

Confidential - Subject to Protective Order

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE: PROPECIA : Master File No. 1:12-md-
(FINASTERIDE) PRODUCTS : 02331-BMC-PK
LIABILITY LITIGATION :
: MDL NO. 2331

This Document Relates to: :
: Honorable Brian M. Cogan
ALL CASES : Magistrate Judge Peggy Kuo

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Videotaped Deposition of PAUL HOWES, taken
before and by Janis L. Ferguson, RPR, CRR, Notary
Public and for the Commonwealth of Pennsylvania,
on Tuesday, June 7, 2016, commencing at 9:34 a.m.,
at the Penn Stater Hotel and Conference Center,
215 Innovation Boulevard, State College, PA 16803.

Reported by Janis L. Ferguson
Registered Professional Reporter
Certified Realtime Reporter

1 the video record.

2 MR. BECKER: All right. So off the record we
3 had a brief colloquy with counsel. We don't
4 have an ELMO, and our computer is not hooked
5 up to the screen. So in lieu of putting --
6 we might put one picture up a little bit
7 later. But in lieu of putting up documents
8 on the screen, we have an agreement that if
9 and when we go to trial, and if the document
10 is offered and accepted into evidence or
11 offered for use at trial, we can refer to the
12 document that we discussed during the
13 deposition, or those portions of it in the
14 picture and picture context with the
15 witnesses. Is that basically our agreement?

16 MR. MORROW: Agreed.

17 MR. BECKER: Okay.

18 BY MR. BECKER:

19 Q. All right. Now, Mr. Howes, I'm showing you
20 an article from the Wall Street Journal dated
21 August 12th, 1997 entitled "Bet on Fewer Blockbusters".
22 Do you see that there?

23 A. Yes.

24 Q. Okay. Direct -- let me direct your attention

1 to the first paragraph of the document. It says, "Some
2 of the nation's best-known prescription drugs are on
3 the brink of a sales plunge, and drugmakers are
4 scrambling to survive it. About 40 drugs with
5 16 billion in sales last year -- one-quarter of the
6 industry's U.S. revenues and an even higher percentage
7 of total profits for some companies -- are set to lose
8 patent protection by the end of 2002."

9 Did I read that correctly?

10 A. Yes.

11 Q. Okay. During this period of time -- and by
12 "this period", I mean the late '90s to early 2007 --
13 Merck was facing the loss of several key patents with
14 respect to significant drugs that produced large
15 volumes of revenue for the company. Correct?

16 MR. MORROW: Objection. You may answer.

17 A. Yeah. Patent expires are known years in
18 advance of when they occur.

19 Q. Right. And there were a series of drugs that
20 were going to go off patent in this 1997 to 2002 time
21 frame that Merck possessed the patent to, right?

22 A. Yes.

23 Q. Okay. Now, as a relatively high-ranking
24 member at Merck, you had an understanding that

1 patent protection affords the company a monopoly
2 on its ability to sell certain drugs. Correct?

3 MR. MORROW: Objection.

4 A. Yes.

5 Q. And as a result of that monopoly, you have
6 the ability to engage in premium pricing or brand
7 pricing for a particular pharmaceutical. Correct?

8 MR. MORROW: Objection. You may answer.

9 A. Pricing -- in this period of time, pricing on
10 an annual basis went up generally less than the rate of
11 inflation. It was very predictable.

12 Q. What I'm getting at is that you can't sell
13 it --

14 A. Right. Illegal competition is not permitted
15 until the patent expires.

16 Q. Okay. A couple of things -- and I didn't go
17 over the rules of deposition before, and I apologize.
18 So depositions are a very weird way of communicating.
19 You knew exactly where I was going with that question,
20 and you answered it. But because of the fact that --
21 if we were having a real conversation, we would do
22 that. But in a deposition, I have to ask my question,
23 and then you have to answer. Otherwise, it reads
24 really poorly on --

1 A. Okay.

2 Q. -- on the deposition.

3 And the other thing, too, your lawyer from
4 time to time is going to object. Unless he tells you
5 not to answer the question, allow him to put his
6 objection on the record, and then go ahead and answer
7 it. Okay?

8 A. So if he states an objection, I should wait
9 until he finishes --

10 Q. When he's done with his objection, then you
11 may go ahead and answer, unless he tells you not to.
12 Okay.

13 A. Thank you.

14 Q. All right. So patent protection, generally
15 speaking -- I'm not asking for a legal conclusion --
16 affords the company to be the sole distributor of that
17 product in the marketplace. Correct?

18 A. Yes.

19 Q. Okay. So, for example, you had during this
20 time period a statin that you were selling. Right?

21 A. Yes.

22 Q. Okay. And you, as the -- you were the only
23 company, as a result of your patent protection, that
24 could sell that statin. Right?

