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

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

November 6, 2017

9:52 a.m.

TRIAL VOLUME 8

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 8

PUBLIC AND IN CAMERA RECORD

NOVEMBER 6, 2017


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P R O C E E D I N G S

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

I have a couple issues to deal with first.

Do we have an update on witnesses, what's going to happen next week? We had talked about this Monday -- I think it's the 13th -- and I said let me know how this develops. Where are we? Are we at a point where you can give me a definitive answer on Monday?

MR. HASSI: Yes, Your Honor. We would prefer to go and we've told the witnesses to be here on Tuesday. I thought we spoke about Tuesday, the 14th.

JUDGE CHAPPELL: Well, there were some things up in the air, like whether you were going to work with complaint counsel and their rebuttal expert was going to testify.

I mean, do you think you've got this week filled or not?

MR. HASSI: We do not have this week filled, Your Honor.

We have our first witness Mr. Figg this morning. We have Dr. Michna. I suspect Mr. Figg will take the balance of the morning, Dr. Michna this afternoon, our economist Dr. Addanki after

that.

And then Wednesday morning, depending on how long Dr. Addanki goes, we have a fact witness, Robert Cobuzzi from Endo.

And that will be all of the witnesses we have this week.

If complaint counsel is prepared to put on Mr. Hoxie, I would think -- and I see that he's here -- I would think that he may go on as soon as Wednesday afternoon or sometime Wednesday.

MR. LOUGHLIN: And we are prepared to put on Mr. Hoxie on Wednesday, if time permits.

JUDGE CHAPPELL: And if he's here to listen to other experts, that's fine. If you want him to testify, if he's hanging out to testify, you can put him on now if you want to, if that's the reason he's around.

MR. LOUGHLIN: No. He's here to listen to the patent expert that he's responding to.

JUDGE CHAPPELL: Okay. All right.

So it looks like now we may not have anyone Thursday this week?

MR. HASSI: That's correct, Your Honor.

JUDGE CHAPPELL: And we definitely are off on Monday, the 15th because of someone in Taiwan?

MR. HASSI: Yes, Your Honor.

So Monday, the -- Tuesday, the 14th --

JUDGE CHAPPELL: I'm sorry. Monday, the 13th we're off.

MR. HASSI: Correct.

And so Tuesday, the 14th we will have two more fact witnesses from Impax Labs, the president of the brand division, Michael Nestor, and its former CEO, Larry Hsu, and those will be our last two witnesses.

JUDGE CHAPPELL: All right. So you believe you'll be wrapping up on the 14th?

MR. HASSI: We believe we will wrap up on the 14th, yes, Your Honor.

JUDGE CHAPPELL: All right.

So Thursday we're here if need be.

And your expert is available for rebuttal Wednesday and spillover to Thursday if necessary?

MR. LOUGHLIN: Yes, Your Honor.

JUDGE CHAPPELL: All right. The 13th is now an official off day for trial.

MR. HASSI: Thank you, Your Honor.

JUDGE CHAPPELL: All right.

One other matter.

I had talked to you earlier about the parties I

expect to be working on a joint stipulation of facts to submit before the briefs are due.

Along those lines, there's this odd order from the two commissioners called Order Specifying Facts Without Substantial Controversy. I intend to use the JX for my decision, so including facts on this odd order, you need to include that on your JX.

MR. HASSI: We will do that, Your Honor.

JUDGE CHAPPELL: I don't intend to cite to something that's odd unless I have to.

MR. LOUGHLIN: Understood, Your Honor.

JUDGE CHAPPELL: I'm not sure why a motion is denied and this thing is issued, but -- all right.

Next witness.

MR. HASSI: Your Honor, respondents call Mr. Anthony Figg to the stand.

And my colleague, Mr. Benjamin Hendricks, will do his questioning.

JUDGE CHAPPELL: Okay.

MR. LOUGHLIN: Your Honor, I just wanted to note for the record that my colleague, James Weingarten, will handle this witness for complaint counsel.

JUDGE CHAPPELL: All right. Thank you.

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Whereupon --

EDWARD ANTHONY FIGG

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

DIRECT EXAMINATION

BY MR. HENDRICKS:

Q. Good morning, Mr. Figg.

A. Good morning.

Q. My name is Ben Hendricks, and I'm going to ask you a few questions today.

Before we start, please state your full name for the record.

A. My full name is Edward Anthony Figg. My business card and letterhead say "E. Anthony" and people know me as Tony.

Q. Thank you.

Can you please introduce yourself briefly.

A. I am a patent attorney, primarily an intellectual property attorney. I've been an intellectual property attorney for somewhere in the neighborhood of 45 years, I'm sorry to say. And I have focused most of my practice in the area of pharmaceuticals, biotechnology, healthcare, although I do work in other areas as well.

Q. And have you been asked to offer expert

testimony in this case?

A. Yes, I have.

Q. Can you please list the topics on which you have been asked to offer expert testimony in this case.

A. Well, I think the overarching question I was asked to look at was whether the settlement of the patent litigation that was pending in 2010 between Impax and Endo with a commercial launch date, the latest commercial launch date of January 1, 2013, whether it was reasonable for a company in the position of Impax to settle on those terms.

Sort of subsumed within that overarching opinions are a number of questions.

One, I was asked to take a look at the issues of the patent litigation and offer my opinion on the likely outcomes on those issues.

I was asked to consider whether the settlement that was reached was within the scope of the patents that were being litigated.

I was asked to look at the likely timing of resolution of that case had it not settled.

And I was asked to provide my views on the prevalence of at-risk launches by generic companies, generic drug companies in the position of Endo -- or

excuse me -- Impax at that time.

And then finally, I was asked to opine about the implications of the fact that the settlement agreement provided Impax with a license and freedom to operate under patents that Endo either would obtain itself based on pending applications or would acquire later and then what the real-world consequences of that license was.

JUDGE CHAPPELL: Hold on a second.

You said you have 45 years experience.

Have you worked on settlement agreements similar to the one at issue in this case?

THE WITNESS: I have worked on settlement agreements similar to this one, settlement agreements of Hatch-Waxman litigation.

BY MR. HENDRICKS:

Q. And Mr. Figg, from what perspective have you considered these topics?

A. I'm sorry. Mr. Hendricks, can you speak up a little?

Q. Yes. Sorry.

From what perspective have you considered these topics?

A. Well, primarily from the perspective of what, in my view, a reasonable litigant in Impax' position at

the time of the settlement, which was really at the very beginning of the patent trial, you know, how would someone -- how would a company in Impax' position have dealt with this situation.

Q. And have you studied the issues, analyzed documents and applied your expertise as a patent attorney to form opinions related to each of the topics you just described?

A. Yes, I have.

Q. Do you hold these opinions with a reasonable level of certainty?

A. I do.

Q. Before I ask you more about your analysis and opinions, let's talk a bit about your background.

Do you have any degrees in the sciences?

A. Yes. I have a bachelor's degree in chemistry and I -- after obtaining that degree, I actually worked as a chemist in the chemical and then the pharmaceutical industry for several years.

Q. And after you obtained your bachelor's degree in chemistry, where did you work as a chemist?

A. I actually, even before graduating from college, I started working with a company which at that time was known as Commercial Solvents Corporation. It later became International Minerals and Chemicals

Corporation. I worked for them as a chemist.

I should correct that. As a chemist, they were always Commercial Solvents. I worked for them later as an attorney actually. But -- so I worked -- I worked in the laboratory as a chemist.

Q. And what type of work did you do as a research chemist there?

A. Well, I should -- I should continue.

After that, I went to work for a pharmaceutical company, Eli Lilly and Company. And I worked as a chemist for them as well.

Even though the name of the first company I worked for doesn't sound like a pharmaceutical company, they actually were involved in developing products for animal health, so it was very much related to biosciences.

And then at Lilly I worked as an analytical chemist and directly in the pharmaceutical industry, working in an area they called analytical method development, so I would develop ways of testing materials.

Q. After you completed your work as a research chemist, what did you do next?

A. Well, actually, while I was a research chemist, I started in law school. And then I completed law

school.

And initially, I went to International Minerals and Chemicals as a patent attorney. Again, most of my work there was in the biosciences area, although there was also work in unrelated areas. I worked for them for several years.

And then I -- I moved to Chicago and I worked briefly for a corporation there known as American Hospital Supply Corporation. I was the patent counsel -- patent and trademark counsel actually for what they called their science business, which included their pharmaceutical company and their human diagnostics company.

Q. To back up, at International Minerals and Chemicals Corporation, can you describe your responsibilities when you worked there as an attorney.

A. Well, I was a patent attorney. I was a fairly junior patent attorney at that point in time. I worked on sort of all aspects of patent law ranging from preparing and prosecuting patent applications for the company, I worked on contracts and licensing arrangements, and I also worked on patent litigation. In that capacity, I was sort of assisting the outside litigation counsel who were representing the company.

Q. And when you worked at the American Hospital

Supply Corporation, what were your responsibilities?

A. Well, they were more or less the same sort of tasks, although I was a little bit higher level at that point and I had more responsibility. But I worked on all of those different aspects that I've mentioned, obtaining patents and trademarks for the company, negotiating and working on contracts, license arrangements, things like that.

And again, they had a fair amount of intellectual property litigation, and so I worked on that in the capacity as an in-house attorney who would work with outside litigation counsel.

Q. And how long did you work at American Hospital Supply Corporation as a patent attorney?

A. I think I was only there for a couple of years.

Q. And what did you do after that job?

A. Well, I -- I was well-acquainted with an attorney here in Washington, who offered me the opportunity to come to Washington and work for his firm, and the firm then was known as Bernard & Brown.

So I came out to Washington in 1980 and joined Bernard & Brown as an associate attorney.

Q. And what type of law did you practice at Bernard & Brown?

A. Well, that was -- again, it was intellectual property. And a lot of my work in those days was in the area of biotechnology and pharmaceuticals. We had a lot of clients in that area and -- but in general, it was the same sort of things that I've referred to, patent procurement, licensing arrangements.

I would work on helping develop opinions and counseling for clients and litigation. And at that point my role in litigation, you know, developed into a more hands-on role, if you will.

Q. And how long did you practice patent law at Bernard & Brown?

A. Well, I became a partner at Bernard & Brown -- Mr. Bernard -- or Mr. Brown passed away shortly after I joined the firm, and another attorney, Mr. Rothwell, joined the firm. A few years after that, somewhere in the mid to late '80s, Mr. Rothwell and I and two other people acquired all of the equity of the firm. And with one slight change on the name of the firm, we've been operating as that same firm since then, you know, up till today.

Q. And today is that firm named Rothwell Figg?

A. Yes. The legal name of the firm is Rothwell, Figg, Ernst & Manbeck. We're known as Rothwell Figg. And Mr. Rothwell -- I'm the only one still around from

that, from that first group.

Q. And where is your legal practice based today?

A. A few blocks from here in Washington, D.C.

Q. And as a partner at Rothwell Figg, what are your daily responsibilities?

A. Well, I have focused my practice over the years largely in the healthcare, pharmaceutical, biotechnology industries, although I do do work for companies outside of those industries, but that's been a mainstay of my practice for a long time.

My firm is still very active in procuring patents and trademarks for clients. I don't so much do that kind of work hands-on anymore. I do supervise others in my firm, and I help clients develop strategies for doing that.

I do a lot of contract work, drafting and negotiating contracts, helping clients with opinions, understanding what their risks and potential liabilities might be if they pursue a particular course of action.

And I'm -- I handle a lot of litigation and I have for quite a while.

Q. And you just said you handle quite a bit of litigation.

Does this include Hatch-Waxman litigation?

A. It does.

I've actually handled Hatch-Waxman litigation since shortly after the statute was enacted in 1984.

Q. And we'll explore this in more detail later, but can you just give a short definition of what you mean by "Hatch-Waxman litigation"?

A. Yes.

In 1984, Congress passed a fairly important comprehensive piece of litigation. It was sponsored by Senator Hatch and Congressman Waxman, so it's affectionately known as Hatch-Waxman. It amended both the Food, Drug and Cosmetic Act and the patent statute in some very important ways.

Q. In your practice, do you regularly try patent infringement cases through trial?

A. Yes, I do.

Q. Have you conducted bench trials in patent infringement cases?

A. I'm sorry. I didn't catch that.

Q. Have you conducted or argued bench trials in patent infringement cases?

A. Bench trials? Yes.

The Hatch-Waxman trials are -- these days are almost always bench trials. Ironically, the very first one I handled was for a -- the patent owner, and

that one actually was a jury trial. But after that, the courts determined that the issues should be triable to the bench, and so most all of them are these days.

Q. Have you argued patent infringement appeals before the Federal Circuit Court of Appeals?

A. Yes, I have.

Q. Do you have a sense of how many appeals you've argued?

A. Well, I know I've been counsel on a large number of appeals and I've participated in the briefing, and so forth. Oftentimes those cases settle, or if there are multiple parties, sometimes I'm not the one who actually does the argument.

I can't really give you a very accurate estimate of how many I've been counsel on. I probably have actually argued in the Federal Circuit -- I don't know. I haven't counted recently -- but a dozen or more times.

Q. Do you know how many patent infringement cases you've been involved in over your 40-year career?

A. Patent infringement cases?

A large number. I mean, my guess is it would be, you know, 70, 75, a hundred. It could be that many. I don't know.

Q. Do you know in how many Hatch-Waxman cases that you've been involved over the course of your career?

A. I don't. I was actually thinking about that because I thought that might be a question. But I would say probably somewhere between 25 and 50. That's about as accurate as I can be.

Not all of those cases go to trial, of course. These cases tend to be complex cases that go on for several years, and many of them are disposed of before they actually get to trial.

Q. I think you already said this, but in what year did you first start litigating Hatch-Waxman cases?

A. My recollection is I started working on one the year following the enactment of the statute, in 1985.

Q. And earlier you mentioned you've served as opinion counsel in Hatch-Waxman cases?

A. Did you say "opinion"?

Q. Yes.

A. Yeah.

Q. Can you describe for the court what it means to serve as an opinion counsel.

A. Well, it's not just for Hatch-Waxman cases. Oftentimes, if a company wants to engage in some

research or some activity or sell a product, they will want to understand what kind of patent risks that might create for them, and so they will come to a qualified patent attorney and ask that attorney to look at their product and give an opinion as to whether that product infringes any patents or not.

Sometimes that involves doing a comprehensive search for patents. And they also might ask the attorney to look at literature and prior art to the patent and provide an opinion about the validity or enforceability of the patent.

And you get that on both sides. Sometimes we'll have patent owners come to us and say, We have a patent. We'd like to know, you know, does it have any vulnerabilities or should we do something else.

Q. Mr. Figg, have you ever served as a mediator for patent infringement disputes?

A. I have. I have served both as a mediator and an arbitrator, actually probably more frequently as an arbitrator.

Q. And what did you do when you served as an arbitrator for patent infringement disputes?

A. Well, it varies from case to case.

Some cases, the parties will come to me and say: We want to resolve this. We don't want to spend

a lot of money on it. We'd like to have our counsel provide briefs to you, and then we'd like for you to decide the case just based on reading those briefs. And I've done several like that.

At the other extreme it's a full-blown evidentiary hearing, and I've handled that sort of case as well.

Q. In your 30 years of litigating Hatch-Waxman cases, have you represented generic drug firms?

A. Yes. Probably -- I can actually only think of one case, the one I mentioned that turned out to have been a jury trial, where I represented what we sometimes call the innovator company or the patent owner in a Hatch-Waxman case. And that case was back in the '90s.

Most of my other if not all of my other cases, I've represented the generic company.

Q. Outside of the Hatch-Waxman litigation context, do you represent patent owners or innovator firms?

A. I do represent patent owners and -- and, as I say, what we refer to as innovator companies, who are conducting research and developing products.

But in Hatch-Waxman in the pharmaceutical industry, the situation has sort of evolved that there

are lawyers who are almost always on the generic side and there are lawyers who are most always on the patent owner side.

JUDGE CHAPPELL: You said earlier you've served as a mediator and arbitrator?

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: How did you get those cases?

THE WITNESS: I'm sorry, Your Honor?

JUDGE CHAPPELL: How were those cases assigned to you as a mediator or arbitrator? Were they court-ordered or how did they come to you?

THE WITNESS: I don't recall any that I've had where I was selected by a court. I think they have all come to me because the parties or the attorneys who were involved knew me or knew of me, and they asked me to serve in that capacity.

JUDGE CHAPPELL: Is your name on some list of mediators or arbitrators?

THE WITNESS: I've never done that, so no, I'm not like a JAMS arbitrator or a -- I've handled ICC arbitrations, but I'm not -- as far as I know, I'm not identified by them as one of their arbitrators, might be something I'd want to do in the future, but so far it's just people who locate me or know me by reputation.

JUDGE CHAPPELL: And these cases where parties have come to you, are they -- have they formed a written agreement where they're bound by your ruling if it's arbitration?

THE WITNESS: I apologize that I keep asking people to repeat themselves, but I'm having trouble hearing, Your Honor.

JUDGE CHAPPELL: You said the parties would come to you, you weren't on an official list or something.

THE WITNESS: Right.

JUDGE CHAPPELL: Did the parties agree in writing that they would be bound by it if it was arbitration?

THE WITNESS: Yes. We would almost always have an arbitration agreement in which they would -- which would define sort of the scope of what I was going to do. I would insist that the ground rules be reduced to writing so that there's no dispute down the road as to whether I did something that was contrary to their expectations. And they would have in that agreement whether it was advisory or whether it was binding.

JUDGE CHAPPELL: Did your experience in mediation or arbitration result in a settlement

agreement like the one at issue in this case?

THE WITNESS: I don't recall that being -- it's very possible. But normally my involvement in the case ended when I rendered my decision. And usually if it's binding, that's the end of the case, so -- so probably not.

Now, mediation very well -- I haven't done that many mediations, but they usually do end up with some sort of an agreement -- if the mediation is successful and you can get the parties to come together, then it will almost always end in some form of a settlement agreement.

JUDGE CHAPPELL: All right.

THE WITNESS: I have trouble, Your Honor, sometimes separating in my mind when I have been involved in a mediation as counsel or when I've been the mediator, but in both situations, it almost always results in either the parties not being able to agree or agreeing and reducing their agreement to writing.

BY MR. HENDRICKS:

Q. Mr. Figg, in your 40 years of practicing patent law, have you been involved in negotiating settlement agreements to patent infringement suits?

A. Yes.

Q. Do you have a sense of how many times you've

been involved in negotiation of a settlement agreement?

A. You know, I -- I'm sorry. I just don't keep track of those things. It's been a fair number of them, quite -- patent litigation in general is -- tends to settle. And Hatch-Waxman litigation is not an exception to that.

Q. And have you negotiated settlements to patent infringement cases on behalf of generic drug companies?

A. Yes, I have.

I will also point out that I'm not always involved even when the case settles. Most of these companies are sophisticated companies who have in-house law departments, so sometimes they'll do the -- all of that settlement negotiation and the drafting of the agreement themselves without the involvement of their trial counsel.

Q. Have any of the negotiations of settlement agreements that you've been involved in been in the context of Hatch-Waxman litigation?

A. Yes.

Q. Do you have a sense of the number of settlement agreements you've helped negotiate in Hatch-Waxman litigation?

A. Well, take this as maybe an educated guess. I'd say 10-15, maybe more. I haven't counted them.

Q. As part of these Hatch-Waxman settlements, have you been involved in negotiating licenses to the patents at issue in those cases?

A. Yes. Often the settlement includes licensing terms.

Q. Have you ever been involved in Hatch-Waxman litigation in which an at-risk launch was considered?

A. Yes. Both at-risk launches by -- were considered by my client and also, as I mentioned, a lot of times these cases involve multiple defendants, and so I've observed, you know, what other defendants in the cases I've been involved in have done.

Q. Mr. Figg, are you admitted to practice law in any courts or tribunals?

A. Yes.

Well, I guess my first admission was in the U.S. Patent and Trademark Office actually. I'm a member of what they call the patent bar, which allows me to handle both -- represent clients in proceedings in the Patent Office both ex parte and inter partes.

I am admitted to the D.C. bar and the Court of Appeals for the Federal Circuit, the Court of Appeals for the D.C. Circuit, the U.S. Supreme Court, and I've

been, you know, admitted pro hac vice in numerous courts around the country.

Q. Are you admitted to practice before the International Trade Commission?

A. I have handled several cases in the ITC. I don't recall as I'm sitting here whether they have a special bar admission that's required. If they do, then I must be admitted because they allowed me to do it.

Q. Are you a member of any professional organizations related to patent litigation?

A. Well, patent litigation and intellectual property law in general. Probably I have been most active in the American Bar Association, but I've also been a member for many years of the American Intellectual Property Law Association, the Licensing Executive Society, the -- an international intellectual property group that's called AIPPI. And I'm probably forgetting some.

Q. Can you describe your activities in the American Bar Association.

A. Can I describe it? I'm sorry. I just didn't hear your question.

Q. Sure.

Can you describe your involvement with the

American Bar Association.

A. Well, I -- I've been a member of that organization for a long time. I started out wanting to be active in it. I joined committees. I ended up chairing committees. I chaired what they call divisions in that group.

So they divide up intellectual property law, for example, in patents, trademarks, copyrights, and so forth. I've chaired the Patents Division.

I became a member of the council, which is the governing body, and later became the chair of the section of intellectual property law, which -- which is actually the largest or at least when I was chair -- I don't know if it still is -- it was the largest organization of intellectual property lawyers in the world.

And -- and I remained active for a number of years after that. I chaired what was called the Patent Law Task Force -- Patent Reform Task Force.

There was a lot of activity in Congress several years ago to make major overhauls in the patent law, and that ultimately became what's known as The America Invents Act. I was very much involved on behalf of the ABA in working with Congress, you know, trying to get the ABA's positions across to Congress.

I was chair for a number of years of the sections amicus brief committee, so we would prepare and submit briefs to the Court of Appeals for the Federal Circuit and the Supreme Court on important patent cases.

And then I later became a member of the amicus briefs committee of the ABA, of the big organization, which was quite an honor and quite an interesting experience because it was a very small committee that basically vetted the briefs filed on behalf of the association, mostly in the U.S. Supreme Court, and so that was quite an interesting experience for me.

On some of the other organizations, I won't -- you know, you can only kind of devote so much of your time to this kind of thing, so I was not nearly as active in the AIPLA, but I was on a number of their committees and worked with that organization for a number of years.

I was on the executive committee of this international organization, AIPPI, for a number of years.

So I don't know. That's probably more than you really wanted to know.

Q. No. That's very helpful. Thank you.

Have you served on any committees connected to

law schools?

A. Yes.

I'm no longer active in that area, but I was on the advisory committee to the Franklin Pierce law school, part of the University of New Hampshire, which has a very active program in intellectual property law, and so I was asked to serve on the advisory committee to that law school for a few years.

And also Georgetown Law School asked me to serve on an advisory committee for, you know, a couple of years. I don't remember how long exactly.

Q. Have you received any honors or awards recognizing your excellence in patent litigation?

A. Well, I -- I guess the main one would be that I have been inducted as a fellow in the American College of Trial Lawyers.

I'm also a fellow of the American Bar Foundation.

I've been named in various publications. There's a publication called Best Lawyers that has named me lawyer of the year for intellectual property litigation for several years, including this current year.

And -- I don't know -- I've been named in other magazines, The Washingtonian and things like

that.

MR. HENDRICKS: Your Honor, I'd like to proffer Mr. Tony Figg as an expert on Hatch-Waxman litigation and settlements for the resolution of Hatch-Waxman litigation.

MR. WEINGARTEN: Your Honor, we object to the proffer.

Mr. Figg may have experience as a patent litigator, but he's being presented here today to offer legal opinions about the interpretation of the Hatch-Waxman statute, the interpretation of court filings in the underlying patent case, the status of antitrust law in 2010.

We believe that's improper legal opinion that Your Honor does not need to decide this case, and we would ask that Your Honor not allow it and he strike the report.

JUDGE CHAPPELL: I find this information relevant under the latest Actavis decision. Your objection is overruled.

To the extent any opinions offered meet the proper legal standards, they'll be considered; to the extent they don't, they won't be considered.

I suggest, if you have concerns, you go into those on your cross-exam.

MR. WEINGARTEN: Thank you, Your Honor.

MR. HENDRICKS: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. Mr. Figg, what did you do to form the opinions that you intend to provide in this case?

A. Well, maybe the most obvious thing is I've practiced patent law and engaged in patent litigation for a long time.

But specifically for this case I -- I have reviewed a fairly large volume of materials, particularly materials that were created during the underlying patent litigation between Impax and Endo, pleadings, expert reports, the patents that were involved, things like that.

I've also looked at the settlement agreement and some of the internal correspondence and testimony surrounding that.

Q. In your estimate, how many pages of materials did you review?

A. I didn't count, but it's a big stack of material (indicating). Much of it I reviewed online or on the computer screen, but quite a bit of material.

Q. Just for the record, about how large do you think that stack was?

A. Well, you know, I don't -- it was probably more than a Bankers Box all put together, perhaps even more than that.

Q. Were there any materials that you would have liked to have reviewed to form your opinions to which you did not have access?

A. No. Everything I wanted to see or asked for I got, some from counsel for Impax, some publicly available documents like court pleadings and things we actually got ourselves.

Q. In your review of the materials, did you evaluate the discovery record of the underlying Hatch-Waxman litigation between Endo and Impax?

A. I certainly looked at materials that I think were produced as part of discovery, but in general, the answer to your question is no.

I started looking at this case from the perspective of its status going into trial, so at that stage, the litigating attorneys had been engaged in discovery. They had sifted through all of that discovery and winnowed it down and had focused on what they thought was important for the case, on both sides of the case, so I took advantage of the fact that they had done all of that work.

JUDGE CHAPPELL: What did you mean when you

asked him if he evaluated the discovery record?

MR. HENDRICKS: Well, if he had reviewed the documents that were produced in the underlying litigation.

JUDGE CHAPPELL: All right. It looks like he answered that.

Go ahead.

BY MR. HENDRICKS:

Q. How much time did you spend on this matter?

A. I think probably up to the present time it's been somewhere in the order of 70 or 80 hours, maybe more.

Q. In your 40 years of experience as a patent attorney, was your review in this case consistent with how you would normally study, review and analyze the issues of a Hatch-Waxman litigation?

A. Yes. I think so.

Q. How does what you did in this case compare to how you typically formulate opinions in work that you do in your daily practice as a patent litigator?

A. Well, it's -- it's very similar. As I say, when you're actually litigating one of these patent cases, you -- you live with it all the way through the discovery process. But when you get to trial and you're getting ready for trial, at that point you have

expert reports, you have documents and -- and you prepare briefs, and you know, you evaluate the case for presentation at trial, so it's not that much different.

It's just what I was asked to do in this case was sort of step in after all of that preliminary work had been done, so I looked at the pleadings, the -- I spent a lot of time with the technical expert reports and economics expert reports that had been presented in the patent case as well as the parties' briefs and orders that had been issued by the court, so it gave me a pretty good sense of what was going on in the patent case at that time.

Q. In your practice, do you typically read court opinions and competing expert reports, review documents and give -- I'll stop there.

Let me just repeat that question.

