UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of:)
IMPAX LABORATORIES, INC,)
a corporation,) Docket No. 9373
Respondent.)
----------)

November 9, 2017
10:35 a.m.
TRIAL VOLUME 11
PART 1, PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL
Chief Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C.

Reported by: Josett F. Whalen, Court Reporter

APPEARANCES:

ON BEHALF OF THE FEDERAL TRADE COMMISSION:

CHARLES A. LOUGHLIN, ESQ.
LAUREN K. PEAY, ESQ.
ALPA DAVIS, ESQ.
Federal Trade Commission
Bureau of Competition
Constitution Center
400 7th Street, S.W.
Washington, D.C. 20024
(202) 326-3759
cloughlin@ftc.gov

ON BEHALF OF IMPAX LABORATORIES:

EDWARD D. HASSI, ESQ.
MICHAEL E. ANTALICS, ESQ.
BENJAMIN J. HENDRICKS, ESQ.
O'Melveny & Myers LLP
1625 Eye Street, N.W.
Washington, D.C. 20006-4061
(202) 383-5300
ehassi@omm.com

FEDERAL TRADE COMMISSION

I N D E X

IN THE MATTER OF IMPAX LABORATORIES, INC.

TRIAL VOLUME 11

PART 1, PUBLIC RECORD

NOVEMBER 9, 2017

WITNESS:	DIRECT	CROSS	REDIRECT	RECROSS	VOIR
HOXIE	2664	2727	2904	2914	

EXHIBITS	FOR ID	IN EVID	IN CAMERA	STRICKEN/REJECTED
CX				
(none)				
RX				
(none)				
JX				
(none)				

P R O C E E D I N G S

- - - - -

JUDGE CHAPPELL: We're back on the record.

Next question.

- - - - -

Whereupon --

THOMAS HOXIE

a witness, called for examination, having been previously duly sworn, was examined and testified as follows:

MS. PEAY: Good morning, Your Honor.

At this time, Your Honor, I tender Mr. Hoxie as an expert in pharmaceutical patent licensing, pharmaceutical patent litigation and pharmaceutical patent prosecution.

I submit that he is qualified by reason of his thirty-plus years of professional experience in the field of pharmaceutical patent law, his education and his training to provide expert testimony rebutting opinions expressed in the expert report of Mr. E. Anthony Figg.

JUDGE CHAPPELL: Anything else?

MS. PEAY: That is all, Your Honor.

MR. HASSI: Your Honor, you may tell me this is a matter for cross, but we have no objection to

qualifying Mr. Hoxie as an expert in patent licensing and patent prosecution. I don't think we've heard sufficient information to qualify him and indeed we don't think he is an expert in patent litigation, Your Honor.

JUDGE CHAPPELL: All right. If that's an objection to him testifying, it's overruled. But as I always say, any opinions that meet the proper legal standards will be considered.

Go ahead.

MR. HASSI: Understood, Your Honor.

MS. PEAY: Thank you, Your Honor.

- - - - -

DIRECT EXAMINATION (continued)

BY MS. PEAY:

Q. Mr. Hoxie, in general terms, can you describe how you came to arrive at your opinions in this case?

A. Yes.

Well, first I reviewed Mr. Figg's report, and then I reviewed the documents cited in Mr. Figg's report, I reviewed some other documents that were part of the discovery record in this case I understand and applied my -- my training, my experience, to analyzing those documents and reached my conclusions and wrote them up in a report.

Q. Let's turn to Mr. Figg's opinion that while the outcome of the '933 and '456 patent litigation was uncertain, the district court's claim construction ruling made an unfavorable outcome for Impax more likely than not.

Have you been asked to respond to that opinion?

A. Yes, I have.

Q. Do you agree with -- first, do you agree with Mr. Figg that the patent litigation is uncertain?

A. Yes, I do.

Q. Next, do you agree with Mr. Figg that the court's claim construction ruling made an unfavorable outcome for Impax more likely than not?

A. I disagree with that conclusion.

Q. Before we get into the details of that opinion, sir, can you please explain generally what the '933 and '456 patents are directed to.

A. Yes. The two patents -- the claims of the two patents that were asserted in this case are directed to controlled-release formulations for oral administration, for example, tablets, that contain certain types of excipients and are used to deliver any active pharmaceutical ingredient. There's no limitation in the asserted claims to any particular

ingredient, active ingredient.

Q. In the patent litigation related to the '933 and '456 patents, did Endo assert infringement claims against Impax?

A. Yes, they did.

Q. Briefly, what did Endo need to show to prove that Impax' generic oxymorphone ER product infringed its patents?

A. Well, Endo need to show -- needed to show that the Impax formulation met each and every limitation of the asserted claims.

Q. In the '933 and '456 patent litigation, did Impax assert that Endo's patents were invalid?

A. Yes, they did.

Q. Briefly, what did Impax need to show to prove that Endo's patents were invalid?

A. Well, Impax needed to show -- Impax raised three grounds of invalidity, anticipation, obviousness and, for certain patents, lack of adequate written description. They would have needed to establish, you know, facts by clear and convincing evidence that would meet the legal standard for -- for those defenses.

Q. At a high level, what opinion have you offered in response to Mr. Figg's opinion that the court's

claim construction ruling made an unfavorable outcome for Impax more likely than not?

A. Well, I feel that -- I -- it's my opinion that the judge's claim construction in some ways introduced additional uncertainty into the case. And although it allowed the case to go forward, so, in other words, I mean, if the judge had ruled differently, perhaps there wouldn't have been a trial at all, so it was favorable to Endo in that sense, but the --

JUDGE CHAPPELL: Hold it. When an attorney stands, you need to cut off your answer and hold.

THE WITNESS: Yes, sir.

MR. HASSI: Your Honor, I think we're getting past the scope of his report. In particular, where he talks about whether, if the judge had ruled differently, there might not have been a trial at all, I don't think, for example, that that's anywhere in his report.

MS. PEAY: Your Honor, Mr. Hoxie addresses his opinion regarding --

JUDGE CHAPPELL: Either show it to opposing counsel or lay a foundation with the witness. We have an objection beyond the scope of the report.

(Pause in the proceedings.)

The other option is concede and move on if you

can't do either.

The pending response which he hadn't finished will not be considered until we resolve the objection.

MS. PEAY: I will withdraw the question and ask it again.

JUDGE CHAPPELL: Thank you.

So the objection is sustained. To the extent there's half an answer in the record, it won't be considered.

MR. HASSI: Thank you, Your Honor.

BY MS. PEAY:

Q. Mr. Hoxie, what opinion have you offered in response to Mr. Figg's opinion that the court's claim construction ruling made an unfavorable outcome for Impax more likely than not?

A. It's my opinion that the court's claim construction created substantial difficulties for Endo in proving its infringement case and furthermore that it opened up additional prior art, which could be used by Impax to argue -- to support its anticipation and obviousness defenses.

Q. Mr. Hoxie, do you hold that opinion with a degree of certainty reasonable in your professional field?

A. Yes, I do.

Q. At a high level, how did the claim construction ruling raise potential problems for Endo's infringement case?

A. The claim construction, which came subsequent to the expert reports in this case, did not -- was not supported by the data that was presented by Endo's experts. And because of the way the claim construction was, it was functional, it was these functional limitations in the claims, there was no -- the experimental data did not support that these limitations were met.

Q. And at a high level, how did the claim construction ruling raise potential problems for Endo in defending against Impax' invalidity case?

A. Well, there was -- there was a basic inconsistency in -- in the -- in Endo's position, which I discuss in my report.

In order to argue that the experimental data was not needed to show infringement in this case, it also undercut their argument that the experimental data would have been required to show that the prior art reference disclosures would -- would anticipate or make obvious the claims.

Q. I'd like to turn to discuss your response to Mr. Figg on the effect -- Mr. Figg's opinion on the

effect of the court's claim construction that -- of -- the effect of the court's claim construction of Endo's infringement case.

Mr. Hoxie, did you review the court's claim construction order in the '933 and '456 litigation?

A. Yes, I did.

Q. Did you review the parties' pretrial briefs?

A. Yes.

Q. And did you review the expert reports filed in that litigation?

A. Scientific experts, yes.

Q. Mr. Figg offers the opinion that the court's claim construction made it significantly more likely that Endo would be able to prove infringement.

Mr. Hoxie, have you been asked to respond to that opinion?

A. Yes, I have.

Q. Do you agree with Mr. Figg's opinion?

A. No, I do not.

Q. What were the primary terms construed under the district court's claim construction order?

A. Well, the most hotly disputed terms were the limitation in the claims that the claims -- that the formulation contain a sustained-release excipient, the definition of "sustained release," and also the -- they

needed to contain a hydrophobic ingredient, and the definition of "hydrophobic" was disputed.

Q. And were these two terms found in all of the asserted claims of the '933 and '456 patents?

A. Yes, they were.

Q. Whose proposed claim construction did the district court ultimately adopt?

A. They adopted Endo's.

Q. At a high level, what is the significance of a claim construction order?

A. Well, a claim construction order defines the terms of the claims for purposes of infringement and also for purposes of determining invalidity, so at a high level, it -- it sort of lays the groundwork for the -- for the attorneys on both sides to determine whether the product is -- is -- whether the accused product infringes the claims and also whether the claims cover or were made obvious by the prior art or whether the claims are overbroad or indefinite or not enabled by the prior art -- or not enabled by the disclosure.

Q. Is a claim construction ever dispositive?

A. It may be.

Q. Under what circumstances?

A. For example, if there is a claim -- if there's

a determination that the accused -- that the accused product does not have -- does not meet one of the limitations of the claims and would not infringe, for example, or a determination that the claim covers -- the claim is interpreted in such a way as to cover the prior art, then it would be anticipated.

I mean, there -- there are many ways.

Q. Mr. Hoxie, what was the definition of "hydrophobic material" that was adopted by the district court in its claim construction order?

A. Well, broadly speaking, the district court adopted a functional definition of the claim, and they said a hydrophobic material was a material that would slow the hydration of the gel matrix without disrupting the gel.

Q. With respect to the term "hydrophobic material," do you agree with Mr. Figg's opinion that the court's claim construction order made it significantly more likely that Endo would be able to prove infringement?

A. I did not -- I did not agree with that.

Q. Why do you disagree?

A. Well, the experiments that were done by -- by -- it was -- it was of course Endo's burden. And the experiments that were done by Endo's experts

were -- did not show that the -- the component, which was the microcrystalline cellulose identified by Endo as the hydrophobic component -- they did not show that the microcrystalline cellulose had any effect on the dissolution of the tablets or the release of the drug.

And that -- and that was conceded by -- that was conceded by Endo's infringement expert, Dr. Lowman. That was a serious problem, that the -- the material that they claimed caused -- you know, was -- the material that they claimed met this functional definition of "hydrophobic material" did not in fact have the effect that it was -- that it needed to have in order to meet that claim limitation meant that the claim was not infringed.

And Dr. -- and Impax' expert, Dr. Elder, particularly in his rebuttal report, laid that out I thought in a very convincing way.

And that raised substantial questions about the viability of Endo's case.

Q. Turning to the claim term "sustained release," do you agree with Mr. Figg's opinion that the court's claim construction made it more likely that Endo would be able to prove infringement?

A. I do not agree with that.

Q. What was the definition of "sustained release"

that was adopted by the district court?

A. The district court again adopted a functional definition that the sustained release was a -- was -- it was an excipient or it described the excipient that would provide a release over -- so -- such that a patient would have therapeutically effective levels of active ingredient in blood plasma after more than twelve hours.

Q. Mr. Hoxie, why do you disagree with Mr. Figg's opinion that the court's claim construction order -- claim construction of the term "sustained release" made it more likely that Endo would be able to prove infringement?

A. I felt that this -- well, I -- it's my opinion that this, this claim construction, introduced a lot of uncertainty. And in particular, Endo did not have data relating to the effect that a single -- that a single tablet would have on blood levels in a patient.

And in fact, Dr. -- Dr. Lowman conceded that the amount of blood -- the amount -- the amount of therapeutically active ingredient in the blood after twelve hours after administration of a single tablet would be -- would be minimal.

And the claims -- the claims that -- that limitation is a limitation that relates to a method of

1 administering the tablet, each tablet over twelve
2 hours, multiple tablets multiple times in multiple
3 twelve-hour periods. But the claims are directed to a
4 controlled-release dosage form, so a tablet. They're
5 not related to a method of administering many tablets
6 over many twelve-hour periods to reach some
7 steady-state blood level that would provide a
8 therapeutic effective amount.
9 Additionally, that -- that claim construction
10 "therapeutically effective amount" leaves open the
11 question of what drug, because the claims are not
12 limited to any particular drug. They're not directed
13 to oxymorphone, for example, specifically.
14 They -- it leaves open the question of what
15 patient. Therapeutically effective amount for a
16 300-pound man or five-year-old child might be quite
17 different.
18 And something -- as Endo itself emphasized in
19 its subsequent patents, the '122 patent and related
20 patents, the therapeutically effective dosage of an
21 opiate of oxymorphone varies very much from patient to
22 patient. Different people respond to that particular
23 drug in very different ways and may even respond to
24 that drug -- the same person may respond to that drug
25 in different ways on different days.

So the problem you have with that claim construction is you don't know whether the claim is infringed until somebody has actually taken the tablet and you measure the blood levels and you find out whether they do or don't have a therapeutically effective amount in their blood after twelve hours. There's really no other way to know.

And as Endo had no -- you know, no clinical data regarding therapeutically effective blood levels after administration of a tablet, only they had data -- the data that Impax had submitted in the context of a method of administering many tablets in successive twelve-hour periods, they didn't have the data they needed to show infringement of that element.

Q. Mr. Hoxie, I'd now like to discuss your response to Mr. Figg's opinion that it was likely that Endo would prevail on the invalidity claims asserted by Impax.

A. Yes.

Q. What invalidity claims did Impax assert against Endo's '933 and '456 patents, if you can remind us?

A. Yes. They asserted anticipation, obviousness and, for certain claims, lack of adequate written description.

Q. What does "anticipation" mean in this context?

A. "Anticipation" means the claim covered something that was already known, something that was already available in the prior art.

"Prior art" is a term used in patent law to refer to prior publications, prior patents, prior -- prior uses and sales, things -- ways in which the -- something might be made available to the public.

The patent claim is not allowed to cover things that are already known. It's not allowed to take away from the public what the public already had, you know, what the public could already do.

Q. And you referred to obviousness.

What does "obviousness" mean in this context?

A. "Obviousness" refers to a situation where the -- what is claimed is maybe not specifically precisely disclosed in a particular prior art reference but is nevertheless obvious to a person of ordinary skill in the art from that reference or from a combination of references or a combination of teachings in the prior art.

Q. And lack of adequate written description, what does that mean in the context of an invalidity claim?

A. Well, the claims needed to -- need to be supported by an adequate written description, as

required by the patent statute. And the description needs to be -- needs to be sufficient so as to demonstrate to a person of ordinary skill in the art that the inventor was in possession of the claimed invention.

Typically, that may be -- there are various factors that go into written description. The most straightforward is where you have an actual example of a -- of what is claimed or you may have where you have, as in this case, a generic claims -- by "generic" I mean that it covers many, many different individual -- for example, this claim covered any pharmaceutical active ingredient in a particular sustained-release formulation. You need to have a representative number of examples.

They pointed out that this particular -- these particular patents only disclosed a single act- -- only disclosed or exemplified in their examples a single active ingredient, a sustained-release form of albuterol, and they didn't disclose, you know, 3 or 4 or 10 or 15 or however many it would take to convince a person of ordinary skill in the art that they had possession of the invention broadly enough to claim all active pharmaceutical ingredients in such a formulation.

Q. And Mr. Hoxie, I'd like to discuss each of Impax' invalidity arguments separately now.

Mr. Figg offered the opinion that the trial judge was more likely than not to side with Endo on the issue of anticipation after the claim construction ruling.

Do you agree with Mr. Figg?

A. I disagree.

Q. Why not -- why do you disagree with him?

A. As Dr. Elder, who was Impax' expert at the trial, had laid out I thought very convincingly, there were a number of prior art documents. And in Dr. Elder's report there's sort of two buckets of prior art documents.

Some prior art documents are directed to a formulation -- for formulations which Dr. Elder contended would anticipate the patent under any claim construction. And then there were a whole number of additional documents where Dr. Elder -- which -- where the formulations contained microcrystalline cellulose.

And microcrystalline cellulose is a very common pharmaceutical excipient. And it's -- Dr. Elder -- as Dr. Elder's report shows, it's found in a great many -- in a great many sustained-release formulations.

1 And if you were going to argue that
2 microcrystalline cellulose was -- you know, had these
3 hydrophobic properties, in the case of Impax' tablet,
4 you would also have to concede that it would have those
5 same properties in the case of all the prior art
6 formulations.
7 So Impax -- or Endo was in a difficult position
8 here because they needed to say, Oh, we don't really
9 need scientific data to prove that microcrystalline
10 cellulose is acting as a hydrophobic excipient in
11 accordance with the judge's claim construction for
12 purposes of proving infringement, but you absolutely
13 need it for purposes of showing anticipation.
14 There was an obvious inconsistency in that
15 argument, and the Impax attorneys -- and I've quoted
16 this I think in my report -- pointed out that there was
17 a direct contradiction between Dr. Lowman, who was
18 Endo's infringement expert, his testimony that
19 microcrystalline cellulose was -- was necessarily
20 hydrophobic within the meaning of the judge's claim
21 construction and the testimony of their validity
22 expert, Endo's validity expert, who said that you
23 couldn't know without testing.
24 So that was -- that was a -- that presented a
25 problem -- that presented a problem for Endo. I don't

think it was nearly as clear-cut as Mr. Figg suggested that it was.

Q. And Mr. Hoxie, in general, what is the significance of having more prior art references relevant to the invalidity analysis?

A. Well, it -- I mean, a patent of course could be invalidated by as little as one prior art reference, but certainly the more prior art references you have, the more difficult it is for the -- it may be for the -- for the -- for the -- for the patentee to distinguish those references.

Q. Let's turn to Impax' invalidity arguments related to obviousness.

At a high level, what were Impax' obviousness arguments?

A. Well, Impax' obviousness arguments were -- were similar to its anticipation arguments. They were simply that there were many sustained-release formulations for many drugs known in the art and/or sustained-release formulations, controlled-release formulations of drugs known in the art, and there were many -- and they cited to a number of particularly patents that -- that described and claimed such formulations.

And what they said was that even if the exact,

specific details of the claims -- and this related largely to the dependent claims that were cited in the case, which had additional limitations -- even if those limitations were not specifically disclosed in a single reference in the prior art, they would be obvious to a person of ordinary skill in the art because you could combine one reference with another reference and -- and -- and come to the claimed invention with a reasonable probability -- with a reasonable expectation of success.

Q. What did Endo argue to overcome Impax' obviousness claims?

A. Endo argued similarly to -- it was pretty much the same argument as they raised with respect to anticipation.

They argued that you would need experimental evidence to show whether the functional limitations in accordance with the district court's claim construction were met with respect to each of the prior art references, and you didn't have that experimental evidence, therefore you couldn't rely on those references.

And again, it raised -- it pointed out -- highlighted the same inconsistency, which was that you didn't have the experimental evidence for these prior

art references, but you also didn't have the experimental evidence with regard to the -- with regard to the -- the Impax -- the Impax formulation.

I mean, what happened was the evidence just came out the wrong way for Endo.

Q. And Mr. Figg offered the opinion that the trial judge likely would have found that secondary considerations identified by Endo supported the nonobviousness of their patents.

Mr. Hoxie, do you agree with that opinion?

A. I do not.

Q. And what are -- what are secondary considerations in general?

A. Well, secondary considerations is -- it's -- it's -- are simply considerations where -- it's simply a situation where, you know, somebody challenging the patent, whether a patent examiner or somebody -- a defendant in an infringement litigation, says this patent is -- this patent is obvious and then the -- the patentee can try to rebut that contention by saying, Well, no, it's not so easy. There are these secondary considerations. The patented product, if it was so obvious, you know, why didn't somebody do it before.

And some of the considerations might be it's very successful, if it was obvious, wouldn't somebody

have done this, it's very -- it has -- it provides unexpected advantages, it -- you know, the -- these kinds of -- these kinds of -- there was a long-felt need, nobody had -- people had wanted something like this for a long time, but the need was not met, so those kinds of considerations, really sort of common-sense kind of arguments that you might make, and to argue that something is maybe not so easy as people might -- with hindsight might think it is.

Q. Why do you disagree with Mr. Figg's opinion that the trial judge likely would have found that secondary considerations identified by Endo supported the nonobviousness of their patents?

A. Well, for secondary considerations to be relevant there needs to be a nexus between the secondary considerations that you're relying on and the claimed invention.

Now, in this case, the patents don't even mention oxymorphone. The patents -- when Endo submitted its New Drug Application, its NDA, for oxymorphone, they didn't mention these patents. These were not initially listed in the Orange Book, which -- they were not identified -- Endo did not identify them to the FDA, as they were supposed to do, as being relevant patents in -- when they filed their NDA. They

only submitted them --

JUDGE CHAPPELL: Go ahead.

MR. HASSI: Your Honor, I think we're drifting well past the report again. I don't think this testimony about listing in the Orange Book, for example, of these patents is -- I don't find that in the report, Your Honor.

MS. PEAY: Your Honor, if I may show --

JUDGE CHAPPELL: Go ahead.

MS. PEAY: -- counsel?

(Pause in the proceedings.)

MR. HASSI: Withdrawn, Your Honor.

JUDGE CHAPPELL: All right. Do you want to continue your answer or start again with the question?

THE WITNESS: I'll wait for the question.

BY MS. PEAY:

Q. Mr. Hoxie, why do you disagree with Mr. Figg's opinion that the trial judge likely would have found that secondary considerations identified by Endo supported the nonobviousness of their patents?

A. Well, as I was saying, there is a requirement that the secondary considerations have a reasonable nexus to the -- to the claimed invention.

And the claims in this case -- the inventors in this case, so McCall and the other one, they did

not work for Endo. This is -- this patent is not -- this patent is -- was not -- was not a -- assigned to Endo at that time. This work was done before the work was -- the work to develop the oxymorphone, the Opana XR formulation, before that work was done.

So this is -- these are patents that relate to a different invention at a different company by different people for a different product. The title of the patent itself is Sustained-Release Formulations (Albuterol) I think. That might not be an exact quote, but it refers to albuterol. Each of the examples in the patent refer to albuterol.

Albuterol is a bronchodilator. It's not an opiate. It's not a painkiller. It has a totally different chemical structure. It has a totally different use. It has totally different physical properties from oxymorphone.

So to say that this -- and then I think -- to say that this patent, you know, is supported by the surprising advantages of an oxymorphone formulation that was developed long after does not meet the nexus requirement that the Federal Circuit requires to support secondary admission of -- admission and consideration of secondary considerations.

Q. In offering his opinion, Mr. Figg points to a

litigation between Endo and Amneal in the Southern District of New York in 2015 to support the secondary considerations of nonobviousness of the '933 and '456 patents.

Do you agree with Mr. Figg's opinion that this court decision would support the nonobviousness of the '933 and '456 patents?

A. I cannot agree.

Q. Why not?

A. That court decision had to do with different patents. It did not have to do with the '933 and the '456 patents. It had to do with later patents which Endo filed and which Endo obtained relating to specific formulations of oxymorphone having specific release characteristics.

And what the court in that case held is that the -- is that the prior art, which included the '933 and '456 patents, did not meet the long-felt need, did not satisfy the demand for a sustained-release oxymorphone patent.

So if you look at what the court actually said in that case, it directly contradicts what Mr. Figg claimed because it -- it -- it says that -- that with respect to those later-filed patents of the -- of Endo, the '122 patent and the other one, that those

patents -- only with those patents was the long-felt need and commercial success, and so forth, all those secondary considerations, only with respect to those patents was that long-felt need met.

And so that directly contradicts the argument that that need had already been met years earlier by the '933 and '456 disclosures.

Q. Let's turn now to Impax' third basis of invalidity. Mr. Figg offers the opinion that it was unlikely that Impax could have prevailed on its written description argument.

Mr. Hoxie, do you agree?

A. I disagree.

Q. Why do you disagree?

A. Well, because Dr. -- as Dr. McCall said, the inventor of the '456 and '933 patent, the -- the -- you could -- the information in the patent relating to the plasma levels, in that case the T-max of -- so T-max is the maximum -- the time point at which you have the maximum concentration of active ingredient in the blood.

He said that those -- that the data relating to albuterol would -- would not tell you anything about what the T-max would be for some other -- for some other pharmaceutical active ingredient which might

have a totally different absorption and metabolism from albuterol.

So I -- I think that there was -- there was not reason to believe that those -- the particular claims for which written description is talking about, which had to do with a T-max of a -- particular -- particular T-max values, blood values after administration of a controlled-release formulation, that those -- that those could be -- that those claims could -- could suggest that -- that the inventors of the '933 and '456 patent had possession of that invention -- invention with respect to, you know, any and all therapeutic active ingredients, I felt that was a -- that would have been a very -- a very -- I felt that Impax had a very good argument there that they did not have possession of the invention in such broad terms.

Q. Mr. Hoxie, in summary, Mr. Figg offers the opinion that the district court's claim construction ruling in the underlying patent litigation between Endo and Impax made an unfavorable outcome for Impax more likely than not.

Can you explain at a high level why you don't agree with Mr. Figg.

A. An unfavorable for what?

Q. An unfavorable outcome for Impax more likely than not.

A. I -- I did not -- I didn't think that the claim construction made it -- made it -- made it more likely than not that -- that Endo would win. I felt that the -- there were -- I felt that there -- that Impax' arguments -- and I felt they were very -- very ably presented by Impax' expert, Dr. Elder. His report I thought was very convincing -- raised substantial -- raised substantial uncertainty with regard to the outcome of the litigation.

I felt that they had -- there was a substantial possibility that Impax would -- would prevail with respect to infringement. And I also felt that there was a substantial --

MR. HASSI: Your Honor?

THE WITNESS: -- possibility that --

JUDGE CHAPPELL: Remember the rule. When an attorney stands, stop speaking.

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: Do you hear me?

THE WITNESS: Yes, sir.

MR. HASSI: Your Honor, the witness has just testified that these issues raised substantial -- raised substantial uncertainty with regard to the

outcome of the litigation. I felt that there was a substantial possibility that Impax would prevail with respect to infringement.

His report says nothing about that. It talks about uncertainty, uncertainty, uncertainty, and all of a sudden now we're moving uncertainty to a substantial possibility. We're drifting well beyond the confines of his report.

JUDGE CHAPPELL: Are you saying that's a new opinion?

MR. HASSI: I'm saying that's a new opinion.

JUDGE CHAPPELL: Response?

MS. PEAY: Your Honor, I can withdraw that question and ask another question just to clarify this.

JUDGE CHAPPELL: Do you want the answer stricken?

MR. HASSI: I do, Your Honor.

JUDGE CHAPPELL: The response is stricken, will not be considered. Objection sustained.

MR. HASSI: Thank you, Your Honor.