1 A. Correct.

2 Q. Now, when that patent expired, that allowed
3 competitors to come into the marketplace. Right?

4 A. Yes.

5 Q. And you could no longer sell that patent for
6 the price -- or sorry. You could no longer sell that
7 product for the price you were selling it at. True?

8 MR. MORROW: Objection.

9 A. (No response.)

10 Q. I mean, you could sell it, but nobody would
11 buy it. Right?

12 A. People did buy it. Fewer people bought it.

13 Q. Right. When a patent expires, is it fair to
14 say that the generics tend to take over the market?

15 A. Over time, they do, yes.

16 Q. And that's because the generics --

17 A. For that single chemical entity. There are
18 other statins.

19 Q. Right. I'm only talking about --

20 A. Right.

21 Q. -- that one product.

22 A. Yeah.

23 Q. And the reason that the generics tend to take
24 over the market over time is because for that same

1 chemical entity, they are charging less than what the
2 brand manufacturer, like Merck, is charging. True?

3 A. Yes.

4 Q. Okay. So during this time period, from 1997
5 through 2002, you were aware of the fact that Merck
6 faced a large number of expiring patents related to key
7 drugs it was selling. Right?

8 MR. MORROW: Objection.

9 A. Correct.

10 Q. Okay. In fact, if you look at Exhibit 227,
11 directing your attention to about a third of the way
12 down the page where it says "at the epicenter"? Do you
13 see that?

14 A. Yes.

15 Q. "At the epicenter of the patent expiration
16 quake is giant Merck and Company, which will lose a
17 lock on four drugs that provide more than half of its
18 6.18 billion U.S. drug sales last year, including heart
19 drugs Vasotec and Mevacor."

20 Do you see that?

21 A. Yes.

22 Q. Okay. So during this time period, prior to
23 the launch of Propecia, Merck was aware of the fact
24 that at least half of its revenue related to four key

1 drugs --

2 A. U.S. revenue.

3 Q. U.S. revenue -- was going to face competition
4 from generic entrants into the marketplace. Right?

5 A. Correct.

6 Q. And that's not necessarily a good thing for
7 the company, is it?

8 MR. MORROW: Objection.

9 A. It all depends on what else is going on with
10 the company, I would say. So it's-- of course, if it
11 doesn't happen, that is better. The fact that it does
12 happen is known. It's predictable. Maybe you're going
13 to show me what their revenues worldwide were each of
14 the following years, what the profitability was. But
15 it's -- it's all --

16 Q. Something you have to plan for, right?

17 A. You have to plan for, correct.

18 Q. And there's a couple of different ways that
19 you can plan to confront generic entrants into the
20 market. Correct?

21 A. Yes.

22 Q. Okay. One of those ways is that you can
23 develop your own generic pharmaceuticals. Correct?

24 A. Yes.

1 (Deposition Exhibit 228 - New York Times
2 article titled "Merck Sets Generic Drug
3 Sales" - marked for identification.)

4 Q. Okay. Let me show you what I've marked as
5 Exhibit 228. Keep 227 there. We're going to come back
6 to it.

7 This is an article from the New York Times
8 dated September 8th, 1992 entitled "Merck Sets Generic
9 Drug Sales".

10 (Discussion held off the record.)

11 Q. It's a long table. I've give you two, and
12 you can just pass one to Chip.

13 All right. So recognizing that it was going
14 to face a number of key drugs going off patent, Merck
15 developed some strategies to -- to backfill in the
16 revenue it anticipated to lose from those particular
17 products. Correct?

18 A. Yes.

19 Q. And one of the methods it chose to undertake
20 was to develop or enter into the generic market.
21 Correct?

22 A. Yes.

23 Q. Okay. Specifically, the very first paragraph
24 of this article says, quote, "An announcement by Merck

1 & Company that it would market lower-priced generic
2 versions of its products signals that even the world's
3 most powerful drug companies cannot ignore the
4 possibility of sharp revenue decline when important
5 drugs lose patent protection."

6 Did I read that correctly?

7 A. Yes.

8 Q. Okay. So one of the things that you did to
9 fend off that loss of revenue was to start to compete
10 in the generic marketplace.

11 MR. MORROW: Objection.

12 Q. True?

13 MR. MORROW: Objection.

14 A. Yes.

15 Q. Turn to the next page of the packet.

16 A. (Witness complies.)

17 Q. The last paragraph of this article says,
18 "Merck also has a joint venture with Johnson & Johnson
19 to sell over-the-counter versions of Merck drugs,
20 notably Pepcid, an ulcer treatment whose patent expires
21 in August 2000. Analysts said Merck might end up
22 selling Pepcid in three forms; the original, a generic,
23 and a non-prescription version."