In your practice, do you typically read court opinions?

A. Do I typically read?

Q. Opinions of courts.

A. Oh, of course.

Q. Do you evaluate the merits of competing expert reports?

A. Yes.

Q. Is it common for you to give clients estimates on the timing of litigation in your practice?

A. Yes. I'm asked to do that with some regularity.

Q. Mr. Figg, I'd like to take a few minutes to ask you some questions about the Hatch-Waxman Act generally.

And I think we'll have a couple demonstratives that we'd like to show. I can hand out a binder if people would like a paper copy.

And Your Honor, may I approach the witness to hand him a binder?

JUDGE CHAPPELL: Did you ask me if I wanted a binder? I didn't understand you.

MR. HENDRICKS: I just would like to hand the witness a binder and complaint counsel if they would like one as well.

JUDGE CHAPPELL: All right. You may approach the witness, but I won't answer for the government. He can let you know.

MR. WEINGARTEN: I'd like a binder, please.

BY MR. HENDRICKS:

Q. And Robert, if I could ask you to put a demonstrative that's been marked RX D-7 on the screen.

And if you want to look at it in paper copy, it

is tab 1 of your binder.

Can you identify this demonstrative, Mr. Figg?

A. Yes. This is a demonstrative that in sort of block diagram form identifies the major components of the Hatch-Waxman Act or what we sometimes call the Hatch-Waxman amendments.

Q. Does this demonstrative summarize information contained in your report?

A. Yes. I addressed these topics in my expert report.

Q. So let's start at the top.

Can you please explain what a New Drug Application is.

A. Yes.

MR. WEINGARTEN: Your Honor, we object. This testimony is pure legal opinion. He's asking Mr. Figg to walk through a statute and provide Your Honor legal interpretation of the statute. Much of this has already been agreed to on Joint Exhibit 1. And we've already heard testimony about much of this from fact witnesses, including Ms. Snowden.

MR. HENDRICKS: Your Honor, we would just like to provide a foundation for the context of the opinions that Mr. Figg will be providing today about litigation under this regulatory framework.

MR. WEINGARTEN: Your Honor, if I may.

JUDGE CHAPPELL: Go ahead.

MR. WEINGARTEN: Regardless of foundation, it appears that counsel is going to put this exhibit up on the screen and lead the witness through the exhibit, so I'm not sure how that is helping with the foundation other than helping with leading.

JUDGE CHAPPELL: He's got you there.

MR. HENDRICKS: I mean, this was simply to help the court --

JUDGE CHAPPELL: I'm going to allow the foundation, but you need to show that the witness has independent knowledge before you show him the exhibit.

MR. WEINGARTEN: Thank you, Your Honor.

JUDGE CHAPPELL: That means take it down.

BY MR. HENDRICKS:

Q. Mr. Figg, have you reviewed the provisions of the Hatch-Waxman Act?

A. Yes. I'm very familiar -- I think I'm very familiar with both the statute and the procedures that are involved.

Q. Do you -- in your 30 years of experience litigating cases under the Hatch-Waxman Act, do you apply those provisions to the facts in controversy of cases?

A. Yes, I do.

MR. HENDRICKS: Your Honor, if I may, we'd like to use the demonstrative as simply a help for the court. We can ask some questions about the Hatch-Waxman Act.

JUDGE CHAPPELL: What I haven't heard is whether he had anything to do with preparing the demonstrative, what his connection is to the demonstrative.

BY MR. HENDRICKS:

Q. Mr. Figg, I think I asked earlier, but does this demonstrative accurately summarize information that you disclosed in your expert report?

A. Yes. And I was -- I was involved in its preparation, but -- I don't have it on the screen in front of me now, but the boxes on this document are pretty much the -- an illustration of the narrative that I provided in my expert report.

MR. WEINGARTEN: Your Honor, we still object to the extent that they want to put it up on the screen. We haven't heard yet from Mr. Figg that he prepared this demonstrative and he did so to assist with his testimony today.

MR. HENDRICKS: Your Honor, I believe the witness testified that he was, quote, involved in its

preparation in his last answer.

JUDGE CHAPPELL: It's a demonstrative. The witness said it was a summary of his expert report. His expert opinions are those that are in the report. I'll allow it as a brief overview or foundation of his testimony but not as a factual finding in the case.

MR. WEINGARTEN: Thank you, Your Honor.

MR. HENDRICKS: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. So, Mr. Figg --

JUDGE CHAPPELL: For example, Hatch-Waxman is a statute. All of us can interpret it on our own. But as a summary or foundation, I'm allowing it.

MR. HENDRICKS: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. For the court, can you explain what a New Drug Application is.

A. Yes.

When the -- when an -- what I've been calling an innovator pharmaceutical company develops a new drug or therapeutic agent, they have to do a lot of preliminary work to get that drug ready for testing in human beings, and so they actually have to get approval of an application from the FDA to do human testing.

And they do a lot of what's called preclinical testing. They do development of the drug, development of the formulation, and so forth. And all of that comes together in what's called a New Drug Application.

So the New Drug Application will include information about the drug itself, its chemistry, how you control it, how you manufacture it. It also will include the results of human clinical studies, usually large-scale, controlled human studies to establish the safety and efficacy of the drug.

And all of that comes together in this filing, which is quite a -- quite an extensive filing, called a New Drug Application, which is filed with the Food and Drug Administration.

Q. And when a New Drug Application is filed, are patents disclosed that cover the drug in the New Drug Application?

A. Yes.

This was actually one of the things that was introduced by the Hatch-Waxman amendments, that the New Drug Application applicant is required to identify any patents that cover the drug itself or an approved method of using the drug.

And those patents are identified to the FDA, and the FDA publishes them in a publication -- it has a

long name, something like Approved Drug Products with Therapeutic Equivalence, but it's -- all of us in this business know it as the Orange Book because back in the days when it actually was a physical book its cover was bright orange.

Q. Thank you.

What is an Abbreviated New Drug Application?

A. Yes.

So this was probably one of the major changes to the law that was brought about by Hatch-Waxman. It provided a streamlined way for the approval of generic drugs, generic versions of approved brand name prescription drugs.

And unlike the NDA, which requires the extensive results of large-scale clinical trials, what the abbreviated new drug applicant is required to do is to show that its drug is the therapeutic equivalent of the approved drug.

Normally what that requires are what are called bioequivalence studies, which are small-scale studies in humans to show that the generic version of the drug is therapeutically equivalent to the brand name, which is sometimes called the reference listed drug or the RLD.

Q. And if today if I state the word "ANDA," do you

understand that to mean an Abbreviated New Drug Application?

A. Yeah. That's a very common abbreviation.

Q. Is there any significance to being the first filer of an ANDA?

A. Yes.

In putting this statute together, Congress provided various incentives, both to the innovator companies and to the generic companies.

And one of the incentives provided to the generic companies was to go to the trouble of putting an ANDA together and conducting the required studies and challenging patents that might have been listed in the Orange Book.

And as the incentive for companies to do that and to do it as early as possible, the first filer is provided with 180 days of exclusivity against other generic companies, so the FDA is not allowed to approve a subsequent ANDA until 180 days after the first applicant launches its product.

Q. Can a first-to-file generic company lose this exclusivity?

A. Yes.

There are provisions in the statute -- and some of these were formalized in a later amendment to the

statute -- called forfeiture provisions, and so it -- there are various things that can trigger a forfeiture. It's actually a fairly complicated part of the statute.

Q. Mr. Figg, can you describe what is meant by a Paragraph IV certification in the context of the Hatch-Waxman Act?

A. Yes.

The -- in addition to the parts of the ANDA that have to do with the safety and efficacy and bioequivalence of the drug, the statute also has provisions addressing the patents that the brand name company has listed in the Orange Book.

And so if there is a patent listed in the Orange Book for this drug, the generic applicant has to file one of four different types of certifications with regard to those patents.

The most important are a Paragraph III certification, which is simply a certification that we, the generic company, are not asking for approval before the patent expires, so that doesn't lead to litigation.

The Paragraph IV certification is a certification that the generic company believes the listed patent to be invalid or not infringed and -- by

its product, and so that's a certification that has to go in to the FDA. Typically it goes in with the ANDA.

Q. And is the branded company notified of the paragraph certification?

A. Yes.

The statute requires that the generic company provide a notice providing the bases on which -- first of all, informing the brand company that it has filed an ANDA seeking approval prior to patent expiration and then notifying the brand company of its legal and factual bases for its opinion that the patent is invalid or not infringed.

Q. What is the significance of the Paragraph IV certification and notice letter under the Hatch-Waxman Act?

A. Well, under the statute, once the notice letter is served on -- it has to be served on the owner of the patent that's listed in the Orange Book and also the NDA holder. Oftentimes that's the same company, but not always.

And the recipients then have 45 days within which to file a patent infringement lawsuit against the generic company. If they file that lawsuit within that 45 days, the FDA then cannot approve the ANDA for a period of up to 30 months.

So the -- most of the Hatch-Waxman litigation that we see involves a lawsuit that was filed that was triggered by that notice letter and that was filed within 45 days of its receipt.

Q. Did the Hatch-Waxman Act create a technical act of infringement on which branded companies can sue?

A. Yes.

What Congress did here was it created a system where the patent issues could be litigated at the same time the medical and scientific merits of the ANDA were being evaluated by the FDA.

Now, at that point in time, the generic company is not selling anything, and it hasn't committed, you know, a traditional act of patent infringement, it hasn't sold anything, and the statute -- one of the amendments the Hatch-Waxman statute made was to the patent statute, which said that the experimental work that the generic company does in order to put its ANDA together is exempt from infringement.

So this allows the generic applicant to do all of the experimental work leading -- and developing the product leading up to the filing of an ANDA without being sued for patent infringement. But in order to

make -- to create subject matter jurisdiction for a federal court, the statute makes the filing of the ANDA itself a technical or what's sometimes called an artificial act of infringement. And that then gives the patent owner the opportunity to file that lawsuit.

Q. And what was the purpose of creating an artificial act of infringement?

A. Well, as I said, it was to create subject matter jurisdiction.

What led up to this -- and please tell me if I'm getting into more detail than anybody really wants to know -- but what led up to this was there was a decision by the Court of Appeals for the Federal Circuit that the experimental work that the generic company did leading up to being in a position to file its ANDA, that that actually was an infringement, that there was not an experimental use exemption for that.

And so the consequence of that case was a generic company couldn't even start developing its product or testing it until after the patents expired, which meant there would be another several years before the public would get the benefit of this generic drug, and so Congress decided we should let the generic company do that work without fear of patent

infringement so that it can -- and then resolve the patent litigation promptly, even before the generic company launches its product usually.

Q. Let's move to the litigation phase under the Hatch-Waxman Act.

Does the Hatch-Waxman Act affect the standards applied in patent infringement litigation itself?

A. The basic issues of patent infringement and validity are the same in Hatch-Waxman as in normal patent litigation.

Q. And so in just a sentence, can you define what you mean by "a patent"?

A. A patent?

Q. Yes.

A. A patent is often looked at as a bargain between the public and an inventor where, in return for the inventor or the company that's making the invention -- in return for their investing in the research and development that was required to create the invention and -- and then in return for the disclosure of the invention, a full disclosure of the invention in the patent application, the public gives the inventor a limited right to exclude others from practicing the invention.

A patent doesn't give the owner of the patent

the right to do anything. It gives the patent owner the right to exclude others from doing what is claimed in the patent.

Q. And in Hatch-Waxman litigation, what issues, on a very high level, are typically in dispute?

A. Most often they are infringement and validity, whether the generic drug or its use will infringe a claim of the asserted patent and whether that claim is valid under the applicable patent statutes.

Q. And which party bears the burden of proving infringement?

A. The patent owner has the burden of proving infringement.

Q. And what is the standard of proof to show infringement?

A. That's a preponderance of evidence standard, so it's often referred to as tilting the scale, you know, one way or the other more likely than not.

Q. Is there anything in the nature of the Hatch-Waxman Act that makes it -- that simplifies infringement arguments for the branded company?

MR. WEINGARTEN: Your Honor, objection. I don't understand, frankly, the question or the foundation that Mr. Figg has to describe the nature of the Hatch-Waxman Act and interpreting it and how it

simplifies infringement arguments for a branded company.

JUDGE CHAPPELL: Foundation?

MR. HENDRICKS: His foundation is practicing --

JUDGE CHAPPELL: You need to lay a foundation with the witness.

BY MR. HENDRICKS:

Q. Mr. Figg, have you made infringement arguments in -- excuse me. Let me rephrase that.

In your years of practicing Hatch-Waxman litigation, have you made arguments to counter the infringement arguments made by branded companies?

A. Yes. I've made arguments counter to the brand company's infringement arguments, and in other litigation I've made arguments of infringement on behalf of the patent owner.

Q. And do you -- in those -- as part of those arguments, do you ever rely on the fact that a generic drug must be a therapeutic equivalent of a brand drug?

MR. WEINGARTEN: Your Honor, objection. Leading.

JUDGE CHAPPELL: Do you ever --

THE WITNESS: That's okay because I didn't hear the question anyway.

JUDGE CHAPPELL: He's not suggesting an answer, so it's not leading. The witness has the choice of yes or no.

MR. WEINGARTEN: Well, Your Honor, I believe he's at least assuming facts that are not in evidence here. He's asking him do you rely on the fact that, and then he's talking about generic drugs with therapeutic equivalence.

JUDGE CHAPPELL: He can assume facts not in evidence. He's an expert. He's going to restate the question anyway. Much ado.

Go ahead.

BY MR. HENDRICKS:

Q. Does an ANDA filer have to show therapeutic equivalence to the branded drug in its application?

A. Yes.

The -- there are a couple of things that are unique to Hatch-Waxman litigation. The -- the generic company has to establish that its product is essentially the equivalent, the bioequivalent, of the patented drug.

And the generic company also is required to copy very substantially the label or package insert, so any instructions for use of the drug or dosages, those sorts of things, the generic company has to copy what

the brand company has done.

JUDGE CHAPPELL: You said the generic company has to establish its product is bioequivalent?

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: Do they have to establish it or do they just certify that that's the case?

THE WITNESS: No. That's something that the generic company has to prove to the FDA's satisfaction, so they -- typically the way this is done, Your Honor, is, for most drugs, not all, they do a study in human volunteers, healthy human volunteers, which show that the drug is -- produces the same blood levels as the branded drug. What they say is it operates to the same extent and level as the brand drug.

So these are done with human clinical studies.

JUDGE CHAPPELL: You're going to need to wrap up your overview because these are not disputed issues in this case.

MR. HENDRICKS: Yes, Your Honor.

BY MR. HENDRICKS:

Q. My question is simply, does the fact that an ANDA must be a therapeutic equivalent have a bearing on the infringement issues in Hatch-Waxman litigation?

A. Yes. It -- the fact that the generic company

has to copy these things from the brand drug and the brand drug's label means that the ability of the generic company to design around the patent is more limited than it would be in a normal patent infringement case.

Q. Mr. Figg, in your experience litigating Hatch-Waxman cases since the act was passed in 1984, do you have an opinion regarding whether branded or generic firms typically prevail in cases that go to trial?

A. Well, based on my own experience and what I've observed in the industry for a long time is that the brand companies actually have somewhat of an edge in these cases, and it has to do with what I just described.

It also has to do with the fact that often, if the generic company cannot avoid infringement, then it has to rely on an argument that the patent is invalid or unenforceable. And the burden of proof on that is quite high. It's clear and convincing evidence.

So yes, I think most people who litigate in this area would recognize that the brand company does have an edge in these kinds of cases. It doesn't mean they win all the time, but they win -- they win probably more often than not.

Q. Did you see any documentary evidence in your review of documents for this case that corroborate that opinion?

A. Yeah. Well, there's one document that was an analyst's report called the RBC Capital Analysts I think, which basically just confirmed what I just said, that -- I think the number they used in that report was the generic prevails about 48 percent of the time and the brand prevails about 52 percent of the time.

Q. Okay. I'd like to move to the specific Hatch-Waxman litigation between Endo and Impax that was settled in 2010.

Are you familiar with that case, Mr. Figg?

A. Yes.

Q. What did you do to familiarize yourself with that case?

A. Well, as I said earlier, I read quite a number of lengthy technical expert reports in which the parties presented the factual bases for and opinion bases for their positions on infringement and validity.

I reviewed the -- of course the patents that were involved in the case and particularly the patent claims, which are the sort of the part of the patent

that defines the scope of the right to exclude.

I reviewed the pleadings in the case. I reviewed briefs that had been filed, both at the claim construction stage as well as the merits stage of the case, and probably some other things that I'm forgetting.

Q. I'd like to turn your attention to Respondent's Exhibit 263.

And Robert, if you could put that up.

It's tab 4 of your binder if you'd like to see it in paper copy.

Can you identify this -- and Your Honor, this document is in evidence and is not subject to in camera -- to the in camera order.

Can you identify this document?

A. Yes. This -- this was the -- a copy of the entry for Opana ER at the time of this patent litigation or immediately prior to the patent litigation that we're talking about, so this was the Orange Book entry. And what we see on this page is Endo had listed with the FDA three patents that it believed would be infringed by the unauthorized use of its product.

Q. Can you briefly describe what these three patents covered?

A. Yes.

They all have to do with the formulation of oxymorphone into a drug product. My understanding is that oxymorphone itself was a very old compound. It had been disclosed many years before.

These patents cover extended-release formulations of oxymorphone. And in general, they have to do with a technology called gel, hydrogel or gel release technology.

MR. WEINGARTEN: Your Honor, we object and move to strike the testimony. Mr. Figg has not offered any foundation that he was involved in creating these patents, that he's qualified to interpret the patents. There's no basis for this testimony.

And also, Your Honor, it's fact testimony. If they want to bring a fact witness to talk about Endo's patents, that would be one thing, but there's no need for an expert legal opinion on the contents of the patents.

MR. HENDRICKS: Your Honor, Mr. Figg evaluates patents every day as part of his job as a patent litigator, and he looks at patents, he explains them. It's simply what he does.

JUDGE CHAPPELL: All right. His opinions are limited to what's in his expert report. And you will

learn, when it comes time for posttrial briefing, that neither side is allowed to cite to an expert witness for facts.

MR. WEINGARTEN: Thank you, Your Honor.

JUDGE CHAPPELL: To the extent any expert tells us about facts they used in forming their opinion and those facts are wrong, that can be an issue.

MR. HENDRICKS: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. Mr. Figg, have you prepared a demonstrative that shows the timeline of events and milestones in the litigation?

A. Yes.

Q. I'd like to put that demonstrative on the screen.

Robert, can you put up RX D-08.

Is this the demonstrative --

A. Yes.

Q. -- that you referred to?

A. Yes.

Q. Does this demonstrative summarize information that is contained in your expert report?

A. It does.

Q. When did Impax submit its ANDA for oxymorphone ER?

Actually, sorry. Strike that.

My question was, when did Impax submit its Paragraph IV certification on oxymorphone ER?

A. Yeah. It might be helpful to Your Honor if the -- what doesn't appear on this chart to the left is that Endo had filed its NDA, got approval, listed its patents in the Orange Book, and all of that had happened before this, and Impax had filed an ANDA.

So in December of 2007, Impax provided its Paragraph IV notice letter to Endo. And you recall that's the event that triggers this 45-day period within which to file suit.

Q. And have you reviewed Impax' notice letters?

A. I have.

Q. What did Impax assert in those notice letters?

A. They asserted that they did not infringe any of the three patents that were listed in the Orange Book.

Q. And just to back up, was Impax the first to file an ANDA for oxymorphone ER?

A. Yes. The documents I've reviewed indicate that Impax was the first to file on I think it was five dosage strengths, and please don't ask me to recite what those five were. But they were the five main dosage strengths for the drug.

Q. Were there any other first filers on other

dosage strengths?

A. Yes. I think we'll see some documents later that show that another generic company, Actavis, was first to file on two dosage strengths.

Q. And what did Endo do in response to receiving Impax' notice letter?

A. Well, as this chart indicates, in January, toward the end of January, Endo sued Impax for patent infringement.

Q. And on which patents did Endo sue Impax?

A. Impax asserted -- excuse me. Endo asserted infringement of what we call the '933 patent and the '456 patent. Those were two of the patents that we saw listed in the Orange Book.

Q. And one of the milestones on this demonstrative is the claim construction hearing?

A. Right.

Q. Can you briefly describe what a claim construction hearing is?

A. Yes. And just stop me if I'm being a little too basic here.

But the -- every patent -- every United States patent has one or more clauses at the end of the patent that are called the patent claims. And it is those patent claims that define the scope of the right to

exclude, so they're sometimes analogized to the metes and bounds in a property deed. They tell the public what you are precluded from doing by this patent.

In cases like this, the claims often contain very technical terms, terms that may not be things that most of us would see in our everyday lives, and so one of the things that the court has to do is rule on what various terms in the claims mean because the parties may dispute the meaning. And we'll see, as we go forward today, there were terms here where the parties had very hot disputes about the meaning.

And so the claim construction, it's also called a Markman proceeding after the Supreme Court case that dealt with this issue.

The parties -- courts normally will set a schedule and they'll put forth a procedure for the parties to exchange the list of terms that they think require interpretation and what those -- what their proffered interpretations are, and then they will file briefs with the court. Sometimes the briefs are supported by expert testimony.

And this all goes in to the court, and then typically there is actually a hearing before the court. And that's called the claim construction hearing or the Markman hearing. It's a very important part of most

patent litigation.

Q. In your experience, can the results of a claim construction hearing be dispositive?

A. Oftentimes it can. And sometimes a defendant's noninfringement position simply goes away depending upon how the terms of the claim are construed. And the same applies on the other side. The court has to construe these terms the same way for infringement and validity, so it works both ways.

Q. And did you review the claim construction briefs in the -- in this case?

A. Yes, I did.

Q. And did you review the court's claim construction orders in this case?

A. Yes, I did.

Q. And did you assist in creating a demonstrative that lays out those briefs and orders?

A. Yes. Yes, I did.

And I would point out, as shown on RX 548, the court actually issued two orders. It issued an order on March 19, and then it amended that order on April 5, so it's really the April 5 order that is -- that controlled the litigation going forward.

Q. And just for the record, the March 19 date was the date of the actual hearing; is that correct?

A. I'm sorry. I'm sorry. You're correct.
Q. But there was --
A. There was an earlier order, and you're right. I apologize.
Q. Robert, can you put up RX D-09.
Is this the demonstrative about the claim construction briefs and orders that you just referred to?
A. Yes.
What's shown in the left-hand column there are terms that were found in the asserted patents' claims that were in dispute.
And then in the middle column you have Endo's and Impax' proposed constructions of those terms.
And then in the last column we have the interpretation that was actually part of the judge's order.
Q. So starting at the top, can you please explain the disagreement on claim construction of the term "hydrophobic material."
A. Yes.
MR. WEINGARTEN: Your Honor, objection. Now he's asking Mr. Figg to interpret court filings. That's not something that's proper testimony for an expert, Your Honor. That's his legal opinion and his

legal advice as to the meaning of the claim constructions that were proposed, and I assume he's ultimately going to try and give you interpretation of the amended order that was issued by the court.

MR. HENDRICKS: Your Honor, as you said at the outset, the -- how the court would have viewed the patent issues are very much relevant under Actavis, under the Actavis case.

JUDGE CHAPPELL: Is this part of his opinion that has been offered in his expert report?

MR. HENDRICKS: Yes, sir.

JUDGE CHAPPELL: Overruled.

THE WITNESS: Yes.

So I should point out that this first term, "hydrophobic material," was a term that is found in all of the claims of both patents. And it's what patent lawyers refer to as a claim limitation. And so it was important to both the infringement and validity issues of the case.

The plaintiffs offered a construction of that term that is a functional interpretation, so in the plaintiffs' view, the term meant a material that is effective to slow the hydration of the gelling agent without disrupting the hydrophilic matrix.

And so the reason we call that functional is it

doesn't really define the material so much by what it is as by what it does.

Now, Impax' construction also included that functional language, but it included also the language "a material which lacks affinity for water, for example, is resistant to or avoids wetting."

So Impax offered a construction that described what the material is as well as what it does.

BY MR. HENDRICKS:

Q. And did the court adopt one party's proposed claim construction of "hydrophobic material" over another?

A. Yes. The district court --

MR. WEINGARTEN: Your Honor, that's -- objection. Now he's asking for Mr. Figg's interpretation of the court order and he's asking what a federal district court did. The court is perfectly capable for itself of reading opinions and orders by other courts.

JUDGE CHAPPELL: I'm going to give you a continuing objection on legal opinions because I don't want to have a spring-butt in here jumping up every time a question is asked.

MR. WEINGARTEN: Thank you, Your Honor.

JUDGE CHAPPELL: So that's overruled, as long

as it's part of the opinion included in his expert report in this case.

MR. HENDRICKS: Yes, this is all described in the expert report submitted.

JUDGE CHAPPELL: Go ahead.

BY MR. HENDRICKS:

Q. I'll ask that question again.

Did the court adopt one party's proposed claim construction of "hydrophobic material" in this case?

A. Yes. The court adopted the Endo construction verbatim.

Q. And moving to "sustained release," can you please explain the disagreement between the parties on how the court should construe that term.

A. Yes.

As we can see here, the plaintiffs -- the term that was in the claim was actually "sustained release excipient," and so the court -- and the parties asked the court to construe that term.

Plaintiffs' construction addressed what does the term "sustained release" mean, and their offer was that the active medicament is released at a controlled rate such that therapeutically beneficial blood levels of the medicament are maintained over a period of at least twelve hours.

And then they -- they offered the construction of "sustained release excipient" to be an excipient that provides for a sustained release of the active medicament. The -- that was the Endo-offered construction.

The Impax construction was "an excipient that provides for therapeutically active medicament to be released from the formulation at a controlled rate such that therapeutically beneficial blood levels and then (but below toxic levels) of the medicament are maintained over an extended period of time."

Q. And Mr. Figg, which party's claim construction of "sustained release excipient" did the court adopt?

A. Well, again, the court adopted the Endo construction verbatim or virtually verbatim. I think it's verbatim.

Q. And so if we look at Endo's construction in the second row and the language from the amended order in the third row, are those word for word the same?

A. Yeah. Yes.

Q. And is that true for the construction of "hydrophobic material" as well?

A. Yes.

Q. And just moving to the final row, could you briefly describe what happened for the construction of

"homopolysaccharide."

A. Yes.

And let me point out that just like "hydrophobic material," the "sustained release" limitation was in all of the claims.

This third one, "homopolysaccharide," only appears in the claims of the '933 patent. And on that one, the parties actually agreed to an interpretation of that term, and the court adopted the parties' agreed definition.

Q. And having reviewed the materials in the Hatch-Waxman litigation and relying on your experience as a patent attorney, in your opinion, did one party win the claim construction phase of this case?

A. Well, yes. I think it's clear that Endo won that phase of the litigation because the court adopted Endo's constructions.

Q. And how would a reasonable litigant in Impax' position have viewed this claim construction order?

A. I viewed this -- I think a person in Impax' position or a company in Impax' position would have viewed this as a significant setback for its case.

