

1 STEPHEN G. DAVIES, D.PHIL.

2 why would they need to discuss anything about
3 the structure.

4 Q So you would agree with me that in
5 the context of this patent discussion of the
6 problem of NSAID-BAC complexation, there's no
7 discussion of the degree of lipophilicity of
8 different NSAIDs, right?

9 MS. LEBEIS: Objection.

10 Mischaracterizes the document, asked and
11 answered, and to the extent it
12 mischaracterizes prior testimony.

13 A There's no reason why they would
14 discuss the lipophilicity -- about a problem
15 that they don't experience.

16 Q In talking generally about the
17 problem of NSAID-BAC complexation, whether or
18 not it's experienced in this patent, the
19 authors of the patent don't discuss differences
20 in lipophilicity between different NSAIDs; is
21 that right?

22 MS. LEBEIS: Objection, same
23 objections.

24 A Well, I don't think that I've seen
25 any evidence that the problem exists anywhere

1 STEPHEN G. DAVIES, D.PHIL.

2 let alone in this patent so --

3 Q Again, Dr. Davies, we're going to be
4 here a long time if you don't answer my
5 questions. So I've heard you testify now that
6 you don't believe there's a problem. We got
7 that. I'm trying to get you to answer the
8 questions I'm asking you.

9 MS. LEBEIS: Counsel, he's answering
10 your questions.

11 Q And, again, my question to you is
12 that in the context of this paragraph that's
13 discussing a general problem of NSAID-BAC
14 complexation, is there any discussion in this
15 patent in that section of differences between
16 NSAIDs in terms of their lipophilicity?

17 MS. LEBEIS: Objection, asked and
18 answered. Mischaracterizes the document
19 and mischaracterizes -- to the extent it
20 mischaracterizes prior testimony.

21 A There's no discussion because there's
22 no problem experienced in this patent.

23 Q And you would agree that in this
24 paragraph that talks about the problem of
25 NSAID-BAC complexation, there's no discussion

1 STEPHEN G. DAVIES, D.PHIL.

2 of the degree of hydrogen bonding among
3 different NSAIDs; is that right?

4 MS. LEBEIS: Objection.

5 Mischaracterizes the document.

6 A There's no discussion because the
7 problem isn't observed in this patent, and
8 that's not the aim of the patent.

9 Q Now, you would agree with me that
10 we're talking here about the "Background of the
11 Invention" section of this '876 patent, right?

12 A Yes.

13 Q And you would agree with me that the
14 "Background of the Invention" section generally
15 doesn't talk about problems that are -- or
16 experimental data that are observed in the
17 context of the patent, right?

18 MS. LEBEIS: Objection. Calls for a
19 legal conclusion. Calls for speculation.

20 A I would think that depends on patent
21 to patent.

22 Q Well, certainly when you publish a
23 paper, when you have a background section of
24 your paper, that's not the section in which you
25 report your experimental data, right?

1 STEPHEN G. DAVIES, D.PHIL.

2 MS. LEBEIS: Objection. No
3 foundation.

4 A You might report the result.

5 Q But, generally, that section is
6 directed to concepts that are known in the
7 background in the relevant field, right?

8 MS. LEBEIS: Objection, no
9 foundation. Asked and answered.

10 A In one of my papers, every statement
11 we would make in the background section would
12 have a reference to it to substantiate whatever
13 comment we were making.

14 Q And those would be comments or
15 concepts that were known in the field already,
16 not new data that you generated in your
17 laboratory, right?

18 MS. LEBEIS: Objection to the form of
19 the question. Vague and ambiguous. No
20 foundation.

21 A I think we would try to put
22 references to everything.

23 Q And those references would reflect
24 what was known in the field already prior to
25 the publication at issue, right?

1 STEPHEN G. DAVIES, D.PHIL.

2 MS. LEBEIS: Objection. Asked and
3 answered. Same objections.

4 A It would be substantiating what we
5 were saying in the background introduction
6 section.

7 Q And that background introduction
8 section would detail information that was known
9 in the relevant field, right?

10 MS. LEBEIS: Objection, no
11 foundation. Asked and answered.

12 A It would show substantiate --
13 substantiatable data, properly referenced --
14 describe substantiatable data with properly
15 referenced.

16 Q And, again, that substantiatable
17 data, properly referenced, would be information
18 that was known in the field, right?

19 MS. LEBEIS: Same objections.

20 A We wouldn't be able to substantiate
21 it if it wasn't known in the field.

22 Q So it would be information that was
23 known in the field then.

24 MS. LEBEIS: Objection.

25 A It would be --

1 STEPHEN G. DAVIES, D.PHIL.

2 MS. LEBEIS: Same objections.

3 A It would be known in the field
4 because we could put a reference to it.

5 Q So a person of ordinary skill in the
6 art reading a patent would understand that the
7 "Background of the Invention" section often
8 sets forth information that's known in the
9 field, right?

10 MS. LEBEIS: Objection to the extent
11 it calls for a legal conclusion. Asked and
12 answered. Calls for speculation.

13 A I don't think that's necessarily
14 true. So I haven't seen any evidence in this
15 case that there is a problem of an insoluble
16 complex.

17 Q Let's see if you can answer the
18 question I'm asking, which is, would a person
19 of skill in the art, reading a background
20 section of a patent, generally understand that
21 that section will include information that's
22 known in the field?

23 MS. LEBEIS: Objection. Calls for a
24 legal conclusion, asked and answered, and
25 calls for speculation.

1 STEPHEN G. DAVIES, D.PHIL.

2 A I'm not sure, if it's not referenced,
3 they would be able to tell whether it was
4 speculation or fact.

5 Q So if a statement in a patent has no
6 reference, in your view, a person of skill in
7 the art would just read it and move on and not
8 pay any attention to it. Is that your
9 testimony?

10 MS. LEBEIS: Objection --

11 A No.

12 MS. LEBEIS: -- to the extent it
13 mischaracterizes prior testimony. Calls
14 for a legal conclusion and speculation.

15 A I think if a person of ordinary skill
16 in the art knew references themselves that
17 substantiated a statement, then that would be
18 fine.

19 MS. RAPALINO: Let's look at another
20 reference, if we could. Let's mark as
21 Davies Exhibit 3 U.S. Patent 5,603,929.

22 (Exhibit 3 was marked for identification
23 and attached to the deposition transcript.)

24 BY MS. RAPALINO:

25 Q Now, Exhibit 3 is another U.S. patent

1 STEPHEN G. DAVIES, D.PHIL.

2 that you considered in forming your opinions,
3 right?

4 A Yes.

5 Q This patent indicates that the date
6 of the patent is February 18th, 1997, right?

7 A That's what it says.

8 Q The patent is entitled "Preserved
9 ophthalmic drug compositions containing
10 polymeric quaternary ammonium compounds,"
11 right?

12 A Yes.

13 Q If you turn to column 1 of the '929
14 patent, Exhibit 3 --

15 A Yes.

16 Q -- and you look at the paragraph that
17 begins at line 27 --

18 A Okay.

19 Q -- you would agree that the patent
20 reports that benzalkonium chloride is widely
21 used in ophthalmic solutions, right?

22 A That's what it says, yes.

23 Q And it goes on in that paragraph in
24 the next sentence to say that BAC and other
25 quaternary ammonium compounds are generally

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considered incompatible with ophthalmic compositions of drugs with acidic groups like NSAIDs. Do you see that?

MS. LEBEIS: Objection.

Mischaracterizes the document.

A It makes that general statement.

Q And then it goes on to make the general statement that this is because the preservative BAC loses its ability to function because it forms complexes with the charged drug compounds. Do you see that?

MS. LEBEIS: Objection.

Mischaracterizes the document.

A It's a general statement without any reference.

Q And that general statement about BAC forming complexes with acidic NSAIDs is not limited to any particular NSAID, right?

A Well, it doesn't even give one example.

Q Right. So it's not limited to even one example, right?

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

1 STEPHEN G. DAVIES, D.PHIL.

2 Mischaracterizes the document.

3 A It doesn't give any evidence that
4 there's a problem with even one. It's just a
5 general statement without any foundation.

6 Q And that general statement is not
7 limited to any particular NSAID. It's about
8 NSAIDs generally, right?

9 MS. LEBEIS: Objection to the extent
10 it mischaracterizes the document. Asked
11 and answered.

12 A Without even giving an example of one
13 occurrence, a person of ordinary skill would
14 have -- wouldn't know on what basis that was
15 being made.

16 Q But you would agree that the general
17 statement itself is not limited to any
18 particular NSAID, right?

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

22 A This is not informing a person of
23 ordinary skill of any instance where there
24 actually is a problem between a carboxylic acid
25 and NSAID and benzalkonium chloride. The

1 STEPHEN G. DAVIES, D.PHIL.

2 actual patent itself is about preservative
3 action, again.

4 Q And this general statement that we
5 just looked at in column 1 ties the formation
6 of complexes between BAC and NSAIDs to the
7 issue of preservatives losing their ability to
8 function, right?

9 MS. LEBEIS: Objection.

10 Mischaracterizes the document.

11 A Well, it doesn't give any evidence
12 that that's true. There would be other ways
13 that preservatives could lose their function.

14 Q But this suggests that one way could
15 be that the preservatives lose their ability to
16 function as they form complexes with the
17 charged drug compounds, right? That's what it
18 suggests?