JUDGE CHAPPELL: And Counselor, I'm advising you, to the extent I need to, do not procure new opinions from your expert witness. He's here for rebuttal only. He's a rebuttal witness. He's

rebutting the opinions of respondent's expert. Keep that in mind.

MS. PEAY: I understand, Your Honor. Thank you, Your Honor.

JUDGE CHAPPELL: Has your witness been advised that he's not allowed to give us new opinions?

MS. PEAY: Yes, he has, Your Honor.

JUDGE CHAPPELL: If not, I'll advise him.

MS. PEAY: Thank you, Your Honor.

JUDGE CHAPPELL: Do you understand that, sir?

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: Stick to your report.

THE WITNESS: I believe, Your Honor, that I was.

JUDGE CHAPPELL: Go ahead.

I've already ruled that you were not.

Go ahead.

THE WITNESS: Thank you, Your Honor.

BY MS. PEAY:

Q. Mr. Hoxie, can you explain at a high level, as expressed in your report, why you don't agree that the district court's claim construction ruling in the underlying patent litigation made an unfavorable outcome for Impax more likely than not.

A. Well, for the reasons that I've -- that I've

already stated, I felt that the district court's claim construction ruling -- that under the district court's claim construction ruling, Endo faced substantially difficulties in showing infringement and that Impax -- that Endo faced substantial difficulties in rebutting Endo's -- or Impax' invalidity defenses.

Q. And Mr. Hoxie, is it your opinion that Impax would have won the litigation?

A. I don't have an opinion one way or the other on that.

Q. Why don't you have an opinion one way or the other?

A. My opinion -- my -- my role here as I understand it is to respond to Mr. Figg's report. I disagree with Mr. Figg's report that Endo would have won. I think the outcome was uncertain.

Q. And Mr. Figg offers the opinion that the district court's claim construction ruling in the underlying patent litigation between Endo and Impax made an unfavorable outcome for Impax more likely than not.

In your opinion, at the point in time after the district court issued its claim construction ruling, could the outcome of the patent litigation be predicted?

A. It could not be predicted at that stage.

Q. Mr. Hoxie, Mr. Figg offered the opinion and he testified that he would give Endo an edge in regards to how the Federal Circuit would ultimately rule on claim construction of the '933 and '456 patents.

Do you agree?

A. I -- Mr. Figg -- I do not have an opinion one way or the other as to how the Federal Circuit would have ruled, but I -- I think I -- Mr. Figg said, and I agree with Mr. Figg, that particularly on the issue of hydrophobic material Impax made substantial -- substantial arguments, and that certainly would have been an issue that could have gone up to the Federal Circuit. And there could have been other issues as well, but that certainly is one issue that could have gone up to the Federal Circuit and could well have presented problems for Endo.

Q. Thank you, Mr. Hoxie.

Moving on to another opinion expressed by Mr. Figg, Mr. Figg testified and offered the opinion in his report that a final judgment in the patent litigation on the '456 and the '933 patents would not have likely occurred until at least the fourth quarter of 2011 and potentially as late as mid-2013.

Have you been asked to respond to that

opinion?

A. Yes, I have.

Q. Do you agree with Mr. Figg?

A. I do not agree.

Q. At a high level, what opinion have you offered in response to Mr. Figg?

A. I think Mr. Figg's opinion assumes that -- I think Mr. Figg's opinion assumes a worst-case scenario in the sense that I mean that -- by "worst-case scenario" I mean that not at each individual step took as long as it could possibly take but that it's not necessarily true that each of these steps would have transpired.

Q. Do you hold that opinion with a degree of certainty reasonable in your professional field?

A. Yes.

Q. Based on your review of Mr. Figg's report, what steps does he opine would have occurred that would have -- would have occurred which would have pushed the litigation out to its final resolution in mid-2013?

A. Well, Mr. Figg first assumes that there -- that -- that Impax would -- would not have launched following -- would not have launched immediately following the trial, that there would have been some

extended period of posttrial briefing, and Impax would have -- would have stayed its hand for that period.

Then he assumes that Impax -- that the -- the outcome of that would have been that Impax would have lost and would not have launched, and then there would have been an appeal.

Then he assumes that following the appeal there would have been a remand and the -- there would necessarily have been a remand which would have taken additional -- which would have taken an additional several months. And that's how we get out -- each of those steps together, this is how we get out to -- to mid-2013.

I think that my conclusions are bolstered by the fact that if -- if indeed the likelihood -- the likelihood was high that there were -- under any circumstances Impax was blocked until mid-2013 and the patents only expired -- and the patents already expired in September of 2013, Endo would have had no real motivation to settle the case. I think the fact that they settled it supports my belief and my opinion that the case could -- that Endo -- that Impax could well have come to market much more quickly and would have been motivated to come to market much more quickly in the absence of a settlement.

Q. Mr. Hoxie, let's take those steps you talked about separately here.

Mr. Figg testified that a reasonable party in Impax' position would have concluded that it was less likely to prevail ultimately in the patent trial.

What is your opinion in response to Mr. Figg's opinion regarding the likelihood that Impax loses at the district court level?

A. Well, as I've said, I think Impax could well have won. And if Impax had won, then Impax might well have launched right then.

And that's supported by, you know, much of the -- the documents from Impax and from Endo where they were discussing the likelihood and timing of -- of -- of an Impax launch. Both Endo and Impax saw that as a -- at least a significant possibility.

Q. And next, if you assume --

MR. HASSI: Your Honor?

JUDGE CHAPPELL: Yes.

MR. HASSI: I'm sorry.

The witness has just testified that both Impax and Endo considered that an Impax launch at risk was a significant possibility. He mentions this once in his report. He doesn't say "a significant possibility." He uses the words, "There could be a reasonable risk

from Impax' perspective."

Once again, we're going well past -- new opinions, Your Honor, is my objection. Thank you.

MS. PEAY: Your Honor, if I may respond, I believe Mr. Hoxie is using "significant risk" in a -- "a significant possibility" and "a reasonable risk" interchangeably.

I can ask him that question. If he considers those to be equivalent?

JUDGE CHAPPELL: Go ahead.

BY MS. PEAY:

Q. Mr. Hoxie, do you consider significant -- do you consider significant possibility and reasonable risk to be different from one another?

A. I -- I don't see that, see it in that way. I don't think -- I'm not using those terms in my mind differently. It was -- if it's a reasonable risk to do something, then there's a significant possibility that it might be done. That is the way I see it in my mind.

I think it might be, you know -- I -- if we want to talk specifically about the documents, I did look at a number of documents. I looked at --

JUDGE CHAPPELL: We're not -- you haven't been asked for that, sir. That's enough.

THE WITNESS: Well, that's what's --

JUDGE CHAPPELL: I said that's enough.

THE WITNESS: I'm sorry, sir.

JUDGE CHAPPELL: Based on the semantics we just heard, overruled.

MR. HASSI: Understood, Your Honor.

JUDGE CHAPPELL: Sir, please stick to the question at hand. We don't need the rambling.

BY MS. PEAY:

Q. Mr. Hoxie, next, if you assume, as Mr. Figg did in his opinion, that Impax would lose at the district court level and appeal, what is your opinion regarding the likely outcome of an appeal?

A. Well, as I said, one possibility is that Impax could have -- could have won the appeal. And there were -- as I said and as Mr. Figg said also in his report, Impax had certainly grounds to appeal on the ground, for example, that the hydrophobic material limitation was not in accordance with the ordinary meaning of the term and as well as there could have been other grounds depending on how the district court -- depending on how the district court ruled and what was in the district court's opinion.

I think when we assume these things, we're getting to several layers of speculation. We don't

know exactly what the district court's ruling would have been. We don't know exactly how detailed it would be. We don't know exactly what findings would have been made on each of the specific issues.

So how the Federal Circuit is going to resolve the appeal is going to depend on how the district court -- what the district court's opinion was, and we don't know what the district court's opinion was, so that's an even more speculative leap, I think.

Q. Mr. Figg testified that even if the Federal Circuit reversed in favor of Impax, it is highly likely that what would have resulted from that would have been a remand by the Federal Circuit to the trial court.

Do you offer an opinion in response to Mr. Figg's opinion regarding the likelihood of a remand?

A. I did.

Q. And what is that opinion?

A. In my opinion, if a remand were, for example, in the -- in the hypothetical posited by Mr. Figg that the appeal was based on the -- the "hydrophobic material" claim construction, if that had been reversed, there may well have been sufficient fact-finding in the trial for the Federal Circuit to

simply enter judgment.

There would only be a necessity for a remand if there were material facts in dispute that needed to be resolved after the remand.

So it could have either been -- and I think -- I mean, I -- I don't necessarily agree that a remand would have been required or additional fact-finding would have been required.

Q. Thank you, Mr. Hoxie.

Switching subjects, Mr. Figg testified that the brand company does have an advantage in Hatch-Waxman litigation and that they win probably more often than not. He also opined in his report that generic challengers in general face an uphill battle in Hatch-Waxman litigation.

Have you been asked to respond to this opinion?

A. I have.

Q. Do you agree with Mr. Figg?

A. I don't agree. I mean, Hatch-Waxman -- I don't agree with that opinion, no.

Q. At a high level, what opinion have you offered in response to Mr. Figg?

JUDGE CHAPPELL: Has he told us anything about his background regarding Hatch-Waxman?

MS. PEAY: He did, Your Honor, yesterday.

JUDGE CHAPPELL: That was in the 35 minutes last night?

MS. PEAY: Yes, sir.

JUDGE CHAPPELL: Thank you.

MS. PEAY: Yes, Your Honor.

JUDGE CHAPPELL: Go ahead.

THE WITNESS: Hatch-Waxman -- the Hatch-Waxman presents -- represents a balance between generic interests and branded pharmaceutical interests. And there are many advantages to generic countries -- companies in Hatch-Waxman litigation.

One advantage is that under Hatch-Waxman they can develop their products without all -- and all the way up through FDA registration without fear of being sued for infringement, patent infringement.

Another advantage is that they can resolve infringement issues prior to product launch because they have this period from -- of at least 30 months where -- where they are -- where they're in litigation and issues can be resolved, so they don't need to -- they don't need to, as would be the case in a normal case, launch their products and wait to get sued.

So there are -- Hatch-Waxman also provides a path for an Abbreviated New Drug Application, a path

that did not exist prior to Hatch-Waxman, to allow them to get abbreviated approval.

And perhaps most importantly, Hatch-Waxman gives the first filers 180 days exclusivity for -- Paragraph IV filers 180 days exclusivity vis-à-vis the other generics, which means that the first filer is in a position to block all the other -- you know, all the other later-filed -- later Paragraph IV filers.

BY MS. PEAY:

Q. Do you hold that opinion with a degree of certainty reasonable in your professional field?

A. Yes, I do.

Q. Mr. Hoxie, I'd now like to discuss the subject of at-risk launches.

Mr. Figg testified that at-risk launches are rare because of the risks they present for generics.

Have you been asked to respond to that opinion?

A. I have.

Q. Do you agree with Mr. Figg?

A. I do not.

Q. What opinion have you offered in response to Mr. Figg?

A. At-risk launches are -- are not rare in situations where there is a market pressure for

generic companies to launch at risk, so -- and I personally have been involved in at-risk launches and I have seen at-risk launches in the course of my career.

Q. Do you hold that opinion with a degree of certainty reasonable in your professional field?

A. Yes.

Q. What is your basis for your opinion that at-risk launches are not rare in situations where there is a market pressure for generic companies?

A. There -- there are always risks for any launch, and any launch of a pharmaceutical product involves a balancing of those risks. In certain cases, the risks of launching and potentially facing patent damages can be outweighed by the risks of losing a market opportunity, and that I think was the situation here potentially.

Q. What are -- do you have any specific examples of situations where a generic company may be motivated to launch at risk due to an uncertain market opportunity?

A. Well, the most -- in my experience, the most common situation is where you have either -- where you have multiple generics who have approval and they're not -- there is no effective exclusivity of

one generic over another, so it becomes a race to market.

And if you -- if a generic company delays a market launch pending a Federal Circuit decision, some other generic company may get on the market and take the entire market. And that's a -- because of the way the generics -- the way the generic market operates, it's -- it's extremely valuable to be the first generic company on the market because you -- once there are multiple generics on the market, it becomes much less profitable.

Q. Are there other situations in which a generic company may be motivated to launch at risk due to an uncertain market opportunity?

A. Well, if their 180-day -- if they have 180-day exclusivity and that's somehow jeopardized, you're close to patent expiry or, as in this case, you were not far from patent expiry and -- yes.

Q. Did Impax face an uncertain market opportunity?

A. Yes, they did.

Q. Why did Impax face an uncertain market opportunity?

A. There were -- there were several drivers -- well, at least two main drivers I think for Impax

wanting to launch early in this case or earlier rather than later.

The first was that it was known by both sides -- by both sides that there was a possibility at least that Endo could switch to an abuse-resistant formulation or something which could be presented to the FDA as an abuse-resistant formulation. If -- excuse me. That Endo could.

If Endo switched to a new formulation, okay, then the Impax product would not be bioequivalent necessarily or automatically substitutable necessarily with the new formulation, so that would create problems for Impax in two ways.

First of all, if they had to launch and there was no predicate drug where they could get automatic substitution and rely on the promotion and sales of that branded drug to drive their sales, that would hurt their sales.

And secondly, there was the risk that the first -- that the first NDA for the first Endo product could actually be withdrawn for a lack of safety or efficacy. And in fact, in this case Endo ultimately petitioned -- filed a citizens petition asking the FDA to do just that, although the FDA declined.

So that was a potential risk.

And then the second risk here, in addition to Endo bringing in a new product, the other risk was that both parties -- that Impax was aware that Endo had pending patent applications that could issue and could cause problems for them down the road.

So as happened in fact, these pending patent applications were pretty much solved at the Patent Office. They had been pending for some time. They did not ultimately issue until late 2012, November 2012. But there was a possibility that they could issue at some time in the future, and so it would not have been to Impax' advantage to wait until Endo had switched to another product and perfected its patent position.

Impax -- what would have made sense for Impax would have been to launch before the new patents issued, before the -- the -- before there was a product switch, make their money and get on and if the problems -- if problems arose, then get off when problems arose, because they can't be sued for patent infringement before the patents issue.

Q. In reaching your opinion responding to Mr. Figg's opinion regarding the likelihood of an at-risk launch, did you review any of Impax' documents?

A. I did.

Q. What did you learn from your review of those documents?

A. What I learned from review of those documents is that Impax was considering the possibility of an at-risk launch maybe as early as mid-2010, that this -- that they had actually sought approval for quotas for launch from the DEA, that they had manufacturing lined up and could make launch quantities in as little as one to two weeks, I think one of the documents said.

They had presentations prepared for the board. It was considered by the board of directors. It was considered by the CEO. There were risk analyses done.

There was, in short, a lot of work towards an at-risk launch, although they did not actually make a final decision prior to the end of the trial.

Q. In reaching your opinion responding to Mr. Figg's opinion regarding the likelihood of an at-risk launch, did you review any of Endo's documents?

A. I did.

Q. What did you learn from your review of those documents?

A. This -- the potential for an at-risk launch by

Impax was also of concern to Endo.

Endo had sales forecasts looking at a variety of scenarios, including -- and the scenarios where Impax launched, the -- the damage to the -- to the Endo -- to the Endo sales was -- was quite dramatic, so this was discussed. It was discussed extensively at Endo, and Endo had developed various strategies to possibly combat it, including the -- possibly an authorized generic, and so forth.

Q. In your experience, what are the risks to branded companies generally from generic at-risk launches?

A. Well, generic at-risk launches can be very, very damaging to the branded company because the generic company will typically take a large portion of sales and put extreme pressure on the pricing. And this damage to the market, you know, you know, they -- it -- that is not really necessarily recoverable by the branded companies.

Even if they sue the generics for damages and the generics are in a position to pay big damages if they win and all of that, then still the damage to -- the damage to the market and the damage to the price may not -- may not be retrievable and may not be fully recoverable in damages from the generic company.

Q. What were the risks to Endo from an at-risk launch of generic oxymorphone ER by Impax?

A. Well, the major risk to Endo was that a generic company might get on the market before they'd successfully switched over to their -- to their new formulation.

If they had had to launch their new formulation against a generic version of the old formulation, convince patients to switch from the cheap, generic, old formulation to a presumably more expensive, non-generic, new formulation, that could have been a tough sale, so for them to have a smooth switch and to optimize their -- their switch to the new formulation and to optimize their exclusivity, they needed to delay any generic launch until after they had their new formulation on the market.

Q. Mr. Hoxie, I'd now like to turn to discuss the license.

Mr. Figg testified that the bottom line is Impax appears to have been the only one who was able to negotiate rights to future patents. In his report, he offered the opinion that the license Impax obtained was unique and provided Impax with freedom to operate.

Have you been asked to respond to that opinion?

A. I have.

Q. Do you agree with Mr. Figg?

A. No.

Q. Starting at a high level, what opinion have you offered in response to Mr. Figg?

A. Well, at a high level, I -- I did not think that the -- the license -- at a high level, I looked at the -- at the -- and offered an opinion regarding the license provisions of the settlement and license agreement. I didn't -- I don't have an opinion about all -- you know, all of the other provisions in that agreement. I'm just focusing here on the -- on the license provisions.

The license provisions in Article IV -- my opinion was that the license granted in article 4.1(a) was a fairly standard, normal license, but there was -- there was an ambiguity created by the provision in 4.1(d) regarding pending applications that eventually turned into patents.

And so, on the one hand, the license was -- was not -- Mr. Figg -- I did not agree with Mr. Figg that the license was a very unusual or special license in terms of providing rights to future patents. That's a fairly normal term. But it was also problematic -- the license was unreasonable and problematic in the

sense that it was ambiguous as to what those rights to future patents were because of the ambiguity introduced by 4.1(d).

Q. Do you hold that opinion with a degree of certainty reasonable in your professional field?

A. Yes, I do.

Q. Mr. Hoxie, are you familiar with the concept of freedom to operate?

A. Yes, I am.

Q. And what is freedom of operate -- freedom to operate in the context of patent licensing?

A. In the context of patent licensing, freedom to operate means the freedom to commercially practice the claimed invention or commercially practice your product, your -- your product, commercially make, use and sell your product commercially without -- with the freedom from being sued for patent infringement.

Q. Mr. Hoxie, why is it your opinion that it is usual or normal to -- for a licensee seeking freedom to operate to seek a license to all potentially relevant patents, including patents that may issue in the future?

A. Well, it's -- if you're -- if you're seeking freedom to operate for your product, that means you want to be able to make, use, sell your product without

being sued for patent infringement. And if you don't have a license to all potentially blocking patents, you don't have that freedom.

So if you have a license to some of the patents you need but not all of the patents you need, it's like having -- it's like you've got a door with four locks on it and you only have keys to three of them. You know, you can -- you still can't get in. You still can't operate.

So in this case it's -- it's -- it would frustrate the purpose of a freedom-to-operate license to get a license to some patents but still be blocked by other patents.

Q. Mr. Hoxie, based upon your review of materials in this case, what are Impax' general practices regarding licensing -- patent licensing for freedom to operate?

A. Well, from what I understand from -- from Ms. Nguyen's testimony, their general practices -- practices were the same -- same as I described and consistent with -- with my experience in patent licenses. That is, you want to get a license to -- you know, to all of the licensor's relevant and potentially blocking patents, and that includes patents which are -- which are pending -- patent applications

which are pending but which may turn into blocking patents down the road.

Q. And you mentioned a Ms. Nguyen.

Do you know who Ms. Nguyen is?

A. I believe she was a patent attorney working at -- at Impax.

Q. Mr. Hoxie, based on your review of materials in this case, was Impax the only ANDA filer on oxymorphone ER that may have believed it obtained a license with freedom to operate?

A. Well, I understand that Actavis also asserted that it had -- it had a license, an implied license under the -- under its settlement agreement with Endo, you know, for the later -- for the later-issued patents, and that in fact it -- it convinced the district court of that. The Federal Circuit apparently did not agree.

Q. Is Impax the only ANDA filer on oxymorphone ER who received the particular license that is set forth in the settlement and license agreement?

A. Well, the -- the -- the specifics of the -- of the Impax license are unique to Impax I believe.

Q. So, Mr. Hoxie, how do you reconcile that with your opinion that it is usual for licensees to seek licenses to all patents, including patents that may

issue in the future, when they're seeking freedom to operate?

A. Well, each of the parties that negotiated with Impax -- with Endo was in a different position. And Impax was in a stronger position to negotiate because it was the first filer, so it had -- it had this, you know, potential -- there was more at stake for Impax because it had potentially this 180-day exclusivity where it could make a lot of money, so it could make more money than the other generic companies, so there was more at stake for Impax, also more at stake for Endo because the timing of the Impax launch dictated the timing of all the successive Paragraph IV filers, so nobody could -- nobody could launch until after Impax' exclusivity was completed, so that gives Impax quite a bit of leverage.

Q. Mr. Hoxie, do you agree with the opinion Mr. Figg expressed in his report that the settlement and license agreement ensured Impax would not be sued on Endo's later-obtained patents?

A. I don't agree with that, no.

Q. You testified earlier that the license Impax obtained under the settlement and license agreement did not provide Impax with unambiguous rights under all present and future Endo patents covering Impax'

product; is that correct?

A. That's correct.

So it did not -- I mean, the -- well, as -- as -- as events showed, I mean, they eventually did get sued under those patents, so the license -- the license failed with respect to those patents, so -- so the license -- so I don't agree with Mr. Figg that there was -- you know, that they were free of risk from being sued under those later patents because they were sued under those later patents.

Q. So, Mr. Hoxie, I'd like to talk a little bit about the specific terms that are in the license that you've referred to.

What sections in the settlement and license agreement inform your opinion?

A. Well, the provisions of Article IV and in particular the license granted in article 4.1(a) and the negotiation provision set forth in article 4.1(d).

Q. Mr. Hoxie, at this time I'd like to ask you to please pick up the binder next to you and turn to Exhibit RX 364.

And Your Honor, this exhibit is admitted into evidence as part of JX 2, and it is not subject to Your Honor's in camera ruling.

JUDGE CHAPPELL: Counting last night, you've

been going about two hours. How much more time do you think you need for direct?

MS. PEAY: 30 minutes, Your Honor.

JUDGE CHAPPELL: All right. For planning purposes, I intend to take about a 30-minute break after direct, and then we're going to go until we finish the witness and end for the day, so if you need to grab a snack, do it during the 30 minutes.

MR. HASSI: Understood, Your Honor. Thank you.

JUDGE CHAPPELL: Go ahead.

MS. PEAY: Thank you, Your Honor.

BY MS. PEAY:

Q. Mr. Hoxie, have you seen Exhibit RX 364 before?

A. Yes, I have.

Q. What is it?

A. RX 364 is the settlement and license agreement between Endo Pharmaceuticals, Penwest Pharmaceuticals, and Impax.

Q. And Mr. Hoxie, did you review Exhibit RX 364 in forming the opinions you offer in this case?

A. Yes, I did.

Q. Ms. Allen, can you please put the first page of RX 364 up on the screen.

Mr. Hoxie, this is the settlement and license

agreement we've been discussing?

A. Yes, it is.

Q. And can you please turn to page RX 364.0009.

And let's take a look at section 4.1(a).

A. Okay.

Q. Mr. Hoxie, do you have experience with license provisions like section 4.1(a)?

A. Yes, I do.

Q. What is that experience?

A. I have negotiated, drafted and negotiated, many, many, many very, very, very similar licenses for freedom to operate in the course of my career.

Q. And based on your experience, what is the implication of section 4.1(a) standing alone?

A. Well, standing alone, 4.1(a) gives a license to -- first to the Endo patents, the existing patents as they're defined there, and it includes any patents that Endo has that would -- that would potentially block the Impax product, so that's typical in my experience that a license would be broad with respect to the patents and restrictive with respect to the product.

Other times licenses are broad with respect to the product but restrictive with respect to the patent, but a freedom-to-operate license like this,

it's going to be broad with respect to the patents. You've got all the patents that Endo has and, you know -- but the product is defined quite specifically as being the Impax product.

And it includes not only the existing patents, but it includes patents granting -- patents issuing on pending applications. And it includes related applications, continuations, continuations in part, and divisionals, and so forth.

So -- yes.

Q. Can you please turn to page RX 364.0011.

A. Yes.

Q. And focusing on section 4.1(d)?

A. Got it.

Q. Mr. Hoxie, do you have experience with license provisions like section 4.1(d)?

A. Not very much like that and not certainly with respect to a fairly critical term like that.

Q. What are your -- what are the implications of section 4.1(d)?

A. Well, I --

MR. HASSI: In light of the gentleman's testimony that he doesn't have experience with provisions like this, I'm not sure why he can give expert testimony interpreting it.

JUDGE CHAPPELL: Number one, is it in his report?

MR. HASSI: I believe this section is mentioned in his report, yes, Your Honor.

JUDGE CHAPPELL: If what he's saying is in his report, he can say it now, and you may inquire on cross. If what he's saying is not in his report, then I'll hear that objection.

MR. HASSI: I'll wait to hear what he has to say then, Your Honor.

BY MS. PEAY:

Q. I'll re-ask the question.

Mr. Hoxie, based on your years of experience in patent licensing, what are the implications of section 4.1(d)?

A. 4.1(d) is at least arguably in conflict with 4.1(a) because 4.1(a) grants this sort of unrestricted license and then 4.1(d) says that if you get pending applications, then you can negotiate an amendment to the terms of the license.

And it's very broad because it's -- it's any terms of the license, so it could be -- it could be anything. It essentially is almost in a way a time bomb. It potentially -- you know, once a pending patent application issues that would block Impax'

product, then the whole license is essentially open for renegotiation.

Q. Based on your review of the materials in this case, was there any dispute between Endo and Impax regarding how to interpret section 4.1(a) and 4.1(d)?

A. Yes, there was.

Q. What was that dispute?

A. Well, Impax said that 4.1(a) granted -- granted a -- an unrestricted royalty-free license, you know, in accordance with its terms and that 4.1(d) would only relate to pending applications to the extent that they would -- they would -- they would cover subject matter outside the scope of 4.1(a), so -- and in particular, Impax was thinking that this somehow related to the subsequent formulation, to Endo's CRF crush-resistant formulation. And there was correspondence and quite considerable correspondence back and forth between Meg Snowden of Impax and her counterpart at Endo regarding that.

Endo's -- Endo's contention was that this related to -- that this entitled them to change the terms of 4.1(a) to make it a royalty-bearing license, and the royalty that they proposed was 85 percent of gross profits.

MS. PEAY: Your Honor, I'm going to be careful

here because some of the specific terms related to how the parties ultimately resolved their dispute have been ordered in camera as part of an exhibit, and we are in a public session, so I will be asking these questions at a high level and without discussing the specifics of any resolution of the dispute, and I plan to ask Your Honor's permission to go in camera to discuss the specifics of the resolution of the dispute later in the -- later in this examination.

JUDGE CHAPPELL: Go ahead.

MS. PEAY: Thank you. Thank you, Your Honor.

BY MS. PEAY:

Q. And Mr. Hoxie, without getting into any specifics regarding any resolution of the dispute, did the dispute between Endo and Impax regarding how to interpret sections 4.1(a) and 4.1(d) result in any litigation?

