IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 1:14-cv-00667-JBS-KMW

CONSOLIDATED (04:49; 05144; 00335;

06893 and 03240)

SENJU PHARMACEUTICAL CO., LTD.,
BAUSCH & LOMB, INCORPORATED and
BAUSCH & LOMB PHARMA HOLDINGS CORP.,

Plaintiffs,

vs.

LUPIN, LTD. and LUPIN
PHARMACEUTICALS, INC.,

Defendants,

INNOPHARMA LICENSING, INC.,
INNOPHARMA LICENSING, LLC,
INNOPHARMA, INC., INNOPHARMA, LLC,

Defendants.

Videotaped Deposition of

STEPHEN G. DAVIES. D.PHIL.

Washington, D.C.

February 22, 2016

Reported by: Michele E. Eddy, RPR, CRR, CLR

February 22, 2016

9:04 a.m.

Deposition of STEPHEN G. DAVIES, D.PHIL., held at the offices of Finnegan Henderson, 901 New York Avenue, Northwest, Washington, D.C., pursuant to Notice before Michele E. Eddy, Nationally Certified Realtime Reporter and Notary Public of the District of Columbia, Commonwealth of Virginia and State of Maryland.

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Jason Levin, Videographer

EXAMINATION INDEX

E X H I B I T S

(Attached to the Transcript)

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STEPHEN G. DAVIES, D.PHIL.

THE VIDEOGRAPHER: We are going on the record at 9:04 a.m. on February 22nd, 2016. This is DVD number 1 of the video deposition of Stephen Davies in the matter of Senju Pharmaceutical Company, Limited, et al., versus Lupin, Limited, et al., filed in the United States District Court for the District of New Jersey, Case Number 1:14-cv-00667-(JBS)(KMW), consolidated cases.

This deposition is being held at the offices of Finnegan, located at 901 New York Avenue, Northwest, Washington, D.C.

My name is Jason Levin from the firm, The Little Reporting Company, with offices in New York, and I'm the videographer. The court reporter today is Michele Eddy, also from The Little Reporting Company.

Will counsel now please state their appearances for the record.

MS. RAPALINO: Emily Rapalino, of Goodwin Procter, on behalf of the Lupin defendants.

DR. MALIK: Jitendra Malik of the law

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firm of Alston & Bird. With me, though not in the room right now, will be James Abe, representing InnoPharma defendants in connection with the litigation only. Per my e-mail with Senju's counsel, we have an agreement that Dr. Davies will be produced separately in connection with the IPR.

MS. LEBEIS: Jessica Lebeis, of Finnegan, on behalf of plaintiffs Senju and Bausch & Lomb.

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STEPHEN G. DAVIES, D.PHIL.,

having been duly sworn, testified as follows:

EXAMINATION BY COUNSEL FOR THE LUPIN DEFENDANTS

BY MS. RAPALINO:

Q Good morning, Dr. Davies.

A Good morning.

Q You've been deposed before, correct?

A I have, yes.

Q So without belaboring it, I would just like to go over the basic rules for the deposition. You understand that I'll be asking you questions today, and you'll be giving me answers and that your answers are under oath as

if you were testifying in court?

A Yes.

Q We can take breaks from time to time. I would ask that if you need a break, you ask for one but not while a question is pending. Is that fair?

A Okay.

Q We should try not to talk over each other. We have a court reporter trying to take down what we say so we should just let each other finish before we begin to respond or ask the next question. Okay?

A Okay.

Q If you don't understand one of my questions, please ask me to clarify. If you answer a question, I'll assume that you've understood it. Is that fair?

A Okay.

Q Is there any reason that you can't testify completely and truthfully today?

A No.

Q How did you prepare for today's deposition?

A I read through my reports and the

references therein.

Q Did you review any materials besides the reports and the materials cited in those reports?

A Not that I recall.

Q Did you meet with anybody in preparation for your deposition?

A I met with Ms. Lebeis.

Q Did you meet with anybody else?

A I said hello to a couple of people, but that was all.

Q For how long did you meet with Ms. Lebeis in preparation for your deposition?

A I've been here for two days. We met for about roughly six hours each day, but both days a considerable amount of time was taken up on another matter.

Q Okay. And did you speak with anybody else in preparation for your deposition?

A No.

Q Did you review any deposition testimony in this case?

A Yes. So I've read the deposition testimony of Lawrence.

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Q Have you reviewed any other deposition testimony in this case?

A Not that I recall, no.

Q Did you review any testimony in the parallel IPR proceedings?

A What's IPR?

Q Inter partes review.

A No, I don't believe so.

Q How many times have you -- have you spoken to any experts in this case?

A No, I haven't, no.

Q How many times have you testified at deposition?

A I don't recall. A number.

Q Has it been more than 100?

A No.

Q More than 50?

A Oh, it's more than ten, but I don't know the exact number.

Q Every time you've testified as a deposition, has that been as an expert witness?

A I believe so, yes.

Q Have you testified at trial?

A I have, yes.

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Q How many times?

A Between five and ten.

Q Apart from those instances where you've testified at deposition or at trial, have there been other cases where you've submitted an expert report?

A There have, yes.

Q In how many cases have you submitted an expert report?

A I don't recall. A number of cases.

Q About how many, would you say?

A Around ten.

MS. RAPALINO: Let's mark as Davies Exhibit 1 the Responsive Expert Report of Stephen G. Davies, D.Phil.

(Exhibit 1 was marked for identification and attached to the deposition transcript.)

BY MS. RAPALINO:

Q Is this a copy of the first expert report you submitted in this case?

A Yes, it is.

Q If you would turn to page 41 of Exhibit 1.

A Yes.

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Q Is that your signature in the middle of the page?

A It is, yes.

Q And you signed this expert report on January 29th of 2016?

A That's correct, yes.

Q Does this report accurately summarize your opinions in this case?

A From the material considered at that time, yes.

Q Are there any corrections you want to make to the report as you sit here today?

A I don't believe so, no.

Q Staying on page 41 of the expert report, in paragraph 84, you list the cases in which you have testified as an expert in the last four years. Do you see that?

A That's correct, yes.

Q Were all of these cases listed in paragraph 84 pharmaceutical patent cases?

A Yes, they were.

Q Let's talk about the first case, Sunovion Pharmaceuticals, Inc., v. Teva Pharmaceuticals USA. Did you testify on behalf

of the patentee in that case?

A I did, yes.

Q And in the remaining cases, the remaining five cases listed in paragraph 84, did you also testify on behalf of the patentee in those cases?

A Depends on what you mean by "on behalf of." I was retained by the patentee, yes, but I testified to help the court rather than on behalf of the patentee.

Q In each of those cases, did you testify that the patent was valid and infringed?

A Well, I gave evidence about what was involved in those particular cases. I'm not sure I ever stated the words you used.

Q Okay. Let's -- let's go one by one. So in the Sunovion Pharmaceuticals case you said that you were retained by the Sunovion, the patentee; is that right?

A That's correct, yes.

Q What was the subject of your opinions in that case?

A It was mostly about chemistry, and

there was some obviousness arguments, as far as I remember.

Q And did you testify in support or against those obviousness arguments?

MS. LEBEIS: Objection, vague and ambiguous.

A I testified that it was nonobvious.

Q Do you remember what law firm retained you in the Sunovion case?

A I think it was Paul Hastings.

Q Now, you mentioned that the subject of your testimony in the Sunovion case was chemistry. Can you be any more specific than that? What was the subject of the chemistry about which you testified?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A I don't remember in each of these cases. I haven't reviewed my reports in those.

Q Let's go on to the second case, AstraZeneca AB, et al., versus Ranbaxy Pharmaceuticals, Inc. In that case, were you retained by the patentee AstraZeneca?

A I was, yes.

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Q What was the general subject of your testimony in that case?

A Mostly chemistry.

Q Were the issues in that case related to synthetic chemistry?

A I don't recall precisely, but it would have been synthetic chemistry, enantiomer separation, medicinal chemistry.

Q In the AstraZeneca AB, et al., versus Hanmi USA, Inc., case, the third case listed in paragraph 84, were you also retained by the patentee, AstraZeneca?

A I was, yes.

Q What was the general subject of your testimony in that case?

A Chemistry.

Q Was it synthetic chemistry in that case?

A The answer is the same as last time. Synthetic chemistry, resolution chemistry, and medicinal chemistry.

Q Just so we're on the same page, how do you define medicinal chemistry?

A Anything involved in the search for

novel pharmaceutical compounds that are of therapy to use.

Q Then in the fourth case, AstraZeneca AB, et al., versus Dr. Reddy's Laboratories, Inc., were you also retained by the patentee, AstraZeneca?

A Yes.

Q What was the general subject of your testimony in that case?

A Chemistry.

Q Would it be those same categories of chemistry, synthetic chemistry, enantiomer chemistry, and medicinal chemistry?

A Yes.

