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 7, 2017

9:49 a.m.

TRIAL VOLUME 9

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

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FEDERAL TRADE COMMISSION

I N D E X

IN THE MATTER OF IMPAX LABORATORIES, INC.

TRIAL VOLUME 9

PART 1, PUBLIC RECORD

NOVEMBER 7, 2017

EXHIBITS	FOR ID	IN EVID	IN CAMERA	STRICKEN/REJECTED
CX				
(none)				
RX				
Number545		2140		
JX				
(none)				

P R O C E E D I N G S

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JUDGE CHAPPELL: Okay. We're back on the record.

Just so I'm clear, do we anticipate to have testimony through Thursday? Or it depends on how this week goes?

MR. HASSI: I think we do subject to -- so schedule-wise, when Mr. Figg is done, Dr. Michna is here and ready to go, and Dr. Addanki will follow him. And then we have Mr. Cobuzzi, who is available on Wednesday.

I mean, if we were to finish with Michna and Addanki today, Cobuzzi is not available until tomorrow, and if Mr. Hoxie is available after that, I think it will go straight through. How long it takes I think depends on how long Mr. Hoxie has, how long the crosses are.

JUDGE CHAPPELL: But your rebuttal expert is available?

MR. LOUGHLIN: He is available, Your Honor.

JUDGE CHAPPELL: I'm just trying to figure this out.

After this witness is finished, you have one more or two more this week?

MR. HASSI: Two more experts and one fact, Your Honor.

JUDGE CHAPPELL: This week?

MR. HASSI: Yes, sir.

JUDGE CHAPPELL: All right.

Okay. Go ahead. Redirect.

- - - - -

Whereupon --

EDWARD ANTHONY FIGG

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

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REDIRECT EXAMINATION

BY MR. HENDRICKS:

Q. Good morning, Mr. Figg.

A. Good morning.

Q. Do you remember yesterday that Mr. Weingarten showed you two cases in which the Federal Circuit Court of Appeals reversed a claim construction ruling but declined to remand the case?

A. Yes, I remember those cases.

Q. And do you remember testifying that you strongly suspect that a record had been developed at the trial court in which the federal court could decide

those issues?

A. Yes.

Q. I'd like to direct you to CX D-03, which is in the white binder. This is a case captioned Merck & Company v. Teva Pharmaceuticals.

A. 03?

Q. Yes, sir.

A. Yes, I have it.

Q. Do you remember Mr. Weingarten asking you questions about this case yesterday?

A. He asked me some questions. Yes.

Q. Can you turn to page 12 of the opinion.

A. The Bates number 12 or the --

Q. I think they're identical.

A. Okay. Yeah, they are.

Yes. Okay.

Q. Was there a dissent to this opinion?

A. Was there a what?

Q. A dissent. A dissenting opinion filed?

A. Oh. Yes. Judge Rader dissented from the claim construction ruling.

Q. And if you turn to page 14?

A. Yes.

Q. At the very bottom of the second column, did Judge Rader write, "Accordingly, the district court did

not err in construing the disputed claim terms" and then describe those terms?

A. I see that. Yes.

Q. Can you then turn to page 10 of the opinion -- or I'm sorry -- page 9, and it's footnote 10 of the majority opinion.

A. Yes.

Q. Did the majority note, in footnote 10, "It makes no difference to this conclusion whether the court begins with the claim construction set forth by the panel or the dissent"?

A. I see that.

Q. What was the claim construction set forth by the dissent?

A. This case dealt with a patent to a class of drugs called bisphosphonates for treating osteoporosis. And the claims specified -- there were two claims, one directed to a method of treating osteoporosis and another to a method of preventing it. For the treatment method the dose was about 75 milligrams and for preventing it -- or excuse me -- it was about 70 and for preventing it it was about 35.

So the dispute centered around the meaning of the word "about," and the district court had construed that to mean exactly 70 and exactly 35. The court of

appeals disagreed and reversed that claim construction and said that "about" means approximately.

There was prior art that disclosed the same weekly dosing but using doses of 80 and 40 I believe. They were close to the doses.

And there was evidence in the record that the inventors had conceded that those differences would have made no difference in the effectiveness, so the court concluded that it didn't even need to rely on the claim construction, as you pointed out in claim 10, but the court also noted that on the record, and particularly the inventors' concession, they could rule that the invention was obvious as a matter of law.

So they had a record on which to base their decision.

Q. And that comports with your testimony yesterday that you strongly suspect that a record had been developed at the trial court?

A. Yeah. My suspicion was borne out.

Q. I'd like to direct you next -- well, before I move on, was there anything else in this case that you would like to discuss that distinguishes this case?

A. Well, the distinguishing feature from -- I mean, we're distinguishing it from what would the

appeal record have looked like had the Impax-Endo case been decided by the trial court and then appealed to the Federal Circuit.

And the point I was trying to make yesterday is that even under the Impax claim construction, there was a dispute between the parties' experts as to whether the material in the Impax product had hydrophobic properties or not. That was a factual dispute. Even if that had made its way into the record, in my opinion, the Federal Circuit would not have resolved that factual dispute on appeal.

I also don't think it would have made it into the record because there would have been no reason for Impax to have of put those arguments into the record based on a claim construction that the court had already rejected.

And in this case, there was a record on which the court could decide the issue.

Q. Thank you for that explanation.

Will you please next turn to CX D-004.

A. Yes.

Q. The next tab in the white binder.

A. Yes, I have it.

Q. And this case is captioned Saffran v. Johnson & Johnson?

A. Yes.
Q. Do you remember Mr. Weingarten asking you questions about this case during his cross-examination?
A. I do.
Q. Can you turn to page 11 of this case, please.
A. I'm there.
Q. Under the heading Infringement?
A. Right.
Q. Is this where the court is applying facts to its new claim construction?
A. It -- it is -- I would state it the other way around. The court is applying its claim construction to the facts that were in the record.
Q. Thank you for that clarification.
And if you turn -- or if you look under the heading Device?
A. Yes.
Q. About halfway down, did the court write, in applying its claim or -- or applying the facts to its claim construction that "But that layer is akin to paint on a chain link fence, not a continuous sheet wrapped around the mesh, and open holes remain between the struts of the accused devices —- as Saffran has acknowledged"?

A. Yes, I see that language.

Q. Does Saffran's acknowledgment of this fact mean there was a fact -- there was no factual dispute in relation to this fact?

A. Yes. There almost could not have been a factual dispute here.

The device that was at issue in this case was a stent that is put into a blood vessel to -- to treat a lesion like a plaque in a blood vessel.

The patent here had to do with a -- the discovery of a membrane that had certain permeation characteristics that could be used to surround a stent and prevent molecules that are involved in the repair of the lesion escaping back into the blood, so this sheet or this sheath would act as a barrier to that.

The accused device, the stent, the Cordis -- the Johnson & Johnson stent, was actually more like a tube made of a wire mesh. It had openings or holes in it and sort of like a -- if you would think of a miniature piece of chicken wire wrapped into a tube.

Johnson & Johnson coated their stent with a -- those wires in the stent with a coating that served to deliver a therapeutic agent but did not require -- did not involve at all a sheet or a sheath.

The district court construed the claim as

encompassing the coating on the Johnson & Johnson stent, the wires of the stent. The Federal Circuit disagreed with that and said, based on everything we see in the record, the claim -- the word "device" in the claim requires a continuous sheet, not coatings on these wires and, as they characterized it here, not like paint on a chain link fence.

So once the Federal Circuit construed the claim as they did, there really could not be any dispute that the Johnson & Johnson device did not have a continuous sheath or sheet.

Q. And the Federal Circuit noted that Saffran acknowledged that very fact?

A. Yes. And they -- the Federal Circuit pointed out that Saffran acknowledged that. They hardly could avoid acknowledging it. The structure of the device was front and center in the record that was created in the district court.

Q. Let's move to the header for the construction of "release means."

A. Yes. I'm sorry -- yeah. I see it. On page 9.

Q. You're there?

A. Uh-huh.

Q. It's on page 11. It's right below the device language we were discussing.

A. Oh, okay.

Q. Here, did the court write, "In addition, our construction of the 'release means' limitation provides a separate and independent basis for a judgment of noninfringement"?

A. Yes.

Q. And if you turn the page, but in the same paragraph, did the circuit court write, "Saffran has not argued otherwise. Moreover, Saffran stipulated before trial that he would not pursue any infringement arguments representing that so-called 'hydrophobic' interactions are equivalent to hydrolyzable bonds, and he is therefore precluded from doing so now"?

A. Yes, the court did say that.

Q. Does the fact that Saffran stipulated that it would not make any infringement arguments under this claim construction comport with your testimony yesterday that you strongly suspected there was a record that had been developed at the trial court that allowed the Federal Circuit to decide the issue?

A. It's entirely consistent with my suspicion.

Q. Is there anything else about this case that you'd like to tell the court?

A. I can explain that last point a little -- in a little more detail if you would like.

The -- the patented device, the sheet, had therapeutic agents attached to it through bonds that could be hydrolyzed or broken by the action of water. And that would serve to release these therapeutic agents gradually to the area of the body that needed them.

The district court construed that term very broadly such that it would encompass things other than agents that were attached by hydrolyzable bonds. The Federal Circuit disagreed with that and said everything in the record indicates that that term means that the bonds have to be hydrolyzable by water.

There was no dispute, as you see in the language you read. There was no dispute that the Johnson & Johnson system did not involve hydrolyzable bonds. Instead, in that system, the therapeutic agent was embedded in the coating, and it was slowly released by diffusion rather than by hydrolysis of those bonds.

So there was a clear record. Once the Federal Circuit reached its claim construction, there was really no dispute between the parties as to the applicability of that claim construction to the facts of the case.

Q. Mr. Figg, does anything in the two cases we

just discussed change your opinion about the likelihood of a remand in the Impax-Endo Hatch-Waxman litigation?

A. They do not. I think that the trial court records on which the Federal Circuit based its decision in these cases just simply would not have existed, and there would have been a factual dispute among the parties that the Federal Circuit would not have resolved on appeal.

Q. In light of these cases that we just discussed, what is your opinion about the likelihood of a remand at the Federal Circuit court level in the Impax-Endo Hatch-Waxman litigation?

A. Yeah. As I testified yesterday, I think it was highly likely, almost a certainty, that if there was a reversal of the court's claim construction and an adoption of the Impax claim construction, the -- the Federal Circuit would have remanded for further trial on the issues of infringement and validity.

Q. I'd like to shift gears.

Yesterday, Mr. Weingarten asked you a number of questions -- let me rephrase that.

Do you remember if Mr. Weingarten asked you questions regarding a litigation between Impax and Endo in which Endo asserted breach of contract and patent

infringement claims against Impax?

A. I remember some questions about that, yes.

Q. Did Mr. Weingarten ask you whether you had seen the complaint in that case?

A. I don't recall being asked about the complaints.

Q. I would like to offer Complaint Counsel Exhibit 3437, and this is the amended complaint to that lawsuit.

Your Honor, may I approach the witness and give him this, this document?

JUDGE CHAPPELL: You said you want to offer it?

MR. HENDRICKS: I want to present it to the witness.

JUDGE CHAPPELL: Oh. Go ahead.

MR. HENDRICKS: Just for the record, it's in evidence. It's on JX 02.

JUDGE CHAPPELL: All right.

MR. WEINGARTEN: Your Honor, before Mr. Hendricks gets started, may I have a continuing objection that this complaint and therefore none of the testimony about the complaint relates to any opinions expressed in the report.

JUDGE CHAPPELL: Is that the document you asked the witness about on cross?

MR. WEINGARTEN: I think I asked if he had ever seen it before his report, the answer to which was no.

MR. HENDRICKS: Your Honor, Mr. Weingarten asked yes- -- he asked two questions related to this document yesterday I believe.

JUDGE CHAPPELL: All right. Your objection is noted.

MR. WEINGARTEN: Thank you, Your Honor.

JUDGE CHAPPELL: Go ahead.

BY MR. HENDRICKS:

Q. Can you identify this document, Mr. Figg?

A. Yes. This appears to be the original complaint in the contract dispute between Endo and Impax filed in August of 2016.

Q. Can you look at the document number at the top of the page where -- can you tell me what document number this was on the court's docket?

A. It says "Document 13."

Q. Would that indicate that it was the amended complaint?

A. Oh. It probably was if there had been twelve earlier documents filed.

Q. So do you recognize this to be the amended complaint?

A. Let me just take a quick look at it.

MR. WEINGARTEN: Your Honor, I rise to object on the grounds of foundation. I think Mr. Figg just testified he's never seen it before and has no basis to know whether it's the amended complaint or not.

JUDGE CHAPPELL: Based on the objection, you need to lay a foundation.

MR. HENDRICKS: I will, Your Honor.

THE WITNESS: Yes. I believe this to be the --

JUDGE CHAPPELL: There's nothing pending.

THE WITNESS: I'm sorry, Your Honor.

JUDGE CHAPPELL: No question is pending.

THE WITNESS: I'm sorry, Your Honor?

JUDGE CHAPPELL: No question is pending.

THE WITNESS: Oh, I thought there was. Sorry.

BY MR. HENDRICKS:

Q. After receiving Mr. Hoxie's rebuttal report, did you review this document?

A. I did.

Q. Can you identify this document?

A. Yes. I can tell from the -- some of the content of it that it was the amended complaint.

Q. And do the claims brought by Endo in this complaint affect the opinions that you offered in your

report about the scope of the patent license in the settlement and license agreement?

A. No, they do not.

MR. WEINGARTEN: Your Honor, I object. I asked him had he ever seen it before. He said he had not. And now they're attempting to introduce new opinions not expressed in the report.

JUDGE CHAPPELL: Well, to the extent you asked him about it, depending on what the record shows, to the extent you asked him about it on cross and whether it had anything to do with his opinion, in fairness, he gets to say on redirect whether it affected his opinion or not and why. If that's in the record, it's allowed; if not, it won't be considered.

MR. WEINGARTEN: Thank you, Your Honor.

JUDGE CHAPPELL: I don't consider it a new opinion for a witness to explain something he may have said on cross based on your questions.

MR. WEINGARTEN: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. Mr. Figg, if you turn to page 25 of this document, under the heading Prayer for Relief --

A. So we're looking at --

Q. I apologize.

A. Yes, I'm on 25, Prayer for Relief. Thank you.

Q. It's a lengthy document because there are some attached exhibits to the complaint, but we won't be looking at those.

Is this where a plaintiff, in your opinion, would typically list the remedies that they're seeking in a complaint?

A. Yes. I -- that's what I understand "prayer for relief" to mean.

Q. What remedies did Endo seek from Impax in this lawsuit?

A. They asked -- there were several here.

They asked for a declaratory judgment that Impax had materially breached the agreement.

They asked for a declaratory judgment that Impax had breached the implied covenant of good faith and fair dealing.

They asked for a declaratory judgment that Impax had infringed the so-called new patents.

They asked for damages arising out of the alleged breach.

They asked for compensatory damages and such other relief as is appropriate for Impax' infringement of the new patents.

They asked for a declaration that the case was exceptional under section 285 of the patent statute.

They asked for an order that Impax' infringement of the '122 and '216 patents was willful and asked for an award of treble damages or enhanced damages.

They asked for an award of attorney fees.

They asked that they be awarded costs and expenses and such other and further legal and equitable relief as the court may deem just and proper.

Q. Did Endo ask for an injunction of Impax' marketing of oxymorphone ER?

A. They did not.

Q. Does Complaint Counsel Exhibit 3437, the amended complaint, contain any admissions made by Endo regarding the scope of the license in the settlement and license agreement?

MR. WEINGARTEN: Your Honor, I object. This is far outside the scope of what I brought up on cross-examination.

If they intended to try to do this on direct, that would be one thing, but they're now attempting a brand-new direct exam on the contents of this complaint when I asked, as Mr. Hendricks said, two questions.

MR. HENDRICKS: And those two questions,

Your Honor, opened the door -- the two questions were specifically aimed at this very document, and they opened the door to questions on redirect about this very document.

And I will limit my questioning to questions about the document to which Mr. Weingarten referred the witness during his cross-examination.

MR. WEINGARTEN: Your Honor, the transcript does not reflect that I referred to document CX 3437. It's not even in the binder that we provided to the witness.

MR. HENDRICKS: Because we have the rough transcript from yesterday, on page 236 -- and this is the rough, the unofficial transcript -- Mr. Weingarten asked: Sir, did you not address or discuss any subsequent -- I -- yes -- any subsequent litigation between Endo and Impax regarding the license in their June 2010 settlement; correct?

Mr. Weingarten continued to ask: In fact, you first saw the complaint -- and this is the document we're discussing today -- that Endo filed against Impax after you served your expert report; correct?

Mr. Weingarten also asked: And you didn't do any review of the pleadings -- this is a pleading in that case -- that had to do with the subsequent

litigation until you saw Mr. Hoxie's rebuttal; correct?

MR. WEINGARTEN: Your Honor, if I may, my question was: You didn't look at this until after you had submitted your report.

If he wanted to ask he did or contradict that, that's one thing, but he can't use that as a venue to then get into a whole new direct exam about the substance of this document.

JUDGE CHAPPELL: The document is in evidence. I can read it myself. Unless you lay a better foundation, the objection is sustained.

MR. WEINGARTEN: Thank you, Your Honor.

JUDGE CHAPPELL: And I mean a foundation connecting it to the cross.

BY MR. HENDRICKS:

Q. Mr. Figg, during the cross-examination yesterday, did Mr. Weingarten ask whether you're aware of the fact that there was a later lawsuit?

A. Yes. I recall that he did ask that.

Q. Do you remember answering "yes, I am aware there was subsequent litigation"?

A. I believe that's what I said. Yes.

Q. And even before you filed your expert report in September, were you aware of this subsequent

litigation?

A. I had been informed just in a very passing way that there was subsequent contract litigation between Endo and Impax.

Q. And in his rebuttal report, did Mr. Hoxie discuss that contract litigation?

A. Yes. He discussed it quite extensively.

Q. And is this the complaint -- or sorry. Strike that.

Did Mr. Weingarten yesterday ask you about your review of the complaint and pleadings in that subsequent litigation yesterday?

A. Yes.

I think that the gist of Mr. Weingarten's questions was he was challenging the opinion that I had offered in my report that Impax was able to negotiate a license that ensured that Impax would not be sued for infringement of patents that would issue to Endo later. And he -- he referred to the subsequent litigation as in a way contradicting or impeaching that opinion that I had provided.

Q. And in your response to Mr. Weingarten's questions, would you like to clarify your position about the complaint and the pleadings that he asked you about?

MR. WEINGARTEN: Your Honor, I object. I don't understand. There's been no foundation laid. He just asked him -- general questions of the witness now about what I may or may not have asked on cross.

JUDGE CHAPPELL: The pending question will be allowed. Overruled.

THE WITNESS: Can you repeat the question, please.

JUDGE CHAPPELL: Let her read it. I don't want to hear another objection.

(The record was read as follows:)

"QUESTION: And in your response to Mr. Weingarten's questions, would you like to clarify your position about the complaint and the pleadings that he asked you about?"

THE WITNESS: Well, as I had explained to Mr. Weingarten, that particular sentence in my report was perhaps poorly worded because it's impossible for someone to ensure that they won't be sued subsequently. It's very easy for someone to file a lawsuit. But it didn't change my 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.

And so after seeing Mr. Hoxie's report, I -- I was curious, you know, was I wrong about that, and so I did go back and look at these pleadings, this complaint, and other documents that were referred to by Mr. Hoxie and they're relevant to this issue.

And as I read the complaint, as I read it, I noted, for example, in paragraph 26 of this complaint, Endo acknowledged that the settlement and license agreement had granted to Impax a license and -- and then later in this complaint they also acknowledged that there was a license to subsequent patents.

The -- as you had elicited from me a few minutes ago, notably, while this complaint has a claim for patent infringement based on Endo's argument that Impax had breached the agreement by not engaging in good-faith negotiations, they never disputed that there was a license and they never asked for an injunction to take Impax' product off the market.

The way I viewed all of this and the way it played out was, this was simply an effort by Endo to get additional money in the form of royalty payments from Impax. And the fact that, as we noted yesterday, that when Endo brought suits on the later patents against a number of other generic companies based on the original Opana ER generic product, they did not sue

Impax, and the only rational reason that they would not have sued Impax was they recognized that Impax was licensed under those patents, and I think that is acknowledged in these pleadings as well.

JUDGE CHAPPELL: I want to follow up on my rulings I've made in this regard now that I've heard this information and pondered it.

I find it unacceptably unfair that an expert cannot tell us about his position when his opinion has been attacked by a rebuttal expert. This response will be considered.

Go ahead.

MR. HENDRICKS: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. Mr. Figg, I'd like you to turn to paragraph 32 of the amended complaint.

A. Okay. I'm there.

Q. You mentioned in your testimony that Endo made admissions that the settlement and license agreement indeed licensed Impax for future patents.

Is there language in paragraph 32 that -- or is the language in paragraph 32 what you were referring to when you made that testimony?

A. Yes.

MR. WEINGARTEN: I'm sorry, Your Honor. I'm

going to object on the grounds that after giving a very long, narrative response, Mr. Hendricks is now attempting to lead the witness to particular parts of the complaint which, again, are outside the scope of what I asked about on cross.

JUDGE CHAPPELL: It's leading. That's sustained.

MR. WEINGARTEN: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. In paragraph 32 of the amended complaint, did Impax admit that "the parties entered into a compromise pursuant to which Impax and Endo agreed that Impax would have a license to any patents issuing from the pending patent applications and other patents Endo might acquire"?

MR. WEINGARTEN: I apologize, Your Honor. It's still leading if he just says "did he" and reads a quote to him from the complaint.

JUDGE CHAPPELL: Sustained.

BY MR. HENDRICKS:

Q. Mr. Figg, in your expert opinion as a patent -- as an attorney with 40 years of experience, can you provide -- can you tell us what your opinion is -- let me -- let me start that question over. I apologize.

In your experience -- using your experience as

an attorney with 40 years of experience, can you please tell us what paragraph 32 says.

A. Yes. This is the paragraph to which I was referring in my answer a few moments ago.

And in this paragraph Endo acknowledges that the settlement and license agreement provided Impax with a license to any patents issuing on pending applications, meaning -- and I'm paraphrasing here -- meaning patent applications that were pending at the time of the settlement and license agreement, and other patents that Endo might acquire, so that would include patents like the Johnson Matthey patent and the Mallinckrodt patent that we talked about yesterday that Endo later acquired. And they are acknowledging here that the settlement and license agreement provided Impax with rights under those patents.

MR. HENDRICKS: Your Honor, may I confer with counsel briefly? I think I can wrap up quickly.

JUDGE CHAPPELL: Go ahead.

(Pause in the proceedings.)

MR. HENDRICKS: That's all I have, Your Honor.

JUDGE CHAPPELL: Recross?

MR. WEINGARTEN: No, Your Honor, nothing further. Thank you.

JUDGE CHAPPELL: Thank you. You may stand

down.

THE WITNESS: Thank you, Your Honor.

JUDGE CHAPPELL: Call your next witness.

MR. HASSI: Your Honor, respondents call Dr. Michna.

We'll send someone to get him.

MR. LOUGHLIN: Your Honor, could I just note for the record that my colleague Maren Schmidt will handle the witness for complaint counsel.

JUDGE CHAPPELL: Thank you.

MS. SCHMIDT: Good morning, Your Honor.

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Whereupon --

EDWARD MICHNA

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

MR. ANTALICS: Good morning, Your Honor.

JUDGE CHAPPELL: Good morning.

I just want to say something to the attorneys.

What just happened with this previous expert was semantics. An expert whose opinion has been attacked by rebuttal can give me a response to that attack or that contrary opinion.

Where we got in trouble there was the examining attorney used common language and said do

you have an opinion about that, which invokes an objection for a new opinion.

It's not a new opinion that that expert is giving. It's a response to someone else's opinion about his original opinion. Using the word "opinion" is not some magic word that's going to mean that a response is not admissible.

Any questions?

MR. LOUGHLIN: No, Your Honor.

MR. HASSI: No, Your Honor. Thank you.

JUDGE CHAPPELL: Go ahead.

MR. ANTALICS: Thank you, Your Honor.

JUDGE CHAPPELL: I bring that up because we're going to have more experts and I don't have to plow that ground again.

Go ahead.

MR. ANTALICS: May we approach the witness, Your Honor?

JUDGE CHAPPELL: Yes.

Go ahead.

MR. ANTALICS: Thank you, Your Honor.

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DIRECT EXAMINATION

BY MR. ANTALICS:

Q. Dr. Michna, could you please state your full

name for the record.

A. Edward Michna.

Q. And Dr. Michna, without getting into all the details of your testimony, could you tell us generally what you're hear to talk about today.

A. I'm here to talk about the clinical use of extended-release opioids and the various options.

Q. I'd like to talk a little bit about your background.

Are you presently employed?

A. I am.

Q. And by whom?

A. Brigham & Women's Hospital in Boston, Massachusetts.

Q. And what is your position at Brigham & Women's?

A. I'm a staff anesthesiologist practicing pain management.

Q. We'll talk a little bit more about that in a minute.

Do you have an undergraduate degree?

A. I -- well, I started off as -- as a pharmacist, and then after pharmacy school at Rutgers I went to law school and obtained a J.D., and then I went to medical school and got an M.D.

Q. Okay. How long did you practice as a

pharmacist?

A. I practiced between the time I graduated and the third year of medical school, so approximately seven or eight years.

JUDGE CHAPPELL: So let me get this right.

You have a pharmacy certificate or degree.

THE WITNESS: I'm a -- I have a bachelor's in pharmacy and I'm a registered pharmacist.

JUDGE CHAPPELL: And you have a J.D.

THE WITNESS: I have a J.D.

JUDGE CHAPPELL: And an M.D.

THE WITNESS: And an M.D.

JUDGE CHAPPELL: What's next?

THE WITNESS: That's what my mother asks.

BY MR. ANTALICS:

Q. Okay. Doctor, after medical school --

JUDGE CHAPPELL: You must enjoy the university.

THE WITNESS: I like learning. Yes.