19 MS. LEBEIS: Objection.

20 Mischaracterizes the document.

21 A But since it doesn't give any
22 examples where it actually happens, it's a
23 meaningless statement.

24 Q It may be true that complexes form
25 which cause the preservatives to lose their

1 STEPHEN G. DAVIES, D.PHIL.

2 efficacy, right?

3 MS. LEBEIS: Objection to the extent
4 it mischaracterizes prior testimony, and
5 asked and answered. Mischaracterizes the
6 document.

7 A Without any examples, it may never be
8 true.

9 Q And it may be true, right?

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

12 A Without examples, you cannot just
13 make the assumption. Otherwise you would have
14 to assume millions of things, billions of
15 things. You need to have a problem that's
16 concrete before you have to worry about it.

17 Q But this patent at column 1 suggests
18 that the problem of complexation leads to
19 preservatives losing their ability to function,
20 right?

21 MS. LEBEIS: Objection, asked and
22 answered. Mischaracterizes the document.

23 A It suggests without any evidence that
24 that might be the case, but unless a person of
25 ordinary skill sees the problem in reality,

1 STEPHEN G. DAVIES, D.PHIL.

2 then it's irrelevant.

3 Q But you can't know with certainty
4 whether or not these complexes form without
5 seeing the test data, right?

6 MS. LEBEIS: Objection. Vague and
7 ambiguous. To the extent it
8 mischaracterizes prior testimony.

9 A You have -- you would not assume
10 there was a problem until you've done a test
11 and found the problem existed.

12 Q You wouldn't know with certainty
13 whether or not a complex formed between a
14 particular NSAID and benzalkonium chloride
15 until you saw the test data, right?

16 A Sorry, I missed the first part of
17 that question.

18 (Record read.)

19 A You would not know, no.

20 Q In this patent, the '929 patent,
21 Exhibit 3, there is no discussion in this
22 section that talks about this potential problem
23 of complexation about differences between
24 NSAIDs in terms of their chemical structure,
25 right?

1 STEPHEN G. DAVIES, D.PHIL.

2 MS. LEBEIS: Objection, no
3 foundation. Mischaracterizes the document.

4 A There isn't, nor would one expect
5 there to be when the problem isn't actually
6 observed.

7 Q There's also no discussion in this
8 section of the patent that talks about the
9 potential problem of complexation between
10 NSAIDs and BAC of the differences in electron
11 density between different NSAIDs, right?

12 MS. LEBEIS: Same objections.

13 A There isn't, nor would a person of
14 ordinary skill expect there to be when the
15 problem isn't presented.

16 Q There's also no discussion in this
17 '929 patent of the differences between NSAIDs
18 in terms of whether they're primary, secondary,
19 or tertiary amines as being relevant to this
20 issue of potential complexation, right?

21 MS. LEBEIS: Same objection.

22 A The patent is not about potential
23 complexation so there would be no discussion.

24 Q There's also no discussion, in this
25 section of the patent that talks about the

1 STEPHEN G. DAVIES, D.PHIL.

2 problem of potential complexation between
3 NSAIDs and BAC, of the differences between
4 NSAIDs in terms of the presence or absence of
5 halogenation on the compounds?

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

8 A There wouldn't be because that's not
9 the problem being addressed by the patent.

10 Q And there's also no discussion in
11 this patent, in the section that talks about
12 the potential complexation between NSAIDs and
13 BAC, about differences in lipophilicity between
14 different NSAIDs, right?

15 MS. LEBEIS: Objection.

16 Mischaracterizes the document.

17 A I lost the end of the sentence, end
18 of the question.

19 (Record read.)

20 MS. LEBEIS: Objection.

21 A There isn't because it's irrelevant
22 to what the main part of the patent is about.

23 Q And there's also no discussion in
24 this patent in the section that talks about
25 potential complexation between NSAIDs and BAC

1 STEPHEN G. DAVIES, D.PHIL.

2 of differences between NSAIDs in terms of their
3 degree of hydrogen bonding, right?

4 MS. LEBEIS: Objection.

5 Mischaracterizes the document.

6 A There wouldn't be because such facts
7 are irrelevant to the rest of the patent and
8 what it's actually dealing with.

9 Q What do you think this patent is
10 directed to, this Exhibit 3, '929 patent?

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

13 A Well, the data that's presented has
14 to do with preservative action.

15 Q So this patent is directed to
16 ophthalmic pharmaceutical compositions with
17 good preservative efficacy?

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

21 A As I said, the data that is presented
22 has to do with preservative action.

23 Q In what kind of formulations?

24 A (Document review.)

25 In diclofenac formulations. This is

1 STEPHEN G. DAVIES, D.PHIL.

2 another one, sulfacetamide and suprofen. Those
3 three are formulated.

4 Q So this patent provides a formulation
5 that's suitable for use with those three
6 compounds; is that right?

7 MS. LEBEIS: Objection.

8 Mischaracterizes the document.

9 A (Document review.)

10 The results seem to be on formulation
11 A, which is sodium diclofenac, in terms of its
12 preservation activity.

13 Q In your view, is the subject of the
14 patent then limited to formulations of
15 diclofenac sodium?

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

18 A That's a legal question. It's not
19 for me to say. But the data is only presented
20 for, as far as I can see, for formulation A,
21 which has diclofenac in it.

22 Q So you don't have an opinion one way
23 or another on whether this patent is limited to
24 formulations of diclofenac sodium or includes
25 other formulations?

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

4 A The data presented and what a person
5 of ordinary skill would see is data on sodium
6 diclofenac.

7 Q Now, if we go back to the paragraph
8 in column 1, starting at line 27.

9 A Yes.

10 Q So if you can keep that open and then
11 go back to Exhibit 2.

12 A Okay.

13 Q And look at the paragraph we looked
14 at in column 1 of Exhibit 2, the '876 patent
15 that starts at line 10.

16 A Starts at line --

17 Q 10.

18 A 10?

19 Q Column 1.

20 A Okay.

21 Q You would agree that the statements
22 in Exhibit 2, the '876 patent, in column 1, are
23 consistent with the statements in Exhibit 3,
24 the '929 patent, at column 1?

25 MS. LEBEIS: Objection to the form of

1 STEPHEN G. DAVIES, D.PHIL.

2 the question. Vague and ambiguous.

3 A They're broadly consistent. They're
4 from the same -- both patents are from the same
5 company. There's no evidence in either of them
6 that they're true or not.

7 Q I think you pointed out, they're both
8 from Alcon Laboratories, Inc., right, both of
9 those patents?

10 A That's correct.

11 MS. RAPALINO: Let's mark as Davies
12 Exhibit 4 European Patent 0306984.

13 (Exhibit 4 was marked for identification
14 and attached to the deposition transcript.)

15 BY MS. RAPALINO:

16 Q Dr. Davies, this is a European patent
17 you considered in forming your opinions in this
18 case?

19 A Yes.

20 Q Is it okay if we refer to that as EP
21 '984?

22 A That's fine.

23 Q This patent has a date of publication
24 of March of '89; is that right?

25 A That's correct, yes.

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2 Q This patent is -- indicates that the
3 applicant is Syntex, Inc., right?

4 MS. LEBEIS: Objection.

5 Mischaracterizes the document.

6 A It says, "Applicant, Syntex, Inc."

7 Q That's a separate company from Alcon
8 Laboratories, right?

9 MS. LEBEIS: Objection. Calls for
10 speculation.

11 A I don't know.

12 Q Well, it doesn't list Alcon as the
13 applicant, right?

14 A It does not.

15 MS. LEBEIS: Objection,
16 argumentative.

17 A It doesn't say Alcon.

18 Q And the inventors listed on this
19 patent are not the same inventors as the --
20 those on Exhibits 2 and 3 that we looked at
21 earlier, right?

22 A They're not, no.

23 Q Now, if we look at page 2 of EP '984,
24 Exhibit 4.

25 A Page 2.

1 STEPHEN G. DAVIES, D.PHIL.

2 Q Page 2.

3 A Okay.

4 Q You see that in the paragraph
5 beginning at line 10, EP '984 describes an
6 earlier patent, U.S. Patent 4,454,151?

7 A Yes.

8 MS. LEBEIS: Is that a question? Is
9 there a question?

10 MS. RAPALINO: Yes, I think we just
11 got an answer to it.

12 A I see the patent number there, yes.

13 Q Yes. And then it goes on to say that
14 "While the formulations described in the '151
15 patent were efficacious, an insoluble complex
16 was found to form between the NSAID and BAC."
17 Do you see that?

18 A That's what it says.

19 Q And if you go down to page 2, line
20 31 --

21 A Yes.

22 Q -- you see there's a sentence that
23 says, "Benzalkonium chloride, a quaternary
24 ammonium compound, has been widely used in
25 ophthalmic solutions and is considered to be

1 STEPHEN G. DAVIES, D.PHIL.

2 the preservative of choice"?

3 A That's what it says.

4 Q You don't disagree that benzalkonium
5 chloride had been widely used in ophthalmic
6 formulations and was a preservative of choice,
7 do you?