24 Did I read that correctly?

1 A. Yes.

2 Q. Okay. So a second way that you can compete
3 with expiring patents is that you can take a drug and
4 make it -- or ask the FDA to make it non-prescription.
5 Correct?

6 A. Yes.

7 Q. That means over-the-counter. Right?

8 A. Correct.

9 Q. And, in fact, that's what you did with
10 Pepcid. Right?

11 A. With a different strength of the Pepcid.

12 Q. Right. So today -- I mean, if the jury goes
13 out and is looking for acid reflux medicine, they can
14 buy Pepcid AC over the counter. Right?

15 A. Yes.

16 Q. Okay. And that's a revenue source for Merck.
17 Right?

18 A. Yes.

19 Q. But it's fair to say that of the three types
20 of revenue sources you have, brand, generic, and over
21 the counter, the way you make the most money, the most
22 revenue, is through the sale of brand drugs. Correct?

23 A. Correct.

24 MR. MORROW: Objection.

1 Q. And so the third way that you decided -- that
2 the company tried to fend off this loss of patent
3 protection was to, in fact, develop new drugs. True?

4 A. Yes.

5 Q. Go back to Exhibit 227, if you would.

6 A. (Witness complies.)

7 Q. Directing your attention to the first page of
8 the document, about two-thirds of the way down, do you
9 see the sentence that starts with "to avert calamity"?

10 A. Um-hum.

11 Q. It says, "To avert calamity, major
12 pharmaceutical companies are racing to find new drugs
13 to replace the billions in dollars in sales they stand
14 to lose. They are embracing risky new technology more
15 quickly and scouting the world for alliances and
16 drug-licensing deals."

17 Did I read that correctly?

18 A. Yes.

19 Q. Okay. And as we just discussed, that was one
20 of Merck's strategies as well; to, quote, develop new
21 drugs. Right?

22 MR. MORROW: Objection.

23 A. Yes.

24 Q. Or find new drugs. Right?

1 A. Um-hum.

2 Q. And that's what they did with Propecia.

3 Right?

4 MR. MORROW: Objection.

5 A. I'm not sure I understand the question.

6 Could you clarify it, please.

7 Q. Sure. Merck developed Propecia in the hopes

8 that it would help to backfill some of the loss of

9 revenue from these expiring patents.

10 A. Merck developed Propecia because it already

11 had the molecule finasteride, and it discovered through

12 research that this product grew hair. That's why it

13 developed the product; to meet an unmathematical need.

14 In meeting unmathematical needs, the company can earn

15 revenue and sustain itself.

16 Q. Okay. We'll get there in just a minute. But

17 what I want to be clear on is the development of

18 Propecia and the launch of it in early 1998 allowed

19 Merck to sell that drug for male hair loss at a brand

20 rate. Correct?

21 A. Yes.

22 Q. Okay. Now, if you see the sentence where it

23 says "still some observers".

24 A. Yes.

1 Q. It says, "Still some observers doubt all of
2 this effort will be enough. It can take 15 years to
3 turn a newly created molecule into an improved product
4 with many more failures than successes along the way.
5 Only about one in 250 chemical compounds that go into
6 the laboratory and animal testing ultimately make it to
7 the pharmacy shelves."

8 Did I read that correctly?

9 A. Yes.

10 Q. All right. So at the time that Merck was
11 facing these expiring patents, it had the happy
12 fortuitiveness that it just happened to have a molecule
13 it could distribute in a completely different way for a
14 completely different use. True?

15 MR. MORROW: Objection.

16 A. Yes.

17 Q. Okay. And that molecule then, which became
18 Propecia, allowed it to sell that product at a brand
19 rate throughout the life of the patent. Correct?

20 A. Correct.

21 Q. And that was, what, roughly 15 years?

22 A. Probably.

23 Q. Okay. So unlike most drugs that Merck's
24 developed, it did not have to go through the 15-year

1 process to develop Propecia through finding a new
2 chemical compound and then engaging in the R & D it
3 would take to bring that to market. Correct?

4 MR. MORROW: Object to the form. You can
5 answer.

6 A. It would have had to do the same level of
7 clinical testing that it would for any new molecule.
8 It -- it could benefit from some of the work that had
9 been done on Proscar, but not all of it.

10 Q. Right.

11 A. Because that was a urol -- urological
12 product.

13 Q. Right. But it didn't take, in fairness, Mr.
14 Howes, 15 years for Propecia to come from idea to sale.
15 Correct?

16 MR. MORROW: Objection.

17 A. I don't know how long it took.

18 Q. Do you know when Merck first identified the
19 need or the potential to be able to use Propecia as a
20 hair replacement drug?

