's utility."
8 MR. DIMOCK: Yes, that's what
9 Justice LeBel said and concluded.
10 MR. DEARDEN: Then in paragraph 39
11 Justice LeBel says "That the invention must be useful
12 as of the date of claim or as of the time of filing
13 is consistent with this Court's comments in AZT" and
14 he reproduces Justice Binnie's paragraph 56 that
15 utility required for section 2 must, as of the
16 priority date, either be demonstrated or be a sound
17 prediction.
18 In paragraph 40, "Nothing in this passage
19 should suggest that utility is a disclosure
20 requirement; all it says is that 'the utility
21 required for patentability must, as of the priority
22 date, either be demonstrated or be a sound
23 prediction'. Utility can be demonstrated by, for
24 example, conducting tests, but this does not mean
25 that there is a separate requirement for the

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1 disclosure of utility. In fact, there is no
2 requirement whatsoever in 27(3) to disclose the
3 utility of the invention." Citing Consolboard at
4 page 521 and Justice Dickson: "I am further of the
5 opinion that 36(1) [now 27(3)] does not impose upon a
6 patentee the obligation of establishing the utility
7 of the invention."
8 Paragraph 41. "In any event, Pfizer
9 disclosed the utility of sildenafil by disclosing the
10 tests had been conducted. Sildenafil was found to be
11 useful before the priority date, which means the
12 requirement in AZT is met. Further, 'evidence as to
13 utility may be found in the reception of the
14 invention by the public. Enthusiastic reception by
15 those to whom it is directed will tend to indicate
16 that the invention is useful'.
17 So Justice LeBel has stated in paragraph
18 41 that commercial success can be considered as
19 evidence of utility. Agree?
20 MR. DIMOCK: There's no doubt about that,
21 Mr. Dearden, that one way of disproving utility is to
22 show that the patent doesn't work, and one way of
23 showing that it has utility -- in certain
24 circumstances where I'm talking about operability,
25 then you can rely on the success of the invention so

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1 long as it's embodied in a commercially successful
2 product.
3 MR. DEARDEN: There's no distinction like
4 you make in your report, sir, in what Justice LeBel
5 says in paragraph 41. Would you agree with that?
6 MR. DIMOCK: I took these paragraphs of
7 Justice LeBel to be obiter dicta because he said
8 "since sound prediction is not an issue the question
9 of whether there is enhanced or heightened disclosure
10 requirement with respect to sound prediction does not
11 arise in this case and need not be addressed. I will
12 now turn to the issue at the heart of this appeal
13 whether patent '446 meets the requirements of section
14 27(3) of the Act."
15 So I don't believe that Justice LeBel was
16 attempting to state the law in the last couple of
17 paragraphs you read to me. He was certainly reciting
18 the law that he understood, generally speaking, but I
19 don't think you can take what he said here as the law
20 as enunciated by the Supreme Court of Canada because
21 it was an obiter.
22 MR. DEARDEN: Mr. President, would this
23 be an appropriate time to take a break?
24 THE PRESIDENT: Yes, a 15-minute break.
25 Mr. Dimock, you know what it means. You are under

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1 testimony.
2 MR. DIMOCK: Yes.
3 *(Recess taken)*
4 THE PRESIDENT: We resume the hearing.
5 Mr. Dimock, can you bear with us for a moment,
6 because the parties have agreed on scheduling for the
7 remaining days of the hearing.
8 Ms. Cheek, could you talk on behalf of
9 both parties? Because we've already discussed it
10 outside.
11 MS. CHEEK: Yes. The parties have agreed
12 that we will adjourn for both Saturday and Sunday.
13 We anticipate completing witness testimony on Monday.
14 The expectation is that the Tribunal will get us
15 their questions at the end of the day on Monday, if
16 other questions don't come before. We would adjourn
17 on Tuesday, and then we will do our closing arguments
18 on Wednesday.
19 THE PRESIDENT: Mr. Spelliscy?
20 MR. SPELLISCY: Yes. This is the
21 agreement.
22 THE PRESIDENT: Your proposal for the
23 parties still factors in the possibility that the
24 Tribunal may ask questions of the experts?
25 MS. CHEEK: It does, and we're prepared

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1 to alter the schedule if needed to ensure the
2 Tribunal's questions are answered, so we in no way
3 wish to rush the process.
4 THE PRESIDENT: Thank you. Mr. Dearden,
5 please continue the cross-examination.
6 MR. DEARDEN: Thank you, Mr. President:
7 Mr. Dimock, your second report,
8 paragraph 95.
9 MR. DIMOCK: I have that.
10 MR. DEARDEN: You say in paragraph 94 --
11 actually go to 95: "Here the Court cited a number of
12 the cases I referenced at paragraphs 92-95 of my
13 First Report, as well as others, in which judges were
14 asked to consider when an invention has been made.
15 Repeatedly, they emphasized that an invention was not
16 reduced to a definite and practical shape (i.e. was
17 not made) if its utility had not been established."
18 In paragraph 96 you say, "This arose in
19 the case of Control Data v Senstar, in which I was
20 trial counsel for Control Data. In its judgment, the
21 Court explained that to make an invention, the
22 inventor had to have done enough work to establish
23 utility or 'the workability of the invention'.
24 And you have a quote which I'll read into
25 the record from Control Data, paragraph 137. "...an

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1 apparatus or device is reduced to practice when it is
2 assembled, adjusted and used. It can be an
3 experiment; it need not be a commercial use, ...[and
4 that] reduction to practice is the testing of the
5 invention to demonstrate utility but not mechanical
6 perfection. The operative means must merely
7 accomplish the desired result. Improvements obvious
8 to the skilled workman to increase its practical
9 efficiency or perfect its operation may still be made
10 to an invention already reduced to practice. Thus,
11 commercial feasibility is not necessarily relevant to
12 the question of 'reduction to practice' so long as
13 the experimental equipment proves the workability of
14 the invention. It does not have to be mechanically
15 perfect."
16 Can you turn to the decision, Mr. Dimock,
17 at tab 23, which is volume 4 of your binders
18 Exhibit R-364, paragraph 137. Do you have paragraph
19 137, sir?
20 MR. DIMOCK: I do.
21 MR. DEARDEN: Your paragraph 96 quoted
22 from paragraph 137 stopped at "mechanically perfect,"
23 but there's more to that paragraph. The additional
24 part of that paragraph reads, "Further, I quote from
25 Euth...: 'It follows that actual reduction to

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1 practice is not the only competent evidence of
2 perfection and adaptation to use, but the inventor's
3 act in filing an allowable application is to be
4 regarded in law as such an efficient and crowning
5 step as to give it the standing of an invention so
6 perfected and adapted'.
7 So the crowning step is the act of filing
8 an allowable application, correct?
9 MR. DIMOCK: That is the crowning step.
10 I should say, Mr. Dearden, that in that case
11 Justice Cullen was asked to decide whether the
12 invention was reduced to practice -- that's an
13 American term -- and he said that he understood the
14 difference to be between our reduction to a definite
15 and practical shape and reduction to practice in the
16 United States is that in the United States it has to
17 be a diligent reduction to practice, but according to
18 that U.S. case the crowning step was the filing, yes.
19 MR. DEARDEN: And the court adopted that,
20 right?
21 MR. DIMOCK: The court cited from that,
22 yes.
23 MR. DEARDEN: Can you turn to
24 paragraph 106 of your First Report, which should be
25 referencing Ciba-Geigy?

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1 MR. DIMOCK: I'm at page 30?
2 MR. DEARDEN: Yes. So paragraph 106 of
3 your First Report says: "The only case that I'm
4 aware of that may be construed as relying on
5 post-filing evidence in support of demonstrating or
6 soundly predicting utility at the time of filing is
7 the Ciba-Geigy v Commissioner of Patents case, a
8 decision cited by Professor Siebrasse. Notably, and
9 as mentioned in his report, the Patent Office refused
10 to consider post-filing evidence when an objection
11 arose concerning the soundness of the predicted
12 utility, and rejected the application. The decision
13 of the Patent Office was later overturned by the
14 Federal Court of Appeal."
15 Ciba-Geigy is at tab 24, Exhibit C-44,
16 volume 4 of the binder.
17 MR. DIMOCK: I have it.
18 MR. DEARDEN: Can you go to page 75, tab
19 24? At the top of the page, the Federal Court of
20 Appeal, Chief Justice Thurlow, says "There is no
21 longer any issue as to the size of the class of the
22 amines or as to the utility claimed for them. Nor is
23 there any issue as to the first or second of the
24 processes claimed. What was considered objectionable
25 about the others by the Patent Appeal Board was that

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1 they were speculative and had not been invented at
2 the time when the application for patent was filed."
3 Then he has a long quote from the Board,
4 and I'm going down to the bottom of the page, second
5 to last paragraph, "Recognizing the insufficiency of
6 the disclosure, the applicant, on October 23, 1972,
7 submitted five new examples illustrating five of the
8 six missing processes. We do not believe, however,
9 that the applicant should be permitted to retain
10 claims on the basis of something done after the
11 event, and not part of the original disclosure."
12 So the Patent Appeal Board holds, on that
13 basis, "we consider the examiner's objection was
14 justified" with respect to the claims that they say
15 there.
16 If you turn the page to page 76, the
17 second paragraph, "On the appeal what was before the
18 court consisted only of the Patent Office file,
19 including the application, specification,
20 correspondence between the examiner and the
21 applicant, amendments, representations and the
22 decisions of the Patent Appeal Board and the
23 commissioner. Also included were descriptions of the
24 five examples of the carrying out of the processes
25 (c) to (g) inclusive which had been submitted to the

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<p>1 examiner for his information in the hope of 2 persuading him that the processes were not mere 3 speculation but would, in fact, work and which are 4 referred to in the foregoing excerpts from the 5 board's reasons." 6 At the bottom of that page the Chief 7 Justice holds, "In this context the use by the author 8 of the word 'possible' does not appear to me to 9 support the view that what was being asserted was 10 speculation. But even assuming that the reactions or 11 methods identified as (c) to (g) inclusive had not in 12 fact been carried out or tested before the 13 application was filed, the board appears to have been 14 satisfied by the examples subsequently submitted and 15 to have found that the amines referred to in the 16 specification can, in fact, be produced by the 17 application of the methods to materials of the kinds 18 defined. It seems to me to follow that if indeed 19 what is in the patent specification was mere 20 speculation or prediction, the speculation or 21 prediction having turned out to be true, ought to be 22 considered to have been well founded at the time it 23 was made. Even at the time it was made it's not 24 improbable that it would have been considered well 25 founded."</p> <p style="text-align: center;">www.dianaburden.com</p>	<p>1140 03:38</p>	<p>1 And if you go over to page 78, the second 2 paragraph or the first full paragraph, "What remains 3 is the question whether the position taken by the 4 Board that the applicant should not be permitted to 5 retain claims on the basis of something done after 6 the filing of the application and not part of the 7 original disclosure should be upheld. In effect, 8 this objection is that the subject-matter of process 9 claims (c) to (g) had not yet been invented when the 10 application was filed. This objection, as well, 11 appears to me to be met by the decision of Pigeon J 12 in the Monsanto case. There, after discussing the 13 decision of Justice Graham in Olin Mathieson, and the 14 limits within which a patent claim embraced untested 15 substances may be valid, Pigeon J held" and he quotes 16 from that decision, and over to paragraph 79: 17 "In the present case the question of the 18 soundness of the prediction having been put to rest, 19 the only question left is the first, that of utility 20 in respect of some area covered. As to this there 21 is, in my view, nothing in the record which shows or 22 tends to show that the processes will not work to 23 produce the amines which are said to have the novel 24 pharmacological usefulness referred to earlier in 25 these reasons, a matter as to which no reason is</p> <p style="text-align: center;">www.dianaburden.com</p>	<p>1141 03:39</p>
<p>1 raised." 2 In conclusion, we see on page 80, the 3 Chief Justice says "On the material in the record I 4 am of the opinion that the commissioner's conclusion 5 that the process claims in question should be 6 rejected based as it is on the reasons of the 7 Patent Appeal Board is not sustainable in law and 8 should not be allowed to stand. I would allow the 9 appeal, set aside the decision and refer the matter 10 back to the Commissioner of Patents to proceed with 11 the appellant's application '368 on the basis that 12 the claims for the processes identified at (c), (d), 13 (e), (f) and (g) and for the new amines described in 14 the specification, when produced by said processes, 15 are not open to objection or rejection on the grounds 16 that the processes are speculative or that they had 17 not been carried out prior to the filing of the 18 appellant's application for a patent." 19 So the Federal Court of Appeal in 20 Ciba-Geigy upheld the claims on the basis of sound 21 prediction, Mr. Dimock? 22 MR. DIMOCK: They did. 23 MR. DEARDEN: And post-filing evidence of 24 five examples that was not in the patent and were 25 done after the application was filed was allowed?</p> <p style="text-align: center;">www.dianaburden.com</p>	<p>1142 03:41</p>	<p>1 MR. DIMOCK: The Court of Appeal did 2 refer to those five pieces to show that the 3 prediction did eventually turn out to be correct, but 4 I submit not that the prediction had been made as 5 found when it was filed, although because what 6 Justice Thurlow said at page 77 where he said even at 7 the time it was made it is not improbable that it 8 would have been considered well founded, so he made 9 the finding that without these other pieces he would 10 have considered based on the disclosure that at that 11 time the prediction was sound, that there was a 12 factual basis and a line of reasoning -- 13 MR. DEARDEN: But he point blank held, at 14 page 77, "It seems to me to follow that if indeed 15 what is in the patent specification was mere 16 speculation or prediction, the speculation or 17 prediction having turned out to be true, ought to be 18 considered to have been well founded at the time it 19 was made." 20 MR. DIMOCK: And Justice Binnie looked at 21 that and concluded that the case could not stand for 22 that but, if it did, it should not be followed. 23 MR. DEARDEN: Right. So as of 1982, 24 which is the decision of the Federal Court of Appeal, 25 Mr. Justice Binnie, not deciding until 2002, this was</p> <p style="text-align: center;">www.dianaburden.com</p>	<p>1143 03:42</p>

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1 the law, right? Ciba-Geigy was the law?
2 MR. DIMOCK: Ciba-Geigy presented a
3 difficulty in that it was Justice Thurlow who had
4 said that, based on what he had seen, having it
5 turned out to be true, was considered to have been
6 well founded at the time it was made. He was saying
7 that yes, the prediction turned out to be correct by
8 these later pieces, but he also said that even that
9 proves that the prediction was correct but it didn't,
10 in my view, and based on what he said and what
11 Justice Binnie said later, it didn't say that the
12 inventors knew that their prediction was sound and
13 had made such a sound prediction at the time of
14 filing.
15 MR. DEARDEN: Mr. Dimock, you keep going
16 back to AZT in -- what is it, back to the future?
17 AZT in 2002. I'm talking about this point in time.
18 1982. The Federal Court of Appeal said post-filing
19 evidence could be considered, correct?
20 MR. DIMOCK: Not for the purpose of
21 showing that, at the time that the application was
22 filed, that the inventors had made a sound prediction
23 based on a factual basis and a line of reasoning.
24 MR. DEARDEN: He said "It seems to me to
25 follow that if, indeed, what is in the patent