Q And then in the fifth case, GlaxoSmithKline, LLC, versus Banner Pharmacaps, Inc., were you retained by the patentee GlaxoSmithKline in that case?

A I was, yes.

Q What was the general subject of your testimony in that case?

A Chemistry.

Q And, again, would it be those same three categories of synthetic chemistry,

enantiomer chemistry, and medicinal chemistry?

A In broad. Other topics may have came up, but that's the broad outline.

Q What were the other topics that might have come up?

A I don't recall.

Q So sitting here today, the ones you recall are synthetic chemistry, enantiomer chemistry, and medicinal chemistry; is that right?

A That's true. I haven't had time to review exactly what I did in each of these cases. In fact, most of the cases, I have nothing to review to look to remind myself.

Q Then in the last case that you list here, Gilead Sciences, Inc., versus Teva Pharmaceuticals USA, Inc., were you retained by the patentee Gilead Sciences, Inc., in that case?

A I was, yes.

Q What was the general subject of your testimony in that case?

A Chemistry.

Q And was it the same three categories

we've been talking about, synthetic chemistry, enantiomer chemistry, and medicinal chemistry?

MS. LEBEIS: Objection to the extent it mischaracterizes the prior testimony.

A I don't recall. Certainly synthetic chemistry. I can't recall whether it was enantiomer chemistry. And it would have been medicinal chemistry.

Q Now, in each of these cases listed in paragraph 84, you testified on behalf of the brand pharmaceutical company, right?

MS. LEBEIS: Objection, asked and answered.

A I was retained by the patentee in each of cases but testified on behalf -- to help the court.

Q Were you being paid by the party that retained you in each of those cases?

A I was, yes.

Q Were you compensated by the court in connection --

A Actually, I don't -- that may not be true. Some of the cases I may have been paid by the lawyers. In fact, all the cases I was

paid by the lawyers.

Q Okay. So you were paid by the lawyers representing the brand pharmaceutical company in each of those cases?

A That's correct.

Q And you weren't paid by the court in any of those cases --

A No.

Q -- for your testimony?

A No.

Q Have you ever offered testimony that a patent is obvious?

MS. LEBEIS: Objection to the extent it calls for a legal conclusion.

A I don't think I've ever been involved in a case where I have come to that conclusion.

Q So you've never testified that a patent is obvious?

A I don't believe so.

Q Have you ever testified that a patent was not infringed?

A I don't believe so.

Q Besides these six cases listed in paragraph 84 of your -- of Exhibit 1, how many

other cases have you offered testimony as an expert?

A I think I answered that previously. So it's a number of cases. I forget how many.

Q I think we said it was about ten. Is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony. Asked and answered.

A Repeat the question.

Q In about how many cases, besides the six listed in paragraph 84 of your expert report, have you offered testimony as an expert?

A Well, I've been in -- I've written reports, as I think I said previously, in a number of other cases. So it's certainly more than ten.

Q So apart from the six cases listed in paragraph 84, are there other cases in which you've testified as an expert prior to the last four years?

A Yes.

Q About how many of those cases have

you testified in?

A I don't recall, but maybe another ten.

Q So we're talking about about 16 cases total that you've offered testimony as an expert; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A Testimony or reports.

Q In each of those approximately 16 cases in which you've offered an expert report or testified, has the subject of your testimony been synthetic chemistry, enantiomer chemistry, or medicinal chemistry?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony. Asked and answered.

A It's been chemistry in general, which has included those, but other things have come up that, if it's within my expertise, I've given testimony about.

Q Can you recall what other subjects in chemistry have come up, apart from enantiomer chemistry, synthetic chemistry, and medicinal

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chemistry, that you've testified about before?

MS. LEBEIS: Objection, asked and answered.

A I don't recall. I'm a chemist so anything that comes up in the general field of chemistry in its broadest sense, I may well have testified about.

Q Now, the issue of enantiomers or stereochemistry is not the subject of your opinions in this case, correct?

A It's not, no.

Q And the subject of synthetic chemistry is not the subject of your opinions in this case, correct?

A That's correct.

Q And medicinal chemistry, as you've defined it, is not the subject of your opinions in this case, correct?

A Well, medicinal chemistry is anything to do with particularly therapeutically useful compounds.

Q And you haven't testified in this case or you haven't offered an opinion in this case about the search for novel pharmaceutical

compounds that are of therapeutic use, right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A I would have to check through to see if that's true. I don't recall that I did, but ...

Q So sitting here right now, you don't recall an opinion you've offered about the search for novel pharmaceutical compounds that are of therapeutic use in this case, right?

A I don't believe I did, no. As I've said, I'm a chemist in the broadest sense.

Q If you turn to Appendix B of your expert report, Exhibit 1, this is a copy of your curriculum vitae; is that right?

A That's correct, yes.

Q Is it up-to-date?

A It was up-to-date on the date at which I signed it -- I signed the report, which is the 29th of January.

Q Are there -- is there anything you would like to update that's happened over the last three weeks since you've signed the report?

A Not that I -- no.

Q Now, you received a BA in chemistry in 1973; is that right?

A That's correct.

Q Did you do any research during your studies for that degree?

A The BA in Oxford is a four-year course. The first three years are mostly theoretical, and the fourth year is an entire research project.

Q What was the subject of that year of research?

A The synthesis and chemical properties of benzene oxide and related compounds.

Q Did you do any work on pharmaceutical formulations during your research for your BA degree?

A I did not, no.

Q Did you do any research on compounds for ophthalmic use during your research for your BA degree?

A I did not, no.

Q Did you do any research on nonsteroidal anti-inflammatory drug compounds

during your research for your BA degree?

A I did not, no.

Q You got your D.Phil. degree in chemistry in 1975; is that right?

A That's correct, yes.

Q Did you do any research during the time you were studying for that degree?

A I did, yes.

Q What was the subject of that degree -- of that research?

A The synthesis and properties of a broad class of molecules containing the functional group epoxide.

Q Did you do any work on pharmaceutical formulations during your research for your D.Phil. degree?

A I did not, no.

Q Did you do any research on compounds for ophthalmic use during your research for your D.Phil. degree?

A I did not, no.

Q Did you do any research on nonsteroidal anti-inflammatory drug compounds during your research for your D.Phil. degree?

A I did not, no.

Q You said that your area of research during your studies for your D.Phil. degree was on a broad class of compounds containing the functional group epoxides; is that right?

A That's correct.

Q What does it -- what do you mean by "a broad class of compounds"?

A Well, there are many compounds of very different types that contain the epoxide functional group.

Q And what properties of that class of compounds were you studying?

A Their physical properties and their chemical properties.

Q Did you identify any physical or chemical properties shared by that class of compounds?

MS. LEBEIS: Objection. No foundation. Vague and ambiguous.

A One thing we discovered was that you can predict the substitution pattern of the epoxide from the carbon 13 NMR chemical shift.

Q I think my question was a little

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different. Did you identify any physical properties shared by compounds within that class that you were studying?

MS. LEBEIS: Same objections.

A Well, what we found was that each molecule that we made behaved differently. So, for example, the NMR -- the reason we could identify them is they all had different NMR characteristics, and their chemical reactions were different.

Q Did you find that any -- there were any properties shared amongst the molecules within the class?

MS. LEBEIS: Same objections.

A I don't think we came to that conclusion, no.

Q What makes you call those compounds a class when they have no shared properties?

A They all have the same functional group.

Q Can compounds within the same class share common chemical reactions?

MS. LEBEIS: Objection, vague and ambiguous. No foundation.

A They can, yes.

Q Why is a particular moiety in a compound called a functional group?

MS. LEBEIS: Same objections.

A Because it has -- a functional group is a part of a molecule that has reactivity.

Q And do the same functional groups on different compounds have -- sometimes have similar reactivity?

MS. LEBEIS: Same objections.

A They can have a particular type of reactivity, but you -- you have to look at a whole molecule in order to determine the precise reactivity that you might expect.

Q You said "the precise reactivity that you might expect." Why did you qualify it that way?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A I could have said general reactivity. It's just at what level you want to try and predict a particular type of reactivity.

Q Well, general and precise are two different things, right?

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MS. LEBEIS: Objection, vague and ambiguous.

A Depends on which way you're using it.

Q Let's move on in your CV. So in 1980 you got a D.Sc. degree; is that right?

A That's correct, yes.

Q Did you do any research in connection with that degree?

A It's a research degree on chemistry of epoxides.

Q Did you do any work on pharmaceutical formulations during that research?

A I did not, no.

Q Did you do any work on compounds for ophthalmic use during that research for your D.Sc. degree?

A I did not, no.

Q Did you do any research on nonsteroidal anti-inflammatory drug compounds during your research for the D.Sc. degree?

A I did not, no.

Q What further work did you do on epoxides during your research for your D.Sc. degree?

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MS. LEBEIS: Objection, no foundation.

A Essentially very little. So the D.Sc., I moved to France, and in the French system you have to have a French degree. So they allowed me to put in the research I published on epoxides during my U.K. degree for consideration of a D.Sc. in the University of Paris, which they awarded me.