8 MS. LEBEIS: Objection. Calls for
9 speculation.

10 A I haven't done that analysis.

11 Q So you don't have an opinion one way
12 or another?

13 A Since I haven't done the analysis.

14 Q So you don't have an opinion one way
15 or another?

16 MS. LEBEIS: Asked and answered.

17 A I haven't done the analysis so I
18 don't. I don't know. And I suspect it depends
19 on the ophthalmic solution as what the
20 preservative of choice is. I've seen others
21 that don't have the benzyl ammonium, the
22 quaternary ammonium compound.

23 Q But you haven't done the analysis one
24 way or another to know when benzalkonium
25 chloride would be a preservative of choice,

1 STEPHEN G. DAVIES, D.PHIL.

2 right?

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

5 A I haven't done the analysis, and I
6 suspect it depends on which formulation we're
7 talking about as to which would be the
8 preservative of choice.

9 Q That suspicion that you have is not
10 based on any analysis that you've done; is that
11 right?

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

14 A I've not done a detailed analysis,
15 but I have seen formulations that don't contain
16 benzalkonium chloride as a preservative.

17 Q Which formulations are those?

18 A I think we saw some earlier in one of
19 the patents we've already looked at.

20 Q Do you want to tell me which
21 formulation that was?

22 A (Document review.)

23 In the '929 patent.

24 (Document review.)

25 Q Apart from the formulation that

1 STEPHEN G. DAVIES, D.PHIL.

2 you've seen in the '929 patent, are you aware
3 of any other formulations for ophthalmic use
4 that don't contain benzalkonium chloride as the
5 preservative?

6 MS. LEBEIS: Dr. Davies, you can take
7 your time looking at the '929 patent in
8 answering counsel's question.

9 Q Just to be clear, though, my question
10 is, apart from the formulations in the '929
11 patent, are you aware of any ophthalmic
12 formulations that don't contain benzalkonium
13 chloride as the preservative? I don't think
14 you need to look at the '929 patent to answer
15 that question. But if you feel you do, please
16 feel free.

17 A I believe I've seen other
18 formulations, yes.

19 Q Can you point to any of those
20 formulations?

21 A Not sitting here at this moment.

22 Q Let's go back to Exhibit 4, the EP
23 '984 patent.

24 Okay. If you look at page 2 again,
25 at line 33, you see that the EP '984 patent

1 STEPHEN G. DAVIES, D.PHIL.

2 goes on to say that "BAC has typically been
3 considered to be incompatible with anionic
4 drugs, forming insoluble complexes which cause
5 the solution to become cloudy or turbid."

6 Do you see that it says that?

7 MS. LEBEIS: Objection.

8 Mischaracterizes the document.

9 A That's what it says.

10 Q It goes on to say that such
11 complexation between an anionic drug and BAC
12 can cause a decrease in the pharmaceutical
13 activity of the drug.

14 Do you see that?

15 MS. LEBEIS: Objection.

16 Mischaracterizes the document.

17 A It's the same as the previous cases.
18 I don't see any evidence that that's true, that
19 there is a problem.

20 Q You would agree, though, that EP '984
21 asserts that that's a problem, right?

22 MS. LEBEIS: Objection to the form of
23 the question, asked and answered, to the
24 extent it mischaracterizes prior testimony.

25 A It makes a broad statement without

1 STEPHEN G. DAVIES, D.PHIL.

2 any evidence.

3 Q And that broad statement is that
4 there's a problem of complexation between
5 anionic drugs and BAC, right?

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

9 A It doesn't give any evidence that
10 such a complex would form.

11 Q But the EP '984 nonetheless makes the
12 broad statement that there is a problem of
13 complexation between anionic drugs and BAC,
14 right?

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

19 A Without any evidence, a person of
20 ordinary skill wouldn't be able to take
21 anything from that.

22 Q Let's look at paragraph -- the
23 paragraph on page 2 just below the one we were
24 looking at.

25 A Okay.

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2 Q Do you see that it says "In the past,
3 as in the case with other ophthalmic drugs that
4 contain a carboxylic acid group,
5 anti-inflammatory solutions of NSAIDs for
6 ocular use have proven to be incompatible with
7 quaternary ammonium compounds such as BAC."

8 MS. LEBEIS: Objection.

9 Mischaracterizes the document.

10 Q Do you see that it says that?

11 A It says those words, but there's no
12 evidence to allow person of ordinary skill to
13 understand if they're correct or not.

14 Q Okay. But those are the words that
15 the patent uses, right?

16 MS. LEBEIS: Objection. Asked and
17 answered.

18 A The words are written down in the
19 patent, but, without any evidence, a person of
20 ordinary skill can't take anything from them.

21 Q And it goes on to explain that this
22 incompatibility is due to the fact that the
23 carboxylic acid group can form a complex with
24 the quaternary ammonium compound, rendering the
25 preservative less available to serve its

1 STEPHEN G. DAVIES, D.PHIL.

2 function and reducing the activity of the
3 active ingredient, right? That's what it says?

4 MS. LEBEIS: Objection,
5 mischaracterizes the document.

6 A That's an assumption for which there
7 is no evidence.

8 Q So this EP '984 patent talks about
9 the general problem of complexation between
10 drugs, ophthalmic drugs in the carboxylic acid
11 group and benzalkonium chloride consistent with
12 the way that that problem was discussed in
13 Exhibits 2 and 3, the '876 and '929 patents,
14 right?

15 MS. LEBEIS: Objection.

16 Mischaracterizes the document. Asked and
17 answered.

18 A In none of the patents is there any
19 evidence that this problem actually exists.

20 Q You would agree, though, that the
21 statement of this problem in EP '984 at the
22 paragraph from line -- on page 2, lines 29
23 through 44 is consistent with the statement we
24 looked at in the '876 patent, Exhibit 2, at
25 column 1, lines 10 through 24, right?

1 STEPHEN G. DAVIES, D.PHIL.

2 MS. LEBEIS: Objection to the form of
3 the question and to the extent it
4 mischaracterizes prior testimony.

5 A They describe the same general
6 purported problem for which there is no
7 evidence being presented. So a person of
8 ordinary skill wouldn't be concerned about it
9 unless they faced it.

10 Q And the discussion in EP '984 of this
11 general problem of complexation between
12 carboxylic-acid-containing compounds and BAC
13 does not mention any differences between
14 different NSAID compounds, in terms of their
15 chemical structure, as being relevant to that
16 problem, right?

17 MS. LEBEIS: Objection.

18 Mischaracterizes the document.

19 A Well, it wouldn't, though, because
20 it's not what the rest of the patent is about.
21 So they wouldn't need to discuss those things.

22 Q There's also no discussion in the EP
23 '984 of any differences between NSAID compounds
24 in terms of their electron density, right?

25 MS. LEBEIS: Same objection.

1 STEPHEN G. DAVIES, D.PHIL.

2 A It wouldn't discuss such matters
3 because they're irrelevant to what the rest of
4 the patent is discussing.

5 Q There's also no discussion in EP '984
6 of differences between NSAIDs in terms of
7 whether they're primary, secondary, or tertiary
8 amines, right?

9 MS. LEBEIS: Same objection.

10 A They wouldn't do because it's not
11 what the patent goes on to discuss.

12 Q There is also no discussion in EP
13 '984 of the impact of the presence or absence
14 of halogenation on NSAIDs as relevant to the
15 issue of complexation, right?

16 MS. LEBEIS: Same objection and
17 objection to the form of the question.

18 A It wouldn't discuss that because it's
19 not relevant to the rest of the patent.

20 Q So there's no discussion, right?

21 MS. LEBEIS: Same objection.

22 A Nor would a person of ordinary skill
23 expect there to be a discussion.

24 Q So there is no discussion in the
25 patent of presence or absence of halogenation

1 STEPHEN G. DAVIES, D.PHIL.

2 of different NSAIDs, right?

3 MS. LEBEIS: Same objection.

4 A There is no discussion because it's
5 irrelevant to the rest of the patent.

6 Q There's also no discussion in the
7 patent of the differences between NSAIDs in
8 terms of their degree of lipophilicity with
9 respect to this problem of complexation, right?

10 MS. LEBEIS: Same objection.

11 A There is no discussion because it
12 would be irrelevant to the rest of the patent.

13 Q There's also no discussion in the
14 patent regarding the degree -- differences in
15 the degree of hydrogen bonding as between
16 different NSAIDs as it relates to the issue of
17 complexation.

18 MS. LEBEIS: Same objection.

19 A No, because it's irrelevant to the
20 rest of the patent.

21 Q And there's also no discussion about
22 the degree of solvation of any of the NSAIDs in
23 this patent in relation to the problem of
24 complexation, right?

25 MS. LEBEIS: Objection.

1 STEPHEN G. DAVIES, D.PHIL.

2 Mischaracterizes the document.

3 A I don't believe so because it would
4 be, well, irrelevant to the rest of the patent.

5 Q Now, let's look at page 4.

6 A Yes.

7 Q And there are some examples given of
8 formulations according to the invention of this
9 patent, right? Do you see the tables?

10 A I see the boxes, yes.

11 Q And each of those formulations on
12 page 4 and over to the top of page 5 lists the
13 active ingredient as NSAID. Do you see that?

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

16 A It said these are preferred
17 formulations. They're not actual formulations
18 unless they release the NSAID in that
19 formulation.