BY MR. ANTALICS:

Q. Doctor, after medical school, what did you do?

A. After medical school, I did an internal medicine internship at Monmouth Medical Center in New Jersey --

Q. Okay.

A. -- followed by a residency in anesthesia at Brigham & Women's Hospital, followed by a pain management fellowship at also Brigham & Women's Hospital in Boston.

Q. Okay. Do you have a specialty?

A. My primary specialty is anesthesia. My subspecialty is pain management and also in palliative care medicine.

Q. Could you describe what palliative care medicine refers to.

A. It's basically caring in terms of pain and symptoms for patients that are dying or suffering an end-of-life disease.

Q. Okay. After your fellowship at Brigham & Women's, what did you do next?

A. I was hired to be on staff at Brigham & Women's Hospital. I practiced anesthesia as well as pain management.

Q. And since when have you -- you're still currently at Brigham & Women's?

A. I'm currently at Brigham & Women's, yes.

Q. And that's since approximately what date? Do you recall?

A. July of 1996.

Q. Okay. Do you hold any titles or leadership

positions at Brigham & Women's?

A. I am a director of the Pain Trials Center at Brigham & Women's. It's a research arm where we do investigator-initiated research, clinical research, and we are also involved in doing FDA approval trials of the Phase II and Phase III kind.

Q. Have any of those involved opioids?

A. Several.

Q. Okay. Do you also treat patients at Brigham & Women's?

A. Yes. I am clinically treating patients four to five days a week.

Q. And how many patients do you typically see in a given day?

A. On average it's about thirty patients. It may be more, may be less.

Q. Do you do any teaching?

A. I do.

We are -- we have one of the largest pain fellowship programs in the country. We have ten pain fellows.

We also have all the anesthesia residents. They have -- they're required to rotate through the pain field.

We also have other residents from other

programs across the country that rotate with us.

And we also have medical students both from Harvard and from other medical schools.

Q. Have you done any writing in your field?

A. I have. I have approximately fifty peer-reviewed articles.

Q. Are you a member of any societies or committees that are related to pain management?

A. I am.

I'm currently on the board of the American Pain Society. I also serve on their public policy committee.

And I am also chairman of the Pain Care Coalition, which is an advocacy effort at the federal level involving the three major pain societies.

I also am on various committees for the anesthesia society and also the American Association of Pain Medicine.

Q. Okay. Do you do any consulting work for the government or pharmaceutical companies?

A. I've done both.

I've been a consultant for multiple pharmaceutical companies in terms of clinical trials and trial development and as an expert in pain management.

I've also served on the FDA advisory committee for anesthesia and analgesia. I've also been an invited speaker at these meetings, at the advisory panel meetings for various medications.

MR. ANTALICS: Your Honor, at this time I'd like to tender Dr. Michna as an expert in the fields of pain management and opioid therapy for the treatment of pain, by reason of his education, training and professional experience.

JUDGE CHAPPELL: Any objection?

MS. SCHMIDT: No, Your Honor.

JUDGE CHAPPELL: Any opinions that meet the proper legal standards will be considered.

MR. ANTALICS: Thank you, Your Honor.

BY MR. ANTALICS:

Q. Dr. Michna, what is an opioid?

A. An opioid is a medication that is derived from opium that's used to treat pain.

Q. And could you tell us a little more specifically how opioids actually treat the pain.

A. Opioids work at what is called the mu receptor, and by acting at that receptor site it modulates one's perception of pain.

Q. Are there different formulations of opioids?

A. There are.

Q. Could you describe the different --

A. There's three general classes. There is an ultra fast --

JUDGE CHAPPELL: Hold on a second. You need to wait for him to finish.

THE WITNESS: Okay. I'm sorry.

JUDGE CHAPPELL: He was in the middle of a question.

BY MR. ANTALICS:

Q. Could you first just describe the different types, and then we'll get into the characteristics of each.

A. There is three types. One is the ultra-fast-acting. One is called immediate release. And the other is extended release.

Q. Okay. With respect to the ultra fast, could you describe what that is.

A. It's typically a medication that is absorbed through the mouth. It has onset for initial pain relief in about 15 minutes. It's for pain that comes on very suddenly and may dissipate within an hour. It's typically utilized for cancer pain treatment.

Q. Okay. Thank you.

What is an immediate-release opioid, the second type that you mentioned?

A. An immediate-release opioid is a short-acting opioid that has -- that's taken orally, that has an onset time between 30 and 45 minutes and may last from three to six hours. It's used for acute pain and for chronic pain.

Q. Okay. Can you give us an example of a product that we might recognize as an immediate-release opioid.

A. Well, the most common one that we utilize is oxycodone. Most people know it by Percocet, which is a combination of oxycodone and Tylenol.

Q. Okay. Now, could you describe the third class, the extended-release opioid. What is that?

A. So an extended-release opioid provides continuous blood level of a particular drug over several hours. Usually the products that are available are over an eight-hour period to twenty-four hours. There's some patch formulations that last from three days up until seven days.

Q. Doctor, are you familiar with the term "FDA indication"?

A. Yes.

Q. Okay. What is an FDA indication?

A. It's the indication that the FDA has approved the medication to be used for clinically.

Q. Are there different indications for any of the extended-release opioids?

A. No.

Q. So are the indications the same for all of the extended-release opioids?

A. They are.

Q. Okay. Has the indication for extended-release opioids changed over time?

A. They have.

Q. Has -- have the indications changed for any particular opioids, extended-release opioids, over time?

A. When the indication has changed, it has been for the entire class of extended-release opioids.

Q. Okay. Doctor, is there any scientific evidence that one opioid is more effective generally than any other in treating any particular group of patients?

A. No. There have been no clinical trials or studies to show that.

Q. Okay. Is there any scientific evidence that one opioid is more effective than another in treating pain from any disease or injury?

A. No. There haven't been any documented studies showing that.

JUDGE CHAPPELL: Is there such a thing as medical evidence?

THE WITNESS: You mean clinical?

Our -- the way we use these medicines are all the same and for the same indication, and there's no difference clinically in our use of these medications.

JUDGE CHAPPELL: I'm just trying to figure out for the record what you mean when you say "no scientific evidence."

THE WITNESS: Well, I mean that there's -- there's no evidence of either scientific or clinical that one is better than another.

BY MR. ANTALICS:

Q. Have all of the extended-release opioids been proven to work?

A. Yes.

Q. Doctor, do all people react the same way to medications, in your experience?

A. No.

Q. Do all patients react the same way to opioids?

A. No.

Q. Okay. So is it possible that an individual patient may tolerate one opioid better than another?

A. Yes.

Q. Okay. Could you explain why that is.

A. Well, we're all different physiologically in the way we tolerate medications. Some people have very high tolerance. Some people have side effects. There's a lot of variability.

Q. Okay. You referred to side effects.

Can you give us an example of a side effect from an opioid.

A. Well, one of the most common side effects from an opioid is constipation.

Q. And what do you do if a patient had the side effect of constipation from an opioid?

A. Well, we typically have patients take a laxative prior to starting, in anticipation that it might be an issue. Should they then further experience it, we would try additional perhaps prescription laxatives. There are now actually medications that actually directly oppose the effects of opioids on the GI tract to reverse the constipation.

Q. Do you monitor the patients when you give them opioids?

A. Yes.

Q. Okay. Could you describe how you monitor the patients.

A. Well, we -- whenever we start any medicine, we

educate the patient about potential side effects and effectiveness and what to look for.

And after we start a medicine, of course we always tell the patients, please, if you have any problems, to call us, we're always available.

And then we'll eventually follow up with the patient to evaluate the efficacy and any potential side effects.

Q. Based on your experience, could most people use most extended-release opioids effectively?

A. Yes.

Q. Are you familiar with the term "REMS program"?

A. Yes.

Q. Could you describe what "REMS program" refers to.

A. REMS is Risk Evaluation and Mitigation Strategies. It was part of FDA legislation. The purpose of it was to assure the benefits of a particular medication outweigh the risks, so it allows the FDA, when they identify there might be a potential problem, to institute actions that try to assure that that balance is maintained in the benefits over the risk.

Q. Is there a REMS program for extended-release opioids?

A. There is.
Q. Have you been involved in that?
A. I have been.
When the first discussions came up, I was -- we were invited as part of the pain societies, and I represented the American Pain Society at many of the meetings.
I also served on one of the FDA advisory committees that addressed this issue.
Q. Which of the extended-release opioids are partici- -- had participated in that REMS program?
A. The REMS for extended-release opioids is a class-wide REMS, so all the medications that are designated extended-release opioids.
Q. You mentioned all of them are in, but I think you also mentioned earlier that some people could react differently to certain opioids?
A. That's correct. But the risk -- the risk-benefit of opioids is across the class. There are some differences in dosing and potential drug interactions, but the -- the risk-benefit is a class-wide problem.
Q. Are you familiar with the term "comorbid condition"?
A. Yes.

Q. And what is meant by "comorbid condition"?
A. Well, it's different medical problems that a patient may suffer from, from heart disease, liver disease, kidney disease, or some other medical ailment.
Q. Are you aware of any comorbid condition for which the patient would not have multiple options among the extended-release opioids?
A. No.
Q. Doctor, how do patients end up coming to see you in the first instance?
A. A majority of our patients are referred by other physicians, usually primary care physicians, other specialists, orthopedic surgeons, neurosurgeons, neurologists.
Q. And what is the procedure you go through when a new patient comes to see you?
A. So we -- when we first see a patient, we do an extensive history and physical. We obtain prior medical records. And occasionally we'll actually even speak to the referring physician to find out more information about the patient and any other issues that he wanted us to address in the consultation.
Q. Doctor, if you conclude that the patient needs an opioid and the patient has never before taken an

opioid, what kind of opioid do you start that patient on?

A. We always start a patient on a short-acting opioid. And indeed, it's in the latest guidelines from the Centers for Disease Control regarding the use of opioids that you always start with a short-acting agent first.

Q. Why do you start with the short-acting agents first?

A. Well, again, we don't know how an individual patient is going to react to a medication, so we prefer to have a shorter-acting drug that's not going to be -- linger along. If somebody has a side effect, we want to reduce the period of time that that patient is going to have the side effect and intervene.

Q. Do you at some point then change the patient from an immediate-release opioid to another type of opioid?

A. Well, it depends. I mean, for acute pain, it's usually a short episode, and those patients are not placed on a long-acting opioid.

For more chronic conditions, they might be very doing very well on the short-acting opioid and we would continue them on it.

In other situations, perhaps dose is -- we have

to increase the dose. The patient is experiencing frequent bouts of what we call breakthrough pain or pain that expresses itself in between the dosing of medications. In those situations, consideration may be given to using a long-acting opioid, which maintains the blood level of the medication more constant over a long period of time, to try to mitigate those periods of additional pain.

Even with that, we may use short-acting opioids in combination for those inevitable periods where patients have increased pain.

Q. Between --

JUDGE CHAPPELL: Wait a second.

Did I understand you to say that you may prescribe a long-acting and a short-acting opioid at the same time?

THE WITNESS: That's correct.

What happens is, if I may, if you want me to talk about this, people have differing pains throughout the day. It depends on activity.

There's three types of what we call breakthrough pain.

There's pain that occurs at the end of dose, meaning the dose is wearing off, and that's called end-of-dose breakthrough pain.

There's spontaneously evoked pain, which frequently occurs in cancer frequently when a tumor is invading nervous tissues, and that -- that occurs. A patient could just be sitting and all of a sudden has this extreme pain. And it comes out of nowhere, which is similar to what I described with the treatment of the ultra-short-acting opioids.

And then there's what we call incident pain, which is, I'm going to have pain if I move around, so if -- if you move your -- you know, stressing a particular joint or area of the body that has the disease that's causing the pain, it might exacerbate during that period, so you'll have an increased pain during that period.

JUDGE CHAPPELL: When you prescribe a long-acting and short-acting opioid to the same patient --

THE WITNESS: Yes.

JUDGE CHAPPELL: -- is it usually -- is it the same brand?

THE WITNESS: Oh, it wouldn't be the same --

JUDGE CHAPPELL: Or the same molecule?

THE WITNESS: It can be the same molecule. But sometimes -- there is a philosophy out there that using different opioids in connection -- in

conjunction with each other, you might get a better pain response.

JUDGE CHAPPELL: At the same time.

THE WITNESS: At the same time.

The breakthrough pain medicine is as needed. It's not around-the-clock.

So you -- the breakthrough medicine you take only when you need it based on the labeling, so I might write a breakthrough medicine as take every four hours as needed, so a patient might not take any of it throughout the day but, say, at night has some activity and suddenly has an increase in their pain. They're allowed at that point to take that additional medicine.

JUDGE CHAPPELL: So just in layman's terms, someone had surgery and they've taken -- I don't know -- a twelve-hour opioid, and six hours in for some reason they have intolerable pain. In that case, that's a person that would have a short-acting to add to the one they've already taken?

THE WITNESS: Well, we typically don't use long-acting agents for postsurgical pain, but if that was the case, yes, that's correct.

JUDGE CHAPPELL: Is that to prevent abuse so that that patient doesn't just pop another long-acting

because of the pain?

THE WITNESS: No. The purpose is to adequately treat that person's pain in a safe manner. It is possible that people -- you know, patients don't always do what I tell them to do or what their doctors do, and that's entirely possible, that somebody would self-medicate. Obviously, we educate against that, but it does happen.

MR. ANTALICS: Thank you, Your Honor.

BY MR. ANTALICS:

Q. Doctor, between immediate-release opioids and the extended-release opioids, is one more effective than another?

A. No. In fact, there was a -- it's all about the individual, as I explained before.

And in fact, there was a recent article on comparing long-acting hydrocodone versus short-acting hydrocodone in a cancer population, and the results of the study showed that equal -- both were equally effective in terms of pain relief and in terms of their side effect profile.

Q. Doctor, when you're going to prescribe a short-acting opioid, what are the factors that you consider?

A. Well, there are many. We look at what the

patient has tolerated in the past.

JUDGE CHAPPELL: Hold on a second.

Did you tell us what you mean by "short-acting opioid"?

THE WITNESS: I did. I can restate it.

JUDGE CHAPPELL: Please do.

THE WITNESS: A short-acting opioid is one that has an onset time of 30 to 45 minutes and typically lasts in terms of its effect between three hours and six hours.

JUDGE CHAPPELL: All right.

BY MR. ANTALICS:

Q. I'm sorry, Doctor. I may have caused that confusion.

When you referred to immediate-release opioid before, is that the same thing in your mind as a short-acting opioid?

A. It is.

Q. Okay.

A. I apologize.

JUDGE CHAPPELL: Immediate release includes a drug that lasts six hours?

THE WITNESS: It can, depending on the particular medication.

JUDGE CHAPPELL: All right.

BY MR. ANTALICS:

Q. Okay. Doctor, you were describing some of the factors you take into consideration when you prescribe an immediate-release opioid.

A. So we look at the patient's prior experience, what opioids they've tolerated in the past, what opioids they haven't.

There's personal preference. Most physicians are comfortable prescribing a certain opioid as their choice and they tend to prescribe that. But there are multiple options to prescribe.

Q. Okay. What opioid do you personally generally prescribe as an immediate-release?

A. As immediate release, it would be oxycodone is -- in the area of the country that I practice, we typically -- you know, oxycodone or Percocet products are the ones that we choose. There's variation across the country --

JUDGE CHAPPELL: Hold on a second.

So the record is clear, you just said oxycodone, Percocet, and some other name I didn't understand.

Are you saying, just so we're clear, are those three different things or are those the same drug?

THE WITNESS: Oxycodone is the opioid. In the

medication called Percocet, there is Tylenol also with it.

So it's more often that Percocet is prescribed than the plain oxycodone.

JUDGE CHAPPELL: What was the other one you mentioned?

THE WITNESS: I'm not sure what I said.

JUDGE CHAPPELL: I thought I heard a third one, but fine.

BY MR. ANTALICS:

Q. Doctor, have you prescribed immediate-release opioids other than Percocet or oxycodone?

A. I have.

Q. Okay. Have the other immediate-release opioids been effective as well?

A. Yes.

Q. Have you observed what immediate-release opioid other physicians in other parts of the country prescribe?

A. Yes.

As I said, in my local area, a lot of people write for oxycodone. In other parts of the country, physicians prefer using a hydrocodone product as their short-acting.

Q. Now, with respect to extended-release opioids,

what are the factors that are important to you when you're prescribing an extended-release opioid?

A. Again, we start with the patient, you know, if there's a medication, an opioid, that they've tolerated before or not tolerated.

Again, it's our own -- as practitioners, our comfort, what opioid that we usually go for because that's what our -- we were used to in our training or that's what we tend to use and we have a good familiarity with those.

And then also it's what is covered by the insurance companies. You know, they -- there are certain opioids that they cover and others that they don't.

Q. Okay. Doctor, if you're --

JUDGE CHAPPELL: How do you determine, when a patient is there and you're prescribing a medication -- you said it depends on -- could depend on what's covered by insurance.

How do you know what insurance covers with a patient sitting in front of you?

THE WITNESS: Well, I mean, typically we know -- at least in what very restrictive area that I practice in, we know that branded products most likely are not covered.

But we also -- we have electronic medical records. And when we put the prescription in that record, up on the screen it will tell me right away whether that is a covered product by this -- the patient's insurance company, and it will also detail, you know, copays and -- which is a fee that a patient also pays at the pharmacy.

JUDGE CHAPPELL: So before you write the script, you're looking at an electronic medical record, and the patient's insurance is there and whether that drug is covered or how it's covered?

THE WITNESS: Well, we don't write prescriptions for the most part anymore. It's all done electronically through the system. But that's correct.

When I put the drug order in the system, as I'm ready to print it or electronically send the prescription to the pharmacy, I will get an immediate feedback as to whether that's a covered medication for that insurance company, also what level of additional pay that the patient has to pay at the pharmacy.

JUDGE CHAPPELL: Is that information, to your knowledge, available just in large hospitals or is that even in small towns where doctors see patients?

THE WITNESS: Well, the electronic -- as part

of the healthcare reform, the electronic medical record has become commonplace throughout the country. I can't say if -- you know, I don't know how many -- what percentage of practitioners actually have that system, but it's -- it's becoming more and more universal and it's -- I believe it's mandated by the healthcare reform.

JUDGE CHAPPELL: So you don't have to really go into what's on a formulary; it just pops right up there in front of you.

THE WITNESS: Well, nowadays, yes. In the -- in the -- before these, we would be informed directly -- well, first of all, by a patient saying, Look, doc, I can't -- this is such a high cost for me, can you prescribe something else. Or the pharmacist would immediately call us and say, This is not a drug that this patient can receive without a prior authorization from the insurance company.

And we used to have and still have drug representatives that would detail us on their medication, so when they came to visit, they would tell us, Here's our product, it's on most insurances, it's at this level or covered or not covered, and that's the way we would have information.

JUDGE CHAPPELL: When they come to visit, the

drug reps, when they come to visit bearing gifts and free lunches?

THE WITNESS: Not anymore.

JUDGE CHAPPELL: Not anymore?

BY MR. ANTALICS:

Q. Doctor, do patients ever tell you that they're not satisfied with the first extended-release opioid that you give them?

A. Yes.

Q. Okay. Are there alternatives for those people who are not satisfied with the first extended-release opioid that they're given?

A. Yes. There are multiple.

Q. Okay. Have you ever seen a patient who did not have multiple alternative options among the extended-release opioids?

A. No.

Q. Doctor, can patients be safely switched from one extended-release opioid to another with equal therapeutic effect?

A. Yes. It's probably done thousands of times each day.

Q. What are the reasons or some of the reasons anyway for switching extended-release opioids?

A. Well, there are several.

The first instance could be that you have a patient on the extended-release opioid and with time there's what we call a tolerance that occurs where the patient doesn't get -- quite get the same pain relief with that medication. And we typically would address that but perhaps by increasing the dose.

But if that process continued and patients were still then having pain, at that point the option would be to say, well, maybe opioids aren't the way to treat your problem, or we could rotate you or change you to an alternative long-acting opioid.

Q. Okay. But are there reasons other than what you just described for switching a patient to a different opioid, extended-release?

A. Yes.

There are times when the formulary or the tiering of the drug on the insurance program changes and where a drug was covered at one point, it soon would be not covered, and at that point we would have to rotate the patient to an alternative medication.

And then there's another approach that's -- again, it would be similar to what I described when the medication is -- is losing efficacy, and we would rotate to another opioid to perhaps provide greater relief at a lower dose for the medication.

Q. Doctor, have you seen or heard of any cases where the switching of extended-release opioids has not been able to be accomplished safely and effectively?

A. No.

Q. Do some patients prefer not to switch?

A. Sure. I think we're all -- as humans, we're afraid of the unknown, so you could understand, if a patient has been on a medication for months or years and getting good pain relief, that there would be some anxiety about switching to a medication that they -- that may not have that same effect.

Q. Does that anxiety mean that the drugs are not therapeutically equivalent?

A. No.

Q. Okay. Could you explain how you go about switching a patient from one extended-release opioid to another.

A. It depends on the dose that a patient is on.

If a patient is on a relatively low dose of medication, we'll directly switch from one medication to another. What we'll do is we'll consult conversion tables that show relative equivalency of the two medications, and then typically we'll cut that dose in half or more just to err on the safe side in terms of

how patients react to it.

We always want to give less because we could always give more. We just don't want to give too much to cause a side effect.

Q. Is changing an extended-release opioid a complex process?

A. No.

Q. Does switching a patient from one extended-release opioid to another involve any monitoring by the physician?

A. Yes.

It could be as simple as, when we're on some of these lower doses, we would switch them and we'd have them call us, you know, immediately if there was any issues. And we would see them in follow-up in a short order most likely. And if at that visit they weren't getting adequate relief, we would increase the dose and then again schedule another follow-up visit.

JUDGE CHAPPELL: Are the patients happy with that follow-up?

I mean, a patient who is in pain and the drug isn't working, I'm sure the last thing they want to do is get in the car and come see you again.

THE WITNESS: Well, we do -- you know, a lot of it is based on education. You know, we take a lot

of effort to talk to the patients with these expectations.

And what I failed to say was that additionally to the change in the medication, we'll provide them with the short-acting or the immediate-release opioid on top of it, so should we be underdosing them, they'll have additional medicine that they could utilize to treat that, the pain that might occur, because of the first switch.

And in my experience, patients don't mind seeing physicians. Actually, there's evidence to show that when patients see doctors more frequently, they actually have lower overall pain levels.

JUDGE CHAPPELL: It may not be seeing physicians they have a problem with. It may be driving through traffic, sitting in waiting rooms all day they have a problem with.

THE WITNESS: I think patients are concerned with treating their pain. And as opposed to treating heart disease, pain is a little bit different. And patients ultimately want to seek relief, and I don't think our patients ever mind coming to us, seeking our advice and help to treat their pain.

BY MR. ANTALICS:

Q. Is there any expense involved in switching

extended-release opioids?

A. Well, these are -- these involve follow-up visits which are not well-compensated, to tell you the truth. They're fairly low reimbursement.

And in fact, a lot of the switching I described is driven by insurance companies, so obviously they've calculated that the -- the savings they have on the medication front more than makes up for the additional cost of the follow-up visit.

Q. Doctor, you talked a little bit about insurance before.

What role, if any, does the patient's insurance coverage play in the choice of the extended-release opioid?

A. It plays a major role.

Q. Okay. In what ways is insurance playing a major role?

A. Well, insurance companies want to use effective drugs that cost the insurance company the least amount of money and cost the patient the least amount of money, so they encourage the use of the lower-cost medications, which are frequently the generics.

Q. Okay. Can you describe what a formulary is?

A. A formulary is a list of drugs, and the list

prioritizes them in terms of their cost and what the cost is to the patient.

It's an encouragement for us to use the lower-cost medications.

Q. And could you describe once again -- you used the term "copay" before. What does "copay" mean?

A. A copay is what the patient pays for the medication at the pharmacy level.

Q. Okay. And did you say that as a physician you're made aware of the copay?

A. I'm made aware based on the -- as I said, on the electronic medical record. It will appear on the screen.

Q. Okay. And is there a particular company that does a lot of the electronic medical records?

A. Well, we use the Epic system, and I believe Epic is -- has about 70 percent of the market in the country.

Q. Okay. Who determines which drugs get preferred status on a formulary?

A. It's determined by the insurance company and their pharmacy directors.

Q. Do you know whether brand name drugs can ever move up to a more preferred tier on a formulary?

A. Yes, they can. Frequently it occurs when the

pharmaceutical company gives what is called a rebate to the insurance company, meaning they'll give them a discount on the medication.

Q. And how do you know that, Doctor?

MS. SCHMIDT: Your Honor, I object on the lack of foundation. This is not in Dr. Michna's report.

MR. ANTALICS: Your Honor, Dr. Michna has extensive testimony in the report about insurance coverage and formularies, and I'm laying the foundation as to how he knows how formularies operate.

JUDGE CHAPPELL: Well, let's see. You haven't been with us for a day or so, but the way it works, when an expert is on the stand and there's an objection beyond the report, you have to lay a foundation indicating where it is in the report with the witness or show it to the opposing attorney.

MR. ANTALICS: Okay.

MS. SCHMIDT: Thank you, Your Honor.

MR. ANTALICS: Paragraphs 21 --

JUDGE CHAPPELL: You don't have to say it on the record.

MR. ANTALICS: Okay.

(Pause in the proceedings.)

MS. SCHMIDT: Your Honor, I have not been able to look at each of the paragraphs, but from my very

recent reading of the report, what Dr. Michna has testified to so far about copays and how brands move up or down tiering levels is in none of the paragraphs that Mr. Antalics has just directed me to.

JUDGE CHAPPELL: All right. She's not satisfied. The objection is pending while you attempt to lay a foundation and show through the witness where it is in his report.

MS. SCHMIDT: Thank you, Your Honor.

BY MR. ANTALICS:

Q. Doctor, do you have a copy of your report up there in front of you?

A. I believe so. Yes.

Q. It's tab 1 in the binder.

Doctor, if I could, could I direct your attention to first paragraph 51 and ask you if that refers to the placement and status of medications on formularies.

(Document review.)