Q What year did you move to France?

A 1977.

Q Did you do research during those three years from 1977 to 1980?

A I did, yes.

Q What was the subject of that research?

A It was a mixture of things, including we were looking at the reactions of a whole range of natural products, including steroids, alkaloids, carbohydrates with transition metal reactants, and then we were looking at general organometallic reactivity as well.

Q Did any of that research relate to work on pharmaceutical formulations?

A No.

Q Did any of that work relate to work on compounds for ophthalmic use?

A It did not, no.

Q If I refer to nonsteroidal anti-inflammatory drugs as NSAIDs, will you understand what I mean?

A Yes.

Q Did you do any work during that time period on NSAIDs?

A Not that I recall.

Q Your CV is not -- the pages aren't numbered, but if you turn to what is the third page of your CV, you list a number of companies that you founded or had a directorship in those companies; is that right?

A I actually founded all of them.

Q Okay. Are all of those companies still in existence?

A They are not, no.

Q How many of them are still in existence?

A Well, maybe I better qualify "in existence." Some of them have been sold or

taken over by other companies, and, therefore, the company under the name here is not in existence.

Q Okay. How many of them are still in existence as an independent company?

A SciInk Limited, Summit Therapeutics, Oxstem Limited.

Q Are any others still in existence as independent companies?

A I don't believe so.

Q Did you have a role in any of these companies apart from founding them?

A Well, often they'd be founded on my research work. And then for some or all of the time, I would be involved in the research that was going on in those companies, and I would be on the board as the director of the company or was chairman occasionally.

Q About -- over the years, since 1992 when you founded your first company, about how much of your time have you devoted to work for these companies?

A I have no idea. Whatever work needs to be done gets done at the time. So I don't

keep track.

Q On a percentage basis, do you know what percent of your time you spent on work for these companies as compared to your academic work?

MS. LEBEIS: Objection.

A No, I don't.

MS. LEBEIS: Asked and answered.

Q Is it fair to say that you've spent most of your career in academia?

A I have had an academic position for most of my career, yes.

Q If we go to paragraph 5 of Exhibit 1, your first expert report, at page 2.

A Okay.

Q You describe your research interests in this paragraph; is that right?

A Some of them.

Q And the research interests that you chose to include in this report are "synthetic organic chemistry and medicinal chemistry and, in particular, the preparation of enantiomerically pure organic compounds, including the asymmetric and stereoselective

synthesis of enantiomerically pure organic compounds for potential therapeutic use." Is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes the document. Argumentative.

A That's what I've written in that paragraph, yes. I'm a general chemist. My research interests are the whole of chemistry. These are what I've particularly spent a lot of time doing research in over the years in my academic career.

Q And I think you testified earlier that none of your opinions in this case relate to synthetic chemistry, right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A Well, my opinions are written down. I don't believe there's synthetic chemistry in there.

Q And none of your opinions in this case relate to the search for novel pharmaceutical compounds that are of therapeutic use, right?

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A I don't believe they do. As I said, my research interests are the whole of chemistry, really.

Q And none of your opinions in this case relate to the preparation of enantiomerically pure organic compounds, right?

A They don't, no.

Q And none of your opinions in this case relate to the asymmetric and stereoselective synthesis of enantiomerically pure organic compounds for potential therapeutic use, right?

A They don't, no.

Q You're a professor of chemistry; is that right?

A I am, yes.

Q You don't have an academic appointment in pharmacy; is that right?

A I don't, no.

Q And you don't have training in pharmacy; is that right?

A I don't, no.

Q You're not a medical doctor?

A I'm not a medical doctor, no.

Q You're not an ophthalmologist?

A I'm not an ophthalmologist.

Q You haven't prescribed ophthalmic products?

A I think that would be illegal.

Q So you haven't done that?

A So I have not done that.

Q Over the course of your career, have you ever done research on compounds for ophthalmic use?

A Yes.

Q What compounds have you researched?

A I would have to look at my list of publications.

Q Feel free to do that. That's at Appendix C to your expert report.

A (Document review.)

There we go. So there are two compounds I've looked at. So if we look at reference 219, in 1993 it was published, this is related to an asymmetric synthesis of the tropinates, so, in particular, (S)-(-)-methyl tropinate. These are compounds that are used to dilate the pupil of the eye. And then the

name of the compound I couldn't remember is pilocarpine.

Q What reference is that?

A Pilocarpine, which is reference 455. This is in 2009, but the actual work was done about 15 years prior to that, where we have "A practical and scalable total synthesis of the jaborandi alkaloid (+)-pilocarpine." This is a very common compound used to dilate the pupil of the eye or for other aspects of eye surgery.

Q So you've published over 560 publications; is that right?

A That's correct, yes.

Q Of those publications, two relate to compounds for ophthalmic use?

A That's roughly correct, yes.

Q Were there any others that you didn't identify?

A Not that I recall, but there may have been precursor ones to these two, which I don't remember.

Q So sitting here today, you remember two out of the 560-plus publications that you've authored that relate to ophthalmic

compounds?

A That's correct, yes.

Q And let's look at the publication number 219 in your CV. That relates -- that publication relates to a synthesis of that tropinate compound; is that right?

A Remind me of the number, sorry.

Q 219, two one nine.

A That's correct, yes.

Q So your work on the tropinate compound related to methods of making it; is that right?

A That's correct.

Q And you didn't do any work on formulating that compound into a pharmaceutical product; is that right?

A That's correct.

Q Let's look at --

A Sorry, because it was already a pharmaceutical product.

Q It had already been on the market before you did your research on synthetic methods?

A Yes.

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Q And you were not involved in formulating it into that pharmaceutical product that was already on the market?

A No, I was not.

Q Then if we look at the other reference that you identified, number 455.

A Yes.

Q This was a publication about -- again, about a synthesis of the pilocarpine compound; is that right?

A That's correct, yes.

Q And your work on pilocarpine related to, again, methods of making it; is that right?

A That's correct, yes.

Q You weren't involved in any work to formulate pilocarpine into a pharmaceutical formulation; is that right?

A It was already on the market.

Q And you weren't involved in the pharmaceutical formulation that was on the market; is that right?

A I was not, no.

Q And you didn't do any work to formulate pilocarpine into a pharmaceutical

product?

A I did not, no.

Q Both of those ophthalmic compounds that you worked on syntheses for, those -- you said they were both used to dilate pupils; is that right?

A That's what I remember. I think pilocarpine has other uses.

Q You didn't study the uses of those ophthalmic compounds, did you?

A I did not, no.

Q Neither of those compounds was an NSAID compound; is that correct?

A That is correct, yes.

Q Over the course of your career, have you done any research on NSAID compounds?

A Not that I recall.

Q You've never published a paper about an NSAID compound?

A Not that I recall.

Q None of your publications relates to formulation -- pharmaceutical formulation work; is that right?

A That is correct.

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Q None of your publications relates to challenges you faced in formulating any pharmaceutical product?

MS. LEBEIS: Objection, vague.

A They don't relate to formulations, so no.

Q And none of the -- none of your publications relates to any challenges you faced in formulating an ophthalmic drug?

MS. LEBEIS: Objection, asked and answered.

A That's a subset of the previous answer so the answer is no.

Q And none of the public -- none of your publications relates to challenges you faced in formulating an NSAID compound into a pharmaceutical?

A That's correct.

Q Have you taught students over the course of your career?

A Sorry, could you repeat the question?

Q Have you taught students over the course of your career?

A All the time.

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Q What subjects have you taught?

A The whole of organic chemistry, the -- and that would be on a tutorial basis. And then I've lectured -- given lecture courses on heterocyclic chemistry, natural product chemistry, pharmaceutical chemistry, transition metal chemistry, heteroatom chemistry. Mechanistic chemistry, if I haven't said that one already. Many courses. Introductory organic chemistry. Revision chemistry.

Q Have you ever taught a class in pharmaceutical formulation?

A I have not, no.

Q And I think I may have asked this already, and I apologize if I did, but have you ever formulated an ophthalmic pharmaceutical product?

A No.

Q Have you ever formulated an NSAID pharmaceutical product?

A No.

Q Have you ever measured the properties of any NSAID compounds?

MS. LEBEIS: Objection, vague and

ambiguous.

A Not that I recall.

Q You've reviewed the patents-in-suit in this case; is that right?

A I've looked at it, at them. Yes, I've looked at them.

Q What is the field to which the patents-in-suit are directed?

MS. LEBEIS: Objection. Vague and ambiguous. Calls for a legal conclusion.

A I don't recall the precise wording, but it may be in my report.

Q I don't see it in your report, but -- so if it's there, maybe you can point me to it, but I'm just asking you, as a general matter, as to what subject the patents-in-suit are directed.

A I wasn't asked to consider the details of the patents-in-suit.

Q You offered an opinion on who the person of ordinary skill in the art is; is that right?