20 Q Right. So these just say generically
21 NSAID for these preferred formulations, right?

22 MS. LEBEIS: Objection.

23 Mischaracterizes the document.

24 A Well, it says "NSAID." It could be
25 one particular NSAID. You have to read the

STEPHEN G. DAVIES, D.PHIL.

1 whole of the rest of the patent to determine
2 whether it's one or any one.
3

4 Q And then if we look at page 6 of the
5 EP '984, Exhibit 4 --

6 A Yes.

7 Q -- there are some more preferred
8 ophthalmic NSAID solutions listed on page 6.
9 Do you see that?

10 A Yes.

11 Q And each of those lists the active
12 ingredient as NSAID, right?

13 A Yes. But, again, that could be one
14 or more. You have to read the whole patent.

15 Q Then if we look at the examples in
16 the EP '984 patent, Exhibit 4, starting at page
17 7, and going on to page 8 --

18 A Yes.

19 Q -- there are examples of
20 representative pharmaceutical formulations. Do
21 you see that?

22 A Yes.

23 Q The active ingredient in some of
24 those formulations is ketorolac tromethamine.
25 Do you see that?

1 STEPHEN G. DAVIES, D.PHIL.

2 A In the first three, which is
3 consistent with the statement underneath the
4 general boxes on page 8, where it says the
5 "most preferred is the ophthalmic solution
6 according to the above formulation wherein the
7 NSAID is ketorolac tromethamine or an isomer
8 thereof," yes.

9 Q And ketorolac tromethamine is an
10 NSAID, right?

11 A Yes.

12 Q It's a carboxylic acid containing
13 NSAID?

14 A Yes.

15 Q And it's an NSAID that's anionic at
16 pH 7 to 9, right?

17 A Yes.

18 Q Each of these formulations in EP
19 '984, Exhibit 4, contain octoxynol 40. Do you
20 see that?

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

23 A It's listed in them, yes.

24 Q Have you ever worked with octoxynol
25 40?

1 STEPHEN G. DAVIES, D.PHIL.

2 A I personally haven't, no.

3 Q Octoxynol 40 is an ethoxylated
4 octylphenol compound, right?

5 A Yes.

6 Q On page 9 of EP '984, under example
7 5, the EP '984 patent compares formulations of
8 ketorolac tromethamine, benzalkonium chloride,
9 and three different surfactants in three
10 different formulations, right?

11 A Yes.

12 Q If you look at line 11 on page 9, it
13 describes the experiment of example 5, and it
14 says, "Three surfactants were evaluated for
15 their ability to dissolve the
16 ketorolac-benzalkonium chloride complex and
17 maintain a physically clear solution over an
18 extended period of time."

19 Do you see that?

20 A Yes.

21 Q The three surfactants that were
22 tested in example 5 were octoxynol 40,
23 polysorbate 80, and Myrj 52. Do you see that?

24 MS. LEBEIS: Objection.

25 Mischaracterizes the document.

1 STEPHEN G. DAVIES, D.PHIL.

2 A I see that. It says tween on -- in
3 the actual table, but ...

4 Q Tween 80 is the same as polysorbate
5 80, right?

6 A As it says above, yes.

7 Q The results presented in the table in
8 example 5 show that the ethoxylated octylphenol
9 surfactant, octoxynol 40, was the best among
10 those tested in that it provided a clear
11 solution at all the time points and conditions
12 tested, right?

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

15 A It says it was superior, yes.

16 Q For the formulations tested in EP
17 '984, the ethoxylated octylphenol surfactant,
18 octoxynol 40, provided the superior results in
19 terms of solubilization at all of the test
20 conditions, right?

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

23 A Well, to the extent that it remained
24 clear all the time, yes.

25 Q For ophthalmic solutions, it's

1 STEPHEN G. DAVIES, D.PHIL.

2 desirable to have a solution that remains
3 clear, right?

4 MS. LEBEIS: Objection. Calls for
5 speculation.

6 THE WITNESS: Can you repeat the
7 question, please.

8 (Record read.)

9 THE WITNESS: I didn't get the first
10 two words.

11 (Record read.)

12 A Yes.

13 MS. LEBEIS: We've been going about
14 an hour. Do you think it's a good time to
15 take a lunch break?

16 MS. RAPALINO: Can I do one more
17 document and then we'll break? Are you
18 okay with that?

19 THE WITNESS: That's fine, yes.

20 MS. LEBEIS: Yes, that's fine.

21 BY MS. RAPALINO:

22 Q In your view, do the results
23 presented in example 5 provide any evidence of
24 complexation between an NSAID and benzalkonium
25 chloride?

1 STEPHEN G. DAVIES, D.PHIL.

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

4 A There's no analytical data to suggest
5 what is making some of these solutions turbid.

6 Q So something is making some of the
7 solutions turbid. You would agree with that,
8 right?

9 A But there's no indication as to what
10 that might be. So you can't assume and you
11 wouldn't assume that it's a
12 ketorolac-benzalkonium chloride complex.

13 Q EP '984 doesn't provide any
14 suggestion about what else that precipitate or
15 turbidity might be, right?

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

18 A It doesn't give you any indication
19 what it is in fact. There's no data produced.

20 Q And just to be clear, EP '984, even
21 if it has no data to back it up, certainly
22 suggests that these surfactants were being
23 evaluated for their ability to dissolve the
24 ketorolac-benzalkonium chloride complex. Do
25 you see that?

1 STEPHEN G. DAVIES, D.PHIL.

2 A Objection to the extent it
3 mischaracterizes the document.

4 A person of ordinary skill reading
5 that would not -- and reading the experimental
6 that's been done would not be able to
7 understand the experiment because it says "were
8 evaluated for their ability to dissolve
9 ketorolac-benzalkonium chloride complex." That
10 would imply that there is solid
11 ketorolac-benzalkonium chloride complex
12 available as solid form and that it was being
13 dissolved. That is not what is -- that is not
14 the experiment that they do.

15 Q So, in your opinion, a person of
16 skill in the art wouldn't understand this
17 experiment in example 5 of EP '984, Exhibit 4?

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

20 A I've told you what the words would
21 mean to a person of ordinary skill. When you
22 dissolve something, you take a solid, and you
23 add a liquid, and you watch the solid dissolve
24 in a liquid.

25 Q So with that semantic definition of

1 STEPHEN G. DAVIES, D.PHIL.

2 dissolve, a person of skill in the art then
3 would be at a loss to understand what was being
4 done in this experiment in example 5 of EP
5 '984. Is that your testimony?

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

8 A They could go back and look at the
9 actual experimental, which is also -- no, that
10 is not a proper description.

11 Q Where do you see the actual
12 experimental?

13 A Well, it lists the ingredients, none
14 of which are ketorolac -- any ketorolac-BAC
15 complex. So they would -- they would -- they
16 would know that -- so this is on page 7 under
17 the box.

18 It says, "The above ingredients,"
19 none of which are ketorolac-benzalkonium
20 chloride complex, "are mixed, adding purified
21 water until they're dissolved, and the pH
22 adjusted to 7.4," then the balance made up with
23 purified water. So they can read the actual
24 experiment that was done.

25 Q So then they would understand what

1 STEPHEN G. DAVIES, D.PHIL.

2 experiment is being done in example 5?

3 A And, therefore, that it isn't what's
4 written above the quote you gave to me, which
5 was the ability to dissolve
6 ketorolac-benzalkonium chloride.

7 Q Now, you don't actually think that
8 the formulations that were tested in example 5
9 were all the formulation that you pointed to on
10 page 7, right?

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

13 A It's given the general experimental
14 of how these solutions were being made up.

15 Q Okay. So you're just pointing to
16 page 7 to show how they're manufacturing the --
17 how they're making the formulation, right, that
18 they're mixing the ingredients and adding
19 purified water until they're dissolved? Is
20 that what you mean?

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

24 A What I'm trying to illustrate is that
25 they really are not starting from

1 STEPHEN G. DAVIES, D.PHIL.

2 ketorolac-benzalkonium chloride complex and
3 trying to dissolve that, which is what is
4 implied in lines 11 to 12 on page 9.

5 Q Okay. But in the context of the rest
6 of the patent, a person of ordinary skill in
7 the art reading example 5 would understand that
8 example 5 is intended to evaluate the ability
9 of these different surfactants to solubilize
10 any complexes that are formed between ketorolac
11 and benzalkonium chloride, right?

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

14 A There is not -- there is nothing
15 in -- no data produced to say that the
16 turbidity is -- turbidity, rather, is due to a
17 complex between ketorolac and benzalkonium
18 chloride.

19 Q That's just what's being suggested by
20 the author, right, without any data, that
21 what's being evaluated here is the ability to
22 solubilize those complexes?

23 MS. LEBEIS: Objection.

24 Mischaracterizes the document.

25 A Well, there's no -- there's no --

1 STEPHEN G. DAVIES, D.PHIL.

2 without any evidence as to what this
3 precipitate or the turbidity is due to, you
4 can't tell what is being solubilized.

5 Q What else, in your view, could cause
6 the turbidity in this solution?

7 MS. LEBEIS: Objection. Vague and
8 ambiguous, incomplete.

9 A Any --

10 MS. LEBEIS: One second. Also
11 incomplete hypothetical.

12 A Without experimentation, you can't
13 tell what the turbidity is due to.

14 Q So you don't have a view, one way or
15 the other, whether there's anything else that
16 could be causing the turbidity in this
17 composition?