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

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1 that post-filing evidence was admitted and was
2 relevant to demonstrating that a prediction turned
3 out to be accurate.
4 MR. DIMOCK: Yes, that's right.
5 MR. BORN: But you're saying that that
6 evidence didn't itself show that there had been a
7 prediction?
8 MR. DIMOCK: That there had been a
9 prediction that was soundly based at the time the
10 application was filed, that's right. You have to
11 look at the disclosure and, as Justice Thurlow said,
12 in that next line, even at the time it was made it is
13 not improbable that it would have been considered
14 well founded. So what Justice Thurlow was saying,
15 put those pieces aside, that the prediction that was
16 made at the time of filing was soundly based, and it
17 was properly disclosed, that the subsequent -- and I
18 say from that, then the subsequent proof of the
19 success of the prediction was just to show that yes,
20 indeed, the prediction had been right.
21 MR. BORN: In your view, is that a
22 relevant issue, then? Are you saying the only real
23 question here is whether, at the time that it was
24 made, the prediction was soundly based, ergo, the
25 fact that it turned out to be right subsequently is

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

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1 inventor had made the invention claimed or whether,
2 on the contrary at that time the processes (as
3 distinct from the products) were speculative."
4 Then they deal with the fact that five
5 new examples, as you see at the bottom, were provided
6 by the applicants of post-filing evidence, not in the
7 patent itself, that illustrated that they worked and
8 that was accepted. The Board got overturned,
9 correct?
10 MR. DIMOCK: That's what it says, that's
11 right. It's the logic of it, Mr. Dearden, that I
12 quarrel with and what Justice Binnie had said in his
13 report, but I've already made my point.
14 MR. DEARDEN: Can we go to the Federal
15 Court of Appeal decision in AZT, which is at tab 25
16 of the same volume, Exhibit C-117, paragraph 50.
17 MR. DIMOCK: Paragraph 50 at page?
18 MR. DEARDEN: 83. This is the decision
19 that got appealed to Justice Binnie in the AZT 2002
20 decision. Start with paragraph 50.
21 "In my view, this Court's decision in
22 Ciba-Geigy stands for the proposition that even where
23 an invention constitutes a speculation as of the
24 priority date claimed in the patent, the patent will
25 not be invalid if it turns out that the speculation

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1 is valid at the time the patent is attacked." And
2 that means at trial, right?
3 MR. DIMOCK: That's right.
4 MR. DEARDEN: "In Ciba-Geigy, this Court
5 held that 'if indeed what is in the patent
6 speculation was mere speculation or prediction, the
7 speculation or prediction having turned out to be
8 true, ought to be considered to have been well
9 founded at the time it was made'. Similarly, in
10 Ciba-Geigy, this Court rejected the proposition that
11 a patent applicant 'should not be permitted to retain
12 claims on the basis of something done after the
13 filing of the application and not part of the
14 original disclosure'.
15 51. "In other words, so long as the
16 inventor can demonstrate utility or a sound
17 prediction at the time a patent is attacked" -- and
18 again, Mr. Dimock, that's at trial, right?
19 MR. DIMOCK: Yes.
20 MR. DEARDEN: -- "the patent will not
21 fail for lack of utility. The time at which
22 usefulness is to be established is when required by
23 the Commissioner of Patents or in court proceedings
24 when the validity of the patent is challenged on that
25 ground. The Commissioner may require a patent's

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1 utility to be demonstrated pursuant to section 38 of
2 the Act, which permits the Commissioner to require an
3 applicant to 'furnish specimens of the ingredients
4 [of a composition of matter], and of the composition,
5 sufficient in quantity for the purpose of
6 experiment'.
7 52. "To conclude that the evidence of
8 actual utility subsequent to a patent's priority date
9 may not be introduced to demonstrate that an
10 invention meets the requirements of the Patent Act
11 would produce illogical results. For instance,
12 suppose that on December 10, 1903, Wilbur and Orville
13 Wright obtained a patent for an airplane, and that by
14 that date, neither brother had successfully flown the
15 plane or could be said to have a 'sound prediction'
16 that a machine heavier than air could fly. Suppose
17 further that one week later, the Wright brothers
18 managed to successfully fly their plane. If the
19 Wright brothers' patent was later attacked, and if
20 uncontradicted expert testimony was provided by the
21 attackers to demonstrate that by December 10, 1903,
22 machines heavier than air could not fly, would their
23 patent be invalid even though all would concede that
24 by the time the attack was brought, such machines
25 could fly? In my view, to so conclude would require

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1 the Court to close its eyes to continuing scientific
2 advancements, and would disentitle patentees to rely
3 on the instinctive sparks that so often engender
4 great discoveries. In Dr. Rideout's words, one of
5 the co-inventors of AZT, combinations of 'instinct
6 and intuition [and] gut reaction' supported by actual
7 evidence of utility at the time the patent is
8 attacked, would not be sufficient to support a
9 patent.
10 53. The decisions cited by A&N in
11 support of the proposition that all pharmaceuticals
12 must invariably be tested on living human beings
13 prior to the priority date claimed in a patent are
14 not applicable to the instant appeal. Firstly, as
15 the trial judge held, the decisions deal with the
16 notion of 'sound prediction', a doctrine that applies
17 only to cases in which a few claimed compounds are
18 tested but many are untested even at the time when
19 the patent is attacked. Such testing requirements
20 simply do not apply where, at the time the patent is
21 attacked, there is evidence of actual utility (i.e.
22 that the pharmaceutical does what the patent
23 promises). Where such utility is demonstrated, there
24 is no need to fall back on the 'sound prediction'
25 doctrine and the experiments that are required to

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1 make such predictions. Since A&N do not dispute that
2 AZT is indeed useful to treat HIV, the '277 patent
3 meets the 'actual utility' test."
4 So 18 years after Ciba-Geigy the Federal
5 Court of Appeal again allows and upholds that
6 post-filing evidence can be relied on to establish
7 utility. Agreed?
8 MR. DIMOCK: Justice Sexton here makes
9 that point, yes.
10 MR. DEARDEN: Tell me if you agree with
11 the next point, paragraph 54. "Finally, if the Court
12 in Ciba-Geigy intended to hold that a higher standard
13 of utility is required for pharmaceutical inventions,
14 as opposed to other inventions" --
15 MR. DIMOCK: I'm sorry, where are you
16 reading?
17 MR. DEARDEN: Paragraph 54 of the AZT
18 Federal Court of Appeal decision in the year 2000.
19 "... if the court in Ciba-Geigy intended to hold that
20 a higher standard of utility is required for
21 pharmaceutical inventions, as opposed to other
22 inventions, this may be explained by the fact the
23 decision in Ciba-Geigy preceded the establishment of
24 Canada's international treaty obligations under NAFTA
25 and TRIPS. Both of these agreements, which have been

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1 incorporated into domestic law, prohibit
2 discrimination based on field of technology. Thus,
3 this Court may not hold pharmaceutical inventions to
4 a higher standard of utility than it does other
5 classes of inventions."
6 Do you take exception to that? Agree
7 with it? Neutral?
8 MR. DIMOCK: I disagreed with Justice
9 Sexton's reasoning and logic when it came out.
10 MR. DEARDEN: What, on NAFTA? That's
11 what I'm talking about.
12 MR. DIMOCK: You didn't ask me whether I
13 agree with what he had said earlier, just whether or
14 not that's what he said. It turned out that his --
15 well, that's what I was trying to say.
16 MR. DEARDEN: What I thought I asked you,
17 going back to the issue of post-filing evidence in
18 AZT that we're looking at here at tab 25, is that
19 18 years after Ciba-Geigy, the Federal Court of
20 Appeal confirmed that post-filing evidence can be
21 relied upon to establish utility, and you agreed with
22 me that that's what the decision has held.
23 MR. DIMOCK: That's what Justice Sexton
24 seemed to be saying. It's not whether I agree with
25 it but that's what he seemed to be saying. He used

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1 the example of the Orville Wright planes, and I think
2 there's some problems with that but, in any event
3 that's what he said.
4 MR. DEARDEN: Seemed to be saying,
5 Mr. Dimock, or he point blank held that?
6 MR. DIMOCK: I'm not going to quarrel
7 with you. That's what he said.
8 MR. DEARDEN: That's what he said. Okay.
9 Tab 26 should be the Cochlear v Cossem
10 decision of Joyal in 1995. Do you have that?
11 MR. DIMOCK: Yes.
12 MR. DEARDEN: Exhibit C-228.
13 MR. BORN: Actually, before you go to
14 that case, did that decision in AZT, the Court of
15 Appeal decision, surprise you?
16 MR. DIMOCK: It did, just on the logic
17 of -- well, what was said by Justice Binnie in the
18 appeal that went to the Supreme Court of Canada was
19 that what Justice Sexton and the Court of Appeal was
20 seeming to approve was that you could apply for a
21 patent on mere predictions and good hunches, and if
22 it turned out that you were right, when it was being
23 attacked, you'd have a valid patent notwithstanding.
24 That was the logic that I thought was not
25 sound when it was delivered by Justice Sexton and

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1 subsequently that logic was said to not be in
2 accordance with the Patent Act and the requirements
3 for making the sound prediction, and so it was
4 Justice Binnie's decision and the entirety of the
5 Supreme Court of Canada which said that that logic
6 should not be accepted.
7 MR. BORN: My question wasn't so much
8 directed at whether you thought the logic was sound
9 but, instead, whether you thought it was a departure
10 from what the law hitherto had been.
11 MR. DIMOCK: I see. Ciba-Geigy, I
12 thought, didn't stand for that proposition but,
13 according to Justice Sexton, he interpreted it to be
14 that way, that he --
15 MR. BORN: Just to push you a little bit
16 further if I can, did you, therefore, A, regard the
17 Court of Appeal's admission of post-filing evidence
18 as a change from prior law or, B, did you regard it
19 as consistent with prior law?
20 MR. DIMOCK: In some respects it did
21 mirror what Justice Thurlow said in Ciba-Geigy, but
22 the logic again didn't make sense, just as Justice
23 Thurlow's logic didn't make sense. Whether it was
24 simply upholding the law, I didn't take it that way.
25 I thought that he was giving reasons for making that

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1 law and I didn't find that to be sound.
2 MR. BORN: Thank you.
3 MR. DEARDEN: Before we deal with the
4 Cochlear case, can we go back to Justice Binnie's AZT
5 at tab --
6 MR. DIMOCK: Where do we find that again?
7 MR. DEARDEN: Tab 2, volume 1. C-213.
8 MR. DIMOCK: I have the case, yes.
9 MR. DEARDEN: Can you turn to paragraph
10 79?
11 MR. DIMOCK: Yes.
12 MR. DEARDEN: So Justice Binnie says "The
13 'after-the-fact' validation theory was accepted by
14 the Federal Court of Appeal at paragraph 51" -- which
15 we've just gone through, right?
16 MR. DIMOCK: Yes.
17 MR. DEARDEN: Then in paragraph 81 of
18 Justice Binnie's AZT decision, he says, "The Federal
19 Court of Appeal was concerned that patents based on
20 'instinct and intuition (and) gut reaction' might be
21 invalidated in a case where the ignorance that passed
22 at the time for 'sound prediction' turned out to be
23 wrong and the inventor eventually vindicated. An
24 example was given of a hypothetical patent on the
25 Wright brothers' airplane. Perhaps all the 'experts'

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1 thought it would not fly, but it did. Would it not
2 be illogical, it was asked, to invalidate a
3 hypothetical patent for a heavier-than-air flying
4 machine because scientific opinion in the pre-flight
5 era was wrong?
6 82. The hypothetical Wright brothers'
7 patent relates to a new and useful product, rather
8 than (as here) to a new use for an old product, but
9 all the same it illustrates, I think, the flaw in the
10 Glaxo/Wellcome argument. The mere idea of a
11 'heavier-than-air flying machine' is no more
12 patentable than would be 'anything that grows hair on
13 bald men'. The patent (even in this improbable
14 scenario) would have to teach precisely how the
15 machine could be made to fly. Section 34(1)(b) of
16 the Patent Act requires the applicant to set out in
17 the specification 'the method of constructing,
18 making... or using a machine... in such full, clear,
19 concise and exact terms as to enable any person
20 skilled in the art... to make, construct... or use
21 it'. This means the Wright brothers' hypothetical
22 patent would have to describe, amongst other things,
23 how to design an air foil that creates 'lift' by
24 reducing the air pressure on upper surface of the
25 wing as the air rushes over it, as well as a suitable

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1 airborne method of forward locomotion. If the
2 essentials of the heavier-than-air flying machine
3 were set out with sufficient precision to allow the
4 reader actually to make a flying machine that flies,
5 it is hard to accept the 'hypothetical' that experts
6 would continue to insist, after it had flown, that
7 the prediction was unsound. (Of course, if the
8 prediction turned out to be wrong, the patent would
9 be struck down for inutility. Leonardo da Vinci's
10 elegant drawings showed exactly how to make a 'bird
11 man' machine but it never could, would or did sustain
12 a person in flight.)"
13 That passage about Justice Binnie finding
14 it hard to accept a hypothetical that experts would
15 continue to insist, after it had flown, that the
16 prediction was unsound turned out to be pretty wrong,
17 didn't it, because generics have experts all the time
18 saying that, you know, drugs that have flown, safe
19 and effective approved drugs, so they've flown --
20 that any expert would actually question. And they do
21 that all the time, right?
22 MR. DIMOCK: Sorry, maybe it's the
23 lateness of the day. I don't understand your
24 question.
25 MR. DEARDEN: I understand. The top

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1 paragraph there before paragraph 83, I'm looking at
2 that passage that Justice Binnie says "If the
3 essentials of the heavier-than-air flying machine
4 were set out with sufficient precision to allow the
5 reader actually to make a flying machine that flies,
6 it is hard to accept the 'hypothetical' that experts
7 would continue to insist, after it had flown, that
8 the prediction was unsound." So all the drugs that
9 have been invalidated post AZT, they give a
10 description about how to make those drugs fly, and
11 the experts put on by the generics most definitely
12 insist, notwithstanding Justice Binnie thinking they
13 never would, they continue to insist after it had
14 flown that the prediction was unsound.
15 That's the name of the game now, isn't
16 it, Mr. Dimock?
17 MR. DIMOCK: I wouldn't call it a game.
18 MR. DEARDEN: It's an expression. That's
19 what's going on now, right?
20 MR. DIMOCK: We're talking about
21 situations where applications are being made hoping
22 that, as was said, perhaps the patent was filed too
23 soon, that there's not sufficient work done to make
24 any prediction of its utility sound so that you are
25 giving to the public its part of the bargain, the