A That's correct.

Q And you understand that "the person

of ordinary skill in the art," that phrase includes the term "the art"?

A Yes.

Q So what is the art to which your person of ordinary skill in the art is directed, in other words, what is the art of the patents-in-suit?

A Well, I think I list that in my paragraph 12, where "The '431, '290, '131, and '813 patents are directed, generally speaking, to aqueous liquid formulations of nonsteroidal anti-inflammatory drug NSAID 2-amino-3-(4-bromobenzoyl)phenylacetic acid, bromfenac, or pharmacologically acceptable salt or hydrate thereof, and the nonionic surfactant tyloxapol for ophthalmic administration."

Q So, in your view, that's the field of the patents; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes the prior testimony.

A I haven't been asked to review or analyze the patent in detail.

Q Okay. But, again, you say in paragraph 12 that the patents are directed,

generally speaking, to that field that you just recited in your previous answer; is that right?

A That's what I've written in paragraph 12, yes.

Q And I think we've established already that you haven't done work on pharmaceutical formulations; is that right?

A I have not, no.

Q And that includes not having done work on aqueous liquid formulations; is that right?

A I haven't, no.

Q And you haven't -- you also said that you haven't done any work on nonsteroidal anti-inflammatory drugs or NSAIDs; is that right?

A Not that I recall.

Q Have you ever done any work on the surfactant tyloxapol?

A I have not, no.

Q And I think you said that you are not an ophthalmologist and have not prescribed ophthalmic products for ophthalmic administration; is that right?

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A That's correct.

Q Did you ever consider whether you didn't have the requisite expertise to address the field of the patents?

MS. LEBEIS: Objection, argumentative. Calls for a legal conclusion.

A I don't believe I'm addressing the field of the patent. I'm responding to the reports of Dr. Lawrence and Dr. Heathcock.

Q And you're not responding from the perspective of the field of the patents in doing so?

MS. LEBEIS: Objection, argumentative. Calls for a legal conclusion.

A I'm responding to the statements they made in their reports.

Q And you're responding to those statements as a chemist; is that right?

A I'm responding to them on my general expertise.

Q And you haven't --

A And --

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Q You haven't formed your opinions from the perspective of somebody in the field of these patents --

MS. LEBEIS: Objection.

Q -- is that right?

MS. LEBEIS: Mischaracterizes prior testimony, argumentative.

A I'm responding to -- my report is responding to the statements made in the reports of Dr. Lawrence and Dr. Heathcock.

Q I understand that. So in making those responses to the statements of Dr. Lawrence and Dr. Heathcock, you're not doing so from the perspective of somebody in the field of the patents-in-suit; is that right?

MS. LEBEIS: Objection --

A I'm --

MS. LEBEIS: -- to the extent it mischaracterizes prior testimony, argumentative.

A I'm doing it as a -- from the point of view of a person of ordinary skill in the art responding to the statements made in the

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reports of Dr. Lawrence and Dr. Heathcock.

Q What art are we talking about when you say "a person of ordinary skill in the art"?

A As defined in paragraph 11. So somebody who has at least a bachelor's degree in the field of pharmaceutical chemistry, chemistry, or related discipline, all the art covered by those topics.

Q And, in your view, a person of ordinary skill in the art need not have any experience with pharmaceutical formulation?

MS. LEBEIS: Objection, argumentative, and to the extent it mischaracterizes prior testimony.

A As I said, I'm responding to the statements in the reports of Dr. Lawrence and Dr. Heathcock.

Q That wasn't my question. My question was, in your view, the person of ordinary skill in the art need not have any experience with pharmaceutical formulation. Is that your testimony?

MS. LEBEIS: Same objections.

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A Well, the -- that is covered by the definition of a person of ordinary skill. I've used this skill -- the skills I have to respond to the points made by Dr. Lawrence and Dr. Heathcock.

Q Does a person of ordinary skill in the art, in your view, need to have pharmaceutical formulation experience in connection with these patents?

MS. LEBEIS: Objection, vague and ambiguous.

A I haven't reviewed the patents in detail.

Q So you don't know one way or the other?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony, argumentative.

A My report is based on my responses to statements made by Drs. Lawrence and Heathcock and the points raised therein.

Q So you don't know one way or another whether the person of ordinary skill in the art, in connection with these patents, would

need to have pharmaceutical formulation experience?

MS. LEBEIS: Objection. Asked and answered, argumentative, and mischaracterizes prior testimony.

A I haven't reviewed the patents in detail.

Q So is that a yes, you don't know one way or another?

MS. LEBEIS: Objection. Same objections.

A I haven't considered that question.

Q So you haven't considered the question of whether a person of ordinary skill in the art, in connection with these patents, would need to have pharmaceutical formulation experience; is that your testimony?

MS. LEBEIS: Objection to the extent it mischaracterizes the prior testimony.

A I haven't reviewed -- I wasn't asked to review the patents in detail, so I won't have considered that.

Q Now, you were asked to provide a definition of the person of ordinary skill in

the art, right?

A Yes.

Q And in connection with doing that, you did not consider the question of whether the person of ordinary skill in the art would need to have pharmaceutical formulation experience; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A I was asked to respond to the points made by Drs. Lawrence and Heathcock and not review the patents in detail. I was not asked to do that.

Q So in forming your opinion about who the person of ordinary skill in the art was, you didn't consider the patents in detail?

MS. LEBEIS: Objection.

Q Is that your testimony?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A I wasn't asked to review the patents in detail.

Q Again, just -- I'm trying to get an answer to my question. My question is, in

forming your opinion about who the person of ordinary skill in the art was, you didn't consider the patents in detail; is that right?

MS. LEBEIS: Same objections. Asked and answered.

A I looked at the patents as an overview, but I didn't consider -- wasn't asked to consider in detail the patents, the content of the patents.

Q And in looking at the patents as an overview, in forming your opinion about the person of ordinary skill in the art, you didn't consider whether or not that person of skill in the art needed to have pharmaceutical formulation experience; is that right?

MS. LEBEIS: Same objections. Asked and answered.

A I was looking at it from the point of view of responding to the reports put in by Dr. Lawrence and Dr. Heathcock.

Q And in doing so, you didn't consider whether or not the person of ordinary skill in the art needed to have pharmaceutical formulation experience; is that right?

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MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony. Argumentative. Asked and answered.

A I've looked at the -- in an overview sense of the patents, looked at the reports of Dr. Lawrence, and formed my opinions on the basis of those reports and the patent overview.

Q And, in your opinion, would the person of ordinary skill in the art of these patents need to have pharmaceutical formulation experience?

MS. LEBEIS: Objection, asked and answered.

A The same answer. I was looking at the reports of Lawrence and Heathcock and not looking in detail at the patents.

Q I'm not asking about what you looked at. I'm just asking a yes or no question. In forming your opinion about who the person of ordinary skill in the art was, did you consider whether or not that person needed to have pharmaceutical formulation experience?

MS. LEBEIS: Objection. Asked and answered.

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A I wasn't asked to consider that point.

Q So you didn't consider it?

MS. LEBEIS: Objection, asked and answered.

A I've explained what I considered, which is an overview of the patents, and my report is a response to the reports of Dr. Lawrence and Dr. Heathcock.

Q And in considering all of that, you concluded that the person of ordinary skill in the art need not have pharmaceutical formulation experience; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony. I believe he's answered the question.

A I didn't offer an opinion on that.

MS. LEBEIS: We've been going over an hour. Is it okay to take a break now?

Q Do you need a break, Dr. Davies?

A A short one.

MS. RAPALINO: Sure.

THE VIDEOGRAPHER: We're going off the record at 10:11 a.m.

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(A brief recess was taken.)

THE VIDEOGRAPHER: We're going back on the record at 10:21 a.m. This is the start of disc number 2 in the deposition of Stephen Davies.

BY MS. RAPALINO:

Q You testified earlier that you've not done work on pharmaceutical formulation; is that right?

A I personally haven't, no.

Q And so you don't have experience in how pharmaceutical formulators select ingredients for pharmaceutical formulations?

MS. LEBEIS: Objection, vague and ambiguous.

A I've been part of a team that has formulated pharmaceuticals, but I haven't personally formulated a pharmaceutical.

Q You have never been involved in the selection of ingredients for a pharmaceutical formulation?

A I have not, no.

Q And you've never been involved in considering the available excipients for an

ophthalmic pharmaceutical formulation; is that right?

A I have not, no.

Q Have you been involved in -- as part of a team in formulating an ophthalmic formulation?

A No.

Q You haven't had any experience in the process that pharmaceutical formulators undertake to make a new pharmaceutical formulation; is that right?

MS. LEBEIS: Objection, vague and ambiguous. Objection to the form.

A I've been involved in a team that has formulated pharmaceuticals.

Q But you've never been involved in a team that's formulated an ophthalmic pharmaceutical formulation; is that right?

A That's correct.