21 A. No.

22 Q. Okay. Would it surprise you that that
23 occurred sometime in the mid '90s?

24 MR. MORROW: Objection.

1 A. That's entirely possible, sure.

2 Q. You were at the company when Proscar came
3 online, right?

4 A. Yes.

5 Q. Okay. To the best of your knowledge, as you
6 sit here today, nobody was talking about using
7 finasteride as a hair replacement therapy prior to the
8 launch of Proscar, right?

9 MR. MORROW: Objection.

10 A. I'm not aware of that.

11 Q. Okay.

12 A. I'm not aware that that statement is correct.

13 Q. You're just not aware of whether it's correct
14 or incorrect?

15 A. Correct.

16 Q. Okay.

17 A. Yes.

18 Q. All right. So let's assume, for the sake of
19 argument, that the concept of developing a hair loss
20 drug first started to be talked about at Merck sometime
21 in the '90s.

22 MR. MORROW: Objection.

23 Q. It's fair to say that that time period
24 from the mid '90s to the launch of Propecia was

1 not a 15-year time frame. Correct?

2 MR. MORROW: Objection.

3 A. I would assume that even if they did not have
4 to do Phase I clinical trials, they would have had to
5 do Phase II and Phase III. And if the product was
6 launched in 1998, it would have been filed maybe at the
7 end of '96. And those trials probably started in 1990,
8 at the latest. So it was the better part of a decade,
9 even with the molecule that had a strong body of
10 scientific data already.

11 Q. Okay. We'll look at some documents about
12 that a little later on in the deposition. But the
13 bottom line is -- and I think you would agree with
14 this -- that Merck was able to build off of the R & D
15 it did related to Proscar when it started to develop
16 Propecia. Right?

17 A. Yes.

18 Q. So it didn't have to go through the complete
19 process.

20 A. Correct.

21 Q. Okay. Now, at the time that this drug was
22 being developed, Merck looked at it as a potential
23 blockbuster-type drug. Correct?

24 MR. MORROW: Objection.

1 A. Yes.

2 Q. Tell the jury what a blockbuster drug is.

3 A. Well, when I first joined the company, that
4 would have been defined as a product that had more than
5 \$100 million in sales. Today's definition would
6 probably be more like a billion. And so 1998 may have
7 been somewhere in the middle of that.

8 Q. So -- but, generally speaking -- and I get
9 your point that the term "blockbuster" and the amount
10 of revenue that's tied to it has evolved over time.
11 Blockbuster drugs are big deals to big pharmaceutical
12 companies, correct?

13 A. Yes.

14 Q. And, in fact, big pharmaceutical companies
15 like Merck rely on blockbuster drugs to keep the
16 company afloat. True?

17 MR. MORROW: Objection.

18 A. They -- they rely on any first-in-class
19 medication. You've -- you've got to be good at
20 something in order to sustain yourself and continue the
21 operation.

22 Q. Right. But those blockbuster drugs,
23 in particular, are really what sustains the company so
24 it can go on to do non-blockbuster-type things. Right?

1 A. Yes.

2 MR. MORROW: Objection.

3 Q. That was a yes, right?

4 A. Yes.

5 (Deposition Exhibit 229 - Merck Publication
6 titled "The Daily" - MRKP0001704574 through
7 MRKP0001704577 - marked for identification.)

8 Q. Let me show you what has been marked as
9 Exhibit 229. Can you tell us, sir, is this an internal
10 Merck publication?

11 A. Yes. It may only be U.S. --

12 Q. It's --

13 A. -- but it's a daily publication. Or it was
14 at that point in time.

15 Q. So I'm assuming that Merck, like most
16 companies, has a way that it communicates information
17 with its employees and staff. Correct?

18 A. Yes.

19 Q. And one of the ways it does it is through
20 articles and publications like this. Correct?

21 A. Correct.

22 Q. All right. Turn to the third page of the
23 document, which is Bates-numbered MRKP0001704576.

24 First, just so you know -- have you ever had

1 your deposition taken before?

2 A. No.

3 Q. Okay. So then that code that I just rattled
4 off is probably pretty Greek to you. These are what we
5 call Bates numbers at the bottom. It's just a way for
6 us to track pages. Okay? So I will from time to time
7 refer to these type of codes.

8 A. (Witness nods head.)

9 Q. Just as a "go to this page".

10 A. Yes.

11 Q. All right. So you're on Bates Page No. 4576.
12 Correct?

13 A. Correct.

14 Q. Do you see the column that says "Enthusiasm
15 for Propecia Comes from Many Voices"?

16 A. Yes.

17 Q. Okay. Directing your attention to the second
18 paragraph down, there's a quote by ABB Aros Security.
19 Do you see that?

20 A. Yes.

21 Q. It says, "This could be a blockbuster. It
22 might take a little while, but you will -- you'll see
23 this as a very high-profile product. Many physicians,
24 for instance, will use this as ammunition to attract

1 new patients. For many men it will be a very viable
2 treatment."