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1 *quid pro quo* as Justice Binnie said, and, you know,
2 in order to get this monopoly that you've got to give
3 something up and it can't be just a mere prediction.
4 It's got to be a sound prediction and the disclosure
5 has to give the facts and the basis for it. So I
6 cannot agree with you.
7 MR. DEARDEN: Mr. Dimock, in sound
8 prediction cases post AZT, safe and effective
9 drugs -- so they actually work, they're being
10 consumed by thousands of patients, they're being sold
11 and the generics want to sell a generic version of
12 that very same drug, those drugs actually work, the
13 generics are putting on experts, questioning or
14 saying that the prediction was unsound. Agreed?
15 MR. DIMOCK: Yes, that's happening, and
16 there are many patents where there is a prediction
17 that turns out not to be correct. That's why you
18 have these safeguards, these -- you know, you have to
19 get past a certain --
20 MR. DEARDEN: Those are inoperability
21 cases, right?
22 MR. DIMOCK: Well, if you can show that
23 your prediction was wrong, that if you predict that a
24 particular drug X would treat disease Y and it turns
25 out it doesn't, then why should you be able to get a

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1 patent if your hunch turned out to be right? You
2 have to be able to give more as part of the bargain
3 to the government to get the monopoly. And I defer
4 to the reasons for judgment of Justice Binnie to
5 explain the basis for that. I'm just giving a very
6 shorthand view of it.
7 MR. DEARDEN: Olanzapine worked, correct?
8 Blockbuster drug called Zyprexa.
9 MR. DIMOCK: It did work for
10 schizophrenia, yes.
11 MR. DEARDEN: And atomoxetine worked for
12 ADHD, treatment of ADHD? Strattera.
13 MR. DIMOCK: Your client's witnesses have
14 put that evidence forward.
15 MR. DEARDEN: You don't dispute it?
16 MR. DIMOCK: I don't dispute it.
17 MR. SPELLISCY: I think there's a
18 question of expertise on whether or not Mr. Dimock
19 knows that they worked.
20 THE PRESIDENT: Sustained.
21 MR. DEARDEN: And Mr. Justice Binnie's
22 prediction in paragraph 82 in AZT that "it is hard to
23 accept the 'hypothetical' that experts would continue
24 to insist after it had flown that the prediction was
25 unsound", turned out to be an unsound prediction,

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1 didn't it?
2 MR. DIMOCK: We're dealing with different
3 situations here. It turned out, as I recall, the
4 Wright brothers had several unsuccessful flights.
5 They didn't succeed with their first airplane. So
6 that's my point.
7 MR. DEARDEN: The guy that invented the
8 light bulb first didn't either and Thomas Edison
9 improved on his patent and takes all the credit today
10 for the light bulb.
11 MR. DIMOCK: However, he did demonstrate
12 its utility, that light shone from the bulb.
13 MR. DEARDEN: All right. Cochlear, tab
14 26 in your binder, but don't open it yet because I'm
15 going to your paragraph 103 of your Second Report,
16 Mr. Dimock.
17 MR. DIMOCK: I have that at page 29.
18 MR. DEARDEN: You say in paragraph 103
19 "In his reference to Cochlear v Cossem Professor
20 Siebrasse cites the following excerpt from the case.
21 '[...]the] utility of a patent may be proven by the
22 reception received from the public i.e. its
23 commercial success' and continued in the very next
24 sentence to state expressly that utility 'is' -- and
25 the word "also" should be there -- "to be judged at

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1 the date of the making of the invention, in light of
2 the knowledge existing at the time'."
3 Now, that passage doesn't stop where
4 you've got the quotation mark there, so let's go to
5 the case.
6 MR. DIMOCK: I just wanted to -- you said
7 that I wanted to put "also" in there. I wanted to
8 put "also" in there just because otherwise the
9 statement without the word "also" I took to be
10 misleading.
11 MR. DEARDEN: "Also" is -- I'm not
12 agreeing on your "misleading" but the word "also"
13 should be there and that's why I read it into the
14 passage, but the passage also should include more
15 words. So let's go to Cochlear. Where did that
16 quote come from, Mr. Dimock, of Cochlear? Page 35?
17 MR. BORN: Page 35.
18 MR. DEARDEN: Page 35 under the heading
19 "Utility."
20 MR. DIMOCK: Yes, I have it.
21 THE PRESIDENT: To be clear, you are
22 quoting here from paragraph 58 of the second
23 Siebrasse report?
24 MR. DIMOCK: Yes, that's right.
25 THE PRESIDENT: And you quoted him or you

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1 quoted directly from the original decision?
2 MR. DIMOCK: I was taking it from his
3 report.
4 THE PRESIDENT: Which I call then a
5 secondary quote. Maybe you are familiar with law
6 publications. They copy simply the footnotes of the
7 previous author, and you see the same error serially
8 quoted. What I learned from my mentor was always go
9 back to the source, the original one, so that's what
10 Mr. Dearden is now doing actually.
11 MR. DEARDEN: That's what I'm doing.
12 Let's look at Utility, page 35, paragraphs (c) and
13 (d) of the decision. Justice Joyal finds "The
14 utility of a patent may be proven by the reception
15 received from the public, i.e. its commercial
16 success... Utility is also to be judged at the date
17 of the making of the invention, in light of the
18 knowledge existing at that time:" Cites Dr. Fox at
19 page 160 and concludes, "In light of its commercial
20 success, there can be little doubt as to the utility
21 of the Cochlear prosthesis." Right?
22 MR. DIMOCK: You've read it correctly.
23 MR. DEARDEN: And what does the Fox say?
24 163, tab 27. Let's go to Fox, page 160, under the
25 heading "Time for decision."

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1 MR. DIMOCK: I have that.
2 MR. DEARDEN: So Dr. Fox says, "Utility
3 is to be judged at the date of the making of the
4 invention and in the light of the knowledge existing
5 at that time. It is, therefore, a relative quality,
6 and the decision as to its existence depends upon the
7 presence or absence of practical utility at the time
8 the invention was made" and he cites the Tubeless
9 case and quotes Justice Byrne. "I can quite
10 understand that an invention may be held useful when
11 applied to a subject-matter not known at the date of
12 the invention, if the original description permits
13 such an application; but I cannot think that an
14 inventor, having patented something which he says
15 will work in relation to one form of object, or with
16 one set of constituents, can be allowed to say it is
17 true my invention will not so work, but it will work
18 when altered by a subsequently discovered material or
19 device'."
20 So what Dr. Fox has quoted there is that
21 utility can't be established by showing utility of a
22 different version of the claimed invention. It can't
23 be a subsequently improved version of the invention
24 to establish the utility. You're stuck with the
25 invention as it was filed?

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1 MR. DIMOCK: Yes. And as he said at the
2 outset, utility is to be judged at the date of the
3 making of the invention and in light of the knowledge
4 existing at that time, and that's the point you've
5 got at the time of the application or the time of
6 making the invention or at the time of filing, that
7 you either have to have a demonstration of utility or
8 a sound prediction.
9 MR. DEARDEN: What the invention is that
10 is being referred to as being made is the invention
11 that you put down in your patent application, not
12 some improved or different version of what your
13 claimed invention was, right?
14 MR. DIMOCK: I'm sorry. I didn't quite
15 catch the question.
16 MR. DEARDEN: Utility isn't allowed to be
17 established by showing the utility of a different
18 version of the claimed invention.
19 MR. DIMOCK: That's right. You've got --
20 you want to deal with the invention as disclosed and
21 whatever promises are made and the claims in suit.
22 MR. DEARDEN: Utility has to be known,
23 not tested. Agreed?
24 MR. DIMOCK: If you know by just having
25 made the device, for example, that it was obvious

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1 that it would have the utility, then you don't have
2 to test it. But if it is not so obvious that what
3 you've made has the utility, then you've got to test
4 it. And that's what the Proctor & Gamble and Bristol
5 Myers case stands for in the Court of Appeal, where
6 the case was asked to decide whether there was a
7 prior inventor, whether he knew or used the invention
8 before the inventor of the Bounce dryer sheet, and
9 the court said that when the prior inventor responded
10 that it was a good try but no success, what they were
11 saying is that to know the invention is to know its
12 utility.
13 MR. DEARDEN: While we have Fox open, can
14 you go to page 159? Under the heading "Infringement"
15 as evidence Dr. Fox writes, "It is also strong
16 evidence of utility of an invention if a patent
17 thereon has been infringed or if an attempt to
18 infringe has been made. As Justice Astbury observed
19 in Turner v Bowman: '...the best evidence of its
20 utility... is the fact that the defendants... have
21 thought fit to use the machine which is alleged in
22 the Particulars of Breaches as an infringement'."
23 So Dr. Fox wrote that in his 4th Edition
24 in 1969, but that statement is no longer true today,
25 is it, Mr. Dimock?

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1 MR. DIMOCK: No, I don't -- I think it's
2 still applicable today because you can defend an
3 infringement case by saying that what you've
4 described doesn't work at all, that it's inoperable,
5 and what the patentee would say in response, well, if
6 you'd copied my invention, how can you say it doesn't
7 work? I don't think it's anything more than that.
8 MR. DEARDEN: So your evidence is
9 infringement today is evidence -- strong evidence --
10 of the utility of the invention if a patent has been
11 infringed or if there's an attempt to infringe?
12 MR. DIMOCK: If the court concludes that
13 there's infringement, therefore the infringing
14 activity comes within the scope of the claims, and
15 there's an argument made by the defendant infringer
16 that the claim is just inoperable, then it might not
17 work.
18 But you have to also consider this,
19 Mr. Dearden, that a claim has a certain breadth, and
20 it may be that one part of it doesn't work and the
21 part that the infringer is working does work. The
22 fact that part of it doesn't work can invalidate that
23 claim, so I'm probably drawing out an exception to
24 your point.
25 MR. DEARDEN: I only want to understand

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1 your evidence. Your opinion is that Dr. Fox's
2 statement at page 159 about infringement as evidence
3 is that today a patentee can -- well, let me make the
4 quote. "It is also strong evidence of the utility of
5 an invention if a patent thereon has been infringed
6 or if an attempt to infringe has been made." So that
7 argument can still be made today?
8 MR. DIMOCK: Yes, it's like the argument
9 it hardly lies in the mouth of the defendant to
10 denigrate that which he has chosen to copy.
11 MR. DEARDEN: But that evidence is
12 admissible as strong evidence of utility today.
13 MR. DIMOCK: On the issue of operability,
14 not on some of the other issues that we've talked
15 about.
16 MR. DEARDEN: Mr. Dimock, can you cite a
17 case decided prior to 2002 that invalidated a patent
18 for a commercially useful invention because the
19 patentee could not demonstrate or soundly predict the
20 utility at the date of filing? Let me say that
21 again, because I see you writing it down.
22 MR. DIMOCK: I don't have your
23 transcript.
24 MR. DEARDEN: These are really handy.
25 Can you cite a case decided prior to 2002 that

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1 invalidated a patent for a commercially useful
2 invention because the patentee could not demonstrate
3 or soundly predict the utility at the date of filing?
4 MR. DIMOCK: As I said, there are so few
5 sound prediction cases, and so right now at this time
6 in this chair, I can't think of any.
7 MR. DEARDEN: So zero. Fair?
8 MR. DIMOCK: None that I can think of
9 right now.
10 MR. DEARDEN: Okay, none. Can you cite a
11 decision prior to 2002 in which the court did not
12 allow the patentee to rely on post-filing evidence to
13 prove utility?
14 MR. DIMOCK: A case before 2002 where the
15 court --
16 MR. DEARDEN: Did not allow the patentee
17 to rely on post-filing evidence to prove utility?
18 MR. DIMOCK: Well, the case I had in the
19 mid-80s, the Cabot case, there was an allegation that
20 the claims were broader than the invention disclosed
21 because the Claimants went beyond the examples and
22 the court held that the disclosure was sufficient.
23 So no, I can't think of any right now. But in that
24 case we didn't have to rely on evidence afterwards
25 and I don't know that I would have put any in because

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1 I don't believe you can. I put in evidence based on
2 what was in the disclosure.
3 MR. DEARDEN: Do you agree, Mr. Dimock,
4 that the first time a drug that was approved by
5 Health Canada as safe and effective was found to lack
6 utility was after the 2002 AZT decision? The first
7 time a drug that was approved by Health Canada as
8 safe and effective was found to lack utility was
9 after the 2002 AZT decision. Agree?
10 MR. DIMOCK: I can't think of any right
11 now, and I presume you're asking me these questions
12 because you know the answer.
13 MR. DEARDEN: I do.
14 Switching topics now, you haven't acted
15 for Apotex, but you've litigated against Apotex?
16 MR. DIMOCK: That's correct.
17 MR. DEARDEN: And Apotex is the largest
18 generic manufacturer in Canada?
19 MR. DIMOCK: Yes.
20 MR. DEARDEN: And Apotex is a prolific
21 pharmaceutical patent litigant in Canada, correct?
22 MR. DIMOCK: Yes.
23 MR. DEARDEN: Half the cases in the four
24 binders at your feet seem to be Apotex cases.
25 MR. DIMOCK: I was just trying to -- I

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1 wasn't trying to avoid your question. I was just
 2 trying to make sure I was answering correctly. But
 3 yes, you're right.
 4 MR. DEARDEN: You did. And Apotex has
 5 been very ably represented by the Goodmans law firm,
 6 has it not?
 7 MR. DIMOCK: Yes.
 8 MR. DEARDEN: And that team of lawyers is
 9 led by Harry Radomski.
 10 MR. DIMOCK: Yes.
 11 MR. DEARDEN: And he has senior back-up
 12 with Andrew Brodtkin, amongst others at that Goodmans
 13 firm?
 14 MR. DIMOCK: Among others, yes.
 15 MR. DEARDEN: And both of them are
 16 reputable and extremely experienced patent counsel?
 17 MR. DIMOCK: Yes.
 18 MR. DEARDEN: We call them frequent
 19 flyers in the Federal courts, right?
 20 MR. DIMOCK: As I said years ago when
 21 some of my clients could not get trial dates because
 22 the pharmaceutical cases were jumping the queue, that
 23 the pharmaceutical cases were choking the court.
 24 MR. DEARDEN: Just as an aside,
 25 Mr. Dimock, because I was trying to figure out from

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1 looking at your CV in the cases you listed that
 2 you've litigated, from 2005 until today, how many
 3 pharmaceutical patent cases have you litigated that
 4 involved the issue of sound prediction of utility?
 5 So from '05 to now, have you had the opportunity to
 6 litigate any cases where the issue was sound
 7 prediction of utility?
 8 MR. DIMOCK: I did work for Ranbaxy
 9 against Pfizer. That's the case you referred to.
 10 Proctor & Gamble and Genpharm.
 11 MR. DEARDEN: Those are all before 2005.
 12 MR. DIMOCK: Yes.
 13 MR. DEARDEN: I'm talking from 2005 to
 14 now. I figured out what ones you were involved in
 15 before but, from 2005 to date, have you done any
 16 pharmaceutical patent litigation that involved the
 17 issue of sound prediction of utility?
 18 MR. DIMOCK: No.
 19 MR. DEARDEN: And from, again, 2005 to
 20 now, how many pharmaceutical patent cases have you
 21 litigated that involve the issue of whether the
 22 promise of utility derived from the disclosure was
 23 demonstrated or soundly predicted at the date of
 24 filing?
 25 MR. DIMOCK: None.