A. Yes. I mean --

Q. Does it all --

A. I'm sorry?

Q. Are you finished?

A. It talks about the status and the placement on the formularies.

Q. Okay. Does it also talk about formulary designations creating incentives for physicians to prescribe lower-cost products?

A. Yes.

Q. Okay. Does it also talk about whether a medication is on a formulary and what its status is on that formulary is usually determined by the cost of the medication to the plan?

A. Yes.

Q. Does it also talk about how lower-cost medications, either generics or brand medications, for which the healthcare company has negotiated rebates from the drug manufacturer are typically placed on the formulary's preferred tier?

A. Yes.

MR. ANTALICS: Is that sufficient, Your Honor?

MS. SCHMIDT: Your Honor --

JUDGE CHAPPELL: The objection is overruled.

MS. SCHMIDT: Okay. Thank you, Your Honor.

May I just note, Your Honor, for the record that the paragraph to which Mr. Antalics has just referred Dr. Michna does not include a single citation, and Dr. Michna is not being proffered as an expert on insurance or formularies but rather as an expert on pain management and the use of opioids in pain

management.

JUDGE CHAPPELL: That will be something for you to inquire into on cross.

MS. SCHMIDT: Thank you, Your Honor.

BY MR. ANTALICS:

Q. Doctor, as I started to ask you, how is it that you came to form -- or to your views about rebates being provided to manufacturers? How did you come to that knowledge?

A. Well, there's several ways.

One, I -- several years ago, I served on the State of Massachusetts Drug Utilization Review Board, which is the state Medicaid. And the Drug Utilization Review Board would review medications for the formulary status for the Massachusetts Medicaid program. And we would frequently hear about, you know, which medications they were receiving rebates for. And a lot of this -- this information is privileged, but, you know, in that setting I was privy to it.

I've also served on -- at consultants meetings where clinicians and insurance form- -- medication -- pharmacy directors were present. And the purpose of the meetings was to discuss how these medications could be at a higher level in the tiering on the insurance formularies as well as how they would be made

more readily available to their patients.

So I had lots of discussions with pharmacy directors and learned a lot about the whole process from them.

Q. Doctor, are branded drugs, in your experience -- I'm sorry -- are generic drugs, in your experience, always cheaper for the insurance company than are branded drugs?

A. Well, part of what I've learned at some of these meetings was that that's not always the case. In fact, they -- they related to me that with these rebates sometimes for the -- you know, the branded product was actually cheaper than the generic.

Q. And is it possible then that the branded drug could be on a more preferred tier than a generic product?

A. Yes.

Q. Do formularies vary from insurance company to insurance company?

A. Yes. And in fact, in insurance companies, depending on the plan, there's different formularies for all the plans.

Q. Do different insurance companies have the same extended-release opioid on different tiers at times?

A. Could you repeat the question.

Q. Sure.

Do different insurance companies have the same extended-release opioid on different tiers at times?

A. Yeah. Frequently. And again, it probably deals with whatever rebate that particular insurance company has received as an incentive from that drug manufacturer.

Q. How frequently do formularies change, in your experience?

A. Well, in the past, it used to be every January we would anticipate there would be changes, but now, in the last few years, there have been formulary changes made throughout the year. Whenever they would get a -- you know, a rebate or there was a change in their pricing, they would make a change in the formulary.

Q. Doctor, I'd like to direct your attention now to a document that is marked for identification only as RX 545.

This document is not in evidence at this time, Your Honor. This is one of the ones we talked about at the status conference.

Can you put that on the screen.

Doctor --

MS. SCHMIDT: I'm sorry, Your Honor. Could we just get a clarification of what this is being offered

on because if it's a demonstrative -- I'm just trying to get clarification on what this document is being offered for, if it's trying to be admitted as an exhibit or if it's a demonstrative, as we did not receive this 24 hours in advance and it's not on JX 2.

MR. ANTALICS: Your Honor, this is not a demonstrative. This is one of the documents that we had offered at the last prehearing conference, and there was an objection to it, and Your Honor I believe said we should wait and you can offer it through a witness if you so choose, and you'll make a decision down the road.

So we are offering this -- or we will be offering, after I lay a foundation, this document not for the truth of the matter asserted therein but for nonhearsay purposes.

JUDGE CHAPPELL: If you're attempting to lay a foundation, go ahead.

MR. ANTALICS: Thank you, Your Honor.

BY MR. ANTALICS:

Q. Can you identify, Doctor, what RX 545 is?

A. Yes, I can.

It is a -- it's a formulary for CIGNA Insurance Company covering a couple of their HMO plans.

Q. Are you familiar with this document?
A. I am.
Q. Okay. Did you rely on this document in writing your expert report?
A. I did.
Q. And it was cited within your expert report?
A. That's correct.
Q. Where did this document come from?
A. This came from the CIGNA website.
Q. And do you rely as a physician on information contained in formularies like this in your day-to-day job?
A. Yes.
MR. ANTALICS: Okay. Your Honor, I'd like now to offer RX 545 into evidence, not for the truth of the matters asserted therein.
JUDGE CHAPPELL: For what reason? What's your theory of admissibility?
MR. ANTALICS: I'm sorry?
JUDGE CHAPPELL: What's your theory of admissibility?
Not for the truth is not a theory of admissibility.
MR. ANTALICS: No, no, no. It's relevant to how price competition works in the industry, and the

fact that CIGNA puts out a formulary such as this, it affects the way physicians prescribe their product regardless of whether a particular statement in -- in the formulary itself is being offered for the truth of the matter. The fact that it lists different drugs in different tiers has real-world practical effects by itself.

JUDGE CHAPPELL: Did the witness say it's something he relied on?

THE WITNESS: It was cited in my report.

MS. SCHMIDT: Your Honor, we object to the admission of the document. The only place that I see that it is cited in this report as well as the other formularies cited in this report are one general string cite for the supposition that "The formularies for different healthcare companies vary widely."

They cite to no specific pages. They cite to no reason of why particular formularies were pulled, how they were pulled, how they're relevant or any particular entries in those formularies.

Given this lack of use within his report and our lack of ability to test for any of his reliance on specific issues within these very lengthy documents at his deposition as he was not being -- there's nothing in his report to indicate that he was going to be

testifying at length about these documents, we object.

JUDGE CHAPPELL: It's being offered not for the truth of the matter. RX 545 is admitted.

The objection is overruled.

(RX Exhibit Number 545 was admitted into evidence.)

MR. ANTALICS: Thank you.

MS. SCHMIDT: Thank you, Your Honor.

BY MR. ANTALICS:

Q. Doctor, I'd like to direct your attention first to what's page 4 of the formulary, but it's the Bates number is RX 545-6.

And I'd like to direct your attention to the middle box that is labeled Key.

Yes, that's the one. Thank you.

And I'd just like to ask you a couple of questions about this, Doctor.

And on the right-hand column where it says "PA - This drug requires prior authorization," could you describe what that means.

A. Prior authorization is a requirement for additional paperwork and documentation explaining to the insurance company why we as clinicians want to utilize that medication for our patient.

Q. And then just down from that, where it says

"ST - This drug has step therapy requirements," how do you utilize information like that?

A. Well, step therapy requirements are typically that a patient has to have tried and failed several lower-cost alternative medications prior to the insurance company allowing the payment for the other drug.

Q. Okay. Now I'd like to direct your attention to the next page, which is -- has Bates number RX 545-7.

And the chart in the middle of the page, if you could highlight that.

Okay. Now, Doctor, if I could direct your attention down to the left-hand side, the lower left-hand side of that chart, where it lists various tiers, could you describe what tier 1 is.

A. Tier 1 is titled Preferred Generic Drugs, so these are the medications that we're encouraged to use because they're the lowest cost and they're frequently associated with the lower copays for the patient.

Q. Okay. And on this formulary they have lower copays for tier 1 drugs?

A. That's correct.

Q. Okay. Now, tier 2 also lists generic drugs.

Could you describe what tier 2 is.

A. Well, tier 2 is generic drugs that are more

costly to the insurance company, and they're also more costly to the patient in terms of the copay that they have to pay at the pharmacy when they get the -- they receive the prescription.

Q. Okay. Now, tier 3 where it says "Preferred Brand Drugs," could you describe what that means to you.

A. So these are more expensive medications that are branded, but they are preferred in that they're -- of the branded medications, they're a lower cost to the insurance company. But again, to the patient this -- the patients incur even a greater copay that they have to pay when they pick up the prescriptions.

Q. Okay. And then if we could turn to tier 4 where it says "Nonpreferred Drugs," what does that refer to?

A. Those are typically branded drugs that are even more expensive to the insurance company and also more expensive to the patient in terms of their -- the copay that they have to pay at the pharmacy.

So in general, the purpose of this is to incentivize clinicians to use the lower-cost medications that are equally effective.

Q. Okay. Now, could you turn to page 6 of this document. That's 6 of the document itself. Its Bates

number is RX 545-8.

And I'd like to direct your attention to the right-hand column where it says "Opioid Analgesics, Long-Acting," all right, the part that's blown up in front of you there.

A. Okay.

Q. Could you just --

MS. SCHMIDT: Excuse me, Your Honor. None of this is in Dr. Michna's report.

MR. ANTALICS: As I mentioned before, Your Honor, Dr. Michna talked extensively about the role of formularies in controlling costs, and I'm just asking him to highlight some of the underlying facts that led to his opinions in his report.

MS. SCHMIDT: Your Honor, if I may be heard.

That would have been fine if they had opted to actually include some of those things in the report. They did not, and this is the first time we're hearing from Dr. Michna on this.

JUDGE CHAPPELL: Why do I sense a fear of formularies on your side of the room, Counselor?

MS. SCHMIDT: Your Honor --

JUDGE CHAPPELL: Because formularies exist, we've had a lot of witnesses talk about them. Why is there such a fear on your side of formularies?

MS. SCHMIDT: Your Honor, there -- I apologize. I don't mean to give off that impression. There is not a fear of formularies.

There is, however, a frustration that, one, there seems to be -- a majority or at least a large portion of Dr. Michna's testimony seems to be addressing things that were not discussed in the -- in detail in his report or even discussed at all.

And even more fundamentally, Your Honor, is that Dr. Michna, as I mentioned earlier, we do not object to him being proffered as an expert in pain management and the use of opioids to treat pain. However, we do object to his use as an expert in formularies or in medication pricing or in any ways in which the insurance works, and he has not been proffered as such.

JUDGE CHAPPELL: The expert is not a fact witness. He's limited to what's in his report. And without a better foundation, the objection is sustained.

MS. SCHMIDT: Thank you, Your Honor.

MR. ANTALICS: Could I be heard further on that, Your Honor?

JUDGE CHAPPELL: You can be heard. I've heard you already on the same topic, but go ahead.

I've said the same thing I said a hundred times in this trial. The expert is limited to what's in the report, and if there's an objection that something is outside the report, you lay a foundation with the witness showing it's within the report or you move along.

Experts are not here to give us facts. They're here to give us opinions, and those opinions are locked in.

BY MR. ANTALICS:

Q. Dr. Michna, earlier, you testified that you relied on this formulary in arriving at your opinions in your report.

A. That's correct.

Q. Okay. And part of what you said in the report was that the formularies were used to -- for -- by the insurance company in order to direct physicians and patients to the lowest-cost effective drugs.

A. That's correct.

Q. Okay. Is the information that was -- it's not in front of you now, but is information on formulary placement that is contained within the formulary itself -- was that part of the information that you used in arriving at your opinion?

A. Yes.

MR. ANTALICS: Your Honor, may I proceed with another couple of questions on this document or should I move on?

JUDGE CHAPPELL: The current question has been objected to and sustained. Next question.

BY MR. ANTALICS:

Q. Dr. Michna, without reference to any particular document -- you can put that away -- do the formularies list for each particular drug what tier placement that particular drug has?

A. Yes.

Q. Thank you.

Is it common, Doctor, for insurance companies to have formularies?

A. Yes. I believe it's universal. And again, the goal is for cost savings. They want to effectively treat their insureds, but they want to do it at the lowest possible cost.

Q. Doctor, I believe you mentioned rotate or the concept of rotation therapy earlier.

Could you describe what is meant by "rotation therapy."

A. Well, it is -- typically, as I described before, it's -- it's a thought process where and a clinical treatment process where patients -- some

patients, not all patients, with time become what we would describe as tolerant of medications, meaning the drug or the medication doesn't have the same pain-relieving effects that it did six months ago, a year ago or two years ago.

At that point, you can increase the dose of the medication or you can decide that it might be more effective to change that patient from one long-acting opioid to another, in the hopes that you regain that pain relief at a much lower dose with a new medication.

Q. And have you personally used rotation therapy in your practice?

A. Yes.

Q. Okay. And when you've utilized rotation therapy, have you always been able to find alternative extended-release opioids that were effective?

A. Yes.

Q. Doctor, do you write prescriptions for oxymorphone ER?

A. I do.

Q. Okay. In what types of cases have you prescribed oxymorphone ER?

A. There are many different situations, some of which patients come to my practice already on the

medication and, if I agree to continue prescribing, I will continue to prescribe for them.

There are other instances where I have a patient on one extended-release opioid, and as we talked about, insurance companies make a decision that that medication is no longer going to be paid for, and they offer us alternatives. And some of those alternatives in the recent past have been Opana as one of them, which is oxymorphone extended release, so in those situations I have switched.

The particular instance was OxyContin or oxycodone extended release. The option that they gave us was, since it wasn't covered anymore, to transition that patient over to oxymorphone ER. And in fact, I did that several times.

Q. Doctor, have you ever seen or heard of a patient who was on oxymorphone ER who did not have multiple alternatives among the other extended-release opioids?

A. No.

Q. Have you ever seen any patient on any other extended-release opioid who did not have multiple options among the extended-release opioids?

A. No.

Q. Doctor, if theoretically there was such a

person out there who could only use oxymorphone ER, could you identify that person in advance?

A. No.

Q. Is there any group of people for whom oxymorphone ER is the only option to treat their pain?

A. No.

Q. Is there any group of people for whom any other particular extended-release opioid is the only option?

A. No.

Q. Is there any medical condition for which oxymorphone ER is the only option to treat the pain associated with that medical condition?

A. No.

Q. Is there any medical condition for which any other extended-release opioid is the only option?

A. No.

Q. Okay. Doctor, in Dr. Savage's expert report, she talked about oxymorphone ER being available in both an injectable and oral form. Do you recall that?

A. I do.

Q. Okay. In your view, Doctor, is having oxymorphone ER in an injectable version and a tablet form a clinically relevant differentiating factor?

A. No. In my over twenty-year career, I have

never seen -- and I've worked in many hospitals -- I've never seen oxymorphone IR stocked in any of them.

Q. What is the typical practice, if there is a practice, typical practice, in hospitals?

A. Well, typically we use, you know, several different injectable forms in the hospital whether it's in the operating room or in -- on the patient floor.

I mean, the -- as I spoke to earlier, the most common opioid that's given to patients when they're discharged from the hospital, at least in the Northeast, is oxycodone-containing products. And there is no IV form of oxycodone available, so, by definition, a majority of the patients are on different IV formulations in the hospital or in the operating room than the oral formulation that they're discharged home on.

JUDGE CHAPPELL: What's the common brand name for oxycodone?

THE WITNESS: Well, it's generic, so in the short-acting form it's oxycodone. The branded names would be the combination with Tylenol that I described earlier, the Percocet or -- and then in the extended release there is -- OxyContin is the brand name notable opioid for the long-acting.

There recently are additional long-acting oxycodone compounds that are now on the market that are branded also.

BY MR. ANTALICS:

Q. Doctor, Dr. Savage talked about something called CYP450 in her report. Do you recall that?

A. I do.

Q. Can you describe what CYP450 is.

A. Cytochrome P450 is a pathway of metabolism in the liver where a majority of the medications that we prescribe generally in medicine are metabolized or broken down in.

Q. Can the various different medications interact with one another in that system?

A. Yes. Frequently, since a lot of the medications we prescribe, you know, concurrent meds for depression and other diseases, are metabolized through that system, there can be effects on the other drugs when they're coprescribed.

Q. Okay. Is oxymorphone ER at all related to the CYP450 system?

A. Oxymorphone is metabolized, but it's not metabolized through that system.

Q. Now, is that a clinically relevant differentiating factor, in your view?

A. No.
Q. And can you describe why.
A. Well, as I already described, most of our patients are on multiple other medications before we prescribe any of the pain medicines, and our approach is always the same. We always start at varying low doses and we titrate the dose up to effect or side effect, so we always err on the side of safety, so we start with very low doses and we work our way up.

So if there was such an effect, you know, we would just -- we'd get pain relief at a much earlier point in the titration than not if it was suppressing it. And if it was inducing the enzymes, meaning causing a more rapid metabolism, it would just result in a patient being on a higher dose, so that would be, you know, the way we would approach it anyway.

Q. Okay. Is there a test available to determine differences in the way people metabolize drugs differently through the CYP450 system?
A. Yes.
Q. Have you ever seen anyone perform that test?
A. I have never performed it, I haven't seen anybody perform it, and I'm not even sure if it's covered by insurance.
Q. Okay. In your experience, do pharmaceutical

companies sometimes promote differentiating factors that are not clinically relevant?

A. Yes.

Q. Okay. Have you had any experiences with Endo concerning the CYP450 issue?

A. Yes.

Several years ago, there was a consultants meeting, and it was -- there was a lot of marketing people at that meeting. And the purpose of it was the -- their sales of --

MS. SCHMIDT: Objection, Your Honor. I move to strike. None of this is in his report.

And by "none of this" I mean his discussion of previous interactions with Endo on the CYP450 issue.

MR. ANTALICS: Your Honor, this is a response to Dr. Savage -- well, first of all, he speaks about CYP450 in the report, as I think counsel acknowledges, but it's also a response to Dr. Savage's criticism of his report in her testimony at trial.

JUDGE CHAPPELL: I'll allow him to respond to her testimony.

MR. ANTALICS: Okay.

JUDGE CHAPPELL: If that's what it is, I'll allow it. Overruled.

MS. SCHMIDT: Thank you, Your Honor.

JUDGE CHAPPELL: He's had no way he could have responded to what testimony she gave here in court.

MS. SCHMIDT: Understood, Your Honor.

Could we just ask for the courtesy of being directed to which testimony of Dr. Savage she -- I was just asking if we could be directed to the testimony to which he's responding now as Dr. Savage testified for several hours.

JUDGE CHAPPELL: He's not going to have to cite you page and line.

MS. SCHMIDT: Okay.

JUDGE CHAPPELL: But he should have a good-faith belief in what he's representing. If not, there are bigger problems.

MS. SCHMIDT: Thank you, Your Honor.

BY MR. ANTALICS:

Q. Go ahead, Doctor.

A. Could you repeat your question. I got lost there a little bit.

JUDGE CHAPPELL: Let her read the question.

(The record was read as follows:)

"QUESTION: Have you had any experiences with Endo concerning the CYP450 issue?"

THE WITNESS: I have.

I was several years ago invited to a

consultants meeting. It involved some of the marketing people from Endo. And it was a result of the fact that they weren't selling as much of the extended-release oxymorphone Opana that they anticipated, and they were looking at ways they could better market the medication.

And during that meeting, they brought up to us, the consultants, what we thought about this aspect of the metabolism and whether that would be -- would resonate with clinicians. And universally we said no because it's really not clinically relevant.

MR. ANTALICS: I have nothing further, Your Honor.

JUDGE CHAPPELL: Will there be any cross?

MS. SCHMIDT: Yes, Your Honor.

MR. LOUGHLIN: Your Honor, could I raise a question before we take a break if that's what you're going to do?

JUDGE CHAPPELL: Go ahead.

MR. LOUGHLIN: I'd like a clarification on your ruling about witnesses being able to respond to things that were not in their report.

I understood when you were talking earlier to be saying that if we open the door on cross to something that a witness -- if we ask on cross about

something that the witness said in response to another expert, that that was fair game, but I did not understand you to be saying that a witness could now in direct examination respond to material in expert reports that we have not brought out.

So in other words, we're hearing for the very first time a response to an expert that was not in anybody's expert report.

Is that what you meant?

JUDGE CHAPPELL: The ruling I just made was I'm allowing this expert to respond to what was brought out in testimony in the trial.

Did you not understand that?

MR. LOUGHLIN: I understood your ruling, Your Honor, but earlier -- this whole -- this whole case we've been operating under an instruction that if it's not in the report, it's not coming in. And I understood earlier, in response to Mr. Figg's testimony, that you were going to allow them to respond -- the expert to respond to something that was brought up on cross-examination.

JUDGE CHAPPELL: No. My ruling was, if I recall, I'm allowing an expert to respond to something in a rebuttal report that says that expert was wrong. I'm allowing them to explain themselves or respond to

that.

That doesn't mean a new opinion. That means an expert can say, "The sun was out yesterday." Your rebuttal expert can say, "She's wrong. The sun wasn't out yesterday." On the stand, the first expert can say -- can address that, not with a new opinion, but can defend themselves and explain and respond to that accusation that they are wrong. I'm allowing that.

That's fair response. That's not a new opinion. I'm not going to allow that expert in my example to say, "No, the sun was out that day and 15 people told me it was." That's -- you know, I'm not going to allow the opinion to change. But I'm going to allow someone to defend their opinion. That's what I'm allowing.

MR. LOUGHLIN: Okay. I want to be clear.

JUDGE CHAPPELL: And the reason I'm allowing that is, you get to have a rebuttal expert report, and respondents don't get to come back with anything after that.

MR. LOUGHLIN: I understand how the scheduling order is set up, Your Honor, but what you're allowing is for them to be able to provide responses that we have never heard before.

JUDGE CHAPPELL: That's fine.

MR. LOUGHLIN: I want to make sure that's what you intend.

JUDGE CHAPPELL: It's a very narrow ruling, and that is that someone can respond to a criticism that was made in a rebuttal report. It's only those that were criticized in a rebuttal report, and I don't think it will apply to anybody except the patent guy.

MR. LOUGHLIN: I think it just applied to Dr. Michna.

JUDGE CHAPPELL: Well, I mean, you've got one as far as a rebuttal expert witness goes. You have rebuttal reports that have come out. And the way I understand the timing, respondent doesn't get to file a surrebuttal or a reply to a rebuttal, whatever you call it, whatever you want to call it, they don't get to respond.

I'm not allowing new opinions, but whether you've heard it or not I do not care. If someone wants to explain and defend themselves, I'm allowing that. That just makes sense and that's fair.

MR. LOUGHLIN: All right. I wanted to make clear that was what you were doing now so that I understand the rules.

JUDGE CHAPPELL: It's very limited. It's not wide open. It's not a wide road for anyone to run

down, and I'm not allowing new opinions.

And the way I understood the way it was presented, someone in a rebuttal report said you're wrong and probably here's why. The expert hadn't had a chance to reply to that. I'm allowing that reply. I'm not allowing new opinion.

So you're not going to hear any new opinions that you haven't heard before. To the extent it's an opinion, I won't consider it. I'm allowing what I consider fair response to a rebuttal where the witness hasn't had a chance to say, I disagree.

MR. LOUGHLIN: Okay. I just want to make sure I understood it because it sounded new to me, Your Honor.

JUDGE CHAPPELL: Well, it might have sounded new to you, but it's the first time I've heard it presented in the way it was presented at the time. And I perceived it to be an unfair situation where someone has the right to respond to a criticism in another expert's report. Again, no new opinions.

Anything else?

MR. LOUGHLIN: No, Your Honor.

JUDGE CHAPPELL: We're going to take a morning break. We'll reconvene at 12:05.

We're in recess.

(Recess)

JUDGE CHAPPELL: Let's go back on the record.

I want to go back to the ruling I made earlier. My ruling was, just so everyone is clear, that an expert's opinions are supposed to be proffered in the report. And my ruling was, based on my understanding, that when an opposing expert brings out an opinion during their testimony in trial, then an opposing expert can respond to that new information. And that's how narrow it is.

And if that's not what occurred before the break, then the answer won't be considered. That's the way I'm ruling on it. I'm allowing fair response to something new that comes up from one side's expert during trial so that during trial an opposing expert can respond to that.

I'm not allowing new opinions to be thrown out there.

Any questions?

MR. LOUGHLIN: No, Your Honor.

JUDGE CHAPPELL: Go ahead with cross.

MS. SCHMIDT: Good afternoon, Your Honor.

And may it please the court.

My name is Maren Schmidt on behalf of complaint counsel.

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CROSS-EXAMINATION

BY MS. SCHMIDT:

Q. Good afternoon, Dr. Michna. We met in Boston on October 3 of this year when I took your deposition.

How are you today, Dr. Michna?

A. I'm well. Thank you.

JUDGE CHAPPELL: Hold on a second.

Mr. Loughlin?

MR. LOUGHLIN: Yes, Your Honor.

JUDGE CHAPPELL: You told me earlier that you heard something you hadn't heard before?

MR. LOUGHLIN: Yes.

JUDGE CHAPPELL: Those are your words.

What is it you hadn't heard before?

MR. LOUGHLIN: My prior understanding was that --

JUDGE CHAPPELL: Not my ruling. I'm talking about the testimony.

MR. LOUGHLIN: Oh.

JUDGE CHAPPELL: What testimony? I thought you were referring to you heard testimony you hadn't heard before. That's the way I understood you, what you said.

MR. LOUGHLIN: From Dr. Michna. I understood

Dr. Michna gave testimony about his experiences with Endo that we had not heard before.

JUDGE CHAPPELL: All right. And I was told, it was represented to me, that he was responding to something your expert said in testimony. That was the basis of my ruling.

MR. LOUGHLIN: I agree, Your Honor.

JUDGE CHAPPELL: And my assumption would be that whatever they're saying your expert said they weren't aware of before the trial, before testimony.

I don't know. I don't read the reports. The evidence I'm hearing for the first time. I don't know what the reports say. I don't know what the depositions say.

MR. LOUGHLIN: My understanding was that they were having Dr. Michna respond to something that was in Dr. Savage's report and that Dr. Michna was giving some new information about his experience with Endo that we had never heard before. And my understanding previously was that was not allowed.

JUDGE CHAPPELL: That's not allowed if it's something that respondent was aware of that was in the expert report.

My ruling was, I'm allowing it based on my understanding from what I was told was it was something

that was brought out in testimony for the first time by Dr. Savage.