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

20 A Until you know what the turbidity is
21 due to, you can't possibly tell what is causing
22 it.

23 MS. RAPALINO: Let's mark as Davies
24 Exhibit --

25 MS. LEBEIS: We went another 10

1 STEPHEN G. DAVIES, D.PHIL.

2 minutes on this reference. Would it be
3 okay to take a lunch break now?

4 MS. RAPALINO: Dr. Davies, do you
5 need a lunch break?

6 THE WITNESS: Yes, can we?

7 MS. RAPALINO: Sure.

8 THE VIDEOGRAPHER: We're going off
9 the record at 12:36 p.m.

10 (A lunch recess was taken.)

11 THE VIDEOGRAPHER: We're going back
12 on record at 1:20 p.m. This is the start
13 of disc number 4 in the deposition of
14 Stephen Davies.

15 MS. RAPALINO: I'm going to ask the
16 court reporter to mark as Davies 5 an
17 international patent application WO
18 94/15597.

19 (Exhibit 5 was marked for identification
20 and attached to the deposition transcript.)

21 BY MS. RAPALINO:

22 Q Is this an international or PCT
23 patent application you considered in forming
24 your opinions in this case?

25 A Yes.

1 STEPHEN G. DAVIES, D.PHIL.

2 Q It was published in July of 1994; is
3 that right?

4 A That's the international publication
5 date, yes.

6 Q And you see that it's entitled
7 "Ophthalmic compositions comprising
8 benzyl-lauryl-dimethyl-ammonium chloride."

9 A Yes.

10 Q Now, benzyl-lauryl-dimethyl-ammonium
11 chloride is sometimes abbreviated LAC, or
12 L-A-C, right?

13 A I believe so.

14 Q That's a different preservative from
15 BAC; is that right?

16 A It's a similar type.

17 Q So they're similar preservative?

18 A They're similar in the sense that
19 they're benzyl ammonium salts.

20 Q Okay.

21 If you look at page 2 of this PCT
22 application -- and if it's okay with you, I'll
23 refer to it as the WO '597 application; is that
24 right?

25 A Okay.

1 STEPHEN G. DAVIES, D.PHIL.

2 Q So let's turn to page 2 of WO '597.
3 And if you look at the first paragraph on page
4 2, WO '597 reports that "BAC is a quaternary
5 ammonium compound that has been widely used in
6 ophthalmic solutions, right?

7 MS. LEBEIS: Objection.

8 Mischaracterizes the document.

9 A That's what it says.

10 Q And then it goes on to say in the
11 second sentence in that first paragraph on page
12 2, "It is also well-known that BAC is
13 considered incompatible with anionic drugs,
14 forming insoluble compounds which cause the
15 solution to turn cloudy."

16 Do you see that?

17 MS. LEBEIS: Objection.

18 Mischaracterizes the document.

19 A I read the words, yes.

20 Q If you go back to the cover page of
21 WO '597, Exhibit 5, you see that the applicant
22 for this international application is Allergan,
23 Inc., right?

24 A Yes.

25 Q That's another pharmaceutical company

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STEPHEN G. DAVIES, D.PHIL.

that specializes in ophthalmic products, right?

MS. LEBEIS: Objection. Calls for speculation.

A I don't know that.

Q You're not familiar with Allergan?

A I've heard of it, but I don't know that its speciality is ophthalmic.

Q Okay. You know it's a pharmaceutical company?

MS. LEBEIS: Objection. Calls for speculation.

A I believe it to be a pharmaceutical company, yes.

Q Then if you look at -- going back to page 2 of WO '597, the next two paragraphs on page 2 go on to describe the reason for the complexation phenomenon that was discussed in the first paragraph, right?

MS. LEBEIS: Objection.

Mischaracterizes the document.

A Well, it doesn't give any evidence in those paragraphs so it's speculation.

Q Right. So it provides some speculation about the reason behind the

1 STEPHEN G. DAVIES, D.PHIL.

2 formation of insoluble precipitates of NSAIDs
3 and quaternary ammonium compounds, right?

4 MS. LEBEIS: Objection to the extent
5 it mischaracterizes the document. Calls
6 for speculation.

7 A It doesn't give any evidence that any
8 cloudiness or precipitate is due to the
9 interaction of the positively charged
10 preservative with the negatively charged
11 active.

12 Q WO '597 here is positing a theory as
13 to what might lead to insoluble compounds due
14 to the association between benzalkonium
15 chloride and a negatively charged acidic drug,
16 right?

17 MS. LEBEIS: Objection.

18 Mischaracterizes the document. Calls for
19 speculation.

20 A They're making -- they put those
21 words in the introductory paragraph without any
22 backup. So I don't know what a person of
23 ordinary skill would take from it in terms of
24 fact.

25 Q But they're positing a theory, right,

1 STEPHEN G. DAVIES, D.PHIL.

2 as to what might lead to insoluble complexes
3 due to the association between benzalkonium
4 chloride and a negatively charged acidic drug,
5 right?

6 MS. LEBEIS: Objection.

7 Mischaracterizes the document, calls for
8 speculation, and asked and answered.

9 A It's what it says in the introductory
10 part for this prep.

11 Q And what it says in these first three
12 introductory paragraphs of WO '597, that's
13 consistent with what we saw in Exhibit 4, EP
14 '984, and Exhibit 3, the '929 patent, and
15 Exhibit 2, the '876 patent, right?

16 MS. LEBEIS: Objection, form of the
17 question. You should feel free to go back
18 and look at those other documents if you
19 need to.

20 A Well, it's not exactly the same
21 wording. This has different suggestions than
22 the other patents.

23 Q The concept, though, is the same, is
24 consistent between this patent, the WO '597,
25 and the earlier Exhibits 2, 3, and 4 that we

1 STEPHEN G. DAVIES, D.PHIL.

2 looked at in terms of the description of the
3 general phenomenon of an insoluble precipitate
4 forming between an acidic NSAID and
5 benzalkonium chloride, right?

6 MS. LEBEIS: Objection.

7 Mischaracterizes the documents. Calls for
8 speculation. Asked and answered.

9 A There can't be a general phenomenon
10 if there's no evidence that it's actually
11 occurring.

12 Q You would agree, though, that this WO
13 '597, consistent with the prior three exhibits
14 that we looked at, Exhibits 4, 3, and 2,
15 provides a general description of a phenomenon
16 even without evidence, but they all provide a
17 consistent description of the phenomenon of the
18 formation of an insoluble precipitate due to
19 the formation -- due to the interaction of
20 benzalkonium chloride and an acidic drug or
21 NSAID, right?

22 MS. LEBEIS: Objection.

23 Mischaracterizes the documents, calls for
24 speculation, asked and answered, and
25 objection to the form of the question.

1 STEPHEN G. DAVIES, D.PHIL.

2 A A phenomenon is something that
3 actually exists that needs an explanation. I
4 haven't seen that -- any evidence that you get
5 a precipitate from benzalkonium chloride and
6 carboxylic acid.

7 Q So your issue is with the word
8 "phenomenon"? Is that the problem?

9 A That's one of the issues, I suspect.

10 Q So why don't we try this. You would
11 agree with the description of this potential
12 problem in WO '597 of interaction between
13 benzalkonium chloride and anionic drugs is
14 consistent with the description of that same
15 problem we looked at in Exhibits 4, 3, and 2,
16 right?

17 MS. LEBEIS: Objection.

18 Mischaracterizes the documents, calls for
19 speculation, asked and answered, and
20 objection to the form of the question.

21 A I don't think in any of the cases
22 it's a problem because it hasn't been shown to
23 exist.

24 Q The speculation in each of these
25 references about a potential problem in the

1 STEPHEN G. DAVIES, D.PHIL.

2 formation of a complex between benzalkonium
3 chloride and an NSAID is consistent as between
4 WO '597 and the other references that we looked
5 at, EP '984, U.S. patent '929, and U.S. patent
6 '876, right?

7 MS. LEBEIS: Objection.

8 Mischaracterizes the documents, calls for
9 speculation, objection to the form of the
10 question, and asked and answered. He's
11 answered this question. You've asked it
12 now several times.

13 A Without some evidence, you don't know
14 the problem exists. And in none of the
15 previous cases we looked at did whatever was
16 being suggested have anything to do with the
17 bulk of the patent.

18 Q Let's look at EP '984 at Exhibit 4.

19 A Yes.

20 Q You would agree with me, would you
21 not, that on page 2 of EP '984 at line 31, the
22 European patent says that "benzalkonium
23 chloride has been widely used in ophthalmic
24 solutions," right?

25 MS. LEBEIS: Objection.

1 STEPHEN G. DAVIES, D.PHIL.

2 Mischaracterizes the document.

3 A That's what it says there, but --

4 Q Then if you look at --

5 A -- I have no way of knowing that
6 that's --

7 Q I didn't ask about what you know. I
8 just asked whether that's what the patent said.
9 Do you understand the question?

10 A That is what the patent says, yes.

11 Q Then if you look at Exhibit 5 that we
12 were just looking at, the WO '597, at page 2 --

13 A Yes.

14 Q -- you see at the top of the page 2,
15 the first sentence also says, "Benzalkonium
16 chloride has been widely used in ophthalmic
17 solutions."