And the reason is that the court's construction of these two top terms, especially, affected both Impax' position on noninfringement and

its position on invalidity. And that's a bit unusual actually. Normally, a construction might affect one in a way that's beneficial to one party but not beneficial to the other. As we'll see, in this case, these constructions actually hurt Impax' case on both the infringement and validity issues.

Q. And in light of the claim construction order, do you have an opinion as to which party was likely to prevail at trial?

A. Yes. I -- I concluded that once this claim construction order issued, I think a reasonable party in Impax' position would have concluded that it was less likely to proceed -- to prevail ultimately in the patent trial.

Q. In your opinion, was Endo's victory a sure thing?

A. I'm sorry?

Q. In your opinion, was Endo's victory at trial a sure thing?

A. No.

These cases are very complicated, and both of these parties were represented by very capable attorneys and they had qualified experts, so there were issues to be litigated.

But based on my experience, this claim

construction was a significant setback for Impax, and my view is someone in Impax' position would have seen this as making it likely that they were not going to prevail at trial.

Q. Now, a while back you testified that one of the issues litigated is infringement; correct?

A. Yes, that's correct.

Mr. Hendricks, can I -- my hearing is obviously not as good as it once was. If you could get a little closer to the microphone. Thank you.

Q. In a Hatch-Waxman litigation, what happens to a generic firm if the court finds that the generic has infringed a valid patent?

A. Yes. The remedy is set forth in the part of the patent statute that was amended by the Hatch-Waxman statute. It's section 274 -- 271(e)(4) of Title 35.

And if the court concludes that the generic drug defendant has infringed a valid claim, then the court issues an order that the generic drug cannot be approved before the expiration of the patent.

So it's essentially an injunction, because a generic drug company can't commercialize its drug without FDA approval.

Q. And --

A. There are actually other provisions in that

section as well we can talk about, but that's the main one.

Q. Thank you.

Earlier you testified that the burden of proof for showing infringement is a preponderance of the evidence; is that correct?

A. Yes.

Q. You mentioned earlier that you reviewed the expert reports submitted in the Impax-Endo Hatch-Waxman litigation; correct?

A. Yes, I did.

Q. Having reviewed these expert reports, how much weight did Impax' expert witnesses put on its noninfringement arguments as compared to its invalidity arguments?

A. I think that their noninfringement position was obviously -- it was obvious to me that that's what they were banking on. And it was a better-developed position I thought than their invalidity positions.

As background, Your Honor, the claim construction ruling here came down very shortly before trial. That normally is not the case. Normally, district judges will schedule the claim construction proceedings fairly early in the process so that the parties know what the construction is as they're

getting ready for trial.

Here, the parties, when they were developing their expert reports, didn't know how the court was going to construe the claims, and so they addressed the infringement and validity issues basically using both sets of constructions.

So then once this construction order issued, they had to tailor their case to that claim construction.

Q. In its expert reports -- well, what effect did the functional definition that the court adopted of "hydrophobic material" in its claim construction have on the arguments that Impax made on infringement?

A. The -- as we saw, the court's construction was that the hydrophobic material was something that reduced the rate of hydration of the gelling agent without interfering with the gel. The gel -- the formation of this gel was part of the controlled-release technology that went into these tablets.

And -- and Endo's position was that what it had really invented was a way of controlling the release of the drug from the tablet through controlling the rate of formation of that gel through hydration. And the -- so what that meant was, a

material would be considered a hydrophobic agent, as required by the claim, if it reduced the rate of water uptake by the gel.

Endo had its expert supervise tests where the water uptake was actually measured. The water uptake of the Impax tablets was actually measured. And they had a company manufacture various versions of the Impax tablet with different percentages of the material that Endo was arguing was a hydrophobic material.

And these tests demonstrated that that material inhibited water uptake, so Endo's argument was, we have actually done the functional tests required by the court's claim construction, and we have evidence that this material in the Impax tablet meets that requirement.

Impax did not do any tests of its own. Impax simply criticized the testing that was done by the Endo expert.

Q. So to summarize that, is it your opinion that the claim construction of "hydrophobic material" required functional testing?

A. Well, as we see from Impax, you can attempt to just rely on the expert's opinion, but the claim construction required proof that the material

inhibited water uptake or hydration of the gel, and so that proof sort of calls out for doing tests to see whether or not it actually does that, and that's what Endo did.

Q. And Impax had no independent tests arguing the opposite?

A. Impax did not test that point at all.

Q. Drawing on your study of the expert reports and briefing in this case and applying your years as a patent litigator, what is your opinion on whether Endo would have prevailed in showing that Impax' generic oxymorphone ER product contained a hydrophobic material?

A. Yes. My view was that it was -- that Endo was likely to prevail in establishing that point to the court's satisfaction.

Q. Were there other infringement claims in dispute in the case between Impax and Endo?

A. Yes. The -- the "sustained release" term that we saw on the claim construction.

In its expert reports leading up to the trial, Impax did not argue that it did not infringe because it didn't have a sustained-release product. But in its trial brief -- and it also didn't include that in its noninfringement contentions, which were required by the

court's local rules.

But in its trial brief it included an argument that Endo could not prove that the Impax material was -- the Impax product was a sustained-release product.

So -- and I can go into the bases for the arguments on both sides of that. I'm happy to do that if you'd like.

One of the sort of threshold problems that Impax -- that I thought Impax was going to have was it didn't provide a basis for that argument in any of its expert reports, so it was not going to be able to present that argument through its expert witnesses. It was doing it basically through its trial brief and through attorney argument, so --

Q. Did Endo's expert reports have evidence under the claim construction of "sustained release" supporting its --

A. Yes.

Q. -- supporting its infringement arguments?

A. This is where this bioequivalence comes back into the picture because, in order to prove to the FDA that its product was bioequivalent to the Endo product, Impax had to submit the -- what's called the pharmacokinetic data. They had to show that the drug

was released in a way similar to the Endo drug and that it achieved the same maximum blood concentration and the same extent of delivery of the drug through a measurement called AUC or area under the curve.

What Impax showed was that -- what Endo showed was that those charts showing how the Impax product compared to the Endo product were almost superimposable.

So this was something Impax had to prove to the FDA, and Endo said, Now you're arguing to the patent court something different than what you said to the FDA.

MR. WEINGARTEN: Your Honor, we object and move to strike.

That answer does not have any basis in the report that was submitted. There's no discussion in the report about area under the curve or Endo making arguments relying on FDA bioequivalence studies that Impax put forward.

MR. HENDRICKS: I think that's incorrect, Your Honor. Mr. Figg does discuss the "sustained release" claim construction, discusses the invocation of a therapeutic equivalence claim --

JUDGE CHAPPELL: All right. Here's what we're going to do. I'm going to hold my ruling until you

can demonstrate with the witness that what he just said is in his report. After you've completed your attempt to do this, I'll rule on the motion.

MR. WEINGARTEN: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. Mr. Figg, in your binder next to you, under a tab -- it's actually labeled Report --

A. Tab what?

Q. It's just -- it's called -- it has "Report" written on the tab.

A. Oh, yeah. Uh-huh.

Q. You'll find RX 548?

A. Right.

Q. Do you recognize this document?

A. Yes. This appears to be the expert report that I submitted in this case.

Q. If you'd turn to paragraph 61 of your report, please.

A. 6-1?

Q. Yes, sir.

A. Yes.

Q. And also paragraph 62.

What are you describing in this -- in these two paragraphs?

(Document review.)

A. In here I'm describing what the court's construction of the term "sustained release" was and that the court construed it to mean that therapeutically beneficial levels are maintained over a period of twelve hours.

And I go on to say that this construction made it significantly more difficult for Impax to show that any of the claims were invalid.

Q. And Mr. Figg, if you turn to page 14 of your report --

A. I'm sorry?

Q. Page 14 of your report.

A. Okay.

Q. You'll see there's footnote 3?

A. Yeah.

Q. That reads, "In its pretrial brief, Impax also argued that its product lacked a 'sustained release' excipient under the district court's claim construction."

A. Yes. This is the part that deals with the infringement issue that I was just talking about. The -- the point that I made in this footnote was --

Q. Mr. Figg, let me just ask first, is this footnote related to the testimony you were just providing to the court?

A. Yes.

MR. HENDRICKS: Your Honor, I believe we've demonstrated that the testimony that Mr. Figg was providing is disclosed in his expert report.

JUDGE CHAPPELL: Withdraw your objection?

MR. WEINGARTEN: Withdraw the objection, Your Honor.

JUDGE CHAPPELL: Thank you.

Go ahead.

BY MR. HENDRICKS:

Q. So, Mr. Figg, we were just discussing why you believed Impax -- or you were describing Impax' arguments related to the "sustained release excipient" claim construction; correct?

A. Yes.

Q. Let me ask, in applying your years as a patent attorney and your review of the record, including the expert reports in this case, which party had the strongest position on the sustained release infringement claim?

A. In my opinion, Endo had the stronger position on that. The -- as I said, the Impax argument was not made in its expert reports or its noninfringement contentions, and it was based on an argument that seemed to be inconsistent with the bioequivalence data

that Impax provided to the FDA.

Q. The last significant infringement issue in the lawsuit was related to homopolysaccharide gum; correct?

A. Yes.

Q. If possible, can you briefly describe what that means?

A. The '933 patent contained claim limitations that required that the formulation include both a homopolysaccharide and a heteropolysaccharide such that those two components would cross-link or react with each other to form a gel.

The parties did not disagree that in construing the term "homopolysaccharide" what that means is it is a polysaccharide, meaning a molecule that's made up of a long chain of sugars, and in that chain, those sugars have to all be the same.

Impax' argument was, well, Endo's argument was that the Impax product contained a homopolysaccharide as well as a heteropolysaccharide and that the homopolysaccharide was a compound known as HPMC, hydroxypropyl methylcellulose. And no one disputed that.

But the dispute was Impax said that the cellulose part of HPMC is a monosaccharide, but it's derivatized by adding the hydroxypropyl groups and the

methyl groups, and so what that means is that you're modifying so that some of these sugar units in the chain are different, so it's no longer a homopolysaccharide.

And Endo disagreed with that through its experts and pointed out that one of the preferred homopolysaccharides identified in the '933 patent itself was a substance called locust bean gum, which also had derivatized groups on the backbone. And they said, you know, your -- your argument would mean that the preferred embodiment in our patent is not covered by our claims.

So that's where the -- that's where the dispute was left, you know, going into trial.

JUDGE CHAPPELL: We've been going two hours. We're going to take a break. When we come back, I'm going to ask you for an estimate on how much time you think you have remaining.

MR. HENDRICKS: I'll look over my outline and will have an estimate for you.

JUDGE CHAPPELL: All right.

We'll reconvene at 12:00 noon.

We're in recess.

(Recess)

JUDGE CHAPPELL: All right. Let's go back on

the record.

What are your calculations?

MR. HENDRICKS: I think I'm roughly halfway done, so two more hours, maybe two and a half at the most.

JUDGE CHAPPELL: All right. Go ahead.

BY MR. HENDRICKS:

Q. Mr. Figg, when we broke, we were discussing the infringement issues regarding homopolysaccharide gum.

And I'd just like to ask, in your opinion, applying your 40 years of patent litigation experience and your review of the expert reports, do you think Endo or Impax had the better of the infringement arguments related to homopolysaccharide gum?

A. I think that Endo had -- was likely to prevail on that issue. There were arguments on both sides, as there always are, but I think the fact that the component that was discussed in the '933 patent itself and described as a homopolysaccharide would have -- would have been disqualified as a homopolysaccharide under the Impax description made Impax' argument more difficult.

And as an aside, even in their invalidity arguments, Impax argued that that same component in the

prior art was a homopolysaccharide, so I think Endo had the better side of that argument.

Q. And just to be clear, had Impax shown noninfringement of the homopolysaccharide infringement -- or of the homopolysaccharide claim, would Impax have prevailed in the case at large?

A. No. The -- there were two patents involved in the case, as we have seen. The '456 patent did not have that limitation, the claims did not have that limitation, so that argument really had nothing to do with infringement of the '456 patent. It only would have disposed of the '933 patent claims.

Q. So just to sum up our discussion of infringement, taking all of the infringement issues we just discussed, what is your expert opinion regarding Endo's ability to meet the preponderance of the evidence standard for proving that Impax' oxymorphone ER product infringed Endo's patents?

A. Yes. My opinion is that Endo would have prevailed on proving infringement based on the constructions of -- primarily of "hydrophobic agent" and "sustained release" but also the "homopolysaccharide" term as well.

Q. Let's move to the issue of invalidity.

What does it mean for a patent to be invalid?

A. There are certain statutory requirements of patentability. They've changed recently, but for purposes of this case, they were all defined in section -- it's primarily in sections 102, 103 and 112 of the patent statute. And what it means essentially is that the claims do not comply with one of the statutory requirements of patentability.

Q. And in the Impax-Endo Hatch-Waxman litigation, which party had the burden of proof?

A. The party challenging validity has the burden of proving that the patent is invalid.

Q. And what is that burden?

A. The burden is clear and convincing evidence, so it's a heavy burden. And the statute is -- the court has to presume that the patent is valid.

Q. What is that presumption based on?

A. There's a statutory provision, section 282 of the patent statute, Title 35, says that the patent is presumed to be valid.

Q. And when it comes to invalidity, does Endo need to prevail on all of the claims in order to overcome the invalidity arguments by Impax?

A. Yes. If -- if -- if -- if Impax had litigated the case and lost on one claim of the -- I don't know -- 30 or 40 claims in the two patents, then the

court would have issued this order to the FDA not to approve the Impax product.

Q. And just so the record is clear, after my question you said "Yes," but I just want to get a clear yes or no answer.

A. Sorry.

Q. I'll ask the question again.

When it comes to invalidity, does Endo need to prevail on all of the claims in order to overcome the invalidity arguments by Impax?

A. Yes.

Q. So --

A. I'm sorry. I'd better hear that question again.

Q. Let me ask it this way.

A. Okay.

Q. There are numerous claims of -- for each patent; correct?

A. And Impax has the burden of showing those claims are invalid; is that correct?

MR. WEINGARTEN: Your Honor, objection. Leading.

MR. HENDRICKS: Your Honor, I'm just trying to create a clear record on this question.

JUDGE CHAPPELL: It's clear from the realtime

that the witness said "Yes," but then what he said after that contradicts the yes, so I'm not sure he understood the question or if that's supposed to be his answer.

MR. HENDRICKS: And that's why I -- I realize I'm asking a leading question. I'm just trying to clarify that.

MR. WEINGARTEN: Regardless of his intent to clarify, Your Honor, it's still leading.

JUDGE CHAPPELL: Well, it is leading, and that's sustained. However, we've already got that information in the record, so rephrase.

BY MR. HENDRICKS:

Q. Do you know how many claims are included in Endo's patents in that -- that were at issue in this case?

A. I believe five claims were asserted from the '456 patent and -- let's see. Don't hold me exactly to this, but I think it was nine claims were asserted from the '933 patent.

Q. Does Impax have the burden of proving each and every one of those claims to be invalid in order to prevail on invalidity?

A. That was the reason I asked you to repeat your question, and I qualified my answer.

JUDGE CHAPPELL: I just realized why the witness is confused. If your question is what I assume it is, and I'm not going to tell you what it should be, but you need to verify that what you're asking is what you want to ask.

MR. HENDRICKS: Thank you, Your Honor.

JUDGE CHAPPELL: Because based on the answer he gave us, he answered it in a way that I think he didn't understand your question.

(Pause in the proceedings.)

BY MR. HENDRICKS:

Q. Mr. Figg, to prevail on invalidity, how many claims does Impax have to prevail on?

A. For any claim for which Impax cannot rebut Endo's infringement contention, it has to prove that claim is invalid.

So Impax has two defenses. One is noninfringement. The other one is invalidity.

So if Impax has rebutted -- successfully rebuts Endo's infringement argument for a claim, then it need not necessarily prove that claim is invalid. But for any claim in which it cannot rebut the infringement contention, its only remaining defense is invalidity, so it would have to prove the claim is invalid.

Q. Thank you.

Let's just -- what arguments did Impax make, at a high level, to attempt to prove the invalidity of Endo's patents?

A. Basically there were three arguments. One was that claims were invalid as anticipated. Another was that the claims were invalid as obvious. And the other was that certain of the claims were not supported by an adequate written description.

Q. Let's start with anticipation.

What does "anticipation" mean in the context of patent infringement litigation?

A. Yeah. I usually fall back on kind of a shorthand that patent lawyers use, is that to be patentable an invention has to be new, useful, and unobvious. Anticipation deals with the first of those, that what's the subject matter of the claim has to be new or novel over what was disclosed to the public or in the public domain before.

In the context of a patent infringement suit, that means that the challenger of the patent has to show that a single prior art reference, a single piece of prior art, discloses all of the elements of the claim arranged in the same way as they are arranged in the claim. And if that can be shown, then the claim is

invalid as anticipated.

Q. In your answer you used the term "prior art."

A. Yes.

Q. Can you define "prior art"?

A. Prior art essentially is what was available in the public domain against which the patentability of the claims is assessed.

In this case, the prior art came in the form of earlier patents, both U.S. and international or foreign patents. But it's normally or most of the time the prior art is patents or printed publications, but there are other kinds of prior art as well.

Q. Did you need to review the prior art to form your opinions about anticipation in this case?

A. I didn't feel that I had to go back and review those basic underlying references. No.

And primarily there were two reasons for that. One was that the expert reports that had been submitted by both sides in the litigation very thoroughly and capably described what was in the prior art and how they were applying the prior art to the patent claims. In large part, they were quoting from the prior art. They were also in many instances in agreement, but where they were in disagreement, that was clearly laid out.

The second reason was, I viewed my role here as to assess what a reasonable party in Impax' position would have thought about the merits of its case going into trial, so I didn't think it was particularly relevant or helpful for me to go back and maybe come up with prior art arguments that the experts for the parties had not come up with, because that would not have been something that would have informed a party in Impax' position of how it viewed the case. That's something that comes, you know, in this case seven years later, after the patents have already expired.

MR. WEINGARTEN: Your Honor, I move to strike that last response. There's nothing in the expert report about Mr. Figg's decision not to review the prior art references.

MR. HENDRICKS: Your Honor, in the expert report Mr. Figg goes into detail in what he did review, and he was asked specifically in his deposition about prior art and disclosed that exact answer during that time.

JUDGE CHAPPELL: The objection is beyond the scope of his expert report. You need to lay a foundation that it's within the scope of the expert report or the objection will be sustained.

MR. HENDRICKS: Thank you, Your Honor.

JUDGE CHAPPELL: When it comes to experts, that's different than fact witnesses. Experts are locked in to the expert report so we don't have expert opinion by ambush in these proceedings.

MR. HENDRICKS: Of course, Your Honor.

JUDGE CHAPPELL: And what I mean by that is, with a fact witness, something may come up and go on for an hour in the deposition that we may not hear here on direct exam. But with an expert, that doesn't matter, because they're limited to the report. You can't create new opinions by way of the deposition of an expert.

BY MR. HENDRICKS:

Q. Mr. Figg, when you --

JUDGE CHAPPELL: Well, actually, I'm looking back at the question now, and I think an expert can tell us why he didn't review or need to review anything. That's not an opinion. That's in support of his opinion, something he needed or didn't need. If that's what he's looking for, I'm going to allow that.

MR. WEINGARTEN: Well, Your Honor, if the opinion that -- if the testimony had been limited to "I didn't look at that," I wouldn't have objected, but

I think he then moved on to an opinion about why it wasn't necessary to look at it, et cetera. I think he's trying to prebut, frankly, some of the cross-examination with stuff that's outside of his report.

JUDGE CHAPPELL: Well, we don't allow opinion creep, but to the extent he's explaining why he didn't review anything, I'll allow that. But you're going to learn after trial that any opinions that are utilized by either side had better be in the report.

MR. WEINGARTEN: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. Mr. Figg, are you offering any expert opinions about the need to review prior art in the review of anticipation claims?

A. No. I don't think that's part of my opinion. My opinion was that having reviewed the case record, I formed opinions about the likely outcome of the case on both the infringement and validity issues.

In my expert report I discussed extensively the expert opinions that I reviewed and the experts' discussions of the prior art. And as His Honor just said, I simply have explained that I didn't feel the need to go back and look at those underlying references themselves because I didn't think that was

my role.

Q. And if you take your report that is in your binder next to you and turn to paragraph 45 of that report?

A. Okay. I'm there.

Q. Can you describe to the court what you disclosed in the chart that is included in paragraph 45 of your report.

A. Yes. What I'm discussing here is the expert reports -- is the expert report that was submitted by Impax, Dr. Elder's expert report, and then Dr. Fassihi, who was Endo's rebuttal expert, and the prior art that they had discussed in their reports. And that's what's identified in the table there.

Q. So you disclosed the specific prior art references in this chart?

A. I disclosed in this chart the references that the scientific experts in the case had discussed and based their opinions on.

Q. Thank you.

Did Impax assert invalidity by means of anticipation for all of Endo's patent claims in this case?

A. No. There were certain claims -- they asserted obviousness for all of the patent claims but not

anticipation.

Q. And why is this relevant to the anticipation claims?

A. I'm sorry. Say that again.

Q. Why is the fact that Impax did not assert anticipation claims for all of Endo's patent claims relevant for this case?

A. Well, it simply means that insofar as they were relying on the invalidity defense, that defense would either be obviousness or, in the case of a few of the claims, lack of written description.

Q. So had Impax prevailed in its anticipation invalidity claims for all of the claims it asserted, is it correct that would not have ended the analysis?

A. That's right.

Q. How did the court's claim construction order affect Impax' invalidity arguments?

A. If we think back, the court's construction of the term "hydrophobic agent" was a functional one, meaning it is a substance that inhibits hydration or water uptake of the gel.

Now, the claims are construed the same way for non- -- for infringement and validity, so to show that the prior art formulations had a hydrophobic agent in them, it was Impax' burden to prove that a substance

in those prior art formulations met that functional requirement, namely inhibited water uptake.

And Impax did not test any of the prior art formulations to show whether or not they inhibited water uptake, so that's why I say this claim construction hurt Impax' case on both the noninfringement and the invalidity side.

And the same was true of "sustained release." The burden was on Impax to prove that the prior art that it was asserting met that "sustained release" requirement. And as Endo pointed out, Impax did not do any testing to determine whether therapeutic blood levels would be maintained for a period of twelve hours in any of the prior art formulations.

So essentially what Endo -- the way Endo responded to these arguments was: There's a failure of proof. You simply haven't done what you have to do to prove anticipation or obviousness.

Q. And having evaluated the content of these expert reports, what is your opinion as to whether Impax could have met its burden of proof to prove invalidity under the doctrine of anticipation?

A. I -- in my opinion, Endo was likely to prevail on that issue.

Q. And I believe earlier you testified that

obviousness was the second issue that was litigated -- or that would have been litigated under the -- under invalidity?

A. Yes. Impax set forth obviousness arguments in its brief and in its expert reports.

Q. What do you mean by "obviousness"?

A. Obviousness is -- the basic premise of patentability is you can't take something away from the public which the public already had, and so if a claimed invention is something that maybe the public didn't have in exact literal form but it would have been obvious over what the public already had, you're not entitled to a patent on that.

And the courts have basically given us guidance that the ultimate question of obviousness is a question of law, but it's based on underlying facts, which is what's in the prior art, what are the differences between the prior art and the claimed invention, what was the level of ordinary skill in the art, and whether there are any other factors that might come to -- called secondary factors that might be relevant to this.

Q. And can you describe those secondary factors that are relevant to the obviousness claims?

A. Yes. The argument is that if an invention was

obvious and had value, commercial value, then it would have been made earlier by somebody else, so if it turns out that an invention is a commercial success, that is an indicator, an indication, that the invention was not obvious.

Similarly, if there was a long-felt need for a solution to a problem for an invention, that that need had not been met by the prior art, that is a secondary indication that the invention was not obvious.

There are other things like praise of the industry. Once the invention comes out, if people in the industry widely praise the invention, that can be evidence of unobviousness. Unexpected results is another one.

So those are generally what we refer to as secondary factors or sometimes they're called objective indicia of unobviousness.

Q. In your review of the materials and applying your 40 years of experience as a patent litigator, have you formed an opinion about whether Impax could have met its burden to prove Endo's patents invalid under the doctrine of obviousness?

A. Yes. For some of the reasons I've already explained and particularly the failure by Impax to establish the hydrophobic agent, the sustained release

requirement of the claims, my view was that Endo was going to prevail on the obviousness issue.

Q. Did Endo make arguments under the secondary factors that you described?

A. Yes.

Endo argued that its drug that was the subject of this litigation was a commercial success, had sold hundreds of millions of dollars. They argued that there had been a long-felt but unmet need for an extended-release version of oxymorphone.

So these were arguments that Endo advanced in support of its nonobviousness position.

Q. And can secondary factors be a significant -- can secondary factors be a significant factor for courts when evaluating obviousness arguments?

A. Well, the cases basically instruct the district courts that if evidence of secondary factors or objective indicia are present, they must be considered. And there are cases that say sometimes they can be determinative. But there are also cases that say, when a very strong obviousness case has been made, secondary factors might not be enough to overcome that.

So it's sort of looked at on a case-by-case basis.

Q. Isn't there a nexus requirement for secondary considerations?

A. Yes.

MR. WEINGARTEN: Your Honor, objection. That one is leading.

JUDGE CHAPPELL: Sustained. Rephrase.

BY MR. HENDRICKS:

Q. Must a brand company show a connection between the commercial -- between the secondary factor and the patent in the case?

A. Yes.

Q. And is that referred to as a nexus requirement?

A. It is.

If -- for example, if you argue that the invention was commercially successful, the patent owner has the burden of showing that that success was attributable to what is claimed in the patent and not -- and not attributable to some other factor, such as huge advertising expenditures or things that are unrelated to the merits of the patented invention.

Q. In your review of the arguments, do you have an opinion as to whether there was a nexus between Endo's patents and the commercial success of Opana ER?

A. Well, I reviewed the arguments that were made

by both sides. And I should point out, when -- for example, when commercial success is advocated as a basis for unobviousness, there is a presumption that if the commercially successful product is covered by the claim, then there is a nexus, so Endo would have enjoyed that presumption here.

Having reviewed everything, again, it was my view that Endo was likely to prevail on this issue.

Q. Did you see any other evidence from later cases that corroborate your opinion on secondary factors?

A. There was a decision out of the Southern District of New York on different patents, but they involved the Opana ER product. And in that case, while the court was not considering the '456 and '933 patents, it did conclude that Endo had established that the commercial success of Opana ER was linked to its controlled-release properties. And those controlled-release properties were the subject of the claims in the '933 and the '456 patents.

Q. You testified earlier that the third invalidity argument advanced by Impax was arguments about written description; correct?

A. Yes.

Q. What must Impax show to meet its burden under

the written description doctrine?

A. Did you say what must Impax show?

Q. Yes.

A. Yeah.

Well, the -- as I mentioned earlier, one of the things that the patent owner or the inventor must do to justify getting a patent is it must make a full disclosure of its invention so that that's now in the public domain, and so the -- there's a statutory provision that the claims of the patent have to be supported by a written description of the invention in the specification of the patent, the body of the patent.