MR. LOUGHLIN: Then I -- maybe I'm mistaken, Your Honor. I did not understand that they hadn't heard about this for the first time in Dr. Savage's trial testimony. I believe that it was -- they heard about this beforehand.

JUDGE CHAPPELL: I don't know who's mistaken and who's not. But my ruling is, something that comes out for the first time in testimony by an expert, an opposing expert will have a chance, in fairness, to respond to that. That's my ruling.

MR. LOUGHLIN: Understood, Your Honor.

JUDGE CHAPPELL: Go ahead.

BY MS. SCHMIDT:

Q. Dr. Michna, is there anything that may affect your ability to give complete, truthful testimony today?

A. No.

Q. And I will just note, if we look at any documents this morning, we will publish them to the screen before you, but there are also paper copies in the binder placed at your chair, and I will direct you to the documents if you need to look at them.

Dr. Michna, for your appearance at your

deposition on October 3 you were compensated $10,000?

A. That's correct.

Q. And for your appearance in court today you are being compensated $18,000?

A. That's correct.

Q. And for all of your services in this matter, including preparing your report, consulting with counsel and reviewing materials, you are compensated at $750 hour an hour?

A. That's correct.

Q. Approximately how many hours have you billed to date?

A. I haven't calculated it. I -- any number I would -- it's probably inaccurate.

Q. And in the past you've also been paid by Endo to do promotional speaking for Opana ER?

A. Yes. Years ago.

Q. And these were dinner speeches promoting Opana ER to prescribers?

A. Yes.

Q. And you were paid by Endo for making those speeches?

A. Yes.

Q. And at the time you made those speeches, you were not a frequent prescriber of Opana ER?

A. I prescribed it. I don't know how many times I prescribed it, though. I don't remember.

Q. Would you call yourself a frequent prescriber of Opana ER?

A. I mean, I don't know what you mean by "frequent." As a percent of all my long-acting opioids, it would, you know, be fairly low.

Q. And in your speeches regarding Opana ER you promoted the benefits of Opana ER?

A. They weren't speeches. As you may or may not know, all the slides are approved with a company with the FDA, and we're limited to basically reading the slides off the presentation. And then if we get individual questions, we can respond.

Q. And so those would be slides prepared by Endo Pharmaceuticals for you to present --

A. With the FDA's approval, yes.

Q. And what were some of those differences that you -- or I'm sorry. Let me rephrase that.

JUDGE CHAPPELL: Hold it.

I want someone to take a piece of 8-1/2" x 11" paper and a Sharpie and I want someone to write the words, in large letters, "Slow down and speak up," and I want her to lay it right there in front of her.

MS. SCHMIDT: I'm writing it myself, Your Honor.

JUDGE CHAPPELL: Thank you.

MS. SCHMIDT: In red.

JUDGE CHAPPELL: Slower and louder.

MS. SCHMIDT: Thank you.

JUDGE CHAPPELL: By the way, it's not the first time we've done this. It's also been done with an expert witness where a sign was hung on counsel table for the witness to look at, who just kept speaking too fast.

Go ahead.

MS. SCHMIDT: Thank you, Your Honor.

BY MS. SCHMIDT:

Q. But the purpose of those presentations was to promote the benefits of Opana ER?

A. The purpose of the presentations is to provide an educational program in regards to a particular drug product. Yes.

Q. And that was for Opana ER and paid for by Endo.

A. For those particular ones, that's correct, yes.

Q. Thank you.

And I believe earlier today you talked about

taking an individualized approach in treating your patients?

A. I'm not sure if I mentioned it today, but yes, that is my philosophy and that's, you know, our general philosophy in the pain management world.

Q. And that extends to taking an individualized approach to opioid therapy?

A. We -- we treat the patient based on their prior experiences, as I've described before, so we treat patients as individuals, and we prescribe according to prior history, medical conditions, et cetera.

Q. And there is variability from person to person in terms of the way they respond to drugs?

A. We never know how a patient is going to respond. As I think I testified earlier, they may have adverse events. It's un- -- you know, it's impossible to predict that, yes.

Q. And it is your opinion that there is no reliable way of identifying which delivery system or opioid is most compatible with an individual patient beyond trial and error?

A. Well, I think that's a fairly wide, broad -- we can maybe take those in steps.

Q. Do you -- do you -- actually, I believe that is your opinion in paragraph 55 of your report.

Do you recall including that statement in your report?

A. If you could show me my report, I'll -- that would be great.

Q. Sure.

If you want to look at the binder.

A. Sure.

Q. And it's in the tab marked RX 549.

And Ms. Durand, if you wouldn't mind publishing this to the screen as well. We're going to take a look at paragraph 55.

A. I'm sorry. What was the tab?

Q. It's the tab marked RX-549, the rebuttal expert report of --

A. I got it now. It was hidden behind the others. Sorry.

Q. No problem.

And paragraph 55 is on page dash -- RX-549.0024.

And Ms. Durand, if you could highlight the last sentence of paragraph 55.

A. Okay. Yes, I see it.

Q. So do you -- you do agree that there is no reliable way of identifying which delivery system or opioid is most compatible with an individual patient

beyond trial and error?

A. Yes.

Q. And not everybody tolerates every opioid?

A. That's correct.

Q. And some individuals may tolerate one opioid better than another?

A. That's correct.

Q. And you have stated that about 50 percent of people don't tolerate the first opioid you try them on; is that correct?

A. Approximately. Yes.

Q. And some people may not be able to take a specific opioid because of other medical conditions?

A. In -- yes.

What we're referring to is, say there is a patient with severe liver disease. In that particular instance, if they really have poor liver function, morphine would probably not be a drug that you'd want to give them. Yes.

Q. And what is it about morphine that would contraindicate it for a patient with severe liver disease?

A. Morphine has a multitude of active metabolites, meaning degradation products in the metabolism that act as active agent. And in liver

disease, when you have a slow metabolism, that means there could be what we call an accumulation of those products in the bloodstream and add to sedation and other adverse events.

Q. And if you only had one long-acting opioid product, approximately 50 percent would fail on a trial of it; is that correct?

A. Yes.

Q. Do you recall stating at your deposition that, quote, if you don't know what you're doing with any of these drugs, you should not be prescribing them?

A. That's correct. I think no practitioner or clinician should ever write for a medication they don't know what the side effects are or the effects are, yes.

Q. So if someone is going to prescribe a long-acting opioid, he should be educated about the drug he's prescribing?

A. He or she should have a working knowledge of that product and the potential side effects, complications, drug interactions, yes.

Q. And that includes an understanding of the potential side effects?

A. That's correct.

Q. That also includes an understanding of how the

drug is dosed?

A. That's correct.

Q. It also includes an understanding of how you approach increasing or decreasing the dose?

A. Yes.

Q. And that also includes an understanding of the particular characteristics of the drug?

A. The individual characteristics, yes.

Q. Earlier today you discussed a program called REMS; is that correct?

A. Yes.

Q. And that is a specific class -- and that is a specific class-wide REMS for long-acting opioids?

A. There is a class-wide REMS for -- that the FDA has initiated for long-acting opioids, yes.

Q. And that is the program you were discussing in your direct testimony today?

A. That's correct.

Q. And the REMS program for long-acting opioids aims to reduce inappropriate prescribing, misuse and abuse of those drugs; is that correct?

A. REMS, as I stated earlier, is -- is meant -- it's meant by the legis- -- you know, the Congress and the legislature to assure that the benefit of the drug exceeds the risks that were perceived.

Q. And the risk that the FDA is concerned about with long-acting opioids is inappropriate prescribing, misuse and abuse of those drugs?

A. I don't -- it's been a while since I, you know, read the reason why they instituted it, but generally, the risks with opioids are as you stated, yes.

Q. And at your deposition in October we looked at one document from the REMS program called the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics.

Do you recall that?

A. I do.

Q. Okay. I'd like to turn back to that document again. It is document CX 3355, also located in your binder.

And Ms. Durand, if we could start at page 3355-001.

And if you could highlight the first two sentences of that paragraph, please.

Oh, I'm sorry. I meant to direct you to the middle paragraph where it's -- after the -- after the two bullet points.

And this reads (as read): FDA developed core messages to be communicated to prescribers in the blueprint for prescriber education (FDA Blueprint),

published the draft FDA blueprint for comment and considered the public comments when finalizing the FDA blueprint. This final blueprint contains the core educational messages.

Do you understand this document to be communicating the core educational messages of the REMS program for long-acting opioids?

A. Basically this is guidance to those that develop an educational program in compliance with the REMS. Yes.

Q. Okay. If you could turn to page CX 3355-006 to 007.

And Ms. Durand, if you could highlight all of that section VI.

And this reads, "Specific drug information for ER/LA opioid analgesic products. Prescribers should be knowledgeable about specific characteristics of the ER/LA opioid analgesic products they prescribe, including the drug substance, formulation, strength, dosing interval, key instructions, specific information about conversion between products where available, specific drug interactions, use in opioid-tolerant patients, product-specific safety concerns, and relative potency to morphine. The attached table is a reference."

Dr. Michna, do you agree that prescribers should be knowledgeable about specific characteristics of the long-acting opioid product they prescribe?

A. Yes.

Q. Do you agree that prescribers should be knowledgeable about the drug substance of the long-acting opioid product they prescribe?

A. I'm sorry. Could you repeat that.

Q. Do you agree that prescribers should be knowledgeable about the drug substance of the long-acting opioid product they prescribe?

A. You mean the drug molecule that's involved.

Q. Yes.

A. Yes.

Q. Do you agree that prescribers should be knowledgeable about the formulation of the long-acting opioid product they prescribe?

A. By "formulation" you mean the length of time that it acts for, yes.

Q. Well, I'm actually just looking at what the FDA says for formulation.

What do you understand them to mean by "formulation"?

A. Formulation is the -- the -- the technical way that the drug is released, so some of the

extended-release formulations release over 24 hours and others over eight hours. That's what I was referring to.

Q. And do you agree that prescribers should be knowledgeable about the formulation of the long-acting opioid product they prescribe?

A. Yes.

Q. And do you agree that prescribers should be knowledgeable about the strength of the long-acting opioid product they prescribe?

A. Yes.

Q. Do you agree that prescribers should be knowledgeable about the dosing interval of the long-acting opioid they prescribe?

A. Yes.

Q. Do you agree that prescribers should be knowledgeable about specific information about conversion between products where available of the long-acting opioid product they prescribe?

A. Yes.

Q. Do you agree that prescribers should be knowledgeable about specific drug interactions of the long-acting opioid product they prescribe?

A. Yes.

Q. Do you agree that prescribers should be

knowledgeable about the use of long-acting opioid products they prescribe in opioid-tolerant patients?

A. Yes.

Q. Do you agree that prescribers should be knowledgeable about product-specific safety concerns of the long-acting opioid product they prescribe?

A. Yes.

Q. And do you agree that prescribers should be knowledgeable about the relevant potency to morphine of the long-acting opioid product they prescribe?

A. Yes.

Q. And Dr. Michna, you don't just prescribe one brand of long-acting opioid, do you?

A. No.

Q. You prescribe several different long-acting opioids?

A. Yes.

Q. You prescribe OxyContin?

A. Yes.

Q. You prescribe methadone hydrochloride?

A. Yes.

Q. You prescribe morphine sulfate ER?

A. Yes.

Q. And that's frequently known as MS Contin?

A. MS Contin was the original brand, but,

you know, now it's generic.

Q. And you prescribe fentanyl?

A. Yes. Fentanyl patch.

Q. And you prescribe oxymorphone ER?

A. Yes.

Q. And you prescribe Hislinga ER, H-I-S-L-I-N-G-A (sic)?

A. Hysingla.

Q. Oh. Thank you.

A. Yes. It's a long-acting hydrocodone product. I believe I've written a prescription for it. I think, as I said in my deposition, that it's a brand-new product. It's very restricted by formularies, so, you know, I think, if I prescribed it, it's been a very small amount.

Q. Okay. But you prescribe the product that you feel is the best for your patient in his or her clinical situation?

A. Yes.

Q. And your priority is the safety and health of your patient?

A. Ultimately, yes.

Q. You also prescribe numerous short-acting opioids?

A. I do.

Q. Do you recall testifying that, quote, I prescribe them all?

A. Yes.

Q. Okay. And if a patient presents a risk of abuse, but the clinical scenario calls for an opioid, you prefer to prescribe morphine or methadone instead of oxycodone, hydrocodone or hydromorphone products; is that correct?

A. That's correct.

Q. And that's your preference because morphine and methadone enter the central nervous system more slowly than oxycodone, hydrocodone and hydromorphone products?

A. That's correct.

Q. And I believe you testified earlier today that you sometimes rotate a patient from one long-acting opioid to another?

A. That's correct.

Q. And you sometimes discontinue opioid therapy altogether; is that correct?

A. Certainly. Yes.

Q. But generally speaking, you can't just abruptly stop treatment with a long-acting opioid?

A. Well, you can if it's at a very low dose.

Q. But in other situations you need to wean the

patient off of a long-acting opioid?

A. Certainly. Obviously, there are clinical scenarios when the risk to the patient is such that, you know, you totally stop the medication, as you can understand, if there's a significant change in their health, they end up in an ICU unit, they're on a ventilator, they're no longer taking oral opioids, and they have some condition where you're worried about saving their life, not giving them pain medicines, so in those situations you can abruptly stop the medicine.

Q. But in other situations, your practice is to wean a patient off of a long-acting opioid?

A. Again, unless there's a clinical scenario that would prohibit that.

Q. Okay. But generally, in your practice, you do wean a number of your patients off of long-acting opioids.

A. Certainly. Yes.

Q. And why is it that you wean them rather than abruptly stopping treatment?

A. Well, depending upon the dose and the amount of time that a patient has been exposed to an opioid, they become what I described earlier as tolerant to that medication. And if you abruptly stop the

medication, they will go through a withdrawal syndrome.

And if you want me to describe that, I will, but --

Q. Yes, please.

What is withdrawal syndrome?

A. When you abruptly -- I mean, the opioid acts throughout the body and it has various effects. We already talked about constipation, so when you abruptly stop an opioid, you can get diarrhea. You can get nervous chills. You can get anxiety associated with it.

Q. It may resemble a severe flu-like illness?

A. They get body aches and pains. Yes.

Q. And it is your opinion that patients can be safely switched to a new long-acting opioid, quote, assuming the switch is performed slowly and with the proper understanding of the medications; is that correct?

A. Yes.

Q. And you agree that it's important to follow the proper steps and protocols when switching a patient's long-acting opioid?

A. Well, I'm not sure what you're referring to, protocols. There are really no protocols. It's

clinical acumen I would say and experience. There isn't a stepwise approach. You have to use your experience.

And again, it all depends on the patient, the clinical scenario, how high the dose is and how long the patient has been on it, determines how quickly you can wean somebody from an opioid.

Q. Do you agree testifying at your deposition that, quote, if you follow the proper steps and protocols that I described earlier, you know, it can be an uneventful process?

A. Yes.

Q. Dr. Michna, what is a conversion table?

A. It was -- pertaining to opioids obviously; right?

Q. Yes. Thank you.

A. It's a table that was developed using healthy males, and it was an attempt to try to make an estimate of equivalency in terms of the effectiveness and the pain-relieving abilities of one opioid to another.

Q. And they use morphine as the universal metric for conversion?

A. I believe it -- it's -- it's termed the morphine equivalence. You have to pick one agent, and

I guess they picked morphine, so they compare the equivalency of the other opioids versus morphine since it's been around probably the longest.

Q. And those conversion tables are still based solely on studies in healthy, young males?

A. Yes.

Q. So the conversion tables are not always precise?

A. Which is why I explained -- yes. Which is why I explained that we always, you know, cut them in half and then even, you know, based again on our feelings, we might even go much lower than that.

Q. So the conversion tables are more of a framework or a best estimate?

A. They're a place to start. And then, as I said, for safety concerns, and you know, we always err on the side of safety, right, so we'll dose at a much lower level than that, again, because a lot of times people might respond even at the lower level where they're at a different level with the other medication.

Q. Are you familiar with the term "incomplete cross-tolerance"?

A. I am.

Q. And what does that mean?

A. Well, it describes, much like I was just

speaking about, where just because opioids are equivalent based on this table doesn't mean that the patients will respond the same at that dosing, so it might require more of the medicine or it might require less, so when you go from one opioid to another, it's unknown at which level you're going to get a therapeutic response.

Q. And I believe earlier today you testified that in a relatively simple case you would start by cutting the opioid prescription in half -- or I'm sorry -- the dosage in half from their current opioid to the new opioid?

A. What I described is, when you have a very low dose of medication, that for the new opioid you'd use that table as a framework, and usually we would at least cut it in half. And again, there might be clinical scenarios we would even go much lower than that. Yes.

Q. And then how do you -- what's the next step after cutting it in half?

A. Well, you give it to the patient.

Q. And is that the end of the process?

A. Well, it may be. If that patient reports that they're having adequate pain relief and they're doing well, that's the end of the process.

Q. And if not?
A. Then it might require an evaluation to see, you know, if the patient is in pain, no side effects. The next step might be to increase the dose of the medication.
Q. And in a patient that was on a moderate to high level of a long-acting opioid, how would your process differ?
A. Again, it depends on the clinical scenario, but typically what we would do is -- you can switch one to the other, but I tend to -- using the same approach we've described before, on very high doses, I tend to start the new opioid at a very low dose and decrease the old opioid down and at the same time providing short-acting or immediate-release opioids as a buffer in case we're underdosing the patient too much.
Q. And then you would slowly decrease the original opioid and gradually increase the new opioid?
A. Well, again, it depends on the dose. It might be, you know, you know, one or two steps or it might be a few more than that. It depends on the dose.
Q. Okay. And for a patient that has been on a long-acting opioid for a very long time at high levels, do you recall testifying at your deposition

that the conversion for those patients might need to be done in an inpatient setting?

A. If you're going to take them totally off the medicine, there are some people that just can't wean -- we're talking about weaning. That was an example of weaning off of opioids I believe.

And when a patient can't as an outpatient wean because they just -- for anxiety reasons, for a multitude of reasons, they just can't tolerate it, it might require inpatient detoxification, yes.

Q. I'm sorry. At your deposition did you not call that switching or down-titrating, that that would be the process?

A. No. I believe that was a specific example of when somebody is on a high dose of opioids and we were taking them totally off opioids.

We don't admit people when we're switching opioids.

Q. And opioids act to relieve pain by binding to opioid receptors that are found mainly in the central and peripheral nervous systems and the GI tract; is that correct?

A. Yes.

Q. And are you familiar with the term "subtype differences"?

A. There are mu receptor subtype differences, correct.

Q. And what are those?

A. There are a number of these receptors that are of different, you know, entities and proteins basically.

Q. And different people have different mu receptor subtypes; is that correct?

A. They have different ones and they change with time.

Q. And can they also change with exposure to an opioid over time?

A. They can, yes.

Q. And the differences in subtype -- mu receptor subtypes from one person to another is what is thought to explain some differences in how we react to different opioids?

A. It's -- it's -- yes. It's a possibility. I don't know how proven it is, but the thought is that that might explain some of it. Yes.

Q. And to switch a patient from branded Opana ER to generic oxymorphone ER, you would not need to go through a -- to switch a patient from branded Opana ER to generic oxymorphone ER, you would not need to down-titrate a patient and go through the rotation

process; is that correct?

A. Typically, because it's the same molecular entity, we would probably not engage in that, but, as I also testified, you know, there's variability in generics in terms of patients' responses, so, you know, they might get less pain relief or they might get slightly more, depending on the product.

Q. But you would start by doing a one-to-one conversion?

A. Typically I would, yes.

Q. And Dr. Michna, you do not keep track of the prices of long-acting opioids; is that correct?

A. On a daily basis, no.

Q. So you are not aware of fluctuations in price for any specific brand drug of opioid?

A. Well, I'd be -- I'd be aware of it if there's dramatic changes because the -- you know, the insurance coverage would certainly change.

Q. So you're aware of dramatic changes but not of fluctuations in price.

A. Unless it is -- clinically impacts, meaning there's a change in the tiering because of that or drug availability to the patient or a patient's copay, which I'd certainly hear about.

Q. And that's what at your deposition you deemed a

dramatic event?

A. Dramatic changes. Yes.

Q. And you don't know all the formularies of your patients' insurers?

A. I don't think anybody knows all the formularies.

Q. You don't pore through the formularies?

You don't pore through the formularies?

A. Maybe if I wanted to go to sleep at night, but no, I don't pore through the formularies.

Q. And your experience is specific to Massachusetts?

A. I only have practiced in Massachusetts. Yes.

Q. And I believe at your deposition you testified that Massachusetts has a long history of managed care?

A. That's correct.

Q. And that Massachusetts has a reputation for being aggressive in formulary management?

A. I think I was referring to the -- what I referred to before, the MassHealth formulary has -- was historically one of the first to really be restrictive.

Q. And what is MassHealth?

A. It is the state Medicaid of Massachusetts.

Q. I'd like now to look at a few passages in the

expert report of Dr. Seddon Savage. In your binder, that is CX 5002.

And Ms. Durand, if you could turn to page CX 5002-007.

In looking at paragraph 12, Dr. Savage writes, in this first sentence, "The experience of pain and its treatment is highly individual."

Dr. Michna, do you agree with that statement?

A. Well, I agree to the fact that patients' responses to medications vary, yes.

Q. Do you disagree with anything in that statement?

A. Well, if you're talking about the experience of pain, I mean, that can vary, but, you know, to use the term "highly individual," I'm not sure I agree with that exact term. But bottom line is, we all experience pain differently, and we respond to therapies differently. Yes.

Q. And looking at the next sentence, Dr. Savage writes, "Pain patients differ significantly with respect to their experience of pain in response to different potentially painful stimuli (such as injuries, illness or strains)."

Do you agree with that statement?

A. Well, it goes with the prior statement that we

all respond differently to pain and the experience of pain.

Q. So you agree with that statement?

A. Yes.

Q. And she continues, "This is due to numerous variables including biogenic predisposition, prior pain experiences, psychosocial differences, medical comorbidities, and environmental context."

A. Yes.

Q. Do you agree with that statement?

A. I do.

Q. Ms. Durand, if you could -- you're a step ahead of me, but I actually just -- actually, that's fine.

Looking at paragraph 13, we're going to start a little bit in the middle of the paragraph.

On the fourth line, she writes, "When drugs are used in pain treatment, it is important to understand that there are also notable differences among individuals with respect to their responses to different drugs."

Do you agree with that statement?

A. I'm sorry. I was trying to find it.

Q. Oh, I'm sorry.

A. That's okay. I'll look on the screen.

Q. Would you like me to read it again?

A. No. I can read it myself. Thank you.

(Document review.)

Again, it's what we've said before, that patients respond differently to different medications. Yes.

Q. And she continues, "This is due to individual variations in molecular binding, as well as cellular and other host responses to the drug (pharmacodynamic effects)."

Do you agree with that statement?

A. Well, I think it's due to more than that. I think we -- in her first statement she went through the whole list. It's biogenetics, which is, you know, your disposition, your prior pain experiences and your psychosocial issues, your comorbidities, your environment, how you grew up, who your parents were, so I don't want to limit it just to that.

Q. So not limiting it just to that, you would otherwise agree with --

A. Otherwise, yes --

Q. Okay.

A. -- if we're thinking about the whole inclusive thing.

Q. And continuing into her next statement, "There are also variations in absorption, distribution and

metabolism of drugs (pharmacokinetic effects) as well as other factors such as psychological status, expectations, or drug tolerance that may affect drug responses."

Do you agree with that statement?

A. That's true. Yes.

Q. And she continues, "As such, treatment of each pain patient must be individualized and tailored to the unique needs of the individual."

Do you agree with that statement?

A. In general. I mean, if -- well, you know, "individualized" meaning should we use opioids at all or should we not, should we use injection therapy for that patient, should we not use any medicine, should we use medicines that work on a neuropathic, so I would agree on a global standpoint that's what we mean by "individualization of care."

Q. Do you disagree with anything in that statement?

A. Based on the context that I just said, yes, I agree.

Q. Yes, you do disagree with something in that?

A. No, no. I agreed but with the caveat of what I just said, in the context of what I just said.

Q. Okay. Thank you.

Now, moving on to paragraph 16, which is on CX 5002-008, and Dr. Savage writes, "Combined with the significant individual variation in pain patients and in the types of pain they experience, this means that individual patients may respond differently to different long-acting opioids."

Do you agree with that statement?

A. That's correct. I mean, again, this is the same statement over and over again. This is about individualization of care and the fact that we respond differently and that certainly we respond differently for all the reasons that we've said before.

Q. And she continues, "And it is difficult to predict how a given patient will react to any given drug."

Do you agree with that statement?

A. That's correct.

Q. You can set that aside. Thank you.

A. Okay.

MS. SCHMIDT: Your Honor, may I have a moment to confer with counsel?

JUDGE CHAPPELL: Go ahead.

MS. SCHMIDT: Thank you.

(Pause in the proceedings.)

I have no further questions, Your Honor

JUDGE CHAPPELL: Any redirect?

MR. ANTALICS: No, Your Honor.

JUDGE CHAPPELL: Thank you. You may stand down.

THE WITNESS: Thank you.

JUDGE CHAPPELL: Next witness.

(Pause in the proceedings.)

Progress report? Where's the witness?

MR. HASSI: I hope he's in the office down the hall. I'll go check, Your Honor.

(Pause in the proceedings.)

Your Honor, it's going to be a couple minutes. They stepped outside and they're coming through security.

(Pause in the proceedings.)

(Discussion off the record.)

MR. HASSI: Sorry for the delay, Your Honor.

Respondents call Dr. Sumanth Addanki.

My colleague, Steve McIntyre, will be doing his direct examination.

- - - - -

Whereupon --

SUMANTH ADDANKI

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

MR. McINTYRE: May it please the court.

- - - - -

DIRECT EXAMINATION

BY MR. McINTYRE:

Q. Dr. Addanki, can you please introduce yourself by stating your full name for the record.

A. My name is Sumanth Addanki. That's spelled S-U-M-A-N-T-H A-D-D-A-N-K-I.

Q. And Dr. Addanki, can you please tell the court about your educational background.

A. I grew up and went to college in India, where I studied economics and engineering. I got my master's degree in economics in India. I worked for the government briefly for the planning commission in India. And then I came to this country in 1980 to join the Ph.D. program at Harvard.