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1 MR. DEARDEN: Sir, can you turn to tab
 2 28, Exhibit C-53? What you should have there is a
 3 written representations made by the defendant Apotex
 4 in the Bristol Myers case. Is that what you have
 5 there?
 6 MR. DIMOCK: Yes.
 7 MR. DEARDEN: And these were written
 8 representations with respect to an issue being argued
 9 before Justice Tremblay-Lamer. Can you turn to 15?
 10 There's a heading there, "Change in law: The
 11 Wellcome decision." See that?
 12 MR. DIMOCK: Yes.
 13 MR. DEARDEN: Paragraph 15 reads, "At the
 14 time of the above discovery, the governing law
 15 relating to sound prediction was the Federal Court of
 16 Appeal's decision in Apotex v Wellcome Foundation" --
 17 so that's our AZT case, right?
 18 MR. DIMOCK: Yes.
 19 MR. DEARDEN: "Pursuant to this decision,
 20 BMS did not need to establish a sound basis for
 21 predicting utility as at the filing date of the '436
 22 patent because nefazodone had eventually been shown
 23 to have antidepressant activity, precisely as counsel
 24 for Apotex had indicated on discovery.
 25 Paragraph 16. "The law changed following

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1 the decision of the Supreme Court of Canada in
 2 December 2002 in Wellcome. The Court rejected the
 3 proposition that speculation as to utility, even if
 4 subsequently confirmed, is sufficient to justify the
 5 grant of the patent."
 6 Mr. Dimock, you agree with the
 7 submissions of counsel for Apotex, that the law was
 8 changed by AZT?
 9 MR. DIMOCK: I disagree.
 10 MR. DEARDEN: Then go to tab 29. You
 11 should have there Exhibit C-532, which is a decision
 12 of Madam Justice Tremblay-Lamer. Go to paragraph 30.
 13 MR. DIMOCK: I have that at the bottom of
 14 page 12.
 15 MR. DEARDEN: Right. Justice
 16 Tremblay-Lamer holds: "Apotex argues, however, that
 17 Mr. Radomski's statement was not so much an admission
 18 as it was an agreement as to the current state of the
 19 law as it existed in February of 2003."
 20 MR. DIMOCK: 2002.
 21 MR. DEARDEN: 2, sorry. "Mr. Radomski
 22 had indicated at that time that there was no issue
 23 with respect to the sound prediction of nefazodone
 24 because" -- and Madam Justice Tremblay-Lamer
 25 italicized "because -- "nefazodone had, subsequent to

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1 the filing of the '436 Patent, been made, clinically
2 tested and was successful. Under the governing law
3 of the time, as established in Apotex v Wellcome
4 Foundation" -- the Federal Court of Appeal's AZT
5 decision, correct? That's what she's referring to
6 there, is the Federal Court of Appeal decision in AZT
7 that we have talked about a few minutes ago?
8 MR. DIMOCK: That's what she's referring
9 to, not to the Supreme Court of Canada decision.
10 MR. DEARDEN: No, the Federal Court of
11 Appeal one, so "Under the governing law at the time,
12 as established by [AZT Federal Court of Appeal], that
13 was enough -- all that was required was for an
14 inventor to demonstrate utility or sound prediction
15 at the time a patent was attacked. Apotex points
16 out, however, that the law changed subsequent to
17 Mr. Radomski's statement. In December of 2002, the
18 Supreme Court of Canada in Apotex v Wellcome
19 Foundation 2002 SCC 77... directed that either actual
20 utility or sound basis for predicting utility was
21 required as of the filing date of the patent. As
22 such, Apotex argues that the statement made by
23 Mr. Radomski in February of 2002 was obviously no
24 longer applicable: The fact that nefazodone had been
25 shown to eventually have utility as an antidepressant

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1 no longer necessarily meant that the '436 Patent was
2 immune to attack based on lack of sound prediction as
3 of the filing date.
4 Paragraph 32. "While I agree that it
5 would have been preferable if Apotex had formally
6 withdrawn its statement in light of the change of the
7 law, I find that the amendments made by Apotex to
8 paragraph 21 in July of 2004 sufficiently
9 demonstrated that lack of sound prediction with
10 respect to nefazodone and nefazodone hydrochloride
11 was a live issue. The amendment to paragraph 21
12 paralleled the change of law with respect to sound
13 prediction: It alleged that even if one of the
14 compounds of the '436 Patent was eventually shown to
15 have the utility promised, there was a lack of sound
16 prediction at the time of filing."
17 I'm not going to read the rest of
18 paragraph 31, but paragraph 32: "I find that given
19 the change of law regarding lack of sound prediction,
20 and given the modifications made by Apotex to
21 paragraph 21 subsequent to that change, it cannot be
22 said that the amendment sought by Apotex on the
23 current motion constitute a radical departure from
24 Apotex's prior pleadings."
25 Do you agree with Justice Tremblay-Lamer

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1 the law was changed by AZT 2002 Supreme Court of
2 Canada?
3 MR. DIMOCK: Before I answer that,
4 Mr. Dearden, was not this decision of Madam Justice
5 Tremblay-Lamer not appealed and she was criticized?
6 MR. DEARDEN: She was criticized by
7 giving the amendment to Apotex so late in the day in
8 the trial. So she allowed --
9 MR. SPELLISCY: Sorry, is that testimony
10 from Mr. Dearden, or is that a question?
11 THE PRESIDENT: No, sorry. First of all,
12 it's Mr. Dimock who asked the question to the
13 examiner, if I may call it that way. Reverse of
14 roles, and he answered, so I will allow the question
15 both ways!
16 MR. DIMOCK: I guess I should have said a
17 statement. It was appealed.
18 MR. DEARDEN: My last document Mr. Dimock
19 is the next tab, tab 30, which is Exhibit C-375. Do
20 you know, sir, Apotex's position about the
21 arbitrariness of Canada's law of utility?
22 MR. DIMOCK: Do I know its position?
23 MR. DEARDEN: Yes.
24 MR. DIMOCK: I guess I don't understand
25 what you mean by that.

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1 MR. DEARDEN: Do you know what their view
2 is of the current state of the law of utility in
3 Canada as being arbitrary or non-arbitrary? Do you
4 know?
5 MR. DIMOCK: The only time I've read what
6 they say is in court proceedings. I'm not aware of
7 any printed publications that they've made as to what
8 their position is, so only what they argue, and like
9 any good law firm -- and they are a very good law
10 firm -- they argue the case as they see it to advance
11 the interests of their client.
12 MR. DEARDEN: And they do so as officers
13 of the court?
14 MR. DIMOCK: We all do, yes.
15 MR. DEARDEN: Yes, we do. So the
16 document you have at tab 30 of the binder is a notice
17 of application for leave to appeal of Apotex in the
18 Plavix case.
19 MR. DIMOCK: And I won't ask this as a
20 question, I'll make it as a statement in answer to
21 your question. Yes, this case did go on appeal and
22 leave was granted by the Supreme Court of Canada, and
23 the day before the hearing was to take place Apotex
24 and Sanofi settled and there was no appeal.
25 MR. DEARDEN: There was no decision of

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1 the Supreme Court of Canada, that's absolutely
2 correct, but what I'm asking you to look at in this
3 notice of application, where, indeed, leave was
4 granted, is one of the submissions made to obtain
5 leave of the Supreme Court is at paragraph 14 under
6 the heading "The proposed appeal raises questions of
7 urgent national interest." Do you have that? So
8 page 4 of the notice is where you'll see heading C,
9 "The proposed appeal raises questions of urgent
10 national interest." Tab 30.
11 MR. DIMOCK: I'm at tab 30.
12 MR. DEARDEN: It's only like two pages
13 in. You look like you're deeper.
14 MR. DIMOCK: Okay. I was looking at a
15 page much later on in the tab.
16 MR. DEARDEN: So you have paragraph 14
17 now?
18 MR. DIMOCK: Yes, I do. Page 4, yes.
19 MR. DEARDEN: Right. So here's what
20 Apotex had to say to the Supreme Court of Canada.
21 "It is well understood that a Canadian patent will be
22 invalid for want of utility if its invention does not
23 do what the patent promises it will do. However,
24 this Court has never guided the lower courts in how
25 they are to identify or characterize the limits of a

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1 patent's promise and how the promised utility relates
2 to the inventive concept of the claims of the patent.
3 Without this guidance, the lower Courts have created
4 and applied a hopeless tangle of contradictory
5 approaches to these questions. The situation is now
6 a 'free-for-all' in which the outcome of cases
7 depends upon the particular judge or panel hearing
8 the dispute, rather than on legal authority. The
9 outcome of cases (particularly cases like the present
10 case, where the stakes to the parties are counted in
11 the hundreds of millions of dollars) must not be
12 determined so arbitrarily. The proposed appeal
13 raises this intolerable confusion for resolution."
14 And Apotex succeeded in getting the
15 Supreme Court of Canada to give them leave to appeal
16 the Federal Court of Appeal's decision in Plavix,
17 correct?
18 MR. DIMOCK: That's correct.
19 MR. DEARDEN: Mr. Dimock, that completes
20 my questions, sir. Thank you.
21 Mr. President, that completes my
22 questions.
23 THE PRESIDENT: Thank you.
24 MR. SPELLISCY: Can we have five minutes?
25 THE PRESIDENT: Five minutes granted.

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1 Mr. Dimock, you know what it means. You're still
2 under testimony.
3 *(Recess taken)*
4 THE PRESIDENT: Mr. Johnston, please
5 proceed with the redirect.
6 **REDIRECT EXAMINATION ON BEHALF OF THE RESPONDENT**
7 MR. JOHNSTON: Thank you, President
8 van den Berg.
9 Mr. Dimock, quite early in your
10 cross-examination you were asked about the Mobil Oil
11 case, and Mr. Dearden put it to you -- this is at
12 11:55:08 on today's transcript -- he put it to you,
13 "Justice Wetston made no findings of promise, did
14 he?" And in your response at 11:55:32 in the
15 transcript, you said: "I just can't put my finger on
16 the particular sentence in Justice Wetston's
17 reasons." You were taken to page 513 of the
18 decision, though you were not given an opportunity to
19 look at that decision in full.
20 The quoted portion -- the portion of your
21 Expert Report which was at issue in Mr. Dearden's
22 questions was in your first Expert Report at
23 paragraph 70 and 71 where you draw the link between
24 Consolboard and Mobil Oil, and if I could direct you
25 to paragraphs 70 and 71 of your first Expert Report,

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1 I wonder if, in reviewing these paragraphs, there's
2 anything more you'd like to add in respect to this
3 issue?
4 MR. DIMOCK: Yes. I was curious myself
5 about the passage I was trying to recall in answering
6 Mr. Dearden, and I didn't want to interrupt his line
7 of questioning this afternoon, but I had found what I
8 was looking for, and that's at page 508 of the
9 Canadian Patent Reporter, and it's at letter B.
10 THE PRESIDENT: Could you help me with
11 the tab, and which volume number?
12 MR. DIMOCK: Yes. It's tab 19 in volume
13 3.
14 THE PRESIDENT: Thank you.
15 MR. DIMOCK: This was the decision of
16 Justice Wetston that Mr. Dearden took me to this
17 morning, and he directed my attention particularly to
18 paragraphs on page 513, but it's page 508 that I had
19 in mind when I was trying to answer his questions,
20 and here Justice Wetston -- and if you go back to
21 page 507 Justice Wetston says, "In order to be an
22 invention worthy of protection, the patent must
23 disclose and claim an invention which works, that is,
24 which achieves the promise it sets out." And then in
25 the second paragraph on page 508 here's what Justice

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1 Wetston said. "The patent specification promises an
2 oriented polypropylene film substrate having enhanced
3 adhesion to a metallized coating. The evidence
4 indicates that this was indeed achieved..." and then
5 he goes on to say something about the bond strength
6 of 90 grams per inch. He concludes, "Therefore the
7 patent is not valid for inutility."
8 So yes, he was asked, or he did look to
9 the specification to see whether or not there was a
10 promise, and he found that there was a promise of
11 enhanced adhesion, and that was met by the claims.
12 MR. JOHNSTON: Thank you.
13 You were also asked now towards the end
14 of your cross-examination regarding a Bristol Myers
15 case, this was at tab 28 of your cross-examination
16 binders, you were taken to written representations by
17 Apotex in this BMS case, then at tab 29 you were
18 taken to the decision of Justice Tremblay-Lamer in
19 that case, and then you indicated in your response to
20 Mr. Dearden that you had understood this matter to
21 have been appealed, and so I wanted to give you the
22 opportunity -- I'd like to bring up that appeal which
23 was not provided to you in your cross-examination
24 binder.
25 If we could pull up C-545, please,

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1 paragraph 23, this is where that issue was discussed
2 by the Federal Court of Appeal. This is C-545,
3 page 10, paragraph 23, if you'd like to take a minute
4 to look at that.
5 MS. CHEEK: Mr. Johnston, if you could
6 also give us a moment to get that exhibit?
7 THE PRESIDENT: Mr. Dimock, do you need a
8 hard copy?
9 MR. DIMOCK: I am myopic, so I have a
10 hard time seeing small print.
11 THE PRESIDENT: Mr. Johnston, could you
12 please provide a hard copy to Mr. Dimock?
13 MR. JOHNSTON: Yes, that will require a
14 minute to go print a hard copy.
15 THE PRESIDENT: You don't have a hard
16 copy here available?
17 MR. JOHNSTON: One moment.
18 THE PRESIDENT: Maybe the Tribunal has a
19 hard copy. (Handed)
20 MR. DIMOCK: I've read that paragraph,
21 and I believe I've got the context of it, yes.
22 MR. JOHNSTON: Based on that, is there
23 anything more you'd like to add in response to
24 Mr. Dearden's questions?
25 MR. DIMOCK: What I think the Court of

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1 Appeal was saying, if I understand it correctly, in
2 the time I've had to look at it -- although I do
3 remember something about the case and the appeal,
4 they waited very long afterwards to say that there
5 was a change in the law; that it was something, if
6 they wanted to make the amendments that they did,
7 they should have done so a lot sooner, and that
8 militated against their abilities to amend now.
9 MR. JOHNSTON: Mr. Dimock, you made
10 reference in one of your responses to a case you had
11 worked on, the Proctor & Gamble case. Am I right
12 this is the 1979 Proctor & Gamble case you were
13 referring to?
14 MR. DIMOCK: Yes, it was.
15 MR. JOHNSTON: Just for clarity of the
16 record to confirm that is Exhibit R-183, the case you
17 were referring to, and it's the case relied upon in
18 your Expert Report?
19 MR. DIMOCK: I believe that's the number,
20 that's right. It's a decision of the -- you say 1979
21 Proctor & Gamble? And the one I was referring to was
22 the decision of Proctor & Gamble v Unilever in 1995.
23 MR. JOHNSTON: That's the decision you
24 were referring to in your response?
25 MR. DIMOCK: Yes.

