

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

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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.

A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFFS:

JESSICA M. LEBEIS, ESQUIRE
FINNEGAN HENDERSON FARABOW GARRETT
& DUNNER, LLP
303 Peachtree Street, Northeast
Atlanta, Georgia 30308
(404) 653-6400
jessica.lebeis@finnegan.com

ON BEHALF OF THE DEFENDANTS LUPIN, LTD. and LUPIN
PHARMACEUTICALS, INC.:

EMILY I. RAPALINO, ESQUIRE
GOODWIN PROCTER, LLP
Exchange Place
53 State Street
Boston, Massachusetts 02109
(617) 570-1000
erapalino@goodwinprocter.com

1
2 ATTENDANCE, Continued

3
4 ON BEHALF OF THE INNOPHARMA DEFENDANTS:

5 H. JAMES ABE, ESQUIRE

6 ALSTON & BIRD, LLP

7 333 South Hope Street

8 Sixteenth Floor

9 Los Angeles, California 90071

10 (213) 576-1000

11 james.abe@alston.com

12 - AND -

13 JITENDRA "JITTY" MALIK, PH.D.

14 ALSTON & BIRD, LLP

15 4721 Emperor Boulevard, Suite 400

16 Durham, North Carolina 27703

17 (919) 862-2200

18 jitty.malik@alston.com

19
20 ALSO PRESENT:

21 Jason Levin, Videographer

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1 STEPHEN G. DAVIES, D.PHIL.

2 THE VIDEOGRAPHER: We are going on
3 the record at 9:04 a.m. on February 22nd,
4 2016. This is DVD number 1 of the video
5 deposition of Stephen Davies in the matter
6 of Senju Pharmaceutical Company, Limited,
7 et al., versus Lupin, Limited, et al.,
8 filed in the United States District Court
9 for the District of New Jersey, Case Number
10 1:14-cv-00667-(JBS) (KMW), consolidated
11 cases.

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

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

20 Will counsel now please state their
21 appearances for the record.

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

25 DR. MALIK: Jitendra Malik of the law

1 STEPHEN G. DAVIES, D.PHIL.

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

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

12 - - -

13 STEPHEN G. DAVIES, D.PHIL.,
14 having been duly sworn, testified as follows:

15 EXAMINATION BY COUNSEL FOR THE LUPIN DEFENDANTS
16 BY MS. RAPALINO:

17 Q Good morning, Dr. Davies.

18 A Good morning.

19 Q You've been deposed before, correct?

20 A I have, yes.

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

1 STEPHEN G. DAVIES, D.PHIL.

2 if you were testifying in court?

3 A Yes.

4 Q We can take breaks from time to time.

5 I would ask that if you need a break, you ask
6 for one but not while a question is pending.

7 Is that fair?

8 A Okay.

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

14 A Okay.

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

19 A Okay.

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

22 A No.

23 Q How did you prepare for today's
24 deposition?

25 A I read through my reports and the

1 STEPHEN G. DAVIES, D.PHIL.

2 references therein.

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

6 A Not that I recall.

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

9 A I met with Ms. Lebeis.

10 Q Did you meet with anybody else?

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

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

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

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

21 A No.

22 Q Did you review any deposition
23 testimony in this case?

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

1 STEPHEN G. DAVIES, D.PHIL.

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

4 A Not that I recall, no.

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

7 A What's IPR?

8 Q Inter partes review.

9 A No, I don't believe so.

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

12 A No, I haven't, no.

13 Q How many times have you testified at
14 deposition?

15 A I don't recall. A number.

16 Q Has it been more than 100?

17 A No.

18 Q More than 50?

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

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

23 A I believe so, yes.

24 Q Have you testified at trial?

25 A I have, yes.

1 STEPHEN G. DAVIES, D.PHIL.

2 Q How many times?

3 A Between five and ten.

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

8 A There have, yes.

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

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

12 Q About how many, would you say?

13 A Around ten.

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

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

19 BY MS. RAPALINO:

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

22 A Yes, it is.

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

25 A Yes.

1 STEPHEN G. DAVIES, D.PHIL.

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

4 A It is, yes.

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

7 A That's correct, yes.

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

10 A From the material considered at that
11 time, yes.

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

14 A I don't believe so, no.

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

19 A That's correct, yes.

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

22 A Yes, they were.

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

1 STEPHEN G. DAVIES, D.PHIL.

2 of the patentee in that case?