3 Did I read that correctly?

4 A. Yes.

5 Q. Okay. And then at the bottom of the page,
6 you see the quote from the Wall Street Journal?

7 A. (No response.)

8 Q. Bottom of the column.

9 A. Yes.

10 Q. It says, "Whatever drawbacks there may be of
11 Propecia, the possibility of combating one of the most
12 common signs of aging in a culture addicted to
13 youthfulness has some analysts predicting that Propecia
14 will become one of the pharmaceutical industry's most
15 successful drugs."

16 Did I read that correctly?

17 A. Yes.

18 Q. Okay. This article is dated January 6th,
19 1998. True?

20 A. Yes.

21 Q. This is on the eve of the launch of Propecia.
22 Correct?

23 A. Correct.

24 Q. So at the time that the product is being

1 launched, the expectation in the company, as well as on
2 the street, was that this drug was going to be a big
3 deal to Merck.

4 A. I -- I don't know if that was the expectation
5 in the company. It's clearly the external expectation.
6 Analysts and -- and others.

7 Q. One of the ways those analysts got that
8 expectation was because Merck promotes its products.
9 Correct?

10 MR. MORROW: Objection.

11 Q. Right?

12 A. Merck does promote its products, yes.

13 Q. And so these analysts didn't just pull this
14 information out of thin air, did they?

15 A. No. But, also, none of them had seen the
16 label of the product either.

17 Q. Okay. So the point being that when analysts
18 are reporting on what they anticipate a particular
19 pharmaceutical will do, how much it will make in terms
20 of gross revenue, some of that information was coming
21 from the pharmaceutical company itself. Correct?

22 A. True.

23 Q. So, in other words, ABB Aros Security and the
24 Wall Street Journal was getting some of its information

1 related to the likely success of Propecia from Merck
2 directly.

3 MR. MORROW: Objection.

4 A. Likely, yes.

5 Q. Okay. Turn, if you would, to the first page
6 of the document.

7 A. (Witness complies.)

8 Q. Now, one of the reasons why Merck thought
9 that this product was going to be particularly
10 successful is because there was a large, untapped
11 market of men who might actually buy Propecia.

12 Correct?

13 A. Yes.

14 Q. In fact, if you look at the first column, the
15 article reports, about two-thirds of the way down,
16 "with a target audience". Do you see that?

17 A. On the left side or the --

18 Q. On the far left side, first column.

19 A. Yes.

20 Q. "With a target audience of 33 million U.S.
21 men, analysts hold high hopes for Propecia."

22 Did I read that correctly?

23 A. Yes.

24 Q. Okay. So Merck saw a large opportunity with

1 lots and lots of potential consumers or customers to
2 buy this particular product that, really, nobody else
3 was in this area at the time. Correct?

4 A. Correct.

5 Q. Okay. And it thought at the time that if it
6 could capture a significant portion of those 33 million
7 men, it could, in fact, develop a blockbuster drug.
8 Correct?

9 A. Yes.

10 Q. Turn to the next page, if you will.

11 A. (Witness complies.)

12 Q. And direct your attention to the far
13 left-hand column. Third paragraph down, starting with
14 "even a scarcity". Do you see that?

15 A. Um-hum.

16 Q. It says, "Even with a scarcity of proven
17 remedies, men spend some \$1 billion annually on
18 treatment."

19 Did I read that correctly?

20 A. Yes.

21 Q. So at the time that Merck was developing
22 Propecia and was getting ready to launch it, it knew
23 that sales related to hair replacement therapy,
24 generally, in the U.S. market exceeded a billion

1 dollars annually. Correct?

2 A. Yes.

3 Q. So it saw a huge opportunity for potential

4 revenue within that market. Correct?

5 A. Correct.

6 Q. And if you go down to the next paragraph,

7 there's a quote by Mr. Casola, who was your subordinate

8 at this time, correct?

9 A. Not at this time, but he was.

10 Q. I'm sorry. You're right.

11 A. Six months later.

12 Q. I'm sorry. You're correct. At this point he

13 was actually -- you weren't working on this particular

14 project.

15 A. Correct.

16 Q. Okay. So he was in charge of it from a

17 marketing standpoint?

18 A. Yes.

19 Q. Okay. So Mr. Casola states, quote, "There is

20 definitely a large group of men searching for help. We

21 just need to communicate the benefits of Propecia to

22 them and motivate them to see their physicians."

23 Did I read that correctly?

24 A. Yes.

1 MR. BECKER: Hey, whoever is typing, can you
2 put your phone on mute.

3 (Discussion held off the record.)