A. Yes, it did.

Q. And Mr. Figg testified that the litigation between Endo and Impax regarding the interpretation of the settlement and license agreement didn't change his view that Impax was able to negotiate a license that provided Impax with rights and freedom to operate under patents that would issue to Endo after the settlement and license agreement.

Mr. Hoxie, does the litigation between Endo and Impax regarding how to interpret the settlement and license agreement affect your opinion regarding whether the settlement and license agreement gave Impax freedom to operate?

A. Well, it confirms my opinion that the provisions were ambiguous and -- and they -- they did in fact cause problems for Impax down the road.

Q. When did the dispute over the interpretation of the settlement and license agreement provisions first arise?

A. It was -- I'm not sure of the exact date. It was sometime after Impax' exclusivity period I think.

Q. And mindful again of this court's in camera order, without addressing the specifics of the resolution of this litigation, what happened after Endo -- when Endo filed its lawsuit against Impax?

A. Well, Endo filed its lawsuit. Impax moved to dismiss the lawsuit. Impax lost its motion to dismiss. There was -- Endo eventually terminated the settlement and license agreement, declared Impax was in breach and sued Impax for infringement under the -- under the patents.

Q. Did Endo's lawsuit against Impax include any other claims besides patent infringement?

A. Well, they included breach of contract claims.

Q. And without going into the specifics of any of the terms, did the parties resolve the litigation?

A. They ultimately did. Yes.

MS. PEAY: Your Honor, at this point I'd like to question Mr. Hoxie about areas that involve information subject to Your Honor's in camera order, specifically information related to Exhibit CX 3275. I request that Your Honor order the courtroom cleared and begin an in camera session.

JUDGE CHAPPELL: All right. For future reference, I don't need that much detail, just ask for an in camera session.

MS. PEAY: Understood.

JUDGE CHAPPELL: At this time we're going into in camera session. I'll need to ask those that are not subject to the protective order to vacate the courtroom.

MS. PEAY: Thank you, Your Honor.

(Whereupon, the proceedings were held in in camera session.)

- - - - -

(The following proceedings were held in in camera session.)

(End of in camera session.)

- - - - -

(The following proceedings continued in public session.)

JUDGE CHAPPELL: We are going to take our 30-minute break.

By the way, do you have an estimate on your time for cross now or do you want to wait until after the break?

MR. HASSI: I would guess 90 minutes, Your Honor. It might be two hours.

JUDGE CHAPPELL: All right.

We'll reconvene at 12:45.

We're in recess.

(Whereupon, at 12:14 p.m., a lunch recess was taken.)

A F T E R N O O N S E S S I O N

(12:47 p.m.)

JUDGE CHAPPELL: Okay. Continue with your cross. We're back on the record.

MR. HASSI: Thank you, Your Honor.

- - - - -

CROSS-EXAMINATION (continued)

BY MR. HASSI:

Q. Mr. Hoxie, you began working on this matter in August of this year; is that right?

A. I was first contacted by the FTC in August. I began working on this matter -- and I was asked if I would be available generally. I began working on this matter when I got Mr. Figg's report.

Q. So the first thing you did was to read Mr. Figg's report?

A. That's correct.

Q. And your report is intended to offer opinions where you disagree with Mr. Figg; correct?

A. That's correct.

Q. And you attended the trial here on Monday when Mr. Figg testified?

A. Yes.

Q. And how many hours have you -- would you estimate you've spent working on this matter?

A. I'm not really sure. I haven't added it up. Probably -- probably fewer than a hundred, probably more than fifty. I'm not exactly sure.

Q. And you're being paid $495 an hour for your type?

A. That's correct.

Q. And the report you submitted on September 20 was intended to include all the opinions that you intend to offer in this matter; correct?

A. Yes.

Q. And you felt like when you provided that report that you had sufficient documentation to form the opinions in your report?

A. I had the documentation that -- that was available. There was documentation -- there was redacted documentation, documents that were held on the ground of privilege, and documents outside the record in this case that if I were looking at this independently sort of as a lawyer for the parties, for example, I would have -- I would have looked at. But I felt I had enough to respond to Mr. Figg's report.

Q. So that's a yes, you felt like you had sufficient documentation to form the opinions you came to in this case?

A. Yes. Yes.

Q. And you did not review any of the discovery record from the underlying Hatch-Waxman litigation in forming your opinions; correct?

A. I reviewed materials from the underlying Hatch-Waxman litigation, but I believe that was all -- those were all materials that were provided in -- in this case, at least they had numbers, Bates numbers from this case.

Q. Sir, you understand my question related to discovery materials from the underlying Impax-Endo Hatch-Waxman litigation.

You did not review any materials from the discovery in that case; correct, sir?

A. I reviewed the expert reports from that case and the materials that I identified in my -- and the materials that I identified in my -- in my report. I don't think I reviewed any materials from that case that have not also -- that are not part of the discovery record in this case.

Q. So no, you did not review any discovery materials from that case, setting aside expert reports; correct?

A. Well, unless there was some overlap between the two cases. The patents, for example, were certainly exhibits in both cases I would think.

Q. So you didn't knowingly review any materials from the underlying Hatch-Waxman case between Endo and Impax; is that right?

A. I assume a lot of the materials in this case were part -- came from that case. I'm sorry. I don't --

Q. You presume that. You don't know that; right?

A. Well, I know that the materials in this case came from that other case. I'm not -- I don't understand the point of your questions, but I...

Q. Sir, you didn't review any of the underlying prior art at issue in the Impax-Endo Hatch-Waxman litigation in forming your opinions in your report; correct?

A. I reviewed the patents that were at issue in the case. I reviewed the subsequent patents, and the earlier patents were prior art to the subsequent patents. I --

Q. Sir, did you -- my question was -- and it was pretty clear -- did you review any of the prior art from the underlying patents, the '933 and '456 patents, yes or no?

A. For the '933 and '456 patents?

I relied on the summaries of reports in the experts' -- the experts provided, as did Mr. Figg. I

did not approach this as I would have were -- as I said, were a litigant -- were a lawyer for the parties.

Q. So that's a no, you did not review the prior art for the '933 and '456 patents; correct?

A. There were -- there were direct block quotes from prior art in the expert reports. I reviewed those. But I did not ascertain whether the quotes -- whether they were misquoted.

Q. Now, your experience is primarily in the area of patenting and licensing pharmaceuticals; correct?

A. Patenting, licensing, and I was global head of IP litigation at Novartis, so litigation management has been a big -- big part of my work in the course of my career.

Q. And that's all work -- strike that.

Since leaving Novartis, the bulk of your practice has been in the area of pharmaceutical and chemical patent prosecution; correct?

A. And licensing and opinion work.

I have been -- I've represented clients, you know, in litigation as well, but that's not the major part of my practice.

Q. You don't have a degree in chemistry; correct?

A. No.

Q. And you're not an expert in chemistry; correct?

A. I'm not an expert in chemistry. I deal with chemistry as part of my job and have for thirty years, but I'm not a chemist.

Q. And you don't have a degree in pharmacology; correct?

A. Again, I've -- I have taken courses in pharmacology. My undergraduate degree was in zoology with -- and which specifically was human physiology, which included pharmacology. But I am not a pharmacologist. I deal with pharmacology and have done as part of my work for thirty years.

Q. You're not holding yourself out in this case as an expert in pharmacology, are you?

A. No. I'm not a pharmacologist.

Q. And you've never been qualified as an expert witness by a judge at a trial before, have you?

A. No. This is my first time testifying at a trial.

Q. And am I correct that you've never had a stand-up role in a patent infringement trial?

A. No, you're not correct.

Q. When was the last time you had a stand-up role in a patent infringement trial?

A. I -- well, in a patent infringement trial specifically?

Q. That was my question, yes, sir.

A. In two thousand -- I can't remember the exact date. After I left Novartis, I was counsel for Almirall Pharmaceuticals in a Hatch-Waxman litigation involving almotriptan. That case eventually settled.

JUDGE CHAPPELL: Can you tell us what you mean, just so I'm clear, by "stand-up role." Do you mean first or second chair? What do you mean by that? Make sure the witness understands what you mean by that.

MR. HASSI: I will clarify, Your Honor.

THE WITNESS: Yes.

BY MR. HASSI:

Q. Other than -- well, strike that.

The almotriptan case you just referred to, that's the one Hatch-Waxman case that you've been involved in in your 13 years of private practice; is that correct, sir?

A. No. I didn't say that at all.

I've been involved in a number of Hatch-Waxman litigations. I've been asked to provide -- one large pharmaceutical company in particular had me -- had me provide an opinion prior to their filing of a

Hatch-Waxman lawsuit. In every Hatch-Waxman lawsuit they wanted it, they wanted a -- they wanted a -- they wanted a second opinion. They didn't want to just rely on the litigator's opinion.

I've also been involved in -- as I think I mentioned earlier, I'm going to a -- a mediation in the Eastern District of Delaware in just a couple -- in just a couple of weeks, but I'm not -- you know, I'm not a -- if your -- if your question is do I -- and I've also handled IPR, you know, preparation of IPR petitions, and so forth.

If your question is am I primarily a patent litigator, no, but that's not the same thing as saying I don't have any expertise in patent litigation.

Q. Well, sir, in your 13 years of private practice, would you agree you've had -- you've been counsel of record in only one Hatch-Waxman case?

A. Counsel of record, I think that's -- I think that's right.

Q. And that was the almotriptan case?

A. Yes.

Q. And in that case, you were of counsel and White & Case was lead counsel; is that right?

A. No. Actually, White & Case was the local counsel. It was filed in the -- it was filed in --

in -- in -- in New York, and I was counsel and I worked with White & Case.

I involved them because my firm does not have the resources to -- to represent, you know, branded companies in pharmaceutical patent litigation. It's -- it involves a lot of lawyers and a lot of resources, and that's not the focus of -- that's not the focus of my firm.

Q. That was a case that was filed in 2006?

A. That's entirely possible. I don't remember the exact date.

Q. And the almotriptan case, I think you said that case settled; right, sir?

A. It did.

Q. And it didn't go to trial; right?

A. No.

Q. It didn't go to a Markman hearing; right?

A. I don't believe so.

Q. And your client, Almirall, never considered a launch at risk in that case; is that right?

A. My client was the patentee in that case.

Q. And the generic didn't launch at risk in that case, did they?

A. No, they didn't.

Q. You've never drafted a Paragraph IV

certification for an ANDA filer; correct?

A. No, that's incorrect. I've drafted quite a few Paragraph IV certifications.

Q. You've drafted -- you drafted Paragraph IV certifications for ANDA filers; is that correct?

A. Yes. And the notification which is sent to the patentee, I've drafted quite a number of those.

Q. Do you recall saying something different in your deposition just a month ago?

A. No, I don't recall saying something different.

Q. Okay.

A. Can you show me my deposition and see --

JUDGE CHAPPELL: Lawman, can you hear him?

THE BAILIFF: Barely.

JUDGE CHAPPELL: You need to keep your voice up. You're going high and low. Try to maintain a higher level.

THE WITNESS: I apologize. I'll try to keep it up.

JUDGE CHAPPELL: Thank you.

BY MR. HASSI:

Q. The last tab in your binder is a copy of your deposition.

A. Yes.

Q. And if you read page 35 -- the question starts

on page 34, and if you'd read page 35 and see if that refreshes your recollection.

(Document review.)

A. Well, it says -- it -- the answer is a little unclear, but the answer says -- I've drafted Paragraph IV certifications for 505(b)(2) filers. I have drafted Paragraph IV certifications for ANDA filers. I did that both at Novartis and I've done that -- I've done that subsequently.

So I -- that -- that's a mistake, because I have drafted those. But I haven't represented -- I haven't represented ANDA filers in court. Those Paragraph IV certifications that I've drafted since leaving Novartis did not -- did not result in litigation.

Q. So on line 12 of your deposition where you said, I have not done that for an ANDA filer, that's a mistake?

A. It says, "I've provided Paragraph IV certifications. I've drafted notice of Paragraph IV certification for companies. I've never done that for an ANDA filer."

I'm not sure why -- that -- that -- that is not correct. I have done that for ANDA filers. Also at Novartis I did that.

Q. Sir, you've never questioned a witness or argued at a Markman hearing; correct?

A. No, that's not correct.

Q. When did you question a witness or argue in front of a judge at a Markman hearing?

A. At a Markman hearing?

Q. Yes, sir.

A. In the seeds litigation with -- there was -- there was a -- a -- there was a Markman hearing in front of a judge and there was -- there was an issue, and I was -- I was -- I argued -- I argued an issue because it was a technical -- it was a technical issue, and I was permitted to argue that for that case. That was in -- I believe it was in Minnesota.

Q. Have you ever argued a Markman hearing in Hatch-Waxman litigation?

A. Have I argued a Markman hearing, no, not personally argued it. I've attended Markman hearings and I've contributed to Markman briefs, but I've not personally argued the motions.

Q. While you were at Novartis, you were involved in maybe a half dozen settlements of Hatch-Waxman cases; is that right?

A. That's right. In my experience, those cases were difficult to settle.

Q. That was all before 2004?
A. When I was at Novartis, yes.
Q. And all of the opinions in your report, sir, are intended to specifically rebut opinions of Mr. Figg; is that right?
A. Yes.
Q. In your report you don't offer any opinions related to the Endo credit?
A. I do not.
Q. In your report you don't offer any opinion on the exclusivity or no-AG provision in the settlement and license agreement; correct?
A. I do not.
Q. In your report you don't offer any opinion on the scope of the patents in relation to the scope of the settlement and license agreement; is that correct?
A. I do not.
Q. In your report you don't offer any opinion that a single consumer was harmed by the settlement and license agreement; correct?
A. I don't offer opinions specifically about consumers being harmed.
I do offer opinions concerning when it would have been possible for Impax to be on the market and -- and -- and their motivations for being on the market

earlier rather than later. I don't -- I don't link that to specifically to consumer harm. That's not my job.

Q. So I take it the answer is no, in your report you don't offer any opinion that a single consumer was harmed by the settlement and license agreement; correct?

A. I only offer an opinion that Impax -- that -- regarding the -- that it appeared to me that Impax was delayed in its -- in its launch, that it had a motivation and incentive to launch earlier rather than later. If that harms consumers, then it harms consumers, or it doesn't, so I don't -- I don't make that second link to consumers.

Q. Sir, your report doesn't offer an opinion that Impax was delayed, does it?

A. It does. It offers an opinion that Impax was motivated to launch -- to launch earlier, that Impax had a strong motivation.

So my opinion is that they certainly could have been delayed. I don't offer any opinions about what necessarily, you know, absolutely did or did -- you know, absolutely would have happened but for this or that, but I do offer the opinion that they -- they could and -- have launched earlier and that they were

economically motivated to launch earlier.

Q. Does the word "delay" appear anywhere in your opinions, sir?

Yes or no?

A. I don't know if the word "delay" appears earlier, but launching earlier rather than later, if you launch later rather than earlier, then there is of necessity a delay. That's definitional.

Q. And earlier and later than what, sir? Can you show me in your report where you said Impax launched earlier or later than a particular date?

A. Impax launched -- my report states that Impax could have launched at risk and that they contemplated launch -- that there were contemplations of launching as early as 2010 or January of 2011. And my report addresses those.

In fact, Impax agreed to launch in January of 2013, so over two years later. And during those two years, things happened which changed the economic structure, the economic situation for Impax, and I outlined those as specifically the switch to the new product by Endo and the issuance of additional patents. Those are all addressed in my report.

So there were consequences to launching later rather than earlier, and there were reasons for Impax

to have launched earlier. And I do -- I go into that in quite some detail in my report, sir.

Q. Sir, in your report you don't offer any opinions regarding the development and co-promotion agreement; correct?

A. I do not.

Q. And in your report you don't offer any opinions about what would have happened if Impax had begun selling oxymorphone ER; correct? Earlier.

A. I offer the opinion that had they begun selling oxymorphone ER earlier, it would have predated -- it could have predated the switch by Endo to the new product, which didn't happen until late 2012, and the issuance of the new patents, which again was in late 2012, so there was nearly a two-year window when they could have -- it would have been economically advantageous for them to launch and where the new patents which caused them such problems later would not have been at issue, so there was a two-year window where it would have been better for them to launch than when they did launch, and I do lay all that out.

Q. Sir, when you said "better for them to launch," who was the "them" in that sentence?

A. Impax.

And it would have benefited the other generic companies, too, because, as I mentioned before, the other generic company -- nobody could launch for the formula -- for the dosage amounts that Impax was the first Paragraph IV filer on until Impax' 180 days of exclusivity was completed, so delaying Impax delayed everybody.

Q. There's no opinion in your report, is there, sir, that Impax would have been better off launching at risk, is there?

Yes or no?

A. My opinion in the report was that there were economic considerations that Impax might have taken for launching at risk, considerations that were not taken into account in Mr. Figg's report, and therefore, I disagreed with Mr. Figg's conclusion that there would not have been a launch -- there necessarily would not have been a launch at risk in this case.

Q. Sir, my question was, there's no opinion in your report that Impax would have been better off launching at risk, yes or no?

A. I think I've explained what my report says. It doesn't have those exact words, but I think in substance it does say that.

Q. You don't --

A. But not --

Q. Sir --

A. Not in those words.

Q. And nowhere in your report do you evaluate the risks and benefits of an Impax launch at risk against the risks and benefits associated with the settlement and license agreement; is that correct, sir, yes or no?

A. All of the risks and benefits associated -- I didn't evaluate the entire settlement and license agreement, only the license provision. I didn't evaluate, for example, the Endo credit and whatever benefit that might have conferred to Impax. That was not part of my assessment.

Q. And you didn't evaluate the benefits in total to Impax from entering into the settlement and license agreement versus the potential of launching at risk; correct?

A. As I said, I didn't evaluate the settlement and license -- all of the implications of all of the provisions in the settlement and license. Specifically, I didn't evaluate the Endo credit.

Q. And you didn't evaluate the economics to Impax of the sales it would have made in a launch at risk and the damages it could have incurred versus the sales it

made by launching pursuant to the settlement and license agreement; correct, sir?

A. I did offer opinions pertaining to that, yes, I did.

Q. You offered opinions as to what sales Impax would have made had it launched at risk versus the sales it made in the real world pursuant to the settlement and license agreement? Why don't you tell me where that's in your report, sir, point me to a paragraph --

A. I referred specifically to sales projections by both Impax and Endo.

Particularly, Endo had quite some detailed analysis of the amount of sales that Impax would have taken. Those documents, they're referenced in my report. They're in footnotes. There's -- and there are quite a number of documents both from Impax and Endo regarding the potential sales that Impax would have were it to launch at risk.

And that was part of my analysis that there were economic benefits to -- to Impax to launch it, to launch at risk, which could have offset some of the risks of launching at risk.

Q. Sir, you're not providing any opinion in your report as to whether Endo would have won its patent

case; correct?

A. I don't provide any -- any opinion as to the ultimate outcome.

Q. And you didn't conduct an assessment of how likely Endo's patents were to be upheld by the district court; correct?

A. Again, I -- I presented what I saw as -- my report was confined to responding to Mr. Figg's conclusion, which I disagreed with, that Endo was more likely than not to win the patent case. I disagreed with that conclusion. But I didn't go further. I didn't go beyond Mr. Figg's report --

Q. And you didn't --

A. -- beyond responding to Mr. Figg's report.

Q. And you didn't calculate the probability that Endo would have won the patent litigation; correct?

A. No. Only that there were significant issues that Mr. Figg failed to consider.

Q. And you didn't calculate the probability that Impax would have won; correct?

A. Same answer.

Q. That's a no? No, I did not calculate the probability; is that your answer?

A. Well, I think the probability -- calculating probabilities for one or the other is kind of the same

question, but yes, the answer is no, I did not calculate that. I simply calculated -- I simply issued an opinion that I disagreed with Mr. Figg's opinion that Endo was more likely than not to win the patent litigation. That's all.

Q. And you've not seen any assessment of the probability that Endo's patents would be upheld; correct?

A. I don't think a numerical probability is possible for such a -- for such a question.

Q. You acknowledge the outcome of litigation is always uncertain; correct?

A. Yes.

Q. And that's true even if there's a rock-solid patent; correct?

A. Yes.

Q. And you're not providing any opinion as to whether the patents in this case were rock solid; correct?

A. I've provided opinions that there were significant issues regarding the validity of the patents and regarding Endo's ability to prove infringement of the patents under the judge's claim construction. That's what -- so there is reason to question their validity, but I don't have any -- their

rock-solidness, but I don't have any ultimate opinions that they're infringed or not infringed or valid or not valid. That wasn't within the scope of my report.

Q. Sir, you're aware that first filers can obtain 180-day exclusivity under the Hatch-Waxman Act?

A. Yes.

Q. And you would agree that the 180-day exclusivity provision is a valuable asset for a first-to-file ANDA filer; correct?

A. Extreme -- well, extremely valuable, particularly if it's unshared.

Q. And you would agree that any blocking power that the first filer may have -- and I use "blocking power" the way you use it in paragraph 25 of your report -- from the 180-day exclusivity comes directly from the Hatch-Waxman Act; correct?

A. Yes.

Q. And Congress designed the 180-day exclusivity provision as an incentive for generic drug manufacturers to challenge patents; correct?

A. That's my understanding.

Q. The 180-day exclusivity is a reward for challenging a patent; correct?

A. Effectively, yes.

Q. And you agree with Mr. Figg that the brand

company prevails in Hatch-Waxman litigation roughly 50 percent of the time; correct?

A. I haven't done the statistics, but I have no reason to doubt that. It sounds about right.

Q. And when you state in your report that you disagree with Mr. Figg's assessment that Hatch-Waxman litigation is an uphill battle, in paragraph 86 of your report, you don't rely on any statistics to support your opinion; correct?

A. I believe I pointed out in my report and there's statistics quoted in the article that's cited in my report that following Hatch-Waxman and apparently as a result of Hatch-Waxman generic business has expanded dramatically in the decades, you know, following Hatch-Waxman. And that's also been, you know, what I've observed in my time in the pharmaceutical industry, that the generics -- generic business has -- has expanded dramatically because of the opportunities that Hatch-Waxman provides for -- largely under the 180-day exclusivity for generic companies to be very profitable for that 180-day period.

Q. Sir, so I understand you offer lots of information about the effects of Hatch-Waxman --

A. Yes.

Q. -- and the litigation that's exploded as a result.

Do you understand that what Mr. Figg was talking about was about winning versus losing in a Hatch-Waxman litigation when he talked about it being an uphill battle for the generic company?

A. Well, I -- I did not --

Q. Did you understand that, yes or no?

A. Do I understand winning versus losing? I think he was -- I think his uphill battle was a -- I think the way it was in his report was -- was -- uphill battle is more broadly than the ultimate victory, although I think there are many aspects to the case, for example, the ability to resolve prior to launch, the ability to avoid being sued for patent infringement while you're developing your product, the ability to -- the fact that the -- the litigation doesn't involve damages typically.

Those are all things that I think make the litigation -- Hatch-Waxman relatively simple and reduce the risk for generic companies. It's a -- it's a -- it's -- so I don't -- I don't see -- as far as the standards of patentability and patent infringement, those are exactly the same in Hatch-Waxman as in any other patent litigation. There's no different standard

of patent infringement for Hatch-Waxman.

So I don't understand -- I don't agree that it's an uphill battle. There -- a generic company has certain advantages, and the standards of patentability are the same, so...

Q. Sir, you've never been counsel of record for a generic pharmaceutical company in a Hatch-Waxman litigation; correct?

A. No. But I managed patent litigation for the second largest generic company in the world for some period of time, so I have some understanding of the risks involved.

Q. And that was before 2004; correct?

A. That particular role was before 2004.

Q. In the last 13 years, you've never set foot in a courtroom on behalf of a generic pharmaceutical company in a Hatch-Waxman litigation; correct?

A. No, not on behalf of a generic pharmaceutical company.

Q. And your report says nothing about the generic company's odds of winning a Hatch-Waxman litigation; correct?

A. Odds of winning?

Q. Odds of winning for a generic, yes, sir.

A. "Odds of winning" is not a meaningful term in

the general abstract. The odds of winning depend on the particular facts and circumstances of a particular case.

It's not helpful in analyzing the case or deciding -- advising a client or making a decision on settlement to know what the odds in general are of winning a case any more than it's very helpful, you know, if you're a cancer patient of knowing what the odds of getting cancer are generally.

You need to look at the facts and the circumstances of a particular case and evaluate the risks and make decisions accordingly. It's a very case-by-case determination.

So a 50/50 chance in general or a 52/48 chance, as Mr. Figg testified, has absolutely no bearing on the odds of winning a particular case.

Q. And so by that answer, do I take it you agree with me that your report says nothing about the generic company's odds of winning a Hatch-Waxman litigation?

A. I -- my report doesn't -- addresses the -- addresses issues that came up in respect of this particular case and things that would affect Endo's chances of winning or losing this particular case, but it doesn't address odds of winning a patent litigation

sort of in the abstract divorced from the circumstances of this case, no, it doesn't.

Q. Your report also does not address or assess all of the risks to Impax associated with a potential launch at risk; correct?

A. All of the risks?

Q. All of the risks, yes, sir.

A. No. There are many risks. The patent -- there could be regulatory risks. The product could kill people. The factory could blow up. It's a very risky business. There are a lot of risks. Looking at patent litigation as the only risk is -- is unrealistic, and it's not the way that people making business decisions, in my experience, look at things.

So there are a number of risks in winning or losing patent litigation, and being held subject to an injunction or damages as a result is one risk out of a number of risks. And not launching carries risks in this case of its own.

Q. But you didn't evaluate the risks, for example, of launching at risk to Impax; correct?

A. I think I did address some of the risks of launching at risk. I mentioned the potential for damages and injunction. I believe that is in my report.

Q. You didn't put yourself in the shoes of Impax as a reasonable litigant in this case, did you?

A. I wasn't in the position of trying -- as I've said, I'm not in the position of trying to be Impax' -- you know, be Impax' counsel.

I'm simply pointing out that sort of as an objective third party Endo had some problems with their case, and I don't think that it was more likely than not that Endo would have won its case. I feel the outcome was uncertain.

And there were a number of risks to Endo, and I've pointed those out. There were risks to Impax of launching at risk. I pointed some of those out. There were risks to Impax of launching at risk, I mean, and there were also risks to Impax of not launching at risk, and I tried to point some of those out.

But I didn't -- I didn't take the second step and evaluate all those risks and say this is what I would do if I were Impax. That was not my -- within the scope of my report.

Q. So you didn't say this is what I would do if I were Impax; right?

A. No. I simply identified risks that I felt Mr. Figg had not identified and the reasons why I disagreed with Mr. Figg's conclusion.

Q. And that's what you were retained to do, was disagree with Mr. Figg's conclusions; correct?

A. Not at all. I agreed with many of Mr. Figg's conclusions. I disagreed with certain of Mr. Figg's conclusions. I was retained to evaluate Mr. Figg's report as somebody having experience in this field.

Q. You agree that an at-risk launch is a launch before the generic firm has a nonappealable judgment; correct?

A. That's -- I agree that that's the way it's commonly used.

Q. And you have not had a client launch a drug at risk where you were advising that client since you entered private practice in 2004; correct?