18 Do you see that?

19 MS. LEBEIS: Objection.

20 Mischaracterizes the document.

21 A That's what it says in the document,
22 yes.

23 Q So those two statements in the two
24 patents we just looked at are consistent with
25 one another, right?

1 STEPHEN G. DAVIES, D.PHIL.

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

4 A Well, that single sentence is they're
5 consistent with one another, but you have to
6 read them in context in each of the patents.

7 Q Okay. Let's look at some more of the
8 context then. If you could go back to Exhibit
9 4, the EP '984.

10 A Yes.

11 Q And let's look at the next sentence
12 on page 2 that starts at line 33.

13 A Yes.

14 Q It says that "BAC has typically been
15 considered to be incompatible with anionic
16 drugs, forming insoluble complexes which cause
17 the solution to become cloudy."

18 Do you see that?

19 MS. LEBEIS: Objection.

20 Mischaracterizes the document.

21 A Well, it actually quotes as the
22 anionic drug salicylates and nitrates.

23 Q Okay. So with that amendment, you
24 agree that's what it says in EP '984?

25 MS. LEBEIS: Objection to the extent

1 STEPHEN G. DAVIES, D.PHIL.

2 it mischaracterizes prior testimony.

3 A There's no evidence that --

4 Q I'm not asking about evidence now.

5 MS. LEBEIS: You need to let him
6 finish answering the question.

7 MS. RAPALINO: He needs to answer my
8 question.

9 MS. LEBEIS: You need to let him
10 finish answering the question and give his
11 full answer to your question before you
12 start with another question.

13 BY MS. RAPALINO:

14 Q Dr. Davies, you would agree that EP
15 '984, starting at line 33, says, "BAC has
16 typically been considered to be incompatible
17 with anionic drugs (e.g., salicylates or
18 nitrates, et cetera), forming insoluble
19 complexes which cause the solution to become
20 cloudy or turbid."

21 Do you see that?

22 A I can see the words written there.

23 Q And then if you look at --

24 MS. LEBEIS: He wasn't finished
25 answering the question.

1 STEPHEN G. DAVIES, D.PHIL.

2 MS. RAPALINO: That was the answer to
3 the question.

4 MS. LEBEIS: He had not finished
5 answering the question.

6 Dr. Davies, you can finish answering.

7 BY MS. RAPALINO:

8 Q Could you turn, Dr. Davies, to --

9 A But there was -- there's no evidence
10 provided that that is a real phenomenon.

11 Q Did you think that was the answer to
12 the question about whether the words were
13 written on the page?

14 MS. LEBEIS: Objection to the form of
15 the question. Argumentative.

16 A I'm giving you the answer I think is
17 the answer I wish to give to the question you
18 asked me.

19 Q You've got to answer the questions I
20 ask, not just give the testimony you wish to
21 give. Do you understand that?

22 A I believe I'm answering the questions
23 you ask.

24 Q So let's go on to my next question.
25 Let's see if you can answer the question I ask.

1 STEPHEN G. DAVIES, D.PHIL.

2 If you look at WO '597, which is
3 Exhibit 5, do you see that in the second
4 sentence, it says, "It is also well-known,
5 however, that benzalkonium chloride is
6 considered incompatible with anionic drugs,
7 forming insoluble compounds which cause the
8 solution to turn cloudy."

9 Do you see that it says those words?

10 A Those are the words that are written
11 down, yes.

12 Q You would agree that that sentence is
13 consistent with the sentence that we just read
14 from EP '984 on page 2, lines 33 through 35.

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

17 A They're not exactly the same words.

18 Q Right. So which words do you think
19 are different?

20 A So which were the lines you were
21 asking me about on the '984?

22 Q Page 2, lines 33 to 35.

23 A That says, "BAC has typically been
24 considered to be incompatible with anionic
25 drugs (e.g., salicylates or nitrates, et

1 STEPHEN G. DAVIES, D.PHIL.

2 cetera)," so it's qualified, "forming insoluble
3 complexes which cause the solution to become
4 cloudy or turbid." So the one in '984 is
5 qualified.

6 Q When you say it's "qualified," you
7 mean that there are examples that are provided
8 of anionic drugs?

9 A Yes.

10 Q And other than the fact that one
11 patent provides examples of anionic drugs and
12 the other one doesn't, those sentences are
13 consistent with one another, right?

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

16 A What's written in the two patents is
17 consistent between the two patents but is
18 meaningless to the person reading it on their
19 own.

20 Q Now, if we look at page 5 of Exhibit
21 5, the WO '597 patent.

22 A Yes.

23 Q The first sentence under "Detailed
24 Description" says that "Flurbiprofen is a
25 classic example of an acidic drug that forms an

1 STEPHEN G. DAVIES, D.PHIL.

2 insoluble ion pair with benzalkonium chloride."

3 Do you see that?

4 A Yes.

5 Q And flurbiprofen is an acidic NSAID
6 with a carboxylic acid moiety, right?

7 A That's correct.

8 Q Bromfenac is also an acidic NSAID
9 with a carboxylic acid moiety, right?

10 A It is an NSAID, and it has a
11 carboxylic acid group, yes.

12 Q And I think we might have established
13 this earlier. Bromfenac is also an anionic
14 drug at the relevant pH for ophthalmic
15 solutions, right?

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

18 A I've said it before, yes.

19 Q Now, if you look at table 1 on pages
20 6 and 7 of WO '597, this is example 5, there
21 are -- this table, table 1, provides two -- the
22 ingredients of two different formulations of
23 sodium flurbiprofen, right?

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

1 STEPHEN G. DAVIES, D.PHIL.

2 A Sorry, you have to repeat the
3 question, please.

4 Q If you look at table 1 on pages 6 and
5 7 of the WO '597 in Exhibit 5, table 1 provides
6 the ingredients of two different formulations
7 of sodium flurbiprofen, right?

8 MS. LEBEIS: Same objection.

9 A That's what it looks like, yes.

10 Q Example A in table 1 contains sodium
11 flurbiprofen and benzalkonium chloride, right?

12 A That's correct.

13 Q Example B in table 1 contains sodium
14 flurbiprofen and lauralkonium chloride, right?

15 A That's correct.

16 Q Under the table -- under table 1 on
17 page 7, the patent reports -- the patent
18 application reports that example A, that's the
19 example with benzalkonium chloride, "results in
20 a cloudy solution with precipitate and loss of
21 antimicrobial efficacy."

22 Do you see that?

23 A Yes.

24 Q And example B, the one that contained
25 the lauralkonium chloride but no benzalkonium

1 STEPHEN G. DAVIES, D.PHIL.

2 chloride, remained as a solution and the
3 solution maintains its antimicrobial efficacy.
4 That's what's recorded there, right?

5 A That's what's written down.

6 Q The only difference between example A
7 and example B, in terms of the formulations
8 presented in table 1, is the identity of the
9 preservative, right?

10 A Yes, that's true.

11 Q So in the formulation with the
12 benzalkonium chloride and the acidic NSAID, the
13 patent reports that it became cloudy with a
14 precipitate and loss of antimicrobial efficacy,
15 right?

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

18 A It just says it's cloudy. It doesn't
19 say what the cloudiness is due to, but it says
20 it's cloudy.

21 Q Right. And then in the other
22 formulation, example B, where the only
23 difference in that formulation was substituting
24 lauralkonium chloride for benzalkonium
25 chloride, it reports that the solution remained

1 STEPHEN G. DAVIES, D.PHIL.

2 clear, right?

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

5 A It doesn't say it's clear.

6 Q It says it remains a solution, right?

7 A Yes.

8 Q Okay. And it maintained its
9 antimicrobial efficacy, right?

10 A That's what it says. I don't see the
11 results on that table that it's done so.

12 Q I'm sorry, what is it that you said
13 you don't see?

14 A In that table it just says the words
15 "it maintained."

16 Q If you turn the page to table -- I'm
17 sorry, to page 8, do you see table 3?

18 A Yes.

19 Q That table reports the results of
20 a -- microbiology results on the example B
21 formulation, right?

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

24 A It doesn't actually say for table 3
25 it's example B. It just says lauralkonium

1 STEPHEN G. DAVIES, D.PHIL.

2 chloride itself is able to maintain its
3 antimicrobial efficacy of a period of up to one
4 year or more.

5 Q Then on page 7, line 13, the patent
6 reports that example B passes the British
7 Pharmacopeia preservative effectiveness test,
8 right?

9 A That's what it says, yes.

10 Q You're not an expert in preservative
11 efficacy, are you?

12 A No.

13 Q You're not an expert in any of the
14 pharmacopeial methods for evaluating
15 preservative efficacy?

16 A No.

17 Q You yourself have never evaluated a
18 formulation for its preservative efficacy, have
19 you?

20 A I have not.

21 Q You would agree that a person of
22 skill in the art reading the information in WO
23 '597 about the sodium flurbiprofen and
24 benzalkonium chloride formulations would
25 conclude that the presence of benzalkonium

1 STEPHEN G. DAVIES, D.PHIL.

2 chloride in example A is responsible for the
3 cloudiness and precipitate formation in the
4 example A formulation, right?