4 Q. I'm sorry. Let me just start over. So you
5 have Exhibit 236 in front of you. Correct?

6 A. Yes.

7 Q. It's stamped September 7, 1994. True?

8 A. Yes.

9 Q. And you appear as one of the recipients of
10 this particular document. Correct?

11 A. Yes.

12 Q. All right. So prior to the last document,
13 almost a -- well, in fact a year before that, you had
14 received a communication from Dr. M.F. Malkin to you
15 and a group of other folks regarding "Worldwide
16 Marketing Needs Report for Finasteride for Androgenic
17 Alopecia in Men". Correct?

18 MR. MORROW: Objection.

19 A. Correct.

20 Q. So you received a document several years
21 prior to the launch, as the president of Merck Canada,
22 that discussed marketing issues related to Propecia.
23 True?

24 A. Yes.

1 Q. All right. First of all, who is Dr. M.F.
2 Malkin?

3 A. I don't know.

4 Q. Do you know, if you look at the first page,
5 who P. Wold-Olsen is?

6 A. Yes.

7 Q. Who is that?

8 A. He was the head of a group called WHHM;
9 Worldwide Human Health Marketing.

10 Q. Okay. Was he a high-level executive at
11 Merck?

12 A. Yes.

13 Q. Okay. So if we look at the first page of the
14 document -- I'm sorry -- second page of the document,
15 Bates No. 583758, do you see the section entitled
16 "Purpose"?

17 A. Yes.

18 Q. It says, "The purpose of this document is to
19 express WHHM's needs with regard to the development of
20 finasteride for the treatment and prevention of
21 androgenic alopecia in men."

22 Do you see that there?

23 A. Yes.

24 Q. Okay. And then it goes on to have a

1 discussion about certain topics including marketing
2 needs. Correct?

3 A. Correct.

4 Q. All right. Turn to Page 3 of the document.

5 A. (Witness complies.)

6 Q. Do you see the section entitled "Marketing
7 Needs"? Page 3 at the top.

8 A. Marketing --

9 Q. Section C there.

10 A. Yes.

11 Q. All right. Directing your attention to the
12 C-2 Dosage Administration Formulation, do you see that?

13 A. Yes.

14 Q. All right. The second full paragraph reads,
15 "As described in recommendation, WHHM supports the
16 introduction of the lowest dose that has the highest
17 efficacy with the best safety profile. However, if it
18 is not possible to eliminate the safety concerns, use
19 of a condom and sexual adverse events in the label
20 inherited from Proscar, we support the introduction of
21 the dosage with the highest efficacy that has a safety
22 profile no worse than that of Proscar. This last
23 scenario will result in a lower sales forecast than the
24 ones submitted in the SOI."

1 Did I read that correctly?

2 A. Yes.

3 Q. What is SOI?

4 A. The first two words -- first two letters
5 would be "statement of", and I think the last letter is
6 "interest". Statement of interest.

7 Q. Okay. So was that a document that
8 essentially laid out the pros and cons of developing
9 Propecia?

10 A. It is more a wish list of what you would like
11 the profile to look like at the conclusion of the Phase
12 III study.

13 Q. Got it. Okay. So what this paragraph was
14 basically saying was that if Merck had to inherit the
15 Proscar label, then -- then the group was advocating to
16 go to as high of an efficacy that it believed would be
17 effective. Correct?

18 A. Yes.

19 Q. But that that scenario would, in fact, result
20 in lower sales than what was forecasted. True?

21 A. Yes.

22 Q. And that's, in fact, what happened. Correct?

23 MR. MORROW: Objection.

24 A. Yes.

1 Q. And --

2 A. There was an expectation that in going to
3 one-fifth the dose of Proscar, there would be fewer
4 side effects. And I don't recall at this stage,
5 because it's 15 years ago for me. But I don't recall
6 the percentage of sexual side effects in Propecia
7 versus Proscar. I think they were less, but not
8 substantially less.

9 Q. So at the time that you were contemplating --
10 Merck was contemplating developing this particular
11 product, it had certain scenarios with respect to
12 labeling and warnings that it was --

13 A. Yes.

14 Q. -- that it was facing. True?

15 A. Yes.

16 Q. Okay. And one of those was a safety profile
17 that included reference to sexual adverse events.

18 Correct?

19 A. Yes.

20 Q. And what Merck was essentially saying in this
21 document is that if we have to do that, our sales are
22 going to take a hit.

23 A. Correct.

24 (Deposition Exhibit 237 - Email -

1 symptoms to resolve while off therapy?

2 MR. MORROW: Objection.

3 A. Well, they also didn't define who might have
4 had sexual dysfunction before they even entered the
5 study. So --

6 Q. Well, that's actually not true. They did,
7 when they called them out for who was eligible and who
8 was not.

9 So my question to you, sir, is: Were you
10 surprised, or did you know that Merck never defined how
11 long resolution would take?

12 MR. MORROW: Objection.

13 A. I wasn't -- I'm not an expert in clinical
14 trial design.

15 Q. As a marketer, if you had to sell a drug
16 where the symptoms resolved a day after you got off
17 versus a year after you got off, which would be harder
18 to sell?