Q So you don't have experience with the process that pharmaceutical formulators undertake to formulate an ophthalmic formulation; is that right?

MS. LEBEIS: Objection, vague and

ambiguous. Objection to the form.

A I haven't done it myself if that's what the question is.

Q And you haven't -- you said you haven't been involved with a team who's been -- who's undertaken the process to formulate an ophthalmic formulation, correct?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A I've been involved in a team that formulates a pharmaceutical -- has formulated a pharmaceutical, but not for an ophthalmic use.

Q Okay. I think my question probably wasn't clear. Let me ask again.

You haven't been involved in a team during the process of formulating an ophthalmic pharmaceutical; is that right?

MS. LEBEIS: Objection, vague and ambiguous.

A Can you repeat the question, please.

Q Sure. Let me withdraw that question and ask a new one.

You haven't been involved, as a member of a team -- even as a member of a team,

in formulating an ophthalmic pharmaceutical; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony. Vague and ambiguous.

A I've not been involved in a team that has formulated an ophthalmic pharmaceutical.

Q When you say that you've been involved in a team that's formulated a pharmaceutical product, what was your role on that team?

A I was a medicinal -- I was a medicinal chemist -- one of the medicinal chemists involved with people of other expertise who were trying to formulate a compound one of my companies had discovered.

Q What was your role as the medicinal chemist in the pharmaceutical formulation process?

A Can you repeat the question?

Q What was your role as the medicinal chemist in the pharmaceutical formulation process?

MS. LEBEIS: Objection to the extent

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it mischaracterizes prior testimony.

A Part of it was describing the solubility properties of the molecules that we discovered.

Q You had no role in that process in selecting the inactive ingredients in the formulation; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony. Vague and ambiguous.

A Well, I was part of the team that was making the overall decisions.

Q Did you personally make any decisions about selection of inactive ingredients in the formulation?

A Of an active ingredient, yes.

Q I think I said "of inactive ingredients in the formulation."

A Well, things were discussed, and, as a team, we came to a conclusion.

Q What was the compound, the active ingredient that you were formulating into a pharmaceutical formulation?

A It's called C1100, and it's a

compound from Summit Therapeutics. It's a company I set up for treating Duchenne muscular dystrophy.

Q What kind of pharmaceutical formulation was that?

MS. LEBEIS: Objection, vague and ambiguous.

A I don't understand what you're asking me.

Q What was the route of administration for the pharmaceutical formulation that you developed for C1100?

A Oral.

Q Was it a tablet formulation?

A It was -- it's a solutional suspension.

Q Solutions and suspensions are two different things, right?

A That's correct, yes.

Q They have different properties?

A They do have different properties, yes.

Q Have you ever worked with sodium sulfide?

A Every chemist has.

Q In what context?

MS. LEBEIS: Objection to the form of the question.

A It's a reducing agent.

Q Have you worked with it in the context of chemical syntheses?

A Yes.

Q Are there any other contexts in which you've used sodium sulfide?

A Not that I recall.

Q Have you ever worked with polyvinylpyrrolidone?

A No.

Q Have you ever worked with benzalkonium chloride?

A I don't recall. So we've done work on phase-transfer catalysis, which uses quaternary ammonium salts, of which that may have been one. I don't recall.

Q Benzalkonium chloride is a quaternary ammonium salt; is that right?

A It is, yes.

Q And you said you've worked with the

class of quaternary ammonium salts, but you can't remember specifically whether you've worked with benzalkonium chloride; is that fair?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A Well, we've looked at phase-transfer catalysis using quaternary ammonium salts. I don't recall whether that was one of them. May well have been.

Q And you've used many different quaternary ammonium salts in phase-transfer catalysis; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A We have used different quaternary ammonium salts, yes.

Q You've used different quaternary ammonium salts for the same purpose of phase-transfer catalysis; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A Yes, that's true.

Q You've never used benzalkonium

chloride in the context of pharmaceutical formulation; is that right?

A I have not, no.

Q And you have never used any other quaternary ammonium compounds or salts in the context of pharmaceutical formulation?

A I have not, no.

Q You've never used sodium sulfide in the context of pharmaceutical formulation; is that right?

A I have not, no.

Q Have you ever worked with polysorbate 80?

MS. LEBEIS: Objection to the form of the question.

A I don't believe so.

Q Turn, please, if you would, in Exhibit 1, Davies Exhibit 1, to paragraph 10 of your expert report.

A I've got 10. Yes.

Q Do you see three lines down in paragraph 10, you state, "Although I respond below, as appropriate, to the statements, opinions, and conclusions of Dr. Lawrence

regarding these references, I do not concede that these references constitute 'prior art' to the patents-in-suit."

Do you see that?

A Yes.

Q I just want to make sure I understand that statement. You haven't undertaken an analysis in your expert report of whether the references Dr. Lawrence cites and relies upon are prior art; is that right?

MS. LEBEIS: Objection. Calls for a legal conclusion.

A You'll have to repeat the question.

MS. RAPALINO: Do you mind reading it back.

(Record read.)

A Well, I've explained my opinion of the references as we -- as I go through my report, which will have bearing on whether they're prior art or not.

Q Are there particular references that Dr. Lawrence cites or relies upon that you believe are not prior art?

MS. LEBEIS: Objection to the extent

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it calls for a legal conclusion.

THE WITNESS: You'll have to repeat that again.

(Record read.)

A Well, you can read in my -- I don't -- I'm not sure that -- of the references I cite, I'm not sure any of them are prior art.

Q I'm not asking about the references that you cite. I'm asking whether there are particular references that Dr. Lawrence cites or relies upon that you believe are not prior art.

MS. LEBEIS: Objection. Calls for a legal conclusion.

A Well, if I've cited them in my report and made comments to the effect that they're not prior art or that the science in it is not relevant, then I regard those as not prior art.

Q So if you haven't stated in your report that a reference is not prior art, then you're not disputing that it is prior art. Is that fair?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

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A I've not -- I've responded to a set of references in Dr. Lawrence's report in this, but I'm not making any -- I haven't formed an opinion on the other references.

Q The set of references in Dr. Lawrence's report that you respond to in your report, have you formed an opinion that those references are not prior art?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony. Calls for a legal conclusion.

A The opinions I've formed are listed in my report.

Q So if you haven't formed the opinion in your report that a reference is not prior art, then you aren't disputing that it is prior art; is that right?

MS. LEBEIS: Same objections.

A I don't think you come to that conclusion because I would think -- as you'll see for most of the statements I make, the conclusion we come to is that I don't think they are prior art.

Q Can you point me to a paragraph about

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a reference Dr. Lawrence relies on where you've concluded the reference is not prior art?

A I don't think I used those words, but you can see from what I'm talking about in the science that I don't think it's relevant and, therefore, not prior art.

Q In your view, if your opinion is that the science is not relevant, is it your view that that reference is not prior art?

MS. LEBEIS: Objection. Calls for a legal conclusion.

A I've just given my opinions of what I think about certain sections of Dr. Lawrence's and Dr. Heathcock reports.

Q What is your -- in your opinion, what does -- what constitutes prior art?

MS. LEBEIS: Objection. Calls for a legal conclusion. Asked and answered.

A I think prior art is a legal definition that is -- and I'm not -- I'm not the judge.

Q So you haven't formed an opinion, then, one way or another, on which references constitute prior art and which do not; is that

right?

A I've addressed in my report the opinions expressed by Dr. Lawrence and responded to them.

Q When you talked about the word -- the term "prior art" in paragraph 10, what did you mean by that?

MS. LEBEIS: Objection. Calls for a legal conclusion.

A I said I don't concede that these references constitute prior art. It's up to the court to decide what is prior art.

Q So you haven't made a conclusion one way or another on whether or not these references are prior art. Is that fair?

A I've given my view of what Dr. Lawrence's -- has stated in her report on the topics that I feel I should respond to.

Q And that did not include an analysis of whether or not those references constitute prior art as you used that term in paragraph 10; is that right?

MS. LEBEIS: Objection. Calls for a legal conclusion.

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A That's for the court to decide.

Q So you haven't undertaken an analysis of whether or not the references are prior art; is that right?

MS. LEBEIS: Objection. Asked and answered. Calls for a legal conclusion.

A You can see from my report what my opinions are about certain sections of what Dr. Lawrence put in her report. It's up to the court to decide what is prior art and what is not.

Q So because it's up to the court to make a decision on what constitutes prior art, you have not undertaken that analysis in your expert report?

A Well, my expert report is what it is. I've taken -- I've given my opinion of parts of science that Dr. Lawrence has put in her report. I've responded to that.

Q Can you point me to any paragraph in your expert report in which you undertake an analysis of whether a particular reference is or is not prior art?

MS. LEBEIS: Objection, asked and

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answered.

A I think it's for the court to decide what is prior art or not. I've laid out my opinions on the science in response to the report of Dr. Lawrence and Dr. Heathcock.