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1 MR. JOHNSTON: If that is Exhibit R-172.
2 Just one more question, Mr. Dimock. You were asked
3 how many pharmaceutical cases have you litigated
4 where the issue of demonstration or sound prediction
5 of utility were at issue. I'd like to ask how many
6 cases outside of the pharmaceutical field, or to what
7 extent have you litigated other cases raising these
8 types of issues?
9 MR. DIMOCK: I was involved as a junior
10 lawyer in Monsanto, which was sound prediction. And
11 I was counsel for Cabot in the case that I referred
12 to earlier that was sound prediction, and I think the
13 chart that I had this morning, Has the Invention
14 Support for Prediction Been Disclosed, and that was
15 the decision of Cabot v 318602 Ontario Ltd, a
16 decision of Justice Cullen -- no Justice Rouleau in
17 1988. And that was a sound prediction case.
18 So I was involved in two of them, the
19 Consolboard case in the Court of Appeal and the
20 Supreme Court of Canada -- that is to say I was not
21 counsel but I helped prepare the brief for those and
22 I was counsel on Cabot and the numbered company.
23 MR. JOHNSTON: Have you recently been
24 involved in any cases involving issues of the promise
25 of the patent?

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1 MR. DIMOCK: Yes. The one I just
2 finished two weeks ago, I brought an impeachment
3 action on behalf of a company called Pollard v
4 Scientific Games over a lottery ticket, and
5 throughout the disclosure of the patent belonging to
6 Scientific Games they had made a promise that, by
7 using the particular design and construction of the
8 lottery ticket, the lottery system would somehow be
9 protected from fraud by customers through what we
10 called in the trial bar code security. And because
11 the claim, we argued, could not satisfy that utility
12 of bar code security, that that was, therefore, an
13 invalid claim and therefore the patent should be
14 impeached. I'm waiting for that decision.
15 There was also a case involving sound
16 prediction -- not sound prediction but promise, and
17 the case I acted on behalf of Dow Chemical v Nova, a
18 Court of Appeal is still under reserve with that
19 decision. We argued that appeal in December. We
20 were acting as Respondent to an attack against the
21 Dow patent by Nova saying that a promise made in the
22 disclosure could not be met and we were arguing that
23 there was no such promise made in the disclosure.
24 MR. JOHNSTON: Thank you. I have no
25 further questions.

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05:08

1 THE PRESIDENT: Application for recross?
2 MR. DEARDEN: None, Mr. President.
3 THE PRESIDENT: Mr. Born has a question.
4 QUESTIONS BY THE ARBITRAL TRIBUNAL
5 MR. BORN: Just one question. Going back
6 to the Mobil Oil case, which we talked about briefly,
7 and the reference that you were taken regarding the
8 promise of the patent.
9 MR. DIMOCK: Yes.
10 MR. BORN: That promise -- and this, I
11 think, is tab 19 in your third bundle.
12 MR. DIMOCK: I have that, Mr. Born, yes.
13 MR. BORN: That promise, if I understand
14 correctly, was in the claims? I'm looking at
15 page 493.
16 MR. DIMOCK: Yes. There was a promise
17 of, as Justice Wetston said, the patent specification
18 promises such and such, an enhanced adhesion. The
19 claims also had enhanced adhesion as an element of
20 it.
21 MR. BORN: When I looked on page 493, I
22 see that in the claims. Is that right?
23 MR. DIMOCK: Yes. The promise that was
24 made in the disclosure of enhanced adhesion carried
25 on into the claim, that's right.

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05:10

1 MR. BORN: I guess what I'm struggling
2 with is when I get to page 513 -- and you'll help me
3 on this if I'm wrong -- when I get to page 513, which
4 was the focus of your cross-examination testimony,
5 the defendant's argument there was that the promise
6 was not the enhanced adhesion that we saw in the
7 claim but, instead, a particular level. The 250 I
8 don't know, grams per inch or something.
9 MR. DIMOCK: They were suggesting that
10 not only was there a promise of enhanced adhesion but
11 a promise of enhanced adhesion at a particular level.
12 MR. BORN: Right, and that particular
13 level promise came from the disclosure, not the
14 claims.
15 MR. DIMOCK: That's correct.
16 MR. BORN: And the court said we don't
17 find that promise.
18 MR. DIMOCK: That's correct.
19 MR. BORN: Okay. Thank you.
20 THE PRESIDENT: I have one question,
21 Mr. Dimock, a discrete question concerning your first
22 Expert Report, paragraph 78. Although we have to be
23 cautious regarding law firm newsletters, in paragraph
24 78 you cite a newsletter of your law firm, I
25 understand it to be, is that correct, of 1987?

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05:12

1 MR. DIMOCK: That's correct.
2 THE PRESIDENT: Congratulations that you
3 could find it still after so many years. But more
4 seriously --
5 MR. DIMOCK: My wife accuses me of being
6 a pack rat.
7 THE PRESIDENT: Okay. You're not the
8 only one!
9 But what you say right there is about
10 dangers of including object clauses in patents, and
11 that follows the Amfac decision, 1986. Could you
12 please elaborate on what is the danger -- or was the
13 danger, because I have a compound question, a second
14 question, is the danger still there today? First,
15 answer the first question what was the danger, and
16 then...
17 MR. DIMOCK: The danger is still there,
18 so I answered the second question first. The danger
19 is still there. And the danger I was trying to make
20 our clients aware of was the same danger that
21 Mr. Hayhurst wrote about to which I referred in
22 paragraph 79, and that is he also said earlier you
23 don't lard up your disclosure with a lot of promises
24 because, if you do, you might have to meet those
25 promises in the claim, so beware. Only make a

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1 promise when you have to. And what I was saying in
2 that newsletter is that avoid -- because you don't
3 have to describe utility of your invention in the
4 ordinary course, as I said earlier today, there are
5 occasions when you have to talk about the utility for
6 a new use patent or a sound prediction or
7 what-have-you, but what I was saying here, unless you
8 have to refer to utility, avoid that because if you
9 are reckless in how you give the objectives and the
10 promises in the patent, your claims could go from a
11 much larger scope down to a very small scope and,
12 therefore, not be able to capture as many
13 infringements as you'd like. That's what I was
14 suggesting.

15 THE PRESIDENT: But could you be more
16 specific what is the danger if you include --

17 MR. DIMOCK: The danger is that the
18 court -- for example, if a patent had these
19 objectives that were considered by the court to be
20 promises, just as in Amfac, I was faced with a
21 disclosure where not only was the invention a good
22 one to throw the potato against a grid of knives to
23 get long slender cuts, but the patent went on to say
24 that a further utility and a promise that we make if
25 you adopt our invention, you're going to separate the

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1 potatoes at the knife and, therefore, your claims are
2 going to be narrowed, and because we had a very broad
3 claim, 16, it was held invalid. So what I was saying
4 is unless you have to, for whatever reason, include
5 promises, don't do so because if you do you're going
6 to be held to them, and your claim may be held to be
7 invalid.

8 THE PRESIDENT: Thank you. Any follow-up
9 questions?

10 MR. DEARDEN: No, Mr. President.
11 MR. JOHNSTON: None.
12 THE PRESIDENT: Thank you, Mr. Dimock,
13 for testifying. You are now released as an expert
14 witness and you are excused.

15 Changeover of five minutes for the next
16 expert, Mr. Levin.
17 *(Recess taken)*
18 BRUCE LEVIN
19 THE PRESIDENT: Before we proceed with
20 the examination of Professor Levin, there is one
21 question on which the Tribunal would like
22 clarification. It's a small question and it concerns
23 the Expert Report of Mr. Siebrasse. Without going
24 into a formal recall of Professor Siebrasse, we
25 wondered whether footnote 98 of the First Report has

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1 the correct citation.

2 SIR DANIEL BETHLEHEM: It's simply a
3 question of clarification. We've been having a lot
4 of references back to the three cases in 2005, and a
5 number of the witnesses have gone back to Professor
6 Siebrasse's report. In footnote 98, which refers to
7 paragraph 72, we see a reference to the three cases.
8 I think our concern about the correctness of the
9 citation relates to the first one, Bristol-Myers
10 Squibb v Apotex 2005, which is referenced as C-190,
11 but when you pull up C-190, that doesn't seem to be
12 the correct case, so we would just like a technical
13 clarification at some point from you, please.

14 MS. CHEEK: I would suggest we will get
15 you an answer to that question, but we go ahead and
16 proceed with Professor Levin.

17 SIR DANIEL BETHLEHEM: Yes.
18 THE PRESIDENT: If you can give it to us
19 tomorrow morning, that's fine, or you can send it by
20 e-mail.

21 MS. CHEEK: We will plan to do that.
22 MR. SPELLISCY: This may actually come up
23 in the cross-examination, so I'm not sure if we can
24 break to get a clarification quickly.
25 THE PRESIDENT: This footnote?

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1 MR. SPELLISCY: The dates of the relevant
2 cases, I think.
3 THE PRESIDENT: These three relevant
4 cases?
5 MR. SPELLISCY: These three.
6 SIR DANIEL BETHLEHEM: So are you
7 proposing that we do break or we don't break?
8 MR. SPELLISCY: If we can get an answer
9 on it quickly. We can confer with our colleagues.
10 THE PRESIDENT: Then maybe it's useful
11 that we resolve it now, because it's relatively easy,
12 I think, to check.
13 MS. CHEEK: I can confirm now that the
14 correct exhibit cite --
15 THE PRESIDENT: C-190 is the correct
16 exhibit cite?
17 MS. CHEEK: The correct exhibit cite is
18 actually C-520, which I suppose we also could submit
19 as an amended C-190. I just think there was some
20 kind of clerical error that we caught later.
21 THE PRESIDENT: It can all happen. We
22 are all human beings. There's no problem.
23 MR. SPELLISCY: This is what we had
24 understood was the correct cite.
25 THE PRESIDENT: Then we're all on the

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1 same page again. Thank you.
 2 Good afternoon, Professor Levin.
 3 PROFESSOR LEVIN: Good afternoon.
 4 THE PRESIDENT: Could you please state
 5 your name for the record?
 6 PROFESSOR LEVIN: Bruce Levin.
 7 THE PRESIDENT: Professor Levin, you
 8 appear as an expert witness for the Claimant in this
 9 case.
 10 PROFESSOR LEVIN: Yes, Mr. President.
 11 THE PRESIDENT: If any question is
 12 unclear to you, either because of language or for any
 13 other reason, please do seek a clarification because,
 14 if you don't do so, the Tribunal will assume that
 15 you've understood the question and that your answer
 16 corresponds to the question.
 17 PROFESSOR LEVIN: Yes.
 18 THE PRESIDENT: Professor Levin, you will
 19 appreciate that testifying, be it before a court or
 20 an arbitral tribunal, is a very serious matter. In
 21 that connection, the Tribunal requests you to give
 22 the statement which is in front of you.
 23 PROFESSOR LEVIN: Yes. I solemnly
 24 declare, upon my honor and conscience, that my
 25 statement will be in accordance with my sincere

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1 belief.
 2 THE PRESIDENT: Thank you.
 3 Professor Levin, could you please go to
 4 your Report to page 14? Your report is dated
 5 December 7, 2015.
 6 PROFESSOR LEVIN: Yes.
 7 THE PRESIDENT: And confirm for the
 8 record that the signature appearing above your name
 9 is your signature?
 10 PROFESSOR LEVIN: I so confirm.
 11 THE PRESIDENT: We have your correction
 12 errata sheet. Are there any other corrections you
 13 wish to make to your report?
 14 PROFESSOR LEVIN: No, Mr. President.
 15 THE PRESIDENT: Thank you. Then,
 16 Ms. Cheek?
 17 MS. CHEEK: Thank you, Mr. President.
 18 Mr. Smith will be conducting the direct examination
 19 of Professor Levin.
 20 THE PRESIDENT: Thank you. Mr. Smith,
 21 please proceed.
 22 MR. SMITH: Thank you.
 23 Professor Levin, the President referred
 24 to the errata sheet that you had submitted. Could
 25 you please turn to that page? I'm sorry, I

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1 apologize. We will deal with the errata after your
 2 presentation. If you would, please proceed to your
 3 presentation.
 4 PROFESSOR LEVIN: Thank you.
 5 PRESENTATION BY PROFESSOR LEVIN
 6 Good afternoon, I am a tenured professor
 7 of Biostatistics at Columbia University in their
 8 School of Public Health in New York City. I was
 9 Chair of the Department of Biostatistics from
 10 2000 through 2011. I have some Honors, and I just
 11 want to say I have performed similar disproportionate
 12 impact analyses in other legal disputes such as
 13 employment and housing discrimination cases. I'd
 14 like to add that this is my first consultation with
 15 Eli Lilly and Company.
 16 I was asked by counsel for Eli Lilly to
 17 do the following, which was to assess the statistical
 18 significance of certain differences in the
 19 proportions of patent lawsuits in which courts
 20 sustained validity challenges on grounds of utility
 21 or on other grounds comparing the pharmaceutical
 22 sector with non-pharmaceutical sectors, both from
 23 2005 onward, which I'd like to refer to as the
 24 post-2005 period, and from 1980 through the end of
 25 2004, which I'd like to refer to as the pre-2005

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1 period.
 2 The graphic on the right-hand side of
 3 this slide represents the question that was posed to
 4 me upon first contact by counsel. They presented
 5 these pie charts showing the 40 percent of
 6 pharmaceutical cases that had been held invalid in
 7 the pharmaceutical cases as compared to none in the
 8 non-pharmaceutical cases, and this was put to me as
 9 whether that was statistically significant.
 10 I'd like to summarize my conclusions.
 11 After the analysis I did I concluded that post-2005,
 12 there is a statistically significant difference in
 13 invalidation rates based on lack of utility between
 14 pharmaceutical and non-pharmaceutical sectors in
 15 Canada.
 16 Prior, pre-2005, there is no significant
 17 difference across sectors. On grounds other than
 18 utility, there is no significant difference between
 19 the invalidation rates. And the above findings are
 20 consistent with the view that Canada's utility
 21 requirement has had a disproportionate impact on the
 22 pharmaceutical sector since 2005.
 23 The data that I was presented for
 24 analysis consisted of a spreadsheet listing all
 25 patent invalidity decisions issued by Canada's