3 A I did, yes.

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

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

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

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

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

22 A That's correct, yes.

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

25 A It was mostly about chemistry, and

1 STEPHEN G. DAVIES, D.PHIL.

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

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

6 MS. LEBEIS: Objection, vague and
7 ambiguous.

8 A I testified that it was nonobvious.

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

11 A I think it was Paul Hastings.

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

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

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

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

25 A I was, yes.

1 STEPHEN G. DAVIES, D.PHIL.

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

4 A Mostly chemistry.

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

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

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

14 A I was, yes.

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

17 A Chemistry.

18 Q Was it synthetic chemistry in that
19 case?

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

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

25 A Anything involved in the search for

1 STEPHEN G. DAVIES, D.PHIL.

2 novel pharmaceutical compounds that are of
3 therapy to use.

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

8 A Yes.

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

11 A Chemistry.

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

15 A Yes.

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

20 A I was, yes.

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

23 A Chemistry.

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

1 STEPHEN G. DAVIES, D.PHIL.

2 enantiomer chemistry, and medicinal chemistry?

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

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

7 A I don't recall.

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

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

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

21 A I was, yes.

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

24 A Chemistry.

25 Q And was it the same three categories

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

13 MS. LEBEIS: Objection, asked and
14 answered.

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

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

20 A I was, yes.

21 Q Were you compensated by the court in
22 connection --

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

1 STEPHEN G. DAVIES, D.PHIL.

2 paid by the lawyers.

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

6 A That's correct.

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

9 A No.

10 Q -- for your testimony?

11 A No.

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

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

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

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

20 A I don't believe so.

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

23 A I don't believe so.

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

1 STEPHEN G. DAVIES, D.PHIL.

2 other cases have you offered testimony as an
3 expert?

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

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

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

11 A Repeat the question.

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

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

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

24 A Yes.

25 Q About how many of those cases have

1 STEPHEN G. DAVIES, D.PHIL.

2 you testified in?

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

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

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

10 A Testimony or reports.

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

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

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

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

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STEPHEN G. DAVIES, D.PHIL.

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

1 STEPHEN G. DAVIES, D.PHIL.

2 compounds that are of therapeutic use, right?

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

5 A I would have to check through to see
6 if that's true. I don't recall that I did, but
7 ...

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

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

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

17 A That's correct, yes.

18 Q Is it up-to-date?

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 A Not that I -- no.

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

5 A That's correct.

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

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

12 Q What was the subject of that year of
13 research?

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

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

19 A I did not, no.

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

23 A I did not, no.

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

1 STEPHEN G. DAVIES, D.PHIL.

2 during your research for your BA degree?

3 A I did not, no.

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

6 A That's correct, yes.

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

9 A I did, yes.

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

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

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

18 A I did not, no.

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

22 A I did not, no.

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

1 STEPHEN G. DAVIES, D.PHIL.

2 A I did not, no.

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

7 A That's correct.

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

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

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

15 A Their physical properties and their
16 chemical properties.

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

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

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

25 Q I think my question was a little

1 STEPHEN G. DAVIES, D.PHIL.

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

5 MS. LEBEIS: Same objections.

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

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

15 MS. LEBEIS: Same objections.

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

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

20 A They all have the same functional
21 group.

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 A They can, yes.

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

5 MS. LEBEIS: Same objections.

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

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

11 MS. LEBEIS: Same objections.

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

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 MS. LEBEIS: Objection, vague and
3 ambiguous.

4 A Depends on which way you're using it.

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

7 A That's correct, yes.

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

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

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

14 A I did not, no.

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

18 A I did not, no.

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

22 A I did not, no.

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

1 STEPHEN G. DAVIES, D.PHIL.

2 MS. LEBEIS: Objection, no

3 foundation.

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

11 Q What year did you move to France?

12 A 1977.

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

15 A I did, yes.

16 Q What was the subject of that
17 research?

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 A No.

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

5 A It did not, no.

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

9 A Yes.

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

12 A Not that I recall.

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

18 A I actually founded all of them.

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

21 A They are not, no.

22 Q How many of them are still in
23 existence?

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

7 A SciInk Limited, Summit Therapeutics,
8 Oxstem Limited.

9 Q Are any others still in existence as
10 independent companies?

11 A I don't believe so.

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 keep track.