A. Not since 2004. The last time I did that was before 2004.

Q. And that was the Augmentin -- before 2004 -- strike that.

You testified that you've been personally involved in at-risk launches; correct?

A. Yes.

Q. And one of those at-risk launches was the Augmentin at-risk launch; correct?

A. That was one example.

Q. And what other examples of at-risk launches do

you have, sir, where you were personally involved?

A. I'm not sure that I recall while I was doing that that the generic -- we're only talking about the generic company. I'm not sure that I remember any others other than Augmentin that were at risk in that sense.

There were some -- certainly some launches -- I'm pretty sure -- I guess we had -- I'm just trying to think. I think we had Federal Circuit decisions in the others before launch where we had a -- some sort of a settlement.

Q. So as you sit here today, you can only think of one at-risk launch where you've been personally involved; correct, sir?

A. No. I've been involved from the branded side where generic companies did at-risk launches.

Q. And what at-risk launches have you been involved in from the brand side where the generic did an at-risk launch?

A. I'm not a hundred percent sure. I'm pretty sure cyclosporine -- there was an at-risk launch for cyclosporine and there might -- I think there was an at-risk launch for pamidronate, pamidronic acid, P-A-M-I-D-R-O-N-I-C acid, which is -- went by the brand name Aredia, A-R-E-D-I-A. I'm pretty sure there was an

at-risk launch in that case, too.

Q. So on the generic side, where a company is making a decision to launch at risk, you've been involved in one of those in your 31-year career; correct, sir?

A. Representing the generic company, yes.

Q. And that was the Augmentin launch at risk?

A. That was a particularly high-profile one, so I remember it particularly well. Yes.

Q. That was when you were in-house at Sandoz?

A. Yes.

Q. Sandoz is a subsidiary of Novartis?

A. I was in-house at Novartis then. The generic subsidiary was -- it -- that was after the merger between Sandoz and Ciba-Geigy.

Sandoz -- Sandoz disappeared for a while as a corporate entity. It was subsumed into Novartis. Then subsequently the generic businesses were consolidated under the old Sandoz name, legacy name, because that name had quite strong goodwill outside of the United States, and so that now -- currently, they now market those -- in fact, the generic business of Sandoz -- Novartis is now under the name Sandoz, but I was -- I was never a part of the -- the -- that Sandoz company. The Sandoz company I was a part of was a --

was a predecessor to that, if you will.

Q. You were part of Geneva for that at-risk launch?

A. Yeah. That was -- that was Geneva and Biochemie. They were subsidiaries of Novartis.

Q. And Novartis at the time was one of the largest pharmaceutical companies in the world; isn't that right, sir?

A. It was then and still is.

Q. At the time a $50 billion company maybe?

A. In market cap?

Q. In market cap.

A. I think it was probably bigger than that.

Q. Okay. In revenues maybe 50 billion?

A. Huh?

Q. Revenues of about 50 billion?

A. I'm not sure what their -- I'm not sure exactly what their revenues were, but it was a very big company.

Q. Now, in paragraph 39 of your report, you state -- do you want to get there first? Do you want to read along with me or do you want me to just read it to you?

A. I -- it's up to you. You're asking the --

Q. I'll read it, and if you need it, we can bring

it up on the screen.

In paragraph 39 of your report, you state, "What Mr. Figg fails to address, however, is that the risk of damages does not mean that [the] generic companies never launch at risk."

Sir, we can agree that Mr. Figg did not offer an opinion that generic companies never launch at risk; correct?

A. Yes.

Q. Now, in your report you state that "If Impax had received a favorable decision at the district court level, a launch prior to the appellate decision could be a reasonable risk from Impax' perspective, taking into account the countervailing risks of delay."

That's your opinion, isn't it, sir?

A. Yes.

Q. And that's the only place in your report where you address the risk of a launch at risk from Impax' perspective; correct?

A. I'm not sure. I'd have to look at my report to see each place where I address that.

Q. I was just referring to paragraph 44. Tell me if you can point to anywhere else in your report where you refer to a launch at risk from Impax' perspective.

(Document review.)

A. May I -- there's a whole section of my report on that issue, the whole section VII of my report about at-risk launches from paragraph 38 through 50, so there's -- there's a lot about Impax' time -- the timing of their launch.

I mean, I'm sure those words only appear in that paragraph, but it's a significant -- that is supported by a number of paragraphs on either side.

Q. Well, we'll talk about the support.

What I was getting at, sir, is, in terms of handicapping the risk and how you framed it, you used "substantial" earlier today, "substantial risk." You didn't use that anywhere in your report, for example; right?

A. I'm not -- I'm not sure exactly what you're talking about. I've talked about a reasonable risk in my report. I spent a lot of time talking about my -- and my -- I spent -- I do spend a considerable amount of time in my report talking about, you know, different risks, the risk of launching and risks of not launching.

I don't recall whether I characterized them specifically as substantial or not. They were risks, which a reasonable businessperson would take into

account.

And I also cite to documents where the parties actually quantified some of those, some of those risks, like quantified projected sales, and so forth.

I didn't have all of the documents relating to that that were -- because there were a number of redactions in the documents from Impax and also documents relating to risk analysis. There was some discussion about the Zorn documents on risk analysis. I didn't have access to those documents as they were withheld by Impax, is my understanding, and there were redactions made by Impax, is my understanding.

Q. Are you done?

A. Yes.

Q. Okay. Sir, your report does not offer an opinion that Impax would have launched before receiving a favorable trial court decision; correct?

A. Before receiving a favorable trial decision?

Q. Yes, sir.

A. No. Impax agreed to delay -- agreed -- submitted a letter to the court saying it would not launch at least before the end of the court proceedings, which were scheduled for June 17, 2010 I believe.

Q. And so you agree your report does not offer an

opinion that Impax would have launched at risk before receiving a decision from the trial court; correct, sir?

A. No, it doesn't offer -- it doesn't offer that opinion.

Q. And you agree that if Impax lost in the district court, it would be enjoined from launching; correct?

A. That was a possibility. They could have been enjoined from launching. They could have posted a bond. They could have taken an expedited appeal. There were many things that could have happened. I didn't really get into all of that.

Q. But among the things that could have happened, you do not expect that Impax would have launched at risk in the face of a district court injunction, do you, sir?

A. No. I don't think they would have violated the injunction.

Q. And your report doesn't offer an opinion that Impax would have launched at risk in the event it won a favorable court decision; correct?

A. My report says that there were economic motivations that -- that -- that -- that would support a launch. But I don't presume to necessarily say what

they would or wouldn't have done, just -- I've not tried -- I'm not trying to get into their heads. I'm just trying say there were these economic factors that would -- would tend to encourage them to launch sooner rather than later.

Q. And you referred to economic factors.

You're not an economist, are you, sir?

A. No.

Q. And in your report you've not calculated the odds that Impax would launch at risk; correct?

A. As I stated previously, I -- I -- looking at risks, there's a risk-benefit analysis. There are risks that would need to be taken into account. I don't sum up those risks and come up with odds.

And I don't presume to have knowledge as to what Impax would or wouldn't do beyond the fact that Impax was seriously considering such a launch as evidenced by the documents which are cited in my report.

Q. And in terms of a risk-benefit analysis, your report does not contain a risk-benefit analysis of an Impax launch at risk; correct?

A. My report contains references to documents that contain sales projections were they to launch, and obviously they would have forfeited those sales if they

didn't launch.

And it also discusses the risks of -- it also contains figures relating to Endo's sales.

So it does contain information relevant to that analysis, but it doesn't -- I'm -- it doesn't do that analysis specifically.

Q. And you saw no indication in the record that Impax had made a decision to launch at risk; correct?

A. I believe the -- that the -- the e-mail from the -- from the CEO said that the decision -- they were -- the decision would turn on the PI, which I interpreted to mean the -- an -- whether there were a PI decision, which I interpreted to mean the decision by the trial court whether there would or would not be an injunction, whether they would or would not be blocked at the end of the trial. That was the way I understood that.

Q. So you understood Impax to be waiting to see if it got a favorable district court decision; correct?

A. Yes.

Q. And you agree that an at-risk launch is a significant decision and would be made at a very high level in a company; right?

A. Yes.

Q. For most companies it's -- we're talking executive committee or board-level decision?

A. Yes.

Q. When you were at Novartis, it was a board-level decision?

A. Yes.

Q. And at the time, Novartis was one of the largest pharmaceutical companies in the world; correct?

A. Yes.

Q. Now, Novartis would make preparations to launch before it knew for certain whether it was going to launch a product at risk; correct?

A. Can you be more specific?

Q. When you were at Novartis, and the company hadn't made a decision whether or not to launch a drug yet, would the company take steps operationally to prepare to launch that drug, for example, to undertake process validation?

A. Well, the entire process of drug research and development is taking steps in the hopes of being able to launch a drug, and a company spends a lot of time on that, and sometimes things pan out and sometimes they don't, if that's the point of your question.

But they don't spend money for no reason. They

don't spend money unless they think there's a reasonably decent chance that they're going to get a return on that investment.

Q. You're not offering an opinion in this case that Impax spent money for no reason, are you; sir?

A. I -- I believe I already testified and referred to the documents about what -- the preparations Impax had made for a launch.

I know from my experience working in the pharmaceutical industry that those things cost money, and so the inference that I draw from that is that Impax, particularly a smaller company like Impax that maybe doesn't have the resources to spend money willy-nilly, would not have spent significant money to launch if they didn't think there was a significant chance that they would -- they would be making sales. They wouldn't make -- spend a lot of money on preparations if they didn't think there was any reason for making those preparations.

Q. Sir, you've never worked for a small pharmaceutical company like Impax; correct?

A. I represent small pharmaceutical companies.

Q. But you've never worked in-house for a small pharmaceutical company, have you, sir?

A. No.

Q. I think I heard you this morning testify that you thought Impax could make launch quantities in one to two weeks. Can you tell me where you got that information, sir?

A. There were some e-mails. The e-mails are cited in my report. If I can look at my report, I might be able to point you to the document.

Q. Why don't you tell us where you see that in your report.

A. It was one of the documents cited in footnote 56 of my report, footnote 56 of my report, where they were talking about the -- the -- I can't remember exactly which e-mail chain it was.

I think it was one of the e-mails involving Chris Mengler, but I don't remember exactly which -- which chain it was -- which e-mail chain it was. But there were -- there were a number of them, and the -- between Chris Mengler and the back-and-forth I think involved -- the CEO was in some of those e-mail chains, Dr. Hsu, Mr. Hsu.

And they had -- and they -- they discussed that there was a quota or that they had to get a quota, and they discussed that they could -- they were making the validation batches and they could -- they could do -- I think they could make -- I think they

had -- they said they can make six batches and that would exhaust their quota and then they would have to go to the DEA and they could -- my understanding is it's possible to get an adjustment to a DEA quota. Novartis had some controlled substances that it sold, so I have some basic familiarity with that process.

So they would have to get -- so they might have -- it would have been a business decision internally whether to launch with a smaller quantity or go to the DEA, ask for additional quantity and launch maybe in January, if they could get approval for a larger quantity --

Q. Sir, my --

A. -- a larger quota.

Q. My question had nothing to do with DEA quota.

My question was simply, could you identify the basis for the testimony you gave this morning that Impax could be -- make launch quantities of oxymorphone ER in one to two weeks. Can you answer that question?

A. Yeah. It's one of -- I believe it's in an e-mail from Chris Mengler.

Q. So it's something you read in an e-mail somewhere that gave you that impression?

A. Well, not in an e-mail somewhere, an e-mail

from the person responsible at Impax. I don't know exactly what Mr. Mengler's responsibilities were, but he was the one who was providing the information to the CEO, so I assume he had some -- and to the board. There were slides prepared for the board.

My understanding was that once they pulled the trigger to launch, they could launch very quickly, and that's documented in the e-mails. But the exact timing of the launch, according to the CEO, would await the decision on whether or not there was an injunction.

Q. Sir, in your report, when you say "a launch prior to the appellate decision could be a reasonable risk from Impax' perspective," you don't define "reasonable risk," do you, sir?

A. A reasonable business risk. I think it could be a reasonable business risk.

"Reasonable business risk" is a term that I try to use for -- in advising clients because I try to avoid things like a 75 percent chance or a 23 percent chance because I think that gives a false sense of accuracy.

So there are risks that the -- that need to be balanced and there are -- if they got a favorable decision and they felt it could be defended on appeal,

it would be a reasonable -- it might be a reasonable risk for them to launch, given the fact that there were these threats to their opportunity, particularly the additional patents and the switch by Endo to a new product. And you know, so those -- so those things would have to be taken into consideration.

It's always nice if you have the exclusivity locked in and secure and you're -- the market is not moving or shifting. Of course, it's preferable to wait until you have a Federal Circuit decision and not take the risk, because you're assured you're going to get your 180 days of exclusivity, you know, you know, in one -- in either event.

But in this case it wasn't clear that the 180 days that would come after a Federal Circuit decision would have the same value as the 180 days at an earlier stage, before there were additional patents and before Endo had switched over to a new product.

JUDGE CHAPPELL: Sir, you just went on there for about 50 lines, 5-0.

The question was, you don't define business risk, do you -- Josett, read that question back.

And sir, I'm instructing you to answer just the pending question.

THE WITNESS: Yes, Your Honor.

JUDGE CHAPPELL: You went for 50 lines there. It was a yes or no.

THE WITNESS: Yes, Your Honor.

(The record was read as follows:)

"QUESTION: Sir, in your report, when you say 'a launch prior to the appellate decision could be a reasonable risk from Impax' perspective,' you don't define 'reasonable risk,' do you, sir?"

THE WITNESS: I define my basis for that statement, so it is in a context. I don't give a specific definition of "reasonable risk," but I state certain factors and I conclude that those factors add up to a reasonable risk.

JUDGE CHAPPELL: Go ahead.

MR. HASSI: Thank you, Your Honor.

BY MR. HASSI:

Q. Sir, you didn't offer any other quantification of what a reasonable risk would be from Impax' perspective in your report, do you?

A. I did not try to quantify those things.

Q. And you've never worked at Impax?

A. No, sir.

Q. You've never worked at a small pharma company like Impax; correct?

A. As I said, I've represented -- I regularly

represent small pharma companies, but I don't -- I'm not an employee.

Q. And you've never represented Impax; correct?

A. No.

Q. And the one pharmaceutical company where you have worked was Novartis; right?

A. Yes.

Q. And they are many, many, many times larger than Impax; correct?

A. They are larger than Impax, yes.

Q. Do you understand in 2010 Impax was a less than a billion dollars in revenue company?

A. I have no knowledge of Impax' revenues, but I -- I understand that they're smaller than Novartis.

Q. Sir, your view of what would be a reasonable risk from Impax' perspective is just your speculation; correct?

A. No. I don't agree with that.

Q. Now, let's talk about the risk to a risk at launch.

One risk is that the launch is enjoined; correct?

A. Yes.

Q. And if you're launching at risk as a generic who's first to file, you can put your 180-day

exclusivity period at risk in the event of injunction; correct?

A. Yes.

Q. And you agree that that 180-day exclusivity can be very valuable to a generic.

A. Yes. I think that's why the CEO mentioned that he wanted to await the determination of the injunction before making a decision.

Q. Now, if he had waited until there was a trial court decision and then Impax had made the decision to launch at risk --

A. Yes.

Q. -- it could still be enjoined; right?

A. Well, it depend -- if the trial court -- if the trial court ruled in Impax' favor, no.

Q. Are you aware of any case in which the trial court ruled in the generic's favor, the generic launched at risk, and then the trial court enjoined the generic?

A. That could happen I guess, but --

Q. It hasn't.

A. -- normally -- but -- but there would be a decision on the -- that's why I think he was saying that the decision would turn on the PI, which I interpreted to refer to the injunction, so the trial

court would decide the injunction presumably at the close of the case. There would have been motions on that I assume.

Q. Are you aware that Mylan launched after a favorable district court decision and got enjoined and lost their 180-day exclusivity? Are you aware of that instance?

A. I -- I don't know -- I don't know the details of the case you -- you refer to, but yes, it's certainly if you -- if you launch and then you're enjoined, you don't get to later restart the 180 days. It's gone. That's -- that -- that -- that's true. I agree with that.

Q. Now, you've never been in a position to put a company's first-to-file exclusivity at risk by launching at risk, have you, sir?

A. I'm -- I'm not sure I totally understand the question.

Q. You've never been asked to make the decision whether or not a generic pharmaceutical company could put its first-to-file exclusivity at risk by launching the product at risk, have you, sir?

A. I would not recommend that a company launch at risk if -- if I thought there was a high chance of them being enjoined. And that hasn't happened to a

company that I've represented.

Q. In the one experience where you had personal experience with a launch at risk, Geneva was not the first to file on Augmentin, was it?

A. That was an antibiotic case, so the -- certain provisions of Hatch-Waxman didn't apply. There were multi- -- so there was not 180-day exclusivity. Geneva was the first to file, but it was -- it was -- it was subject to certain aspects of Hatch-Waxman but not others because of the -- the nature of the FDA reg- -- the FDA laws. It was approved under section 505 -- 507 rather than 505 of the Food, Drug and Cosmetics Act.

Q. Geneva was racing to market, racing, for example, Teva to try and get out there first?

A. Yes. Teva and Ranbaxy.

Q. And so unlike the situation where you've got first-to-file exclusivity, which you referred to as a blocking position, there you had to race; right?

A. Yes.

And I mean, I've seen that happen in other cases where there are -- oftentimes generic companies might -- particularly under the new version, they share exclusivity, and then there's a race, so as I said in my direct testimony, that's a common -- that's a common

fact pattern for launches at risk.

Q. It's not a fact pattern that applied here to Impax in light of their first-to-file exclusivity; right?

A. No. As I explained, the underlying issue, though, is the concern of the -- the risk of losing your -- your shot at the market opportunity. That was the concern -- that's what I felt was the common theme there.

Q. Now, another risk to an at-risk launch is paying lost profit damages; correct, sir?

A. That's correct.

Q. And indeed, you agree with Mr. Figg that at-risk launches present significant risks due to the measure of damages that could be the branded company's lost profits and the possibility of treble damages and even an award of attorneys' fees; correct?

A. Yes. That can happen.

Q. And lost profit damages can be in the billions if the sales of the branded drug are high enough; correct?

A. That's correct.

Q. And you didn't evaluate the magnitude of the potential lost profit damages that Impax could have faced if it launched at risk; correct?

A. No. That would have been a complicated analysis because it would have depended on whether -- on the exact timing of the launch and things like whether or not Impax still had the reference listed drug on the market or it switched to a new product. That would have affected the damages calculation.

Q. You didn't do any calculation of the potential damages that Impax could face in this case from an at-risk launch; right?

A. I just tried to identify the risks. I didn't try to quantify them.

Q. And you didn't do any analysis of the potential profitability of an at-risk launch for Impax to weigh against those downside risks; correct?

A. I referred to the documents and the projections of forecasts both from Endo and -- from Endo and from Impax in my report, but I didn't do an independent calculation beyond what the parties to the litigation had done.

Q. And you didn't do a comparison to weigh the sales that Impax could have made if it had launched at risk against the sales that it did make and has made since 2013 as a result of the settlement and license agreement; correct?

A. I did offer an opinion that the sales would be

lower if there was no predicate drug to drive sales for the generic product.

In other words, if you don't have the benefit of automatic substitution, the sales are likely going to be lower, so I did offer that opinion. But I didn't offer the -- the -- so I'm not sure if that's -- if that's responsive to your question or not.

Q. I don't think it is, but is the answer no, I did not weigh the sales that Impax might have done -- might have earned in an at-risk launch against the sales it actually made in the real world; correct?

A. No. I think that the answer I gave is an opinion on that question, but...

Q. You didn't do the math, did you, sir?

A. No. I relied on the -- what the parties -- the math that the parties did.

Q. Okay. Let's do a little math --

A. Okay.

Q. -- about what the damages of an at-risk launch look like.

Are you aware that complaint counsel has introduced evidence in this case to suggest that at the time of the settlement Endo's Opana sales -- Opana ER sales were worth about $20 million a month?

A. Endo's Opana ER sales --

JUDGE CHAPPELL: Hold it.

MS. PEAY: Objection, Your Honor. This line of questioning is outside the scope of the witness' direct and his report.

MR. HASSI: Your Honor, this witness wants to testify that it was a reasonable business risk for Impax to launch at risk. He's not done the calculations in terms of what that risk looks like. I thought it might be interesting for Your Honor to hear what those numbers look like.

JUDGE CHAPPELL: Are you saying this is impeachment?

MR. HASSI: I am saying that.

JUDGE CHAPPELL: Overruled.

MR. HASSI: Thank you, Your Honor.

MS. PEAY: Thank you, Your Honor.

THE WITNESS: Excuse me?

BY MR. HASSI:

Q. Sir, are you aware that complaint counsel has introduced evidence to suggest that Endo's Opana ER sales at the time of settlement were approximately worth $20 million a month?

A. That Endo's Opana ER sales were -- their total sales were $20 million per year.

Q. Per month.

A. Per month. Okay.

Q. Okay. You take that first -- take that as an assumption.

A. I don't know -- I will take that as an assumption.

Q. And let's estimate they had a 90 percent margin on those sales. Is that about fair?

A. It could be fair, yeah.

Q. So that would mean its profits were about $18 million a month?

A. That's possible, yeah.

Q. And so if Impax sold a month's worth of Opana ER at risk, they could be risking as much as $18 million in damages; right?

A. Per month.

Is that what you're saying?

Q. Yes.

Do you agree with that?

A. They could be risking that, yes.

Q. And those damages could be trebled in a Hatch-Waxman case; correct?

A. If they could show the infringement was willful.

Q. And so if we trebled 18 million in damages, that would be $54 million in damages a month; correct?

A. It is correct, but I would say that the hypothesis here is that they would have waited to -- that they would have launched upon receiving a favorable district court ruling regarding the injunction, so I think the likelihood that they'd be viewed as willfully infringing when they had a favorable district court decision is -- is not high.

Q. Well, so let's do it both ways. We'll do treble damages and we'll do single damages.

A. Okay.

Q. Now, we talked about the fact that Impax was first to file and had 180 days exclusivity; right?

A. Right.

Q. So if you were Impax, you'd want to get the benefit of those 180-day sales; right?

A. Right.

Q. And so if you were going to launch at risk, you'd launch six months worth of product at risk; right?

A. You would try to do that, yes.

Q. Okay. So using the treble damages first, because I've already done the math, six months at $54 million a month, that's $324 million in potential damages; right?

A. That's in the treble damages scenario.

Q. Yes, sir.
A. Yes.
Q. Okay. So in a treble damages scenario, Impax could being risking as much as $324 million over a six-month period; right?
A. Well, that's kind of up to Impax, because Impax can control how much it sells. And Impax -- so if Impax wanted to reduce its risk, it could sell less, so it could do some sort of a compromise there. And Impax sales would be constrained by the DEA quotas and the manufacturing capacity potentially.
So I think there's other assumptions -- other factors you'd have to look at before coming up with a, you know, maximum amount. And as I said, I don't accept your assumption that treble damages would have flowed from a launch that complied with --
Q. Okay. Let's go --
A. -- the court's ruling.
Q. Let's go with single damages.
A. Okay.
Q. A third of 324 million is 108 million; correct?
A. A third of -- excuse me?
Q. 324 million in damages, one-third of that would be $108 million in damages over a six-month period;

right?

A. Right.

Q. Now, you mentioned a moment ago a footnote you'd looked at, footnote 56, and you have in there Mr. Mengler's board slides where he considered how much Impax expected it could make, were it to launch at risk, in the first six months; right?

A. Uh-huh.

Q. You saw that when you reviewed information in your report?

A. Yes. But I -- I think you were assuming that Impax takes -- your assumption -- the way you're doing the math, you're assuming that Impax takes 100 percent of Opana ER sales and they sort of max out on that. I don't think they would have taken 100 percent of sales, and as I said, they could -- they could control their sales to -- to control their risks.

I don't know that they -- I don't know that the forecasts -- I don't know that any of the forecasts that I saw showed them taking a hundred percent of sales of -- you know, from day one. And that, in my experience, would be unlikely.

So no, I don't totally -- I don't agree with your hypothetical.

Q. Well, if you were trying to calculate the

1 downside risk, 108 million single damages, 324 million
2 treble damages would be a good way of putting a cap on
3 the downside risk; right?
4 A. No. The downside risk is capped by what you
5 decide to sell. It's not -- it's not a situation
6 where Impax is sort of -- has no control over --
7 control over -- over that amount.
8 So if you're saying that they could have --
9 their maximum -- they could have gotten $108 million
10 in -- in sales, you know, right -- you know, or they
11 could have -- what are you saying exactly?
12 Because you've postulated they're going to take
13 a hundred percent of Impax' sales -- of Endo's sales,
14 and I don't -- I think we have actual numbers that they
15 looked at regarding their likely sales. And if we want
16 to do -- I'm happy to do math with you, but it would be
17 more constructive to look at the actual projections and
18 the actual risk analyses in the case.
19 Q. Sir, you didn't do that math in your report,
20 did you?
21 A. No, I didn't do that math in my report.
22 Q. I'm trying to walk you through a simple
23 hypothetical so that we can understand the risks.
24 Now, the maximum risk is that they take a
25 hundred percent of the sales; right?

A. Uh-huh.

Q. And that would be your 108 million in single damages or 324 million in treble damages; right?

A. Right.

Q. Okay. And so their maximum risk is $324 million; right?

A. That would be their maximum risk and their maximum benefit. Yes.

Q. And they could control that by selling less than $324 million worth of product; right?

A. Well, I think all of the projections suggested they would sell less even if they wanted to sell more because there was also the issue of the -- of Endo coming along with an authorized generic which would have -- they projected would have taken about 50 percent of the sales.

So they would have -- their market share would have been less than -- significantly less than 100 percent, probably less than 50 percent, so the total amount of sales we're talking about are -- are less, and the total risk is correspondingly less. And if they wanted the risk to be still smaller, they could simply decide to sell less, sell limited quantities.

So there were a lot of -- there's a huge amount

of assumption in your question which is not reflected in the reality of any of the projections of any of the parties.

Q. So let's use an assumption you just made, which is they take 50 percent of the sales, and let's cut those damages estimates by half, shall we?

So 108 million becomes 54 million in damages if single damages; right?

A. Okay.

Q. And treble damages would be 162 million?

A. What did you say? Fifty- --

Q. 54.

A. 54 million.

Q. And 162 million; right?

A. Okay. Yeah.

Q. Now, in footnote 56 you looked at Mr. Mengler's board slides; right?

A. Yes.

Q. And the slides themselves are in camera, but I've got a copy in the binder if you want to look at them, but do you recall he projected that in the first six months if they were to launch at risk Impax would earn about $28 million in sales?