19 MR. MORROW: Objection.

20 A. It depends on --

21 Q. Well, let's --

22 A. -- what the side effect is.

23 Q. Sexual dysfunction and erectile dysfunction.

24 If you had to market a product for the sale of -- that

1 had an adverse event that everybody concedes can happen
2 while on the drug, that can range from erectile
3 dysfunction, loss of libido, loss of sensation, sexual
4 dysfunction, and you had to tell the public that those
5 events could take a year or longer to resolve, versus a
6 day, which one would be easier to sell?

7 MR. MORROW: Objection.

8 A. The latter.

9 Q. And that's because men had an understanding
10 that sex and the ability to have sex was important to
11 them. Right?

12 A. Yes.

13 Q. And if they knew that it could take a year or
14 that they may never recover from these symptoms, they
15 weren't going to buy this drug, were they?

16 MR. MORROW: Objection.

17 A. They would have to make a tradeoff between
18 that and how important their hair loss was to them.

19 Q. Well, you had data that showed that there was
20 a substantial number of men who, based on the threat
21 that they might get it, wouldn't even touch the stuff.
22 Right?

23 MR. MORROW: Objection.

24 A. Correct.

1 Q. All right. So you knew internally that if
2 these sexual adverse events were prolonged or
3 lengthened or never went away, that that would be
4 something that would impact sales in a negative way.
5 Right?

6 MR. MORROW: Objection.

7 A. Yes.

8 (Deposition Exhibit 238 - Report -
9 MRKP0001787636 through MRKP0001787644 -
10 marked for identification.)

11 Q. Let me show you what I have marked as Exhibit
12 238.

13 MR. MORROW: I'm sorry. 238?

14 MR. BECKER: 8.

15 Q. Do you have that documents there in front of
16 you, sir?

17 A. Yes.

18 Q. Okay. It's a document that is -- the subject
19 is entitled "Evaluation of the 1998 Direct-to-Consumer
20 Advertising Campaign for Propecia, End-of-Year Report
21 on the Consumer Awareness and Action Study" dated
22 March 15, 1999. Do you see that?

23 A. Yes.

24 Q. And you are listed in the distribution list.

1 Correct?

2 A. Yes.

3 Q. Okay. Let me direct your attention to the
4 top of the page. Do you see where it says, "This is an
5 information report. Please destroy by March 1st, 2001.
6 Available from the MIC after this date."?

7 Do you see that there?

8 A. Yes.

9 Q. Okay. What is the MIC?

10 A. I believe it stands for Marketing Information
11 Center.

12 Q. Okay. So the author of this -- well, let me
13 ask you this: Was it company policy that this type of
14 an internal market analysis be destroyed by its
15 recipients?

16 A. I don't know.

17 Q. Do you know whether or not Merck had a
18 document destruction policy?

19 A. It has a records retention policy.

20 Q. Okay. Do you know, were these type of
21 documents slated for destruction within that retention
22 policy?

23 A. I don't know.

24 Q. Okay.

1 A. I mean, it wasn't -- it was obviously
2 retained in a repository.

3 Q. Do you know how -- were -- were emails
4 subject to that document retention policy?

5 A. I don't know.

6 Q. Okay. Do you remember if you saved a copy of
7 this document? Or would you have destroyed it per
8 these instructions?

9 A. I don't know.

10 Q. All right. You had an understanding at the
11 time --

12 A. The objective is that it's -- it's
13 proprietary market research information, and you don't
14 want it ending up in an analyst report. Whatever it is
15 on any product. It's proprietary. So that's why they
16 want to keep it in one location and not have it lying
17 around people's desks, and when people leave the
18 company, they join -- leave Merck, go join Pfizer, they
19 take all this stuff with them. That's why they have
20 policies like that.

21 Q. So that's the point. It was intended to be
22 only for internal Merck use. Correct?

23 A. Yes.

24 Q. And the vast majority of the copies were to

1 be destroyed. Right?

2 A. Yes.

3 Q. All right. So let me direct your attention
4 to the first page of the document titled "Summary". Do
5 you see that?

6 A. Yes.

7 Q. Directing you to the third -- sorry -- fourth
8 and fifth bullet point, the fifth one says, "Sexual
9 side effects and side effects associated with pregnant
10 women (women not handling Propecia) are the predominant
11 side effects recalled by respondents."

12 Did I read that correctly?

13 A. Yes.

14 Q. And then the bullet point above that says,
15 "40 percent of those men aware of Propecia are aware of
16 side effects associated with taking the product. Of
17 those, side effects would prevent 50 percent of the men
18 from taking the product." Correct?