Q. And can you please describe your studies at Harvard.

A. At Harvard I had two fields of specialization, econometrics, which is the use of statistics and statistical methods to analyze economic data, and the other field was finance, which is the study of capital markets.

I also worked during my time at Harvard on a large project funded by the National Science Foundation,

where we studied the research and development activities, patenting, R&D expenditures, and the like, of firms both in the U.S. and abroad.

Q. And Dr. Addanki, did you do any teaching while you were at Harvard?

A. Yes, I did. Throughout my tenure at Harvard. I taught first as a teaching assistant and then as an instructor on the faculty. I taught econometrics and statistics.

Q. And what degree did you receive from Harvard?

A. I received my Ph.D. in economics in 1986.

Q. Dr. Addanki, I want to turn to the first exhibit to your report. Your report is in evidence as RX 547. And this should be in the first tab of the binder that is placed next to you on the table.

We're going to turn to RX 547.0089.

Do you recognize this document, Dr. Addanki?

A. Yes, I do. It's my CV.

Q. And what is your current position?

A. Well, I'm a managing director at NERA Economic Consulting. And NERA is also known as National Economic Research Associates.

I've been there for 31 years. I was called a senior vice president before this, but then someone changed all the titles, so now I'm known as a managing

director.

Q. And generally, what does NERA do?

A. NERA is a firm of applied microeconomists, which means that we do research and do consulting and study the way firms interact with one another in markets, how firms interact with customers in markets, and how market outcomes then get shaped by those interactions.

Q. And do you yourself specialize in any particular kinds of economic inquiry?

A. Yes. Within the field of applied microeconomics I have three areas of specialization.

The first is the economics of antitrust and competition policy.

The second is the economics of intellectual property.

And the third is the economics of calculating patent damages or other kinds of economic damages.

Q. And have you lectured or published articles in these areas?

A. Yes, I have.

I wrote some of the early treatises on the calculation of economic damages in patent infringement cases.

I've written a number of articles and given a

number of speeches and lectures on various of the areas of specialization and various combinations of them.

A past chairman of the Federal Trade Commission invited me to testify at hearings they were holding on innovation-based competition in a global economy, and I gave that testimony.

I have -- I've been invited to speak and lecture on these subjects on numerous occasions.

Q. And who, generally speaking, are your clients at NERA?

A. I have different kinds of clients. For the most part, they're corporations, large and small, both U.S. corporations and foreign ones.

I have worked for government agencies.

I've worked for nonprofit entities, trade associations, and occasionally even private individuals.

Q. Can you tell us a bit more about your work for government agencies?

A. Certainly.

I've been retained several times by the U.S. Department of Justice, by their Antitrust Division, to serve as the outside expert, the economic expert, for cases that they were planning to take to court, either

investigating a merger or investigating various kinds of conduct of firms.

I helped the FTC prepare for trial in a merger case it was bringing to court where it was challenging a hospital merger.

I've worked for --

JUDGE CHAPPELL: Which case was that?

THE WITNESS: Sorry?

JUDGE CHAPPELL: Which case was that?

THE WITNESS: This was Poplar Bluff, Your Honor.

JUDGE CHAPPELL: What state is Poplar Bluff in?

THE WITNESS: Poplar Bluff is Missouri.

JUDGE CHAPPELL: I didn't hear you.

THE WITNESS: Missouri.

JUDGE CHAPPELL: Missouri?

THE WITNESS: Yes.

JUDGE CHAPPELL: When was that? A few years ago?

THE WITNESS: I believe that was in 1997.

I was not the trial witness. I was helping the trial witness in that case.

JUDGE CHAPPELL: That was before my time. Thank you.

THE WITNESS: I have then also worked for state AGs, state agencies, for New York and New Hampshire, serving as an antitrust expert.

I've worked for the Canadian government on a couple of occasions serving as an economic expert.

BY MR. McINTYRE:

Q. And I believe you mentioned intellectual property and economic damages as two areas of specialization.

Do you have any experience calculating economic damages in patent infringement cases?

A. Yes.

In addition to writing some of the early articles on the economics of calculating these damages, I've actually calculated them on numerous occasions and testified about them in federal court on numerous occasions.

Q. And what experience do you have with the pharmaceutical industry?

A. Well, the large project I worked on at Harvard when I was a graduate student, because it was studying the R&D and patenting activities of firms, and because the pharmaceutical industry is probably one of the most prolific in terms of patenting, it was a focus of our investigations and our study.

So my study of the pharmaceutical industry goes back decades. I'd say that really in the last 18 years I've spent a great deal of my time studying various aspects of the pharmaceutical industry and in my consulting and my writing.

Q. You just mentioned your writing.

Have you published any articles on this topic?

A. I've published several articles on various aspects of the economics of the pharmaceutical industry.

And most recently, Cambridge University Press brought out a handbook of intellectual property antitrust, and I was invited to contribute the chapter on pharmaceutical antitrust, which I did do, and that book came out I believe early this year.

Q. And have you provided any expert testimony on pharmaceuticals?

A. Yes, I have.

Probably most relevant I testified before the Senate judiciary committee on the economics of brand and generic pharmaceutical competition, and that was about four years ago.

I've also testified on numerous occasions in state and federal courts about matters having to do with pharmaceuticals, pharmaceutical antitrust, as well

as other issues in pharmaceuticals.

Q. You mentioned testifying before the Senate judiciary committee.

Who was it that invited you to give that testimony?

A. So that was actually by invitation of the judiciary committee itself, and I was told that I was being asked to testify to provide my views as an expert on the subject.

Q. Have you provided any other expert testimony on pharmaceutical -- on the pharmaceutical industry?

A. Yes.

In addition to what I just said about testifying in federal and state courts, I testified here, in this very courtroom, in a case involving reverse payment settlements in the pharmaceutical industry that was the FTC v. Schering-Plough about 15 years ago I think.

And I've testified in various arbitrations in the U.S. and abroad, as well as in federal court in Australia on pharmaceutical antitrust, and in Canada before a tribunal on pharmaceutical pricing.

Q. In the Schering-Plough case who did you testify on behalf of?

A. That case was one where the FTC had sued

Schering-Plough and Upsher Smith, were the parties that actually went to trial with the FTC, and I appeared here as a trial witness on behalf of Schering-Plough.

MR. McINTYRE: Your Honor, respondent hereby tenders Dr. Sumanth Addanki as an expert in the economics of antitrust, intellectual property, and competition in the pharmaceutical industry, and respondent submits that he is qualified by reason of his academic credentials, his research and publications, and his substantial experience consulting and testifying as an expert in these fields.

JUDGE CHAPPELL: Objection?

MR. LOUGHLIN: I just want to understand.

Did Mr. McIntyre mean that he's an expert in the economics of intellectual property or intellectual property?

MR. McINTYRE: We are tendering him as an expert in the economics of intellectual property.

MR. LOUGHLIN: We have no objection to that, Your Honor.

JUDGE CHAPPELL: All right. Any opinions that meet the proper legal standards will be considered.

MR. McINTYRE: Thank you, Your Honor.

BY MR. McINTYRE:

Q. Dr. Addanki, can you please briefly describe your assignment in this case.

A. Yes. Of course.

I was asked to review the FTC's allegations in this case, to provide the appropriate economic framework, a description of the appropriate economic framework, within which to analyze those allegations, to actually apply the appropriate economic methodology in that framework and evaluate whether in fact the settlements at issue here -- the settlement at issue here was anticompetitive and to comment -- to review and comment on the opinions of Drs. Noll and Bazerman.

Q. And have you performed those assessments and reviews that you just described?

A. I have.

Q. And without stating the substance of your opinions, have you reached any conclusions based on your work?

A. I have.

Q. And do you hold your opinions in this case to a degree of certainty that is reasonable for someone in your professional field?

A. Yes, I do.

Q. And Dr. Addanki, I just want to begin by asking

this question.

Based on your experience and knowledge of the economics of the pharmaceutical industry, can agreements that settle patent litigation between a brand company and a generic company ever be anticompetitive?

A. Absolutely, yes.

As I've written about and testified on numerous occasions, whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it.

And if you perform that analysis, you can reach a conclusion about it. But there is no knowing beforehand, before you do that analysis, whether a given settlement is going to be pro- or anticompetitive.

Q. So what then from the economic perspective is the appropriate test for determining whether a particular settlement is anticompetitive?

A. Well, it's really not any different from what we would do in any kind of rule of reason antitrust

case.

From the economic standpoint, the first step in the analysis of a case of this kind is to assess whether the patentee, the brand drug manufacturer in a case like this, possessed monopoly power.

That's because, from the economic standpoint, settlements of this nature are only anticompetitive when they preserve or enhance monopoly power that already exists or create monopoly power that didn't exist. When there isn't monopoly power, we don't need to inquire any further. The settlement will not be anticompetitive.

Q. And this first step you just described, looking at monopoly power, is that sometimes referred to as the monopoly power screen?

A. That's exactly what it's called. Yes, sir.

Q. And why is it important that we apply that step in analyzing settlements like the one at issue in this case?

A. Well, because, as I've said, we know what monopolists do. When a firm has monopoly power, it restricts output, charges monopoly prices, all of which harm consumers.

Now, if we believe that that monopoly power is being -- has the potential to be enhanced or preserved

through a settlement, then we want to look further and see if it was.

But if there is no monopoly power to start with, there's really no reason to inquire any further, because the last thing we want to do is spend our time second-guessing the agreements and settlements and contracts into which firms without monopoly power are entering into, because it's a huge waste of resources.

And in any event, settling litigation, patent litigation, can be procompetitive and generally a good outcome to begin with.

Q. So I believe you said that the first part of the analysis would be applying the monopoly power screen.

What would we do next?

A. Well, again, as I said, if you find that there's no monopoly power, we stop there because there's no reason to proceed any further.

If you find that there has been monopoly power or there was monopoly power at the time of the settlement, more precisely, then we move on to the second prong of the test, which is to ask whether that monopoly power would have been more effectively or completely dissipated absent the settlement than it was with the settlement.

And so what that involves is really understanding what the world would have looked like had the settlement before us not occurred and in that alternative world, which we economists sometimes refer to, Your Honor, as the but-for world, in that but-for world, the world but for the settlement, would the monopoly power that you've found have been dissipated more completely or more effectively than it has been actually under the settlement.

Q. Could you give us an example to help us understand how this inquiry works in practice.

A. Certainly.

In a case of this nature, a simple example might be one in which really the completeness and effectiveness with which the monopoly power is dissipated hinges entirely on a question of when would the generic entry have occurred.

So in that case, in that simple case, the inquiry resolves itself, Your Honor, into just a simple question: Would entry have occurred but for the settlement sooner or later? And in that simple case, if it would have occurred sooner but for the settlement, then you can conclude that the settlement was anticompetitive.

And if in fact settlement would have occurred

later but for the -- pardon me -- entry would have occurred later but for the settlement, you can infer that the settlement was actually procompetitive.

Obviously, if the case is more complex than that, you need to perform further analyses, but that would certainly be the test in a simple case.

Q. And is this the same test that you have applied when analyzing such agreements in the past?

A. Yes, it is. Because essentially the analysis of -- the economic analysis under the rule of reason hasn't changed for decades. It is -- this is the way we approach it.

And even though I understand that the law has gone through some -- some twists and turns, this is the approach that I have adopted as an economist, and it's the same approach I described in the Schering-Plough case 15 years ago.

Q. And just to be clear, Dr. Addanki, is your test the same as Dr. Noll's three-part test?

A. No, it is not.

Q. Okay. Then I want to talk a little bit more about applying this test.

First of all, how do we evaluate whether there was monopoly power?

A. Well, as in any antitrust case of this kind, we

start with defining the relevant market and assessing competitive conditions within that market.

Q. And when we're analyzing a relevant market in a case involving pharmaceuticals, are there any special considerations we need to take account of?

A. Well, as a matter of fact, given the institutional idiosyncrasies I would say of the pharmaceutical industry, there absolutely are.

And we need to pay particular attention to these institutional features of the pharmaceutical industry because they have a profound effect on how we analyze competition and competition issues. And it's very different from how we might approach it in an everyday case that doesn't involve pharmaceuticals, that involves some other kind of consumer product.

Q. You referred to institutional features of the pharmaceutical industry.

Can you please describe further what you mean by that.

A. I'd be happy to. I've prepared a couple of demonstratives that would help illustrate what I'm talking about and help me perhaps through this, through this discussion. If I may have the first one?

Q. Sure.

And do these demonstratives explain opinions

that are expressed in your report?

A. Yes, they do.

Q. We can go ahead and put up RDX 15.

Is this one of the demonstratives that you just described?

A. Yes, it is.

Your Honor, I'm distinguishing here two different purchasing decisions, the bread purchasing decision -- for people who are not following some sort of gluten-free diet, it's a very familiar purchasing decision -- and I'm going to contrast this both from the standpoint of the characteristics of the decision itself and from the standpoint of how those characteristics are going to influence how we have to analyze this from the economic standpoint, distinguish it for those two -- on those two bases from what happens in a pharmaceutical purchasing decision.

So just -- and one of the reasons I picked bread is because that is actually one of the industries for which the Department of Justice has hired me as their outside expert and I happen to know a fair amount about the industry and I've done a great deal of analysis of the industry.

But the industry -- the purchasing decision for bread, Your Honor, is very straightforward. I, the

consumer, go to the store, scan the shelves of the bread aisle. And if I had a favorite brand, I will see if it's on sale, and if it is, it's a lucky day for me I pay the price, take my bread, go home and eat it or feed it to my family.

Alternatively, it may be that I have a second or third favorite brand, and if those are on sale, I might opt to buy one of those instead of my favorite brand and, again, pay for it, take it home and consume it.

So I am the consumer, the person who's going to consume the bread, I am the decision maker, the one who chooses which bread to buy, and the payer, the one who pays for the bread, all rolled into one. And this is the typical case of the consumption decision in most, the overwhelming preponderance, of what we're familiar with.

Now, when I'm analyzing competition in this industry, Your Honor, the manufacturer -- I know what the manufacturer is going to do. They're going to try to convince me to buy more of their bread, and they're going to do it possibly in a couple of different ways. They're going to hold price promotions.

So if Arnold bread wants to compete with Pepperidge Farm bread, they may send me a coupon,

particularly if there's been checkout information suggesting that there's a lot of Pepperidge Farm bread being purchased at this store. They may send coupons, put them in the store, send them to me.

Alternatively, they may introduce new flavors and send me a mailing or put an in-store display saying try the new flavor.

So whether it's price competition or non-price competition, it's targeted to the consumer because the consumer is really the decision maker, the payer and the consumer all in one.

Now, the situation is really quite a bit different in the prescription pharmaceutical case.

And if we could have the next demonstrative, please.

Q. Sure. Why don't we put up RDX 16.

And is this the demonstrative you just referred to?

A. Yes, it is.

Q. Can you please walk us through this.

A. And clearly, Your Honor, this is more complicated, and frankly, this is actually simplified from the actual realities on the ground, but it has the salient features that we need to focus on.

So, again, I'm the patient over on the extreme

right. And just to fix ideas a little bit, I need to be treated for an acne condition, and I'm probably going to be prescribed antibiotics for it.

Now, I don't go to a pharmacy and buy antibiotics and go home and consume them. That's not the way it works, as we know. I go to a physician, a healthcare practitioner of some kind -- I've called them prescribers here because even though the preponderance of them are indeed physicians, it's increasingly common for there to be nurse practitioners and physician assistants actually writing prescriptions.

So the prescriber writes the prescription, gives it to me, and I take it to the pharmacy. And at the pharmacy, the pharmacy is going to get in touch with my insurance, because the reality of the prescription pharmaceutical industry is that very few prescriptions are paid for entirely out of pocket by the patient. There's going to be insurance of some kind, a prescription plan of some kind, whether it's through a commercial insurer, through Medicare, Medicaid, a pension, you know, a union, a retirement benefit, whatever it is.

And the pharmacy is going to do whatever transaction it does with the insurance company and then

tell me, Okay, Dr. Addanki, your copay is $10, please -- here's -- here's your medicine. And I take it home, and I take my doses, and then I report back to the physician.

Now, in this situation, there are so many different entities involved, right. The decision maker is not me, the patient. It's the prescriber who's making the prescription decision in the first place.

I do pay a portion of the payment, but the bulk of the payment is borne by a third-party payer, the insurer or the -- you know, one of their agents.

So we have a complete disjunction, Your Honor, among the three roles that are all combined in one in the bread purchasing decision. The consumer, the decision maker and the payer of most of the cost are all disjointed. They're three different entities.

And so when we analyze competition in this business, there are in fact very different layers of competition, many of which don't actually impact me, the patient, at all. There is instead competition among drug manufacturers competing with one another for the prescribers' attention. And there's competition among drug manufacturers for favorable treatment by third-party payers.

Focusing on the prescribing competition for a moment, Your Honor, I don't as a patient observe most of what happens here, but I as an analyst can look at it.

And the drug manufacturers compete in a variety of different ways -- and I'm speaking here about brand drug manufacturers. We'll get into generic manufacturers later. The brand drug manufacturers are competing in a variety of different ways to get the prescribers to prescribe their medicines rather than competing therapeutic alternatives.

And they will provide -- and it depends on the therapeutic category. But they may provide information. They may provide clinical information, clinical research. They may provide samples. They may provide things that would help aid patient compliance, you know, patient assistance of some kind.

So there are a variety of different things that the drug manufacturers do to compete for the physicians' attention, for the prescribers' attention.

Q. And Dr. Addanki, you just described how drug manufacturers will compete at the prescriber level.

Are there other important layers of competition that we need to analyze in cases involving pharmaceuticals?

A. Yes, indeed. And this is a very important layer of competition.

Drug manufacturers, when they're competing with other therapies for the treatment of a condition, will also compete very vigorously in many instances for favorable formulary coverage with insurers, with third-party payers.

Q. You just mentioned formulary coverage.

Can you please explain to us what a formulary is.

A. Yes. A formulary, Your Honor, is just a way that -- and we've probably heard about this already in the court, in court in this case. They're simply how insurers promote competition among prescription pharmaceutical suppliers and control costs.

So the formulary is simple enough. It is simply the list of pharmaceuticals that for which the insurer will actually reimburse pharmacies if one of the covered lives under the insurer's plan presents a prescription for one of those drugs.

That doesn't mean that the formulary treats all of those -- all of those drugs on the formulary the same way, because the formularies also have tiers. And the tiers, spelled T-I-E-R-S, represent the degree to which, from an economic standpoint, the payer, the

insurer, is favoring one product over another.

So tier one is the most preferred tier from the economic standpoint. And tier one, the preference is expressed -- that economic preference is expressed, Your Honor, in the way the costs are shared between the insurer and the patient.

So for a tier one product the patient is going to have the lowest copayment, so in other words, that is the most attractive from the patient standpoint in terms of how much the patient, he or she, is going to pay at the pharmacy.

And a tier two product, correspondingly, is going to involve more payment on the patient's part and less, proportionately, payment on the insurer's part, a tier three further still.

And a product may even be on tier four for some formularies or not covered at all, in which case the patient is going to pay, should he or she choose, the entire cost.

And this is the mechanism that insurers use to promote competition and lower costs for therapeutic categories in which there are therapeutic alternatives freely available.

Q. Can you explain further how formularies promote competition?

A. Well, what they do is, if they recognize a therapeutic category -- and this is from my decades of experience studying the pharmaceutical industry -- in a therapeutic category in which there are good alternatives available, basically the insurer will invite the manufacturers to provide bids about what kind of rebates the manufacturer is going to be willing to give back to the insurers for the use of that manufacturer's product by covered lives under the insurer's plans.

So it's an accounting system through which they actually measure and monitor how much use there's been, so if we're talking about antibiotics for acne and we're talking about one of the manufacturers selling a doxycycline product, that NDC, the use of that NDC, will actually be monitored, and rebates will be paid on the basis of how many pills were consumed by this insurer's covered lives.

And so what the insurers do is invite manufacturers to bid. And the motivation on both sides is a carrot and a stick, because the insurer says, if I put you on tier two, which is the most favored brand tier on a formulary, you will get lots of volume because of the way the copayment arrangements work. The prescriptions will be driven to you, the

tier two brand. And if I like your deal, I'll put you on tier two. Give me a good price and you'll get the volume. If I don't like your price, I may put you on tier three or tier four or even block you, in which case you're not getting any of the prescriptions, so if your price isn't keen enough, you're not going to get the volume.

Q. Does this process that you just described -- does it happen much in the pharmaceutical industry?

A. It happens all the time. It's a fact of life in the pharmaceutical industry.

JUDGE CHAPPELL: You referred to these as rebates. It doesn't sound like in your description you're talking about rebates. It sounds like you're talking about an agreed sales price or a purchase price.

Why are you talking about rebates?

THE WITNESS: Because, Your Honor, the insurer never takes possession of the product, right. The product doesn't pass through the insurer. The insurer is only doing payments, right.

So they are paying -- they're going -- maybe I can use an example.

If you've got a pill that costs a dollar at the list price, the pharmacy is going to pay close to a

dollar for the pill of that -- or for that pill.

Likewise, when the pharmacy is reimbursed, because you can't really have the pharmacy being out of pocket for the pill, the insurer, between the copay and the insurer's payment, is going to reimburse a dollar or so for that pill, a little more because the pharmacy has costs.

So what's happening is, you may get 40 cents back as a rebate from the drug manufacturer to the insurer to defray part of that dollar. And that's how it actually works in practice.

JUDGE CHAPPELL: So even though it's a rebate, the agreed price is 60 cents, not a dollar.

THE WITNESS: Absolutely.

So it is a net price reduction. Absolutely. But it's -- it's expressed in the form of a rebate because there isn't a physical transfer of title to the product, you know, of the pills themselves ever to the insurer, so the payments work just exactly like a net price reduction.

JUDGE CHAPPELL: In your example, the pharmacy is paying a dollar.

THE WITNESS: Yeah.

JUDGE CHAPPELL: To the insurance company?

THE WITNESS: The pharmacy is paying the dollar

to buy the drug.

JUDGE CHAPPELL: To the supplier?

THE WITNESS: To the supplier. And it typically goes through a wholesaler, but that's just a detail.

JUDGE CHAPPELL: So the profit, in your example, is made more by the insurance company than the pharmacy.

THE WITNESS: Well, Your Honor, the insurance company never buys the pill, right, so it's really a question of they are getting insurance premiums for which they have to provide benefits, coverage benefits.

JUDGE CHAPPELL: Okay. I'm following.

So you're saying no money goes to the insurance company.

THE WITNESS: No money from the pills goes to the insurance company except the rebate, right.

JUDGE CHAPPELL: If there's none going to the insurance company and there's this rebate of 40 cents in your example, where does that 40 cents come out of the dollar for whoever is paying for the drug?

THE WITNESS: Absolutely.

So the insurance company is paying a dollar, right. What's happening is the dollar payment they're

making for that pill --

JUDGE CHAPPELL: I thought you said the insurance company doesn't pay anything.

THE WITNESS: Sorry, Your Honor. They agree with the pharmacy.

So the pharmacy buys a pill. They fill the prescription. The insurance company plus the patient is reimbursing the pharmacy for the dollar, right.

And so there is a payment -- so the pharmacy is whole, right, because the pharmacy bought the pill, bought the pill for a dollar. They're being made whole because they've got the dollar. And the insurance company is out of pocket a dollar. Let's assume -- put aside the copayment for a moment, right. They're paid for the pill. And that 40 cent rebate or 60 cent or whatever it is reduces the effective cost to the insurance company for having bought the pill.

So what Your Honor said in the beginning is probably actually the right way to think about it. They are in fact paying for pills, but they're paying their reimbursement price that they pay the pharmacy less the rebate.

JUDGE CHAPPELL: So the insurance company is paying someone. They're not paying the drug maker. They're paying the pharmacies.

THE WITNESS: Yes.

BY MR. McINTYRE:

Q. But I believe you mentioned ago that these third-party payers, the insurance companies, invite the drug manufacturers to bid; is that right?

A. Right.

Q. And how do the manufacturers respond?

A. Well, again, as I said, because there is this carrot and stick involved, they will typically respond. It varies from case to case. You know, a manufacturer may decide that it doesn't want to bid for that insurer's business. But typically, they're going to respond with some offers, and the insurance company will then evaluate those offers. And sometimes that process goes back and forth between the insurance company and the manufacturers.

Q. So there are actually negotiations between the drug company and the insurance company?

A. There absolutely can be and these happen typically every year.

Q. Do you see this process playing out for all drugs?

A. No, you don't in fact see it play out for all drugs. It -- in some therapeutic categories you see it a lot, in some categories you see it less, and in some

categories you may not see much of it at all.

Q. So what can you infer as an economist when you do see this type of process happening in a given category for a drug?

A. Well, I think you make two important inferences. Particularly, if you're an economist assessing competition, there are two important inferences that come from this.

If I see manufacturers competing for formulary placement and formulary placement responding in a therapeutic category to these competitive actions, the two inferences I draw from there as an economist about competition are, first, that the alternatives in this therapeutic category are in fact regarded as good therapeutic substitutes for one another.

And that's simply because, Your Honor, there is nothing credible about an insurer's threat not to cover a product unless it actually has good therapeutic substitutes. Likewise, manufacturers are not going to respond unless they feel the threat that they could be dropped or demoted is a credible threat.

So you can infer as an economic matter that there is in fact therapeutic substitutability absolutely in there.

The second thing you can infer is that

economic substitutability is actually happening, because if the insurers didn't think they could actually drive volume by adjusting their formularies, drive volume to a favored product versus a nonfavored product -- and again I'm talking about the favoring being just the tiers of the formulary. It's not a question of medical preference; it's a question of economic tiering -- the insurers wouldn't bother if they didn't know they could actually drive volume.

So you know that there's price changes going on, because these are net prices that are being changed by these rebates, and that there is substitution taking place and contemplated to be taking place in response to those net prices. And that is the essence of economic substitution, so you see economic substitution going on.