5 MS. LEBEIS: Objection.

6 Mischaracterizes the document.

7 A I don't think I can agree with that
8 because we don't know the result of what
9 happens if you leave out the benzalkonium
10 chloride altogether. So you have a -- if you
11 look at example B, you have a non-cloudy
12 solution that does contain lauralkonium
13 chloride. You take that out, and it goes
14 cloudy. That does not mean it's responsible
15 for the thing you've added, which is
16 benzalkonium chloride.

17 Q Okay. So you can't conclude one way
18 or another from that data whether or not
19 benzalkonium chloride is responsible for the
20 cloudiness of example A?

21 A I can't, no.

22 Q It's certainly possible that the
23 presence of benzalkonium chloride is
24 responsible for that cloudiness, which is --
25 and removal -- or replacement of benzalkonium

1 STEPHEN G. DAVIES, D.PHIL.

2 with lauralkonium chloride resolved that issue,
3 right?

4 MS. LEBEIS: Objection.

5 Mischaracterizes the document, calls for
6 speculation, asked and answered.

7 A You can't make the conclusion that it
8 is responsible from that.

9 Q Right. But without making any
10 conclusion, it's possible, that's one
11 explanation for what's observed here, that it's
12 the presence of benzalkonium chloride that's
13 responsible for that cloudiness, right?

14 MS. LEBEIS: Same objections.

15 A I don't -- I wouldn't speculate
16 without the proper experimental data.

17 Q Let's look at your expert report at
18 page 5. This is in Exhibit 1.

19 A Sorry, which page?

20 Q Page 5.

21 A Page 5. Okay.

22 Q You have a footnote 1 there at the
23 bottom. Do you see that?

24 A Yes.

25 Q And in the second sentence of your

1 STEPHEN G. DAVIES, D.PHIL.

2 footnote, you write, "An NSAID and a quaternary
3 ammonium compound, however, cannot form a
4 complex and can only potentially form a salt."

5 Do you see that?

6 A Yes.

7 Q So you agree that an NSAID and
8 benzalkonium chloride can potentially form a
9 salt, right?

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

12 A I'm talking about chemical
13 differences between what a complex is and what
14 a salt is.

15 Q Right. And you wrote, "An NSAID and
16 a quaternary ammonium compound can only
17 potentially form a salt, right?"

18 MS. LEBEIS: Objection.
19 Mischaracterizes the document.

20 A It's defining what a salt is and what
21 a complex is. There's no -- I don't see how a
22 complex can be formed between an NSAID and a
23 quaternary ammonium complex -- compound.

24 Q But you do see how a salt could be
25 formed between an NSAID and a quaternary

1 STEPHEN G. DAVIES, D.PHIL.

2 ammonium compound?

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

5 A These are definitions of what a salt
6 and a complex are, and an NSAID itself can't
7 form a salt, and a quaternary ammonium compound
8 can't form a salt with something else directly.

9 Q Right. But an interaction of the
10 NSAID and the quaternary ammonium cation could
11 form a salt, right?

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

14 A In principle, anything with a
15 negative charge can form a salt with something
16 with a positive charge. Whether or not it ever
17 does depends on the particular circumstances
18 and what the positive and the negative charge
19 are. If you put them into solution, then
20 essentially you have a solution of a salt, but
21 whether it will ever form a solid salt is --
22 you can't predict.

23 Q So it might, but it might not?

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

1 STEPHEN G. DAVIES, D.PHIL.

2 A You have no way of telling unless you
3 do the experiment.

4 Q Now, this point you're making in
5 footnote 1, that's a -- I think you said before
6 it's a definitional point, right? You're
7 defining what a complex is and what a salt is?

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

10 A What I'm showing is that under the
11 definition of complex and salt, NSAIDs and
12 quaternary ammonium compounds won't form
13 complexes.

14 Q Because of -- you wouldn't use the
15 terminology "complex" to refer to the potential
16 entity that would be formed through interaction
17 of an NSAID and a benzalkonium chloride ion; is
18 that right?

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

21 A Well, I've written down in this
22 footnote exactly what a complex and a salt is
23 and what a person of ordinary skill would
24 understand a complex and a salt is, and
25 Dr. Lawrence's defini- -- use of complex is not

1 STEPHEN G. DAVIES, D.PHIL.

2 correct.

3 Q Let's go back again just for a moment
4 to Exhibit 2, the '876 patent.

5 If you look at column 1, line 16 --

6 A Sorry, I've got the wrong exhibit.

7 Q We're in Exhibit 2, '876.

8 A Okay. Column 1?

9 Q Column 1.

10 MS. LEBEIS: Make sure that you're
11 there before answering.

12 Q Line 16.

13 You would agree that the authors of
14 the '876 patent, right or wrong in your view,
15 right or wrong, they refer to whatever is --
16 whatever they're hypothesizing is the
17 interaction between BAC and NSAIDs as insoluble
18 complexes. Do you see that word "complexes" on
19 line 16?

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

22 A Well, they're using the word
23 "insoluble complexes" but without any evidence
24 that they would actually form. Since they
25 can't form complexes, I'm not -- I don't expect

1 STEPHEN G. DAVIES, D.PHIL.

2 them to be formed, and a person of ordinary
3 skill reading this wouldn't expect complexes to
4 be formed.

5 Q Okay. So we've established that the
6 '876 patent uses that term "complexes," right?

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

9 Q Would you agree with me that the '876
10 patent uses the term "complexes"?

11 A The word "complexes" is written in
12 the '876.

13 Q Then let's look, if you would, at
14 the -- Exhibit 3, the '929 patent.

15 A Yes.

16 Q And if we can go in Exhibit 3 to
17 column 1, line 34.

18 A Yes.

19 Q And you would agree that the '929
20 patent also uses the word "complexes" in
21 describing this phenomenon, right?

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

24 A Well, I don't think there is a
25 phenomenon, and maybe it is because they can't

1 STEPHEN G. DAVIES, D.PHIL.

2 form complexes.

3 Q Okay. But you see that it uses the
4 term "complexes" there to describe the
5 interaction between NSAIDs and BAC?

6 MS. LEBEIS: Objection to the extent
7 it mischaracterizes the document and to the
8 extent it mischaracterizes prior testimony.
9 Objection to the form of the question.

10 A It uses the word "complexes," but
11 there's no evidence that an interaction between
12 an NSAID and benzalkonium occurs.

13 Q Then if you look at Exhibit 4, which
14 is the EP '984 patent we were looking at
15 earlier --

16 A Okay.

17 Q -- and we look at page 2, line 34 --

18 A Yes.

19 Q -- the EP '984 patent also uses the
20 word "complexes" to describe the interaction
21 between BAC and anionic drug compounds, right?

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

24 A Well, without any evidence it's a
25 hypothetical interaction. They use the word

1 STEPHEN G. DAVIES, D.PHIL.

2 "complexes," but there's no evidence that
3 complexes or salts form.

4 Q So it's your view that a person of
5 skill in the art -- and, again, a person of
6 skill in the art related to these patents that
7 are at issue, that person wouldn't use the word
8 "complex" in talking about the interaction of
9 NSAIDs and benzalkonium chloride even though
10 each of the prior art references that we looked
11 at just now all use that word in referring to
12 that interaction --

13 MS. LEBEIS: Objection.

14 Q -- is that right?

15 MS. LEBEIS: Objection to the extent
16 it mischaracterizes prior testimony. And
17 objection to the form of the question.

18 A Whatever the personal people writing
19 these patents are using for a term to describe
20 the precipitate or whatever, there's no
21 evidence that such a precipitate exists.

22 Q But in your view, all these people
23 writing these patents, they're all wrong to
24 refer to it as a complex, right?

25 MS. LEBEIS: Objection.

1 STEPHEN G. DAVIES, D.PHIL.

2 Mischaracterizes prior testimony and
3 argumentative.

4 A It's not -- it does not fit within
5 the absolute definition of a complex or a salt.

6 Q From a chemist's perspective.

7 A From any scientist's perspective.

8 Q Except for these scientists who wrote
9 these patents, right?

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

12 Argumentative. Asked and answered.

13 A There's no evidence what the
14 precipitate is so they may well think it is a
15 complex, but I can't see how one forms.

16 Q Could you envision a way in which a
17 salt might form between an NSAID and
18 benzalkonium chloride?

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

21 A I can envisage a way that a salt can
22 be formed in solution. Well, as I said
23 previously, potentially a salt can form from
24 anything that has a plus charge with anything
25 that has a minus charge. And whether it does

1 STEPHEN G. DAVIES, D.PHIL.

2 requires experimentation to find out.

3 Q So, potentially, a salt could form
4 between the plus charge of the benzalkonium ion
5 and the minus charge of an NSAID compound at
6 pHs relevant to ophthalmic solutions?

7 MS. LEBEIS: Objection to the form of
8 the question. Calls for speculation.
9 Improper -- incomplete and improper
10 hypothetical.

11 A It's a theoretical possibility, but
12 without any evidence, you don't know it's going
13 to happen.

14 MS. RAPALINO: Let's mark as Davies
15 Exhibit 6 U.S. Patent Number 5,110,493.

16 (Exhibit 6 was marked for identification
17 and attached to the deposition transcript.)

18 BY MS. RAPALINO:

19 Q Exhibit 6 is another U.S. patent you
20 reviewed in forming your opinions in this case?

21 A (Document review.)

22 I don't recall looking at it at this
23 moment. Can you refresh my memory?

24 Q Okay. We'll just take a look at the
25 patent, and maybe, as we look at it, that will

1 STEPHEN G. DAVIES, D.PHIL.

2 refresh your memory. This patent issued in May
3 of 1992, right? That's the date of the patent?