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1 Federal courts between January 1, 1980 and, at the
2 time, August 10, 2015. I'd like to emphasize that
3 that was the entire census, all the cases that had
4 been so decided. There were 234 cases in the
5 spreadsheet.
6 Of those, 17 were not challenged on
7 either grounds of utility or obviousness or novelty
8 or sufficiency or any combination of those, so I
9 removed those 17 cases from analysis and focused on
10 those 217 which did involve at least one such
11 challenge. There were 129 cases post-2005 and 88
12 cases pre-2005 among those 217 that I studied.
13 The analysis consisted of
14 cross-classifying the cases that involved a challenge
15 on grounds of utility. Table 1 before you shows that
16 cross-classification. In the post-2005 period
17 39.7 percent, almost 40 percent of the pharmaceutical
18 cases that were challenged on grounds of utility were
19 held invalid, whereas in the non-pharmaceutical
20 sector, none of the eight were held invalid on those
21 grounds.
22 In the lower right-hand corner of the
23 slide you'll notice P equals 0.0245. In statistics
24 this is known as the P-value, and it indicates
25 statistical significance. In a moment I'd like to

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1 explain in more detail what I mean by "statistical
2 significance", but let me just say here that when the
3 P-value is less than .05, we will refer to that as
4 "statistically significant", and would lead to a
5 rejection of the null hypothesis.
6 So what do I mean by the null hypothesis
7 and how do we test it?
8 The null hypothesis states that the
9 positive difference that we observe in the
10 proportions of pharmaceutical versus
11 non-pharmaceutical cases with a finding of inutility
12 in the post-2005 period is due merely to chance. The
13 word "chance" is there. I will define what I mean by
14 "chance" momentarily.
15 In distinction to the null hypothesis,
16 the alternative hypothesis states that the observed
17 difference in proportions is due not to chance but to
18 substantive reasons. Specifically, that Canadian
19 utility law has had a disproportionate impact on the
20 pharmaceutical sector since 2005.
21 The question that the words above,
22 referring to "chance" and "null hypothesis" results
23 in a question: How frequently would we see inutility
24 proportions between the two sectors, pharmaceutical
25 and non-pharmaceutical, differ by at least as much as

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1 we actually have observed in these cases by chance
2 alone?
3 The answer to that question is the
4 P-value. So on the previous slide, when it said P
5 equals .0245, what it meant was that, by chance, we
6 would expect a separation of those two invalidity
7 proportions by that much, or even more so, only
8 2.45 percent of the time.
9 I've prepared a graphical display to
10 portray, hopefully concretely, what we mean by
11 chance. This is an illustration of what we call an
12 urn model. In front of you there's notionally an urn
13 in which I've put 71 chips colored green and colored
14 red, 71 because I was studying 71 cases involving
15 grounds of utility challenges. 46 of the chips are
16 green reflecting that, in the actual data, there were
17 46 cases held valid, and 25 chips are red, reflecting
18 the fact that, again, among those 71 there were 25
19 holdings in total of invalidity on utility grounds.
20 Now, the particular separation of these
21 chips on the basis of whether they are pharmaceutical
22 cases or non-pharmaceutical cases is one way we could
23 split this urn full of chips, but it is only one of
24 many ways, and if by "chance" what we mean is that we
25 should consider other ways, in fact, all of the ways

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1 that we could possibly split this urn into two groups
2 reflecting the number of pharmaceutical cases and
3 non-pharmaceutical cases, in fact randomly -- that
4 being the meaning of "chance" -- how often would we
5 find the observed results.
6 So on the next slide I've notionally
7 imagined drawing, or withdrawing, eight chips from
8 the urn at random and without replacement. Close
9 your eyes, don't look at the colors, withdraw eight
10 chips at random. Strictly speaking, that means all
11 possible subsets of eight chips would be equally
12 likely because it's at random.
13 Question: What color would these
14 withdrawn chips be, likely? And on the next slide we
15 see that, in fact, what we observed was all of the
16 eight chips were green, referring to the fact that
17 all of the non-pharmaceutical sectors were held as
18 valid. How likely is that? And the answer to that
19 is the P-value. So on the next slide we see, having
20 withdrawn eight random chips, all being green, the
21 likelihood of that is only 2 1/2 percent -- less than
22 2 1/2 percent of the time.
23 Because that proportion, that
24 probability, is less than 5 percent, we say that the
25 result is "statistically significant" and gives us

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1 grounds to reject the null hypothesis in favor of the
2 alternative hypothesis.
3 So to summarize my conclusions from
4 table 1, post-2005 we saw a 39.7 percentage point
5 difference in pharmaceutical versus
6 non-pharmaceutical utility-based invalidation rates,
7 that percentage point difference being clearly the
8 difference between 39.7 and 0. That difference is
9 statistically significant. Its P-value is .0245.
10 So, as I said, we reject the null in favor of the
11 alternative.
12 I was next asked to consider the similar
13 analysis pre-2005, so these are different cases;
14 there were 27 cases pre-2005, also deciding a
15 challenge on grounds of utility. If you notice two
16 things, first of all, the numbers of cases were
17 substantially smaller. In the lower right-hand
18 corner we see P equals 1.0. Since that's greater
19 than .05, we find no statistical significance.
20 The second thing you'll notice is that,
21 again, while the numbers are small, there is an 8.3
22 percentage point difference; however, in the opposite
23 direction to the hypothesized direction under the
24 alternative hypothesis. We might call that 0 minus
25 8.3 percent, a minus 8.3 percentage point difference.

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1 As a caveat, I do not make much of the
2 result in this table for the simple reason that the
3 numbers are so small, so I neither conclude to accept
4 the null hypothesis nor to reject it. The numbers
5 are too small. We call such a situation a low power
6 situation, "power" meaning the likelihood that, even
7 if there were a true difference under the
8 alternative, the chance that we would declare it as
9 statistically significant is quite low.
10 So I will summarize what I just said. A
11 minus 8.3 percent difference, sometimes we say that's
12 a difference in direction opposite to that specified
13 by the alternative hypothesis. We do not reject the
14 null hypothesis in this case. This difference is not
15 statistically significant.
16 Next, I was asked to consider in table 3,
17 the same analysis back to the post-2005 period, this
18 time where cases were decided based on challenges
19 other than utility, specifically in this table on
20 grounds of non-obviousness or novelty. Here what we
21 see are more substantial numbers in the marginal
22 totals. In the lower right-hand corner we see P
23 equals .593 so, again, we find no statistical
24 significance to this difference.
25 The distinct difference between this and

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1 the previous slide is, when we look at the actual
2 invalidity proportions, they're very, very close.
3 There's only a 0.2 percent difference between the
4 41.1 percent difference in pharmaceutical cases found
5 invalid on other grounds versus the 40.9 percent
6 invalidation proportion in non-pharmaceutical cases.
7 So here we have greater confidence when
8 we reject the null hypothesis -- when we don't reject
9 the null hypothesis to understand the reason, the
10 reason being that there's only a trivial difference
11 in the proportions themselves.
12 I'd like to add while I don't have a
13 slide for this, I also repeated the analysis,
14 including grounds of sufficiency. So when we have
15 non-obvious or novelty or sufficiency or any
16 combinations of those grounds, the results were
17 substantively the same. There was no significant
18 difference.
19 So to summarize table 3, post-2005 there
20 was a 0.2 percentage point difference in invalidation
21 rates across the pharmaceutical and
22 non-pharmaceutical sectors on grounds other than
23 utility, whether that be including or excluding
24 sufficiency. That difference arising from two very
25 close proportions, roughly 41 percent. That

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1 difference is not statistically significant. And
2 that brings me essentially to the end of my key
3 findings.
4 Just to recap, post-2005, that
5 39.7 percent difference in the proportion of
6 utility-based invalidations is statistically
7 significant. Before 2005, the 8.3 percentage point
8 difference in the opposite direction to that
9 specified by the alternative was not statistically
10 significant. And post-2005, the small, 0.2
11 percentage point difference in the proportions of
12 invalidations on other grounds between pharma and
13 non-pharma sectors was not statistically significant.
14 These three bullets are consistent with
15 the Claimant's view that Canadian utility law has had
16 a disproportionate impact on the pharmaceutical
17 sector since 2005.
18 Thank you.
19 MR. SMITH: Thank you, Professor Levin.
20 **DIRECT EXAMINATION ON BEHALF OF CLAIMANT**
21 MR. SMITH: The errata referred to
22 earlier I believe are reproduced on demonstrative
23 slide 1. Could you please pull up that slide. That
24 is at tab 3.
25 MR. BORN: 3? Or 4.

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1 MR. SMITH: Thank you. Tab 4.
 2 PROFESSOR LEVIN: Yes.
 3 MR. SMITH: Professor Levin, could you
 4 please explain the changes that are shown on
 5 demonstrative slide 1?
 6 PROFESSOR LEVIN: Yes. There were four
 7 errata that were identified. I'd like to begin, if I
 8 may, with the second line. This is the Pfizer Canada
 9 Inc. v Canada case, alternately referred to in
 10 Dr. Brisebois' report as Apotex v Pfizer. This is
 11 the only case involving a challenge on utility
 12 grounds. The correct coding is not useful. I'd like
 13 to be very clear. The only error that was involved
 14 was a typographical error that appeared in Appendix C
 15 in my original report, but it was coded correctly in
 16 my analysis. So the tables that we've been looking
 17 at did not have any influence of this printed
 18 typographical error.
 19 Then the first line and the third line
 20 represent coding errors for grounds of sufficiency,
 21 one not useful, the other useful in the
 22 pharmaceutical sector on top and non-pharmaceutical
 23 sector on line 3. These did not affect our
 24 comparisons on grounds of utility, clearly because
 25 the coding error was in the sufficiency column. And

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1 then the fourth line, similarly, was coding errors on
 2 grounds of non-obviousness and novelty.
 3 MR. SMITH: Professor Levin, do these
 4 errata have any effect on the conclusions you just
 5 summarized?
 6 PROFESSOR LEVIN: No, they do not. The
 7 statistical significance of table 1 remains because
 8 none of these cases, including Apotex v Pfizer, were
 9 in error on utility grounds. Nor did the other
 10 analyses, table 2 and table 3, remain not
 11 statistically significant.
 12 MR. SMITH: Are you familiar with the
 13 second witness statement of Dr. Marcel Brisebois?
 14 PROFESSOR LEVIN: Yes, I've reviewed it.
 15 MR. SMITH: In that statement
 16 Dr. Brisebois suggests at paragraph 10 that after you
 17 submitted your report, additional Canadian cases have
 18 been decided and published that should be considered.
 19 What, if anything, did you do in response to this
 20 comment?
 21 PROFESSOR LEVIN: I requested an updated
 22 database, which would include not only these
 23 corrections of errata but also the additional more
 24 recent cases since my report, and on the next
 25 demonstrative slide we see what those cases are.

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1 There were nine cases in total. You'll notice that
 2 two of those cases were not challenged on grounds of
 3 utility, so for the utility analysis there were seven
 4 additional cases which I included in my reanalysis.
 5 MR. SMITH: How, if at all, did your
 6 conclusions change as a result of analyzing this
 7 updated dataset that is shown on demonstrative slide
 8 2?
 9 PROFESSOR LEVIN: They did not change at
 10 all. The table 1 remains statistically significant.
 11 The other two tables remain statistically not
 12 significant. On the next demonstrative slide I have
 13 an updated table referred to here as table 1A. What
 14 you see is the seven additional cases in the lower
 15 right-hand corner. Now there are 78 cases, 69 of
 16 which were pharmaceutical, nine of which were
 17 non-pharmaceutical. There was an additional case in
 18 the interim in the non-pharmaceutical sector. When
 19 we look at the proportions found invalid on utility
 20 grounds, we find, if anything, the proportion has
 21 increased a bit. It's now 40.6 percent, almost
 22 41 percent, whereas in the non-pharmaceutical sector
 23 the percentage is still zero. Zero out of 9 this
 24 time.
 25 The increase in the proportion slightly

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1 and the increase in the sample size has caused the
 2 P-value to become smaller, meaning there's a bit more
 3 statistical significance than previously. The
 4 P-value is now .014 approximately, meaning that
 5 there's only a 1.4 probability one would find this
 6 kind of split by chance alone.
 7 MR. SMITH: So those updated findings
 8 with respect to utility appear on table 1A and
 9 demonstrative slide 3.
 10 Next, could you please discuss any
 11 changes in what appeared as table 2 in your report,
 12 based on your analysis of the updated dataset?
 13 PROFESSOR LEVIN: Yes. On the next
 14 demonstrative there's absolutely no difference in my
 15 original table 2 because, as I said, the corrections
 16 and the updated cases all occurred after 2005. So
 17 table 2 remains the same.
 18 MR. SMITH: Finally, could we please turn
 19 to demonstrative slide 5, and would you please
 20 discuss any changes to your conclusions in table 3
 21 from your original report?
 22 PROFESSOR LEVIN: Yes. Table 3A is the
 23 only one that had some additional changes to it based
 24 on the errata and the additional cases but not
 25 substantive changes. That is to say, the proportions

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1 are still not as close as they were but still
2 certainly within the realm of chance. The P-value on
3 the lower right-hand corner is still not
4 statistically significant.
5 MR. SMITH: In his second statement,
6 Dr. Brisebois suggests at paragraphs 20-26 that your
7 dataset should have excluded what are referred to as
8 PM(NOC) cases and counted only actions for
9 infringement or impeachment.
10 PROFESSOR LEVIN: Yes.
11 MR. SMITH: What, if anything, did you do
12 in response to that statement?
13 PROFESSOR LEVIN: Well, I asked for a
14 revised dataset which would now exclude the PM(NOC)
15 decisions and redid the analysis. On the next
16 demonstrative, updated table 1B, it contains actions
17 only. You see that the sample numbers -- I should
18 say the universe numbers here are drastically smaller
19 and still -- I should say notwithstanding the
20 proportion of invalid cases in the pharmaceutical
21 sector held invalid on utility grounds -- has, if
22 anything, continued to increase. There's now almost
23 43 percent of the cases among the 14 held invalid
24 still versus 0 percent among the non-pharmaceutical
25 cases.