Q. Do you consider this a form of price competition?

A. It absolutely is.

Q. Can you explain why?

A. Well, it's because as, you know, we had the -- as Judge Chappell and I just discussed, it is about the price being paid by the system for this drug. It affects the net price being received by the manufacturer, which ultimately is the price being paid

by the medical system to the manufacturer.

So it is absolutely price competition.

Q. And how effective --

JUDGE CHAPPELL: Let's -- we're going to take a break here. We're going to take our lunch break. We will reconvene at 2:45.

We're in recess.

(Whereupon, at 1:45 p.m., a lunch recess was taken.)

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

(2:46 p.m.)

JUDGE CHAPPELL: Okay. We're back on the record.

Next question.

MR. McINTYRE: Thank you, Your Honor.

BY MR. McINTYRE:

Q. Now, before the break, Dr. Addanki, we were discussing price competition for placement on formularies. Do you recall that?

A. I do.

Q. And I believe you testified that drug manufacturers would offer rebates to insurance companies or other payers in response or in return for formulary placement. Did I get that right?

A. Yes.

Q. And the insurance companies, they reimburse pharmacies for the cost of the drug; is that right?

A. They reimburse pharmacies for what the pharmacies have paid for the drugs from the wholesaler or the manufacturer or wherever the pharmacies get the drug from.

Q. And who pays the rebate to the insurance company?

A. The drug manufacturer.

Q. And so that reduces the net price that the insurance company pays for the drug?

A. Yes.

Exactly as I walked through in the example, if you talk about a pill that has a list price of a dollar, in the trade it's going to cost approximately a dollar to go to the pharmacy. The pharmacy dispenses a prescription and will get back approximately a dollar, with a little more for its own costs. And that dollar is being borne by the insurer and the patient, that cost.

And the rebate from the drug manufacturer -- in my example I think it was 40 cents -- that 40 cent rebate essentially makes the net cost to the insurer 60 cents or close to that and the net price received by the drug manufacturer 60 cents, so what the 40 cent rebate has done is basically reduced the net price paid by -- ultimately by the insurer and patient to the manufacturer.

Q. Thank you.

And this process of competition that you describe, how --

JUDGE CHAPPELL: Hold on a second.

In this example, and is this how it works in practice, once that drug is prescribed, the customer

or the patient has nothing to do with the price; correct?

THE WITNESS: That's correct, Your Honor.

But if I may, what can happen sometimes, right, is I take -- I'm the patient, and I take my script, my prescription, to the pharmacy. And the pharmacy, instead of telling me, okay, this is a $10 copay, may tell me, This is a $75 copay because this is a tier three drug on your formulary, or a tier four drug. And I'm going to say, I don't want to pay $75 in copayment, so the pharmacy may then say and in all probability will say, Well, I can talk to your doctor to see if there is a lower-priced alternative that's on a better tier on your formulary, on your insurance formulary.

And when that happens, they're communicating with the physician and the insurer. Now, all of this happens electronically, Your Honor, automatically now. But if we go back ten years, there was more of the phone calls going on.

And then the physician will change a prescription, prescribe a different drug, which is on a more preferred tier of the formulary, and then the pharmacy will only need to take a $10 copay from me.

But I don't control the price paid for by the

pharmacy or to the pharmacy for the drug as a patient.

JUDGE CHAPPELL: As the patient.

THE WITNESS: Right.

BY MR. McINTYRE:

Q. Now, this process of competition that you've been describing, how effective can it be in practice?

A. In practice it can be very effective indeed depending on the therapeutic category. Certainly, in therapeutic categories I've seen, the net prices being received by the drug manufacturer are going down over time even as perhaps the list prices are going up, and certainly we know that, as a general matter, the average cost of pharmaceuticals is going up.

But in specific therapeutic categories, this competition can drive prices down so that net prices received and paid are going down all the time.

Q. And so how, if at all, does examining the list prices inform an analysis of competition?

A. Well, it doesn't inform the analysis of competition at all, Your Honor, because list prices and net prices actually paid can go in completely different directions depending on how these rebates are working out.

They are in fact, though, as we explained through the example, the list price does anchor what's

being transacted between the pharmacy, the manufacturer, and the insurer.

So if the list price is a dollar, that's the amount that will be paid more or less and reimbursed more or less; whereas, if the list price were two dollars, that would the amount being paid and reimbursed more or less.

Q. Now, stepping back for a minute, how is competition for formulary placement probative of market definition?

A. Well, as I think I had described as to what I infer as an economist studying competition, if I observe a lot of formulary competition going on, I can infer that these products, the therapeutic alternatives in this class, are actually being viewed as therapeutic substitutes for one another and moreover that there's economic substitution going on, because the way the formularies drive their costs down is by driving prescriptions to the low tier drugs on the formulary, which are the drugs for which they pay less net prices.

So what you've got going on is you've got substitution going on in response to price competition, which is, of course, exactly the kind of competition we're talking about when we're analyzing antitrust cases, when we're analyzing relevant

markets.

Q. So we've talked a bit about competition at the physician level and at the payer level.

Is there any other competition that we need to keep in mind when analyzing the pharmaceutical industry?

A. Yes, there is. And there's competition even for the patients' attention.

And there's really two types of that, Your Honor. One is, increasingly we see direct-to-consumer advertising of pharmaceutical products, so --

JUDGE CHAPPELL: Is there any way to stop that?

THE WITNESS: I wish there were, Your Honor, particularly when, you know --

JUDGE CHAPPELL: Especially on television during sports.

THE WITNESS: On television you can't stop it. And they pop up on Web pages that you're on. You wonder why -- I wonder why I'm getting this, right, and I see no rhyme or reason to it.

But that's one type of -- which, obviously, that doesn't prompt me to go out and buy the product the way it might for bread or steak knives or

something, but it may prompt me to go and ask my doctor, Well, is this a product that's good for me? And that's obviously what they're going after.

But a much more important form of competition at the patient level is actually another form of price competition. And Your Honor, the -- this is actually relevant to the question you had asked a couple of minutes ago.

So going back to the formulary competition story, which is ubiquitous, if a manufacturer's offer is deemed just not that good, not good enough, so the insurer, for instance, places that manufacturer's product on tier three or tier four so that when I, the patient, get a prescription for that product, I go into the pharmacy and the pharmacy tells me that's a $75 copay, I may have been given a card, either sent in the mail or picked up at the doctor's office when he or she gave me the prescription, a copay coupon or a patient assistance card they're called, and what they do is they directly rebate some of the cost of the copay.

They -- it's a direct arrangement. It's normally handled by a third-party, but it's an arrangement by which the manufacturer will directly remit to the pharmacy part of that copay, knowing that

they're on a disadvantaged tier and trying to blunt the effect of that third tier formulary placement.

So they'd say perhaps, You'll pay $25 and no more for your copay, and this coupon or card will pick up the rest. And that's a direct arrangement between manufacturer and pharmacy.

JUDGE CHAPPELL: Aren't those customer rebates --

THE WITNESS: Those are customer rebates.

JUDGE CHAPPELL: -- only used when the brand name is trying to blunt competition from a generic for the same type drug?

THE WITNESS: Not necessarily, Your Honor. It's also used when -- in competing with other brands.

So in this formulary competition, if one of the -- I've seen this happen a lot, right -- if the -- the antibiotic, the particular antibiotic, ended up getting a three tier -- a tier three placement so that the copayment was going to be $50 or $60, and the coupon says, okay, your copayment will be no more than $10, that makes it less unattractive for me to be filling a prescription for a tier three drug because it's not going to cost me any more than a tier two drug.

So it is blunting some of the effect of the

formulary choices, but it doesn't have to be with generics. It absolutely can be with brand-to-brand competition as well and frequently is.

JUDGE CHAPPELL: Have you ever seen one of these when it's not a tier three or higher drug, a customer rebate?

THE WITNESS: I don't believe I've seen them when it's a tier two drug, because a tier two preferred brand is typically a fairly affordable copayment like $15, maybe $20, depending on the drug, and whereas a tier one would be typically about $5 or so.

JUDGE CHAPPELL: I guess what I'm getting at, though, is, are you saying these rebates affect the market, the customer rebate?

THE WITNESS: They -- yes, they do. Because they're another way that manufacturers are competing on price to say, well, I'm going to give back some so that the net price to me is going down, but I'm going to try to overcome the incentives that are being created by the formularies.

It's not very successful, but it's an attempt, and it helps keep the thing -- keep the competition going.

JUDGE CHAPPELL: Let me ask another way.

Have you ever seen a rebate being used like this when there's only one brand drug on the market with no competition?

THE WITNESS: No. No. It is the hallmark of when there's actually competition.

BY MR. McINTYRE:

Q. And Dr. Addanki --

THE WITNESS: You know, let me back up for a second, Your Honor.

The one thing you do see is, for very expensive drugs, cancer treatments, things like that, where the per-dose cost could be, you know, two or three thousand dollars, there are patient assistance programs, where, if you're an indigent patient, you can apply for those, and they will give you the drug for free or at a very nominal price.

But I don't view that as a competitive instrument. It's really -- it's really the -- the company is trying, you know, to be good citizens, and I've seen that.

BY MR. McINTYRE:

Q. Dr. Addanki, we may talk more about this later, but in your review of the discovery record in this case, did you see any evidence that Endo or other manufacturers of long-acting opioids engaged in these

types of patient copay programs?

A. Yes, I did.

Q. And you saw that during the 2009 and 2010 period?

A. Before and after and during. Yes.

Q. Okay. Now, before we proceed, are there any other institutional features of the pharmaceutical industry that we need to be aware of for purposes of analyzing competition?

A. Your Honor, at some point we'll want to talk a little bit more about the specifics of brand-generic competition and some of the implications of that, but I think we can talk about that as it comes up in my testimony.

Q. Now, let's go ahead and turn to your assessment of the monopoly power in this case.

In assessing monopoly power, where do we start?

A. Well, a logical place, as I said, and we normally start here in an antitrust case, is with definition of the relevant market.

Q. Okay. And how does an economist like yourself approach the market definition or the relevant market in a case like this?

A. Well, again, it's always the same basic

exercise. We're trying to identify all of the alternatives that act as competitive constraints on the product at issue in the case.

In this case, the product at issue is Opana ER, so we're trying to assess what the set of products is to which customers of Opana ER could and realistically would turn in the event of a price increase. That's the exercise we're engaged in.

Q. So how do we identify the set of products that customers may view as alternatives to Opana ER?

A. Well, given that this is a pharmaceutical product and it's being used to treat conditions, a good starting point is, well, what is Opana used to treat and what other things are used to treat that same condition.

And so I would start in a pharmaceutical certainly by looking at the label.

Q. Did you review product labels in this case?

A. I did.

Q. Could we go ahead and put up RX 30. This document is in evidence, and it is not subject to in camera treatment.

I'd like you to blow up the left-hand column.

First of all, do you recognize this document, Dr. Addanki?

A. Yes. This is some -- this summarizes the label and the different information that's part of the -- the label and package insert. And it's telling us basically what the indications are that are approved by the FDA for Opana ER. And if I remember correctly, this is the original label that was approved for Opana ER.

Q. And why don't we go ahead and blow up the indications and usage.

Can you tell us what, according to this labeling information, Opana ER was indicated for?

A. Yes. It's indicated for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.

Q. And you mentioned that this was the original labeling language.

What did you mean by that?

A. Well, around 2013, if I remember correctly, the FDA harmonized the label information for the long-acting opioid products and made them much more similar to one another. And I think that changed the language of the Opana ER label a little bit.

Q. And did you review those other product labels as part of your analysis?

A. I did.
Q. Did you prepare a demonstrative on this point?
A. Yes. There was a demonstrative on this point.
Q. Why don't we go ahead and put up RX D-17.
And is this the demonstrative that you just referred to, Dr. Addanki?
A. Yes, it is.
Q. And can you walk us through what this demonstrative is telling us?
A. Well, this is a -- simply extracting the same indications and usage information from those label summaries for all of the long-acting opioids shown on this page, and they include Opana ER, Avinza, OxyContin, Exalgo, Embeda and Kadian.
Q. And these are all long-acting opioids?
A. These are all long-acting opioids.
Q. And it appears that all of them were -- have the same or substantially the same language, saying that the products are indicated for the management of pain severe enough to require daily, around-the-clock long-term opioid treatment and for which alternative treatment options are inadequate.
Did I get that correct?
A. That's correct.
And really when I was talking about the change

from the previous, the original Opana ER label, it's that last phrase "for which alternative treatment options are inadequate" that apparently was added. That's the main change.

Q. And just to be clear, which products have this now standardized labeling language?

A. Certainly all the products shown on this page, and I believe there are other long-acting opioids as well that have this harmonized label.

Q. Now, are labels sufficient to tell us that these products are substitutes for one another?

A. Well, no. We know that off-label use is very much a fact of life in pharmaceuticals, so I would look beyond just the labels. The labels are certainly a convenient and useful starting point, but I think you could get useful information on clinical use from other sources as well.

Q. So what other kinds of sources would you look to?

A. Well, one of the things one could look to in some therapeutic categories is you have clinical guidelines suggesting how products should be used for the conditions that they're being used for or should be used for.

Q. And as part of your analysis in this case, did

you review clinical guidelines?

A. I did.

Q. And did you include those in your report?

A. I did.

Q. Let's go ahead and put up the exhibit that's been designated as RX 122. This is also in evidence.

Do you recognize this document, Dr. Addanki?

A. I do. It's a document I cited in my expert report.

Q. Now, let's skip to slide 8 of this exhibit.

And do you recognize this slide, Dr. Addanki?

A. Yes. It's a slide that's actually extracted and put pretty much into -- as it is into my report.

Q. Now, how did this slide inform your analysis?

A. Well, this is an analgesic ladder from the World Health Organization talking about how the treatment options for pain depend upon the severity and the nature of the pain.

And it shows that the molecules, the ingredients in those long-acting opioids, the set of opioids we had looked at on the previous exhibit, Your Honor, on the labels, they're treated as being on the third rung, and they're all there on that third rung, of opioids for moderate to severe pain.

So this document suggests to me that, again,

the ingredients in those long-acting opioids are regarded as what you use for the most severe kind of pain.

Q. Have you reviewed any of the testimony and expert reports offered by medical experts in this case?

A. I have. I've reviewed the testimony of Dr. Savage and the expert reports of Dr. Savage and Dr. Michna.

Q. And how, if at all, did the medical experts' opinions influence your economic analysis in this case?

A. Well, I'm not a clinician, so I rely -- I defer to them for the clinical opinions, but it certainly reinforced the idea that was being brought out by these sources that we've already talked about, that these long-acting opioids are used for much the same purposes and are probably interchangeable.

Q. In addition to looking at these sources, have you carried out any independent investigation of your own as to whether these products are in fact used for similar purposes?

A. Yes, I have.

I was able to get data from IMS, which I gather has changed its name as of a day or two ago,

but IMS has been the standard data source for almost anything having to do with the distribution and use of prescription pharmaceuticals, so I got data from them on how these long-acting opioid products were actually being used, meaning, what are the conditions for which they were being used, over the last ten years or so.

Q. And did your analysis -- did you reflect your analysis of this data in your report, Dr. Addanki?

A. I did.

Q. Why don't we go back and take a look at your report. This once again is Exhibit RX 547 and this should be the first tab in your binder.

And Robert, let's go to Exhibit 4, which is RX 547.0105.

And can we blow up the top of that.

Does this chart reflect the analysis you were just referring to, Dr. Addanki?

A. Yes, it does.

Q. Now, can you walk us through what this table represents?

A. Certainly.

This is a data set. As I said, it's from IMS. It's called their NDTI, which stands for National Diseases and Therapeutics Index. And it's based on a sample that they have of physicians that

they survey every month, and they ask the physicians to list all of the medications that they've prescribed as well as the diagnoses codes, using a standard classification system, for which they have prescribed those medications.

And I got these data, limited them to the long-acting opioids whose -- whose generic names are shown in columns (c) through (h) and tabulated over a slightly longer than ten-year period all of the use of those opioid products, long-acting opioid products, by diagnosis code. And just these are just -- so let me walk through a specific line.

The first line, the diagnosis code -- and that's called an ICD-9 code. It's a standardized diagnosis system that's used internationally -- 7242 is lumbago, which is lower back pain.

And what the number under column (c) 9.9 percent shows, Your Honor, is that 9.9 percent of the time that fentanyl or any product containing fentanyl in this long-acting opioid category was prescribed, it was prescribed for lumbago.

Likewise, over in column (g), of all the times oxymorphone, which is of course Opana ER or its generics, was prescribed in the sample, 9.25 percent of the time it was prescribed for lumbago.

And I did this for all the diagnosis codes -- I had to cut it off at some point because it would have become an extremely long table. I think it's about four pages long as it is -- and I just tabulated it for all these products.

Q. And what do you conclude on the basis of this analysis?

A. Well, a couple of things really.

One is that these products are used for really a staggering number of different diagnosis codes. There's pages of different codes here. Clearly, there are some uses that are more commonplace than others, post-operation pain, lumbago, chronic pain syndrome. And there are others that are used for, you know, just a tiny percentage of the total use.

But the striking thing is that all of these products are used to a greater or lesser extent for all of these indications. It's rare to find an indication for which there's no use at all of one of these products.

And typically, whenever a product is used for an indication, there are definitely other products being used for the same indication.

Q. And what does that tell us, if anything, about the relevant market in this case?

A. Well, it tells us again, from a clinical standpoint, there doesn't appear to be any reason why those products would not be interchangeable for one another, because they are being used for many of the same things or virtually all of the same things.

The other interesting point is that if you look at the column (g), which is the oxymorphone column, there's no indication for which oxymorphone had any significant use for which there isn't at least one other long-acting opioid available that was also used for the same indication.

Q. And just to be clear, are each of the long-acting opioids listed in this table prescribed with the same frequency for every diagnosis code?

A. No, they're not. Nor would I expect them to be. But they are all or virtually all prescribed for virtually all of these diagnosis codes.

Q. And the fact that they are not all prescribed with the same frequency, does that matter at all when it comes to evaluating whether they belong --

(Counsel and witness speaking at the same time and cautioned by court reporter.)

BY MR. McINTYRE:

Q. And so the fact that these long-acting opioids are not all prescribed with the same frequency, does

that matter at all when it comes to evaluating whether they belong in the same product market?

A. No, it does not.

Q. And why not?

A. Well, because what the table is telling us is that they are all in fact used.

Now, there may be specific idiosyncrasies suggesting that physicians who prescribe for a particular indication here may, because of habit, tend to prescribe a certain molecule more often, whereas physicians in another specialty where another indication is more commonplace may, for idiosyncratic reasons, have some preference that drive them in another direction.

But they're all being used for all the indications overwhelmingly, so again there seems to be no reason why clinically, from the data on use over ten years, that they couldn't be substituting.

Q. And does it matter that for certain diagnoses one or more of these long-acting opioids may not be used at all?

A. Again, those are rare in this table, but even when they do occur, because they are used interchangeably or at least used in common for the overwhelming majority of these diagnosis codes, it's

pretty clear that even if it were not somehow usable for a particular diagnosis code, even if it were true that the lack of use represents some inability to use it for that diagnosis code, the competition for the other diagnosis codes is sufficient to put them in the same relevant market if they in fact compete in that way.

Q. We can go ahead and put that one aside.

Did you consider any other clinical evidence in your analysis, Dr. Addanki?

A. Well, yes. Having studied therapeutic substitution for many years in my work on pharmaceuticals, I'm aware that even when products are used for the same therapeutic purposes, they may not be good substitutes for one another if they have very different risk profiles, so basically, a product that poses a lot of risk to use may not be a great substitute for a product that is relatively not risky to use.

So I did go ahead to see if there was any evidence of any striking differences in the risk profiles among these long-acting opioids.

Q. And what did you find when you studied the risk profiles of long-acting opioids?

A. Well, based on what I learned from the

clinicians who testified in this case, I learned that there were no significant such differences.

I'm not a clinician myself, so I have no clinical opinion of my own, but what I did do was look at the way these products are regulated. And they're actually regulated by two separate federal agencies, the Drug Enforcement Agency and the Food and Drug Administration.

So the DEA recognizes that all long-acting opioids present a significant risk of abuse and addiction, and it puts all long-acting opioids, and certainly all of the products that we're talking about here and more, in their Schedule II so that the -- the DEA does not distinguish in its assignment of products among these, so there's no evidence from the DEA standpoint that there's any product here that has a materially worse risk profile than the others. They all have risks for abuse and addiction.

Q. And you mentioned the FDA as well.

What do you see there in terms of the FDA's regulation?

A. Well, apart from its regulatory role of approving the products, the FDA also institutes or has manufacturers put in place what are called REMS programs, R-E-M-S, which stands for Risk Evaluation and

Mitigation Strategies. And it's basically when a pharmaceutical product that's approved for use in the U.S. presents risks in use, it's a structure that's put together to try to manage those risks, and the manufacturers are -- have to sign on to this.

And in this case, all of the long-acting opioids we're talking about were under a common REMS program.

Q. Was there any other clinical evidence that you considered?

A. Nothing else comes to mind.

Q. All right. And so taken together, what do you conclude from all of this clinical evidence?

A. Well, what the clinical evidence tells us so far, tells me so far, is that the products are indicated for similar use for the treatment of chronic, severe pain that won't respond to other things; they are actually used for very much the same set of indications, and it's a huge set; and there's nothing about their risk profiles that suggest that there would be any impediment to interchanging one for the other except from a therapeutic standpoint.

And so there's no clinical impediment that I could find for all of these to be regarded as being in the same relevant economic market.

Q. Now, aside from clinical evidence regarding the use of long-acting opioids, what other kinds of evidence did you consider in your analysis?

A. Well, to me as an economist, the clinical evidence is important, but the most important evidence is economic evidence. And that, to me, would be evidence about how these different products actually compete with one another in the market, in the marketplace.

Q. And what do you mean when you say "actually compete with one another in the marketplace"?

A. Well, we talked a little bit earlier about the layers of competition, competition for the physician, competition for the payer, competition even for patients.

And when we review the actual and vertical evidence, if we find that the market participants are engaging in competition at all of these levels, that all of the products in this group of long-acting opioids are in fact competing with one another at all these different levels, and that's what the evidence is telling us, then that satisfies me as an economist that they belong in the same relevant market.

And if I don't see such evidence, then I have to rethink whether they belong in the same relevant

market.

Q. So what kinds of evidence did you consider in evaluating competition?

A. Well, in different kinds of cases one can consider different kinds of evidence.

In the pharmaceutical industry, it's very useful to look at documents and reports being prepared contemporaneously by industry participants in the ordinary course of their business, because if I see repeated mention of either competitive interactions with or even just monitoring a company or product, that tells me that that company or product is likely to be viewed by the one generating the reports or doing the reporting as a significant competitor.

Q. So what kinds of documents are we talking about here?

A. We're talking about, you know, business plans, strategic documents, competitive analyses, reports of what actually happened in the case of particular opportunities, and so on, again, ordinary course of business documents that are talking about competitors and competition.

Q. And you may have just touched on this a bit, but can you help us understand why these documents are useful indicators of the relevant product market?

A. Well, again, it's a matter of economics. It's expensive to monitor and track what's going on at another firm or what's going on with another product in the marketplace, and I would not expect people working for a company, say, in the antibiotics space to be monitoring other products and companies potentially in that space unless they represented opportunities and threats, because why waste the resources on tracking and following and monitoring and comparing yourself with someone else who's not in fact representing any kind of opportunity or threat to you. It doesn't make economic sense.

MR. McINTYRE: Now, Your Honor, we're going to have a stretch of the examination here where we look at a number of third-party documents and data that are predominantly subject to in camera treatment. We've attempted to group these all together in one part of the examination so that we don't have to go in and out of an in camera session, but respectfully we would request, Your Honor, that we have an in camera session for this part of the examination.

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

informed by our bailiff, Lawman, when you can reenter.

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

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

(End of in camera session.)

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(The following proceedings continued in public session.)

JUDGE CHAPPELL: We've been going about an hour and 45 minutes. We're going to take our afternoon break. We'll reconvene at 4:40.

We're in recess.

(Recess)

JUDGE CHAPPELL: Okay. We're back on the record.

Next question.

MR. McINTYRE: Thank you, Your Honor.

BY MR. McINTYRE:

Q. Dr. Addanki, did you review the testimony that Dr. Noll offered in this courtroom last week?

A. I did.

Q. And so are you aware, Dr. Addanki, that the University of Pittsburgh Medical Center situation involving long-acting opioids was discussed during his examination?

A. I believe it was. Yes.

Q. And are you familiar with that situation?

A. I am. Actually, I have reviewed documents pertaining to it and cited it in my report.

Q. Why don't we go ahead and turn to RX 87.

And do you recognize this document,

Dr. Addanki?

A. I do.

Q. And is this the UPMC study that you just described?

A. Yes, it is.

Q. So Robert, why don't we blow up the leftmost column.

And Dr. Addanki, can you please walk us through what this document shows.

A. Certainly.

Q. And so what was -- I'm sorry. Strike that.

What was the study that was done?

A. The study that was done was -- so stepping back for a minute, this is the University of Pittsburgh Medical Center, and this is the health plan that we're talking about here, so it is an insurer.

And what was done here was, the formulary for the health plan, they removed OxyContin from the formulary and made the formulary such that the only branded long-acting opioid on it would be Opana ER.

MR. LOUGHLIN: Your Honor, I can't tell if this is intended to be a response to Dr. Noll or something that's in his report.

This was discussed by Dr. Noll in response to cross-examination by respondent's counsel. We did not

bring this out.

JUDGE CHAPPELL: Is this in his report?

MR. McINTYRE: Yes. I believe Dr. Addanki just testified that he discussed this study in his report.

JUDGE CHAPPELL: I knew he -- I heard him say he discussed the study, but this document?

MR. McINTYRE: This document. Well, I can ask the witness --

JUDGE CHAPPELL: Go ahead and lay a foundation, and I'll hold the objection in abeyance until we know more.

BY MR. McINTYRE:

Q. Dr. Addanki, I believe you testified that you recognize this document?

A. Yes. I believe that I've reviewed this document and I've cited this document in my report.

Q. Thank you.

And I believe you were just discussing the change in the formulary status at UPMC.