A. They would earn -- excuse me -- a hundred and twenty --

Q. No. 28, not 100, just 28 million.
Do you recall that?
A. I don't know how that relates to the market penetration, like how that relates to the amount of the -- the amount of Endo's sales they were taking. If you're saying that that corresponds to 50 percent of, you know -- a 50 percent market share, then I'll take your word for it, but -- but you have to understand that's implicit in your question.
Q. I do understand that's implicit in my question. I'm not making a representation that that 28 was calculated on exactly 50 percent of the share, but you agree that's a reasonable assumption for how much of the market Impax might take based on generic penetration.
A. I don't agree with that assumption at all. I mean, there's a slide there. It must -- it must -- probably -- there are -- is there data or evidence as to what that market penetration would correspond to? Because without that number, it's just -- you're just throwing numbers around. I'm sorry. I -- I think that they -- I think it would be possible for Endo to do those risks -- for Impax to do those risk calculations. And the evidence that I saw saw those risk calculations were in fact done, but they were

redacted. But there is reference to them in the Impax materials.

And despite those risk calculations, it was referred to by I think the head of their -- their -- the group that was managing it as a good candidate for at-risk launch. The CEO said the decision would be made on the preliminary injunction ruling. There was a presentation to the board, although the board didn't make a final decision.

So that calculation was done, and it seemed that whatever numbers they came up with -- and I'm sure Ms. Snowden is perfectly capable of doing the math -- they would have -- they would have -- they were still viewed as, I think in the words of one board member, you know, a good candidate for at-risk launch, so -- so that's all I can tell you.

Q. Sir, you would agree with me that in a lost profit damages analysis, if Impax expected to make $28 million in selling six months worth of product, the lost profit damages they would owe to Endo would be greater than that $28 million, wouldn't you?

A. That's very possible.

Q. By definition, they'd be larger; right?

A. That depends on their profit -- that depends on Endo's profit margins, but very -- very often that

is the case. It's certainly possible for the lost profits damages to exceed the generic company's sales. And I think I said that.

Q. Indeed, the generic typically, indeed always, sells at a discount to the brand; right?

A. No, not always. If you're the sole generic, they sometimes sell at a premium to the brand, and they still get a significant market share because automatic substitution ensures reimbursement assumes the price is lower even when it's not. There are lots of instances of that, so it's -- it's -- when you're in a -- when you're in an exclusive generic position, you can't necessarily assume that the price is going to be significantly discounted. It will come in typically just a little under, but not a huge amount.

Q. So just so I understand your expert testimony, it's possible that in this case that if Impax had launched at risk as an exclusive, it would have charged more for its generic Opana ER than for Endo's branded Opana ER; is that your testimony?

A. I'm testifying that that's -- that I have seen that situation happen with -- with -- with sole-source generics. That's a thing that can happen. I'm not offering an opinion as to whether it necessarily would have happened in this case.

Q. Now, in your report, sir, you say, "Impax had reasons to be motivated to launch as soon as possible."

You said that; right?

A. Yes, I did.

Q. And that's as soon as possible after a favorable district court decision, we just established; right?

A. That's correct.

Q. And you identify in your report two sources of risk if it didn't launch immediately, one, the prospect of new patents and, two, the risk of reformulation; right?

A. Yes.

Q. And I think this morning you introduced a third source of risk, and that was if it's close to the patent expiry; right?

A. Yeah. I mean, that wouldn't have been an issue in 2010, but it certainly begins to be an issue in 20- -- in 2013 because there is no exclusivity in this case after September of 2013 when the patents expire.

Q. So that risk would have come into play sometime in 2013; is that right?

A. That's correct.

Q. So it's not a risk we need to analyze here; right?

A. Well, it's kind of a risk we need to analyze here because Mr. Figg's report has the -- has them likely not launching until mid- -- not having a final decision until mid-2013, so if they're blocked until almost just before patent expiry, then it seems like the situation is going to be, you know, a -- the same for Endo, and Impax is going to lose its -- potentially lose its exclusivity and/or part of its exclusivity, so three months of its exclusivity if you follow Mr. Figg's timing or -- and Endo is going to come out in much the same position it would have been in anyway, so there's sort of no motivation to settle, so that's the reason why it's relevant to the analysis, if you take those assumptions.

Q. Sir, using the assumption you just gave, Impax would be better off settling and launching on January 1, 2013; right?

A. If you assume that they otherwise would have been blocked until patent expiry, then yes, it was better I suppose to get -- to get something than -- than nothing.

Q. Now, with respect to the risk of new patents, new patents don't issue overnight without warning;

correct?

A. That's correct.

Q. And so Impax could wait and see if the new patents issued; right?

A. I'm assuming that Impax was probably tracking the prosecution of those patents quite closely.

Q. And so there was no reason to rush to launch at risk; they could track the patents and see what was happening with them.

A. Well, you know, if they get allowed, there would be a -- it would take them some time to launch. And even if the patent is allowed, there's a time period -- it depends on the case, but how long it takes from the time you get a notice of allowance to the -- then there's a three-month period to pay the issue fee. They may have paid the issue fee early, you know, in advance of the three months and then tried to expedite the thing. They maybe could get -- then maybe they could get a -- get it granted more quickly, but it would still be a period of some months, but it wouldn't be such a long period that you would kind of want to -- you know, sleep on things.

You would want to -- you would want to be moving things along because you wouldn't have a huge amount of time.

The other thing is that three months, I want to emphasize, is still a big deal for a generic company. If they can get three months of sales before the patent launch, you know, that would still be -- that would still be valuable to them because they can fill up the pipeline and make all their sales, so it would have been the first one, so...

Q. Sir, those pending patents didn't issue until late 2012; right?

A. That's in fact how it turned out, so in fact they had -- it turned out they had over two years, but they couldn't have known that they would have the full two years.

Q. So in all likelihood, Impax could have waited to see not only whether it won in the district court but whether it won in the Federal Circuit by late 2012; right?

A. As I said, it wasn't predictable exactly when they would issue. It turned out they issued in 2012. They might have issued later. They might have issued earlier. They might not have issued at all. That was yet another uncertainty that the parties had to contend with.

Q. Well, is it your opinion that Impax should have launched at risk during the litigation with Endo over

the '933 and '456 patents for fear that Endo might someday get more patents?

A. Well, that was one of -- that was one of the -- that was one of the risks that was known to the parties and significant as -- as a significant risk, that Endo might get more patents, they could block them and sue them and would have additional hurdles to contend with, as in fact turned out to be the case. They did eventually get additional patents, and additional patents did eventually cause problems, as Mr. Figg pointed out.

Q. The risk was that if Endo got more patents, Impax might have to launch at risk as against those patents; correct?

A. That's correct.

Q. So your solution is to launch at risk against the patents that are known for fear of the patents that may come; right?

A. Well, in this particular case I think that was -- that was -- that was certainly something to think about, the idea of get on and get off quickly because you're going to make most of your money in that initial -- that initial launch period before you have other generic competition anyway.

And then after six months, additional generic

1 companies are going to get on the market because the
2 exclusivity has then passed, so then the product
3 becomes, you know, fully generified (phonetic), and
4 that makes it much less profitable for the -- for -- it
5 makes it less profitable for everybody because the --
6 there's then competition on price.
7 And as I mentioned before, the first generic
8 very often will charge a relatively high price for its
9 generic drug, but once you have multiple generics, then
10 of course there's price competition.
11 Q. And those multiple generics would have to be
12 launching at risk; right?
13 A. That -- that -- that would just depend on so
14 many things. That would depend on -- by that time, six
15 months have gone by. By that time, we have a
16 Federal Circuit decision that could have been favorable
17 to Impax as well.
18 Q. Sir, the second reason you mentioned that
19 Impax should have considered launching at risk was
20 because, if Endo stopped selling the original Opana ER
21 in favor of the reformulated product, Impax would not
22 get the benefit of Endo's sales; right?
23 A. That's correct. The automatic substitutions.
24 Q. Now, Endo couldn't start selling reformulated
25 Opana until it got that product approved by the FDA;

right?

A. That's correct.

Q. And as of the time of settlement, Endo had not even filed the NDA for reformulated Opana ER; correct?

A. That's my understanding. Yes.

Q. And you agree with me that companies don't get approval for drugs overnight without warning; right?

A. That's correct.

Q. It's a process that takes a significant amount of time for those things to play out; right?

A. Yes. In that case there would have been a -- the FDA would have been subject to a one-year clock, so it would have taken one year, ordinarily one year, and then it might take a couple months longer, but it would ordinarily take one year from the supplemental NDA filer or from the new NDA filing.

Q. Did Endo in fact get FDA approval within one year of the NDA filed in 2010?

A. I don't know exactly when it did its filing, but it would have been close because they had to do their trials and then submit their NDA, so probably that's about right, because they got the approval in 2012, so they got the approval two years later.

I don't remember the exact timing of the approval. It is in my report, though.

Q. So, again, in terms of the immediate need to launch at risk, you could have waited until the reformulated drug was approved, and by then Impax would have known -- likely would have known what the Federal Circuit had done with the decision; right?

A. Yeah. I guess. That would have been -- but you still would have -- that still would have been substantially earlier than the time they agreed on.

I mean, January 2013 was long after all of that, so you're arguing maybe they could have launched in 2011 sometime, maybe later 2011 or early 2012. Yeah, I mean, those -- those -- there was a whole two-year window there before the new patents issued and before they had the new drug.

So they didn't have to launch, you know, if that's your point, they didn't have to launch right immediately upon getting the judge's decision. They might have launched and I think there were several forecasts suggesting a launch in 2011, January of 2011 or so.

Q. Well, sir, if I understood your report, you held up these new patents and the risk of reformulation as reasons that Impax should launch at risk; right?

A. That's correct.

Q. And as it turns out, Impax didn't have to launch at risk if in fact it could have gotten a Federal Circuit decision before the new patents were approved and before the reformulated drug was approved. That's what you're telling us now; right?

A. Well, as the timing worked out, but remember Impax at the time of the settlement negotiation had -- they didn't know whether -- I mean, the -- the -- the submissions that Endo would have made to the FDA are confidential.

As far as Impax knew, the new drug -- you know, the new formulation, it could have come out anytime or never. I mean, it was -- it was -- it was uncertain.

And also as far as the new patents go, they could have gotten, you know, a -- they could have gotten -- one of them I think was up on the Federal Circuit, but the other one was not, so they could have gotten a -- possibly a notice of allowance and gotten -- gotten a patent issued relatively quickly.

So although in fact it took a couple of years for those, those things to materialize, the new patents and the new product, Impax had no way of knowing that at that time. They just knew these were threats on the horizon that could come at some point, maybe sooner,

maybe later.

Q. Sir, I agree these were threats on the horizon at the time Impax settled.

The point of your suggestion that they would launch at risk is, if they're launching at risk, it means they didn't settle and they're in litigation; right?

A. They're on appeal.

Q. So they're on appeal. They're deciding whether or not they've gotten a favorable district court decision. That's your hypothesis; right?

A. Yes.

Q. And now the question is, having gotten a favorable district court opinion, do they launch at risk or do they wait and see what happens with respect to approval of the reformulated and the new patents; right? That's what we're talking about here.

A. Well, I think as I've -- as I've tried to express, if you -- if you wait until the things happen, if you wait until the new patents are allowed and you wait until the new formulation is approved, you've maybe waited a bit too long, so -- and you can't know exactly when those things are going to happen, and the FDA proceedings are secret, so you can't -- there's no way to track or monitor it, unless

you have a spy at Endo.

Q. Sir, did you analyze how much time expired between when Endo got approval for reformulated Opana ER and when they launched it?

A. I believe that information is in my report. I don't have the exact numbers. I think they got approval sometime in early 2012 and they launched or -- and they launched sometime in later 2012, but I -- I don't have those exact dates.

Q. And under that time frame, Impax would have had several months, months, to launch its generic oxymorphone should it have decided to launch at risk; right?

A. Well, in this -- in this world that we're talking about, if -- if Endo had been facing a threat of a generic launch, it might have hustled to get its product to the market a little quicker, so I can't assume that everything would be the same.

I mean, there's so many -- if they had launched earlier, it would have changed so many -- so many assumptions, I mean, if they'd been on the market, if they were still in litigation. They might have acquired the '779 patent and shut Endo down, and then they would have been the, you know, branded company and Endo would have been struggling in litigation against

them.

There were so many things that could have happened that, you know, these are all possibilities that were not taken into account in Mr. Figg's report, and that's why I felt like his conclusions weren't as -- you know, did not take all the variables into account.

Q. So you just want to make sure that we raise all the possibilities that could have happened in the hypothetical world; right?

A. Yeah. I'm just saying the world would have been -- the world would have been different, so I don't think -- you're asking me to assume that they would have had certain amounts of time and certain things would have been the case, and I'm telling you the world would have been different and the motivations of the parties would have been different in that hypothetical world, so I don't think that they would have necessarily played out exactly the way they did in fact, because the motive -- the drive -- the economic drivers of the parties would have been different.

Q. But you don't know what would have happened in this hypothetical world, do you?

A. No one does for sure.

Q. And in your report, you don't opine that an at-risk launch would have been a reasonable risk for Impax, only that it could have been a reasonable risk from Impax' perspective; correct?

A. That's correct. It would have depended on particularly the district court decision.

Q. Now, you mentioned Endo's view of the risk that Impax would launch at risk; correct?

A. That's correct.

Q. And in your experience, branded companies like Endo view the prospect of an at-risk launch by a generic company with terror. That's in your report; right?

A. That's true.

Q. And you stated that Endo's contemporaneous business documents reflect a view that an Impax at-risk launch was a real possibility; correct?

A. Yes.

Q. Did you review RX 86 in coming to your conclusions?

A. I'm not -- I'm not sure I know that document by heart. Can you --

Q. Robert, can we put up RX 86.

There's a copy in your binder if you'd prefer to look at a paper copy, but we're going to put it up

here on the screen as well.

I apologize. I don't think we've given you a binder yet. That's the FTC's binder.

Your Honor, may I approach to give the witness a binder?

JUDGE CHAPPELL: Go ahead.

BY MR. HASSI:

Q. Sir, have you seen this document before?

A. I'm not -- I'm not sure if I have actually.

Q. Okay. You don't recall whether you reviewed this in the context of opining that Endo's contemporary business documents reflect a view that an Impax at-risk launch was a real possibility?

(Document review.)

A. I'm not a hundred percent sure if I've seen -- if I saw this document, but I -- it -- I looked at -- I have looked at several presentations, and if it's in my report, then I -- I looked at it at some point.

Q. Okay. Well, let's take a look at page 9 of this document.

And you'll see a heading at the top of page 9 that says "Impax Not Likely to Launch at Risk."

Do you see that?

A. I see where it says that.

Q. Okay. And you understand this is a

June 2010 Endo document?

A. The document has at the top something called FULD & Company, Inc.

Q. Are you familiar with FULD & Company?

A. I'm not.

Q. Okay. Do you understand they're consultants doing work for Endo in this instance?

A. Yes.

Q. Okay. And they did this work in and about the time that the case settled, June 2010; right?

A. That's the date of the report. Yes.

Q. And on the page that -- page 9, which is headlined Impax Not Likely to Launch at Risk, it says, "GPOs, Wholesalers, Pharmacists, Academic Key Opinion Leaders and most Financial Analysts doubt Impax would launch at risk."

You see that; right?

A. Yes. Although, in the context of this report, they're saying launch at risk before there's a court decision.

I think there's two kinds of launching at risk. One is launching, you know, before you have the district court decision. That's a sort of a high-risk at launch -- launch at risk. And then there's the -- you get a favorable court decision and you launch prior

to a final Federal Circuit decision.

So those are -- I think Mr. Figg referred to this also in his testimony.

So there are different levels of launch at risk. I don't -- we've been talking in this proceeding and we've sort of agreed that a launch at risk means after a favorable district court opinion but before a final Federal Circuit decision. That's the way we've been using that term. But I don't know that everybody necessarily uses it exactly the same way.

Q. Okay. Well, the contemporary business documents of Endo that you reviewed, they were all prior to any district court decision; right?

A. Right. But they were all forecasting a launch after, after the district court decision or at, you know -- they were forecasting a launch at the earliest in July or that I saw in July of 2010, which would have been sort of -- which would have been after a district court decision. That's also consistent with -- with the e-mails from the -- from the CEO that it would be -- that -- that it would depend on the -- the PI decision.

Q. There's an e-mail from the Endo CEO predicting when Impax would launch at risk?

A. The Impax -- the Impax person.

The Endo -- the Endo internal documents were looking -- there were also Endo internal documents that were looking into, for example, what would be involved in getting an authorized generic on the market as a defensive strategy and what those sales would be.

And they had a number of risk scenarios contemporaneous with this document. They had scenario one, scenario two, scenario three -- I think it went down through scenario six or something -- evaluating all possible risk scenarios.

And one -- certainly one of the scenarios was that Impax launched immediately, then was a scenario that Impax maybe launched a little later. There was a scenario where they launched with an authorized and not.

So there was a lot of internal Impax documents -- I mean, Endo documents relating to their perception of Impax' launch at risk that suggested that even -- whether they thought it was likely or unlikely, it was nevertheless a serious enough possibility that they were spending time war-gaming it, going through all their possible defenses and preparing for it.

Q. And that would be consistent with your experience working at Novartis where people forecast lots of different scenarios, upside, downside, risks, et cetera; right?

A. Yes.

Q. Now, this document on page 9 goes on to say -- and this is the middle quote in blue -- "We haven't heard anything about a launch of oxymorphone any time soon... We do not anticipate any of these companies to launch at risk... We would know from the sales reps about the launch a few months in advance and have not heard anything."

You see that; right?

A. I'm sorry. What do I -- where -- "We haven't heard anything," that's on page 9.

Q. Do you see that?

A. Yes. It says that the person at AmerisourceBergen has not heard about a launch of oxymorphone.

Q. And AmerisourceBergen, you know that to be a big company that buys pharmaceuticals; right?

A. Yeah.

Q. They'd be one of the biggest customers for a generic launch such as oxymorphone ER; right?

A. They would be a customer. I don't know exactly

what the channels would be for this, for this particular product. Pharmaceuticals go through different channels.

Q. Let's go to page 10.

And this page represents Financial Analysts' Views: Impax Launch at Risk.

Do you see that?

A. Yes.

Q. Do you see at the top of the page someone from Roth Capital Partners says, "Impax will wait until they settle in the court... I do not think Impax will launch at risk"?

You see that; right?

A. Yes.

Q. Did you take that into account when you said that Endo -- Endo's contemporary business documents reflect a view that the Impax launch at risk was a real possibility?

A. I'm sorry. That's a statement by Roth Capital Partners. That's not a statement by Endo.

Q. But it's a statement in an Endo document presented to Endo evaluating whether Impax would launch at risk; isn't that right, sir?

A. Yeah. It says -- I mean, it says what it says and it is what it is, but it doesn't -- it doesn't

nullify the fact that there were contemporaneous documents where they were taking this seriously.

If you look at the next quote I think that's from UBS, that maybe presents a more accurate, more detailed or more in-depth analysis of the situation.

Q. So you would agree with UBS' analysis where they said (as read): I would doubt that they will launch at risk. I would suggest that they are going to wait until the legal proceedings are done. Well, you have to look at two main things. The first is the history of what the company has done in the past. Impax tends not to launch at risk. But the other thing you have to look at is the merits of the patent that's being challenged. Is it clear-cut? Is the original patent really strong? Is Impax skeptical that the challenge to Endo's patent will hold up in court? How confident does the generic company feel that the challenge is valid? So it is more than just looking at the history of what Impax has done. But still looking as a whole, I do not think that they will launch at risk.

You agree with that statement; right?

A. Yeah. I don't know exactly what they mean by "hold up in court" because now -- it seems to me that these -- as I said, launch at risk, it -- the "hold up

in court" implies that there -- is there a risk that they're going to launch prior to a court decision, and I -- I think, you know, that is one question.

And then there is the question of, if they get a favorable court decision, are they going to -- are they going to launch pending a Federal Circuit appeal.

So like I said at the beginning of this discussion, I don't know how they're defining "launch at risk," but it implies, when you talk about settling in court and is it going to hold up in court, that their focus is more at the trial court and not in the federal -- not in the Federal Circuit, you know.

I don't think they're -- I don't see anything here about, you know, 2013 launches or anything like that.

Q. Well, sir, you would agree that this contemporary Endo business document reflects that Impax was unlikely to launch at risk; correct?

A. I think it reflects the views of certain people regarding a launch prior to the -- the -- the trial court decision. I -- I think it's ambiguous as to whether it reflects a launch after a favorable -- a favorable court ruling. I think that would have a significant impact probably on these views.

Q. Sir, let's talk about the risks to the second

generic company to launch at risk.

You can set that aside.

Sir, you would agree that the risks to the second generic company to launch at risk are lower?

A. Excuse me?

Q. You would agree, sir, that the risks to the second generic company to launch a particular product at risk are lower; correct?

A. That's correct, yes.

Q. First, they don't have first-filer exclusivity to lose?

A. Well, yes.

Q. And second, the patent holder may have a harder time arguing for damages based on the patentee's lost profits because it can market with multiple -- because in a market with multiple generics it can be difficult to show that, but for the generic sale, the sale would have gone to the patentee rather than to another generic.

You agree with that; right?

A. That's correct, yes.

Q. And so the second company, second generic company to launch at risk, faces a lower damage exposure than the first; right?

A. It also has -- it faces lower damage exposure

also because it has typically much, much, much lower sales, so less -- less risk, less opportunity.

Q. And the -- in terms of the less risk, the second company's damage exposure would typically be a reasonable royalty on the generic company's sales; right?

A. That's the minimum damages under the patent statute. Yes.

Q. And so, for example, in this case, when Actavis launched at risk in 2013 after Impax' risk, it -- excuse me -- after Impax' licensed launch, it faced a less -- a lower damages risk; correct?

A. I believe with respect to some strengths.

Actavis had first filer status with respect to some dosage strengths and it had second -- second filer status or subsequent filer status with respect to other dosage strengths, so it would have different risks for different dosages.

Q. But on the strengths where it was second filer after Impax, it would only face reasonable royalty damages for its 2013 launch at risk; right?

A. That -- that's possible. That would have -- they certainly would have had a good argument for reasonable royalties rather than -- rather than lost profits, especially also I think at -- I'm not sure,

but I think at that point their -- their Endo product had switched so that also would have contributed to the lost profits analysis insofar as Endo didn't have the -- you know, the -- the brand -- it wasn't -- you weren't able to show a direct -- a direct automatic substitution with -- from the branded drug to the Actavis drug.

Q. But the lower risk to Actavis was -- the risk to Actavis was lower in part because Impax was already on the market; right?

A. Yes. And also because -- because Endo had changed its product by then and no longer would be selling the original formulation.

Q. Sir, in paragraph 13(b) of your report, you offer the opinion that "At-risk launches are not uncommon in situations where the generic company is at risk of losing its market opportunity if launch is delayed."

That's one of your opinions in this case; right?

A. Yes.

Q. And you used the double negative "not uncommon."

Should we understand your report to say that at-risk launches are common?

A. I wouldn't say that. I wouldn't say they're common, but they're common in particular situations. As I said, the multi- -- you know, where you have multiple exclusivity holders and a race to market is a situation where they're most common. But they -- they certainly -- they certainly can happen.

And I think as Mr. Figg pointed out, it is true that some companies have a greater appetite for risk than others. That's true, too.

So there are a number of factors to take into consideration.

Q. Okay. So, for example, multiple exclusivity holders, that would be if more than one company was first to file?

A. That's one scenario. Yeah.

Q. And that's not a situation that existed here for Impax; right? They were the sole first filer?

A. That's correct. For those dosage strengths, yeah.

Q. And in terms of companies having a greater appetite for risk, you're aware, aren't you, for example, that Teva has done roughly half the launches at risk that have occurred in the last 15 years?

A. Yes. Teva is a company that has a -- you know, a high willingness to take risks.

Q. And a far higher willingness to take risks than, for example, Impax, which as of this point in time had never had, for example, a first-to-file launch at risk; right?

A. I think they did have -- I don't know if -- I don't know the details. I think they did have an at-risk launch. I don't know if they actually went -- I don't know exactly what happened with that case, but there certainly was -- they were -- they were in an at-risk launch situation before because I believe it was disclosed in the CID responses that they were trying to use that as leverage against Endo in the settlement discussions. They said, Oh, you know, we've got a history of doing this, we've done it before, we'll do it again.

So to what extent they were bluffing and to what extent that was really true I don't know, but they -- they apparently did use that as a negotiation tactic. That's in the CID responses that are referenced in my report.

Q. And the at-risk launch that's referenced in the CID responses, that's when Impax launched at risk on OxyContin, the 80 milligram dose of OxyContin in 2005; right?

A. Right.

Q. But that was after Teva had launched at risk on OxyContin in 2005.

Are you aware of that?

A. I don't recall all the details, but yeah, it could well have been.

Q. But if Impax was second to launch at risk, it would have benefited, as we just discussed, the fact that Teva had already launched at risk; right?

A. As -- as I said before, it's -- it's a -- being the first to launch at risk is a -- is a higher risk. It's also a higher reward, so you have to sort of net those two to come up with a -- come up with a number.

Q. And you -- are you aware that when Impax launched at risk on OxyContin, it was after a favorable district court decision?

A. I don't know the details of Impax' launch of OxyContin. That's outside the scope of my report.

Q. Now, you've not done any empiric work to quantify how common at-risk launches are; correct?

A. No, I haven't.

Q. And you've only personally, as we've already established, had experience with one at-risk launch in your 31-year legal career; right?

A. No. That's not what I testified.

Q. I'm sorry. Only one on the generic side. You think there might have been some on the brand side.

A. Right.

Q. But you don't remember whether they were in fact launches at risk?

A. I'm pretty sure they were, but I -- I'd have -- I'd have to go back and check. I'm pretty sure cyclosporine was. Well, cyclosporine I'm sure was. I'm not sure -- I'm not sure about the pamidronate.

JUDGE CHAPPELL: Do you have an estimate of how much time? You're getting close to two hours.

MR. HASSI: I probably have another two hours at this rate, Your Honor.

JUDGE CHAPPELL: Another two hours?

MR. HASSI: Just looking at my outline, yes, Your Honor.

JUDGE CHAPPELL: Better get busy.

MR. HASSI: Yes, Your Honor.

BY MR. HASSI:

Q. Sir, do you know how many Hatch-Waxman cases are filed annually?

A. Excuse me? How many Hatch-Waxman cases are filed?

Q. Annually?

A. Annually? I don't know that number.

Q. You haven't looked it up?
A. No, I haven't.
Q. Okay. Let's bring up RX D-20.
Your Honor, this is a demonstrative. It's the Lex Machina report.
A. Okay.
Q. Have you seen this, sir? It's a report related to Hatch-Waxman ANDA litigation from 2017.
A. I don't really recall it honestly, but I -- I'm -- if you could show me what you want to ask me, I'll try to respond.
Q. Let's look at page -9. There's a chart at the top of the page Overview.
And do you see at the top of page 9 this company has analyzed the number of ANDA filers filed in any given year from 2009 to 2016?
A. Yes.
Q. And they run from a low of 236 to a high of 468 cases?
A. Yes.
Q. And if you go to the next page, and that's page -10 and the blue box, Robert, if you could blow that up.
Do you see in the middle paragraph they calculate and they say, "In 2016, 316 ANDA cases were

filed" and that "Between 2009 and 2013, an average of around 269 ANDA cases were filed per year"?