And Impax had to demonstrate that the invention claimed in these claims that it was challenging was not supported by an adequate written description in the body of the patent.

Q. On how many of Endo's patent claims did Impax assert a written description invalidity claim?

A. My recollection is, when they got to trial, it was only three. It was claims 41, 42 and 43 of the '933 patent.

Q. So if we assume that Impax failed to meet its burden on anticipation and obviousness, if Impax did meet its burden for written description, would Impax

have prevailed in the case?

A. No. That only would have disposed of those three claims.

Q. For the three claims for which Impax made written description arguments, have you applied your expertise as a patent litigator to the materials reviewed and formed an opinion about which party was more likely to prevail?

A. Yes. And this is a fairly complicated issue, and I'll try to generalize.

In my opinion, this actually was a pretty close call. I think both sides made defensible arguments about the written description. I came out thinking that Endo even on this issue had the edge because the issue was whether numerical values for something called T-max or the time after you give the tablet until you see a maximum plasma, blood plasma, concentration was within a certain numerical range.

Those exact numerical ranges were described in the Endo patent. But they were described for a different drug than oxymorphone, and so that was the basis for Impax' argument. But Endo's argument was and its experts' argument was, we disclosed those precise numbers in the specification, so that's a good enough written description.

Again, it was a close call, but I think even there I would give Endo an edge on that issue.

Q. So, Mr. Figg, we just reviewed all of Impax' invalidity arguments.

Do you have an opinion as to whether Impax would have proven by clear and convincing evidence that Endo's patents were invalid?

A. Well, that was going to be litigated, and the issues certainly could have come out either way. But having evaluated all of the materials that I evaluated, I think it was likely that Endo was going to prevail on these validity issues.

Q. And taking the issues that we discussed, meaning the issues about infringement and the issues about invalidity, have you formed an opinion as to the likely outcome of the litigation had the parties not settled?

A. Yes. If the parties had not settled and if I'm correct that Endo would have prevailed on at least one claim, then the result would have been the court would have issued this injunction under section 271(e)(4) and Impax would have been prevented from marketing its product until those patents expired.

Q. And when did the '456 and '933 patents expire?

A. They were set to expire I believe in September

of 2013.

Q. Is it your opinion that Endo's success at trial was a sure thing?

A. No. As most patent lawyers would tell you that in patent litigation it's hard to find a sure thing.

Q. So recognizing that the litigation was uncertain, I'd like to turn to the timing for completing the litigation had the parties not settled.

Did you form opinions related to the potential timing that it would have taken Impax and Endo to complete their case but for the settlement?

A. Yes. I've looked at that issue.

Q. And were you involved in the creation of a demonstrative that lays out your opinions on that issue?

A. Yes. I -- I think the demonstrative was taken from my -- what I said in my expert report, and then I helped put the demonstrative together.

Q. I'd like to put up demonstrative RX D-10.

Is this the demonstrative you just referred to?

A. Yes.

Q. Can you identify this demonstrative?

A. Well, this is a demonstrative exhibit that is

essentially a timeline of what would have happened had the case not settled when it did. I suspect it's already been put in evidence that the settlement occurred right at the beginning of trial in June of 2010, so what we see here is what would have happened after that.

Q. And when was the patent infringement trial scheduled to conclude?

A. Yeah. The scheduling -- I think the judge had indicated that the trial had to be concluded by June 17, 2010.

Q. In your years of litigating patent infringement cases, how long does it typically take for the trial court to issue an opinion after the close of trial?

A. Well, as you can tell from the issues that I've already discussed, this was a pretty complicated case, and these patent cases often are. The judge would have had to have issued findings of fact, conclusions of law, issued the decision. In my experience, that takes -- can take quite a while.

I've estimated in this case somewhere in the range of four to five months. But I've certainly had cases where it's taken a lot longer for the judge to issue the decision, and it also happens from time to

time that the judge will get a decision out earlier than that. But that's -- in my view, that's a reasonable estimate.

Q. In coming to your estimate of four to five months, did you look at any statistics regarding the median time between the end of trial and the release of an opinion by the trial court?

A. Yeah. I actually asked one of my associates to look at the statistics that are provided by a service. And we looked at Hatch-Waxman cases that were decided at about this time, in about this time frame, in New Jersey, where this case was litigated. And we saw a range of dates, but the average was about four to five months.

Q. And does this average comport with your experience litigating Hatch-Waxman cases?

A. It does.

And I've had quite a bit of experience litigating cases in New Jersey, so I have a sense of how long it takes the courts in New Jersey to issue decisions after an issue has been briefed and argued. I was actually kind of surprised to find -- none of my New Jersey cases ever went to trial, so I didn't have personal experience with the time after trial to the opinion, but I have personal experience in other

jurisdictions.

Q. In your opinion, would the party that lost at the trial level likely have appealed the decision to the Federal Circuit Court of Appeals?

A. Yes. These cases are very frequently appealed.

Q. How long does it take for the Federal Circuit typically to docket the appeal?

A. Normally that's fairly short. That's about a month, 30 days.

Q. And what is your conservative estimate for how long it would take the Federal Circuit Court of Appeals to release its opinion from the time the appeal was docketed?

A. Did you say to issue its decision?

Q. Yes.

A. Yeah.

So we show on this chart November of 2011, which is about eleven months after the docketing of the appeal. And that number is based primarily on statistics that the Federal Circuit itself keeps.

I do regard this as a very conservative estimate, because this eleven months includes cases that are settled, so those are disposed of much -- in a much shorter time.

It also includes cases -- there aren't many of them, but occasionally the Federal Circuit will issue what it calls a rule 36 affirmance, so it just decides the case without issuing an opinion. Those typically come very quickly after oral argument, so that also would skew this number toward the low side.

It's very hard to predict, but some Federal Circuit cases take substantially longer than this, a couple of -- some of them even up to a couple of years. But I -- on this chart, I decided to use the conservative estimate that was consistent with the court's statistics.

Q. In your experience litigating before the Federal Circuit Court of Appeals, do you have an opinion on how often those appeals tend to get extended or the timing for those appeals gets extended?

A. Yeah. The Federal Circuit is pretty generous with extending the time for parties to file their briefs. And in most appeals there are three briefs. There's the appellant's opening brief, the appellee's brief and the appellant's reply brief.

And I've got cases going right now in the Federal Circuit where the parties, both parties, have asked for extensions of the time for filing their

briefs. Obviously, that can drag out the time to the decision.

Q. Is an option in the Federal Circuit Court of Appeals to file a motion for reconsideration after a decision is reached?

A. Requests for rehearing or rehearing en banc are common in the Federal Circuit. Yes.

MR. WEINGARTEN: Your Honor, objection. I don't see anything in the report on motions for rehearing or rehearing en banc.

MR. HENDRICKS: Your Honor, I will concede that the terms "rehearing en banc" aren't in the report, but Mr. Figg in detail talked about that there are numerous ways that decisions of the Federal Circuit Court of Appeals can be delayed.

MR. WEINGARTEN: If it's not in the report, Your Honor, then we move that the -- if it's not in the report, then we respectfully move that the testimony regarding the motions for rehearing and rehearing en banc be stricken.

JUDGE CHAPPELL: The objection is sustained. The motion to strike is granted. The answer will not be considered.

MR. WEINGARTEN: Thank you, Your Honor.

MR. HENDRICKS: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. If Impax had won at the trial level, in your opinion, what is the earliest date that Impax could have entered free from patent infringement risk?

A. I'm sorry. Could you --

Q. I'll rephrase that.

If Impax had won at the trial level, what is the earliest likely date, in your opinion, that Impax could have entered free from the risk of the Federal Circuit Court of Appeals reversing the trial court's opinion?

A. Well, it would be upon -- free of that risk would mean when the Federal Circuit issues its mandate affirming the district court's decision, so it would have been at some point after November 2011, using the dates that are on this chart, or it would have been after the decision, whenever that decision is issued.

Q. And if Impax had lost at the trial level, would you expect Impax to appeal?

A. Yes. I would expect that there would have been an appeal.

Q. And having analyzed the issues in the litigation, on what issue, in your opinion, do you believe Impax would have focused its appeal?

A. I think the centerpiece of an appeal by Impax

would have been the court's claim construction, the district court's claim construction.

Q. Do you have an opinion -- strike that.

If Impax prevailed in its appeal on the claim construction issue, what do you believe would have been the likely result of the Federal Circuit Court of Appeals opinion?

A. I'm sorry to keep doing this, Mr. Hendricks, but I missed the last part of your question.

Q. No problem.

If Impax prevailed in its appeal on the issue of claim construction, what do you believe would have been the likely result?

A. Yes.

So if Impax appealed and argued to the Federal Circuit that the decisions on infringement and validity were wrong because the court applied the wrong claim construction, and the Federal Circuit agreed with that, then I think it is highly likely that what would have resulted from that would have been a remand by the Federal Circuit to the trial court.

Q. And why do you believe that a remand was highly likely?

A. Well, having reviewed the expert reports that the parties had exchanged before trial, it is clear

that Endo had arguments supported by expert testimony and scientific documents that there was infringement even under the Impax claim construction.

Now -- so there would have been a dispute between the parties about infringement and perhaps even validity even if -- even under the Impax construction.

But going into trial, there would not have been a record developed on that because the parties -- once there is a claim construction, then the evidence that the parties put into the case are based on that claim construction, so Impax would not have put in -- or Endo -- I'm sorry -- would not have put in its evidence of infringement, for example, based on the Impax claim construction because the court had not adopted that construction.

And so the Federal Circuit would have simply said, the claim construction is wrong, we're overturning it, but we don't have a record before us to decide the case under the correct claim construction, so all we can do is remand to the trial court to try the case under the correct claim construction.

Q. Mr. Figg, but isn't it true that Impax' position under its own claim construction was supported

by a number of very authoritative sources?

A. Oh, I -- Impax had very qualified expert witnesses who explained their positions, and they were supported by documents, such as scientific treatises. But similarly, Endo had the opposite opinions from its expert, and those opinions also were supported by documentary evidence.

So there would have been a fact -- a triable issue there which the Federal Circuit -- I don't think it would have even had a record on which to decide who was right about that. And in any event, the Federal Circuit normally would not get involved in fact-finding. It would -- it would reverse and ask the trial court to do the fact-finding.

Q. If the Federal Circuit remanded the case based on a different claim construction, what is your conservative estimate as to when the case would then be resolved?

A. My estimate is that the remand would likely take somewhere between 6 months and 18 months. And I tend to think more toward the latter, because, as I say, the only way that the trial court could deal with it earlier is if it already had a record on that. And I don't think a record would have been made, so that means the trial judge would have to schedule a new

trial. And the evidence would come in. It would basically take the same -- it might not take entirely the same length of time, but it would take essentially the same length of time as an original trial.

Q. And to be clear, the scenario we are discussing right now about a remand assumes that Impax wins its initial appeal at the Federal Circuit Court of Appeals; correct?

A. Yes.

Q. What would be the result if Impax lost on appeal at the Federal Circuit?

A. Well, if Impax lost at the trial court level and lost at the appellate level, the judge's order precluding FDA approval would stand and Impax would not be able to market its product prior to expiration of the patents.

Q. So we just talked about when Impax could have potentially launched its product without patent risk, so let's talk a little bit about the risks that Impax could have faced had it launched its product before obtaining a favorable decision from the Federal Circuit Court of Appeals.

How would you characterize a launch by Impax before a final decision from the Federal Circuit Court of Appeals?

A. Well, in this business, those are typically referred to as at-risk launches.

Q. And can you define "at-risk launch"?

A. Yes. An at-risk launch means that the generic company is launching its commercial product, is introducing its commercial product, into commerce before it has a decision from a court that exculpates it from liability.

Q. And at what points are an at-risk launch likely to happen during a Hatch-Waxman litigation -- actually, let me rephrase that question. Strike that.

What are the points at which a generic firm may decide to launch at risk during a Hatch-Waxman litigation?

A. There essentially are two points. I think we saw in an earlier timeline that Impax' -- the 30-month stay of approval of Impax' product was set to expire in June of 2010, so it -- and it had received tentative approval from the FDA before that, so theoretically, Impax could have obtained approval to sell its product and it could have launched its product before receiving any decision from the trial court.

And then the next point that would be regarded as an at-risk launch would be after a trial court decision but before a decision of the Court of Appeals

for the Federal Circuit.

Q. And if the generic firm launches at risk before a ruling by the trial court, what risks does the generic firm face?

A. Well, the primary risk that would be on the mind of a generic company in that situation is, if it lost on the issue of liability, it would be exposed to damages, monetary damages, for patent infringement.

MR. WEINGARTEN: Your Honor, objection.

Mr. Figg has testified what the primary risk would be on the mind of a generic company. I understand he's an expert witness, but we believe he lacks foundation to testify as to what's in the mind of a generic company.

MR. HENDRICKS: I can rephrase the question. I don't think I asked him to tell us what would be in the mind of a generic --

JUDGE CHAPPELL: Rephrase the question.

The pending question and the answer will not be considered.

MR. WEINGARTEN: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. Let's just try that again, Mr. Figg.

If the generic firm launches at risk before a ruling by the district court, in your role as a patent

litigator, what risks do you believe a generic company would face?

A. The risk of -- there would actually be several risks.

One would be the risk of losing the case and being found liable for monetary damages.

The second would be that once the generic company launches its product, the case then becomes an action for damages rather than an injunction, and so typically in that case or often in that case the patent owner would demand a jury, and the case would be tried to a jury.

And third, launching the product puts the first filer's 180-day exclusivity in jeopardy.

Q. You mentioned that the patent owner would demand a jury.

In your opinion as a patent litigator, would having a jury be more beneficial to the patent owner or to the challenger of that patent?

MR. WEINGARTEN: Objection, Your Honor. This is not in the report.

MR. HENDRICKS: I don't believe that's accurate, but may I have one moment.

If I can direct your attention to paragraph 89 of the report. That's on page 39.

MR. WEINGARTEN: I'll withdraw the objection, Your Honor.

JUDGE CHAPPELL: All right. Go ahead.

MR. HENDRICKS: Can we read back the question, please.

(The record was read as follows:)

"QUESTION: You mentioned that the patent owner would demand a jury.

"In your opinion as a patent litigator, would having a jury be more beneficial to the patent owner or to the challenger of that patent?"

THE WITNESS: In my opinion, it would be -- it often is more beneficial to the patent owner, which is why patent owners typically demand juries in these kinds of cases.

You've already got a taste of the kinds of arguments that are made in these cases, very highly scientific, technical arguments. And the burden of proof, especially on invalidity and clear and convincing evidence, if a jury is confused and doesn't understand these arguments, then basically it's left with saying I haven't been clearly and convincingly persuaded that the challenger has won its case, so -- the burdens are the same. It doesn't matter whether it's a bench trial or a jury trial. The burdens are

the same. It's just a question of presenting a case to a lay jury.

BY MR. HENDRICKS:

Q. If a generic drug company launches at risk after -- if a generic drug company launches at risk after winning at the district court level but before a final decision by the Federal Circuit Court of Appeals, what legal risks does the generic drug company face?

A. Well, again, the risks that the Federal Circuit will reverse or will remand and the decision is ultimately reversed, which again will expose the generic company to damages.

And also, depending on the timing, if the generic launches its product and then has to take that product off the market, that can jeopardize the 180-day exclusivity or the value of the 180-day exclusivity.

Q. Is it possible for the generic firm to launch after losing at the district court level but before a reversal at the Federal Circuit Court of Appeals?

A. No. That normally would not be possible, because if the generic loses at the trial level, the trial court will issue this 271(e)(4) order, precluding the FDA from approving the ANDA, so the generic can't launch without that approval.

Q. So we've talked a little bit about lost profit damages.

Can you explain what you mean by "lost profit damages"?

A. I'm not sure we have actually. But I can --

Q. Then let me actually back up then. I believe we talked about damages.

How are damages calculated in an at-risk launch situation?

A. Yeah. Well, the statute says that the patent owner when -- after it prevails on proving infringement of a valid claim is entitled to damages that it suffers no less than a reasonable royalty.

And so we typically look at patent damages as falling into two categories. One is lost profit damages. The other is reasonable royalty damages.

In a case like this, where Endo has its branded product on the market and Impax comes to market with a direct generic competitor to that product, the patent owner would typically seek and be entitled to lost profit damages in that situation.

What that means is --

Q. I was just going to ask, can you describe how lost profit damages are calculated?

A. Yeah.

So what "lost profit damages" means is that the patent owner -- the damages are the profit that the patent owner would have made on sales that it can show that it lost to the generic product.

So it's a but-for test, but for the infringement, the patent owner would have made those sales and would have made the profit on those sales that it would make in a single-supplier market.

Q. If a generic firm is forced to pay the brand's lost profits as damages, will launching at risk ever be profitable for the generic?

A. Well, never say never I guess, but I can't think of any situation where it would because the whole point of a generic drug is it's offered at a significant discount to the brand drug, so typically the generic company will sell the product at, you know -- the percentages vary, but 50 percent, 60 percent, 70 percent of the brand price.

For a product like -- in lost profit damages, the court looks to the incremental profit margin, so it's basically the revenues minus the cost of selling, cost of selling the product or cost of goods. Those in the pharmaceutical industry are often and almost always for a mature product like the one we're discussing are very high. They're in the 90 percent range.

So you can see that the profits that the brand company loses would almost always be greater than the total revenues that the generic company receives.

Q. And if the generic firm were to launch at risk, is there a risk that the lost profit damages would be trebled?

A. The -- there is that risk. The patent statute has a provision that if the generic -- or if an infringer is found to have willfully infringed the patent, then the court has the discretion of increasing the damages up to three times.

Q. One of the other risks of an at-risk launch that you mentioned was losing the value of 180-day exclusivity period.

Can you explain what you meant by that?

A. Well, the 180-day exclusivity period starts when the generic company launches its product. And often this is a valuable -- a valuable benefit that the generic company has because it's essentially selling without any competition from another generic.

But if the generic company launches and then a court enjoins the further sale of that product, it still has triggered the beginning of its 180 days, so it's going to have lost some of that 180-day exclusivity in the process.

Q. So if there is an injunction, that injunction also does not toll the clock on the 180-day exclusivity?

A. That's right. Once the product is launched, that triggers the beginning of that 180-day period.

Q. Are attorneys' fees also at issue -- or I should -- are attorneys' fees at issue in these cases?

A. They can be at issue if the court -- if the trial court finds the case to be exceptional, and that's provided in the statute. Then it has the authority to award attorney fees to the prevailing party.

Q. Relying on your 30 years of experience in Hatch-Waxman litigation, do you have an opinion as to the frequency of at-risk launches in Hatch-Waxman litigations?

A. Well, in my experience in this area of the industry and the litigation, at-risk launches are rare. And I base that not only on what I've observed my own clients doing but what other companies that have been involved in cases that I've handled, you know, how they behave.

So I think it's pretty well-accepted that because of the risks and particularly the risk of incurring lost profit damages, generic companies are

reluctant to launch at risk. It doesn't mean it doesn't happen, but they're reluctant to do it.

Q. Does the size of the generic firm affect your analysis about at-risk launches?

A. Well, obviously different companies have different tolerance for risk. And some generic companies have become pretty large enterprises.

For example, Teva Pharmaceuticals has become a very large pharmaceutical company. A lot of the at-risk launches when they do occur we see coming from companies like that who have more of a financial ability to absorb that risk if they're wrong.

Q. And in your experience dealing with generic pharmaceutical companies, do you consider Impax to be one of the smaller generic pharmaceutical companies?

A. Well, I -- Impax has sort of been on the fringes of cases I've litigated for decades, but I've never represented Impax, so I didn't really have any direct knowledge, although I always regarded it as one of the smaller companies. I saw something in the record that was provided to me from one of the Impax executives who himself said Impax is a small company, small generic company.

Q. Have you seen anything else in the record in this case that corroborates your opinion that at-risk

launches are rare?

A. Well, I referred to this RBC Capital Assets report earlier. They analyzed the prevalence of at-risk launch and characterized them as rare.

Q. Mr. Figg, let's turn back to the Impax-Endo Hatch-Waxman litigation.

How was that case ultimately resolved?

A. The Endo-Impax Hatch-Waxman litigation?

Q. Yes.

A. It was resolved by a stipulated dismissal based on a settlement.

Q. I'd like you to look at what is Complaint Counsel's Exhibit 2626. It is in tab 7 of your binder.

And this document is in evidence, not subject to in camera review.

A. I'm looking for 2626 tab 7?

Q. Yes. You'll find it in tab 7 of your binder.

A. Yes.

Q. Can you identify this document?

A. Yes. This is the settlement and license agreement that Endo and Impax entered shortly after the patent trial began.

Q. Have you reviewed this document in its entirety?

A. Yes, I have.
Q. In your 40 years of experience as a patent attorney, have you reviewed similar settlement and license agreements?
A. Yes. I've -- different firms and lawyers use different forms, but I've certainly reviewed and been involved with settlements of this nature.
Q. Have you negotiated similar settlement and license agreements?
A. Yes.
Q. If you look at the bottom of page 1, does this document define a commencement date for the latest date and time Impax could begin to sell oxymorphone ER?
A. Yes. It defines that date as January 1, 2013.
Q. And given your opinions about the underlying litigation and applying your 30 years of experience litigating and settling Hatch-Waxman patent infringement cases, have you formed an opinion about whether the January 1, 2013 license date was reasonable?
A. Yes. Given everything I've seen and factoring in my evaluation or my assessment of how that patent litigation was likely to come out, what the timing of its resolution was likely to be, I think this was a very reasonable date for Impax to agree to. It allowed

them to get on the market eight months before these patents would expire.

Q. In your opinion, does the January 1, 2013 license entry date represent a delay of entry compared to the date Impax could have reasonably expected to enter had it not settled the case?

A. I actually think it was not a delay of their entry date. Obviously, if they lost, they were not going to enter until eight months after this date. But even if they won, it's my view that resolution of the case would not have occurred until after this date.

Q. As part of your work -- you can set that aside for now. We may come back to it.

As part of your work as a Hatch-Waxman patent litigator, do you inform yourself of the legal landscape surrounding Hatch-Waxman settlements?

A. Well, I try to keep abreast of things.

Q. And how do you keep abreast of the legal landscape related to Hatch-Waxman settlements?

A. I do what most lawyers do. I read the services that report on cases and trade press that report on the outcome of significant cases. If I see a case that I think is pertinent to my practice, I will

try to read that case and just try to keep myself up-to-date.

Q. And have you reviewed the Supreme Court's decision in the FTC v. Actavis case?

A. I have.

Q. Do you know when the Supreme Court released that opinion?

MR. WEINGARTEN: Objection. Your Honor, at this point I'm not sure what he's trying to elicit. The court is perfectly aware of the FTC v. Actavis case, and surely he's not trying to elicit Mr. Figg's legal opinion about the import or meaning of an antitrust case that directly bears on this case.

JUDGE CHAPPELL: I think I heard a government witness talking about this case just the other day.

MR. WEINGARTEN: Thank you, Your Honor. You may be thinking of Dr. Noll, who testified only as to economics and did not offer an opinion about the import or meaning of Actavis itself.

JUDGE CHAPPELL: Well, the current question is does he know when it was released. I'm allowing that. That's overruled.

MR. WEINGARTEN: Thank you, Your Honor.

THE WITNESS: I don't remember the exact date, but it was after the case we're talking about. It was

well after the case we're talking about.

BY MR. HENDRICKS:

Q. Does 2013 seem correct?

A. Yes.

MR. WEINGARTEN: Objection, Your Honor. Leading.

THE WITNESS: Well...

JUDGE CHAPPELL: Do you really think there's a dispute on when that was released? And if there's not a dispute, would you please spare us the pain of all these objections.

MR. WEINGARTEN: I will, Your Honor. Withdrawn.

JUDGE CHAPPELL: And how many times have you stood up and objected that something wasn't in the report and then you were corrected and it was in the report, so let's just please be a little more judgmental about your objections, a little more prudent.

MR. WEINGARTEN: I will try, Your Honor.

JUDGE CHAPPELL: Thank you.

BY MR. HENDRICKS:

Q. Does 2013 seem about right?

A. Yes.

Q. In your review of cases regarding Hatch-Waxman

settlements, as of 2010, had any appellate courts ruled on the relevant analysis for Hatch-Waxman settlements?

MR. WEINGARTEN: Your Honor, I apologize. I don't mean to wear thin the court's patience, but now he's asking for Mr. Figg's opinion about the case law regarding reverse payment settlements and antitrust case law about those settlements.

MR. HENDRICKS: Your Honor, I'm not going to ask him to interpret any of these cases. I just want to ask him, in his role as a patent litigator and which he's giving expert opinion today, was he aware of these cases and how would a reasonable litigant have -- have, you know, viewed these cases.

JUDGE CHAPPELL: I'm allowing that. The objection is overruled.

THE WITNESS: Yeah. The -- I was aware of the issues surrounding some of these kinds of settlements of Hatch-Waxman cases, and it was directly relevant to my practice, so I would try to inform myself of, you know, what the current state of the law was.

If that -- I'm not sure that was your question actually.

BY MR. HENDRICKS:

Q. No. Thank you. I think that was responsive.

In your opinion, how would a litigant as of June 2010 have viewed that current state of the law?

A. The -- the prevailing test at the time, as I understood it, was to look at whether the parties settled the agreement within the bounds or the scope of the patent owner's patent.

Now, you know, I understand that that law evolved over time and there were some cases that went the other way, but the -- in 2010, in June of 2010, I think that was the prevailing view.

JUDGE CHAPPELL: You had asked a question before the last objection. I overruled the objection. And I don't think he answered that pending question, so the record is complete.

MR. HENDRICKS: Thank you, Your Honor. I'll return to that question.

JUDGE CHAPPELL: It has to do with appellate courts.

BY MR. HENDRICKS:

Q. Mr. Figg, in your review of cases touching on Hatch-Waxman settlements as of June 2010, had any appellate courts ruled on the relevant analysis for Hatch-Waxman settlements?

A. Yes. I was familiar with many of those cases. The Eleventh Circuit, the Second Circuit, the

Federal Circuit had -- had been presented with Hatch-Waxman settlements and had basically adopted this rule of whether the settlement fell within the scope of the patent.

Q. And as of June 2010, were there contrary appellate-level decisions?

A. There were some that came later. I'm not sure there were any contrary ones at that point in time.

Q. In June of 2010, in your opinion, how would a reasonable litigant in Impax' position have viewed the scope-of-the-patent test?

A. Well, the -- the settlement that was reached was based on the fact that the Impax product was within the scope of the claims of the Endo patents. And the market entry date that was provided in the settlement agreement was within the temporal scope of those patents; in other words, they were allowed to launch the product before the patents expired. They weren't -- there was no effort to extend the patent exclusionary right beyond the expiration.

Q. And have you reviewed the patents at issue in the underlying Hatch-Waxman litigation?

A. Yes.

Q. Did you form any opinion as to whether the 2010 settlement and license agreement fell within the

scope of those patents?

A. Yes. In my opinion, it did.

Q. Let's turn back to the settlement and license agreement, which again is tab 7 in your binder.

Having reviewed the settlement and license agreement, in your opinion, does this agreement provide Impax with any other benefits in addition to the certain licensed entry date?