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

7 MS. LEBEIS: Objection.

8 A No, I don't.

9 MS. LEBEIS: Asked and answered.

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

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

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

16 A Okay.

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

19 A Some of them.

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

8 A They don't, no.

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

14 A They don't, no.

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

17 A I am, yes.

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

20 A I don't, no.

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

23 A I don't, no.

24 Q You're not a medical doctor?

25 A I'm not a medical doctor, no.

1 STEPHEN G. DAVIES, D.PHIL.

2 Q You're not an ophthalmologist?

3 A I'm not an ophthalmologist.

4 Q You haven't prescribed ophthalmic
5 products?

6 A I think that would be illegal.

7 Q So you haven't done that?

8 A So I have not done that.

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

12 A Yes.

13 Q What compounds have you researched?

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

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

18 A (Document review.)

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

1 STEPHEN G. DAVIES, D.PHIL.

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

4 Q What reference is that?

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

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

14 A That's correct, yes.

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

17 A That's roughly correct, yes.

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

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

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

STEPHEN G. DAVIES, D.PHIL.

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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.

1 STEPHEN G. DAVIES, D.PHIL.

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

5 A No, I was not.

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

8 A Yes.

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

12 A That's correct, yes.

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

15 A That's correct, yes.

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

19 A It was already on the market.

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

23 A I was not, no.

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

STEPHEN G. DAVIES, D.PHIL.

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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.

1 STEPHEN G. DAVIES, D.PHIL.

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

5 MS. LEBEIS: Objection, vague.

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

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

11 MS. LEBEIS: Objection, asked and
12 answered.

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

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

19 A That's correct.

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

22 A Sorry, could you repeat the question?

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

25 A All the time.

1 STEPHEN G. DAVIES, D.PHIL.

2 Q What subjects have you taught?

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

12 Q Have you ever taught a class in
13 pharmaceutical formulation?

14 A I have not, no.

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

19 A No.

20 Q Have you ever formulated an NSAID
21 pharmaceutical product?

22 A No.

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

25 MS. LEBEIS: Objection, vague and

1 STEPHEN G. DAVIES, D.PHIL.

2 ambiguous.

3 A Not that I recall.

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

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

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

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

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

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

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

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

24 A That's correct.

25 Q And you understand that "the person

1 STEPHEN G. DAVIES, D.PHIL.

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

4 A Yes.

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

9 A Well, I think I list that in my
10 paragraph 12, where "The '431, '290, '131, and
11 '813 patents are directed, generally speaking,
12 to aqueous liquid formulations of nonsteroidal
13 anti-inflammatory drug NSAID
14 2-amino-3-(4-bromobenzoyl)phenylacetic acid,
15 bromfenac, or pharmacologically acceptable salt
16 or hydrate thereof, and the nonionic surfactant
17 tyloxapol for ophthalmic administration."

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

9 A I have not, no.

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

13 A I haven't, no.

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

18 A Not that I recall.

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

21 A I have not, no.

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

1 STEPHEN G. DAVIES, D.PHIL.

2 A That's correct.

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

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

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

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

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

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

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

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

24 Q And you haven't --

25 A And --

1 STEPHEN G. DAVIES, D.PHIL.

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

5 MS. LEBEIS: Objection.

6 Q -- is that right?

7 MS. LEBEIS: Mischaracterizes prior
8 testimony, argumentative.

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

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

18 MS. LEBEIS: Objection --

19 A I'm --

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 reports of Dr. Lawrence and Dr. Heathcock.

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

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

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

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

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

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

25 MS. LEBEIS: Same objections.

1 STEPHEN G. DAVIES, D.PHIL.

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

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

11 MS. LEBEIS: Objection, vague and
12 ambiguous.

13 A I haven't reviewed the patents in
14 detail.

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 need to have pharmaceutical formulation
3 experience?

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

7 A I haven't reviewed the patents in
8 detail.

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

11 MS. LEBEIS: Objection. Same
12 objections.

13 A I haven't considered that question.

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 the art, right?