Q So sitting here today, you can't point me to any paragraph in your expert report in which you undertake an analysis of whether any particular reference is or is not prior art; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A I've given my opinion on some of the pieces of science that Dr. Lawrence has put in her report on what I think of the science. It's up to the court to decide then whether that's prior art or not.

Q So you haven't made that determination in your expert report about whether a reference is or is not prior art. Is that your testimony?

MS. LEBEIS: Objection, asked and answered.

A I've done an analysis of the science.

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It's up to the court to decide what is prior art and what is not.

Q You haven't concluded one way or another whether any particular reference is or is not prior art; is that right?

MS. LEBEIS: Objection, asked and answered.

A It's up to the court to decide. So I've -- my analysis is on whether the science -- what I think about the science and my analysis of the science.

Q Your analysis is not a determination of whether any reference is or is not prior art. Is that right?

MS. LEBEIS: Objection. Asked and answered. Calls for a legal conclusion.

A That is for the court to decide what is prior art or not.

Q Not for you to decide; is that right?

MS. LEBEIS: Objection, asked and answered. Argumentative.

A It's for the court to decide.

Q Again, I think -- I'm just asking for a direct answer to my question. Did you or did

you not undertake an analysis in your expert report about whether any particular reference is or is not prior art?

MS. LEBEIS: Objection. He's given an answer. It's asked and answered.

A My analysis is based on the science and what I think of the science, and I'm responding to Dr. Lawrence's report -- parts of Dr. Lawrence's report.

Q And there is no paragraph in your expert report where you make a determination whether any particular reference is or is not prior art. Is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony. Asked and answered.

A I don't recall. I've given you my answer. I'm doing an analysis of what Dr. Lawrence wrote in her report or some of the aspects of what she wrote in her report. It's up to the court to decide what's prior art and what isn't prior art.

Q And you are not going to offer any testimony to the court about whether a

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particular reference is or is not prior art; is that right?

MS. LEBEIS: Objection. Asked and answered. Calls for a legal conclusion.

THE WITNESS: Could you repeat the question.

(Record read.)

MS. LEBEIS: Same objections.

A I think I -- I think I should reserve the right to do so depending on what comes up.

Q So you understand that you're required to set forth the opinions about what you're going to testify in your expert report?

MS. LEBEIS: Objection. Calls for a legal conclusion.

A I've told you the basis on which I wrote the report, which is on the science -- some of the science topics that came up in Dr. Lawrence's report. I'm responding to that report.

Q To the extent you haven't offered -- made a determination in your expert report that a particular reference is or is not prior art, you will not testify to the court about whether

a particular reference is or is not prior art, right?

MS. LEBEIS: Objection. Calls for a legal conclusion.

A I don't think -- I don't know how to answer that.

Q Are there any opinions that are missing from your expert report that you formed in this case?

MS. LEBEIS: Objection, argumentative.

A I don't recall.

Q Let's turn to paragraph 18 of your expert report at page 7.

A Yes.

Q You point in this paragraph to structural differences between bromfenac and diclofenac; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes the document.

A What I say in paragraph 18 is that bromfenac and diclofenac have different base structures.

Q You would agree that both bromfenac

and diclofenac are phenylacetic acid derivatives, right?

A That's true, yes.

Q Both bromfenac and diclofenac contain a carboxylic acid moiety?

A Amongst other functional groups, yes.

Q They both contain a carboxylic acid moiety, right?

A Amongst other functional groups, yes.

Q I'm not asking about other functional groups. I'm just asking whether bromfenac and diclofenac both contain a carboxylic acid moiety.

MS. LEBEIS: Objection, asked and answered.

A They both do, amongst other functional groups.

Q Now, ketorolac, that's another compound upon which you give an opinion, right?

A Yes.

Q Ketorolac also contains a carboxylic acid moiety, right?

A Amongst other functional groups, it does, yes.

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Q Flurbiprofen is another compound on which you give an opinion; is that right?

A It is, yes.

Q Flurbiprofen also contains a carboxylic acid moiety, right?

A Amongst other functional groups.

Q Bromfenac, diclofenac, ketorolac, and flurbiprofen are all NSAIDs; is that right?

A Yes.

Q As members of the class of NSAID compounds, bromfenac, diclofenac, ketorolac, and flurbiprofen are all anti-inflammatory agents, right?

MS. LEBEIS: Objection, no foundation.

A I believe so, yes.

Q Each of those NSAIDs, bromfenac, diclofenac, ketorolac, and flurbiprofen exerts its anti-inflammatory action by inhibiting one or more of the cyclooxygenase, or COX, enzymes; is that right?

MS. LEBEIS: Objection, no foundation.

A I didn't do an analysis in detail of

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the active site that was being interactive with by each of these individually, some of them, certainly, that's true. I don't know whether it's true for all of them.

Q For rendering your opinions, you didn't consider the structural features of these compounds in relation to their mechanism of action biologically?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony. No foundation.

THE WITNESS: Can you repeat the question.

(Record read.)

A I didn't look at the active sites for each of -- that each of these was acting on in detail, no.

Q Bromfenac is anionic at the relevant pH for ophthalmic formulations, right?

MS. LEBEIS: Objection to the form of the question. Incomplete hypothetical.

THE WITNESS: Can you repeat the question, please.

(Record read.)

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A pH is around 7 to 9. It's essentially 100 percent ionized.

Q Diclofenac is also essentially 100 percent ionized at a pH of around 7 to 9; is that right?

A That is correct.

Q Ketorolac is essentially 100 percent ionized at a pH of around 7 to 9, correct?

A Yes.

Q And flurbiprofen is also essentially 100 percent ionized at a pH of around 7 to 9, correct?

A That is correct.

Q My original question talked about the relevant pH for ophthalmic formulations, and then you spoke of a pH of around 7 to 9. So is it your view that a pH of around 7 to 9 is the relevant pH for ophthalmic formulations?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A Well, they're essentially 100 percent ionized at anything above 5.

Q What is your understanding of the relevant pH for ophthalmic formulations?

A Somewhere between maybe 6 and 8.

Q Are you aware of any pharmaceutical formulations with a pH above 8?

A I may have seen one somewhere, but I don't recall where.

Q Each of the compounds, bromfenac, diclofenac, ketorolac, and flurbiprofen, is a weak acid, right?

A That's correct, yes.

Q The PKAs for each of those compounds is in the range of about 3.5 to 4.5?

MS. LEBEIS: Objection to the form of the question.

A More or less. Maybe a little higher, but around that range.

Q Which of the compounds do you think has a PKA higher than 4.5?

A I haven't done an analysis of the actual PKAs of each of these. I haven't seen any data that show anybody has measured the PKAs. PKA depends on the structure of the whole molecule. So there's so many functional groups in these molecules, it's hard to be absolutely certain where their PKA -- what

their each individual PKA will be. But it's in the -- roughly in that range.

Q In looking at the properties of these different compounds, you didn't consider the PKA; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A I certainly did consider the PKA in the sense that I know what the range is, and, in the appendix to my report, there is a diagram that shows where you would expect ionization to be, and it's well -- any of the formulations that were discussed are well within the range. That means they're essentially 100 percent ionized.

Q What does 100 percent ionized mean?

A Nothing is ever 100 percent ionized.

Q What does essentially 100 percent ionized mean?

A A very small amount is left in the protonated form.

Q Could you turn to paragraph 13 in your expert report.

A 13?

STEPHEN G. DAVIES, D.PHIL.

Q Uh-hmm.

A Okay.

Q And in this paragraph you've expressed your understanding of an obviousness analysis; is that right?

A Yes.

Q You haven't reached a conclusion in your expert report that any of the claims of the patents-in-suit are or are not obvious; is that correct?

MS. LEBEIS: Objection to the extent it mischaracterizes the document.

A I wasn't asked to provide an opinion on any of the claims of the patent.

Q So you didn't reach a conclusion in your expert report about the obviousness or nonobviousness of any of the claims; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes.

A I wasn't asked to consider the claims of the patent.

Q Because you weren't asked to consider the claims, you didn't offer any opinion in

your expert report about the obviousness or nonobviousness of any of those claims; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony and the document.

A I didn't form an opinion on whether the claims are obvious or not.

Q Did you review the claims in detail in forming your opinions in this case?

MS. LEBEIS: Objection, asked and answered.

A I read the whole patent as an overview but did not form opinions on the obviousness of the claims.

Q You offer an opinion that a person of ordinary skill in the art would not have sought to modify any of the prior bromfenac formulations; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes the document.

A You would have to show me where in my report where that says -- you're referring to.

Q We can come to that in a moment.

STEPHEN G. DAVIES, D.PHIL.

You're aware that there are a number of references in the prior art that describe the formation of a complex between NSAIDs having a carboxylic acid group and benzalkonium chloride, right?

MS. LEBEIS: Objection. Vague and ambiguous. No foundation.

THE WITNESS: You'll have to repeat that question, please.

(Record read.)