A. Yeah. Although -- although I would note that the way they're counting those numbers there, they're counting cases where you have multiple defendants. They're counting those as separate cases, whereas very often these cases -- that doesn't reflect the number of products for which there was an ANDA case. It reflects the number of generic ANDA filings, so there might be ten ANDA filings on one product, so that might only reflect, you know, a much lower number of products.

Q. But you didn't look at these statistics in coming up with your opinion that at-risk launches are common; right?

A. No, I didn't. As I said, I -- I don't think that the general statistics are necessarily that relevant to the individual situation in this case.

Q. Okay. Now, you're aware that Dr. Noll came up with a list of -- with the assistance of the FTC, came up with a list of 48 at-risk launches over a 15-year period?

A. That's -- that's possible.

Q. You've seen --

A. I mean, Dr. Noll can speak to that. That's not

part of my report.

Q. You've seen Exhibit 4 to Dr. Noll's report, haven't you, sir?

A. Excuse me.

Q. You've seen Exhibit 4 to Dr. Noll's report, the list of at-risk launches?

A. I've seen Dr. Noll's report. I don't know if I've seen all the exhibits to Dr. Noll's report.

Q. Well, if Dr. Noll came up with a list of 48 at-risk launches over a 15-year period, you'd agree that's about three per year?

A. I have no reason to necessarily question that.

Q. And three at-risk launches per year as against 269 ANDA litigations on average would be about a 1.5 percent --

A. Well --

Q. -- at-risk launch --

A. -- by ANDA litigations, you know, like a lot of these cases really, you know, disappear, disappear very early. You know, the generic companies will file something. It will -- they'll go quick, try to get a little discovery, and then they'll just -- they'll just fold.

So, I mean, a lot of them are not really -- although the numbers are higher -- that you're showing

here are higher than, you know, the number of cases that are actually hotly litigated and they're also inflated by the fact that you have all these piggyback filings -- you know, once one person files, you know, ten others piggyback on that filing and that -- that sort of inflates the numbers unrealistically, but -- so I wouldn't say that that percentage is a very meaningful percentage. If it's at-risk launches where you have a first filer opportunity, it might be higher.

Q. Okay. Well, let's look at -- you're aware that Royal Bank of Canada did an empiric analysis of at-risk launches?

A. The Royal Bank of Canada now?

Q. Yes, sir. It's RX 425 in your binder.

And Robert, if you could please bring that up.

A. Yeah, I'm familiar with this document. That was cited in Mr. Figg's report.

Q. And you've read this and understand it's an analysis of Hatch-Waxman litigation from 2003 to 2009?

A. Yes, it's an analysis. Yes.

Q. And it looked at all of the at-risk launches during that period 2003 to 2009?

A. Yes.

Q. And if we go to page 11 of the report, at the

very top -- Robert, if you could blow up the paragraph.

Do you see in the middle of this paragraph it says, "Also, as previously discussed, at-risk launches are fairly uncommon"?

Do you see that?

A. Yes.

Q. So RBC, after doing an empiric analysis, concluded that at-risk launches are fairly uncommon.

Do you agree with that?

A. I think as I've said -- I think in my report I said they are not uncommon in certain situation -- they're not uncommon in situations where there is a strong economic incentive to launch at risk, where the exclusivity, for example, is not secure because you have multiple filers. I think that's what it says in my report.

So this is at-risk launches generally, and I would say, you know, generally there -- there's -- they're not -- they're -- they -- I would agree with that statement as a general proposition. And yes, I would agree more in 2010 than in -- than today. I think they -- they've become more common over time.

Q. So you'd agree they were less common in 2010; right?

A. Yes, they were less common in 2010. And they were even less common in 2003 or '4. I mean, they have gotten more common with time. The tolerance for risk has evidently grown or the market incentives for launching early have grown, one or the other.

Q. And you've not made any effort to identify at-risk launches that were the result of a lack of security that caused the -- caused the generic company to therefore launch at risk to get its share of the market?

A. I haven't done the kind of numerical analysis that you're talking about, but I have given examples and I have looked, you know, at -- I've looked at at-risk launches.

I mean, I'm familiar with the concept and I'm familiar with the fact that this is -- this is a -- you know, this is always -- this is always a risk for a branded company, you know, that there might be an at-risk launch. That's something that can happen. And it's a big risk because, when it happens, it can be devastating.

Q. And when you say you've given examples, you've given one example, and that's the Augmentin at-risk launch that you participated in when you were at Novartis?

A. I thought that was the close -- most on point, but I've mentioned others.

Q. Can you identify any other examples, as you sit here today, of an at-risk launch with --

A. I've mentioned the cyclosporine situation where we were on the other side of the launch. And then we -- I mean, there -- you know, there are -- there are at -- as I -- you know, this is -- this term "at-risk launch" is a little bit fuzzy because, I think as I said at the beginning, every launch is to some degree at risk.

You know, there are patents, but this is a particular -- you know, all launches are risky and there's -- there are risks of patent infringement that you address. And sometimes the risks are relatively high, and sometimes the risks are relatively low. When you're in litigation, of course, they're relatively high. They are less high after you've got a district court decision, and they're still less high after you've got a Federal Circuit decision, so, you know, there -- there are -- there are levels of risk. It's not a -- it's not a binary, it's at risk or it's totally at risk or it's totally safe.

I feel that when you try to do these statistics it's very unrealistic in the sense that it's

not such a -- it's not such a binary decision, in my experience.

Q. Sir, my question was --

JUDGE CHAPPELL: Hold on a second.

We're going to take a short break. And when we come back, I'd like for you to clarify with the witness what "at-risk launch" means.

We'll reconvene at 3:05.

We're in recess.

(Recess)

JUDGE CHAPPELL: Back on the record.

Go ahead.

BY MR. HASSI:

Q. Mr. Hoxie, before the break, Judge Chappell asked me to ask you to define "at-risk launch."

You would agree that as used in your report, an at-risk launch is a launch before a generic firm has a nonappealable judgment in a litigation; correct?

A. Yes.

Q. Let's talk about the patent litigation between Impax and Endo.

Now, the standard of proof for the brand firm to prove infringement is preponderance of the evidence; correct?

A. That's correct.

Q. And the standard of proof for the generic firm attempting to prove invalidity is clear and convincing evidence; correct?

A. That's correct.

Q. And Hatch-Waxman cases are typically bench trials?

A. That's usual. Yes.

Q. And you would agree that a bench -- that a judge -- excuse me -- sitting in a bench trial would understand the difference between a preponderance of the evidence standard and a clear and convincing evidence standard; correct?

A. I'm not sure that anybody really understands that difference, but a judge would understand that better than most.

Q. So the answer is yes, a judge would understand it?

A. A judge would try to understand, yes.

Q. Do you agree that claim construction can be a very important factor in patent infringement cases; correct?

A. Yes.

Q. And you would agree that in many cases claim construction can be dispositive?

A. Yes.

Q. And you agree that each party would advocate for a claim construction that would be most advantageous for their case going forward; correct?

A. Yes.

Q. And you agree that a claim construction ruling can change how parties present their case at trial; correct?

A. Yes.

Q. And that may mean that a party cannot present certain evidence if it's irrelevant to the chosen claim construction; correct?

A. That would depend on the judge, whether the judge wanted -- I mean, the scope -- the scope of -- of -- the -- how the judge would have -- how the judge would handle a particular objection in a particular case and how they'd define what's relevant.

A judge might well want to make a record even on -- you know, on certain issues to allow the Federal Circuit some latitude on appeal.

For example, in a patent case, there's no relevance to validity once the noninfringement has been established. Nevertheless, the Federal Circuit says you have to go on and make findings about validity so that the Federal Circuit can avoid the risk of a do-over, which they try to do. There's a number of

cases on that.

Q. Sir, are you suggesting that judges will allow irrelevant evidence as an alternative in case their claim construction ruling is overruled by the Federal Circuit?

A. I'm suggesting judges have some latitude in what they allow at trial, and federal district judges may well try to develop a full record at trial, in my experience.

Q. Now, you don't offer an opinion as to whether Impax or Endo would have won the patent litigation; right?

A. I do not.

Q. You believe the outcome was uncertain?

A. It was.

Q. And you believe the patent litigation presented risks to both Endo and Impax; correct?

A. Yes.

Q. And the risk to Impax was that losing the case would mean it would not be able to market its oxymorphone ER product until at least September 2013 when the patents expired; correct?

A. That's -- that's correct.

Q. And you agree that if the court were to rule that Impax infringed either of the two patents and

found the infringed patent to be valid, the court would enter an injunction under 274(e) of Hatch-Waxman; correct?

A. Most likely, yes.

Q. And so Impax had to win against all of the claims at issue in the litigation to avoid an injunction if the patents were valid; correct?

A. That's -- that's the most likely result. Yes.

Q. And you say the outcome is uncertain, but you disagree with Mr. Figg that it is more likely than not that Endo would have won following the claim construction ruling; correct?

A. That's correct.

Q. But your report doesn't offer any prognosis on the outcome other than uncertain; correct?

A. That's correct.

Q. Now, claim construction is typically decided following a hearing referred to as a Markman hearing?

A. That's right.

Q. And prior to the Markman hearing, you didn't have any opinion as to who had the stronger position as between Impax and Endo; correct?

A. Excuse me. Prior to the Markman hearing?

Q. Yes, sir.

A. No. I -- I was looking at the state of affairs

as they existed at the time the settlement and license agreement was negotiated. That was the focus of my report.

Q. You would agree that the court adopted Endo's proposed claim construction of "hydrophobic material" word for word?

A. Yes.

Q. And the court adopted Endo's proposed construction of "sustained release" word for word.

A. Yes.

Q. And you agree that the claim construction of "hydrophobic material" required particular tests.

A. That -- that was -- that was likely that it would have required some kind of testing, yes, because it was a functional definition, unless you could show that those elements would be somehow inherently met.

Q. And Endo's experts commissioned tests aimed at proving that Impax' product infringed because it contained hydrophobic material; correct?

A. Endo -- Endo's attorneys commissioned certain tests. We don't know the extent of what tests were done. We only know the extent of the tests that were eventually presented, so there could have been other tests that weren't presented that were unsupportive of their case. That's why it's done through attorneys.

And those tests, in the view of Impax' expert and I think were very convincingly stated by Impax' expert, did not establish infringement.

Q. Sir, I didn't ask you anything about Impax' expert, did I?

A. Impax' expert was --

Q. No, sir. My question was --

A. -- part of the basis of my report, so that's why I refer to it in my report.

Q. Sir, I'm just trying to get out of here today, and if you could answer the question I ask without volunteering additional information from your report, we'll all finish a little bit sooner. Okay?

Can you try to do that?

A. I can try, but I'm trying to give a fair and balanced answer to your questions.

Q. Okay. Try to listen to my question.

And you would agree, sir, that a rational litigant would have tailored the tests to ensure that they would satisfy their proposed claim construction; correct?

A. No. The tests are science. You do the tests. You find out what they find out. There are limits to the amount of tailoring that can be done to establish a fact which isn't a fact.

In this case, the tests were done. They didn't support Endo's case, so I don't know -- and I don't have any basis for your assertion that they could have been tailored differently to provide a better result for Endo.

And I note that the tests were performed after the claim -- after the parties had made their claim construction submissions, not before, so Endo didn't necessarily know that the evidence wasn't going to support its position. As it turned out, it didn't --

Q. Sir --

A. -- according to Impax' expert.

Q. -- it was attorneys, not scientists, who set up the tests; right?

A. It was attorneys who -- who retained the firm Anderson Labs that did the tests, and the tests were -- I -- I don't know the details of how -- how it was determined what tests would be conducted. I assume the experts were involved to some extent at least.

Q. And you would expect Endo's attorneys, in commissioning scientific tests, would tailor those scientific tests to Endo's claim construction that they were advancing in the litigation; right? That's what you would do as a lawyer; right?

A. Right.

And the tests, critical tests, showed that the concentration of the level of microcrystalline cellulose did not affect the dissolution and release of the active ingredient, which was the function that it was supposed to perform, in accordance with the judge's claim construction, so the Impax product failed the tests. And I don't have any basis for believing the tests could have been provided -- designed differently so as to provide a more helpful result to Endo.

Q. Now, you'd agree that Impax' expert witnesses didn't conduct any testing of their own in support of their position under the court's claim construction; correct?

A. They didn't need to, wasn't their burden.

Q. Your position is simply that Impax' criticisms of Endo's testing would have prevented Endo from proving infringement by a preponderance of the evidence; correct?

A. It's not -- not criticisms of the testing but what the testing showed. The testing didn't show that it affected release of the active agent. It didn't perform the hydro- -- the MCC didn't perform the function that it was supposed to perform. Dr. Lowman agreed with that.

Q. Does Dr. Lowman, Endo's expert, agree with your position, sir?

A. Yes, he does. He agreed that it did not affect the dissolution of the product. That's in a footnote in his report.

Q. And the rest of his report?

A. In the rest of his report he tried to make some arguments why it nevertheless fell under the -- why the -- why other testing nevertheless supported his position, water uptake testing.

But as -- as Dr. Elder pointed out very convincingly, that testing did not actually relate to the hydrophobicity or the effect of water absorption by MCC, microcrystalline cellulose, in isolation. All it showed was that sugar, lactose, absorbs water better than wood pulp, which is microcrystalline cellulose.

Q. Sir, this was a battle of the experts between a couple of Ph.D. chemists, Dr. Lowman and Dr. Elder; correct?

A. Yes.

Q. And you side with Dr. Elder; correct?

A. I don't side with anybody, but I do feel that Dr. -- I felt that Dr. Elder -- Elder's report and his rebuttal report was -- was very persuasive on that

topic.

Q. You don't have a Ph.D. in chemistry, do you, sir?

A. No, sir.

Q. And you offer no opinion as to how Impax' arguments would have ultimately fared; correct?

A. No.

Q. And in your report you don't offer any opinions as to who would or wouldn't have won on any particular issue, including infringement; correct?

A. That's correct.

Q. Now, with regard to infringement, you recognize that a generic company must certify to the FDA that its product is bioequivalent to the reference listed drug; correct?

A. Yes.

Q. And Endo cited Impax' statements about bioequivalence as proof of its infringement arguments; correct?

A. I'm -- they cited that in their pretrial brief. They tried to make arguments along those lines.

Q. And so, for example, with regard to infringement of the sustained-release excipient claim, Impax certified to the FDA that its product is

bioequivalent to Opana ER and provides continuous, around-the-clock opioid treatment when dosed every 12 hours; correct?

A. That's correct. But it has nothing to do with patent infringement. I'm sorry. I'm not following you.

Q. Sir, in your report you don't offer any opinions disagreeing with Mr. Figg's statement that the patent owner is aided in proving infringement by the fact that the generic drug is designed to be bioequivalent to the brand drug to obtain FDA approval; correct?

A. I disagree with that statement.

Q. But you don't offer any evidence --

A. I do offer the opinion that there's not a nexus between the patent claims and the product at issue, and so that's part of that opinion. There's no nexus because those claims don't have anything in particular to do with the products.

Saying you're bioequivalent to Endo's product does not mean that you infringe some claim by a patent which was invented by different people years earlier which doesn't mention Endo's product, so I -- there's no nexus. I explained that at some length earlier today.

Q. Sir, the word "bioequivalent" doesn't even appear in your report, does it?

A. I don't believe it does. It's not relevant to patent infringement.

Q. And the term "therapeutically equivalent" doesn't appear in your report, does it?

A. I don't believe "therapeutically equivalent" appears, no. That's not relevant to infringement. That's relevant to FDA approval, different -- different legal issue, different legal standard, different -- different issue entirely.

Q. And your report doesn't address the relationship, if any, between infringement and bioequivalence or therapeutic equivalence; correct?

A. Well, there is no relationship.

Therapeutic equivalence relates to -- as used by the FDA, relates to equivalence to the reference listed drug, bioequivalence to the reference listed drug.

Patent infringement relates to what meeting each and every limitation of a claim of the patent. The reference listed drug is not a claim of the patent. They're just -- they're -- it's apples and oranges. This is -- they're totally different legal standards for totally different purposes.

Q. Sir, you read Impax' Paragraph IV notice letters to Endo?

A. Yes. I believe I did, yeah.

Q. And you're aware that at the time Impax sent Endo its Paragraph IV notice letter, Impax did not even claim Endo's patents were invalid; correct?

A. I don't think it's necessary for them to do that, but I -- they said what they said. I don't remember the details of what they said, but it's certainly not a requirement that you raise all issues in a Paragraph IV notice, in my experience.

Q. Sir, yes or no, are you aware that at the time Impax sent Endo its Paragraph IV notice letter, Impax did not even claim that Endo's patents were invalid?

A. And as I said, I remember there was a Paragraph IV letter, I don't remember the specifics of the Paragraph IV letter, and I don't think it's relevant to my analysis.

Q. So you didn't take into account the fact that Impax did not claim Endo's patents were invalid in its Paragraph IV letter; is that right?

A. They weren't required to do that, and they would prefer not to have to do that, so why would they. I mean, I just don't know -- I'm sorry. I -- it's not relevant to my report, and so no, I did not

take it into account.

Q. Sir, patents are presumed valid by statute; correct?

A. That's correct.

Q. And to overcome the presumption, Impax would have to prove each and every claim of the patents were invalid by clear and convincing evidence; correct?

A. That's correct.

JUDGE CHAPPELL: Ironsides, welcome.

MR. MITCHELL: Thanks.

BY MR. HASSI:

Q. And sir, clear and convincing evidence is a higher burden than preponderance of the evidence; correct?

A. That's my understanding. Yes.

Q. And you don't offer an opinion in your report about which party would prevail on invalidity; correct?

A. No.

Q. You only opine that Impax' validity arguments could have made it more difficult for Endo to prevail; right?

A. That's correct.

Q. And you didn't say in your report that Impax' validity arguments would make it impossible for Endo to

prevail; correct?

A. No, I didn't say that.

Q. Now, you testified earlier today that the court's claim construction opened the door to Impax bringing in new prior art; is that right?

A. Or additional prior art. Yes.

Q. You didn't review the underlying prior art that was the basis for Impax' anticipation claims; correct?

A. No. I read the summaries in the expert reports.

Q. And you would agree that the prior art anticipated Endo's patents under the court's claim construction -- excuse me.

You would agree that to prove the prior art anticipated Endo's patents under the court's claim construction, the prior art would need to function in the manner described by the claim construction; correct?

A. That's correct.

Q. You agree that Impax did not conduct any studies to show the prior art met the construction of "hydrophobic material"; correct?

A. No. They didn't conduct any studies in relation to the prior art formulations.

Q. And you agree that after the claim construction decision, it was too late in the case for Impax to conduct those studies and offer them as evidence in the case; correct?

A. That's correct.

Q. Expert discovery had closed by then; correct?

A. Yes.

Q. And the same would be true for introducing new prior art; correct? Expert discovery had closed by then.

A. That's correct.

Q. So given that expert discovery had closed, whether or not Endo had -- their claim construction had opened the door to Impax bringing in new prior art was irrelevant at this stage of the case; right?

A. I think what I testified is that in Dr. Elder's report, in the prior art that was listed in Dr. Elder's report, there were two categories of prior art, one category of prior art where the examples in the references had material that was unambiguously hydrophobic, like a wax, for example.

And then there were others where they contained microcrystalline cellulose, sustained-release tablets that contained microcrystalline cellulose, and so the question was could you argue that the microcrystalline

cellulose was inherently performing the function in those sustained-release tablets that had compositions very similar to the Impax formulation.

So that was -- that was -- those were the categories of art that we were looking at, so by opening up the functional definition and bringing in microcrystalline cellulose, which is not in -- in -- which does not meet the ordinary meaning of "hydrophobic material," that opened up the door to saying that these other references that also contained hydrophobic -- that also contained microcrystalline cellulose met the hydrophobic claim limitation.

That's the way it was explained by Dr. Elder in his report. You can look at his report.

Q. Sir, my question was a yes-or-no question as to whether it was irrelevant, and I can't honestly tell from your answer whether you answered me yes or no.

Is the answer yes, it was irrelevant or no, it was not irrelevant?

A. I think your question had a predicate --

Q. Can you --

A. -- about new prior art and bringing new prior art into the case, but I'm telling you the prior art was in the case, and so it was -- the predicate of your question that the art was not in the case and

hadn't been identified by the experts is wrong, and so that's why the confusing answer, because your question was predicated on a false assumption.

Q. So when you said Endo -- the claim construction ruling opened the door to new prior art, you meant prior art that wasn't new but was already in the case?

A. Yes. That was new under that claim construction that would not have been available as prior art under the other claim construction --

Q. Okay.

A. -- the Impax claim construction.

Q. Now, you didn't actually review any of that prior art to determine if the claim construction really substantially increased the number of prior art references potentially relevant to Impax' anticipation claims; correct?

A. I relied on the summaries in the expert reports. On both sides.

Q. And in your report you opine only that Endo's position created significant litigation uncertainties; correct?

A. That's correct.

Q. You didn't present any opinion as to the ultimate outcome of invalidity by means of

anticipation; correct?

A. No, I did not.

Q. And the burden on anticipation was on Impax; correct?

A. That's correct.

Q. And that burden was clear and convincing evidence?

A. That's correct.

Q. Sir, with regard to obviousness, you agree the success story of the product evidences the nonobviousness of the claims?

A. If the product is embodied by the claims, yes. When you have a patent that's about the product, yes, then the success story of -- of the product is relevant to the claims. But when you have a patent which had really nothing to do with the product until long after the NDA was filed and the product was approved, no, then I don't think it's very relevant.

Q. So I heard a yes and a no. I'm not sure which applies here.

With regard to obviousness, do you agree the success story of the product evidences the nonobviousness of the claims, yes or no?

A. It depends on whether there is a nexus, as we've discussed and as Mr. Figg discussed.

Q. Now, the claims here -- some of the claims here had to do with sustained release; correct?

A. They had to do with controlled-release formulations that had a sustained-release ingredient. Yes.

Q. And before Endo launch Opana ER, there was no sustained-release form of oxymorphone; correct?

A. Not of oxymorphone, but the claims aren't limited to oxymorphone. They're directed to all -- any and all forms of therapeutic active ingredients.

They're very, very broad claims, so there were -- so the oxymorphone story is not relevant to those claims because they're not specifically about oxymorphone. They're about sustained-release formulations generally, and sustained-release formulations generally have been known for quite a long time.

Q. Sir, you would agree that Endo was successful in introducing the first sustained-release form of oxymorphone?

Yes or no?

A. In the United States, I believe so.

Q. And you're aware that in 2009 Opana ER had over $172 million in sales?

A. That sounds about right. Yeah.

Q. And you don't offer any ultimate conclusion as to whether the claims in the patents were obvious or unobvious; correct?

A. I don't offer that ultimate conclusion.

Q. And you don't offer an ultimate conclusion on the issue of how the issue of invalidity by means of written description would have come out; correct?

A. I don't offer any ultimate conclusions on invalidity under written description.

Q. And in your report you only say that Endo may have faced difficulty defending Impax' written description claims; correct?

A. That's correct.

Q. And you recognize the issue is uncertain; correct?

A. Yes.

Q. Now, Impax was not the only ANDA filer that Endo sued on the '933 and '456 patents; correct?

A. That's correct.

Q. And despite your expert interpretation of the case, none of those other ANDA filers chose to actually challenge Endo's '456 and '933 patents through the conclusion of trial; correct?

A. Endo settled with everybody I believe.

Q. So Sandoz settled; correct?

A. Endo settled with Sandoz. That, to me, suggests that Endo wasn't confident that it could win its case. That's why it settled.

So yes, they settled with everybody. They caved all the way around. Because they got their delay. They got what they wanted. That was my interpretation.

Q. Was that your interpretation of the Barr settlement, too?

A. Huh?

Q. Was that your interpretation -- you're aware that Endo and Barr settled as well; correct?

A. The other generic companies didn't present a threat to Endo because they couldn't launch until after Impax launched, so once they'd settled with Impax, the other litigation didn't matter.

There was no reason to continue to put their patents at risk and jeopardize -- potentially have somebody else get on the market, because if somebody else had won and knocked out their patents, you know, that would -- you know, they could have used that to trigger the 180 days exclusivity and precipitate -- you know, put Impax in a position of a premature launch or the hundred -- or launch by any of the parties after -- after when Impax failed to launch.

So it was -- I don't -- once they settled with Impax, all they had to do was try to protect their patent from attacks by others, and they did that.

Q. And that's once they settled with Impax; right?

A. Right.

Q. Do you know whether any of those ANDA filers and Endo settled before Endo and Impax settled?

A. As I've testified previously, it was all about Impax and when Impax launched. That -- that was the driver because that controlled the entire generic market. All the others were subsidiary to Impax' exclusivity, so the settlements with them are not -- are not a big deal. And what I notice is that Endo settled with them and if -- and, you know, apparently in a -- in an effort to avoid putting its patents at risk.

Q. Sir, you're aware that Endo and Actavis settled more than a year before Endo and Impax settled; is that right?

A. I don't know the details of the Endo-Actavis settlement. I don't recall them. I remember there was a settlement.

Q. But in your prior answer you talked about the fact that once they settled with Impax, then the

settlements with the other ANDA filers weren't particularly relevant; right?

A. Well, Actavis had -- did -- had been first to file on those -- on the two smaller doses -- well, the lower dosage, the two lower dosage forms, so Actavis had, you know, a little something there.

But whether they settled before or after, it didn't matter because the controlling -- the controlling factor for the generics on those dosage strengths that represented the bulk of the market was when Endo launched because -- or when Endo's exclusivity was triggered.

So the fact that they settled with the other generic companies, as I've said, is not that surprising because why would they want to have their patents put at risk when the only patents they had the exclusivity and that blocks everybody --

JUDGE CHAPPELL: You said "when Endo launched." Did you mean when Impax launched?

THE WITNESS: When Impax launched. I apologize.

MR. HASSI: I think he also meant Impax' exclusivity.

BY MR. HASSI:

Q. But, sir, be that as it may, any one of these

ANDA filers, Sandoz, Actavis, Barr, Roxane or Watson, could have taken that litigation against Endo to trial and to a conclusion; correct?

A. They could have done, yes.

Q. And had they won and gotten the patents invalidated, they'd have the opportunity to launch; correct?

A. No. They would still be subject to Endo -- to Impax' exclusivity. It would trigger the 180 days. And then -- so Impax -- Impax would -- it would precipitate -- it would have to precipitate a launch by Impax.

I'd have to go back and look at the -- I'd have to look at the -- I think the settlement and license agreement deals with that scenario, but, you know, whether Impax, you know, could -- could -- could launch earlier in that circumstance, but it would start -- it would trigger the start of the 180 days --

Q. So if Sandoz --

A. -- once the final decision of noninfringement or invalidity in favor of anybody, any Paragraph IV challenger.

Q. So, sir, if Sandoz or Actavis or Barr or Roxane or Watson, had they thought they had a strong

case against Endo, they could have pressed the issue and gotten the opportunity to get into the market sooner; correct?

A. They could have had the opportunity to get into the market sooner, but --

Q. And --

A. -- with everybody else and not before Endo, not sooner -- I mean -- excuse me -- Impax.

Q. And sir, each of those companies you would expect would have been aware that Endo was considering reformulation and that Endo had additional patents coming down the pike; correct?