3 A Yes.

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

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

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

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

18 MS. LEBEIS: Objection.

19 Q Is that your testimony?

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

5 MS. LEBEIS: Same objections. Asked
6 and answered.

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

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

17 MS. LEBEIS: Same objections. Asked
18 and answered.

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

13 MS. LEBEIS: Objection, asked and
14 answered.

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

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

24 MS. LEBEIS: Objection. Asked and
25 answered.

1 STEPHEN G. DAVIES, D.PHIL.

2 A I wasn't asked to consider that
3 point.

4 Q So you didn't consider it?

5 MS. LEBEIS: Objection, asked and
6 answered.

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

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

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

18 A I didn't offer an opinion on that.

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

21 Q Do you need a break, Dr. Davies?

22 A A short one.

23 MS. RAPALINO: Sure.

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

1 STEPHEN G. DAVIES, D.PHIL.

2 (A brief recess was taken.)

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

7 BY MS. RAPALINO:

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

11 A I personally haven't, no.

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

15 MS. LEBEIS: Objection, vague and
16 ambiguous.

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

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

23 A I have not, no.

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

1 STEPHEN G. DAVIES, D.PHIL.

2 ophthalmic pharmaceutical formulation; is that
3 right?

4 A I have not, no.

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

8 A No.

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

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

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

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

20 A That's correct.

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

25 MS. LEBEIS: Objection, vague and

1 STEPHEN G. DAVIES, D.PHIL.

2 ambiguous. Objection to the form.

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

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

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

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

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

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

19 MS. LEBEIS: Objection, vague and
20 ambiguous.

21 A Can you repeat the question, please.

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 in formulating an ophthalmic pharmaceutical; is
3 that right?

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

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

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

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

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

21 A Can you repeat the question?

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

25 MS. LEBEIS: Objection to the extent

1 STEPHEN G. DAVIES, D.PHIL.

2 it mischaracterizes prior testimony.

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

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

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

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

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

17 A Of an active ingredient, yes.

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

5 Q What kind of pharmaceutical
6 formulation was that?

7 MS. LEBEIS: Objection, vague and
8 ambiguous.

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

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

14 A Oral.

15 Q Was it a tablet formulation?

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

18 Q Solutions and suspensions are two
19 different things, right?

20 A That's correct, yes.

21 Q They have different properties?

22 A They do have different properties,
23 yes.

24 Q Have you ever worked with sodium
25 sulfide?

1 STEPHEN G. DAVIES, D.PHIL.

2 A Every chemist has.

3 Q In what context?

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

6 A It's a reducing agent.

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

9 A Yes.

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

12 A Not that I recall.

13 Q Have you ever worked with
14 polyvinylpyrrolidone?

15 A No.

16 Q Have you ever worked with
17 benzalkonium chloride?

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

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

24 A It is, yes.

25 Q And you said you've worked with the

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

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

17 A We have used different quaternary
18 ammonium salts, yes.

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

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

24 A Yes, that's true.

25 Q You've never used benzalkonium

1 STEPHEN G. DAVIES, D.PHIL.

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

4 A I have not, no.

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

8 A I have not, no.

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

12 A I have not, no.

13 Q Have you ever worked with polysorbate
14 80?

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

17 A I don't believe so.

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

21 A I've got 10. Yes.

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

1 STEPHEN G. DAVIES, D.PHIL.

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

5 Do you see that?

6 A Yes.

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

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

14 A You'll have to repeat the question.

15 MS. RAPALINO: Do you mind reading it
16 back.

17 (Record read.)

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

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

25 MS. LEBEIS: Objection to the extent

1 STEPHEN G. DAVIES, D.PHIL.

2 it calls for a legal conclusion.

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

5 (Record read.)

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

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

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

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

19 MS. LEBEIS: Same objections.

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

25 Q Can you point me to a paragraph about

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

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

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 right?

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

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

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

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

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

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

20 Q And that did not include an analysis
21 of whether or not those references constitute
22 prior art as you used that term in paragraph
23 10; is that right?

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

1 STEPHEN G. DAVIES, D.PHIL.

2 A That's for the court to decide.

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

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

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

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

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

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

25 MS. LEBEIS: Objection, asked and

1 STEPHEN G. DAVIES, D.PHIL.

2 answered.