A I don't think I've seen a scientific reference that shows there's a complex form between a carboxylic acid and benzalkonium chloride.

Q You're aware that there are patent references in the prior art that describe the formation of a complex between NSAIDs having a carboxylic acid group and benzalkonium chloride, right?

MS. LEBEIS: Objection, vague and ambiguous. No foundation. Asked and answered.

A I've not seen any experimental evidence to show that, that I recall, that

shows that a complex is formed between a carboxylic acid and benzalkonium chloride.

Q But you've seen references in the prior art literature that describes such complexes, whether or not it's with experimental evidence, right?

MS. LEBEIS: Objection, no foundation, vague and ambiguous.

A You'll have to tell me what you mean by "describe."

Q Why don't we take a look.

MS. RAPALINO: Let's mark as Davies Exhibit 2 U.S. Patent Number 5,558,876.

(Exhibit 2 was marked for identification and attached to the deposition transcript.)

BY MS. RAPALINO:

Q Do you have Exhibit 2 in front of you?

A I do, yes.

Q You considered this patent in connection with forming your opinions in this case, right?

A I believe so.

Q This patent -- is it okay if I call

STEPHEN G. DAVIES, D.PHIL.

it the '876 patent?

A Yes.

Q The '876 patent issued on September 24th of 1996, correct?

MS. LEBEIS: Objection. Calls for a legal conclusion.

A The patent on the front says the "Date of patent, September 24th, 1996."

Q The title of the patent is "Topical ophthalmic acidic drug formulations." Do you see that?

A That's what it says, yes.

Q The patent is assigned, on its face, to Alcon Laboratories, Inc. Do you see that?

A Yes.

Q That's a pharmaceutical company known for ophthalmic products, right?

MS. LEBEIS: Objection. Calls for speculation.

A I don't know that.

Q The patent is directed generally to stable, preserved, ophthalmic formulations containing an acidic drug, right?

MS. LEBEIS: Objection to the extent

it mischaracterizes the document.

A You would have to show me where it says that.

Q If you look at the abstract on the cover page of the document --

A Yes.

Q -- the abstract indicates that the patent is directed generally to stable, preserved, ophthalmic formulations containing an acidic drug; is that right?

A That's what it says, yes.

MS. LEBEIS: Objection. Mischaracterizes the document.

Q Look at column 1 of the '876 patent.

A Okay.

Q And if you read the first paragraph under "Background of the Invention" in column 1, from line 10 to line 24.

MS. LEBEIS: Do you want him to read it out loud?

Q No, you can read that to yourself.

A (Document review.)

Okay.

Q That first paragraph under

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"Background of the Invention" in the '876 patent describes the problem with acidic NSAIDs with carboxyl groups that they tend to form insoluble complexes with quaternary ammonium preservatives such as benzalkonium chloride, or BAC.

Do you see that?

A Well, it makes a general statement to that effect, but I haven't seen any evidence to say that that is correct or not.

Q That's what the patent says, though, right?

MS. LEBEIS: Objection to the extent it mischaracterizes this document.

A It's a general statement at the introductory part of this patent, but there's no -- I haven't seen any scientific basis to support that.

Q And the patent doesn't limit that statement regarding this problem of complexes between NSAIDs and BAC to a particular acidic carboxyl-group-containing NSAID, right?

MS. LEBEIS: Objection to the form of the question.

STEPHEN G. DAVIES, D.PHIL.

A It's a general introduction. You would have to read the specification and the claims to see what the patent is actually providing evidence for.

Q You would agree, though, that in this introductory statement, it's not -- the statement regarding this problem of complexation is not limited to any particular NSAID; is that right?

MS. LEBEIS: Objection to the extent it mischaracterizes the document and to the extent it mischaracterizes prior testimony.

A Well, a person of ordinary skill regarding this document would read that as a general comment and then look, would certainly not assume that it includes all NSAIDs. Would look to the whole patent to see what actually was being put forward with evidence in the patent and what the patent itself was dealing with. It wouldn't take that as a definitive scientific statement of fact.

Q Okay. So we're going to look a little bit later in the patent in a moment, but let's stick with that first paragraph for now.

STEPHEN G. DAVIES, D.PHIL.

You see that, in fact, the first paragraph describes the fact that many NSAIDs have been formulated with other than desirable preservatives because the compounds form complexes with desired preservatives, such as benzalkonium chloride?

A Which line --

MS. LEBEIS: Objection. Hold on one second. Objection to the extent it mischaracterizes the document.

A Which line were you referring to, please?

Q Starting at line 17, the sentence that begins, "Many NSAIDs."

A Okay.

These sort of general statements without any scientific reference or basis are meaningless. And a person of ordinary skill would look at the rest of the patent to find out what is actually involved.

Q You would agree, though, that this paragraph in the '876 patent describes the phenomenon that many NSAIDs have been formulated with other than desirable

STEPHEN G. DAVIES, D.PHIL.

preservatives because the NSAIDs form a complex with desirable preservatives, such as benzalkonium chloride, right?

MS. LEBEIS: Objection. Mischaracterizes the document. Asked and answered.

A It's a completely general statement that has no scientific foundation. Nothing is referenced here. A person of ordinary skill wouldn't take into consideration this type of problem unless they actually experienced it.

Q So I'm not asking you -- for you to comment on the quality of the statement. I'm just asking you whether or not the '876 patent indeed reports that many NSAIDs have been formulated with other than desirable preservatives because the NSAIDs form a complex with desirable preservatives such as benzalkonium chloride.

MS. LEBEIS: Objection.

Q Does the '876 patent report that?

MS. LEBEIS: Objection. Mischaracterizes the document. Asked and answered.

STEPHEN G. DAVIES, D.PHIL.

A It doesn't report that at all because it doesn't provide any evidence for that. It might say it as a broad statement at the beginning of the introduction, but it doesn't give any evidence for a person of ordinary skill to understand that that is always a problem.

Q This patent proposes a formulation to overcome the problem that it discusses in that first paragraph in column 1; is that right?

MS. LEBEIS: Objection, vague and ambiguous. Mischaracterizes the document.

A We would have to look at the whole patent to determine what the patent is actually providing.

Q You're not familiar with the solution proposed in this patent?

A Well, I've read the --

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A -- I've read the patent, and you would have to show me where stability data was produced.

Q Do you know what the solution is

that's proposed in this patent, the '876 patent, to the problem of complexation?

MS. LEBEIS: Objection, asked and answered.

A Well, I think I answered that, but I'm not sure stability is -- any stability data was given, but we would have to check. I think it's to do with efficacy.

Q I don't think my question related to stability or efficacy. I'm just asking whether you know what solution is proposed in this patent to the problem of complexation between the NSAID and benzalkonium chloride.

MS. LEBEIS: Objection. Mischaracterizes the document. Asked and answered.

A I don't know there is any evidence there was a problem in this patent.

Q Let's assume that the patent reports the problem of complexation between NSAIDs and benzalkonium chloride. Can you make that assumption?

MS. LEBEIS: Objection. Incomplete and improper hypothetical.

STEPHEN G. DAVIES, D.PHIL.

A Why would I want to -- why would one make that assumption?

Q I'm asking you to -- I'm asking you a hypothetical. I want you to assume that regardless of what you think of the quality of the statement, the patent makes the statement that there's a problem of complexation between NSAIDs and benzalkonium chloride.

MS. LEBEIS: Objection.

Mischaracterizes the document. Incomplete and improper hypothetical.

A This document doesn't show there is a problem between the active in this patent and benzalkonium chloride.

Q And you say that because there's no experimental data showing that when you mix an NSAID and benzalkonium chloride you form a complex? Is that your view?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A I don't think there's any information in this patent to say that there is a problem in this particular case -- that problem appears in this particular case.

STEPHEN G. DAVIES, D.PHIL.

Q What particular case are you talking about?

A That there are insoluble complexes with quaternary ammonium preservatives in this -- described in this patent.

Q So I'm asking you for the basis. What is your basis for saying that there's no information in this patent to say that there is a problem of complexation between NSAIDs and benzalkonium chloride?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony. Asked and answered.

A Well, you'll have to show me where in the patent it says that there was a precipitate that was due to a complexation of the active plus the NSAID plus the benzalkonium chloride. Otherwise, the problem doesn't exist.

Q Well, we looked at the paragraph in column 1 that reports that that is a phenomenon that has occurred, right, that there's been formation of a complex between acidic drugs with carboxyl groups and benzalkonium chloride. Do you see that?

STEPHEN G. DAVIES, D.PHIL.

MS. LEBEIS: Objection.

Mischaracterizes the document.

A That is a general statement that has no reference or any description of why -- of how that can be shown to be true, and you have to read the whole patent to see what the patent is actually discussing. And it, as far as I recall, doesn't address that sort of problem at all.

Q What problem do you think this patent is addressing?

A Well, example 4, for example, gives preservative efficacy data.

Q If there was a complexation between an NSAID and benzalkonium chloride, you would agree that would impact the preservative efficacy of the formulation, right?