Can you once again explain for us what the change in formulary status was?

JUDGE CHAPPELL: I can see why government counsel was confused, because you started out asking about whether this witness heard the testimony of the

government expert.

MR. McINTYRE: Uh-huh.

JUDGE CHAPPELL: So with that lead-in, I think it was reasonable to anticipate you were talking about what was said by that witness in court.

MR. McINTYRE: I understand, Your Honor, and I apologize.

JUDGE CHAPPELL: But we're back to his report now; correct?

MR. McINTYRE: We are. And I apologize for the confusion.

BY MR. McINTYRE:

Q. What was the change in formulary status that was described in this study?

A. The change in formulary status was that OxyContin was going to go off formulary, it would not be covered, and the only branded long-acting opioid on the formulary would be Opana ER. And there would be morphine sulfate extended release, fentanyl and methadone in generic form covered.

Q. And what happened after UPMC instituted these changes?

A. Well, so if you go to the middle of this one-pager and blow up what says -- what's titled Subset Analysis Results -- go a little further down below

that. It's really the figure 2 I'm focusing on. Thank you.

And it talks about there having been, before the formulary change, 1,639 members with a paid claim for OxyContin. And it tracked what happened to that group and found that, after the formulary change, 329 remained on OxyContin, presumably for medical reasons, and the other 1,310, representing almost exactly 80 percent of the original 1,639, did not use OxyContin, were not given OxyContin. Of that number, 1,142 were given a different opioid and 168 did not get an opioid at all.

So the 1,639, 80 percent of them were switched off OxyContin, most of those to another opioid.

UPMC also tracked what happened to its costs and found -- and I think this is over I believe on the right, if I remember correctly.

Q. Let's take a look at figure 4, please.

A. Well, yes, first of all, Exhibit 3 shows a little bit more about what happened to opioid use pre and post. And the darker grayish blue in the post pie chart which has 19.31 percent represents Opana ER, so clearly Opana ER got many of the prescriptions that had been on OxyContin earlier. And it --

Q. I'm sorry, Dr. Addanki.

What was Opana ER's percentage before the formulary change?

A. It looks like 1.62 percent.

Q. And then after the change --

JUDGE CHAPPELL: Hang on a second.

If these pie charts are correct -- and the point of this was moving oxycodone off the formulary; right?

THE WITNESS: That's correct.

JUDGE CHAPPELL: Well, if this pie chart is correct, if I'm looking at the right color, and if it's the yellow, it only went from 21.9 to 17.1?

THE WITNESS: Well, what seems to be happening here is that that is oxycodone ER I'm guessing, which was not the branded OxyContin, Your Honor.

JUDGE CHAPPELL: So it was only the name brand that was --

THE WITNESS: It was the brand that was taken off formulary, is my understanding.

JUDGE CHAPPELL: OxyContin, not oxycodone?

THE WITNESS: That's correct. That's certainly what is described and discussed up here.

JUDGE CHAPPELL: And can we go back to the screen before that where they showed the numbers, the flowchart?

MR. McINTYRE: Sure.

Can we go to figure 2, Robert.

JUDGE CHAPPELL: I remember this chart from the other witness.

So the lower right, 12.83 percent, if I'm reading that correct, almost 13 percent of these people stopped opioids altogether.

THE WITNESS: That's correct.

JUDGE CHAPPELL: So they probably didn't need it anyway.

THE WITNESS: That may well be, Your Honor.

JUDGE CHAPPELL: 13 percent.

THE WITNESS: May well be, yeah.

BY MR. McINTYRE:

Q. And I believe you mentioned a moment ago, Dr. Addanki, that the switch in the formulary status of these drugs had an effect on UPMC's costs. Did I get that right?

A. Yes.

So that's tracked in figure 4.

Q. And so what are we looking at here?

A. And it actually tracks, for the patients who did not remain on OxyContin, it's tracking what happened to them -- what will happen to the total costs, both the opioid part of the cost and the medical

cost, the total medical cost. And it shows that the costs went down for that group of patients when they were switched off OxyContin.

Q. And do you recall what the authors of this study concluded about -- I'm sorry. Go ahead.

A. It concluded that they could effectively switch -- they could remove OxyContin from the formula -- formulary -- pardon me -- effectively switch patients away from OxyContin, in large part, and actually save money in the process.

Q. And so what do you as an economist infer from these events?

A. Well, this is entirely consistent with everything else I've been talking about, the evidence I've seen, suggesting that there was economic substitution going on because there was competition via pricing, the rebates, to the payer layer of this market, the industry, and that competition for formulary coverage was in fact economic substitution. And this is another instance of an insurer describing its experience with implementing a formulary change and tracing through the consequences and effects.

Q. So, Dr. Addanki, we've now looked at a document showing some specific situations showing evidence of competition for formulary placement.

Did you also analyze any data on formulary coverage to see if it was consistent with the evidence we just discussed?

A. Yes, I did.

I analyzed data that are available from another data syndication company called MMIT, which actually tracks the formulary treatment of pharmaceutical products by commercial insurers and Medicare insurers and reports those data to those who are willing to subscribe to it.

Q. And do you report the results of your analysis in your report?

A. I do.

Q. Let's turn back to your report.

Once again, this is Exhibit RX 547. And we're going to start with Exhibit 7A, which is 547.114.

And does this chart -- is this one of the charts you produced in conducting the analysis you just described?

A. Yes, it is.

Q. And could you please walk us through what this chart -- what it conveys.

A. Yes, I will.

And Your Honor, this is actually a -- this is actually quite complicated, so I'm going to take my

time to explain this carefully.

MMIT is this Managed Markets Insights and Technologies, that outfit, and what they do is they actually track what commercial and Medicare payers are doing with their formularies. And they report on the number of lives being covered by those plans.

The plans that they track account for some very high percentage. I forget the exact number, but it's in the high nineties or in the mid-nineties, of covered lives in the United States, so they've got pretty good coverage, MMIT.

And what they report on is specific formulary treatment of all the pharmaceuticals on the formulary.

Now, I got the data for the long-acting opioids. And what I've shown here is how the formularies distinguish among the long-acting opioids in their formulary treatment. And I've shown it, because I think it's the most sensible way to show these data, by each bar represents the percentage of covered lives represented by the plan that has the treatment that I'm describing here.

So let me start with the first bar for Avinza.

I actually divide up what the formularies do with Avinza into five categories of either Avinza is treated by the plan just the same as every other LAO --

and that's the bottom dark blue subsegment. And obviously, that is going to be equal for all the products because that's symmetric equal treatment for all the products by that proportion of the plans representing about 14 percent of the covered lives.

The red sub-bar is talking about the covered lives represented by the plans that treat in this case Avinza as being the most preferred brand. And what we mean by -- what I mean by that is that there is no brand preferred to Avinza by that -- by the plans accounting for that -- I don't know -- 15 to -- 55 percent or so of lives. But there are brands less preferred than Avinza on the formulary.

And of course, Your Honor, this preferred we're talking about has nothing to do with medical preference. It just has to do with the formulary tier, the preference in terms of the economics that the plan is imposing.

Likewise, the green sub-bar is saying that for Avinza, about 25 percent or so of the covered lives represented by plans that had Avinza in the second position, which means there was one brand, possibly two brands, sharing a position that was better in the formulary than Avinza's, but they may have been brands in lower positions.

Correspondingly, the orange sliver indicates Avinza is for being in the third position, meaning there were brands that were in at least two positions better than Avinza. And as I said, that's a sliver.

And then the final piece for this chart is those plans where they required prior authorization, meaning, if you walked in with a prescription to the pharmacy, it was not going to be covered. It had to be authorized ahead of time through some review process by the plan.

So that's what's been done for each of the products shown here, long-acting opioids, Avinza, Embeda, Exalgo, Kadian, Opana ER and OxyContin.

Q. Now, is this analysis restricted to branded long-acting opioids?

A. It's not just restricted to branded long-acting opioids, it's restricted in this chart to branded long-acting opioids that did not have an AB-rated generic available at the time of this chart, June 2010.

Q. And why did you limit the analysis in that way?

A. Well, this goes back a little bit to what I was saying earlier about brand and generic competition, Your Honor. And if any of these products

has an AB-rated generic product available, say OxyContin happened to have one available, well, we know exactly what's going to happen to OxyContin. OxyContin is going to go to tier four or blocked or not covered on the formulary, and oxycodone, the AB-rated generic, will go to tier one.

We know that happens. That happens very predictably. And the reason it happens, of course, is that if there's going to be oxycodone used by members of the plan, the plan wants to drive the prescriptions to the generic oxycodone. And that's just the way the institutional structure of this market works.

Now, we could put that in, and if there were AB-rated generics, they would always be at tier one, and all we'd be doing is adding another layer or another bar here or another few bars here.

But if we're asking the question what's the evidence about competition based on price among the molecules involved in this long-acting opioid market and we say, well, Avinza and Embeda, Exalgo, Kadian, Opana ER and OxyContin all represent certain molecules and delivery mechanisms, when you put them on a equal footing in the competition, then it's very easy to see what's going on with the formularies.

I could absolutely put in the generics, but as

I said, I know what's going to happen. Generics are going to be on tier one uniformly or virtually uniformly, and any brand that has a generic -- so if I put MS Contin on here, for instance, I know exactly where it would be. It would be the least preferred brand or prior authorization or even NDC blocked, just not covered. And the generic MS Contin ER -- pardon me -- morphine sulfate ER would be on tier one. We know that.

It doesn't actually tell us anything about how the competition at the payer level is going on because that's not what's going on where when the -- the manufacturers go in and make their offers to these payers.

So as I said, the chart is difficult enough to look at as it is, I could have added that further complication, it wouldn't have changed anything, but we would still be focusing on the same things, when these products are competing on an equal footing, what's going on.

Q. Going back to the slide, what conclusions can you draw from your analysis?

A. Well, it's very clear from the way that these different bars look, apart from the blue bars being, obviously, by construction the same across all the

products because they represent the lives on the plans that treat all the products exactly the same, the other stacks are very different.

And if you just focus for a minute on, say, Opana ER and OxyContin, which is the biggest brand in the market, you see that more covered lives -- there were plans accounting for more covered lives treated OxyContin as their most preferred brand than treated Opana ER as their most preferred brand.

Likewise, more plans -- and I think it's the plans accounting for more covered lives -- treated Opana ER as the second most preferred brand than treated OxyContin as the second most preferred brand.

If you compare Opana ER and Exalgo, Opana ER was regarded as preferred by plans that accounted for many more lives than Exalgo was. And Exalgo was given second place much more often than Opana ER was.

So you've got a variety of choices being made by formularies represented in these charts where the products are all being given, treated differently by different plans, and so there's a lot of diversity in the outcomes that you see from the formulary competition.

Q. Thank you.

Can we switch to the very next exhibit, 7B.

And the last one we were looking at was commercial plans; right?

A. That's correct.

Q. And is this a similar analysis of Medicare plans?

A. This is a similar analysis for the Medicare Part D plans.

And again, you see that there's substantial variation in what's going on, a somewhat smaller, but not much, percentage of the lives represented by plans that treat all the products the same. But once you get beyond those, there's actually a mild preference on the Medicare plans for Opana ER over OxyContin. And Exalgo and Embeda get very little coverage as the first choice, the first preferred brand. Kadian has a substantial amount of kind of first preferred location.

So, again, you see the same picture of this competition is playing out differently at different plans, so different plans are making different choices about what's going to come first, second or third.

Q. Did you do any other analyses using the MMIT data?

A. I did a couple of things.

One thing I did was -- this is a snapshot at

the time of the settlement that's at issue in this case, June 2010.

I also looked at how these formulary statuses for the different products changed over time. And in particular, we can focus -- because there's a lot of them, we can focus on the ones I did for Opana ER over OxyContin.

Q. Why don't we go ahead and pull up Exhibit 9I. This is page 126 of Dr. Addanki's report.

Is this one of the analyses you just described?

A. Yes, it is.

So here what I'm talking about, Your Honor, is for Opana ER for commercial plans specifically, going from 2007 to 2008 -- and that's what the first bar represents -- what proportion of plans, as measured by the percentage of covered lives that they account for, changed the status of Opana ER going from '07 to '08, and it turns out that about a third of the covered lives represented by plans that changed the status of Opana ER, of which a somewhat higher proportion made it more preferred on their formulary than the proportion that made it less preferred on the formulary.

You had less churn -- this is churn meaning

sort of changing, switching around in formulary positioning -- less of that going on in '09. It kind of ticks back up in 2010.

In 2011, apparently they did well with managed care formularies because of the 22 or so percent of lives represented by plans that changed Opana ER's status on the formulary, many more of them were positive changes for Opana, made it a better position. Opposite happened in 2012.

So this is telling us that in the commercial plans on Opana ER there was a lot of movement going on. There was movement going on in the formulary placement.

And when we look back at the evidence that I described on the efforts that were being made and the recognition on Endo's part that it needed to be competing for the formularies, you can see that this is the effects, this is the results of not just Endo's competitive efforts but all the other LAO suppliers' competitive efforts. And yes, to be sure, we're talking about the branded LAO suppliers here.

Q. Let's turn to Exhibit 9J, the very next page.

And is this essentially the similar analysis but with Medicare plans?

A. That's correct.

Q. And do we see the similar degree of churn here?

A. You actually see somewhat more churn because, instead of being around 20 to 30 percent of the covered lives having changes in Opana's status, you see 40 to 45 percent, so there's more -- more action, more activity going on in terms of the changes. Or it could just be that the plans that were changing represented a much bigger proportion of the covered lives under Medicare Part D.

And again, you see sometimes they were making Opana more preferred, and in 2012 Opana became substantially less preferred for 30 percent of covered lives.

Q. And what about OxyContin? Did you perform a similar analysis to see if there was churn in the formulary treatment of OxyContin?

A. I did.

Q. Let's turn to Exhibit 9M. This is page 130 of Dr. Addanki's report.

And is this -- does this chart reflect the analysis that you performed of OxyContin?

A. Yes, it does.

Q. And what does this tell us about competition?

A. And again on commercial plans you had about

20 percent of covered lives going from '09 to 2010 changing over -- excuse me -- changing status for OxyContin. The plans were changing status, formulary status. And more than half the time OxyContin was becoming less preferred, although it was becoming more preferred for about 7 percent of the covered lives, 7 percent or so.

In 2011 you had somewhat less churn; in 2012 you had more. And overwhelmingly in 2012, OxyContin, when it changed, became less preferred. That was about 20 percent of the covered lives for which it became less preferred.

Q. And when you said when OxyContin changed, what were you referring to?

A. I'm referring to the status on the formularies, for those formularies that changed OxyContin's status, what happened, how many covered lives did they represent as a percentage of the total and what happened.

Q. And Dr. Addanki, have you reviewed the rebuttal report that Dr. Noll offered in this case?

A. Yes.

Q. And are you familiar with the criticisms that he posed in that report?

A. I am.

Q. Did Dr. Noll criticize you for failing to account for the fact that Avinza, Kadian and Embeda are all based on morphine sulfate?

A. Yes, he did.

MR. LOUGHLIN: Objection, Your Honor. This discussion of Dr. Noll's points in the rebuttal report are not in Dr. Addanki's report.

MR. McINTYRE: Well, I don't know how Dr. Addanki could have preemptively responded to points that were made in Dr. Noll's rebuttal report.

MR. LOUGHLIN: Exactly the point, Your Honor.

MR. McINTYRE: If I'm not mistaken, I believe that we had a similar debate this morning?

MR. LOUGHLIN: Well, you weren't here, but I don't think so.

JUDGE CHAPPELL: Is this about information that came out at trial or was in the written report?

MR. McINTYRE: The written report, Your Honor.

JUDGE CHAPPELL: I think my ruling on this is, a witness on the stand can respond to criticisms in the rebuttal report if that witness hasn't had a chance to file a written response.

MR. LOUGHLIN: I understood your ruling this morning to be that a witness on the stand can respond to something that another witness said in the witness

chair so long as it was not in the rebuttal report.

JUDGE CHAPPELL: That's today.

MR. LOUGHLIN: That's today.

JUDGE CHAPPELL: I think it was yesterday we had a situation where -- I don't know what day it was anymore. They're running together -- where someone was criticized in your expert's rebuttal report and that person hadn't had a chance to respond. And to ask a witness on the stand if they have a response to what was the criticism, I allow the response, but I don't allow a new opinion.

MR. LOUGHLIN: My recollection is the opposite, Your Honor, that last night, when this came up, you said no, if it's not in the report, it's not coming in.

JUDGE CHAPPELL: I said no new opinions. That's always been my rule. No new opinions are allowed. But I allow response of criticism while someone is here.

I think I used words like it is unacceptably unfair not to allow an expert to respond to criticism. Do you recall that?

MR. LOUGHLIN: That was this morning, Your Honor. I do recall that. And then you and I had a subsequent discussion about what that meant.

JUDGE CHAPPELL: Well, when you were asking me for clarification, I thought you were talking about the testimony that came out in trial. But I've always said that a witness can respond to something in a rebuttal report because the cutoffs don't allow them to do anything in writing.

No new opinions, but can respond to criticism in the rebuttal report, that's allowed. And if that's your objection, it's overruled.

MR. LOUGHLIN: So what is the difference between a response and an opinion, Your Honor?

JUDGE CHAPPELL: An opinion is coming up with a new idea. A response is defending yourself when someone said you're wrong, you're an idiot, you're a fool, you're wrong because. A response is not the same as a new opinion.

You're sticking to your same opinion, I assume, if you're an expert, but you're responding to what someone has said to criticize your opinion. That's not a new opinion. Two different things.

MR. LOUGHLIN: Just so I'm clear, we're all clear, what we're going to hear has never been heard before by complaint counsel.

JUDGE CHAPPELL: Whether you heard it or not is of no import to me, sir. What's important to me is,

someone can respond to criticism of their opinion if they've not had a chance to do that before now. They're not allowed to offer new opinions, but they're allowed to respond to criticism of their opinion.

MR. LOUGHLIN: All right. I just want to make sure we all understand what's going on here, Your Honor. Thank you.

MR. McINTYRE: Thank you.

BY MR. McINTYRE:

Q. Dr. Addanki, what is your response to Dr. Noll's criticism that your analysis of the MMIT data failed to account for the fact that Avinza, Kadian and Embeda are all based on morphine sulfate?

A. It is not a valid criticism because -- for two reasons.

One, my analysis in the series which starts with the number 9 of the exhibits -- and we looked at some of them just now -- which track changes in formulary status don't depend on how you treat the morphine sulfate products. We're already talking about the status of Opana ER or OxyContin or other -- each other product we're talking about.

Moreover, if you do combine the morphine sulfate products that are branded morphine sulfate products and treat them as one monolithic product,

you're still going to see the formulary variation and the churn that I'm talking about in these exhibits, so it's not a criticism that actually affects the outcome of my analysis in any way and certainly doesn't change the conclusions one can draw from it.

MR. LOUGHLIN: Your Honor, I move to strike the part on -- after "Moreover." That seems to be a new opinion about combining products.

MR. McINTYRE: Your Honor, if I may.

JUDGE CHAPPELL: Go ahead.

MR. McINTYRE: Can I attempt to establish a foundation within Dr. Addanki's report to support the response that he just gave?

JUDGE CHAPPELL: He doesn't get to proffer new opinions. That's the rule.

MR. McINTYRE: I understand, Your Honor.

JUDGE CHAPPELL: And if that's a new opinion, it's not going to be considered.

MR. McINTYRE: I understand.

JUDGE CHAPPELL: And when we get to posttrial briefing, the parties are going to point out. If this is an opinion that's not in his report, it won't be considered.

To that extent, the objection is sustained.

MR. McINTYRE: The point I was trying to make,

Your Honor, is that I believe this opinion is reflected within the four corners of Dr. Addanki's original report.

JUDGE CHAPPELL: If it's in his report, that's a different issue.

MR. McINTYRE: Okay. I can attempt to establish foundation within his report, Your Honor.

JUDGE CHAPPELL: All right.

BY MR. McINTYRE:

Q. Let's turn to Exhibit 8A in Dr. Addanki's report, and this is RX 547.116.

And Dr. Addanki, does this in any way speak to the criticism we just discussed from Dr. Noll?

A. What Exhibit 8A does is it expresses the formulary status of each of the products shown relative to the formulary status of Opana ER.

The -- certainly when one looks at a product that isn't based on morphine sulfate, one can make reasonable inferences about the relative formulary status. If some of these changes that happened over time in -- pardon me. The -- as to whether that criticism would affect this or not, it would appear different if one combined these products, but the conclusions one could draw from it would be the same.

Q. And to be clear, what are those conclusions,

Dr. Addanki?

A. That there is churn, there are differences in the way these formulary competitions play out in terms of the formulary positioning that's given by different plans, which is entirely consistent with there being and is evidence of there being competition at the formulary stage at the payer level.

Q. Now, Dr. Addanki, we spent lot of time today reviewing various business documents as well as several portions of your report.

Taken together and stepping back for a bit, what does all of this evidence tell you as an economist about the relevant market in this case?

A. I think it's very clear that the evidence that we've been looking at and that I've been talking about points to the relevant market being no smaller than the market for long-acting opioids in the United States.

Q. You testified earlier that you have reviewed both the original report and the rebuttal report of Dr. Noll, so I take it you are aware, Dr. Addanki, that Dr. Noll reaches a very different conclusion about the relevant market?

A. I am.

Q. And just so we're all on the same page, what

conclusion does he reach regarding the relevant market in this case?

A. Dr. Noll concludes that it is a relevant market for oxymorphone ER, which would be Opana ER and generic oxymorphone ER.

Q. And do you recall that one of the bases for Dr. Noll's opinion on the relevant market has to do with certain clinical differences that he says exist between Opana ER and other long-acting opioids?

A. I do.

Q. And based on your review of the evidence, do you agree that these ostensible clinical differences between Opana ER and other long-acting opioids are economically significant?

A. I'm not a clinician, but the clinical evidence I've reviewed suggests that they are not major. I've certainly heard evidence from the clinicians in this case that they were not major clinical differences.

But for me as an economist the far more important question is not whether there were clinical differences at all or not but did those clinical differences serve to prevent competition, economic competition, and effective economic competition among all of these products. And the evidence I've seen overwhelmingly indicates no.

Q. And do you recall that another basis for Dr. Noll's opinion about the relevant market is that he says switching costs are sufficiently high that other long-acting opioids are not effective substitutes for Opana ER?

A. Yes. I'm aware of that. And once again, the evidence we've reviewed tells me that Dr. Noll is wrong for a few reasons.

One, as we've heard from the clinicians, switching can and does occur, and switching can and does occur in response to economic forces, such as formularies.

Second, as I pointed out when reviewing some of the documents here in court today, there are plenty of new patients starting opioid therapy each month, and clearly for new patients there's no question of switching costs. And indeed, we saw that Endo was concerned about not getting adequate shares of new patient starts on opioid therapy.

And finally -- and also we saw that UPMC was a situation where an insurer did the experiment and reported on the result and had no problem switching patients and actually saving money.

And finally, the totality of the evidence we've looked at, if there were prohibitive switching

costs, you wouldn't see the efforts by managed care and by manufacturers responding to managed care to be getting the best terms possible for the most favorable position on the formulary because that underscores, as I'd said earlier, the fact that -- when you see that happening, that underscores that economic substitution is in fact taking place, so whatever the switching costs were, they were not an impediment to economic substitution. And that's what counts.

Q. Thank you.

Now, Dr. Noll has also suggested that the relevant market is limited to oxymorphone ER because, among other things, when Impax' generic oxymorphone product entered the market in January 2013, it took sales away from Endo's reformulated Opana ER but ostensibly did not take sales away from other long-acting opioids.

Do you recall that, Dr. Addanki?

A. I do.

Q. And as an economic matter, do you agree with that analysis?

A. I'm not aware of any analysis, econometric or statistical analysis, that Dr. Noll did to support his conclusion that that is in fact what happened. It's impossible to tell, looking at a picture of aggregate

sales of products, what was actually going on as far as switching among products was concerned.

I have studied switching among products in response to market events, and it's not easy to do. One needs a great deal of data, which are frequently not available.

So there's no such study. And in contrast, we've got very substantial evidence of switching, of competition, price-based competition that leads to switching through formulary coverage, so it seems to me that when I look at the weight of the evidence, I don't see any compelling evidence that there was any lack of competition between Opana ER and any of the other LAOs.

Q. Now, I believe Dr. Noll has also opined that there is no price competition, or words to that effect, between Opana ER and other long-acting opioids.

Do you agree with that assessment?

A. No. I think it's entirely contradicted by the evidence we've been talking about. Competition at the patient level and at the payer level are price competition, and we've seen plenty evidence of that, I've seen plenty evidence of that.

Q. Now, now that we've talked about your opinion

regarding the relevant market in this case, let's turn to monopoly power.

First of all, in your view, did Endo possess monopoly power in Opana ER?

A. It did not.

Q. And why not?

A. Well, Endo's share of the relevant market, the long-acting opioid market in the United States, never even reached 10 percent. With less than 10 percent market shares, it's simply inconceivable that a product could command monopoly power. It just can't happen.

Q. And did you prepare a chart or another exhibit in your report identifying Endo's market share of Opana ER through the relevant period?

A. I did.

Q. Let's turn back to your report, Exhibit 10. This is 547.132.

Is this the chart that you were just referring to?

A. Yes, it is.

Q. And if you could please walk us through what this is depicting.

A. This is a tabulation and then a chart, Your Honor, of the long-acting opioid marketplace where

I've combined all of the brand and generic products that use a particular active ingredient, so those are fentanyl, hydromorphone, morphine sulfate, oxycodone, oxymorphone and tapentadol.

JUDGE CHAPPELL: Do you have anything more recent than January 2013?

THE WITNESS: Do I have any more recent? Not in my report, Your Honor.

I don't believe. I can check that.

JUDGE CHAPPELL: I mean, I saw charts earlier that were cutting off in 2010. This one is January 2013. We're now in 2017.

THE WITNESS: Right.