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

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

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

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

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

23 MS. LEBEIS: Objection, asked and
24 answered.

25 A I've done an analysis of the science.

1 STEPHEN G. DAVIES, D.PHIL.

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

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

7 MS. LEBEIS: Objection, asked and
8 answered.

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

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

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

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

20 Q Not for you to decide; is that right?

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

23 A It's for the court to decide.

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

6 THE WITNESS: Could you repeat the
7 question.

8 (Record read.)

9 MS. LEBEIS: Same objections.

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

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

11 MS. LEBEIS: Objection,
12 argumentative.

13 A I don't recall.

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

16 A Yes.

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

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

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

25 Q You would agree that both bromfenac

1 STEPHEN G. DAVIES, D.PHIL.

2 and diclofenac are phenylacetic acid
3 derivatives, right?

4 A That's true, yes.

5 Q Both bromfenac and diclofenac contain
6 a carboxylic acid moiety?

7 A Amongst other functional groups, yes.

8 Q They both contain a carboxylic acid
9 moiety, right?

10 A Amongst other functional groups, yes.

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

15 MS. LEBEIS: Objection, asked and
16 answered.

17 A They both do, amongst other
18 functional groups.

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

21 A Yes.

22 Q Ketorolac also contains a carboxylic
23 acid moiety, right?

24 A Amongst other functional groups, it
25 does, yes.

1 STEPHEN G. DAVIES, D.PHIL.

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

4 A It is, yes.

5 Q Flurbiprofen also contains a
6 carboxylic acid moiety, right?

7 A Amongst other functional groups.

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

10 A Yes.

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

15 MS. LEBEIS: Objection, no

16 foundation.

17 A I believe so, yes.

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

23 MS. LEBEIS: Objection, no

24 foundation.

25 A I didn't do an analysis in detail of

1 STEPHEN G. DAVIES, D.PHIL.

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

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

7 A That is correct.

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

10 A Yes.

11 Q And flurbiprofen is also essentially
12 100 percent ionized at a pH of around 7 to 9,
13 correct?

14 A That is correct.

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 A Somewhere between maybe 6 and 8.

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

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

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

10 A That's correct, yes.

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

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

17 Q What does 100 percent ionized mean?

18 A Nothing is ever 100 percent ionized.

19 Q What does essentially 100 percent
20 ionized mean?

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

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

25 A 13?

1 STEPHEN G. DAVIES, D.PHIL.

2 Q Uh-hmm.

3 A Okay.

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

7 A Yes.

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

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

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

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

20 MS. LEBEIS: Objection to the extent
21 it mischaracterizes.

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

12 MS. LEBEIS: Objection, asked and
13 answered.

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

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

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

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

25 Q We can come to that in a moment.

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

11 (Record read.)

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

12 Q Why don't we take a look.

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

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

17 BY MS. RAPALINO:

18 Q Do you have Exhibit 2 in front of
19 you?

20 A I do, yes.

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

24 A I believe so.

25 Q This patent -- is it okay if I call

1 STEPHEN G. DAVIES, D.PHIL.

2 it the '876 patent?

3 A Yes.

4 Q The '876 patent issued on September
5 24th of 1996, correct?

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

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

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

13 A That's what it says, yes.

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

16 A Yes.

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

19 MS. LEBEIS: Objection. Calls for
20 speculation.

21 A I don't know that.

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

25 MS. LEBEIS: Objection to the extent

1 STEPHEN G. DAVIES, D.PHIL.

2 it mischaracterizes the document.