A. Yes. One thing that -- and I mentioned this at the outset of my testimony this morning.

One thing that Impax was able to negotiate was not only rights under the two patents that were being litigated but rights under all three of the patents that were listed in the Orange Book, as well as any patents that Endo might get in the future either on pending patent applications, applications that were pending at the time, or patents that it might later acquire.

Q. And can you point me to the section in the settlement and license agreement where this broad license is located?

A. Yes.

The license is -- there's a section entitled License and Covenant Not to Sue. It's Article 4. And section 4.1 deals with the license -- 4.1(a) deals with

the license and 4.1(b) deals with the covenant not to sue.

Q. In this same section, have you reviewed section 4.1(d)?

A. I'm sorry. 4.1?

Q. (d).

A. (d) as in dog?

Q. Yes.

A. Yes, I have.

Q. In your opinion, does section 4.1(d) alter the scope of the license and covenant not to sue in sections 4.1(a) and (b)?

A. No.

MR. WEINGARTEN: I'm sorry, Your Honor, to rise again, but I have to object. Nowhere in the report does Mr. Figg quote section 4.1(d) or compare it to 4.1(a). Those passages are just not in the report.

MR. HENDRICKS: Your Honor, the only thing true that -- that he did not quote section 4.1(d), that is true, but what Mr. Figg did is he reviewed the entire license, all of section 4.1, he evaluated it, and I'm simply asking him to define the scope of that license, and that is very much within the scope of his report.

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

If he can point me to a paragraph where Mr. Figg engaged in this analysis of the license provision discussing the words, explaining what it meant, other than that it was broad.

JUDGE CHAPPELL: You'll need to ask the question that covers whatever information is in the expert report.

Sustained.

MR. WEINGARTEN: Thank you, Your Honor.

JUDGE CHAPPELL: The answer will be disregarded.

MR. HENDRICKS: I'm sorry, Your Honor. Just one moment.

(Pause in the proceedings.)

BY MR. HENDRICKS:

Q. Mr. Figg, earlier today you used the term "freedom to operate."

What do you mean by that?

A. "Freedom to operate" in the patent sense means that some commercial activity that a party wishes to engage in is not covered by a valid patent claim.

Q. Is it your opinion that the license in the settlement and license agreement provided Impax the freedom to operate?

A. Yes. Under both the litigated patents as well

as future patents that Endo might obtain in this area.

Q. And is that opinion based on your reading of the entire settlement and license agreement?

A. Yes, it is.

Q. In your opinion, why did Impax want to secure a broad license in the settlement agreement?

JUDGE CHAPPELL: It sounds like you're changing gears a little here?

MR. HENDRICKS: Yes, a little.

JUDGE CHAPPELL: All right. We'll take our lunch break now.

We'll reconvene at 2:30.

We're in recess.

(Whereupon, at 1:28 p.m., a lunch recess was taken.)

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

(2:33 p.m.)

JUDGE CHAPPELL: Back on the record.

Next question.

BY MR. HENDRICKS:

Q. Mr. Figg, would a reasonable litigant in Impax' position in 2010 have been concerned about the effects of follow-on patents?

A. Yes. In my experience, that's something that the generic companies expect the brand companies to do. The -- there's a term used called lifecycle management, and part of lifecycle management for the brand company is to get additional patents to sort of build a fence of patents around its product so that they're not reliant on just one or two patents.

Q. In your review of the record, did you see any documentary evidence that Impax was in fact concerned about follow-on patents before the settlement was signed?

A. Yes. I recall seeing that there was a reference to Endo's reliance on follow-on patents in a trade publication that was circulated among the management team in Impax and also that there were communications among the management team members, indicating that they expected Endo to rely on

yet-to-issue patents.

Q. I'd like to show you one of those documents. If you could turn to tab 8 of your binder. We'll also put it on the screen.

This is Respondent's Exhibit Number 398. It is in evidence and not subject to in camera order.

And Robert, if you can just blow up the bottom two e-mails in this chain.

Can you identify this document, Mr. Figg?

A. This is a document that was -- that I had reviewed. It's an e-mail string between members of Impax' management team.

Q. And in the bottom e-mail, who is Mr. Larry Hsu?

A. I've seen him identified in documents as -- at one point he was the CEO of Impax. I don't know what his position was at this particular time. I don't see his title. But he was a high executive with the company.

Q. And in the last sentence of that bottom e-mail, he wrote, "It is also interesting to know that the settlement does not cover pending patents."

What settlement is he referring to here?

A. I think what they're talking about here is details of the settlement between Actavis and Endo become -- became public. And he was commenting on the

fact that Actavis was not -- apparently not able to get rights to pending patents.

Q. And above, Mr. Ted Smolenski states, "Endo must be banking on those pending patents."

In the context of a generic pharmaceutical company that is in the midst of Hatch-Waxman litigation, what do you understand Mr. Smolenski to be referring to here?

A. Well, it's -- it's a little bit of a misnomer actually. What -- the more correct term would be "pending patent applications," so he was referring to applications that Endo had pending at the time that had not yet matured into patents, and that would cover the Opana ER product.

Q. And we can put that document away.

In your experience, would a generic firm be aware of the existence of a brand's pending patent applications that are relevant to a generic drug the generic tends to market?

A. Yes. In my experience, this is something of great interest to generic companies because they know that this is something that brand companies want to do if they can, so you try to keep abreast of what additional patent protection the brand company is trying to get.

Q. And in your opinion, did the settlement and license agreement give Impax a license to Endo's patents that would issue from pending patent applications?

A. Yes. As we saw earlier, the -- both the license grant as well as the covenant not to sue covered patents that Endo would obtain either on its own pending patent applications or could acquire from others.

Q. Can you explain how Endo would acquire a patent relevant to the oxymorphone ER product from others?

A. I'm sorry, Mr. Hendricks. Can you say that again, please.

Q. Sure.

You mentioned in your last answer that Endo could have patents that issue from patent applications that are pending. You also mentioned they could acquire them from others. I'm just asking you what you meant by that latter statement.

A. Well, there's actually an example in this case, a patent that was owned by another company that covered what we call the API, the active oxymorphone ingredient, and I've seen documents indicating that Endo obtained rights to that patent from the patent

owner. There actually were two where that happened.

Q. So is it correct that a brand company can purchase patents from other companies and then assert those patents?

A. Yes. The brand company can either buy the patents outright or it can obtain a license with the right to enforce the patents. That's often done.

Q. And you may have mentioned this, but let me just ask.

Did Endo's pending patent applications that were pending at the time of the settlement in 2010 -- did those issue after the settlement and license agreement was signed?

A. Yes. My recollection, they got -- they got three patents on applications that were pending at the time. They got at least two on applications that were pending at the time and they got yet a third patent based on their own application.

Q. And after the signing of the settlement agreement, did Endo acquire additional patents?

A. Yes. There was a patent owned by a company called Johnson Matthey, and I believe Endo acquired rights under that patent. And then through a settlement of a proceeding in the Patent Office they acquired rights to a patent that was owned by a company

called Mallinckrodt.

Q. And having reviewed the settlement and license agreement, do you have an opinion as to whether Impax was licensed to practice all of the future-acquired patents with regard to oxymorphone ER?

A. Yes. The -- they either got a license or a covenant not to sue.

Q. So we'll come back to those later patents in a second, but first I'd like to talk about the other ANDA filers in -- that were in the original set of litigation.

Were you involved in creating a demonstrative about what you would term as the first wave of litigation in your report?

A. Yes. We have a demonstrative that was based on information I had put in my report, and I assisted in putting this demonstrative together.

Q. I'd like to put up demonstrative RX D-11.

Is this the demonstrative to which we just referred?

A. This is a demonstrative exhibit that summarizes what we've been referring to as the first wave litigation.

Q. What do you mean by "first wave"?

A. Well, this is -- we've been talking a lot about

the June 2010 litigation between Impax and Endo. That was one of the cases that was part of the first wave litigation. But a number of other generic companies had filed ANDAs with Paragraph IV certifications, and they had been sued by Endo also on one or both of those patents.

Q. And in the second table, is that the list of those generic companies that were sued?

A. Yes.

Q. Did any of the other ANDA filers choose to stand on the merits of their patent claims and challenge Endo's patents through trial?

A. No. They all settled.

Q. And applying your 40 years of experience as a patent litigator, can you draw any conclusions from the fact that all the other ANDA filers chose not to litigate Endo's patents through trial?

A. Well, these -- these other generic companies are sophisticated, major players in the generic market. I and my firm have represented several of them.

So they're accustomed to patent litigation. They're accustomed to litigating patents. The fact that they all decided to settle this case I think reinforces the notion that it was probably a prudent

decision for Impax to settle.

Q. Are you familiar with the scope of the licenses that were included in these other settlements?

A. Yes. We just saw a reference to the Actavis settlement. And I've actually seen that settlement agreement. I think on the others I've seen descriptions of the settlements and other court filings. I don't recall that I've actually seen those settlement agreements.

But the bottom line is, Impax appears to have been the only one who was able to negotiate rights to future patents.

Q. And you mentioned that you'd reviewed the Actavis settlement.

Do you remember -- do you remember the date that Endo licensed Actavis in that settlement?

A. You're going to have to refresh my recollection. I believe Actavis got an earlier entry date than Impax, but I don't remember the actual date of the settlement agreement.

Q. And I can refer to your --

A. I think it was prior -- go ahead, please.

Q. It's in paragraph 99 of your report. And I can just read it.

You wrote, "The settlement between Endo and Actavis permitted Actavis to launch its 7.5 milligram and 15 milligram dosages of the ANDA product on July 15, 2011."

Does that --

A. Yes.

Q. -- refresh your recollection?

A. Yeah, it does. Thank you.

That was the date they were authorized to launch, though the settlement was obviously earlier than that.

Q. Well, in your opinion, why was Actavis able to obtain a settlement that licensed Actavis' two first-to-file strengths as of July 2011?

A. Well, when I reviewed the situation surrounding that, I saw documents that indicated that these two strengths, dosage strengths on which Actavis was first to file, were actually very minor products. They only constituted 3 or so percent of the total market.

So if you look at it from Endo's perspective, if Endo insists on litigating with Actavis, they still put their patents at risk. It doesn't matter that Actavis only has 3 percent of the market. They still -- their patents would still be exposed to the

same risk, so it made sense for Endo to get rid of Actavis, if you will, by settling with them and get rid of that lawsuit.

Q. Thank you.

Besides Impax, did any of the other ANDA filers secure licenses to patents issuing from Endo's pending patent applications?

A. From the documents I've seen, none of them did obtain licenses to future patents.

Q. Did any of the other ANDA filers get a license to patents that would be acquired by Endo after the settlements were signed?

A. No.

Q. Did any of the other ANDA filers secure a covenant not to sue from Endo regarding patents Endo would license in the future covering oxymorphone ER?

A. No.

Q. In short, did any of the other ANDA filers secure the freedom to operate through their settlements with Endo in the first wave of litigation?

A. No. Impax -- from what we've seen in the record, Impax was the only one who negotiated rights to those future patents.

Q. And did Endo bring any later patent infringement claims on patents that issued or were

obtained by Endo after the first wave of litigation was settled?

A. Yes. There were two additional waves of litigation. Endo obtained two patents on -- that covered the Opana ER product, and there was litigation in the Southern District of New -- well, in New York. It was either the Southern District or the Eastern District. We'll see that I suppose -- but in New York, where they sued several of these companies for infringement of those patents, but they did not sue Impax.

Q. Well, let's talk about that second wave of litigation now.

Mr. Figg, were you involved in the development of a demonstrative summarizing your report about the second wave of litigation?

A. Yes.

Q. Robert, if we could put up RX D-12.

Is this the demonstrative to which I just referred?

A. Yes.

Q. Can you identify this demonstrative?

A. Yes. This describes what I was referring to as the second wave of litigation.

And if you look at the box on the left side of

this exhibit, it refers to the patents at issue.

The '122 patent and the '216 patents -- patent were patents that Endo obtained on -- based on its own patent applications.

And the '482 patent was a patent that was owned by another company, a company called Johnson Matthey, to which Endo obtained rights.

Q. And in the bottom right corner of the table under Patents at Issue there's an X in the Validity row.

Can you explain what that means?

A. You're talking about the box on the left, the red X in the lower right-hand corner?

Q. Yes. It's the quadrant under '482 Patent and Validity.

A. Yeah. The '482 patent covered the active ingredient, the oxymorphone active ingredient, and what it claimed was a maximum concentration of an impurity, so it was directed to a -- if you will, a purified form of the API, the active pharmaceutical ingredient.

It turns out that a patent owned by another company claimed that same invention, and those two patents became involved in a proceeding in the Patent and Trademark Office called an interference.

And during the interference, the other

company, which was Mallinckrodt, was found to be the prior inventor and prevailed in the interference, which resulted in the cancellation of the claims of the '482 patent.

Q. And in that proceeding, did Endo obtain patent -- or sorry -- obtain rights to the Mallinckrodt patent?

A. Yes.

At that point Endo had control of the Johnson Matthey patent, so it was the party who was actually participating in the interference proceeding, so as a result of the interference, they -- they ended up settling by acquiring rights to the Mallinckrodt patent.

Q. I think we'll come back to that patent in just a few minutes, but first, can you tell us when the '122 and '216 patents will expire?

A. Yes. That's indicated on -- in the left-hand box here. The '122 patent expires February 4, 2023, and so does the '216 patent.

Q. In the second wave of litigation, did Endo sue Impax for infringement of the '122 and '216 patents for the original oxymorphone ER product?

A. No.

Q. Have you reviewed the '122 and '216 patents?

A. Yes.
Q. And in your opinion, would the '122 and '216 patents have likely covered Impax' original formulation oxymorphone ER product?
A. Yes. I think if they -- if Impax had not had the license to future patents in its settlement agreement, there's little doubt in my mind that Endo would have included claims of infringement against Impax for the original generic Opana ER.
Q. Did Endo sue Impax on these patents with regard to a generic version of a reformulated version of oxymorphone ER?
A. Yes. That was not --
Q. Why did --
A. That was -- okay. I'll let you ask your question.
Q. Why would Endo have sued Impax on the reformulated version but not on the original version of oxymorphone ER?
A. Well, Endo developed -- that -- what we're calling the reformulated version was a crush-resistant form of the tablet. It was not the subject of Impax' ANDA that led to the first wave of litigation.
And if we go back and look at the settlement and license agreement, that agreement only gave Impax

rights to manufacture and sell that ANDA product, the product that was the subject of its original ANDA, so Impax had no rights to Endo's crush-resistant product.

Q. Leveraging your 40 years of experience in patent litigation and reviewing the claims that Endo has brought, do you believe that if Endo did not believe the settlement and license agreement licensed Impax' original oxymorphone ER product that Endo would have sued Impax in the second wave of litigation?

A. Well, I can't read Endo's mind, but they sued everybody else, and I can't think of any reason they would not have sued Impax.

Q. Looking back at RX D-12, which generic firms did Endo sue on the original formulation?

A. Actavis -- can we go back to that exhibit? It was Actavis, Barr, Sandoz, Impax, Watson. I think I've got most of them. Roxane.

Q. Oh, I see. Let me re-ask that question.

Well, let me just ask this.

During the second wave of litigation, did Actavis and Roxane make any arguments related to their settlements from the first wave of litigation?

A. Yes. They argued -- and this was in the litigation in New York.

They argued that by virtue of the license to

the original Orange Book patents, they had an implied license, and actually Roxane even argued they had an express license under the future patents, which would have included these patents that were the subject of the second wave litigation.

Q. And did Endo challenge those arguments?

A. Yes. Endo disagreed with that.

Q. And how did those arguments ultimately fare in court?

A. Well, they did okay in the district court in New York. The judge -- this issue arose in the context of a motion for preliminary injunction that Endo had filed and -- and so Judge Griesa in New York concluded that he would apply the equities that are required in the context of a preliminary injunction proceeding and concluded it would be unfair to subject Actavis and Roxane to these later issued patents given that Endo had licensed them under the first patents.

Q. And did Endo appeal that decision to the Federal Circuit?

A. They did. They appealed that denial of preliminary injunction to the Court of Appeals for the Federal Circuit.

Q. And what did the Court of Appeals for the Federal Circuit decide?

A. The Federal Circuit disagreed and reversed Judge Griesa's decision on that, and they said there was neither -- by that time Actavis no longer -- Actavis didn't argue there was an express license. They argued that there was an implied license. But the Federal Circuit said there was no license express or implied.

Q. Before the Federal Circuit ruled on the appeal we just talked about, did Actavis launch oxymorphone ER?

A. Yes.

Q. Was this launch at risk?

A. Yes, it would have been at risk. I mean, they were still litigating these patents.

Q. Did Actavis' launch occur after Impax had launched its oxymorphone ER product?

A. Yes.

Q. In your expert opinion, did Impax' presence on the market as of January 1, 2013 alter the risk faced by Actavis in its at-risk launch?

A. Yes, it did.

Because, if we go back to the notion of lost profit damages, to recover lost profit damages, the patent owner has to show that but for the infringement it would have made the sale. It would have been

difficult or impossible for Endo to have shown that but for Actavis' infringement Endo would have made the sale because Impax already had a generic version of the product on the market.

So the notion would be, those generic sales would not have gone to Endo, they would have gone to Impax, and so it would have reduced the damages exposure that Actavis had.

Q. So would lost profit damages have been at issue with regard to the Actavis at-risk launch in 2013?

A. I don't think so. I think that when you're talking about two generic competitors, the notion that those sales would have gone back to the higher-priced brand instead of to the other generic on the market would have been a very difficult argument to make.

Q. What happened after the Federal Circuit ruled that Actavis' and Roxane's settlement agreements did not license them to the '122 and '216 patents?

A. Yeah.

So the case went back to Judge Griesa. Judge Griesa held a trial on these '122 and '216 patents, found that the patents had not been proven invalid and that the generic companies infringed them. And he issued a judgment -- he issued a

decision -- maybe you're going to have something with the dates. I'm bad with the dates.

But he issued a decision and then ultimately issued a judgment and indicated that there would be a subsequent trial on damages if his liability decision was affirmed.

Q. Now, I'd like to point you to Respondent's Exhibit 525, which is in tab 11 of your binder.

This is in evidence and is not subject to in camera order.

Is this the decision about which you just spoke?

A. This is the most recent decision.

Judge Griesa issued findings of fact and conclusions of law in August of 2015, and then there were numerous posttrial motions filed by both sides for him to modify or set aside his decision. And he had briefing on all of that. And I think he even had additional argument on that. And then he issued this, what he titled his Omnibus Opinion, which we have in Exhibit RX 525.

Q. And if you would turn to the Conclusions section of the opinion, which is unsurprisingly on the last page, page 25.

A. Yes.

Q. And for the record, that's RX-525.28.
A. Yes, I have it.
By the way, I noticed it was the Southern District of New York.
Q. Yes. Thank you.
A. Yeah. But --
Q. Did Judge Griesa write in his conclusion that he decided to enjoin moving defendants from making or selling their generic products prior to the expiration of the '122 and '216 patents?
A. Yes.
Q. And what was the effect of that decision?
A. Yeah.
So -- so one of the issues in the posttrial motions was whether he should issue essentially a permanent injunction in the form of this 271(e)(4)(A) order and whether he should stay that pending the appeal. And he concluded that he would enter that order, that the order would remain in place, that Actavis is enjoined, and he would not stay the injunction pending the appeal.
Q. In the next sentence Judge Griesa references scheduling a damages trial.
A. Right.
Q. Do you know what he's talking about there?

A. Yes.

As I understand from reading this, the parties had agreed to bifurcate liability and damages earlier in the proceeding, and so after the decision came down, Endo said -- asked the judge to schedule the damages trial. And Judge Griesa said, Look, let's -- let's wait and see what the Court of Appeals for the Federal Circuit does before we have a damages trial.

So this case is still on appeal today. And if -- if Judge Griesa's opinion and judgment are affirmed, then it will go back to that court for a damages trial.

Q. What would be the subject of that damages trial?

A. It will just be damages. The liability will have already been determined, so the question will be what -- what damages must Actavis pay for its infringement of these patents.

Q. And when you say what damages Actavis must pay, are you referring to -- sorry. Let me start that over.

When you said what damages Actavis must pay for its infringement of these patents, is the infringement you're speaking of a result of their at-risk launch?

A. That's correct.

Q. We can set that exhibit aside.

In light of Judge Griesa's order, can any of the generic firms involved in the second wave of litigation sell generic oxymorphone ER today?

A. No. They have been enjoined by the court.

Q. And how long will these generic firms be enjoined from selling generic oxymorphone ER under Judge Griesa's opinion?

A. Until the expiration of the '216 and '122 patents, which I think we saw in the earlier demonstrative is sometime in 2023.

Q. You mentioned that the appeals of Judge Griesa's opinion are still continuing; is that correct?

A. Yes. That's right.

Q. Do you know when the trial in this case wrapped up?

A. It's actually summarized in here. I don't have these dates committed to memory. But he -- he said -- in the first paragraph of his opinion, he says he -- in the flurry of filings following a five-week, consolidated bench trial and a 154-page opinion of August 14, 2015, so the trial I think was back in 2014, if I'm not mistaken.

Q. So I think for the record the trial was in

spring 2015.

A. Okay.

Q. Does that seem correct?

A. Well, I don't have the dates committed to memory, but he issued an opinion on August 14, 2015, so it was before that date.

Q. Okay. Thank you.

Do you know the status of the appeal of Judge Griesa's opinion today?

A. Yes.

And again, if we see what happened here, he issued his opinion on liability after the trial on August 14, 2015, and then there were posttrial motions filed. He didn't enter his omnibus opinion until April 29, 2016, in which he ruled on those posttrial motions, so nine months or so passed between his opinion and this.

And then my understanding is, a judgment entered on this shortly thereafter, I think in September of last year, and the oral argument has been scheduled in the court of appeals for December of this year.

Q. So if we assume that the trial in this case wrapped up in April 2015, about how many months have passed between the end of the trial, again assuming

that was April 2015, and the oral arguments of the appeal?

A. Yeah. So it's about 30-some months I believe.

Q. Does 34 months sound about right?

A. 34 months, yeah.

And that will be the argument, so there won't be a decision from the Federal Circuit probably for several months after the argument.

MR. WEINGARTEN: Your Honor, I'm going to rise to object. There is no expert opinion in this report about the timing of the Federal Circuit's decision of the currently pending appeal. Paragraph 123 says that the appeal is currently pending. It doesn't say anything about counting out months or timing.

MR. HENDRICKS: Your Honor, Mr. Figg's report addresses at length the potential timing of an appeal of the original litigation between Impax and Endo.

He, as we heard earlier today, opined that -- his conservative estimate for the 2011 November opinion. And I simply want to ask him -- I'm simply showing that how this timing of this case would -- sorry. I'm not being very clear. But I'm simply asking -- comparing the timing of his estimates to the timing of this real-world example.

JUDGE CHAPPELL: You can only ask him what's in

his report.

Sustained.

MR. WEINGARTEN: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. Mr. Figg, did Endo file any additional patent infringement lawsuits related to oxymorphone ER after the second wave of litigation?

A. Yes. There was a third wave of litigation in Delaware.

Q. And were you involved in creating a demonstrative summarizing your opinions about the third wave of litigation?

A. Yes.

Q. Robert, if you could put up RX D-13.

Is this that demonstrative?

A. Yes.

Q. What patents did Endo sue for infringement in the third wave of litigation?

A. So they -- they had two patents which we've referred to as the '737 and '779 patents.

Q. And can you briefly describe what those patents are.

A. Yeah.

The '737 patent claimed a method of administering the drug and making dosing decisions

based on the presence of certain components in the patient's bloodstream, so it was -- it was a method of treatment, if you will.

The '779 patent was the Mallinckrodt patent that survived the interference with the Johnson Matthey patent and which Endo bought or acquired rights to.

Q. And when do these patents expire?

A. The '737 patent was set to expire in June of 2027 and the '779 patent was set to expire in November of 2029.

Q. And does RX D-13 list the generic drug manufacturers that Endo sued on the '737 and '779 patents?

A. Yes.

Q. Having reviewed the patents at issue in the third wave of litigation, do you have an opinion about whether Endo would have had a colorable claim that Impax' original oxymorphone ER product infringed these patents if you set aside the settlement and license agreement?

A. Yes. My opinion is they sued all these other companies on the original generic Opana ER products, and there's no reason -- the only reason they would not have sued Impax is because of their understanding

that Impax had obtained a license to these patents or a covenant not to sue by virtue of the June 2010 settlement and license agreement.

Q. Did Endo sue Impax on its reformulated version of oxymorphone ER in the third wave of litigation?

A. Yes. I believe so.

Q. And again, why would they have sued Impax on the reformulated version but not the original version of oxymorphone ER?

A. Because that was not the subject of the settlement and license agreement.

Q. And at the trial court level, has the third wave of litigation been resolved?

A. Yes. At the district court level it has.

It was tried before Judge Andrews in the District of Delaware. He had ruled that the '737 patent was invalid because it claimed patent-ineligible subject matter. But he upheld the validity of the '779 patent and found that it was infringed by the defendants.

Q. I'd like to turn your attention to Respondent's Exhibit 544. This is tab 13 of your binder.

A. Tab?

Q. Tab 1-3, 13.

A. Yes.

Q. RX 544 is in evidence and is not subject to in camera review.

Is this the Judge Andrews opinion to which you were referring?

A. Yes, it is.

Q. And if you turn again to the last page of his opinion under the Conclusion section, did Judge Andrews write, "Defendants failed to prove by clear and convincing evidence that claims 1 through 6 of the '779 patent are invalid"?

A. Yes. That's what it says.

Q. What does that mean?

A. Well, the -- the -- infringement was not an issue in this case. There was no dispute that the API that was used in the defendants' generic products met the requirements of the '779 claim, which specified the maximum levels of this impurity, so the only defense that the generic companies had at that point was invalidity.

And Judge Andrews has concluded that the generic companies had failed to provide clear and convincing evidence that the claims of the '779 patent were invalid, so he entered judgment for Endo.

Q. And what is the likely effect of this opinion?

A. Well, again, this -- this is -- I believe this is on appeal. The -- but if this decision is affirmed on appeal, these companies will not be able to sell their generic Opana ER products until 2029 when this patent expires.

Q. And since the time that you submitted your expert report, has Judge Andrews released his final order?

A. I'm sorry.

Q. You submitted your expert report in September of this year; correct?

A. Yes.

Q. And since that time, has Judge Andrews released the final order that is referenced in this opinion?

A. Yes.

Q. Were you involved in the creation of a demonstrative about that order?

A. Yes.

Q. Robert, I'd like you to put up RX D-14, please.

MR. WEINGARTEN: Your Honor, we object. This is now expressly about an order that did not exist at the time --

JUDGE CHAPPELL: Is this order an order from the court that's public record?

MR. HENDRICKS: Yes, sir.

JUDGE CHAPPELL: Is it on the joint of JX?

MR. HENDRICKS: No.

JUDGE CHAPPELL: Would you like me to take official notice of this public record?

MR. HENDRICKS: Yes, sir.

JUDGE CHAPPELL: I will.

MR. HENDRICKS: Thank you.

May we show RX D-14?