A. Yes.

Q. And so if they wanted the opportunity to launch Opana ER, they would have been motivated, if they had a strong case, to continue litigating against Endo if they thought they could win; correct?

A. They would have -- it's -- it's not a great result to clear the pathway for Impax, let Impax take all the profits, and then you come in 180 days later with five other generics, so the market opportunity for them was not -- was not great.

So they didn't have the same motivation that Impax had. They had maybe an opportunity to get a small piece of the market, but it wasn't a great

opportunity.

Q. So it wasn't a great opportunity, but wouldn't you agree that it's a better opportunity than never getting to come to market, the way Sandoz never got to come to market, Barr never got to come to market, Roxane never got to come to market, Watson never got to come to market? Wouldn't you agree that pressing the litigation, if they thought had a chance of winning, could have been a better opportunity?

A. No. Not necessarily. It depends what their profitability would have been on the market.

If they got on the market and they weren't making substantial profits that would justify the litigation expenditures and the -- and the internal trouble and expense and the cost of manufacturing, and so forth, then no, it would not have been a better opportunity.

Nobody wants to be the generic company that's carrying the ball for everybody else. That was the whole point of the 180-day exclusivity as a motivation, because before that there weren't -- you know, that was the whole problem. In areas where we don't have Hatch-Waxman, that's what we see, nobody -- nobody wants to be the linebacker that clears everything out and makes a hole for everybody else to come in because

what's the point. If you don't have the exclusivity, it's not -- it's not a very attractive opportunity.

Q. And sir, yes or no, you have not done an analysis of Sandoz' case against Endo or Actavis' case against Endo or Barr's case against Endo or Roxane's case against Endo or Watson's case against Endo; correct?

A. No, sir.

Q. Now, in your report, you opine that Mr. Figg's opinions for the likely timing of the Impax-Endo Hatch-Waxman litigation case is a worst-case scenario; correct?

A. Yes, sir.

Q. And in your report, you don't offer any opinion as to when the trial court was likely to release its opinion in Impax-Endo Hatch-Waxman litigation; correct?

A. Correct.

Q. And you didn't do any review of average times required to resolve Hatch-Waxman cases; correct?

A. Correct.

Q. And you've only been involved in one Hatch-Waxman case while in private practice; right?

A. Yes. I've been involved in -- that's not true actually. I've only been involved as -- as -- as

counsel of record in one Hatch-Waxman case. I've -- as I testified, I've been involved in quite a number of other cases as opinion counsel, as an expert or otherwise or supporting mediations or -- or -- or dispute resolutions.

Q. Sir, you didn't evaluate how quickly Judge Hayden renders opinions; correct?

A. I mean, I think Judge Hayden is a she, and no, I didn't.

Q. I agree that Judge Hayden is a she.

I didn't say anything that she was a he, did I?

A. No. You said "his opinions." I'm sorry.

Q. I didn't, but that's all right.

Sir, you agree there's a zone of uncertainty around the timing for trial court's opinions?

A. Yes. I mean, I've had cases where they -- they issued the opinion literally from the bench at the end of trial, and I've had cases where they took their own sweet time. It does vary considerably.

Q. And in your report you don't offer any alternate date to the date offered by Mr. Figg as to when the parties might expect a decision from the Federal Circuit; correct?

A. I -- I don't have any dispute that Mr. Figg --

that the times that Mr. Figg puts out for each of those individual steps are, you know, fair, reasonable, conservative average estimates.

My dispute with Mr. Figg is whether each of those steps would have been required and whether each of those steps would have actually been -- been viewed by -- necessarily viewed by Impax as a block to launch, so if that helps you.

Q. Well, let's talk about which of those steps would or would not have been required.

You agree that a decision from the trial court would be required; correct?

A. Yes.

Q. And if Impax did not wish to launch at risk following that decision, an appeal to the Federal Circuit would also be required; correct?

A. Well, even if they did launch at risk, then there would still be an appeal to the Federal Circuit. It wouldn't affect their launch timing, though, but yes, there still would have been an appeal to the Federal Circuit.

Q. And you don't disagree -- you do not disagree with Mr. Figg's estimates as to the time it would take to get a district court opinion; correct?

A. I think in this case, as demonstrated by the

letter which was referenced in my report, you know, where they were promising not to launch before the end of trial, I think the court was very well aware that an imminent launch was at least a possibility, hence the letter.

So I think the district court would have understood that there was some urgency by the parties, particularly if the decision was to allow the parties to go forward.

So I think that it would depend on the circumstances. It would depend on the judge. It would depend on the judge's caseload. But I don't think that looking at averages is necessarily all that relevant.

Q. Sir, none of that opinion about urgency or lack of urgency appears in your report; correct?

A. Urgency or lack of urgency? I'm not sure. I don't think -- I'm not sure if it does.

I testified regarding the necessity for each of these steps and regarding the timing. I testified I disagreed with Mr. Figg. I'm elaborating on the basis for my opinions in response to your questions. I'm -- but I'm not offering -- my opinion remains what it says in my report. I don't agree with Mr. Figg about the timing.

Q. I'm sorry. You do or don't agree with Mr. Figg about the timing?

A. I don't agree with Mr. Figg about the timing that there would be basically a holdup to the launch till mid -- potentially mid-2013, because I don't think all of the steps required by Mr. Figg are necessarily accurate.

I think, as I've said, with regard to the specifics of the length of time for a federal appeals decision and the length of time for a remand, you know, those -- I don't dispute that those could take some time and the time estimates in Mr. Figg's report are reasonable averages, but I dispute that they would all be necessary or that they would necessarily be relevant to Impax' launch date.

Q. And sir, again, my question was just a yes-or-no question, do you agree with Mr. Figg, yes or no.

If I ask you a yes-or-no question, can you try to answer it yes or no?

A. Well, you asked me if I agree with Mr. Figg. My answer was no, I agree with him in some respects but not in other respects, so sorry if that's not a yes or no.

Q. Sir, you testified that Mr. Figg said it would

be -- that there would necessarily be a remand. Do you recall that testimony?

A. Excuse me? There would necessarily be what?

Q. A remand. From the Federal Circuit.

That's the basis for your objection; correct?

A. Yes. Mr. Figg said he felt that would be nearly a certainty I think when he testified on Monday.

Q. So you're aware that his report says there would potentially be a remand; right?

A. A remand was a possibility if they lost and if there were additional findings of fact required, but nobody could possibly know that without the district court decision and the Federal Circuit decision. Remands happen, so yes, they're in the realm of possibility.

Q. But to be clear, your only objection with Mr. Figg with regard to the timing of an appeal in this case relates to that step of a remand; correct?

A. Yeah. I think that's the major -- that's the major dispute. I think that he was maybe -- I don't -- as I testified previously, I don't know that the length of time for the district court's decision would have been quite as protracted as he presented it, but my major dispute with him is that I don't

think a remand would have been necessary, and I don't think that the district court appeal time would have necessarily affected Impax' launch date. That's the major point of contention here, is the impact on the launch date.

Q. Sir, do you agree with his estimate, his conservative estimate of one year from docketing to decision in the Federal Circuit?

A. That sounds about right.

Q. Indeed, it can often take longer; correct?

A. It can.

Q. For example, you're counsel of record in a case before the Federal Circuit right now called Actelion Pharmaceuticals v. Lee, et al.; is that right?

A. Yes, I am.

Q. And did you take your experience in the Actelion matter into account in forming your opinions in this case?

A. I don't recall exactly that I did.

Q. That appeal was docketed on November 15, 2016; correct?

A. That's correct.

Q. And oral arguments are not scheduled until December; correct?

A. That's correct.

Q. That means oral argument would be some 13 months after the appeal was docketed; correct?

A. That's correct.

Q. And Mr. Figg's conservative estimate was therefore two months shorter than the appeal you're currently handling for --

A. No. In that case, the opposing counsel requested an extension. The oral arguments had originally been docketed earlier, and then the other side requested extension and we did not oppose it.

You know, whether -- whether Impax would have been -- if Impax felt that the appeal was blocking its -- its -- blocking its launch, then Impax might have tried to expedite matters and not simply agreed to extension, so it can be variable depending on how the parties -- the urgency of the case.

In that case, getting a decision from the Federal Circuit one or two months later doesn't really matter.

Q. But, sir, you'd agree the Federal Circuit typically does not issue decisions the same day as they're argued?

A. No, they don't.

Q. It typically takes months to get a decision?

A. It can do, yes.

Q. Well, let's look at another example of timing.

You're aware of the second wave of litigation that Endo brought against the ANDA filers in the Southern District of New York?

A. Yes.

Q. Relating to Opana ER?

A. Yes.

Q. And you're aware that Judge Griesa tried that case in April of 2015?

A. Yes.

MS. PEAY: Objection. Your Honor, objection. This is outside the scope of direct.

JUDGE CHAPPELL: Response?

MR. HASSI: Your Honor, this is cross-examination of the witness with regard to his opinions on timing of an appeal in this case.

JUDGE CHAPPELL: Impeachment?

MR. HASSI: It is impeachment, yes.

JUDGE CHAPPELL: Overruled.

MS. PEAY: Thank you, Your Honor.

BY MR. HASSI:

Q. You are aware that Judge Griesa's trial opinion in that case didn't come out until a year later in April 2016; correct?

A. I don't recall the exact timing, but I'm -- I have no reason to dispute that sitting here today.

Q. So that's seven to eight months longer than Mr. Figg's four to five-month estimate that he used in his report; correct?

A. Yes.

And as I said in response to the previous question, I felt that if the judge was going to rule in Impax' favor, she might well have ruled more expeditiously because that would affect potentially the launch timing. If she was not going to rule in Impax' favor, then Impax isn't getting to the market and the timing is -- the timing is less urgent. And I do think judges, you know, do take those things into account.

Q. And what is your basis for your view that judges take into account the benefits to certain of the litigants in deciding how to time the release of their opinions?

A. People can file motions to expedite proceedings, and I think judges do take into account the public interest involved in whether a generic gets to the market or not. That would be -- if you have a de facto injunction situation pending, you know, that's something the judge can and should -- should take into

account.

Q. But you don't know whether -- you can't cite to a specific example of a judge taking that into account, can you?

A. Taking public interest into account? In determining whether to issue an injunction?

I think in general injunction -- proceedings involving injunctions, if it was -- if we were talking about an injunction situation where Endo is requesting an injunction at the end of trial or not, they are typically handled on an expedited basis --

Q. So that's all --

A. -- expedited schedule.

Q. That would be true of all Hatch-Waxman litigation; right, all several hundred cases filed a year?

A. Well, it -- it -- I think there's some -- you know, I think judges do take into account, you know, market realities to some extent of -- and the public interest and whether there's an urgency to get a case resolved quickly or whether there's not. I think -- I think they are concerned about that, in my experience.

Q. Now, the case before Judge Griesa, in which he took a year to issue his opinion, was an injunction

case; correct?

A. I don't know the specific market urgency for getting -- you know, for getting -- for getting on -- getting -- getting -- going forward with that. I don't recall the -- can you remind me of the exact timing of that case?

Q. The timing?

A. Yeah.

Q. The trial took place in April of 2015.

A. Uh-huh.

Q. The opinion was filed in April 2016.

And are you aware that it was docketed in August of 2016?

A. I -- I don't have those -- those dates, you know, right -- right at the tip of my -- right at the front of my brain. But yeah, I mean, as I said, judges can take longer, they can -- but they can also take much shorter times.

And as I said, I have also been involved in cases where judges have ruled from the bench, you know, and issued very eloquent opinions just sitting right there after taking a 15-minute recess.

So it depends a lot on the case and it depends a lot on the judge, and I don't know that you can extrapolate from a case involving different patents,

different parties and a different judge in a different court to draw conclusions about what would have happened or could have happened in this case.

Q. But you've got no personal experience before Judge Hayden that would allow you to offer an opinion in this case about how quickly or for that matter how eloquently her decision would have been rendered?

A. Excuse me?

I have no personal experience before Judge Hayden following a Hatch-Waxman trial, no.

Q. Now, the appeal of Judge Griesa's decision is scheduled to be heard on oral argument in front of the Federal Circuit in December.

Are you aware of that?

A. I believe I heard that. Yes.

Q. So from the end of the April 2015 trial to the December 2017 oral argument -- and that's not decision; that's just oral argument -- that's 32 months; correct?

A. There were special factors in that case. If you recall, there were -- there were multiple patents. I think there was a delay while another proceeding was decided, and the case has been -- was consolidated. I think the first appellant -- I don't remember the exact details, but the first appellant went out, and

then there was a stay while waiting for resolution of the cases with the other appellants for the consolidated appeal.

I don't remember all the details right now, but there were some somewhat unusual circumstances in that case which were not present in the Impax case.

Q. Well, one --

(Counsel and witness speaking at the same time and cautioned by court reporter.)

BY MR. HASSI:

Q. Sir, if you apply that same 32-month timeline from Judge Griesa's trial to the oral argument to the time when Judge Hayden would have finished the trial of the Impax-Endo case, 32 months would take us into the spring of 2013 before that case would be argued before the Federal Circuit if the same timeline applied; correct?

A. If -- if those times applied, yes, that would be the case. The case would become moot in September of 20- -- in the -- in the Impax case that we're talking about here, not this other case, but in the Impax case under the '456 and '933 patents, that case would be moot and everything would be done in September of -- of 2013 because the patents would be expired. There were no outstanding damages issues or

any other issues. The case would be over then.

So at the latest, it wouldn't extend beyond September of --

Q. Sir, I was simply asking you to do the math.

Thirty-two months from June 2010 would take us into spring of 2013; correct?

A. That is correct, yes.

Q. And in the real world, by spring of 2013, Impax was selling oxymorphone ER pursuant to a license; correct?

A. Yes.

Q. And so if the timing that applied to the second wave of Endo's patent litigations applied to that first wave appeal, Impax would not only not be selling, it would still be waiting for an appellate court decision; correct?

A. Well, yes, if. As my grandfather used to say, if pigs had wings, they could fly.

Q. Have you reviewed the third wave of litigation in Delaware related to Endo's patents?

A. I've reviewed it generally. I don't know if I'm conversant with all the specifics.

Q. Are you aware in that case Judge Andrews conducted a bench trial in February 2017?

A. I have no reason to doubt that.

Q. And Judge Andrews' final judgment was entered on September 15, 2017; correct?

A. I don't know if I've read Judge Andrews' final September judgment.

Q. Would you like to see a copy?

A. Is that the one where -- which is referenced in Mr. Figg's report?

Q. It is referenced in Mr. Figg -- well, strike that. I'm not sure it is referenced in Mr. Figg's report. The final judgment came after -- the litigation is referenced in his report.

A. Okay.

Q. But in any event, you're aware that from the time of the close of trial till the resolution of that case at the district court level was seven months in that case?

A. If you say so.

Q. That's two months longer than Mr. Figg's conservative estimate here; correct?

A. That's two months longer, yes.

Q. Now, with respect to a remand, you would agree that remand by the Federal Circuit is appropriate when there's a need for further findings of fact; correct?

A. Yes.

Q. And you'd agree that the claim construction

ruling can change how the parties present their case; correct?

A. It certainly can, yes.

Q. And so arguments aimed at a claim construction that had been rejected by the trial court might be excluded as irrelevant to the trial; correct?

A. That could happen.

Q. Sir, I touched on a moment ago the second wave of litigation.

You're aware that between December 2012 and May 2013 Endo sued eight generic drug manufacturers for patent infringement related to oxymorphone ER?

A. I haven't counted them up, but I'll take your word for it.

Q. Endo didn't sue Impax with regard to its original formulation of oxymorphone ER; correct?

A. No, that's not correct.

Q. In the litigation that I'm speaking of in the Southern District of New York, did Endo sue Impax with regard to its original formulation of oxymorphone ER?

A. They didn't -- they did ultimately sue Impax with regard to the original formulation of oxymorphone ER.

Q. Sir, we'll get --

A. Not in that particular litigation.

Q. Okay. We'll --
A. Not in the litigation you're referring to I guess.
Q. Great. We'll get to that litigation in just a minute.
But in the litigation that was filed between December 2012 and May 2013 by Endo in the Southern District of New York, you agree that Endo did not sue Impax with regard to original oxymorphone ER; correct?
A. In that litigation, no.
Q. And that's because Endo had granted Impax a license to patents which you spoke about earlier in your direct testimony; correct?
A. Well, Impax hadn't even -- hadn't even launched in September of -- what -- what did you say, 2012?
Q. December 2012 to May 2013.
A. Right.
So Impax didn't even launch until January 2013. And then Impax -- the provisions of 4.1(d) didn't kick in until the end of the period of exclusivity.
Q. So is it your testimony that the reason Endo didn't sue Impax was because they hadn't launched yet?

A. Well, I'm saying they couldn't have sued them -- I'm saying they weren't -- they -- they had sued them, and then they had settled the suit, and they got some sort of a license. And the license was ambiguous, and so they didn't -- they dropped the -- they had been suing them. They dropped the suit. And then at some point in time later they sued them again, including under those patents.

So that was -- I mean, those are the facts.

Q. Sir, when Endo sued eight different ANDA filers in the Southern District of New York over the '122 and '216 patents, they did not sue Impax on original oxymorphone ER; correct?

A. They didn't sue them at that time.

Q. And of those eight ANDA filers, only one, Actavis, had launched; correct?

A. I believe that's right.

Q. So they sued seven other ANDA filers, although those ANDA filers had not launched oxymorphone ER; correct?

A. Yeah.

Q. And they did not sue Impax with respect to original oxymorphone ER; correct?

A. They had sued them earlier, then they had settled that litigation, and then they reasserted those

patents, so they sued them twice under those patents, so I don't agree when you say they didn't sue them under those patents. They sued them actually in two different litigations under those patents. That's why I'm having trouble with your question.

And I think we all agree that they weren't sued in that particular litigation, but they'd been sued earlier and they'd been sued later.

So when you say they weren't sued, it's very confusing.

Q. Well, sir, prior to the contract's royalty dispute in 2016, would you agree with me that Endo never sued Impax pursuant to the '122 and '216 patents?

A. Pursuant to those patents.

Q. So when you said they sued them earlier, you're referring to, what, the '933 and '456 patents that we've been talking about?

A. Yes.

Q. Okay. You understand they sued a number of ANDA filers, including Sandoz and Actavis and Barr and Watson and Roxane, on those patents?

A. Yes.

Q. And then they sued those same ANDA filers in a second round of litigation in New York, not with respect to the '933 and '456 patents, but with respect

to the '122 and the '216 patents; correct, sir?

A. I believe so, yes.

Q. And they did not sue Impax at that point in time on the '122 and '216 patents; correct, sir?

A. Not initially they didn't sue them.

Q. And the reason that they did not sue Impax at a time when they sued all the other ANDA filers was because Impax got a settlement and license that covered the '122 and '216 patents in the June 2010 settlement with Endo; correct, sir?

A. No.

They had thought they had a license, but it turned out it was ambiguous, and so there was a dispute. There was an ambiguity. It wasn't clear-cut one way or the other. And that's why there was litigation, and that's why they ultimately wound up getting sued under those patents, those very same patents, despite having that agreement.

Q. Sir, is it your testimony that Endo chose not to sue Impax in 2012 or 2013 on the '122 and '216 patents because they knew they were going to have a dispute in 2015 and 2016 over whether Impax would pay a royalty on those patents? Is that your testimony?

A. They -- they -- they had -- Impax had some

sort of a license. The terms and the scope of that license were not clear, so they didn't get sued initially, but they did get sued later. And there was -- there was fighting and there was demands for 85 percent gross profits royalties and all of that, so it -- I think it's not -- it's not -- there's not a clear-cut yes-or-no answer to your question as to why Endo did what it did when it did it.

JUDGE CHAPPELL: This has gone on far too long. Any expert's opinion on the reason why Endo sued or didn't sue, it's not dispositive. Move on.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: I don't care if it's in somebody's report or not. I don't care about some expert's speculation on any reason why or why not somebody sued somebody else. I can make that determination myself.

MR. HASSI: Understood, Your Honor.

JUDGE CHAPPELL: If need be done, which I'm not agreeing to that either at this point.

MR. HASSI: Thank you, Your Honor.

BY MR. HASSI:

Q. Now, sir, you're aware that Judge Griesa eventually enjoined the other ANDA filers from launching generic oxymorphone ER until the '216 and

'122 patents expire in 2023?

A. That's my understanding.

Q. And you're aware that Judge Griesa's order did not affect Impax' ability to sell its generic oxymorphone ER product; correct?

A. I don't believe Impax was a party to that litigation.

So that's correct.

Q. And during that second wave of litigation, you're aware that Actavis actually launched oxymorphone ER at risk?

A. Yes.

Q. And the fact that Impax was already on the market lessened Actavis' risk for that launch; correct?

A. The fact that Impax was on the market, yes, that reduced -- that reduced Actavis' risk, yes.

Q. And Actavis was ultimately removed from the market by Judge Griesa's order; correct?

A. Ultimately, that's correct.

Q. And after Judge Griesa's injunction took effect, Impax was the only generic firm selling oxymorphone ER; correct?

A. The only generic firm?

Yes, I -- I believe that's correct. Selling

that formulation, yes.

Q. And you're aware, sir, that Judge Andrews of the District Court of Delaware upheld the '779 patent covering oxymorphone ER; correct?

A. Yes.

Q. And Judge Andrews enjoined all unlicensed generic drug manufacturers from selling oxymorphone ER until the '779 patent expires in 2029; correct, sir?

A. That's correct. But that was not a patent owned by Endo at the time of the settlement and license agreement. That's a patent that could have been acquired by Impax or Endo or some third party, so the relevance of that to my report and to the settlement and license agreement, we're really getting very far from what I -- from what's in my report.

Q. Sir, I didn't ask you whether Endo owned the patent or was simply enforcing it pursuant to a license, did I?

A. Endo had no rights in the patent, none at all, not speculative, not partial, not in contemplation, at the time of the settlement and license agreement in June of 2010, and Impax could just as well have bought that patent as Endo if there hadn't been a settlement and license agreement, and then they would have blocked Endo, so --

Q. Sir, again --

A. -- the relevance of that to the settlement and license agreement of 2010, I don't see it. They had no ability to offer that license.

Q. Not my question, sir.

Sir, Judge Andrews --

JUDGE CHAPPELL: Hang on a second.

I'm going to instruct you -- and I don't want to have to do it again -- you answer the question that's pending, not the question you hoped would be pending. Do you understand me, sir?

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: Go ahead.

BY MR. HASSI:

Q. Sir, yes or no, Judge Andrews enjoined all unlicensed generic drug manufacturers from selling oxymorphone ER until the '779 patent expires in 2029?

A. I believe that's true.

Q. And Impax' sale of original generic oxymorphone ER was not affected by Judge Andrews's injunction; correct?

A. That's correct.

Q. Sir, you agree that the objective of negotiating a patent license agreement is to obtain freedom to operate?

A. That was -- that was the objective I believe, yes.

Q. And you testified earlier you reviewed the settlement and license agreement between Impax and Endo; correct?

A. Yes, I did.

Q. And the section 4.1(a) is the license?

A. Yes, it is.

Q. And 4.1(a) by itself is unambiguous as a license; correct?

A. All by itself, yes. I think so.

Q. And 4.1(b) is a covenant not to sue; correct?

A. That's correct.

Q. And you believe that both that license provision and covenant not to sue provision are fairly standard; correct?

A. Yes.

Q. You don't believe there's any ambiguity in the terms of section 4.1(a) or 4.1(b) of the settlement and license agreement; correct?

A. Taken all by themselves, no, I don't think -- I don't think they're ambiguous.

Q. The problem was a separate royalty term in 4.1(d)?

A. I'm sorry. There's no mention of -- the word

"royalty" doesn't appear in 4.1(d).

Q. The ambiguity comes in section 4.1(d); correct?

A. 4.1(d) creates an ambiguity. Yes.

Q. And you agree that the language of 4.1(a) is broad and licenses Endo -- excuse me -- licenses Impax to Endo's future patents; correct?

A. Yes, that's correct.

Q. And Endo granted Impax a license and covenant not to sue for infringement of the patents listed in the Orange Book at the time, as well as any continuations, continuations in part, or divisions of those patents or patent applications owned or controlled by Endo that could cover the product described in Impax' ANDA; correct?

A. That's correct.

Q. And Endo has never contested that it gave Impax that license in June of 2010; correct?

A. Endo has never contested the existence of the agreement, but they did contest whether they had a license in accordance with that -- in accordance with that paragraph, which is a royalty-free license.

Q. Sir, at your deposition, you stated that you believe all of the generic drug manufacturers, all of the ANDA filers, effectively had the same license as

far as the license term goes; correct?

A. I don't -- I'd have to look exactly what I said, but they all had licenses. The licenses I believe I testified were not -- you know, were not word-for-word identical. And Actavis certainly thought that it had licenses under the future patents. I think that's what I testified.

Q. Actavis thought it had what it called an implied license; correct?

A. That was the argument that they made and that the district court accepted.

Q. And the Federal Circuit shot that argument down, didn't it?

A. Yes, they did.

Q. And as to the other ANDA filers, you would agree that none of them got the broad patent license that Impax got; correct?

A. Their licenses were not exactly the same as Impax' license, no.

Q. You would agree that the license Impax got was unique among the ANDA filers to Endo's Opana ER; correct?

A. Well, that depends on whether you believe that Impax actually had an unambiguous license under the future patents, because although they did have a

license in 4.1(a) under the future patents, that was subject to the condition in 4.1(d) which said that the -- any term relating to those future patents could be renegotiated.

And there was disagreement among the parties about what the impact of that negotiation provision in 4.1(d) actually meant, but the way Endo interpreted it, they did not effectively have a license. And since they didn't have freedom to operate, they had keys to the door for the earlier patents but not for the later one, unless they wanted to pay an 85 percent royalty on gross profits, which is kind of like not having a license at all.

Q. Sir, it is a fact that Endo did not sue Impax on generic oxymorphone ER in the second wave of litigation in the Southern District of New York; correct?

A. Not in that litigation, no.

Q. And Endo did not sue Impax on generic oxymorphone ER in the third wave of litigation that it brought in the District of Delaware; correct?

A. That's correct.

Q. And you didn't actually read the other settlements and license agreements with the other ANDA filers; correct?

A. I don't believe I did. I read the Actavis -- I -- I think I have the Actavis one. I don't know that I had all the others.

I don't believe that they had licenses to the future patents, if that's your question. But the question was, I'm not sure that Impax had an unambiguous license either.

Q. Sir, I didn't ask you whether Impax had an unambiguous license.

A. Okay.

Q. You're aware that Endo has specifically said that the other generic companies did not obtain the same licensing terms as Impax; correct?

A. Correct. Impax had different licensing terms from anybody else. That's true.

Q. And therefore, as Mr. Figg opined, Impax' license was unique among the ANDA filers; correct?

A. It was unique among the ANDA filers in many respects but not in respect of whether -- of getting a licensed freedom to operate for the product.

They all had the license under the existing Orange Book listed patents. Endo -- Impax also had a license under the future patents, but that was -- that was ambiguous for the reasons that I've previously stated, so it wasn't clear-cut. That's why there was

litigation. That's why they got sued.