MS. LEBEIS: Objection, incomplete hypothetical. No foundation.

A I don't know the answer to that. I don't see you can make that statement. I think there would be cases where it would change the efficacy and cases where it wouldn't.

Q Benzalkonium chloride is a

preservative, right?

A Amongst other properties, it's a preservative, yes.

Q It's used in ophthalmic formulations as a preservative; is that right?

MS. LEBEIS: Objection. No foundation. Misleading.

A It can be, but it is being used for other things.

Q And if the preservative in an ophthalmic formulation were in a salt or complex with the active ingredient, that could certainly impact its preservative efficacy, right?

MS. LEBEIS: Objection, incomplete hypothetical.

A It may or it may not.

Q And so you would test it to see whether it did?

MS. LEBEIS: Objection, no foundation. Incomplete hypothetical.

A You're assuming that a complex forms between the ammonium and the carboxylate, for which I've seen no evidence.

STEPHEN G. DAVIES, D.PHIL.

Q Right. So I think you were trying to point to example 4 to talk about the problem that was being addressed by this patent. So what is it about example 4 that tells you what problem is being addressed?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A Well, example 4 is addressing -- is looking at preservative efficacy. That's -- that's what it says.

Q And so you believe the problem that is addressed by this patent is an issue of preservative efficacy?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony.

A I think the patent is concerned with preservative efficacy.

Q You would agree that this patent is also directed to bromfenac, right?

A Is also directed to?

Q Bromfenac.

MS. LEBEIS: Objection, no foundation.

A Well, the preservative efficacy in

example 4 is all on diclofenac.

Q The patent in example 3 gives examples of formulation -- of a formulation of bromfenac, right?

A Bromfenac is in the list of the compounds formulated, but no data is given about those -- about that formulation.

Q And then if we look at column 2 of this patent at line -- starting at line 20.

A Yes.

Q You see that the patent says that "Acidic drugs, which can be formulated according to the present invention include NSAIDs, including but not limited to diclofenac, bromfenac, flurbiprofen, and others," right?

A That's what it says, but it doesn't give you any data about the formulations.

Q You would agree that this paragraph also says that benzalkonium chloride is used to preserve the formulations, right?

A That's what it says, but there's no data in this patent to show that is the case for anything other than -- there's no data on

anything other than diclofenac.

Q So you would agree that preservative efficacy here is a test of the preservative efficacy of benzalkonium chloride, right?

MS. LEBEIS: Objection to the extent it mischaracterizes the document.

A I don't think so because the example 4 is changing the amount of caffeine present. So this has to do with how caffeine affects the preservation.

Q Right, but the preservative, the agent providing the preservative efficacy is the benzalkonium chloride, right?

MS. LEBEIS: Objection to the extent it mischaracterizes the document.

A Well, I can't -- you can't read a person of ordinary skill would be able to tell that.

Q Even though the patent says explicitly in column 2 that benzalkonium chloride is used to preserve the formulations?

MS. LEBEIS: Objection, argumentative.

A Right, but as soon as you look at

formulation A, in example 4, I think it says -- or at least above it, maybe it's not A -- "The initial preservative efficacy test for the formulations had indicated that the formulations had poor preservation only against S. aureus." So it's not working as a preservative against that in that case.

Q Let's look again at column 2.

A Yes.

Q And you see the last sentence in the paragraph that begins at line 20 --

A Yes.

Q -- talks about caffeine and Vitamin E TPGS "to reduce discomfort, and it also potentiates the preservative efficacy of benzalkonium chloride."

Do you see that?

MS. LEBEIS: Objection. Mischaracterizes the document.

A Can you repeat the question.

Q Do you see that it talks about potentiating the preservative efficacy of benzalkonium chloride?

A That's what it says.

STEPHEN G. DAVIES, D.PHIL.

And a person of skill in the art then would understand that benzalkonium chloride is acting as the preservative in these formulations?

MS. LEBEIS: Objection.

A Well, the data doesn't show that. They say they've put it in there to act as a preservative is what they say. And then they give some preservative efficacy that is obviously dependent upon caffeine. So how would a person of ordinary skill not know it's caffeine doing the preservative action?

Q If a person of skill in the art relied on the general statements in paragraph 1 under "Background of the Invention." column 1, the person of ordinary skill in the art would understand that there was a general problem of complexation between NSAIDs and BAC, right?

MS. LEBEIS: Objection. Incomplete and improper hypothetical. Mischaracterizes the document. Asked and answered.

A I don't know of any evidence, not as presented herein, that says that there is a

problem with acids and benzalkonium chloride.

Q Again, I wasn't asking about evidence. I just want to know if a person of skill in the art reading paragraph 1 under "Background of the Invention" in column 1 relied on that paragraph, the person of skill in the art would understand there was a general problem of complexation between NSAIDs and BAC, right?

MS. LEBEIS: Objection, incomplete and improper hypothetical. Mischaracterizes the document and asked and answered.

A Well, a person of ordinary skill would not take general comments like that at face value. They would ask the question, do I have a problem? Is this actually a problem? What is the evidence?

Q Okay. You don't believe that a person of skill in the art would ignore a statement like that, do you?

MS. LEBEIS: Objection. Mischaracterizes -- to the extent it mischaracterizes prior testimony,

argumentative.

A They would read it, but they would ask the question, is this actually true? Is it true for my particular scenario, if they're interested in formulating something, and only worry about it if it turned out to be true, and I don't know of any examples where --

Q So it would certainly raise a question in the mind of the person of ordinary skill in the art about whether this might be true for their formulation, right?

MS. LEBEIS: Objection to the extent it mischaracterizes prior testimony. Asked and answered.

A I think they would just read that and move on.

MS. LEBEIS: Do you think we could -- it's been about an hour. Is it okay to take another short break, since you're moving on.

MS. RAPALINO: Sure.

THE VIDEOGRAPHER: We're going off the record at 11:23 a.m.

(A brief recess was taken.)

STEPHEN G. DAVIES, D.PHIL.

THE VIDEOGRAPHER: We're going back on the record at 11:35 a.m. This is the start of disc number 3 in the deposition of Stephen Davies.

Q Dr. Davies, did you have any conversations with Ms. Lebeis on the break about the substance of your testimony?

A Absolutely not.

Q Did you have any conversations with anybody on the break about the substance of your testimony?

A I didn't see anybody else.

Q So you didn't have any conversations with anybody else on the break?

A No.

Q Let's go back again to Davies Exhibit 2, the '876 patent. And you recall we were looking at the general statement in the "Background of the Invention" section about the problem of complexation of NSAIDs and benzalkonium chloride. Do you remember that?

A Yes.

MS. LEBEIS: Objection to the extent it mischaracterizes the document.

STEPHEN G. DAVIES, D.PHIL.

Q There is no discussion in this patent of any differences between NSAIDs in terms of their chemical structure here, right?

MS. LEBEIS: Objection to the extent it mischaracterizes the document.

A I don't see why there would be. There isn't, but I don't see why there would be.

Q And there's no discussion in this section of the patent of any differences between NSAIDs in terms of their electron density, right?

MS. LEBEIS: Objection to the extent it mischaracterizes the document.

A There isn't anything -- discussion like that, and I don't see why there would be in the context of this patent.

Q And, again, in the context of this statement, this general statement about the problem of NSAID-BAC complexation, there's no discussion here of differences between different NSAIDs in terms of whether they are primary, secondary, or tertiary amines?

MS. LEBEIS: Objection.

Mischaracterizes the document.

A I don't believe it's been confirmed there is a problem between NSAID and a quaternary ammonium preservative.

Q In the context of the statement in this patent about the problem of complexation between NSAIDs and benzalkonium chloride, there's no discussion of the differences between NSAIDs in terms of their primary, secondary, or tertiary -- whether they are primary, secondary, or tertiary amines, right?

MS. LEBEIS: Objection.

Mischaracterizes the document. Asked and answered.

A There is no discussion of that and it would be irrelevant to the document -- to the substance of the document.

Q And there's also no discussion in this patent, in the context of its general statement about the problem of complexation between NSAID and BAC, of differences between NSAIDs in terms of the presence or absence of halogenation on the compounds?

MS. LEBEIS: Objection.

Mischaracterizes the document.

A There isn't, but it would be irrelevant to what is going on in the -- is the substance of the patent.

Q And you would also agree that in the patent's discussion of this problem of complexation of NSAIDs and BAC, there is no discussion of differences between the different NSAIDs and their degree of lipophilicity, right?

MS. LEBEIS: Objection.

Mischaracterizes the document.

A There's no evidence in this patent that that problem exists.

Q But with regard to this general statement in the patent, in the '876 patent, about the problem of NSAID-BAC complexation, you would agree that there's no discussion of the differences between different NSAIDs in terms of their degree of lipophilicity, right?

MS. LEBEIS: Objection.

Mischaracterizes the document, asked and answered.

A They don't experience the problem so