JUDGE CHAPPELL: Go ahead.

Not for the fact of his opinion, but whatever the document is, if it's a public record and it's in evidence, I can look at it.

MR. HENDRICKS: And I would simply like --

JUDGE CHAPPELL: Is there any objection to me taking judicial or official notice of a public document?

MR. WEINGARTEN: No, Your Honor. I just want to be clear, it's not on JX 2,and it's not been otherwise admitted or submitted for complaint counsel's review prior to this demonstrative.

JUDGE CHAPPELL: But should they do so, you won't object.

MR. WEINGARTEN: I don't object to Your Honor taking judicial notice.

JUDGE CHAPPELL: Thank you.

MR. HENDRICKS: Your Honor, at this time I would move to put Judge Andrews' final judgment into evidence. I have a copy here.

JUDGE CHAPPELL: You need an exhibit number.

MR. HENDRICKS: It is -- we will mark it as Respondent's Exhibit RX 575, Your Honor.

JUDGE CHAPPELL: Any objection?

MR. WEINGARTEN: We don't object so long as it's admitted for nonhearsay purposes. All the other filings like this that we had notice of and that are on JX 2 have been admitted for nonhearsay purposes, not for the truth of the matters asserted.

JUDGE CHAPPELL: How are you offering the exhibit?

As a public record?

MR. HENDRICKS: We're offering the exhibit for its effect on the real world, Your Honor, not for the truth of whether or not the patents are valid as a matter of law but for the effect of Judge Andrews' opinion and order.

JUDGE CHAPPELL: To show the status of the case?

MR. HENDRICKS: I think that's another way to put it. Yes, Your Honor. Yeah, and the legal effect,

as I said, on the parties in the real world.

JUDGE CHAPPELL: Well, the legal effect can probably be surmised from the fact that it occurred, but he's saying no objection if it's offered like other court documents that have been offered. Is that the way you're offering it?

MR. HENDRICKS: Yeah. I don't have a problem with that, Your Honor.

JUDGE CHAPPELL: All right. With that understanding, it's admitted. RX --

MR. HENDRICKS: 575.

JUDGE CHAPPELL: -- 575 is admitted.

(RX Exhibit Number 575 was admitted into evidence.)

BY MR. HENDRICKS:

Q. Mr. Figg, can you please describe the effects of Judge Andrews' final judgment on the defendants that litigated the third wave infringement cases to conclusion.

MR. WEINGARTEN: I'm sorry, Your Honor. It's in evidence, but it was not in his report, and so I appreciate Your Honor can take judicial notice of it, but that does not mean it's a proper subject of expert opinion, given that this order didn't even exist until ten days after the report was served.

JUDGE CHAPPELL: Sustained.

MR. WEINGARTEN: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. Mr. Figg, are you aware that Mr. Hoxie submitted an expert report in rebuttal to your report in this matter?

A. Yes.

Q. Have you reviewed that report?

A. I'm sorry?

Q. Have you reviewed Mr. Hoxie's report?

A. I did review it when it came in, yeah.

Q. Does anything in Mr. Hoxie's report change the substance of your opinions you have described today?

MR. WEINGARTEN: Your Honor, we object. Mr. Hoxie's report, by definition, came after the expert report that Mr. Figg submitted, so I don't understand how he can have opinions that were properly disclosed having to do with Mr. Hoxie.

MR. HENDRICKS: Your Honor, Mr. Hoxie filed this report, admittedly, after Mr. Figg's, and so it is not specifically addressed in his report, but Mr. Figg had no chance to provide an opinion --

JUDGE CHAPPELL: I understand that. I agree with you. However, the way the rules are, unfair though they may be, the rules are rigged so that

that's the way it works here in this proceeding. And I may not agree with the rules, but I follow the rules. They get to rebut; you don't. Talk to your congressman I guess.

Sustained.

MR. WEINGARTEN: Thank you, Your Honor.

MR. HENDRICKS: Thank you, Your Honor.

JUDGE CHAPPELL: Not that it's fair in any way, shape or form, but those are the rules we're dealt with.

MR. HENDRICKS: I understand, Your Honor.

BY MR. HENDRICKS:

Q. Mr. Figg, in your opinion and as an expert in Hatch-Waxman litigation and Hatch-Waxman settlements, what has been the effect of Impax' decision to settle the litigation with Endo in 2010 with a broad patent license?

A. Well, the effect was that Impax was able to launch its product in January of 2013, eight months before the original patents expired. But equally importantly, Impax was able to continue with the sale of that product right up to the present day because, as we saw, Endo did not sue Impax for infringement of the second wave patents or the third wave patents for the original Opana ER product.

And I believe the real-world effect of that is, it's a bit ironic, but there is only one Opana ER product on the market today, and that's the Impax product. And it wouldn't be on the market had Impax not entered the settlement and license agreement in June of 2010.

Q. And in your opinion, had Impax not entered the settlement and license agreement with Endo in 2010, how long would it be until Impax could market its oxymorphone ER product?

A. If the -- from the decision from New York, those patents don't expire until 2023, and the decision -- Judge Andrews' decision from Delaware, the patent there doesn't expire until 2029, so unless those decisions are overturned on appeal, Impax wouldn't be on the market in the foreseeable future.

Q. Mr. Figg, to conclude, I'd like to turn back to the list of topics that you provided the court earlier this morning at the very beginning of your testimony.

What is your opinion about the likely result of the Hatch-Waxman litigation had Impax not settled with Endo in 2010?

A. Yes. In my opinion, it was likely that Endo was going to prevail on the issues of infringement and

validity in that case.

Q. And what is your opinion about whether or not the 2010 settlement and license agreement fell within the scope of Endo's patents at issue in that Hatch-Waxman litigation?

A. Yeah. My opinion is the settlement fell within both the subject matter and the temporal scope of the patents that were being litigated.

Q. And had Impax not settled with Endo in June 2010, what is your conservative opinion regarding the likely timing for the completion of that litigation?

A. If -- if Impax lost at the Federal Circuit level, they wouldn't have been able to launch their product until September of 2013 at the earliest. But even if they won at the Federal Circuit level, my opinion is, the issue would have been claim construction, it would have been remanded, and it would have been close to the same date that they ultimately agreed to launch.

Q. And had Impax not waited until the completion of the litigation to launch oxymorphone ER, that is, decided to launch at risk, what is your opinion regarding the risks faced from Impax from such a launch?

A. Yeah. Well, just to summarize, they would have been exposed to lost profit damages, their patent case would have become a more difficult, if you will, case because it would have become almost certainly a jury trial at that point, and they would have jeopardized their first-to-file exclusivity.

Q. Given what --

JUDGE CHAPPELL: Hold on a second.

In the kerfuffle earlier about commenting on the rebuttal report, under the scheduling order, respondent did have the opportunity to file a motion or ask the relief if they thought complaint counsel's rebuttal expert went beyond the scope of fair rebuttal. I didn't see any filing like that.

MR. HENDRICKS: There was no filing, Your Honor. And I do not believe it went -- believe for that -- at least that specific issue we're going to address that Mr. Hoxie went beyond the scope, but basically Mr. Hoxie raised an argument that we believe is incorrect and that Mr. Figg should have the opportunity to address because it's somewhat new.

MR. WEINGARTEN: Your Honor, it sounds like they didn't file a motion, and they admit just now that Mr. Hoxie's opinions were not outside the scope of Mr. Figg's original opinions, so I think there's

no -- no issue there, no basis for Mr. Figg to begin opining about a new opinion that came out ten days after his report was served.

MR. HENDRICKS: If I may, Your Honor.

Mr. Hoxie's report was a direct criticism of Mr. Figg's report, and as I said, they raised a new issue as part of that criticism. The FTC or complaint counsel was able to question Mr. Figg about -- in fact, they chose to question Mr. Figg about that fact in his deposition for I believe over 20 pages of transcript.

And further, while I agree that that specific issue that Mr. Hoxie raised is not specifically addressed in his report, that -- that subject matter is very -- is discussed at length in Mr. Figg's report, which is why I believe it is appropriate for him to give testimony on that today.

JUDGE CHAPPELL: Your redress is going to be you'll be allowed wide latitude in your cross-exam of this rebuttal expert to attempt to make your point.

MR. HENDRICKS: Thank you, Your Honor.

BY MR. HENDRICKS:

Q. Mr. Figg, given we know that Impax did settle the case, what is your opinion as to the real-world effects of the patent license obtained by Impax?

A. The real-world effect is that there is a product on the market and available to consumers today that would not be there had Impax not had the foresight to negotiate licenses to future patents.

Q. And finally, given each of these opinions, what is your opinion as to the reasonableness of Impax' decision to settle the Hatch-Waxman litigation with Endo for a January 1, 2013 licensed entry date?

A. Well, for all the reasons I've explained, I think that was a very reasonable and prudent decision for Impax to make. It's -- it got them on the market eight months before the patent expired. They avoided the uncertainty that remained in the patent litigation. And -- and they got on the market, in my view, about the same time they could have expected to get on the market if they had prevailed in everything, so I think it was reasonable for them to settle on that term -- those terms.

MR. HENDRICKS: Your Honor, I think I'm finished with my direct examination, but may I confer with counsel before I conclude?

JUDGE CHAPPELL: Go ahead.

(Pause in the proceedings.)

MR. HENDRICKS: I can yield the witness, Your Honor.

JUDGE CHAPPELL: Redirect?

I'm sorry. That would be cross.

MR. WEINGARTEN: Thank you, Your Honor.

JUDGE CHAPPELL: I'm getting ahead of myself.

MR. WEINGARTEN: Good afternoon, Your Honor.

Good afternoon, Mr. Figg.

THE WITNESS: Good afternoon.

MR. WEINGARTEN: We have a binder for the witness. May I approach the witness, Your Honor?

JUDGE CHAPPELL: Go ahead.

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CROSS-EXAMINATION

BY MR. WEINGARTEN:

Q. Mr. Figg, you won't need the binder for a little bit I hope, but I'd like to begin by talking with you about your qualifications if I may.

A. Sure.

Q. You are not an economist; correct?

A. Correct.

Q. And you are not proffering yourself today as an expert in antitrust economics?

A. That's correct.

As I've explained, there is an interplay between patent law and antitrust law, and so I occasionally get involved in antitrust issues, but I'm

not representing that I'm an expert in antitrust law.

Q. And you've never served as an executive at a pharmaceutical company?

A. I have served as patent and trademark counsel for the company -- for the pharmaceutical arm of the company I worked for, so I'll let you decide whether that's an executive or not. I tend to think of an executive as being someone on the management team.

Q. Well, under your definition, sir, of an executive as someone on the management team, you've never served as an executive at a pharmaceutical company; correct?

A. That is correct.

Q. You've never served as a businessperson in a management role in a pharmaceutical company; correct?

A. That's correct. My role was as in-house counsel.

Q. You have never served on the board of directors of a pharmaceutical company; correct?

A. That's correct.

Q. In the 1970s, you worked in-house as patent and trademark counsel for a corporation with a pharmaceutical division?

A. That's right. And the pharmaceutical division fell under my responsibility.

Q. Other than that experience, you have not served as in-house counsel at a pharmaceutical company; correct?

A. Well, as I -- it depends on how you define "pharmaceutical company," but I won't quibble. The first company that I worked for as an attorney had an animal health division, and so I worked on products that were designed for animal health.

Q. The company you're referring to is International Mineral and Chemicals?

A. Yes.

Q. And do you remember testifying that you would not call International Minerals a pharmaceutical company?

A. Yes. And I think I just said that. I'm just pointing out that they did have an animal health business and that business was part of my responsibility as a patent attorney.

Q. You have never acted as the decision maker at a pharmaceutical company with respect to a decision about settling Hatch-Waxman litigation?

A. That's correct.

Q. You've never been the decision maker at a pharmaceutical company with respect to decisions about whether to launch a pharmaceutical at risk; correct?

A. I regard that as a business decision. I provide advice on the legal issues. The decision whether to do that or not is a business decision that I don't make.

Q. And in fact, you don't know if you've ever been involved in a meeting where the ultimate decision of whether to launch at risk was made; correct?

A. I don't recall that I have been in a meeting where that ultimate decision was made.

Q. And you've never worked for Impax Laboratories?

A. That's correct.

Q. Never represented Impax as counsel?

A. I've never represented Impax as counsel.

Q. Never served as a judge presiding over a patent case?

A. I've served as an arbitrator, but not a judge.

Q. Okay. And the question was, sir, you've never served as a judge presiding over a patent case; correct?

A. I think that's what I just said. Yes.

Q. Okay. And regarding your arbitration experience, you have never been asked to serve as an arbitrator for a Hatch-Waxman case; correct?

A. I don't think so. I don't recall one.

Q. Okay. And is it right, sir, that you can't

recall an instance in which you were asked to take over a case after the close of fact discovery?

A. That's correct.

Q. And you can't remember ever being asked to take over a patent case after the close of expert discovery.

A. That's correct. I can't recall an instance where that occurred.

Q. And you can't remember any instance in which you were retained to provide advice as a patent litigator after a court had issued its claim construction opinion in a Hatch-Waxman case; correct?

A. I'm sorry. Can I hear the question again, please.

MR. WEINGARTEN: May I ask the court reporter to please read the question.

(The record was read as follows:)

"QUESTION: And you can't remember any instance in which you were retained to provide advice as a patent litigator after a court had issued its claim construction opinion in a Hatch-Waxman case; correct?"

THE WITNESS: As asked, the answer is no, that's not correct.

BY MR. WEINGARTEN:

Q. Okay. Do you remember testifying, sir, that

you can't remember coming in and taking over a case full stop after the discovery phase?

A. Well, that's a different question. And yes, I do remember giving that testimony at my deposition.

Q. And are you saying here today, sir, that you have taken over as counsel of record for a case after claim construction opinions were issued?

A. Look, I really don't want to quibble with you. Your question was have I ever provided advice in a Hatch-Waxman case after claim construction. The answer to that is yes, I have, but it's cases that I've handled, that I've been handling.

If your question is have I been brought in to a case that I was not involved in and asked to provide such advice, I can't remember one.

Q. Okay. Thank you for that clarification.

In fact, sir, you can't remember a case that you have taken through litigation at the trial level where you were not involved from the very beginning of the matter; correct?

A. I can't remember taking over a case that I didn't handle from the beginning.

Q. And you're not proffering yourself --

A. My memory may not be perfect on that and you may find one, but I don't remember one as I'm sitting

here.

Q. I appreciate that.

And you are not an expert in FDA regulation?

Well, strike that.

Have you ever worked at the FDA, sir?

A. Worked for the agency?

Q. Yes, sir.

A. No.

Q. Okay. Are you proffering yourself today as an expert in how the FDA decides to approve drug applications?

A. I certainly wouldn't present myself as an expert on how the FDA conducts its safety and efficacy evaluations.

I have been involved in a number of cases where either on -- as an intervenor supporting the FDA's decision or as a party opposing the FDA's decision on the interpretation of the patent provisions of the Hatch-Waxman amendments to the Food, Drug and Cosmetic Act, so your question was a little broad, and I have had experience in that area.

Q. But you would not present yourself as an expert on how the FDA conducts safety and efficacy evaluations of NDAs or ANDAs?

A. That's correct.

I mean, obviously, I've had a lot of cases where those issues were prominent facts, so I have familiarity, but you're right, I would not present myself as an expert in that area.

Q. You're being compensated for your time on this matter; correct?

A. I am. My law firm is being compensated for the time I'm investing in this matter.

Q. And your billing rate for your work on this matter is $895 per hour; correct?

A. That's correct.

Q. And I believe you testified on direct exam that you believe you spent approximately 70 to 80 hours on the matter so far?

A. That's a -- that's an estimate, maybe a guesstimate, but it's in that ballpark.

Q. And in doing this work on -- strike that.

In doing your work on this matter, you're being assisted by other individuals at your law firm?

A. Yes. I asked one of my associates to help me winnow through the large volume of documents, and then he got busy, and so I asked another of my associates to come in and help.

Q. And the time of those other individuals that assisted you at your firm is also being billed to Impax

or Impax' counsel?

A. My firm is including their time in the bills that -- and you raised an interesting question. I think the bills go to Impax.

Q. Okay. And do you know, sir, the total amount that your firm has billed to Impax for its work on this matter?

A. I do not.

Q. Now, Exhibit B of your expert report, sir, is the list of materials you considered in reaching your opinions; correct?

A. Yes.

Q. And if a document is not listed on Exhibit B, then you did not look at that actual document; correct?

A. Yes. I think I explained at my deposition, the intention was to put on that exhibit all the documents to which I had access. There may have been one inadvertently left off, but I can't identify it if there was. But that was certainly the intention.

Q. And you testified on direct examination that your review for this matter was consistent with your normal process in a Hatch-Waxman litigation; correct?

A. My -- my evaluation of the issues of the patent litigation I think I applied the same sort of

analysis that I would in other situations, yeah.

Q. And as a litigator in Hatch-Waxman cases, you review the prior art that may be relevant to the underlying patents; correct?

A. When I'm handling a patent litigation from start to finish, I certainly do review the prior art and a lot of other documents, but it's unusual to be asked to come in and evaluate a case that is essentially trial-ready, which is what I did here.

Q. And as we established before, you've never been asked -- strike that.

You have no experience coming in to evaluate a case as counsel of record that is trial-ready at the moment you've been brought on?

A. I haven't been asked to do that, but I think it's pretty clear that it's a different task.

Q. Okay. For your report in this case, sir, regarding the prior art, you relied on what the Endo and Impax experts said in their reports and also on the trial briefs; correct?

A. Yes.

Q. You did not look at any of the actual prior art references in any of the -- strike that -- that are referenced in those expert reports or in the trial briefs; correct?

A. That's correct. And I explained the reason for that during my direct examination.

Q. Understood.

Just to be clear, you did not independently review any of the prior art references that were at issue in the underlying patent case.

A. That's right. I relied on the record that had been developed by the parties and their experts going into the trial because that's the basis on which the case was going to be decided by the trial judge.

Q. And in a typical case, if your firm were representing the generic defendant, you would ask for documents to be produced by the patent holder?

A. Yes. Discovery is typically quite extensive in these cases.

Q. And once your firm gets those documents from the patent holder, your firm would review them?

A. Yes.

Q. And then your firm would also review documents from your own client to see what should be produced and to assess whether any of the documents are important to the case or not; correct?

A. Correct.

Q. And as a litigator in Hatch-Waxman cases, you review the discovery record; correct?

A. I either review them or I have people on my litigation team who review them and they distill them down and apprise me of the significant facts that are revealed by those documents.

Q. And reviewing the discovery record is an integral part of the litigation process; correct?

A. Yes. When you are taking a litigation from start to finish, it's an integral part of it.

Q. And it would not be possible to render advice to a generic pharmaceutical company that was engaged in Hatch-Waxman litigation without reviewing the discovery record; correct?

A. Again, the -- it would not be possible to litigate the case from start to finish effectively without a review of the discovery record. That's different from providing advice based on the record that has already been established in a case that's ready for trial and actually has gone to trial.

Q. In your experience, sir, am I correct you're not sure it would even be possible, the way litigation progresses, to render advice to a generic pharmaceutical company engaged in Hatch-Waxman litigation without having any review of the discovery record; correct?

A. In a case that I'm litigating from start to

finish, that's certainly correct.

Q. Okay. In reaching the opinions in your report in this matter, sir, you did not consider any of the documents that Impax produced in discovery in the underlying patent case; correct?

A. Any of the documents that Impax produced?

Q. Correct.

A. I think I saw some. I think some are listed on Exhibit B, but I certainly didn't review the entire discovery record.

Q. I see.

And is it your testimony that Exhibit B of your report includes documents produced by Impax in the underlying patent litigation discovery?

A. I can't remember as I'm sitting here right now whether it did or didn't. There were certainly internal communications and things like that, but those may have been produced in the discovery in this proceeding.

Q. Yes, sir.

Your list -- your testimony is your list may include communications and documents produced as part of this Federal Trade Commission proceeding; correct?

A. Yes.

Q. But you're not sure if your Exhibit B includes

any documents produced in the underlying patent litigation?

JUDGE CHAPPELL: You've asked him enough about Exhibit B. Unless you're going to show it to him, move on.

MR. WEINGARTEN: Okay.

JUDGE CHAPPELL: I mean, it's a simple fix. Show it to him or move along.

THE WITNESS: I just don't remember.

BY MR. WEINGARTEN:

Q. Okay. Well, let's take a look. Perhaps it will refresh your recollection as Your Honor suggests.

If you can look in your binder, please, there's a tab that says "Report."

A. I'm sorry.

Q. In your binder there is a tab that is labeled Report?

A. Yes.

Q. And if you would turn -- it's RX 548, and if you would turn to RX 548.0065, please.

THE REPORTER: Mr. Weingarten, the acoustics are really bad, so if you'd slow down a little bit, we'll all be able to understand what you're saying a little better. Okay?

MR. WEINGARTEN: Thank you. I apologize.

THE WITNESS: I'm glad you said that. I thought it was my hearing. But I'm really having trouble understanding both you and Mr. Hendricks from that vantage point, so --

MR. WEINGARTEN: I will do better.

THE WITNESS: Thank you.

BY MR. WEINGARTEN:

Q. If you would please turn to page RX 548.0065.

A. Yes. I have it.

Q. And what is that page, sir?

A. This is Exhibit B to my report.

Q. And the first part of that document, sir, lists documents produced in connection with In Re Impax Laboratories, Inc.; correct?

A. Yes, it does.

Q. Okay. Those are the documents --

A. The point I'm making is, whether -- so these documents obviously have been produced in connection with this proceeding. Whether any of them also was produced in connection with the underlying patent case I just can't remember.

But I don't -- I don't really challenge I think the point you're making, that I did not go back and look at the discovery record in the patent case. I relied on the case that had been developed up to the

point of trial by the parties.

Q. Okay. Thank you, sir, for that. You can set that aside for the time being.

A. Okay.

Q. Now, as part of your involvement in Hatch-Waxman cases as a patent litigator, you would talk to in-house counsel for your client; correct?

A. Yes.

Q. And in fact, sitting here today, can you recall ever litigating a Hatch-Waxman case in which you did not discuss the merits of the case with in-house counsel for your client?

A. No, I can't remember such an instance. If I'm asked to litigate a case from start to finish, I'm almost certainly going to be interacting with my client's in-house counsel.

Q. And in the course of litigating a Hatch-Waxman case, you occasionally talk to executives of the company you are representing; correct?

A. Yes.

Q. You did not talk to anyone at Impax about the merits of the patent case between Endo and Impax that settled in June 2010; correct?

A. That's right. I offered my opinions of what I perceived to be from the perspective of a reasonable

litigant in Impax' position. I did not focus on what was going on inside of Impax at that time.

Q. And you did not talk to Impax' outside counsel that represented Impax in the underlying patent case; correct?

A. That is correct.

Q. Okay. Do you know who Ms. Margaret Snowden is?

A. I've seen her name in some of the papers. I believe she's intellectual property counsel for Impax.

Q. And you have never talked to Ms. Snowden about the opinions in your report; correct?

A. No. Correct.

Q. Do you know who Ms. Huong Nguyen is? And "Nguyen" is spelled N-G-U-Y-E-N.

A. I've seen the name.

Q. Okay.

A. An Impax employee.

Q. And you never talked to Ms. Nguyen about the opinions in your report; correct?

A. That is correct.

Q. And you also did not talk to anyone affiliated with Endo about the merits of the patent case between Endo and Impax that settled in 2010; correct?

A. Correct.

Q. Okay. And you did not consider any Impax privileged materials in the course of forming your opinions; correct?

A. I'm not aware that I did.

Q. Okay. And you did not review -- or strike that.

You did not have access to the privileged communications of Endo or Impax when you were forming your opinions; correct?

A. I believe that's correct. I'm not aware of seeing any privileged communications.

Q. Now, for some of the materials listed on your materials considered list, you only reviewed excerpts; is that right?

A. Yes. As I said, the -- some of the, for example, deposition transcripts and things were lengthy. I relied on others to help me kind of winnow through that.

Q. And Exhibit B does not indicate which of the documents you reviewed solely in excerpted form; correct?

A. Yes, that's correct.

Q. Now, I'd like to talk to you a little bit about the opinions that you are offering today and which you are not offering today.

Now, your report contains all of the opinions you had formed at the time the report was submitted; correct?

A. Well, pertinent to this case, yes.

Q. Okay. So your report contains all the opinions that were pertinent to this case; correct?

A. That was my goal.

Q. Okay. And you are not offering any opinions as to whether in 2010 Endo's patents were valid or invalid; correct?

A. That's correct.

Q. You are not assessing whether Impax was going to win or going to lose; correct?

A. No. I don't think that is correct.

Q. Well, sir, I'd like to direct you to your deposition then. If you'd please turn to your binder, and I believe the first tab is labeled with your deposition.

A. Right.

Q. If I might ask you to look at page 147, lines 15 --

A. Hang on just a minute.

Q. Sure.

A. 147?

Q. Uh-huh. Lines 15 and 16.

Do you recall testifying that "What you're assessing here is not was Impax going to win or was it going to lose. What you're assessing is what -- what is it reasonable to think Impax' perception of its chances would have been at that time"?

A. Yes.

You're actually asking me a question there about some hypothetical person who comes to a different conclusion than the one I came to. But it is correct that I viewed my role here as to assess the -- how a reasonable litigant in the position of Impax would have perceived this case at the time of the settlement, but I would say it should be apparent from the testimony I've already given that I have also formed and provided my opinions on what I thought the likely outcome of that litigation and the various issues of that litigation would have been.

Q. I see.

When you testified, sir, in your deposition that "What you're assessing here is not was Impax going to win or was it going to lose," was that testimony truthful and accurate when you gave it?

A. Well, in the context that it was given, I certainly intended it to be truthful, but I've explained that context in response to your question.

Q. Sir, is it your testimony that you are in fact providing an opinion about the validity or invalidity of Endo's patents?

A. No. That really isn't the issue. It's kind of irrelevant today. Those patents have expired. But I was providing and have provided my opinion on what I thought the outcome would be on the issues of infringement and validity.

Q. And your opinions, sir, are not about how the actual litigants, Endo and Impax, actually understood their positions at the time of the patent litigation; correct?

A. I was -- that's correct. I was trying to provide more of an objective opinion as to what a reasonable litigant in their position would have perceived.

Q. You are not opining about the actual state of mind of Endo or Impax --

A. That's right. If someone had Impax thought they had an ironclad case of winning or losing, I was not privy to that.

Q. Are you aware, sir, that there was a -- you can put that to the side for the moment. Thank you.

Are you aware, sir, of the existence of a development and co-promotion agreement between Endo and

Impax that was also executed in June of 2010?

A. I am aware of the existence of that agreement.

Q. And am I correct, sir, that you are not offering any opinions in this matter regarding the contents of that agreement?

A. That's correct.

Q. And you are not offering any opinions in this matter regarding whether Endo made any payments to Impax in connection with the settlement in June 2010.

A. That's right. I was not asked to and I have not looked at whether there was a payment and, if there was a payment, what its value would have been at the time of the settlement.

Q. And you are not offering any opinion about the amount of litigation costs saved by Endo or Impax as a result of having settled the patent case; correct?