19 A. Yes.

20 Q. Okay. So 40 percent of the -- of the mean
21 who had an understanding or a brand awareness of
22 Propecia were aware of the fact that sexual side
23 effects could occur if they took the drug. Right?

24 A. Yes.

1 Q. And of those people who were aware,
2 50 percent said I'm not touching it. Right?

3 A. Yes.

4 Q. Okay. So, in other words, 20 percent of the
5 guys who had awareness of Propecia said, we are
6 absolutely never taking this thing. Right?

7 A. Yes.

8 Q. All right. And at the time that they had
9 that view of the drug, there was no warning for
10 persistent to permanent erectile or sexual dysfunction.
11 Correct?

12 A. Correct.

13 Q. Does it stand to reason that if 20 percent of
14 the men who were in the pool of guys who could use the
15 drug would not touch it, recognizing that the symptoms
16 could go away, that that percentage would have gone
17 even higher if they thought that use of the drug could
18 cause permanent, persistent problems for them?

19 MR. MORROW: Object to the form.

20 A. Yes. The converse is also true, though.

21 Q. Turn to -- turn to Page 7641.

22 A. (Witness complies.)

23 Q. And, specifically, I want to direct you to
24 the section "Awareness of Side Effects". Do you see

1 the heading there, "Awareness of Side Effects"?

2 A. Yes.

3 Q. There's a figure under that, Figure 5, "Side
4 Effects, Components, Total Ad Recall".

5 A. Yes.

6 Q. And it starts out in -- at the bottom June
7 and goes to late December on the -- on the -- on the
8 lower axis. Do you --

9 A. Yes.

10 Q. -- see that?

11 A. Yes.

12 Q. And then on the -- on the left side tracks
13 the -- a percentage number. Right?

14 A. Okay.

15 Q. Do you see that there?

16 A. Yes.

17 Q. Okay. And then the first graph is the graph
18 of people who were aware of sexual side effects.
19 Correct?

20 A. The first bar?

21 Q. The first bar.

22 A. Okay.

23 Q. And if you look at that, you basically --
24 well, describe for us what this chart is laying out.

1 A. I -- I can't read the labeling on the bars.

2 Q. Okay. So -- I have that same problem. These
3 are relatively new.

4 (Discussion held off the record.)

5 Q. Okay. Here's how I read it: The first
6 bullet point is "sexual side effects". Do you see
7 that?

8 A. Yes.

9 Q. The second graph is "pregnant women shouldn't
10 handle". The black --

11 A. Yes.

12 Q. And on the clear one --

13 A. That one goes up over time.

14 Q. -- is birth defects to unborn children. And
15 general warning has a side effect, health warning.
16 Those are the bars that are denoted.

17 A. Yes.

18 Q. Do you see that there? So, basically, this
19 chart is graphing the number of men in the focus groups
20 you looked at who had a recognition of the brand
21 Propecia, along with certain side effects that were
22 disclosed in the labeling. Correct?

23 A. Yes.

24 Q. Okay. And if you turn to the next page, it

1 tracks -- the Figure 6 indicates, "Would side effects
2 prevent you from using Propecia?" Do you see that?

3 A. Yes.

4 Q. Okay. And then it's "yes", "no", "don't
5 know". Do you see that?

6 A. Um-hum.

7 Q. And the lowest that "no" answer ever -- or
8 "yes" answer ever appears to be is just below
9 40 percent baseline. Do you see that?

10 A. Yes.

11 Q. And then every other month thereafter hovers
12 around the 50 percent or higher number. Correct?

13 A. Yes.

14 Q. And that led to the conclusion that if you
15 were aware of sexual side effects, those men who were
16 aware of it, around half would not take the drug.

17 A. Right.

18 Q. Turn to Page --

19 A. And it wasn't just the sexual side effects.

20 It was the combination of the two; the fact that it was
21 dangerous to be even touched by a female of
22 child-bearing years, that affects men's behavior as
23 well as women's -- I mean, women don't use this
24 product.

1 Q. Right.

2 A. But they didn't want it in the house.

3 Q. But this chart charts it out specifically

4 for -- strike that. I -- I hear what you're saying.

5 Fair enough.

6 Go to Page 87644; the last page of the

7 document.

8 A. (Witness complies.)

9 Q. Do you see the heading that says "Next Step"?

10 A. Yes.

11 Q. It says, "Fear of side effects is one barrier

12 of action that the TBG is interested in better

13 understanding. A & A questions have been revised to

14 understand the role of side effects in preventing men

15 from acting and how the -- and how the product in DTC

16 campaign can be revised to minimize these concerns."

17 Do you see that there?

18 A. Yes.

19 Q. So the walkaway from this was that we

20 understand we have a problem with sexual side effects,

21 and we, as a company, have to figure out how to address

22 that.

23 A. Yes.

24 Q. Okay. That never really worked, did it?