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1 You'll see that the P-value, being less
2 than 5 percent, is still significantly significant.
3 And a comment that I'd like to draw the Tribunal's
4 attention to is that when we have markedly reduced
5 marginal totals such as we have here and, yet, we
6 still have statistically significant difference, it
7 arises because of the large substantive difference in
8 the proportions of invalidity.
9 MR. SMITH: In his second statement
10 Dr. Brisebois also suggests at paragraph 17 that the
11 dataset should have been compiled by counting patents
12 rather than individual cases. What, if anything, did
13 you do in response to that statement?
14 PROFESSOR LEVIN: I asked for a new
15 dataset in which the unit of analysis was patents,
16 because I wanted to see if the findings held up on
17 the basis of patents. I do want to point out, before
18 we discuss the results, that there is an important
19 distinction that should be kept clearly in mind,
20 which is what is the unit of analysis. I was asked
21 to consider the difference in proportion of patent
22 lawsuits, cases, and what are the invalidity
23 proportions on a case basis. I call that the unit of
24 analysis.
25 Here, we're changing the question. We're

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1 now asking whether there's a difference in the
2 proportion of patents held valid or invalid. And
3 owing to the fact that you can have several patents
4 under consideration in a single case, one has to deal
5 with the issue of the clustering of the unit of
6 analysis within the case. So there are methods of
7 addressing that. But, nevertheless, on the next
8 slide we see what the result was following Canada's
9 own approach, which was to ignore the clustering of
10 patents within cases, and simply looking at the
11 comparison of invalidity proportions without worrying
12 about whether, when we withdraw individual patents
13 from the urn, they're splitting up individual patents
14 from the same case.
15 What we see is 36.8 percent invalid in
16 pharmaceutical sectors versus that same 0 out of 9 in
17 non-pharmaceutical sector. You see in the lower
18 right-hand corner that the P-value is still about .02
19 and, therefore, still statistically significant.
20 MR. SMITH: Next, Dr. Brisebois suggests
21 that three individual cases were miscoded. What, if
22 anything, did you do in response to Dr. Brisebois'
23 proposed correction to the Pfizer v Canada case
24 discussed at paragraph 9 of his report?
25 PROFESSOR LEVIN: Once again, I requested

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1 the specific particular cases and modified the
2 analysis to reflect Dr. Brisebois' suggestions. On
3 the next slide we continued to deal at the unit of
4 analysis of patent, because that's what Dr. Brisebois
5 was using, and I added Bayer v Apotex and removed the
6 Wenzel case and, yet again, what we see is the
7 difference persists. It's a large proportional
8 percentage point difference, 36.4 versus 0. The
9 P-value is still below 5 percent, so those two
10 modifications did not alter the conclusion of
11 statistical significance.
12 MR. SMITH: Professor Levin, for the
13 record I asked you about the Pfizer v Canada case in
14 paragraph 9 of Dr. Brisebois' report. Did you make
15 reference to that case earlier in your presentation
16 in your errata?
17 PROFESSOR LEVIN: Yes, I did. That was
18 the case on the second line of the demonstrative.
19 That was the case that merely was a typographical
20 error but which was correctly analyzed in my table.
21 MR. SMITH: In your summary of updated
22 table 1D on demonstrative slide 8, you just referred
23 to the other two cases to which Dr. Brisebois
24 suggested that corrections be made, and those cases
25 are Wenzel Downhole Tools and Bayer v Apotex

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05:55

1 discussed at paragraphs 7 and 10 of his Second
2 Report. Is that correct?
3 PROFESSOR LEVIN: Yes, it is.
4 MR. SMITH: Finally, Dr. Brisebois
5 suggests at paragraph 8 of his report that cases such
6 as Eurocopter, cases with split outcomes across
7 claims within a single patent, should be coded both
8 as a win and as a loss for the innovator. In other
9 words, counted twice. What, if anything, did you do
10 in response to Dr. Brisebois' statement regarding
11 these split claims cases?
12 PROFESSOR LEVIN: Well, I was asked to do
13 the calculation, even though initially I strongly
14 objected to doing that for the simple reason that in
15 my opinion, the approach Dr. Brisebois has taken here
16 is entirely statistically invalid. It's invalid and
17 inconsistent, in fact. It's invalid because it
18 violates a fundamental statistical rule, which is
19 that when you're classifying units such as we are
20 here as either valid or invalid, the classification
21 system must be mutually exclusive and exhaustive.
22 That means that every patent, if that is your unit,
23 must be classifiable as one or the other, not both.
24 I understand the rationale Dr. Brisebois
25 took, which was to somehow reflect the different

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05:56

1 claims clustered within given patents in Eurocopter,
2 but that's an inconsistent approach. Inconsistent
3 because he could have, but did not, enumerate all the
4 individual claims, shifting the unit of analysis down
5 to the level of claims clustered within patents. He
6 could have asked what was the proportion of all
7 claims held invalid, but he did not do that. Nor did
8 I.
9 You have to decide on your unit of
10 analysis. If you're talking about claims, well, go
11 do that analysis. If you're talking about patents,
12 however, you can't all of a sudden clone a patent and
13 call it both valid and invalid. Obviously, for
14 example, if you look at the total number in the
15 margin of the table, you'd get the wrong number of
16 patents. So this is not a statistically valid
17 approach.
18 MR. SMITH: Nonetheless, did you perform
19 the analysis as suggested by Dr. Brisebois using his
20 coding, coding you consider improper for these split
21 claims cases?
22 PROFESSOR LEVIN: Yes, I did.
23 MR. SMITH: What were the results?
24 PROFESSOR LEVIN: The difference was not
25 statistically significant at that point. I looked at

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05:58

1 various versions of this, looking at the corrections,
2 looking at the patents. All of them with that
3 inappropriate coding scheme resulted in a loss of
4 statistical significance.
5 MR. SMITH: Professor Levin, could you
6 please summarize your overall findings in response to
7 Dr. Brisebois' statements?
8 PROFESSOR LEVIN: Yes. In my opinion,
9 the variations in the data, the variation in the
10 approach, whether it be patent or case, removing the
11 PM(NOC) cases, with the sole exception of what I
12 consider to be an entirely invalid statistical
13 approach, all of those results confirm the
14 statistical significance of the difference between
15 pharmaceutical and non-pharmaceutical proportions of
16 invalid cases, or patents for that matter, post-2005.
17 The other findings in my table 2 and
18 table 3 also remain unchanged. I want to point out
19 that that is not a foregone conclusion. That is to
20 say, if we assume that we'd always get the same
21 result, that's not generally the case. The fact that
22 we did get the same result, as I said with the
23 exception of the inappropriate tact, actually
24 bolsters confidence in the robustness of the
25 statistically significant finding or the lack thereof

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05:59

1 in tables 2 and 3.
2 MR. SMITH: Thank you. Mr. President,
3 that concludes our direct examination.
4 THE PRESIDENT: I think we will continue,
5 then, the cross-examination tomorrow, unless you have
6 not a long cross-examination?
7 MR. SPELLISCY: I think the
8 cross-examination will be longer than negative five
9 seconds. So I would suggest it's probably going to
10 be a bit longer than we would want to do tonight. I
11 think it's best to wait until tomorrow, which puts us
12 slightly behind our optimistic schedule, but maybe we
13 can make up some more ground tomorrow.
14 THE PRESIDENT: I cannot leave tonight
15 without knowing how you have calculated the P-value.
16 What's the formula?
17 PROFESSOR LEVIN: It's a formula that
18 involves three so-called binomial coefficients. When
19 you want to calculate, if we could go back to the
20 urn --
21 THE PRESIDENT: I know how you calculate
22 if you roll two dice and you know that the dice are
23 fair, the null hypothesis.
24 PROFESSOR LEVIN: Yes.
25 THE PRESIDENT: Then I see then if you

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06:01

1 get two times 6 you get 36, then I think it is then
 2 you get a 2.8 percentage because you diverge -- you
 3 divide by 36 and the calculation goes on. So there I
 4 understand the calculation of the P-value. But how
 5 do you calculate it here? What is the formula?
 6 PROFESSOR LEVIN: Yes. The formula was
 7 introduced by Sir Ronald Fisher, the father of
 8 biostatistics in his book called The Design of
 9 Experiments.
 10 Looking at the demonstrative slide here,
 11 we see the red and the green chips. Now we're going
 12 to withdraw eight at random. So how many ways are
 13 there of withdrawing a certain number of green chips?
 14 For example, let's ask ourselves all the green
 15 chips --
 16 THE PRESIDENT: May I cut you short here,
 17 with all due respect. In this case what is the
 18 formula you used to arrive at -- and if you go to
 19 slide -- and actually for your main finding, if you
 20 go to slide 6, table 1.
 21 PROFESSOR LEVIN: Yes.
 22 THE PRESIDENT: You see here this. What
 23 is the underlying formula, so how you get to the
 24 number?
 25 PROFESSOR LEVIN: Yes. It's a product of

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06:02

1 two binomial coefficients divided by a third binomial
 2 coefficient. A binomial coefficient counts the
 3 number of ways you could withdraw these chips from
 4 the urn. So the formula is 25 -- choose 25 whose
 5 value is 1. That first 25 is from the bottom margin.
 6 The second 25 is from the first row. You multiply
 7 that by 46, choose 38, the so-called binomial
 8 coefficient, 46 from the bottom row and 38 from the
 9 top row. And that's a very large number. The way
 10 you calculate a binomial coefficient is you multiply
 11 46 times 45 times 44 for 38 factors and divide by 38
 12 factors. Calculators can do this quite readily. And
 13 then, finally, you divide by the total 71, choose 63.
 14 THE PRESIDENT: I suggest tomorrow we
 15 have drawing board and you take us through the
 16 calculation.
 17 PROFESSOR LEVIN: I'd be happy to.
 18 THE PRESIDENT: Does the name
 19 Pierre-Simon Laplace tell you something?
 20 PROFESSOR LEVIN: I know Laplace very
 21 well. I'm not following your reference.
 22 THE PRESIDENT: Because you said that the
 23 P-values were invented or developed by -- and then
 24 you used a name. But my understanding is -- but
 25 please correct me if I'm wrong -- that Pierre-Simon

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06:04

1 Laplace was the original inventor of the P-value, is
 2 that correct? In 1770, I think it was.
 3 PROFESSOR LEVIN: Yes, I was referring to
 4 Sir Ronald Fisher as the inventor of the so-called
 5 Fisher Exact Test, which is exactly what I've used
 6 here. That P-value is the result of applying
 7 Fisher's Exact Test.
 8 THE PRESIDENT: So you don't use
 9 Laplace's method?
 10 PROFESSOR LEVIN: Laplace was talking
 11 about an entirely different mathematical problem,
 12 that of predicting whether the sun will rise the next
 13 day.
 14 THE PRESIDENT: Let's wait for that
 15 tomorrow. Can't wait! Thank you so much.
 16 You're under testimony, Professor Levin.
 17 That means that you are not allowed to discuss this
 18 case with anyone.
 19 PROFESSOR LEVIN: Yes.
 20 THE PRESIDENT: We will see each other
 21 tomorrow at 9:00.
 22 (Hearing adjourned at 6:05 p.m.)
 23
 24
 25

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1194/10	2006-2014 [1]	963/20 964/17
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1068/21	1138/19	1058/8
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1177/11	1092/14	1058/25
1177/21	1148/15	1059/5 1059/9
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22 [5] 962/11	1221/5 1221/6	1023/8
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	1127/10	1162/14
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1049/23	1051/24	972/17 973/8
1050/5 1050/8	29 [3] 1162/17	34 [7] 972/3
1050/16	1175/10	977/3 1120/25
1050/25	1184/17	1124/2
1051/4	2:00 [1]	1124/10
1051/10	1084/4	1124/15
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1071/10	1127/19	965/21 965/22
1079/19	1128/21	35 [7] 1047/25
1123/22	1138/1	1092/8 1114/7
1124/3	1175/12	1163/16

3	1131/2 1150/1	1200/17
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1163/17	1221/11	1028/18
1163/18	1221/11	1028/19
1164/12	38-47 [1]	1030/1
355 [1] 968/10	963/22	40.6 percent
36 [7] 1047/14	380 [1] 964/18	[1] 1210/21
1124/11	381 [2] 973/14	40.9 percent
1130/2 1130/4	981/18	[1] 1206/5
1132/5 1220/1	39 [1] 1131/10	404 [1] 985/25
1220/3	39.7 [2]	40th [1]
36.4 [1]	1204/4 1204/8	1028/23
1215/8	39.7 percent	41 [4] 1082/11
36.8 percent	[2] 1200/17	1132/8
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364 [1]	3A [1]	1133/5
1136/18	1211/22	41 percent [2]
37 [2] 984/7	3AL [1]	1206/25
1130/6	953/16	1210/22
375 [1]	4	41.1 percent
1178/19	40 [2] 1023/15	[1] 1206/4
38 [10] 963/3	1131/18	412 [2] 971/13
963/3 963/11	40 percent [2]	972/14
1073/21	1199/5	414 [2] 958/1

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415 [2] 959/20 960/8	1091/18	5 percent [3] 1203/24
42 [2] 1005/8 1006/5	469 [1] 1111/20	1213/2 1215/9
43 [1] 963/6	47 [10] 962/4	50 [3] 1148/16
43 percent [1] 1212/23	962/5 963/1	1148/17
44 [6] 963/25 964/5 1066/7	963/3 963/11	1148/20
1066/10	963/14 963/16	507 [1] 1183/21
1138/15	963/22	508 [3] 1183/8
1221/11	1052/18	1183/18
447 [1] 1095/24	1053/19	1183/25
449 [2] 982/14 982/19	48 [1] 960/8	51 [4] 984/17
45 [1] 1221/11	48 minutes [1] 1078/17	985/7 1149/15
46 [6] 1071/19 1202/15	480-Box [1] 953/7	1156/14
1202/17	49 [2] 953/12	513 [7] 1054/23
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	493 [2] 1189/15	1059/18
	1189/21	1182/17
	4th [1]	1183/18
		1190/2 1190/3
		52 [2] 986/12

5	1163/22	1112/13
52... [1] 1150/7	59 [1] 1050/14	1112/19
520 [2] 1080/4 1195/18	6	1115/8
521 [1] 1132/4	60 [3] 962/11 1023/8 1067/3	1116/16
53 [3] 1052/1 1151/10 1174/2	61 [3] 998/24 999/19 1082/4	1182/23
532 [1] 1175/11	613.233.1781 [1] 954/17	1182/25
54 [2] 1152/11 1152/17	63 [1] 1221/13	71 [8] 1054/17
544 [1] 1052/13	640 [1] 1130/4	1182/23
545 [2] 1184/25 1185/2	69 [1] 1210/15	1182/25
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56 [3] 1048/21 1049/7 1131/14	7	1202/14
57 [1] 1050/7	70 [16] 1054/4 1054/7 1054/9	1202/14
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	1086/21	1221/13
	1088/10	72 [1] 1194/7
	1099/24	75 [4] 1060/18
	1101/16	1062/13
	1104/1 1106/1	1138/18
		1147/16
		76 [1] 1139/16
		77 [5] 1126/10
		1126/12
		1143/6
		1143/14