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

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

7 A Yes.

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

12 A That's what it says, yes.

13 MS. LEBEIS: Objection.

14 Mischaracterizes the document.

15 Q Look at column 1 of the '876 patent.

16 A Okay.

17 Q And if you read the first paragraph
18 under "Background of the Invention" in column
19 1, from line 10 to line 24.

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

22 Q No, you can read that to yourself.

23 A (Document review.)

24 Okay.

25 Q That first paragraph under

1 STEPHEN G. DAVIES, D.PHIL.

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

8 Do you see that?

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

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

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

8 A Which line --

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

12 A Which line were you referring to,
13 please?

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

16 A Okay.

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

5 MS. LEBEIS: Objection.

6 Mischaracterizes the document. Asked and
7 answered.

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

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

21 MS. LEBEIS: Objection.

22 Q Does the '876 patent report that?

23 MS. LEBEIS: Objection.

24 Mischaracterizes the document. Asked and
25 answered.

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

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

19 A Well, I've read the --

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

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

25 Q Do you know what the solution is

1 STEPHEN G. DAVIES, D.PHIL.

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

4 MS. LEBEIS: Objection, asked and
5 answered.

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

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

15 MS. LEBEIS: Objection.

16 Mischaracterizes the document. Asked and
17 answered.

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

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

24 MS. LEBEIS: Objection. Incomplete
25 and improper hypothetical.

1 STEPHEN G. DAVIES, D.PHIL.

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

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

10 MS. LEBEIS: Objection.

11 Mischaracterizes the document. Incomplete
12 and improper hypothetical.

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 Q What particular case are you talking
3 about?

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

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 MS. LEBEIS: Objection.

3 Mischaracterizes the document.

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

11 Q What problem do you think this patent
12 is addressing?

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

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

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

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

25 Q Benzalkonium chloride is a

1 STEPHEN G. DAVIES, D.PHIL.

2 preservative, right?

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

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

7 MS. LEBEIS: Objection. No
8 foundation. Misleading.

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

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

16 MS. LEBEIS: Objection, incomplete
17 hypothetical.

18 A It may or it may not.

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

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

17 A I think the patent is concerned with
18 preservative efficacy.

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

21 A Is also directed to?

22 Q Bromfenac.

23 MS. LEBEIS: Objection, no
24 foundation.

25 A Well, the preservative efficacy in

1 STEPHEN G. DAVIES, D.PHIL.

2 example 4 is all on diclofenac.

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

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

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

11 A Yes.

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

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

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

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

1 STEPHEN G. DAVIES, D.PHIL.

2 anything other than diclofenac.

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

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

8 A I don't think so because the example
9 4 is changing the amount of caffeine present.
10 So this has to do with how caffeine affects the
11 preservation.

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

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

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

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

23 MS. LEBEIS: Objection,
24 argumentative.

25 A Right, but as soon as you look at

1 STEPHEN G. DAVIES, D.PHIL.

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

9 Q Let's look again at column 2.

10 A Yes.

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

13 A Yes.

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

18 Do you see that?

19 MS. LEBEIS: Objection.

20 Mischaracterizes the document.

21 A Can you repeat the question.

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

25 A That's what it says.

1 STEPHEN G. DAVIES, D.PHIL.

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

6 MS. LEBEIS: Objection.

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

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

20 MS. LEBEIS: Objection. Incomplete
21 and improper hypothetical.

22 Mischaracterizes the document. Asked and
23 answered.

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

1 STEPHEN G. DAVIES, D.PHIL.

2 problem with acids and benzalkonium chloride.

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

11 MS. LEBEIS: Objection, incomplete
12 and improper hypothetical.

13 Mischaracterizes the document and asked and
14 answered.

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

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

23 MS. LEBEIS: Objection.

24 Mischaracterizes -- to the extent it
25 mischaracterizes prior testimony,

1 STEPHEN G. DAVIES, D.PHIL.

2 argumentative.

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

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

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

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

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

22 MS. RAPALINO: Sure.

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

25 (A brief recess was taken.)

1 STEPHEN G. DAVIES, D.PHIL.

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

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

9 A Absolutely not.

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

13 A I didn't see anybody else.

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

16 A No.

17 Q Let's go back again to Davies Exhibit
18 2, the '876 patent. And you recall we were
19 looking at the general statement in the
20 "Background of the Invention" section about the
21 problem of complexation of NSAIDs and
22 benzalkonium chloride. Do you remember that?

23 A Yes.

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

1 STEPHEN G. DAVIES, D.PHIL.

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

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

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

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

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

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

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

25 MS. LEBEIS: Objection.

1 STEPHEN G. DAVIES, D.PHIL.

2 Mischaracterizes the document.

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

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

13 MS. LEBEIS: Objection.

14 Mischaracterizes the document. Asked and
15 answered.

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

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

25 MS. LEBEIS: Objection.

1 STEPHEN G. DAVIES, D.PHIL.

2 Mischaracterizes the document.

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

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

12 MS. LEBEIS: Objection.

13 Mischaracterizes the document.

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

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

22 MS. LEBEIS: Objection.

23 Mischaracterizes the document, asked and
24 answered.

25 A They don't experience the problem so