Q. Let's talk about that lawsuit.

That's your reference to a 2016 litigation between Impax and Endo over the 2010 settlement; is that right?

A. Yes.

Q. And at that point in time Impax had been selling oxymorphone for almost three years before Endo brought the lawsuit?

A. I believe that's right.

Q. And what triggered the lawsuit was not any ambiguity over the license and covenant not to sue, what triggered the lawsuit was Endo's view as to whether Impax was negotiating in good faith over any royalty to be paid to Endo pursuant to that section 4.1(d); correct?

A. No.

Q. What part of my statement was incorrect, sir?

A. Well, if you read the correspondence between Meg Snowden and the Endo representative regarding 4.1(a), Meg Snowden thought that 4.1(a) was a clear, unambiguous license that was not affected by 4.1(d). Endo disagreed with that.

So there was an ambiguity as to whether 4.1(a) was or was not affected by 4.1(d) or subject to

4.1(d), so that was the ambiguity. Because if it was, then -- then -- then no -- then that would actually change the terms of that provision 4.1(a) and make them no longer an absolute license but subject to negotiation in any respect, including royalties but also including, you know, temporal restrictions, and so on.

Q. Sir, you'd agree that the very first communication that was the subject that brought up this dispute between Impax and Endo, Endo stated that the parties need to negotiate a license fee for licensed patents that issued following the execution of the settlement; correct?

A. There was such a communication. I don't know if it was the first communication. I don't know how early the parties started talking exactly.

Q. But it referred to a fee for licensed patents; correct, sir?

A. That's what Endo wanted. Yes.

Q. And so what Endo sued Impax for was for breaching the settlement and license agreement for failing to negotiate with Endo in good faith and compensating Endo with respect to those patents; correct?

A. Yes. And they sued them for patent

infringement.

Q. And you're aware that those infringement claims were stayed pending the disposition on the contract claims; correct?

A. I believe that's right. I don't have a specific recollection.

Q. And that's because, if Impax won on the contract claims, there was no basis for infringement claims; correct, sir?

A. That's correct.

Q. And Endo did not seek an injunction in that case to prevent Impax from selling oxymorphone ER; correct?

A. They didn't file a motion for injunction. The complaint seeks equitable relief. But as Impax had been on the market, as you say, for three-plus years, it would have been difficult I think to get a preliminary injunction.

Q. Indeed, you agree this would really be a case about money damages; right?

A. There could have been an injunction at the end of the case. But yes, there would have been certainly a money damages element. It would have been difficult to get a preliminary injunction since it had been on the market for such a long time without being sued.

1 That's true.
2 Q. Sir, you'd agree that in its complaint, Endo
3 concedes that it gave Impax a license to any patents
4 issuing from the pending patent applications and the
5 other patents Endo might acquire; correct?
6 A. I believe so. Yeah.
7 I think the other patents was a little more
8 ambiguous in 4.1(a), but that's -- that's ultimately
9 what Impax got.
10 Q. Can we bring up CX 3437, the amended complaint,
11 please.
12 And let's go -- sir, do you recognize this as
13 the amended complaint brought by Endo against Impax in
14 the case we've been talking about?
15 A. Yes.
16 Q. Let's look at paragraph 49 if we could.
17 A. Okay.
18 JUDGE CHAPPELL: Has your time estimate
19 changed?
20 MR. HASSI: I'm close to wrapping up,
21 Your Honor.
22 BY MR. HASSI:
23 Q. Do you see that in paragraph 49 Endo concedes
24 that as part of the New York litigation, Endo would
25 have sued Impax for infringing the '122 and

'216 patents with respect to the Impax generic non-CRF oxymorphone ER tablets, as it had sued all of those other generics, but for the fact that unlike Endo's settlements of the New Jersey litigations with those generics, Endo's settlement with Impax included the above-described compromise pursuant to which Impax' license included rights to future patents?

Do you see that, sir?

A. Yes, I see that.

Q. And you agree that Endo conceded that the reason it did not sue Impax in the second wave of litigation in the Southern District of New York was because they had granted a license in the 2010 settlement and license agreement; correct, sir?

A. That's what Endo says here.

Q. Could you bring up paragraph 31.

Sir, do you see here that Endo alleged in this litigation -- and you're familiar with pleadings in federal court pursuant to rule 11; right, sir?

A. Yes.

Q. And do you see that Endo conceded that if Impax had prevailed in the New Jersey patent litigation, Impax would not have obtained the rights under any additional future patents that Endo might obtain, such that Endo would have been free to sue Impax for

infringing those patents and to seek an injunction barring Impax from selling its proposed generic tablets?

Do you see that?

A. That's correct.

Q. And you agree that had Impax continued the litigation, continued the litigation in New Jersey, the 2010 litigation, it never could have gotten as a remedy in that litigation the broad patent license it got in the settlement and license agreement; correct?

A. Correct. That's why I said they needed to get on early before those patents issued.

Q. And so it goes on to say, "From Impax' perspective, a favorable judgment in the pending New Jersey litigation might well have become a Pyrrhic victory if Endo were successful in obtaining additional patents in the future."

You agree with that; right, sir?

A. No.

Q. You don't agree that continuing to litigate in New Jersey could have become a Pyrrhic victory if Endo got additional patents?

A. Well, if we're assuming in this world that they had continued the litigation and they hadn't settled and they had launched early, they could have

gone on, they could have made, you know, tens or many hundreds of millions of dollars before they were forced off the market by the patents that issued in late 2012, so they had a two-year window to sell product, 180 days of which would have been -- they would have been the only -- only generic on the market, so I would not call that a Pyrrhic victory. I'd call that a substantial victory.

Q. That would require winning the litigation; right?

A. It would have required -- yes.

Q. And as to your estimate of hundreds of millions of dollars, you've never seen a single Impax document that suggested it could make hundreds of millions of dollars selling Opana ER as a generic, have you, sir?

A. Well, I was relying on what you -- you projected earlier about the -- about the Endo sales and what you were saying about the -- Impax' potential -- you know, potential ability to take over those sales. But I don't have any specific estimates on that.

There are sales forecasts referenced in my report. And there are -- it's substantial amounts of money, but they don't go out for a full two-year

period. It would depend on when they launched.

Q. You were relying on my estimate of the damages Impax could owe to Endo for what the profits Impax could have earned; is that what you're saying, sir?

A. Well, if you're saying it's, what, $138 million a year and you're saying they're taking most of that market or all of that market, and they're doing it for possibly as long as eight -- as two and a half years, that is hundreds of millions, plural, even if they didn't sell at quite at Impax -- at quite at Endo's level.

So maybe it -- maybe it would only be, you know, tens of millions. It would be a large number potentially, more than Pyrrhic, is all I'm trying to convey.

Q. Robert, could you go down one more paragraph in the complaint, please, paragraph 32.

Sir, you understand, based on this complaint, that section 4.1(d) was a compromise entered into between the parties pursuant to which Impax and Endo agreed that Impax would have a license to any patents issued from the pending patent applications and other patents Endo might acquire, but that once the scope of future patent rights became known with certainty, the parties would negotiate in good faith over the terms of

an amended license to such future patents that would fairly compensate Endo for granting Impax a benefit, a license to future patents, that Impax could not obtain via the then-pending litigation even if Impax prevailed in that litigation.

You agree with that, right, sir?

A. Yeah. I mean, the agreement says what it says. This is Endo's interpretation of it. I don't really disagree with this interpretation, but I mean, Impax also had interpretations.

Impax' interpretation was that the 4.1(d) did not apply at all to the -- to the -- to the Impax product. They were -- they were arguing that it would only apply to other products, notably the CRF product, so Impax did not agree with this interpretation.

So this is Endo's interpretation. Impax had another interpretation. As I said in my report, it was an ambiguous situation.

Q. The lawsuit between Impax and Endo, this contract dispute, was eventually settled; correct?

A. That's correct.

Q. And before the lawsuit was settled, it's your opinion that the settlement and license agreement was terminated; correct?

A. That was Endo's contention. That wasn't my

contention. I'm sorry.

Q. Sir --

JUDGE CHAPPELL: Wait a second.

You asked him if that's his opinion. Are you asking him if that's something he based his opinion on? Because that's a fact, what you just asked him.

MR. HASSI: Actually, I think it's not a fact, Your Honor, and that's why I think it's an opinion.

BY MR. HASSI:

Q. In your -- if I may, Your Honor -- in your report, you say, "Endo sued Impax for breach of the license agreement and patent infringement and later terminated the agreement."

You say that in paragraph 27 of your report, don't you, sir?

A. That's correct.

Q. Okay. And then your testimony I think I heard this morning was that the settlement unterminated the agreement; is that right?

A. Yes.

Q. And you would agree with me that in your 30 years of practicing law, you've never unterminated an agreement, have you, sir?

A. Yes. That's why I thought it was a little unusual.

I mean, they -- Endo said the reason -- the predicate for Endo suing Impax for patent infringement was that there was no -- that they had terminated the agreement. Otherwise, they couldn't have sued them for patent infringement. They could just have sued them for damages.

So the predicate of suing for patent infringement and potentially ultimately an injunction was that the agreement was terminated. And I think they say that -- I'm pretty sure they say that somewhere in this complaint, but I can --

Q. Sir, whether the agreement was terminated and, to coin a new phrase, unterminated or whether this litigation never effectively terminated the agreement, Impax never stopped selling oxymorphone ER; correct?

A. As far as I know, that's right, yes.

Q. And Endo never asked the court for an injunction to stop Impax from selling oxymorphone ER; correct?

A. They filed a lawsuit for patent infringement seeking, among other things, equitable relief. That certainly could have ultimately resulted in a permanent injunction against the sale of oxymorphone, so no, the -- a lawsuit for patent infringement threatens your right to continue selling something, in my

experience.

Q. Sir, in your 31 years of experience as a litigator, when you ask for an injunction, don't you actually ask for the injunction as opposed to unspecified equitable relief?

A. As -- as -- first of all, in -- in -- the patent provides a right to exclude, so if they're found to be liable for patent infringement, the normal relief for being found liable for patent infringement is an injunction, and so I certainly think that that was -- that was not in any way excluded.

I mean, they didn't seek preliminary injunctive relief because, as I said, Impax had been on the market for a long time. I think that would have been very difficult to get.

But I don't think there's anything in here that suggests that had they been -- had they found Impax liable for patent infringement, that an injunction would not have been the logical consequence of that finding.

Q. You agree that they never specifically asked the court for an injunction; right?

A. As far as I'm aware, they did not.

Q. And had they specifically asked for an injunction, they would have been unlikely to get one in

light of the fact that this is really just a case about money damages; right?

A. They would have been unlikely to get a preliminary injunction. Permanent injunction would be a different standard.

Q. Sir, in paragraph 14 of your report, you state, "Mr. Figg offers the opinion that Impax' license, 'covering both existing and patent applications,' 'was unique among the litigants,' because 'none of the other ANDA filers secured broad rights to later-acquired patents.'"

Do you see that?

A. I don't have my report in front of me, but I -- that's what I said, yes.

Q. Okay. And you agree with Mr. Figg that the license that Impax got was unique among the ANDA filers; right?

A. I don't -- I agree that the license was different -- that it was -- that each license was different. But I think that insofar as the other licenses provided only rights to -- only explicitly provided rights to the existing patents and the Impax -- and Mr. Figg is claiming that the Impax license provided rights to the future -- future issued patents, it was ambiguous, in light of

paragraph 4.1(d), whether those rights to the future patents were really effective.

So that was the -- that was the ambiguity, that was the problem, so they -- in -- if -- if Impax had -- if Endo had won this litigation that they -- that they filed, then the consequence would be, no, they did not have a right to the future patents. They did not have the license that they thought they had, which was a royalty-free license to all of the patents.

I'm sorry if that's a confusing answer, but that's what I've said I think multiple times.

Q. Sir, in your opinion, it would be normal to seek a license that would give your client freedom to operate?

A. Yes, it would.

Q. And you would agree that none of the other ANDA filers got a license that gave them freedom to operate; correct?

A. Well, they had licensed freedom to operate up until the new patents issued. They had a license under some patents. I don't know the details of all the other ANDA filers' licenses.

Q. Using that definition, Impax had freedom to operate until those other patents issued and Endo sued

in 2016; correct?

A. Well, until those other patents issued they had that, yes.

JUDGE CHAPPELL: Mr. Hassi, you must have a different definition of "wrapping up" than I do.

THE WITNESS: Than what?

MR. HASSI: Sorry about that, Your Honor.

Give me a minute, Your Honor. May I confer with counsel for a minute?

JUDGE CHAPPELL: Go ahead.

(Pause in the proceedings.)

MR. HASSI: I'll really try to wrap up now, Your Honor.

BY MR. HASSI:

Q. Sir, you don't offer any opinions about the effect of the settlement and license agreement in the long-acting opioid market; correct?

A. The effect of the settlement and license agreement on the market? No, I don't offer opinion.

Q. And as you sit here today, you're aware that Impax is selling oxymorphone ER; correct?

A. Yes. As far as I'm aware, yes. I don't actually know for a fact whether they are or not.

Q. And as you sit here today, you're aware that no other company besides Impax is selling

oxymorphone ER; correct?

A. I don't -- as far as I know, that's -- that's accurate. But again, I haven't -- I don't actually know. I don't have personal knowledge of that. It's not part of my report.

MR. HASSI: I have no further patience. Thank you for --

JUDGE CHAPPELL: Any redirect based on the cross?

MS. PEAY: I have some brief redirect.

JUDGE CHAPPELL: Go ahead.

I'm hanging on that word "brief" you used, Counselor.

MS. PEAY: Less than 20 minutes?

JUDGE CHAPPELL: All right.

- - - - -

REDIRECT EXAMINATION

BY MS. PEAY:

Q. Good afternoon again, Mr. Hoxie.

A. Good afternoon.

Q. Do you recall Mr. Hassi asking you just a little bit ago about whether Endo terminated the settlement and license agreement with Impax?

A. Yes.

Q. Okay. I'd like -- Ms. Allen, can you bring up

on the screen Exhibit CX 2944.

And Mr. Hoxie, I'm sorry I don't have a hard copy for you.

Mr. Hoxie, have you seen this document before, Exhibit CX 2944?

A. Yes, I have.

Q. Mr. Hoxie, did you cite to this in your report?

A. Yes, I did.

Q. Okay. Can you turn to page 2 of the exhibit, Ms. Allen.

Mr. Hoxie, what is this, this document, starting on page 2?

A. Yeah. This is a letter from Endo to Impax, terminating the settlement and license agreement. It's dated October 31, 2016.

Q. Thank you.

You can take that document down, Ms. Allen.

And Mr. Hoxie, do you recall Mr. Hassi showing you earlier this afternoon RX -- Exhibit RX 086?

A. I'll have to look at that document.

Which one was that, please?

Q. It is -- it is at tab 5 of respondent's binder. It's the Lex Machina --

A. The Lex Machina report? Yes, I see that.

Q. -- report. Or actually, hold on one second.
I think -- sorry. I think I have the wrong -- my apologies. It's at tab 4 --
A. Okay. Tab 4.
Q. -- of the binder. It is the presentation dated June 8, 2010.
A. I've got it.
Q. And was this a presentation that appears to have been made to Endo by FULD & Company?
A. It appears so, yes.
Q. And Mr. Hassi walked through a few pages of this presentation with you earlier this afternoon; correct?
A. Yes.
Q. Mr. Hoxie, can you please turn to page 11 of the document.
A. Okay.
Q. And Mr. Hoxie, do you know who Piper Jaffray is or what Piper Jaffray is?
A. I don't know a lot of details. They're a finance firm I believe.
Q. And if you read here, starting at the second paragraph, it says, "Though much of the Street is assuming that an at-risk launch is highly unlikely for a smaller generics player like Impax, we're not so sure

given the company's rapidly expanding cash position and therefore ability to take on liability risk."

Do you see that?

A. Yes, I do.

Q. Is this expressing a different view than the views that were expressed by the financial analysts' views that you reviewed with Mr. Hassi earlier this afternoon?

A. It expresses a different view, yes.

Q. You can put that -- take that document down.

And I believe that -- do you recall earlier this afternoon that you and Mr. Hassi came to terms on what an at-risk launch means?

A. Yes.

Q. And what was that definition?

A. I believe we've been using "at-risk launch" to refer to a launch after the 30-month exclusivity is up, the 30-month stay of approval is up, obviously, and before a Federal Circuit decision.

Q. Did you use the terms "before a nonappealable judgment" earlier when you spoke with Mr. Hassi?

A. I think that that's the specific, yeah, so it could be -- you might not have a Federal Circuit decision if you didn't appeal the judgment.

Q. And do you recall this afternoon Mr. Hassi

asking you about the Royal Bank of Capital (sic) report --

A. Yes.

Q. -- the Royal Bank of Canada Capital Markets report?

A. Yes.

Q. And he asked you some questions -- did he ask you some questions about the discussion of at-risk launches that are in that report?

A. Yes, he did.

Q. Do you know how the RBC defines "at-risk launches" for the purpose of that report?

A. I don't.

Q. Ms. Allen, can you put Exhibit RX 425 up on the screen.

And is this -- this is the exhibit you were discussing with Mr. Hassi earlier this afternoon?

A. Yes.

Q. Okay. Ms. Allen, can you please turn to page RX 425.0007.

And if you can zoom in on the top paragraph which is titled At-Risk Launches.

A. Yes, I see that paragraph.

Q. I'm sorry, Mr. Hoxie.

And I'll read to you the second sentence of the

paragraph: "We define an at-risk launch as any launch without a lower court ruling."

Do you see that?

A. Yes.

Q. Is that consistent with the definition of "at-risk launch" that you agreed upon with Mr. Hassi this afternoon?

A. No, that's not consistent.

Q. Ms. Allen, you can take that document down.

Mr. Hoxie, do you recall that Mr. Hassi asked you a number of questions about quantifying the risks of launching at risk?

A. Yes, he did.

Q. Based on your review of his report, did Mr. Figg quantify the risks of launching at risk?

A. No. Not in numerical terms, no.

Q. Are your opinions that you are offering regarding launching at risk in response to Mr. Figg's opinions?

A. Yes, they are.

Q. In your review of the materials in this case, did you see any Impax documents that quantified the risks of launching at risk?

A. I didn't -- I saw Impax documents referring to risk analysis, but I think the actual documents and

portions of the documents that I saw that actually contained the specific analysis were redacted or withheld.

So I don't -- I don't have -- I didn't see any documents that specifically quantified the risk in numerical terms.

Q. Mr. Hoxie, do you know if the numbers Mr. Hassi asked you to assume regarding the potential quantifiable risks of launching at risk are in any way reflected in Impax' own analysis of an at-risk launch?

A. I have -- I have -- I don't know if Impax specifically quantified the risk. Impax did forecasts, and so they had numerical -- they had a numerical analysis of forecasts under different, you know -- but I don't -- I don't recall anybody saying that they had a -- you know, a 58 percent chance of winning and a 42 percent chance of losing. I don't recall anything like that.

Q. Did you offer an opinion in your report quantifying the risk to Impax from an at-risk launch?

A. I did not.

Q. Did you offer an opinion -- the opinion in your report that Impax would have launched at risk?

A. No, I didn't offer that opinion.

Q. Did you offer the opinion that Impax should

have launched at risk?

A. No.

Q. Mr. Hoxie, in your report, did you provide any opinions regarding the ultimate pricing of Impax' generic Opana ER product?

A. No. I don't -- I didn't give an opinion on that -- how -- I did not give an opinion on how it would be priced. I think there is some information in the materials that I cited to both from Impax and Endo with projections, but I didn't -- I didn't offer any opinion on that.

Q. And do you recall at I believe near the beginning of Mr. Hassi's cross that you -- that he asked you some questions regarding your experience with Hatch-Waxman litigation?

A. Yes.

Q. Okay. And he asked you -- do you recall that he asked you a number of questions about your experience as counsel of record?

A. Yes.

Q. So can you explain, what roles have you had with respect to Hatch-Waxman litigation?

A. Well, I've -- I've -- as I -- as I said yesterday, I've -- I've been responsible for managing Hatch-Waxman litigation, and I was actually head of

intellectual property litigation for Novartis, brand and generic, worldwide, which included a lot of Hatch-Waxman litigation.

And in that capacity, I would -- I would -- I would look at freedom to operate for identified patent risks, identify -- I would deal with, when we received Paragraph IV certifications, responding to those certifications, lining up outside counsel, working with outside counsel to develop strategies, reviewing motion -- pleadings and motions and legal memoranda that were filed in the cases, helping to prep witnesses, attending the trials, sometimes as a corporate representative, and negotiating settlements or trying to negotiate settlements with my counterparts on the other side.

And then since -- since that time, I've been extensively involved in advising pharmaceutical companies on the branded side regarding Hatch-Waxman litigation and provided opinions to them, provided second opinions to counsel opinions, work -- you know, worked -- and worked with them to develop strategies and, you know, to support litigation where it was necessary.

So I have had some considerable experience in dealing with Hatch-Waxman litigation and in making

decisions and advising senior management both in Novartis when I was working there and in other companies, clients, since I've left Novartis regarding risks and regarding approaches to settlement and to litigation in the Hatch-Waxman context.

Q. And what has been your role in negotiating Hatch-Waxman settlements?

A. When I was at Novartis, I would typically be the lead negotiator for Hatch-Waxman settlements because it's primarily a patent issue, and so as the person in charge of patents, I would be in charge of that negotiation from Novartis' perspective.

And then there would typically be a business development and licensing person and possibly a general attorney involved, so it would be a team of, you know, two or three or four people.

Q. Mr. Hoxie, have you had experience related to claim construction briefing?

A. Yes, I have.

Q. What is that experience?

A. I've -- I've been involved in numerous cases where there were claim construction briefs. I've assisted in writing those briefs.

I've made determinations as to strategically how the claims ought to be -- how the claims ought to

be interpreted or what would be of maximum benefit strategically for us, for my client, in having claims interpreted in a particular way.

And I've advised management regarding the impact of claim construction briefings on the trial and on their likelihood of success at trial.

MS. PEAY: Thank you, Mr. Hoxie. I have no further questions at this time.

JUDGE CHAPPELL: Anything further?

MR. HASSI: A couple of brief questions, Your Honor.

- - - - -

RECROSS-EXAMINATION

BY MR. HASSI:

Q. Sir, counsel showed you a piece of paper purporting to terminate a license agreement.

Did you see that?

A. Yes, I did.

Q. Okay. Now, you've -- I think you testified earlier today you've worked on hundreds of license agreements; is that right?

A. Well, a large number. A large number, yes. Probably hundreds if you count every kind of license, yes.

Q. Ever get a letter purporting to terminate any

of those -- one of those licenses?

A. Yes. It's not common, but I've certainly been in situations where licenses were terminated.

Q. Ever get a letter purporting to terminate a license and you disagreed with the purported termination?

A. I've been I think on the sending end of those letters. I'm trying to recall a situation where I was on the receiving end. But I -- people often, when they're in that circumstance, do disagree.

Q. And it would be up to a court to decide who was right and who was wrong as between Impax and Endo as to whether the license was actually terminated?

A. That would depend on the circumstances. That would depend on the circumstances of the case.

In this case, I think Endo said it was terminated, they declared it was terminated, on the basis of breach. But whether there was a breach I think would have had to have been determined by the court.

Q. And you didn't do an analysis of, for example, the termination provision in the settlement and license agreement as opposed to -- and the claims that Endo was making related to that; right?

A. Not in depth. I understand the agreement was

terminable in the event of breach, but I don't remember the details.

Q. And you're not offering an opinion as to whether the agreement was breached; right?

A. No, I'm not.

Q. And with respect to Endo's complaint, I think you said this morning, anyone with $400 can file a complaint; right, sir?

A. That's correct.

MR. HASSI: Thank you, sir. I have nothing further.

JUDGE CHAPPELL: Anything further?

MS. PEAY: If I may have one moment to confer with counsel?

JUDGE CHAPPELL: Go ahead.

MS. PEAY: Thank you, Your Honor.

(Pause in the proceedings.)

Nothing further, Your Honor. Thank you.

JUDGE CHAPPELL: Thank you. You may stand down.

MR. HASSI: Your Honor?

JUDGE CHAPPELL: Yes.

MR. HASSI: I did want to advise you -- and for that matter, I haven't had a chance to tell complaint counsel this -- I received an e-mail late last night

from Mr. Hsu. It looks like he may not be able to be here on Tuesday.

He said he would -- he's got a family emergency. He said he was going to try to give me an update tomorrow. I will let the court know as soon as I know.

But given that he's in Taiwan and the family emergency is in Taiwan, I think it's unlikely that he's here on Tuesday. I wanted to alert the court to that.

JUDGE CHAPPELL: You were scheduling him and one other witness?

MR. HASSI: Him and one other witness. The other witness will still be here on Tuesday. I just -- I doubt, based on the information I received from Mr. Hsu last night, that he'll make it on --

JUDGE CHAPPELL: Well, perhaps we should wait until both witnesses are available so we can have at least most of a day.

MR. HASSI: Certainly that --

JUDGE CHAPPELL: Let's see what develops.

We will say that Tuesday is tentative right now, because I see no need to gather for a short -- one short witness. I think you represented it's not going to take long.

MR. HASSI: He's relatively short. I would say he's similar to Mr. Cobuzzi. He was Mr. Cobuzzi's counterpart on the development and co-promotion agreement. He's the Impax employee, the head of brand division, so I say short, between one to three hours between direct and cross I would think.

JUDGE CHAPPELL: When do you expect to know more from Mr. Hsu?

MR. HASSI: His e-mail last night indicated that he would let me know Friday morning Pacific Time, so I hope to know something tomorrow.

JUDGE CHAPPELL: Anything?

MR. LOUGHLIN: Your Honor, we're happy to go on Tuesday or we're happy to wait. It's up to you, it's up to the court.

JUDGE CHAPPELL: If I'm correct, we have two witnesses remaining.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: Two witnesses that would be one day.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: Together.

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: Let's see what you can find out by Monday. Send everyone an e-mail, OALJ but,

you know, the usual, the usual suspects.

And if it appears that Mr. Hsu can be here later in the week -- let's see. Next week is not Thanksgiving.

MR. HASSI: No, it's not, Your Honor.

JUDGE CHAPPELL: If, for example, he can be here Wednesday or Thursday but not Tuesday, then we should move our one day next week, unless someone has some irreconcilable conflicts.

MR. LOUGHLIN: We don't have any irreconcilable conflicts --

JUDGE CHAPPELL: So let's all try to keep next week open. Let's see what develops.

My staff will e-mail everybody by close of business Monday on whether we have to be here Tuesday morning or not. Okay?

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: Anything further?

MR. HASSI: No, Your Honor.

JUDGE CHAPPELL: Until we meet again, we're in recess.

(Whereupon, the foregoing hearing was adjourned at 5:02 p.m.)

CERTIFICATE OF REPORTER

I, JOSETT F. WHALEN, do hereby certify that the foregoing proceedings were taken by me in stenotype and thereafter reduced to typewriting under my supervision; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

s/Josett F. Whalen
JOSETT F. WHALEN
Court Reporter