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<p>8</p> <hr/> <p>8.3 [3] 1204/21 1204/25 1207/7</p> <p>8.3 percent [2] 1204/25 1205/11</p> <p>80 [1] 1142/2</p> <p>80 percent [2] 965/4 965/15</p>	<p>9</p> <hr/> <p>9.04 [3] 962/14 963/4 963/7</p> <p>9.04.01a [1] 963/24</p> <p>9.04.01b [2] 962/20 963/14</p> <p>90 grams [1] 1184/6</p> <p>92-95 of [1]</p>	<p>A</p> <hr/> <p>a fault [1] 1102/21</p> <p>a.m [1] 957/1</p> <p>ab [1] 1031/24</p>

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ab initio [1]	961/14 962/23	1041/18
1031/24	963/19 967/14	1042/19
abbreviated	968/19 977/7	1045/14
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abilities [1]	982/15 986/16	1055/14
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able [11]	1000/24	1059/5
1002/1	1011/3 1013/9	1061/25
1003/24	1013/15	1067/16
1010/12	1014/19	1070/6
1011/4	1015/23	1071/22
1016/24	1017/5	1084/17
1053/11	1017/10	1084/18
1083/13	1017/23	1085/24
1110/15	1019/14	1086/4 1088/8
1160/25	1030/11	1092/15
1161/2	1032/14	1100/4
1192/12	1033/17	1101/11
ably [1]	1033/18	1102/6
1172/5	1038/3 1038/4	1102/18
abolish [1]	1038/11	1105/6
1074/3	1039/14	1105/13
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<p>A</p> <p>accept... [10] 1055/17 1056/4 1084/1 1084/2 1107/14 1158/5 1158/14 1159/6 1161/23 1205/3</p> <p>accepted [5] 1017/11 1086/2 1148/8 1155/6 1156/13</p> <p>accomplish [1] 1136/7</p> <p>accordance [3] 1023/4 1155/2 1196/25</p> <p>according [10] 977/18</p>	<p>1029/23 1035/4 1036/9 1045/22 1052/1 1060/14 1115/1 1137/17 1155/13</p> <p>Accordingly [2] 1121/18 1128/2</p> <p>accurate [3] 1098/25 1099/9 1146/3</p> <p>accuses [1] 1191/5</p> <p>ACE [1] 1127/3</p> <p>achieve [2] 984/25 1039/17</p> <p>achieved [5] 1041/9 1055/6 1055/21</p>	<p>1097/5 1184/4</p> <p>achieves [1] 1183/24</p> <p>achieving [1] 1125/24</p> <p>acid [2] 1001/3 1001/5</p> <p>acknowledge [1] 1145/25</p> <p>acronym [1] 1066/22</p> <p>across [5] 1012/4 1044/2 1199/17 1206/21 1216/6</p> <p>act [48] 958/10 958/16 958/18 958/22 959/3 971/2 971/20 971/21 972/3 972/6 973/25 974/24 977/3 983/1</p>
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<p>A</p> <p>act... [34]</p> <p>984/21 984/23</p> <p>985/1 986/10</p> <p>995/2 1005/9</p> <p>1006/5</p> <p>1030/25</p> <p>1031/5</p> <p>1031/24</p> <p>1032/9</p> <p>1032/12</p> <p>1045/22</p> <p>1046/4</p> <p>1046/12</p> <p>1046/21</p> <p>1047/2 1047/6</p> <p>1048/6 1049/2</p> <p>1050/16</p> <p>1067/3 1079/6</p> <p>1120/25</p> <p>1123/22</p> <p>1124/3</p> <p>1130/10</p> <p>1133/14</p>	<p>1137/3 1137/7</p> <p>1150/2</p> <p>1150/10</p> <p>1155/2</p> <p>1157/16</p> <p>acted [5]</p> <p>1028/16</p> <p>1029/1 1029/5</p> <p>1171/14</p> <p>1188/17</p> <p>acting [1]</p> <p>1188/20</p> <p>action [20]</p> <p>958/2 971/24</p> <p>972/2 972/5</p> <p>972/7 972/8</p> <p>972/10 983/21</p> <p>994/4 1067/5</p> <p>1067/25</p> <p>1074/4 1074/8</p> <p>1074/15</p> <p>1074/17</p> <p>1074/19</p> <p>1075/19</p>	<p>1075/19</p> <p>1076/4 1188/3</p> <p>Action' [1]</p> <p>972/8</p> <p>actions [9]</p> <p>960/14 971/22</p> <p>983/18 983/18</p> <p>1068/17</p> <p>1069/20</p> <p>1074/5 1212/8</p> <p>1212/16</p> <p>active [2]</p> <p>1069/7</p> <p>1096/15</p> <p>activity [11]</p> <p>1004/22</p> <p>1091/7</p> <p>1095/15</p> <p>1095/22</p> <p>1096/3 1096/5</p> <p>1096/11</p> <p>1096/18</p> <p>1096/25</p> <p>1168/14</p>
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1025/22	1066/14	adapted' [1]
1033/9	1077/20	1137/6
1094/23	1091/24	add [5]
1136/25	1097/5 1129/4	1100/22
1150/8 1151/6	1130/14	1183/2
1151/21	1135/11	1185/23
1176/19	1154/13	1198/14
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1206/1	1158/20	added [4]
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979/22 991/10	1160/12	1129/12
996/4 996/16	1164/10	1215/5
1002/19	1194/22	addition [1]
1008/23	1195/18	1120/1
1010/4 1013/3	1202/1	additional [14]
1018/3	1218/23	965/25
1019/12	1220/19	968/13 988/9
1021/12	ad [1] 1009/8	1025/8
1026/8	ad hoc [1]	1025/20

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1209/17	1000/14	1058/17
1209/23	1001/17	1058/22
1210/4	1082/19	1059/6 1059/9
1210/14	adequately [1]	1059/10
1210/17	1106/14	1060/11
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address [1]	1161/12	1189/18
1120/20	adhesion [29]	1189/19
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1000/4	1055/20	1190/6
1005/12	1056/11	1190/10
1012/6	1056/12	1190/11
1133/11	1056/13	adjourn [2]
addressee [1]	1056/16	1134/12
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addressing [3]	1056/21	adjourned [1]
1121/1	1057/8	1222/22
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	advantages [3] 1035/21 1041/8 1050/19	
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1003/8	1158/6	1087/13
1017/23	1158/15	1120/20
1051/21	1159/7	1149/18
1057/7	1159/13	1152/5
1080/22	1161/24	1155/22
1084/15	1171/6 1171/9	1156/6
1094/10	1191/3 1198/1	1169/21
1101/11	1199/11	1173/19
1101/18	1209/16	1196/1
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1116/14	1196/3 1198/6	1214/25
1122/2	afterwards [2]	1215/6
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1129/4	again [23]	1066/15
1139/10	964/9 981/17	1067/4
1141/5	1037/17	1171/15
1141/12	1041/17	1173/9 1186/8
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agent [3]	1007/21	1153/13
986/1 986/6	1015/19	1153/24
1041/15	1046/8	1160/6 1171/3
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1013/17	1092/21	1183/20
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989/9 991/8	1065/24	1119/14
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1013/15	1088/17	1135/17
1018/13	1091/20	1135/22
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1018/18	1095/14	1139/25
1023/25	1098/2	1140/11
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happened [8]	1159/6	1018/16
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1044/7 1061/4	1185/12	1026/23
1062/13	1185/14	1028/11
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1110/21	1020/23		1058/3
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1097/25	1107/17	1144/4 1144/6
1099/15	1107/20	1144/8
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1100/23	1110/14	1144/24
1102/5	1111/17	1145/8 1147/3
1102/10	1115/19	1153/13
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1102/15	1125/18	1153/25
1102/16	1125/19	1153/25
1102/18	1125/19	1154/3 1154/5
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1103/10	1133/7	1155/25
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1009/16	1038/10	1192/7 1201/2
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1055/12	1094/19	1220/16
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958/17 968/10	1120/10	1222/6
970/4 970/22	1122/4 1125/4	here's [4]
977/17 979/11	1133/19	1019/18
984/21 995/23	1135/11	1096/6
996/21 997/20	1146/23	1180/19

H	1089/23	1044/4
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high [8] 966/1	1029/4	1049/3 1050/9
1016/4 1016/8	1104/21	1050/22
1042/8	1140/2	1051/17
1056/12	1163/25	1055/12
1057/12	himself [1]	1058/6
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1016/4 1016/8	his [49]	1090/8 1090/9
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1037/14	1020/22	1095/18
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1152/20	1025/11	1138/9 1140/1
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1013/16	1108/3	1005/22
1013/20	1113/23	1023/25
1013/21	1124/19	1025/7
1014/9	1157/14	1032/13
1016/15	1157/23	1042/8 1079/7
1017/23	1158/10	1083/16
1019/5 1019/9	1159/10	1087/25
1019/18	1168/6 1173/2	1101/25
1024/6 1024/7	1173/20	1106/16
1043/2	1180/24	1111/23
1045/10	1181/1 1187/3	1121/1
1050/17	1187/5 1192/9	1121/10
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1065/13	1201/23	1139/8
1076/9	1203/4	1147/23
1076/12	1203/18	1162/11
1082/19	1210/5	1175/16
1085/2	1219/15	1176/16
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1085/3	1006/21	1077/25
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1106/22	1014/17	1085/4 1085/7
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1107/25	1019/10	1118/21
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1014/9	1030/19	1062/18
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1014/15	1031/25	1071/3 1071/4
1014/16	1035/11	1072/20
1016/10	1036/14	1077/13
1016/17	1036/24	1077/14
1016/24	1037/13	1079/12
1018/7 1018/9	1039/2 1039/2	1082/22
1018/11	1039/3	1085/8
1018/12	1040/18	1090/12
1018/12	1040/25	1093/19
1018/18	1044/7	1105/15
1019/22	1044/16	1105/21
1020/14	1052/23	1106/23
1020/17	1053/11	1107/19
1021/6 1021/6	1055/24	1107/25
1024/5	1060/4 1060/6	1108/4 1110/7
1024/11	1060/7	1121/5 1127/2
1024/12	1060/10	1128/18
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1150/23	1203/11	1150/17
1150/25	1203/13	1150/19
1151/2 1151/8	1205/8	1154/1
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963/16 963/23	986/4 986/15	1044/11
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964/11 964/15	990/15 990/19	1046/2
964/20 965/1	990/24 992/7	1046/14
965/10 965/13	993/15 994/24	1046/18
965/17 965/20	995/6 995/10	1046/22
967/14 967/21	997/17 999/25	1047/3 1047/7
969/3 969/6	1001/20	1047/8
969/11 969/18	1002/5 1003/6	1047/15
969/25 971/14	1004/8 1007/6	1047/24
971/17 971/25	1007/15	1048/3
973/12 973/17	1007/21	1048/11
973/22 974/19	1008/2 1016/1	1048/22
975/5 975/9	1017/8 1018/2	1049/8
975/13 975/25	1021/15	1049/11
976/3 976/6	1021/19	1049/19
976/11 976/18	1023/11	1052/4
977/5 979/18	1023/17	1052/11
982/6 982/16	1023/23	1052/17
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983/14 983/16	1026/3	1053/20

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1060/16	1081/2 1081/6	1116/25
1060/21	1083/1 1084/1	1118/3
1063/11	1085/14	1121/25
1064/7	1086/10	1122/13
1064/11	1086/16	1124/4
1064/22	1086/20	1124/20
1066/20	1086/23	1127/13
1068/18	1090/1	1128/8
1069/7	1090/13	1128/13
1069/17	1090/17	1130/24
1070/1	1094/12	1131/8
1070/17	1097/3 1098/8	1133/24
1071/11	1098/17	1134/2
1071/16	1100/4	1134/11
1071/20	1101/18	1134/20
1072/7	1102/18	1137/18
1072/13	1104/3	1137/22
1072/18	1106/21	1138/2 1144/7
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1145/21	1178/23	1211/13
1146/4	1179/14	1211/22
1146/19	1179/15	1212/10
1149/19	1179/21	1215/17
1152/9	1180/18	1216/3
1154/11	1180/18	1217/22
1156/8	1183/4	1218/8
1156/11	1183/12	1219/24
1156/16	1184/8	1220/6
1160/15	1185/13	1220/21
1161/10	1185/21	1220/25
1163/20	1186/14	1222/3
1163/24	1186/25	1222/19
1166/1 1169/8	1188/1 1189/9	yesterday [5]
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1171/22	1189/16	1027/17
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1172/17	1196/17	[2] 994/19
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yet [8]	979/14 980/19	1063/2
1019/12	987/2 1002/2	1067/13
1020/8	1037/20	1069/7
1020/15	1040/10	1076/16
1068/24	1074/13	1089/6
1141/9	1083/2 1088/9	1108/18
1162/14	1101/2 1110/5	1110/2 1146/5
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1129/12	963/19 967/14	1217/10
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1019/17	1196/15	1018/23
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1021/7	962/11 962/11	1019/16
1022/17	963/13 967/9	1020/25
1030/25	968/11 968/25	1022/10
1032/21	970/9 970/10	1022/18
1033/2 1033/4	973/18 973/19	1023/7
1033/7	973/20 974/17	1023/10
1033/17	974/20 980/20	1023/10
1065/16	981/19 981/25	1023/13
1081/7	986/12 986/17	1023/16
1103/18	988/6 991/25	1023/16
1118/2	996/13 997/15	1035/21
1119/24	998/15 999/19	1036/7 1036/9
1129/14	1001/7 1016/3	1043/18
1160/2 1163/4	1017/6	1044/25
1164/22	1017/12	1046/10
1166/4	1018/5 1018/7	1052/14
1166/19	1018/8	1053/22
1167/3 1167/3	1018/11	1053/25
1168/3	1018/14	1060/14

Y	1089/3 1090/2	1125/15
your... [131]	1090/19	1125/18
1060/17	1092/5 1092/7	1126/6 1133/4
1061/14	1092/14	1134/22
1061/21	1095/3	1135/7
1062/1 1062/2	1098/20	1136/17
1062/12	1099/3	1136/21
1062/13	1100/11	1137/24
1062/16	1103/15	1138/3
1062/19	1103/18	1145/25
1064/9 1066/7	1103/20	1146/21
1070/11	1103/21	1158/23
1071/9	1106/7	1160/23
1071/13	1107/24	1161/1
1071/17	1110/11	1161/13
1073/17	1111/5 1111/5	1162/14
1073/20	1111/6 1113/5	1162/15
1078/8 1078/9	1118/19	1162/15
1079/1	1118/19	1163/12
1080/21	1119/3	1166/11
1082/5	1119/16	1166/12
1082/11	1119/24	1168/8
1082/23	1124/10	1168/24
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