A. Well, in my direct examination I didn't offer any opinions about that. I think you and I discussed that a little bit during my deposition.

Q. Do you offer any -- you do not offer any opinions in your report that you submitted in this matter, sir, about any saved litigation costs, do you?

A. I did not address that in my report nor did I address it during my direct testimony, and I think I've explained to you that my experience is typically

they are not the driving force in these kinds of cases.

Q. But, sir, that opinion is not in your report, is it?

A. I don't remember, but I don't think so.

Q. Let me talk to you a little bit about your methodology, sir, if I may.

Now, I believe you testified, the decision whether or not to settle a Hatch-Waxman case is a business decision; correct?

A. Ultimately it's a business decision informed by factors that are coming in from other people.

Q. And you received or had access to the information described in your report?

A. I don't understand your question.

Q. The question is simply, you received or had access to all the information that is described in your report; correct?

It's not meant to be tricky.

A. I just don't understand what you're asking. I'm sorry.

Q. Did you receive and have access to the information that is described in your report?

A. Well, I obviously had access to it or it couldn't have found its way into my report.

Q. Okay. And you reached your conclusions by applying your experience as a patent litigator to that information.

A. As a patent litigator and just as a patent lawyer and intellectual property lawyer in general, yeah.

Q. And you reviewed the materials cited and otherwise described in your report, you applied your experience, and you reached your conclusions; correct?

A. That's what I tried to do.

Q. And other than your experience as a patent attorney, there is no other experience that you applied in reaching your opinions in this case?

A. I'm not sure how to answer that question. Obviously, I'm opining about a patent case and the settlement of a patent case, so my experience as a patent attorney come to bear, but probably other experiences do as well. I'm not sure what you're getting at.

Q. Well, let me direct you to your deposition, please, again, sir. If you would please look in your binder under the Deposition tab, and I'll direct you to page 105.

A. Okay. I'm there.

Q. At lines 10 through 16, the question -- you can

put this up on the screen, please, Ms. Clark. It's 105 lines 10 through 16 of the deposition.

The question was asked, just as I did here, "Other than your experience as a patent attorney, is there any other experience that you applied in reaching the opinions in this case?

"ANSWER: Oh, okay. I think I get your point.

"No, I don't think so. You asked me earlier have I ever held like a business executive position. No. The answer is no."

A. Yeah.

Q. You gave that testimony; correct, sir?

A. I did.

Q. And it was truthful and accurate when you gave it?

A. It was.

Q. Okay. Thank you, sir. You can put that to the side.

JUDGE CHAPPELL: We're going to take our afternoon break now.

MR. WEINGARTEN: Yes, Your Honor.

JUDGE CHAPPELL: When we come back, I'm going to ask you for a ballpark estimate on how much time you need.

MR. WEINGARTEN: Yes, Your Honor.

JUDGE CHAPPELL: We'll reconvene at 4:15.

We're in recess.

(Recess)

JUDGE CHAPPELL: We're back on the record.

Next question.

Do you have your estimate?

MR. WEINGARTEN: Between one hour and one hour and a half, Your Honor.

JUDGE CHAPPELL: All right. We may finish tonight; we may not.

Go ahead.

MR. WEINGARTEN: Thank you, Your Honor.

BY MR. WEINGARTEN:

Q. Before the break, Mr. Figg, we were talking about how you reached the conclusions you reached in your report. Do you remember that?

A. I remember some -- your general questions about that.

Q. Okay. And my next question on this subject, sir, you cannot summarize your methodology; correct?

A. When I was asked about that in my deposition, I tried to get clarity from you as to what you meant by that.

I think the methodology that I used is apparent from my report and from the testimony I've

given here today. But if you mean something different from that, you're going to have to tell me what it is.

Q. Well, but my question, sir, is -- well, let's go to your deposition. Let's look -- if you would get your binder, please. If you would turn to page 108 of your deposition.

And Ms. Clark, if you could please put page 108 lines 18 through 23.

"QUESTION: Can you summarize your methodology, sir?

"ANSWER: No.

"QUESTION: Okay.

"ANSWER: No, because I don't know what you mean by that."

So, sir, in response to the question can you summarize your methodology, your answer was no; is that right?

A. This question -- that is -- you read it correctly. But this question followed a series of questions where I tried to get you to explain what you meant.

And as I say, my methodology should be apparent from the report I've given, the opinions I've given. You obviously have some -- some different meaning in mind, but I have not been able to ascertain what that

meaning is.

Q. Sir, regardless of whatever you may think I have in my mind, the question at the deposition and your sworn testimony was: "Can you summarize your methodology?" and the answer you gave was "No"; is that correct?

A. The answer was: "No, because I don't know what you mean by that."

Q. Okay. And so your testimony today is you do not know what it means to be asked to summarize your methodology.

A. My testimony today is I believe my methodology of analyzing the facts of the case were clear from my report. And if -- therefore, I don't really understand what you're asking when you ask that.

JUDGE CHAPPELL: Are you asking if he used some model or guideline?

MR. WEINGARTEN: I'm simply trying to understand, Your Honor, as an expert witness what method he applied to reach his conclusions.

JUDGE CHAPPELL: You're assuming that a method is required rather than honesty and hard work?

MR. WEINGARTEN: Whether that's the method, he could have answered that way, Your Honor, but he didn't.

THE WITNESS: I didn't hear the last part.

BY MR. WEINGARTEN:

Q. Your answer to my question can you summarize your methodology was not honesty and hard work; correct?

A. My answer is accurately reported here. I said, I cannot answer it because I don't know what you mean by that. And if we looked at the testimony before that, I had tried to elicit from you what you were getting at and so I could answer your question, but you wouldn't give it to me.

Q. So I take it again the answer that you gave on that date was not honesty and hard work was your methodology; correct?

A. I think honesty and hard work and applying the knowledge that I've gained over a few decades as a patent attorney and a litigator were all part of the methodology I applied here, a careful analysis. They were all part of it. I didn't say those things because I thought all of that was apparent from the analysis that I included in my expert report.

Q. You didn't say those things in your deposition; correct, sir?

A. I think I just said that.

Q. And that deposition testimony was sworn

testimony; correct, sir?

A. Of course.

Q. Okay. I'd like to ask you just a few questions, please, about the entry date that was agreed to in the settlement between Endo and Impax.

You are not offering any opinion about the reasonableness of any other potential entry dates besides January 1, 2013; correct?

A. Yes. I didn't -- I didn't really look at that issue. I was asked to look at whether the agreement that was reached was, in my view, a reasonable agreement.

Q. And now I'd like to ask you a little bit about your opinions about the patent case and in particular your opinions about uncertainty in patent litigation.

You would agree, sir, that there is uncertainty in almost all litigation; correct?

A. Well, I don't know that I'm competent to opine about all litigation, but certainly there is uncertainty in complex patent litigation of the type we're discussing here.

Q. Do you remember testifying at your deposition that there is uncertainty in almost all litigations?

A. If I said that, it was an overgeneralization because, for example, I've never handled a personal

injury litigation or a products liability litigation. I would assume that those have uncertainties as well. It's just that I'm not the person you should be asking about that.

Q. I see.

When you gave that answer, sir, that there's uncertainty in almost all litigations, your testimony is you were overgeneralizing?

A. I think what I thought you were asking at the time was all patent litigation.

Q. Well, would you agree, sir, that there is uncertainty in all patent litigation?

A. I would say I've not encountered one where I didn't think there was uncertainty involved.

Q. And the outcome of Hatch-Waxman patent litigations is uncertain?

A. Yes, it is.

Q. And the ultimate outcome at the trial level of the Endo and Impax patent litigation that was ongoing in June 2010 was also uncertain?

A. I would agree with that. Yes.

Q. And the outcome of any appeal, had there been an appeal from that trial litigation, would also have been uncertain; correct?

A. I think the ultimate outcome would have been

uncertain, yes.

Q. And it is your opinion, sir, that at the time the parties entered the settlement, the outcome of the patent litigation was uncertain; correct?

A. I'm trying to figure out if you're asking a different question than the one you asked before. The outcome of that case I would say was uncertain.

Q. And it was uncertain at the time the parties entered the settlement; correct?

A. Oh, yes.

JUDGE CHAPPELL: Just so we're clear based on what he's been hearing today, when you ask a question, is it your opinion, are you asking him is it his opinion or is it an opinion that he has written down in a report for this case?

MR. WEINGARTEN: Thank you for clarifying, Your Honor.

JUDGE CHAPPELL: Because another opinion may come out that you're not expecting.

MR. WEINGARTEN: I mean the opinions in his report, and I'll try to keep it to that. Thank you, Your Honor.

BY MR. WEINGARTEN:

Q. You would agree, sir, that predicting the outcomes of Hatch-Waxman trials and appeals is not an

exact science; correct?

A. I would, yes.

Q. And the issues on an issue-by-issue basis have a remainder of uncertainty that cannot be quantified; correct?

A. Some issues may be more predictable than others, but in general I agree with your statement.

Q. And the outcome and the way a judge ultimately rules on these kinds of issues in patent cases has pretty wide error margins, would you agree, sir?

A. I'm not sure I heard your question correctly.

Q. Sure.

The outcome and the way the judge ultimately rules on these kinds of issues has pretty wide error margins?

A. Well, that --

JUDGE CHAPPELL: Are you assuming that the judge is always in error?

MR. WEINGARTEN: No, sir, I'm not.

THE WITNESS: I think you're probably quoting something I said in my deposition there, and if I said that, it wasn't very well-phrased.

But predictions about the outcomes of cases are -- it's not an exact science. There is a level of error that's associated with those predictions. If

there were not, then people would be able to make perfect decisions about what to do in litigations.

BY MR. WEINGARTEN:

Q. And if your client, sir, were to press you to provide a percentage for their chances in litigation, you would emphasize to them that litigation is uncertain.

A. That's right. And I -- I usually try to avoid providing those percentages of probability of success or failure because they imply a level of accuracy that I don't think is there.

Q. In fact, it's your practice to resist assigning percentages at all to the outcomes of your clients' cases; correct?

A. It is. I prefer to use more general terms like it's likely you have a significantly likelihood of winning or losing on this issue, it's a very close call. I will say things like that to try to get across to a client what I think about the case, but I do -- I do try to resist providing percentages.

Q. And thank you for that answer.

Let's discuss a little bit your use of the terms "likely" and "more likely than not" in your report in this matter.

A. I'm sorry. You tailed off at the end.

Q. In your report in this matter, sir, you used the phrases "likely" and "more likely than not" throughout; correct?

A. In my report?

Q. Yes, sir.

A. Yes.

Q. And I'd like to talk to you about that a little bit if I may.

A. I'm sorry. Again --

Q. In each of the instances in your report where you use the terms "likely" or "more likely than not," you would not assign a probability percentage to those words; correct?

A. That's correct. The -- I used the word "likely," but then I proceeded to explain the bases for my opinion, so what I hoped to convey in my report was a sense of my level of confidence in that opinion.

Q. When you used the word "likely" in your report, you did not have a specific percentage of probability in mind; correct?

A. That's right. I think it probably varied from issue to issue, which you would be able to ascertain from the context and the explanation in my report for how I arrived at that opinion.

Q. And when you used the word "likely," did you

mean probable?

A. Well, it could mean probable.

Q. Okay. Well, when you used the word "probable," that does not mean a specific percentage either; correct?

A. That's right.

Q. And nor can you assign a percentage to the meaning of "more likely than not"; correct?

A. Yes. I think that's correct.

Q. I'd like to just talk to you a little bit about the claim construction in the underlying patent litigation.

Now, you saw the claim construction opinion as causing a significant problem for Impax; correct?

A. A significant what?

Q. Problem for Impax; correct?

A. Yes. I saw that as a setback for Impax' case.

Q. But you are not opining in your report that Impax had a zero percent chance of overcoming that problem; correct?

A. Correct.

Q. Now, Impax' main expert in the patent case was Dr. Elder; is that right?

A. Yes.

Q. And you reviewed Dr. Elder's reports?

A. I did.
Q. And in your report in this matter, you are not offering the opinion that everything Dr. Elder opined upon was incorrect; is that right?
A. Of course not.
Q. Now, I believe on your direct testimony you said that Impax had emphasized its noninfringement arguments. Do you remember that?
A. That Impax?
Q. Had emphasized its noninfringement arguments.
A. Well, I'm not sure exactly what you're referring to.
Impax explained -- its noninfringement position was the basis for its notice letters to Endo. And I think what I said was I believe that Impax had developed its noninfringement position better than it had developed its invalidity positions.
Q. Do you remember opining in your report, sir, that Impax had focused most of its efforts on its noninfringement defense?
A. Yes. And I still think that's the case.
Q. And in your opinion, as expressed in your report, Impax likely believed it had a strong noninfringement position; correct?
A. Prior to the claim construction, I think that

is correct.

Q. And it is your opinion, as expressed in your report, that Impax' position on noninfringement appears to have been well-founded; is that correct?

A. Yes. I believe that they had adequately explained their opinion through their expert and had supported that opinion, but it didn't carry the day with the judge.

Q. Well, the judge did not ultimately rule on infringement in this matter; correct?

A. I thought your question was about claim construction.

Q. My question, sir, was, it's your opinion that Impax' position on noninfringement appears to have been well-founded.

A. Based on its claim construction.

Q. Okay. And Impax had good-faith arguments that its product did not infringe Endo's patents?

A. Based on its claim construction.

Q. And you would agree, sir, that no one would think that Impax made its noninfringement arguments in bad faith; correct?

A. That was the conclusion that I reached after reading all these materials.

Q. And you would not characterize any of Impax'

arguments in the district court as being frivolous; correct?

A. I didn't see any that struck me as frivolous.

Q. And Impax went into the Markman proceeding with a reasonable position; correct?

A. I think they argued a reasonable position, one with which the judge did not agree --

Q. Well --

A. -- which happens from time to time.

Q. -- even following the court's claim construction ruling, the infringement issues were the subject of a battle of experts over difficult technical issues; correct?

A. I'm not sure -- you have to kind of place that in time for me.

Q. Well, let's -- do you remember opining, sir, in your report that following the court's claim construction ruling, the infringement issues of whether MCC is a hydrophobic material and whether HPMC is a homosaccharide became a subject of a battle of the experts over difficult technical issues?

A. Can you point to me where we are?

Q. Sure.

A. I think I need to look at that in context.

Q. Absolutely.

If you would, please, open in the binder the report tab.

A. Yeah.

Q. It's RX 548.0030.

A. 30?

Q. Yes, sir.

It's the first complete sentence on that page.

And does looking at that sentence refresh --

A. Yes.

Q. Sorry. Let me -- please let me finish the question.

Does looking at that sentence refresh your recollection that you opined that following the court's claim construction ruling, the infringement issues of whether MCC is a hydrophobic material and whether HPMC is a homosaccharide became the subject of a battle of the experts over difficult technical issues?

A. That's what it says.

And the point I'm trying to make there is that even under the court's interpretation of "hydrophobic material," the -- Impax wasn't giving up. It was criticizing and challenging the Endo expert's water uptake experiments and -- and their -- their relevance to the infringement question.

Of course, Endo's experts were defending those

experiments and pointing out that Impax didn't do any experiments, all it was doing was criticizing.

I also note there's a typo in that paragraph. "Homosaccharide" should be "homopolysaccharide."

But again, I tried to explain in my direct testimony that the issue of whether the Impax product contained a homopolysaccharide, the experts disagreed about that. And the trial judge was going to have to sort that out. I provided my opinion on how I thought it would come out.

Q. Thank you, sir.

You can put that to the side, please.

You can certainly see some scenarios where things could have gone badly for Endo; correct?

A. That's why patent litigation is uncertain, because the -- the -- the court is going to hear testimony and assess credibility and decide who to believe and who not to believe, and it's difficult sometimes to predict the outcome of those things ahead of time.

Q. So do you recall testifying, sir, at your deposition that you can see certain scenarios -- strike that -- that you can certainly see scenarios where things could have gone badly for Endo, and so we don't know how it would have come out?

A. If you say I testified to that effect in my deposition, I won't dispute it. I think it's a true statement. Things could have gone badly for either side.

All I could base my opinions on were the record that had been developed and the opinions and the bases for those opinions that had been explained in the expert reports.

Q. And you are not offering an opinion in your report about whether the claim construction opinion that the district court judge issued was correctly decided; correct?

A. That's right. I didn't see that as what I was asked to do or what I should be doing. The question was what impact did that claim construction ruling have on the litigation.

Q. And if Impax had appealed the district court's claim construction ruling, that would have been a fair issue to litigate at the appellate level?

A. I think so. Yes.

Q. And you would agree that claim construction issues are more often the source of a reversal by the Federal Circuit than disputes about facts?

A. At that point in time, the Federal Circuit regarded claim construction to be a pure issue of law

which it reviewed de novo, and so naturally, when the appeals court has the opportunity to do a de novo review, the frequency with which it comes to a conclusion different from the trial judge is greater than under a, you know, clearly erroneous standard or something like that.

Q. So during the time periods that you describe in your report, you would agree that claim construction issues were more often the source of a reversal by the Federal Circuit than disputes about fact?

A. I think I just said that. Yes.

Q. And you don't offer an opinion about how the Court of Appeals for the Federal Circuit ultimately would have come out on the question of the district court's claim construction; correct?

A. I know you and I had a lengthy discussion about that.

My view is that even with a de novo review, when you are challenging the decision of a district judge who has -- in this case he -- he reviewed testimony. He heard arguments from the parties. You're trying to convince the appeals court that that judge made a mistake even though it's a de novo review.

So I think I explained during my deposition, even on the appeal I probably would give Endo an edge, but -- but I think it would have been an issue that was fairly litigable and it would have been a fairly close call.

Q. And as it pertains to the opinions you offered in your report, sir, you don't offer an opinion about how the court of appeals ultimately would have come out on the district court's claim construction; correct?

A. Well, I'm not sure whether I specifically addressed that precise question, but I think I did make it clear that I thought the overall outcome of the litigation was likely to be in Endo's favor, and I would include in the litigation the appeal.

Q. Well, I'm sorry, sir. I guess my question is about the contents of your report, and I appreciate you said you're not sure, but I want to be clear.

Sitting here today, you're not aware of any opinion in your report about how the federal Court of Appeals for the Federal Circuit would ultimately have ruled on the district court's claim construction.

A. What I said was, I don't believe that in my report I specifically say I think the Federal Circuit would have affirmed or reversed the claim

construction. But I offered a general opinion -- and you and I talked about this during my deposition -- that after reviewing everything, my opinion was that Endo was likely to prevail in the litigation, and in my mind that would include the appellate process.

Q. Well, let me ask you this, sir.

A reasonable litigant in Impax' position would have had a more optimistic view of its chances of succeeding on appeal than it would have had of its chances of succeeding in the district court; correct?

A. I think Impax' view of its chances on appeal on the claim construction issue would have been more optimistic than its chances of winning on the infringement and validity issues at the trial court based on the claim construction that the trial court issued.

Q. So is the answer to my question yes or no, sir?

A. The answer to the question is the question (sic) I just gave. The question -- the question you asked didn't qualify what would happen at the district court as being based on the claim construction that the trial judge had provided.

Q. Do you remember testifying, sir, that you think so, yeah, a reasonable litigant in Impax' position

would have had a more optimistic view of its chances of succeeding on appeal than they would have had of their chances of succeeding in district court?

A. I may very well have said that, but implicit in that is succeeding at the district court, given the claim construction that was issued by the district court.

Q. Okay. Your opinions in your report, sir, do not rely on any analysis of the potential for a design-around by Impax; correct?

A. I'm not sure I understand that.

Q. Sure.

You're familiar with the term "design-around"?

A. I am familiar with that term.

Q. Okay. And my question is, you don't express any opinions in your report that rely on any analysis of a potential design-around by Impax; correct?

A. Well, the design-around efforts would have come long before the litigation because the Impax product was developed and designed prior to their filing of their ANDA. Once they have filed their ANDA, it's very difficult for them at that point to change the product, so they're kind of stuck with the product they've developed.

Now, perhaps they tried to design around in

developing that product. I don't know.

But I'm a little confused by your question.

Q. Okay. Well, do you remember testifying, sir, at your deposition that, no, your opinions in this case do not rely on any analysis of the potential for a design-around --

A. Where are we in my deposition?

Q. Okay. If it would refresh you to look, it's page 177 lines 7 through 10.

And let me know when you've had a chance to review that.

(Document review.)

A. Well, you're taking that answer out of context, sir.

Q. Well, my question for you, sir, was, do you remember testifying in response to the question -- I'm sorry. Please let me finish my question -- do you remember testifying in response to my question "Do your opinions in this case rely on any analysis of the potential for a design-around by Impax?

"ANSWER: No"?

A. You read that correctly. But you didn't read the lengthy answer that preceded that in which I just had explained to you that the generic company design-around opportunities are limited because of the

necessity for it to develop a product that's bioequivalent to the reference listed drug.

Q. Be that as it may, sir, the question was, do your opinions in this case rely on any analysis of the potential for a design-around by Impax?

Are you changing your testimony from your deposition?

A. That testimony is accurate, as I have explained earlier, because once the ANDA is filed, the opportunity for designing around has passed unless you decide as a generic company to withdraw your ANDA, design a new product and submit a new ANDA and start back at the beginning.

Q. I appreciate that, sir, but I guess the answer then is no, none of the opinions in your -- in this case in your report rely on an analysis of the potential for a design-around; is --

A. Mr. Weingarten, I have agreed that you read this correctly.

Q. Okay.

A. But I tried to explain the context of my answer.

Q. I see.

And is it your position, sir, that your -- all of your answers in your deposition require some sort of

context to be understood truthfully and accurately?

A. I would encourage you in reading them to read them in context. Yes.

Q. Okay. Generic challengers don't always lose Hatch-Waxman cases; is that right?

A. That is correct.

Q. Okay. And you talked on your direct examination about a report from the Royal Bank of Canada. Do you remember that?

A. The RBC report?

Q. Yes, sir.

A. Yeah.

Q. Okay. And you testified that it corroborated your opinion that brands have a slight edge in Hatch-Waxman litigation?

A. I don't know if I used the word "corroborated," but it -- the number they gave was consistent with the opinion I gave in my direct examination.

Q. Did you conduct your own quantitative -- strike that.

You did not conduct your own quantitative analysis of win-loss rates for generic companies in Hatch-Waxman cases; correct?

A. That's correct. I did not go back and review every case and create a chart. One of your experts did

that I believe.

Q. And the RBC report, sir, says that Impax had won 67 percent of the cases that it had taken to trial during the time period studied. Do you remember that?

A. Over that period of time that they were analyzing, that's right.

Q. Okay. And you didn't have any access to any of the underlying data for the RBC report?

A. Only to the extent that it was explained in the report itself.

Q. Okay. And did not undertake -- you did not undertake your own quantitative analysis of how often at-risk launches occur; correct?

A. If by "quantitative" you mean a percentage number, no. I based my opinion on my experience over the years.

Q. Okay. I'd like to talk to you a little bit about the timeline that you've set forward in your opinions --

A. Okay.

Q. -- about appeal and otherwise.

Now, you opine that based on information you reviewed and your experience, it is reasonable to assume that a litigant in Impax' position would have expected entry of judgment by the district court

approximately four to five months after the trial; correct?

A. Yes. I think that was a reasonable time frame to use --

Q. And what --

A. -- could be considerably shorter, could be considerably longer, as we've seen in some of the cases we've discussed here today.

Q. And what that means in practical effect is you opine that the trial court could have issued its decision by November 2010; correct?

A. I'm sorry. I don't have the timeline committed to memory.

Q. If it would help refresh your recollection, sir, please turn to your report, paragraph 84.

It's on page RX 548.0039. And it's the table at the top of the page --

A. Oh, I'm sorry. I'm --

Q. Paragraph 84.

A. Hang on.

Yes.

Q. Okay. And does it refresh your recollection, sir, that your opinion is that posttrial briefing and decision after trial could have occurred as of November 2010?

A. That is the date that I used as a reasonable number, and I explained in the paragraph below that I regard that as a conservative estimate.

Q. Okay.

A. But I also acknowledge, some judges are very fast, and it could have come earlier than that. But there could have been posttrial motions and other things that could have made it a lot later than that.

Q. I appreciate that.

I'd like to talk to you a little bit about the information that you relied upon in reaching that opinion about the time it would take to issue a judgment.

You can set that aside, please, sir.

A. Go ahead.

Q. I'm asking you to please set it aside, sir. It's not fair to anyone to have you refreshing your recollection as we're going. If you need to be refreshed --

A. I wasn't refreshing. It was just opened to that page because you were asking me about it.

Q. I understand. If you need to be refreshed, please let me know.

Now, you reviewed the results of a customized report showing the time to decision following five

bench trials in Hatch-Waxman cases in the District of New Jersey; correct?

A. Yeah. We talked about that in my direct examination I think.

Q. And you did not review the underlying facts of any of those five cases --

A. I was focusing on the timing only. That's correct.

Q. And you did not review the legal issues in any of those five cases; correct?

A. That's right. I didn't look at the underlying cases. I just looked at the timing.

Q. And Judge Hayden is the judge who presided over the Endo-Impax patent case that we have been discussing today?

A. She is.

Q. And Judge Hayden did not preside over any of the cases on the customized report that you reviewed; correct?

A. I believe that's correct.

Q. Okay. And you did not disclose in your report in this case any research about how long it takes Judge Hayden to decide Hatch-Waxman cases; correct?

A. We've -- that's right.

I focused on cases that were decided in that

time frame and I -- our -- my intention was to list all of them, so these five cases were the five cases in the Hatch-Waxman arena that went from trial to decision during that time frame.

Q. For purposes of -- strike that.

In your expert report in this matter, sir, you did not undertake any review of Judge Hayden's caseload or docket as it stood in 2010; correct?

A. That's correct.

Q. And I believe you said before, it's possible Judge Hayden could have ruled from the bench at the end of the trial in mid-June 2010; correct?

A. I've seen cases in which that has happened. I would say they are rare, but it does happen.

Q. And it was --

A. I've seen judges dictate their lengthy opinion from the bench, yes.

Q. And it was possible that Judge Hayden could do the same here.

A. It -- it is possible that she could have. It is possible that she -- that it would have gone much beyond November because of things that both she did and the parties did, so that's why we use an average.

Q. I'd like to talk a little bit about the experience that you relied upon in reaching your

opinion that it would take four to five months for a trial court decision to issue.

I believe you stated on direct, but I want to confirm, sir, you have never litigated a Hatch-Waxman case through trial to judgment in the District of New Jersey; correct?

A. I think that's right. And I was actually kind of surprised because I've had a number of cases in New Jersey. It's one of the popular venues for Hatch-Waxman cases. But it looks like all of the ones I handled were resolved one way or the other before trial.

But I had many cases in which, for example, there were Markman proceedings and then a decision following the Markman proceeding or motions and decisions on motions, so I'm generally aware that it's a busy court.

Q. I understand.

But the answer is you have not litigated a Hatch-Waxman case --

A. I said that.

Q. -- to --

A. I said that.

Q. I'm sorry. Please let me finish the question.

You have not litigated a Hatch-Waxman case

through trial to judgment in the District of New Jersey.