I believe there are charts that are in the record that go further out, Your Honor. I had stopped this chart at the time of the generic entry that actually occurred by Impax as being the period -- the date at which, you know, there was -- if Impax was in fact doing anything to improve market conditions through its entry, that happened in January 2013, so this stops there.

But I'm fairly sure we have the data, and I believe there may be charts in the record, too.

BY MR. McINTYRE:

Q. And so I believe you may have touched on this

earlier, but if Endo did not possess more than 10 percent of the market during the period depicted here, is there any way that it could have exercised monopoly power?

A. Absolutely not, no.

And as you can see, it doesn't even get close to 10 percent in the sense of not being almost 10 or any other kind.

JUDGE CHAPPELL: But are you -- is this your opinion as of January 2013? Is there a time period on your relevant product market definition?

THE WITNESS: So I've not seen any evidence that the product market changed after that, Your Honor, but I believe there was a cutoff on document production, so I don't believe I've reviewed a lot of material that was much later than that, than the 2013-2014 time frame.

JUDGE CHAPPELL: I mean, it's your opinion. I'm asking you --

THE WITNESS: No. I understand.

JUDGE CHAPPELL: -- are you saying --

THE WITNESS: And I'm just trying -- I'm trying to sort of think through the answer.

I don't believe that anything has changed materially in the long-acting opioid marketplace, but

it's true that the majority of the evidence that I've reviewed pertains to the period from the time -- from before the time of the settlement to about a little after the time of Endo's -- pardon me -- Impax' entry.

JUDGE CHAPPELL: So your relevant product market definition is for what time period?

THE WITNESS: It's for the time period through that early 2013 time frame.

BY MR. McINTYRE:

Q. Dr. Addanki, why would you focus on the period before and after settlement agreement for your economic analysis?

A. Because what we're concerned about is if there was -- as I said at the outset, the test for the competitive effects is, first, was there monopoly power being exercised by Opana ER. And that would be monopoly power that existed at the time of the agreement that was going to be somehow preserved, maintained, because of the agreement, in a way that it wouldn't have but for the agreement.

And if we believe that there was monopoly power, either we assume it or we find it, then the question is did the agreement, the settlement agreement, in any way impede the dissipation of that monopoly power.

And as the settlement provides for an entry date in January 2013, there's really a question of was there any monopoly power through that time, and I think that is really all I need for purposes of my analysis.

Q. And do you recall, Dr. Addanki, that in his opening report Dr. Noll describes what he calls various direct tests for monopoly power?

A. I do.

Q. And do you agree that Dr. Noll has directly tested for monopoly power?

A. No, I do not. I don't believe that actually any of his tests constitutes a meaningful test for monopoly power.

Q. Now, let's go through them one by one.

First, are you aware -- do you recall Dr. Noll's opinion that the -- a high Lerner Index --

JUDGE CHAPPELL: Hold on a second.

I'm hearing -- I don't know if it's intentional or by mistake or -- I would like for the record to be clear. I'm hearing "market power." I'm hearing "monopoly power."

Can you clarify what the witness' opinion is, is it the same thing, is it different, and are you mistakenly using one or the other. I'm not sure, but

I'm seeing both in the record.

MR. McINTYRE: I apologize, Your Honor. My intention has been to use the term "monopoly power," but I can ask the witness whether and to what extent we should distinguish between those terms.

JUDGE CHAPPELL: Well, I've heard the witness use both terms, so why don't you clarify.

Because if the record isn't clear, nothing is going to help us. Whether it's for you or against you, it needs to be clear.

MR. McINTYRE: Thank you, Your Honor. I will try to clarify.

BY MR. McINTYRE:

Q. Dr. Addanki, can you describe how you view the terms "monopoly power" and "market power."

A. I should make the statement very clearly on the record, Your Honor, that I am speaking about monopoly power, and if the words "market power" show up for some reason, those are entirely unintentional. I'm referring to monopoly power.

And if I may, the reason I'm doing that is because economists, my profession, has done all of us a bit of a disservice by using "market power" in a very loose way.

So from the antitrust standpoint, as I've

explained earlier, what we care about is the power of a firm to harm consumers by restricting output or doing something else to prevent consumer benefit from obtaining in a marketplace.

That is a very specific kind of power that I would refer to as monopoly power.

What's confused the matter is that market power is sometimes referred to simply when there's a price over marginal cost, so when a price is higher than marginal cost, in a trivial sense, a firm has "market power."

But none of the antitrust scholars who write on the subject in economics confuse those two different concepts. You can have a price -- and we're just about to talk about that actually -- you can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.

And I believe, Your Honor, we're just about to talk about that.

But I intend only to be speaking of monopoly power because that's the appropriate test for whether

or not an agreement or arrangement even could be anticompetitive in its effect.

Q. And to clarify, if we -- if a defendant in an antitrust case does not have monopoly power, is it possible that a settlement agreement such as the one at issue here could be anticompetitive from an economic standpoint?

A. Well, as long as you restrict it to an antitrust case such as this, an analysis under the rule of reason of, say, a contract or a settlement agreement, that's absolutely correct, that it cannot be anticompetitive in effect if there is no monopoly power being exercised or preserved.

Q. And was this the monopoly power screen that you referred to earlier?

A. That's exactly right.

Q. Now, you just talked about --

A. And I just want to mention that --

Q. Go ahead.

A. -- I don't believe that your -- the government's expert and I have a disagreement on this subject either. I think we both agree that the monopoly power screen is the necessary first step.

Q. Dr. Addanki, what is a Lerner Index?

A. Your Honor, the Lerner Index is simply another

word for gross margins. It is the gross margin being earned by a firm on its sales.

Q. And do you agree with Dr. Noll that a high Lerner Index is indicative of monopoly power?

A. No, I do not. I do not.

And frankly, if Dr. Noll really believes that, he's at odds with what economists have known for decades, which is that high gross margins or high Lerner Indexes actually tell you nothing at all about monopoly power. And that's because, Your Honor, there are plenty of industries in which the way costs are incurred by firms, most of the costs are fixed.

A very commonplace example in all our experience is the software industry. All of the costs of developing a piece of software are upfront costs. The marginal cost of selling another unit of software, today especially, is essentially zero. The costs of maintaining and upgrading software are fixed in the sense that they don't depend on how many units you sell.

So you've got a lot of fixed cost, virtually no marginal or variable cost. You've got astronomical gross margins, astronomical Lerner Indexes. But that doesn't mean that any of the thousands of app developers out there or certainly all of the app

developers out there have monopoly power. That just doesn't make any sense, as antitrust economists have recognized for decades.

The basic problem with the use of the Lerner Index, if I may just explain a little further, is that it implicitly assumes that the competitive benchmark price is represented by marginal cost. And that just simply cannot be right in the real world in most industries.

It may be useful as a textbook case or a pedagogical example in a classroom, but it's no use at all in analyzing real-world industries where there are substantial fixed costs that need to be covered. And again, antitrust economists and scholars have noted this for a long time.

JUDGE CHAPPELL: There was that term "real-world" again, been hearing that a lot lately.

Go ahead.

BY MR. McINTYRE:

Q. Now, as you may recall, Dr. Addanki, in his opening report, Dr. Noll also opined that he believes Opana ER had monopoly power because Endo could use its patents to block entry.

Do you recall that?

A. I do. And once again, Dr. Noll's opinion is

just incorrect.

We have known for a very long time now that patents do not confer monopoly power. All that a patent does is give you the right to exclude someone from making a direct copy of what you make.

So in this case Endo's patents did prevent competitors from making direct copies of Opana ER. But to the extent that other long-acting opioids competed with Opana ER, the patents had no ability to block them. And in fact, there was entry of competing products even while Endo had its patents.

Q. Well, what about the fact that a generic product is generally cheaper than a brand product? What, if anything, does that tell us about whether a brand company commands monopoly power?

A. Again, nothing whatsoever.

Our own everyday experience is replete with examples of generic products and brand products coexisting on the same supermarket shelf, the same store shelf, and the generic product will sell for less than the brand product. The Arnold branded bread is going to sell for $2.50 alongside a generic bread or store brand bread for $1.50.

Brands have value and generic products --

JUDGE CHAPPELL: You haven't bought bread

lately, have you, sir?

THE WITNESS: Pardon me?

JUDGE CHAPPELL: I don't think you've bought bread lately at these prices.

THE WITNESS: Well, we're talking about small loaves, Your Honor.

JUDGE CHAPPELL: All right.

THE WITNESS: And the same thing is true of aspirin. Bayer Aspirin sells for more than store brand or generic aspirin. And that's not at all uncommon. We're going to see generics sell for less than brands. They're viewed as different products.

BY MR. McINTYRE:

Q. But isn't an AB-rated generic the same as the branded drug?

A. No. Certainly not.

It has a rating from the FDA that means that a pharmacy can substitute the product when dispensing a prescription, but it's not the same product. It's not made by the same company. It's made by an entirely different manufacturer. It may be many different manufacturers if there are many different generics. It may have different inactive ingredients, different excipients. It's not the same product.

JUDGE CHAPPELL: Isn't your bread example --

that doesn't seem to apply here because, with bread, the consumer makes the decision, walks in a store and decides whether to buy the store brand or the name brand. But as I heard you say today and I've heard others say, the consumer doesn't really drive that truck when it comes to the drugs. The insurance company or someone else -- that's why I'm not -- I'm not seeing your bread example translate into the market we're dealing with in this case.

THE WITNESS: I understand, Your Honor.

And I think that in fact, in my experience, again, having studied the pharmaceutical industry over many years, it does depend a fair amount on the therapeutic category.

So in some therapeutic categories, the fact that a product is AB-rated doesn't mean -- and the physicians know this -- and again, I'm speaking from my study as an economist, not as a clinician -- and the physicians are aware that not only may the generics be different from the brand in how they actually would work in a given patient, not talking about what basis the FDA has for an AB rating but that in a given patient a generic may work differently, one of the things that they're sometimes concerned about also is that different generics may operate differently,

differently from the brand.

And because you as a patient, not only do you not get to choose between the brand and the generic when you go to the pharmacy, you have even less choice, if a generic is being dispensed, as to whose generic that's going to be, is that going to be a Teva generic, is that going to be an Apotex generic, is it going to be an Actavis generic, an Impax generic, or is it going to be something from Ranbaxy or something from overseas. You don't know, and you have no control over it.

And in some therapeutic categories physicians don't mind that at all; in some they mind it a lot. And all that I was underscoring is that they're different products.

The last point, though, on the generic brand price issue is that for a generic to be listed as a generic and to be sold as a generic, it has to be offered at a discount from the brand price. And that's just institutional. For it to be listed as a generic, it has to be offered at a selling price below the brand price, and so you're going to have a price difference in every brand-generic comparison no matter whether the brand has a hundred equally good therapeutic substitutes or none.

So whether the brand has monopoly power or not, the generic is going to be listed for a lower price because that's what has to happen for it to be a generic.

BY MR. McINTYRE:

Q. Dr. Addanki, circling back to a few minutes ago, His Honor pointed out that, in the pharmaceutical market, frequently it's not the patient that's driving the truck when making purchasing decisions, it may be, for example, an insurance company, may be the physician.

Is that why we need to look at competition at the physician level and at the payer level when evaluating markets and competition in pharmaceuticals?

A. Exactly. We need to look at all layers of competition because they're all important in driving sales.

Q. Thank you.

Dr. Addanki, do you believe that there is any direct test that can be conducted for the existence of monopoly power?

A. Yes, there is. Sometimes.

And I just want to also just point out that the trouble with a Lerner Index test or a price comparison test for brand versus generic is that it's always going

to give you the same answer. A test that doesn't discriminate a situation where there is monopoly power from one where there isn't but will always tell you yes isn't really a test of anything at all. It's more like a dogma.

Now, you want a test that's able to actually distinguish the presence of monopoly power from the absence of it. And the way we've gone about it in my report, to define the market and look at the conditions of that market, is generally the right way to do it.

But in some instances you can actually get what the economists call a natural experiment, so if you believe that there could be monopoly power that will be dissipated by generic entry and you actually have the opportunity to observe the impact of generic entry, you can look to see if the generic entry in fact dissipated monopoly power. And to do that, you would look to see if there was any output expansion in the wake of that generic entry.

You can do that, and that's a real direct test which you can apply sometimes.

Q. You just mentioned natural experiments.

Did you see any natural experiments in this case?

A. Well, we actually did have the opportunity to observe what happened when Impax entered with its generic oxymorphone ER.

Q. And what happened?

A. And there was no output expansion attendant upon that entry.

Q. Why is output a -- how does that measure monopoly power? Can you explain that to us?

A. Well, again, Your Honor, we know what monopolists do. They monopolize a market, which means that there's not enough competition constraining them. And the way they harm consumers is by restricting output and charging monopoly prices.

And if I think that an entry is going to dissipate that monopoly power, then I'm going to expect to see that when that entry happened that consumer harm will be lifted, and there would be more product being sold in the marketplace, undoing the consumer harm that was wrought by that exercise of monopoly power. And when I don't see that, I can safely infer that there wasn't any monopoly power being exercised before the fact.

And as I've said, because the products are different and because of the rules governing brand generic competition, price really doesn't get you

there. Output actually lets you measure something real.

Q. And you said a minute ago that when Impax entered the market with its generic oxymorphone product, you didn't see an expansion of output.

A. That's correct.

Q. Can you explain what you mean by that?

A. I mean that when you actually look at the combined total of prescriptions dispensed for Opana ER and the generic oxymorphone ER and you just smooth out that series, because it's very choppy because there are week-to-week and month-to-month variations, you don't see any evidence that there was any output expansion following Impax' generic entry.

Q. Have you ever seen other instances where there was an expansion of output when a generic came on the market?

A. Absolutely. I've studied the impact of generic entry in many, many cases. And sometimes total output goes up, sometimes it stays the same, and sometimes it goes down.

Q. Do you have any examples?

A. I believe they're in this very marketplace.

When the generic OxyContin came in in 2004, I believe there was expansion.

When Zocor, which is -- was a blockbuster cholesterol drug, went generic about ten years ago, there was substantial output expansion noted.

Q. And so in summary, did you see any evidence here that would lead you to believe that Endo had monopoly power in Opana ER?

A. I did not.

Q. So, Dr. Addanki, now that we've covered monopoly power, it might make sense to turn to competitive effects.

Are you aware that Dr. Noll relies on a three-part test for determining whether a settlement is anticompetitive?

A. Yes.

Q. And do you recall that the first of those steps is, did the settlement agreement eliminate the possibility of entry during some period after the date on which the FDA gave final approval to the ANDA?

A. Yes.

Q. And do you recall that the second step is, did the generic entrant receive a payment that is large compared to the savings to the brand name firm in ending the infringement litigation before the court renders a verdict?

A. Yes.

Q. And do you recall that the third step is, was the payment unjustified in that it does not plausibly reflect a payment for other goods and services?

A. I do.

Q. And what are your views about this approach to assessing competitive effects?

A. Well, again, I don't believe it's a test because I don't think it really distinguishes anticompetitive from procompetitive settlements, and that's for a few reasons.

First, it has no monopoly power screen in it. And to me, that is a very obvious shortcoming, particularly because I gather that Dr. Noll does not in fact disagree that that is the first step, the monopoly power screen.

So setting that aside, as far as the other prongs that you mentioned are concerned, any term-split settlement of any kind is going to foreclose entry by the generic before the entry date specified in the settlement, so that's going to happen with any term-split settlement.

Now, as for the payment, generally speaking, certainly the existence of a large payment, if you satisfy yourself that there was a large payment, might be something that would trigger an inquiry as to

whether a settlement was anticompetitive in its effect, but it couldn't possibly substitute for that factual inquiry.

And as I said, the inquiry is a factual one, was monopoly power less effectively dissipated through the settlement that you're analyzing than it would have been otherwise in the but-for world but for the settlement. And there is no way a payment alone can simply obviate that factual analysis because, as the articles I've written and cited in my report have noted, the existence of a payment does not make, even a large payment does not make an agreement anticompetitive, because there are all kinds of reasons that firms may enter into agreements that include payments that are nevertheless procompetitive in the effect they have on consumers. And the literature is there, and I believe Dr. Noll is aware of that literature.

And in particular in this case, it's true that a payment of $102 million was made under the Endo credit provision, but certainly it would be absolutely not something that anyone could have calculated with any degree of certainty as to what a payment might be, if any, made under these provisions back in June 2010.

And as I think we've heard testimony about,

the payment of $102 million happened to represent a perfect storm of unpredicted events and in particular the shutdown of the Novartis plant that essentially maximized the amount that would be payable by Endo under the provision relating to the Endo credit.

JUDGE CHAPPELL: We're approaching 6:55 (sic). How much more time do you need for direct?

MR. McINTYRE: Your Honor, I probably have about 15 more minutes.

JUDGE CHAPPELL: I want to finish direct today if we can.

Go ahead.

MR. McINTYRE: Okay. I'll try to hurry through.

BY MR. McINTYRE:

Q. Now, you mentioned that there was a perfect storm just now.

Can you expand on what you mean by that?

A. Your Honor, the Endo credit provision, it worked in a -- it had various formulae in it, but the essence of it was, over the period from the time of the settlement through Impax' entry date under the settlement, the parties would monitor the maximum quarterly sales, prescriptions, achieved by Opana ER and record the maximum as one of two comparators.

The other comparator would be the quarterly sales in the fourth quarter of 2012 just before Impax' entry.

And if the difference between that highest sales number and the fourth quarter 2012 number exceeded a certain threshold, the payment will be triggered, and the payment would depend on how big that difference was.

Now, knowing those terms and given that Endo had already applied just a month after its -- and was fully intending to apply for a label for the reformulated product, Endo clearly was going to be planning a transition of patients from Opana ER to reformulated Opana ER.

And knowing how these provisions work, I as an economist would expect that Endo would manage that transition to minimize its patient loss and to minimize whatever payments it was going to make. And that just wouldn't have been that complicated a process.

That plan went completely awry because, at the end of 2011, the Novartis plant that actually supplied Opana ER shut down. And Endo then was in crisis mode because they had no product to put into the pipeline and they had to hurry up and try to get their

manufacturing process for the revised product up and running, which they did do, but it meant that by the time the fourth quarter of 2012 rolled around, there was no Opana ER, the original Opana ER, being dispensed. And that is what created a situation in which that payment under the Endo credit provision was absolutely as big as it could have been.

And this plant shutdown certainly, from my standpoint as an economist, would not have been something that anyone would have been predicting back in 2010.

Q. Dr. Addanki, do you agree with Dr. Noll's opinion that Impax received a large payment as of June of 2010?

A. No. I don't think there's any way to know what -- certainly there's no way to know what either party thought was going to be payable in June 2010 -- payable in the future at the time that they signed the agreement. And I think as an economist I would say there's no way to calculate any meaningful value for that number.

Q. So can you summarize your opinion about Dr. Noll's three-part test.

A. It's not a helpful test because in particular it does not address the question that we really need to

address, which is, we have a settlement, if we believe that there was monopoly power being exercised, did that settlement end up costing consumers, in terms of consumer benefit, because it ended up dissipating that monopoly power less completely, less effectively than might have happened without the settlement. That's the test, and that's really the only test.

Q. Dr. Addanki, are you aware of any evidence or analysis that's been offered in this case that the $10 million payment that Impax received under the DCA was large and unjustified?

A. I'm not.

So I've only been focusing on the payment under the Endo credit and no-AG terms.

Q. And so are you aware of any evidence or analysis that's been offered in this case that persuades you as an economist that Impax received a large and unjustified payment under the Endo credit or the no-AG term whether taken together or separately?

A. Well, as a matter of fact, Impax received a check for $102 million, so I'm not sure I understand your question.

Q. I'm sorry. Let me rephrase that.

Are you aware of any evidence or analysis that's been offered in this case that persuades you as

an economist that, as of June 2010, Impax received a large and unjustified payment under the Endo credit or the no-AG term whether taken together or separately?

A. No. I have seen no such evidence.

Q. Thank you.

Now, we've talked a bit now about Dr. Noll's approach to these cases.

How do you go about -- how would you as an economist go about analyzing the competitive effects of a settlement such as the one at issue here?

A. Well, exactly as I've described, I would do the monopoly power screen, and then if I found monopoly power, I would go ahead and ask whether the settlement interfered with the dissipation of that monopoly power in some way.

Q. And so if we assume for argument's sake that there was monopoly power here -- and I understand that your opinion is that there was not -- how would you go about evaluating the competitive effects of the Impax-Endo settlement?

A. Well, we have a settlement that we have before us under which there was entry. And if we are assuming that generic entry by Impax would dissipate the monopoly power you've asked me to assume, then the question simply is but for the settlement would Impax

have entered in a way that would have much more effectively dissipated its monopoly power you've asked me to assume. And clearly that is going to involve consideration of the but-for world, what would happen but for the settlement.

Q. And so can you describe the analysis that you performed here of the competitive effects of the Endo-Impax settlement agreement?

A. Yes.

The first thing to keep in mind is that there isn't an alternative settlement that we can possibly postulate that the parties would have entered into. To suggest that the parties would have agreed to a settlement that was materially different from the settlement they actually agreed to, the one before us, is pure speculation.

From an economic statement standpoint, there's no basis to do that, particularly when we know, again, from the articles that I've written and cited in my report, that it's often just not possible to settle patent litigation.

And so there's lots of impediments to settlements, and so the real alternative -- the only real alternative we have to the settlement before us for the but-for world is that the parties would have

continued to litigate. And then we have to ask, well, what would have happened in terms of dissipating the assumed monopoly power had the parties continued to litigate.

Q. And so what can we say here about that but-for world in which the parties continued to litigate?

A. Well, we have the benefit here of knowing what actually happened in the real world, what Endo did and what transpired. And what we know is that Endo was very assiduous about acquiring and asserting more patents against all the ANDA filers on original and reformulated Opana ER. It got its own patents as well as acquired patents from others and asserted them against the generic companies.

Q. And what does that -- the fact that Endo has asserted its patents against other generic companies, what does that tell us about the competitive effects of the Impax-Endo settlement agreement?

A. Well, what it tells us in the but-for world is that Endo and Impax would have been embroiled in litigation for years to come after that settlement.

Q. And so if Impax and Endo had continued to litigate the original patent case, wouldn't you assume that there would have been a final, nonappealable judgment in that case?

A. Well, I've been told, I've been asked to assume, and I believe there's been testimony about it, that the final appellate decision on the Impax-Endo litigation on the original patents would have been no earlier than the end of 2011.

JUDGE CHAPPELL: That's not the question you were asked.

I'm not going to consider that answer because he didn't answer the question you asked.

MR. McINTYRE: I'm sorry. I can rephrase.

BY MR. McINTYRE:

Q. In your report, Dr. Addanki, did you rely at all on the report of Mr. Figg that's been offered in this case?

A. I did.

Q. And can you explain in what sense you relied on his report.

A. I relied on his report for the assumption in my report that there would not be a decision on appeal to the Federal Circuit until the end of 2011 of the original litigation between Endo and Impax.

Q. And so if I'm not mistaken, Dr. Addanki, the first additional patent that Endo acquired after the settlement was the one it bought from Johnson Matthey in March of 2012.

Now, if Impax could have gotten final judgment in the patent case by as early as November 2011, then assuming that Impax would have prevailed in that case, couldn't it have just launched oxymorphone then?

A. Well, the patent that we're talking about that Endo acquired from Johnson Matthey was in fact a patent that issued -- they acquired it, no doubt, in March 2012, but it was a patent that Johnson Matthey received at the end of 2010, and it's a patent that Johnson Matthey had put Endo on notice of being pending in 2009, so Endo knew throughout that period that the Johnson Matthey patent was pending.

When it issued at the end of 2010, in the real world where there was a settlement in June 2010, there was less urgency for Endo to be acquiring that patent from Johnson Matthey, something that it subsequently did in March 2012.

And as an economist, I would assume, I would conclude, based on the economic incentives operating here, that that same acquisition that Endo made in March 2012 would have been made much sooner because of the urgency of wanting to get that additional patent protection on Endo's part.

So I would certainly expect, as an economist, that Endo would have got that patent from

Johnson Matthey significantly earlier, given that it would not in the but-for world have settled with Impax.

Q. And I think you mentioned the Johnson Matthey patent issued in -- I'm sorry -- the end of 2010? Did I --

A. End of 2010, that's correct.

Q. Okay. And did Endo proceed to acquire or obtain even more additional patents after that?

A. Yes, it did. It was issued more patents that it asserted then against the ANDA filers.

Q. And it has asserted those patents against other generic companies?

A. It has.

Q. And so if, as you say, Endo and Impax would have been embroiled in patent litigation for years, what does that tell us, if anything, about consumer benefits in the but-for world of continued litigation?

A. Well, again, if we assume that there was monopoly power and that Impax' entry was going to dissipate that monopoly power, the consumer benefit would only come if there was entry by Impax, based on the assumptions we've made, and that entry by Impax, if there had been ongoing litigation, would have been entry at risk by Impax, a launch at risk.

JUDGE CHAPPELL: We're past 6:05. You may finish your direct tomorrow morning.

As far as scheduling, am I correct that we have one fact and one rebuttal expert to go this week?

MR. HASSI: Yes, Your Honor, that's correct.

JUDGE CHAPPELL: And are the chances good that we could finish tomorrow with these two witnesses?

MR. HASSI: I think so. I don't know how long counsel has planned for the rebuttal witness, but I assume he's not all that long.

MR. LOUGHLIN: Your Honor, I don't have an estimate of our rebuttal expert. I apologize.

JUDGE CHAPPELL: Your rebuttal expert, though, is rebutting the patent expert only; correct?

MR. LOUGHLIN: Yes. Mr. Figg, correct.

JUDGE CHAPPELL: All right.

So I'm just saying there's a possibility we won't be here Thursday --

MR. HASSI: That is a possibility.

JUDGE CHAPPELL: -- based on what we've moved through till now.

MR. HASSI: We think that's a possibility, Your Honor.

MR. LOUGHLIN: It's possible, Your Honor.

JUDGE CHAPPELL: And Monday is out because of

travel or something?

MR. HASSI: Yes, Your Honor.

JUDGE CHAPPELL: All right. We'll reconvene at 9:45 in the morning.

We're in recess.

(Whereupon, the foregoing hearing was adjourned at 6:07 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