A. The answer I just gave you has not changed.

Q. And the answer was --

A. I have not.

Q. The answer is yes; correct?

A. I have not litigated -- I couldn't find a case that I litigated in New Jersey through trial.

Q. Thank you, sir.

Now, the experience you cite in your report is a case you litigated in the District of Delaware; correct?

A. That's right.

Delaware is another very popular venue for Hatch-Waxman cases.

Q. And that case, needless to say, was before a different judge than the Endo-Impax case?

A. Of course.

Q. And that case was, needless to say, in a different court than the Endo-Impax case; correct?

A. It was.

The two courts are comparable congestion, if you will.

Q. And your case in Delaware had a different set of facts than the Endo-Impax case that was pending in

New Jersey?

A. It had a different set of facts, although the complexity of the facts I think were comparable.

Q. Did you -- you didn't offer an opinion comparing -- in your report, sir, you didn't offer an opinion comparing the facts in your Delaware case to the facts of the Endo-Impax case, did you?

A. No. I was just responding to your question.

Q. That's fair.

But that opinion does not appear in your report; correct?

A. No. I was responding to your question about the complexity of the facts.

Q. Let's discuss for a minute, sir, the Federal Circuit appeal.

Now, I believe you opined that a favorable judgment for Impax from the Federal Circuit would not have likely occurred until at least the fourth quarter of 2011. Is that right?

A. I think what I said was a conservative estimate based on the court's statistics was that the appeal from docketing would be about eleven months, and I think that did come out somewhere around November of 2011.

Q. Okay. So your opinion expressed in the report

is an appellate opinion would not have issued until at least November 2011?

A. No, I didn't say that. I said that it's conceivable it could have come out earlier, but -- but my opinion is that is a very conservative estimate and likely would have come out considerably later than that.

Q. And you cannot exclude the possibility, however, that the Federal Circuit decision could have been sooner than the fourth quarter of 2011; correct?

A. I can't exclude that possibility, but I have had significant experience in the Federal Circuit, and I don't see that happening very often.

Q. Okay. Now, your opinion, sir, in your report is that a win for Impax on appeal would have likely resulted in a remand rather than a reversal; is that correct?

A. I think -- I think it's almost -- having analyzed the situation, I think it's almost a certainty that the Federal Circuit would not have decided the ultimate issues if it reversed on claim construction, it would have remanded to the district court.

Q. And in your report, sir, you didn't use the word "certainty" with regard to the idea of a remand,

you said "likely"; isn't that right?

A. That's right.

Q. Okay.

A. But I explained why I thought it was likely, and I think in the context you'll see that I have a fairly high level of confidence in that one.

Q. Let's go into that, please.

You did not conduct any analysis of the rate at which the Federal Circuit reverses on claim construction and then remands the case for further proceedings; correct?

A. That --

Q. In your report I mean.

A. Well, I don't recall doing that in my report. But that's not how you would analyze that question. You would analyze that question by looking at what the record would be before the Federal Circuit.

Q. Well, you're not aware, sir -- let me strike that.

In preparing that opinion, sir, about the likelihood of a remand, you asked a colleague at your law firm to look and see if a case could be found in which claim construction was reversed, but the court then proceeded to decide the issues without a remand; isn't that right?

A. I did ask a colleague to see if we could find a situation in which the court had done that, and we did not find a case that seemed on point where that had happened.

Q. And that answer from your colleague informed your opinion in your report; correct?

A. Not necessarily, no.

I -- I -- I tried to explain in my direct examination that if the Federal Circuit reversed the district court's claim construction, then the issue would be, for example, under Impax' definition of "hydrophobic agent," is there a hydrophobic agent in the Impax product. The experts disagreed about that.

But the point is, the Federal Circuit can only decide the appeal based on the record that is established in the trial court. There wouldn't have been a record because Impax wasn't going to put that evidence in once it lost on the claim construction, so it would have had to have gone back to the trial court to develop a record.

So I don't think it's fair to say you're just going to look at the statistics on a question like that. You have to look at what is the Federal Circuit going to have in front of it on which it could base a decision.

Q. My question was simply, sir, the answer from your colleague informed the opinion you expressed in your report.

A. And my answer is, to a very minor extent. Much more important to me is what would the record have looked like if the Federal Circuit had reversed on the claim construction.

Q. Are you familiar with the case Saffran v. Johnson & Johnson, Federal Circuit 7 -- Saffran v. Johnson & Johnson, 712 F.3d 549 (Fed. Cir. 2013)?

A. What was the first name?

Q. Saffran, S-A-F-F-R-A-N.

A. I'm not familiar with the -- as -- the facts of that as I'm sitting here.

Q. Okay. It's not cited in your report, is it, sir?

A. I don't recall that it is.

Q. Okay. I'd like you to turn in your binder to what's been labeled as CX D-004.

A. CX --

Q. D, as in dog, 004.

I believe you'll find behind that tab a copy of Saffran v. Johnson & Johnson.

A. I have it.

Q. Okay. Ms. Clark, can we put that up on the

screen, please.

Now, let's turn if you would, please, sir, to page 004-003, the first paragraph of the opinion.

And Ms. Johnson (sic), can you blow up what it says underneath Lourie, Circuit Judge, that first paragraph on the bottom left. I'm sorry, Ms. Clark. Thank you.

Now, you see, sir, Johnson & Johnson and Cordis Corporation appealed --

A. Yes.

Q. -- from a judgment in which the district court held Cordis liable for infringement of Saffran's patent?

A. I see that.

Q. And the court writes, "We conclude that the district court erroneously construed the claims of the '760 patent and that, under the correct construction, Cordis is entitled to a judgment of noninfringement as a matter of law. Accordingly, we reverse."

Do you see that?

A. I see those words.

Q. So the Federal Circuit in that case reversed the claim construction ruling; correct?

A. Yes.

Can you tell me whether the record had been

established at the district court that allowed it to make that decision?

Q. Unfortunately, sir, I'm the one who gets to ask the questions today, so my question now pending is --

A. Then let me answer your question.

This is a very lengthy opinion.

Q. Uh-huh.

A. And the Federal Circuit -- this does not change my view at all --

Q. Uh-huh.

A. -- that the Federal Circuit will not decide a substantive issue of infringement or validity unless it has a record upon which to decide it. And the Federal Circuit is very much disinclined to being the fact-finder and resolving disputed facts at the appellate level.

Now, I can't tell you what happened in this case, but I think for you to conclude from the summary of the opinion that this somehow applies to the situation that would have existed in the Impax case is a bit of a stretch.

Q. I'm not concluding, sir; I'm just asking you the question.

The Federal Circuit did not remand this case

for further proceedings; correct?

A. It said it reversed.

Q. And so it did not remand; correct?

A. It reversed. It did not remand.

Q. Thank you.

Are you familiar with the case of Merck v. Teva, 395 F.3d 1364 (Fed. Cir. 2005)?

A. I don't have that case committed to memory. It actually sounds somewhat familiar.

Q. Okay. It's not cited in your report, though, is it?

A. I don't think so.

Q. Okay. Maybe you could turn, sir, to the tab that's marked CX D-003.

And Ms. Clark, you can put the first page up on the screen there, please.

And let's turn to CX D-003-003, the first page of the opinion.

And Ms. Clark, can you blow up the language that appears under Gajarsa -- blow up the language in the first paragraph of the opinion under Judge Gajarsa's name, G-A-J-A-R-S-A.

And do you see there, sir, the Federal Circuit wrote that Teva Pharmaceuticals appeals the final judgment of the District Court of Delaware which, after

a bench trial, found Merck's U.S. Patent Number -- and it's the '329 patent -- not invalid as anticipated or obvious? Do you see that?

A. I see that.

Q. And the court continues, "The district court further found the '329 patent to be enforceable, and the '329 patent claims 23 and 37 constructively infringed by Teva's Abbreviated New Drug Application under" and then it cites to the Hatch-Waxman; correct?

A. Where are you reading?

Q. That same -- that same paragraph, sir.

It says the district court further found the patent to be enforceable? Do you see that?

A. Oh, yes.

Q. And it says the patent claims were constructively infringed by Teva's Abbreviated New Drug Application.

Do you see that?

A. Yes.

Q. And the court is referencing the Hatch-Waxman Act? Do you see that?

A. Yes.

Q. So this was a Hatch-Waxman case on appeal?

A. That appears to be the case. I'm not familiar with this case.

Q. And Ms. Clark, you can put down that paragraph, and we want to go to the next paragraph in the right-hand column where it says "We disagree." Thank you.

And the appellate court continued: We disagree with the district court's construction of the claim term "about" in certain of the claims of the patent.

Do you see that, sir?

A. Yes.

Q. Then the court says, "Because we further hold claims 23 and 37 obvious in light of the prior art, we vacate the judgment of the district court and hold the claims invalid and not infringed."

Do you see that?

A. I see those words.

Q. Okay. And so those are two examples, sir, in which the Federal Circuit reversed on claim construction and did not remand for further proceedings; correct?

A. I would have to read this case and the other one you showed to me, but I strongly suspect that a record had been developed at the trial court on which the Federal Circuit could decide those issues.

This doesn't in any way change my view that a

remand in the case we're talking about was highly likely if claim construction had been reversed.

Q. In the case that we've been discussing between Endo and Impax, there never was a record to go up on appeal because the case settled; correct?

A. Yeah. My point is, obviously there was not a record. The case was terminated. But my point is, as the parties put in their evidence, if the trial had gone forward, the evidence they would have put in would have been based on the claim -- the judge's claim construction.

For example -- so my point is, Impax would not have argued it doesn't infringe under the Impax claim construction. The judge wouldn't have wanted to hear that because he didn't adopt -- she didn't adopt Impax' claim construction.

So my point is, there would not have been a record either on -- in noninfringement or invalidity under the correct claim construction.

Now, I would have to look at these two cases that you've shown me here today, and so anything I say about them would be speculative, but I strongly suspect that because of the way the cases progressed there actually was a record created on which the court could base its decision.

Q. And you can't say to a certainty, sir, that there would not have been a full record had the Impax-Endo litigation continued through trial and judgment; correct?

A. That's correct. All I can say is, in my experience, once the judge issues its claim -- the court issues its claim construction, the parties are expected to present evidence consistent with that claim construction, not to continue to try to argue the claim construction position that they lost.

Q. Now, I'd like to ask you this, sir.

Even under your own opinions and assumptions in the report, if there had been no remand from the Federal Circuit, then there could have been a final decision on the patent case as early as November of 2011; correct?

A. I hate to make you do this, but I kind of lost your question in the middle.

Q. That's okay.

My question, sir, was, accepting your assumptions and opinions as expressed in the report, if there had been no remand, then there could have been a final appellate decision on the patent case by November 2011; correct?

A. As I've said, you are correct. I regard that

as a very conservative, optimistic view of the timing, but it is possible, and it's possible it even could have come earlier than that.

Q. And even if the case were remanded for further proceedings and went all the way to final judgment again in the district court, your opinion is that final judgment could have occurred as early as May 2012; correct?

A. Yes. I think that is extremely unlikely, but it's possible. And that's -- the fact that it's possible is the reason I put it in my report.

Q. And you're not offering any opinion in your report, sir, on the likelihood of Impax winning its case if it had gotten all the way back to a remand and then another trial and judgment; correct?

A. You're right.

Q. Okay. Your opinion, sir, is that it's likely there would have been a remand and that a reasonable litigant would have understood that the remand proceedings could have stretched beyond the January 1, 2013 entry date in the settlement agreement between --

A. They easily could have done that, yes.

Q. I'm sorry. I didn't hear the answer to the question.

A. I said, "They easily could have done that, yes."

Q. So, sir, my question is, if all of your opinions are right and Impax was likely to lose at trial and the timeline for a final decision after appeal, after remand, stretched past January 1, 2013, why would a rational litigant in Endo's position agree to a January 1, 2013 entry date?

A. Because things could have gone the other direction as well.

Q. Thank you.

I'd like to talk to you about this license provision.

A. About what?

Q. The license provision that you discussed a little bit on --

A. Okay. I just didn't hear you.

Q. -- direct.

Now, you opined that Impax was able to negotiate a prospective license and/or covenant ensuring that it would not be sued on Endo's later-obtained patents; correct?

A. I did say that, and I will acknowledge that was a poor choice of words.

Q. I see.

Do you no longer stand behind that opinion, sir?

A. It was a poor choice of words. One can never ensure that their competitor is not going to sue them. It's pretty easy to bring a lawsuit in this country. I -- and you and I talked about that extensively during my deposition.

Impax could not ensure that Endo wouldn't sue it, but what Impax did do was it negotiated the terms of an agreement that gave it rights and freedom to operate under patents that Endo would obtain in the future.

Q. And I hear you, sir.

But the word you used in your report that was served in this matter was "ensuring"; correct?

A. I think I just acknowledged that. Yes, sir.

Q. And you don't actually quote any language from the license in the June 2010 settlement in your report; correct?

A. Do I quote the license agreement itself in my report?

I don't remember whether I did or not, but I'm not sure there would have been a reason for me to. I cited to it.

Q. Okay. My question wasn't whether there was a

reason to or not.

My question was, sitting here today, can you tell us -- can you confirm you did not quote the license language in your report?

A. I don't remember including quotes from the license agreement. I remember citing to the license agreement.

Q. Now, you state in your report that you reviewed the claims of what's been called the '779 patent?

A. I'm sorry?

Yes, I did review the claim of the '779 patent.

That's the one on the impurity; right?

Q. I'm sorry, sir. I'm just asking the questions.

A. Well, I'm just trying to get clarification. That -- we've talked a about a lot of patents. I think that's the one that covers the -- the API with the --

Q. Let me ask you this.

A. -- little bit amount of impurity.

Q. Sir, if I mention that it's the Delaware decision affect the '779 patent --

(Counsel and witness speaking at the same time and cautioned by court reporter.)

BY MR. WEINGARTEN:

Q. The decision regarding the '779 patent that you

discuss in your report and that you discussed on direct examination was a --

A. Right.

Q. -- Delaware decision; correct?

A. I did discuss the Delaware decision, and I think you're correct that was one of the patents that was dealt with in that litigation.

Q. One of the patents was found invalid; correct?

A. It was found to be invalid because it was directed to patent-ineligible subject matter under a very interesting area of the law that's developed over the last few years.

Q. But nonetheless, found to be -- nonetheless, held by the district court to be invalid; correct?

A. It was held to be invalid under section 101 of the patent statute.

Q. And the Delaware decision regarding the '779 patent that was held to be valid, that is on appeal currently; correct?

A. It is, correct.

Q. And you're not --

A. Technically, it wasn't held to be valid. It was held that the -- that the challenger had failed to prove that it was invalid.

Q. I appreciate that.

And you're not offering any opinion about how that appeal of the '779 patent will turn out, at least in your report; correct?

A. I -- I have not addressed that point. You're correct.

Q. Okay. And you are aware sitting here today that subsequent to the execution of the settlement agreement between Endo and Impax, Endo purported to terminate the license; correct?

A. At one point in time they -- they purported to terminate the license, yes.

Q. And sitting here today, you're aware that after Endo and Impax settled, Endo brought a suit against Impax, alleging a breach of the settlement agreement from June of 2010 and patent infringement; correct?

A. It's a little more complicated than that, but what they alleged was that there was a provision of the agreement that required Impax to come back and renegotiate in good faith the terms of the license following Impax' exclusivity period.

And Endo's allegation was that Impax had refused to engage in those negotiations and therefore was in technical breach of that provision of the agreement. And their argument was the license itself

was predicated upon Impax' being in compliance with the agreement --

Q. Mr. Figg --

A. -- and therefore, their argument was that the license no longer applied and they were therefore free to include a claim for patent infringement.

Q. Mr. Figg, I'm only interested in whether you're aware of the fact that there was a later lawsuit, sitting here today.

A. Well, I think I answered your question. Your question -- that wasn't exactly your question.

Q. Let me withdraw --

A. But yes, I am aware there was subsequent litigation.

Q. I will withdraw both questions.

In your report that you submitted in this matter, sir, you did not address or discuss any subsequent litigation between Endo and Impax regarding the license in their June 2010 settlement; correct?

A. That's correct. I looked at these issues after receiving Mr. Hoxie's report.

Q. In fact, you first saw the complaint that Endo filed against Impax after you had served your expert report; correct?

A. I believe that's correct. Yes.

Q. Okay. And you didn't do any review of the pleadings that had to do with that subsequent litigation until after you saw Mr. Hoxie's rebuttal; correct?

A. That's right. I saw Mr. Hoxie's discussion of that case, so I went back and pulled those pleadings and looked at them to find out what it was he was talking about.

Q. Because none of that had been considered by you when you wrote and submitted your original report on September 5 of this year.

A. Well, when you say "none of that," that's probably an overgeneralization. I had not reviewed those pleadings or that case, but it -- it didn't alter my opinion that the license agreement that Impax entered gave it a license and a covenant not to sue under patents that would subsequently issue to Endo.

Q. Well, whatever opinions you offer about that license and covenant in your original report, you did not -- you did not analyze or address Endo's suit against Impax at a later date; correct?

A. That opinion that I just told you about is in my report. But I agree with you, I did not address that subsequent contract litigation or its settlement between Impax and Endo before submitting my report.

Q. I'd like to talk to you a little bit, please, sir, about your opinions about the scope of the patent, if I may.

Now, you have a section of your report in which you opine, "The settlement agreement was within the bounds of well-established case law when it was entered"; correct?

A. Yes. I address that in my report.

Q. And you opine in your report that in your opinion, the settlement complied with the scope-of-the-patent test as defined by the Federal Circuit courts of appeals at the time the settlement was signed; correct?

A. Yes.

Q. I'm sorry. I didn't hear you.

A. Yes.

Q. Now, I believe you testified, but I want to confirm, sir, you are not holding yourself out as a specialist in antitrust law; correct?

A. Well, I think I answered your question earlier. There is an interplay between patent law and antitrust law, and so, for example, I have included antitrust counterclaims in patent cases that I've litigated, but -- but I don't hold myself out as an expert in the field of antitrust law.

I -- I have a lot of experience with Walker Process-type claims and antitrust principles that are directly relevant to patent cases.

Q. But you do not --

A. I'm sorry for the long answer, but just to say no would have been a little bit misleading I think.

Q. Well, it's correct, sir, that you do not hold yourself out as a specialist in antitrust law.

A. That's correct.

Q. Thank you.

And I believe you discussed on your direct examination about some of the circuit opinions regarding scope-of-the-patent test that existed as of June 2010. Do you remember that?

A. I think I just cited some of those opinions in courts of appeals.

Q. Uh-huh.

And are you aware that the Sixth and D.C. Circuits had adopted different standards than the Second and Eleventh Circuits as of June --

A. Yes. And I cited those cases in my report.

Q. And the patent litigation between Endo and Impax was pending in New Jersey; correct?

A. Yes.

Q. And the District of New Jersey is within the

Third Circuit; correct?

A. Yes.

Q. And you're aware that the Third Circuit as of June 2010 had not held that settlements within the scope of the patent are presumed legal; correct?

A. Well, that's right. But the case that was pending in New Jersey was the patent case. That would have been appealed to the court of -- been appealed to the Court of Appeals for the Federal Circuit.

Q. Uh-huh.

A. If -- if there were an antitrust issue raised, we're not sure where that would have gone I don't think.

Q. My question was simply, sir, that as of June 2010, the Third Circuit had not held that settlements within the scope of the patent at issue were presumptively legal under antitrust law; correct?

A. That's right.

I was just trying to clarify, though, that just because the patent case was there, which would have gone to a different court of appeals, we don't know whether an antitrust issue would have gone to the Third Circuit or the Second Circuit or some other circuit.

Q. And you're aware that Impax is headquartered in

California?

A. I understand that Impax is a California -- I don't know whether they're incorporated actually, but I believe their headquarters are in California.

Q. And California is within the Ninth Circuit; correct?

A. Yes.

Q. And you are aware that as of 2010, the Ninth Circuit had not issued any ruling that reverse payment settlements that fall within the scope of the patents at issue are presumed legal?

A. I was not aware of any. That's correct.

Q. Okay. And so a reasonable litigant, to your point, sir, in June of 2010 might not know which circuit's law would apply to the issue of whether the settlement violated the antitrust law; correct?

A. I think that's correct.

The only point I was trying to make in my expert report is we had a number of decisions out of several different circuits that held that the scope-of-the-patent test was the correct test.

And I also cited in there the brief that the solicitor general filed urging I think that the tamox- -- I've forgotten which case it is now -- not be heard by the Supreme Court because this issue had been

resolved in these other courts.

Q. And you're not offering an opinion in your report, sir, as to whether the settlement between Endo and Impax violated the antitrust laws as they existed on June 8, 2010; correct?

A. I am not offering such an opinion.

Q. Okay. And you're not offering opinions about the legality of the settlement under later antitrust law; correct?

A. That's correct.

Q. And you're not offering an opinion that the state of the law at the time the agreement was executed is relevant to deciding whether the agreement is lawful as of today; correct?

A. Can you repeat your question or have it read back, please.

Q. Sure.

You are not offering an opinion in your report that the state of the law at the time the agreement was executed is relevant to deciding whether the agreement is lawful as an antitrust matter as of today.

A. I'm not offering an opinion about whether or not it was lawful. I was simply pointing out that there was this body of case law that defined the

scope-of-patent test, and in my view, the settlement and license agreement that was entered complied with that test.

But the ultimate question of who is liable or whether anyone is liable for antitrust violations is not for me to say.

Q. And you would doubt that this court would want to hear that opinion in any event; correct?

A. I would doubt very seriously that Judge Chappell wants my opinion on that, but he can tell me if he does.

Q. I'd like to just talk to you a little bit about the at-risk launch scenarios.

A. Yeah.

Q. And I believe you testified that they were rare -- it was rare for a generic company to launch at risk; correct?

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

Q. Okay. And the opinion you offered in your report was that at-risk launches are rare; correct?

A. Yes.

Q. Okay.

A. Or actually, to be more precise, were rare at that point in time that we're talking about.

Q. I see.

Well, sir, can I ask you to please look in your report at page RX 548.0039, heading D as in dog.

And Ms. Clark, can you please put heading D on the screen.

JUDGE CHAPPELL: Can you give me an update of how much time you need?

THE WITNESS: What page are you on?

MR. WEINGARTEN: I'm sorry. I'm going to ask -- answer the judge's question first.

Fifteen more minutes, Your Honor, tops.

JUDGE CHAPPELL: All right.

BY MR. WEINGARTEN:

Q. Page RX 548.0039, heading D.

You wrote in your report, though, in the present tense, correct, "At-Risk Launches Are Rare and Present Significant Risk to Smaller Pharmaceutical Companies Like Impax"?

A. I acknowledge that that heading uses the present tense, but the context of my report was analyzing what the situation was at the time the settlement was entered.

Q. I see.

And you're -- you can take that down, please, Ms. Clark.

A. I'm sorry. I didn't hear that.

Q. I'm directing that comment to Ms. Clark.

Your question, sir, is you are not offering any empirical claims when you use the word "rare"; correct?

A. It's simply based on my experience. I didn't do a numerical analysis of that.

Q. And generic companies do launch at risk on occasion; correct?

A. That is correct.

Q. And your report that you served, sir, does not include any analysis as to how often a generic company is required to pay damages after an at-risk launch; correct?

A. I didn't do a numerical analysis of that either.

Q. Okay. And none of your opinions in your report, sir, rely on an analysis of Impax' financial statements; correct?

A. I didn't look at Impax' financial statements.

Q. And none of the opinions in your report relies on an analysis of Impax' financial condition as of June 2010; correct?

A. I didn't consider their financial conditions.

Q. And you didn't compare Impax in any empirical sense to other pharmaceutical companies; correct?

A. Well, only to the extent that I saw testimony or I saw evidence that Impax was regarded as one of the smaller generic companies, which was consistent with what I thought about Impax at the time, but I didn't do any analysis beyond that.

Q. Okay. You opine in your report, sir, that if you were counseling Impax in June 2010, you would not have recommended Impax launch at risk because the risks were substantial.

Do you remember offering that opinion?

A. I remember that that is in my report. And I also remember this was another example where I explained to you in my deposition that that again may have been a poor choice of words.

I try to avoid advising a client, a generic company or a client, whether they should launch at risk or not. What I try to do is advise them of what I perceive the patent risks to be, and then whether they decide to accept that risk or whether there are business considerations that influence, that's their decision. It's not my decision, so I try to avoid giving that advice.

And I apologize if I perhaps overgeneralized in my report.

Q. So you would agree, sir, that that opinion in

your report at paragraph 92 about how you would or would not have recommended a launch at risk to Impax is an overgeneralization, to use your word?

A. Yes.

My advice in that situation would have been that there are substantial risks if you proceed with this litigation that you will lose, and if you launch at risk, you run the risk of losing and being liable for lost profit damages to Endo. That would have been the type of advice I would have given.

Now, they might decide they're perfectly happy to accept that risk, and that's their decision, it's not mine.

Q. Sir, that answer that you just gave may be what you're saying today, but it's not what you wrote in paragraph 92 of your report; correct?

A. It's very much implicit in what I said here in paragraph 92.

Q. So is that another example where, to understand the meaning of your report, we have to understand the implicit meaning?

A. I think it's pretty clear actually what I was saying in this report.

Q. So it's not implicit --

A. I mean, you may disagree, that's fine, but I --

I think it's clear that what I -- I had explained what these risks were in the words leading up to what you're reading, so it was clear what risk I thought they would be running and how significant I saw that risk as being.

So that's the kind of -- that's what I think you would take away from paragraph 92.

Q. The advice that you say you would give in paragraph 92, in the second sentence, is the kind of advice that you try to avoid actually giving to your clients; correct?

A. Well, this statement is technically accurate. It says, "I would not have recommended that Impax launch at risk because the risks were substantial." I may very well have advised them the risks were substantial. I would not have recommended that they launch at risk.

The point I'm making is, I also would not have recommended that they don't launch at risk, because that's their decision, not mine.

Q. Correct.

And the type of advice that you give to your clients is not about whether to launch at risk or not; correct?

A. That's right. I advise them of what I perceive

the risks to be.

Q. And so that sentence there in paragraph 92 is not the type of advice that you would give to your clients; correct?

A. Well, as I've just told you, this statement technically is correct. It says, "I would not have recommended Impax launch at risk," and that is a true statement.

Q. And it's only true because you do not make such recommendations at all either way; correct?

A. That's right.

The rest of the sentence is also true, and I would have advised them of that, that I felt that the patent risks were substantial.

MR. WEINGARTEN: If I can have a second to confer with my colleague, Your Honor.

JUDGE CHAPPELL: Go ahead.

(Pause in the proceedings.)

MR. WEINGARTEN: I'm ready to pass the witness. Thank you, Your Honor.

Thank you, Mr. Figg.

JUDGE CHAPPELL: Will there be any redirect; and if so, how long do you need?

MR. HENDRICKS: Fifteen minutes, thirty minutes at the very most, but closer to fifteen I think.

JUDGE CHAPPELL: Not going to happen today. It's almost 5:40.

We'll reconvene tomorrow morning at 9:45.

We're in recess.

(Whereupon, the foregoing hearing was adjourned at 5:38 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