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

6 A It says the date of the patent is May
7 1992.

8 Q It's entitled, "Ophthalmic NSAID
9 formulations containing a quaternary ammonium
10 preservative and a nonionic surfactant," right?

11 A And a nonionic, yes.

12 Q The first sentence of the abstract on
13 the cover page of the '493 patent, Exhibit 6,
14 describes the invention as directed to a
15 "stable, clear, antimicrobially effective
16 ophthalmic formulation," right?

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

19 A So that's the first part of the first
20 sentence, yes.

21 Q Right. And the rest of that sentence
22 more specifically describes the subject of the
23 patent as formulations including "especially a
24 carboxylic acid group-containing drug or an
25 NSAID, a quaternary ammonium preservative, and

1 STEPHEN G. DAVIES, D.PHIL.

2 a nonionic surfactant all in an aqueous
3 vehicle," right?

4 MS. LEBEIS: Objection.

5 Mischaracterizes the document.

6 A Well, that's what it says in the
7 abstract. Whether that's what it does in the
8 rest of it, we would have to have a look.

9 Q That's what the abstract says anyway,
10 right?

11 A You've just read from the abstract,
12 so yes.

13 Q If you look at column 1, starting at
14 line 36 --

15 A Okay.

16 Q -- the patent says, "While the
17 formulations described in the '151 patent were
18 efficacious, a complex was found to form
19 between the NSAID and BAC." Do you see that?

20 A That's what it says, yes.

21 Q And, again, this patent uses the term
22 "complex" to describe the interaction between
23 NSAID and BAC, right?

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

1 STEPHEN G. DAVIES, D.PHIL.

2 A Well, I assume it's quoting from the
3 '151 patent rather than using it itself.

4 Q But it repeats then what the '151
5 patent -- what you suppose the '151 patent
6 says, which is that it's a complex that forms
7 between the NSAID and BAC?

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

10 A We would have to look at the '151
11 patent to see what it actually says. I haven't
12 seen any evidence that precipitate forms
13 between an NSAID and BAC.

14 Q Again, just to be clear, this patent,
15 the '493 patent, refers to a complex. It uses
16 the word "complex" when talking about the
17 interaction between NSAID and BAC, right?

18 MS. LEBEIS: Objection to the extent
19 it mischaracterizes the document and prior
20 testimony and asked and answered.

21 A Well, the word "complex" is there,
22 but looks like it's a quote from the '151
23 rather than the authors of the '493 using it.

24 Q And if we look at the bottom of
25 column 1, line 65, in the '493 patent, which is

1 STEPHEN G. DAVIES, D.PHIL.

2 Exhibit 6 --

3 A Okay.

4 Q -- it says, "Benzalkonium chloride, a
5 quaternary ammonium compound, has been widely
6 used in ophthalmic solutions and is considered
7 to be the preservative of choice."

8 Do you see that?

9 A That's what it says there, yes.

10 Q That's consistent with the
11 descriptions of benzalkonium chloride that
12 we've seen in some of the other patents we've
13 looked at, right?

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

16 A Similar statements have been made but
17 without any substantiation.

18 Q Then the next sentence goes on to
19 say, "However, BAC has typically been
20 considered to be incompatible with anionic
21 drugs (e.g., salicylates or nitrates, et
22 cetera), and can be inactivated by
23 surfactants."

24 Do you see that?

25 A That's what it says there.

1 STEPHEN G. DAVIES, D.PHIL.

2 Q If you go to column 2, line 8, the
3 '493 patent also says that "These NSAIDs have
4 proven to be incompatible with quaternary
5 ammonium compounds such as BAC because they can
6 form a complex with them, rendering the
7 preservative less available to serve its
8 function, as is the case with other ophthalmic
9 drugs that contain a carboxylic acid group."

10 Do you see that?

11 MS. LEBEIS: Objection.

12 Mischaracterizes the document.

13 A Well, you're reading from the patent
14 so I can see the words.

15 Q So that statement in the '493 patent,
16 that's consistent with statements we've seen in
17 the prior -- each of the prior patents that
18 we've looked at, right?

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

21 A Well, similar statements have been
22 made in other places but without demonstration
23 that it forms a complex.

24 Q And if we look at column 4 of the
25 '493 patent --

1 STEPHEN G. DAVIES, D.PHIL.

2 A Yes.

3 Q -- you see that there's a paragraph
4 that begins at around line 20 that starts,
5 "NSAIDs useful in the practice of this
6 invention"?

7 A Yes.

8 Q That paragraph lists a number of
9 NSAIDs for use in the formulations of this
10 invention, right?

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

13 THE WITNESS: Can you repeat the
14 question, please.

15 (Record read.)

16 A It lists some NSAIDs, yes, none of
17 which are bromfenac. But it lists some.

18 Q And the patent here doesn't describe
19 any structural differences between these
20 different NSAIDs that would affect their use in
21 this formulation, right?

22 A Well, it just names them, so -- and
23 in context of the patent, they wouldn't need
24 to.

25 Q And there's no discussion in this

1 STEPHEN G. DAVIES, D.PHIL.

2 patent of any differences in electron density
3 between those different NSAIDs that would be
4 relevant to the use of these patents in this
5 formulation?

6 A Such a discussion wouldn't be
7 relevant to this patent so they wouldn't need
8 to discuss them.

9 Q There's also no discussion in here of
10 any differences between any of those listed
11 NSAIDs in terms of whether they're primary,
12 secondary, or tertiary amines as relevant to
13 whether they would be useful in this
14 formulation?

15 A They obviously didn't think it was
16 necessary to do so, no.

17 Q There's also no discussion here of
18 the presence or absence of halogenation of the
19 different NSAIDs listed here as being relevant
20 to their use in this formulation, right?

21 A They don't need to in the context of
22 the patent.

23 Q There's likewise no discussion here
24 of differences in lipophilicity as between
25 these different NSAIDs listed in column 4 with

1 STEPHEN G. DAVIES, D.PHIL.

2 respect to their usefulness in the formulation
3 of the patent, right?

4 A There's no discussion because they
5 wouldn't need to.

6 Q And, likewise, there is no discussion
7 here about the differences in degree of
8 hydrogen bonding as between the different
9 NSAIDs set forth in this patent as useful in
10 this formulation?

11 A The same answer. They don't need to
12 discuss it in the context of the patent.

13 Q The nonionic surfactants that are
14 called out as useful in the formulations in
15 this patent at column 4, starting at line 32,
16 include preferably polyoxyethylated
17 surfactants, right?

18 A That's what it says, yes.

19 Q And I think you -- is that the same
20 as saying polyethoxylated octylphenol
21 surfactant?

22 A Yes.

23 Q And I think you said earlier that
24 octoxynol 40 is one such surfactant, right?

25 A Yes.

1 STEPHEN G. DAVIES, D.PHIL.

2 Q Tyloxapol is another polyoxyethylated
3 surfactant, right?

4 A It's one of a very large family of
5 such compounds, each of which have their own
6 properties.

7 Q So tyloxapol is in the family of
8 polyethoxylated surfactants?

9 A It has chains of polyoxyethylated
10 groups attached to it. In that sense, yes.

11 Q And it's actually a polyethoxylated
12 octylphenol surfactant, right?

13 A Well, you say oligomer of -- not an
14 oligomer. It's a co- -- it's got a group --
15 it's got seven such head groups and seven
16 chains.

17 Q You wouldn't want to call it an
18 oligomer, would you?

19 A It's not an oligomer.

20 Q Okay.

21 A I misspoke.

22 Q And it's an -- the head group -- the
23 head groups in tyloxapol are octylphenol head
24 groups, right?

25 A It has -- tyloxapol has seven such

1 STEPHEN G. DAVIES, D.PHIL.

2 head groups.

3 Q By "such," you mean seven octylphenol
4 head groups?

5 A Substituted octylphenols, yes.

6 Q So you would agree that it's in the
7 family of polyethoxylated octylphenol
8 surfactants?

9 A It's one of a very large number of
10 such things, each of which will have its own
11 properties.

12 Q As of 2003, how many polyethoxylated
13 octylphenol compounds have been used in
14 approved ophthalmic solutions?

15 MS. LEBEIS: Objection. Calls for
16 speculation.

17 A I haven't done that analysis.

18 Q So you didn't consider how many
19 ethoxylated octylphenol surfactants were in use
20 in approved pharmaceutical products in reaching
21 your opinions in this case?

22 MS. LEBEIS: Objection, asked and
23 answered, form of the question.

24 A I didn't do the analysis of how many
25 there were.

1 STEPHEN G. DAVIES, D.PHIL.

2 MS. RAPALINO: Let's mark as Davies
3 Exhibit 7 U.S. Patent 5,504,113.

4 (Exhibit 7 was marked for identification
5 and attached to the deposition transcript.)

6 BY MS. RAPALINO:

7 Q This is another U.S. patent, right?

8 A It's a United States patent, yes.

9 Q Do you recall whether you considered
10 this patent in forming your opinions in this
11 case?

12 A I believe I did, yes.

13 Q It's a patent that the date of the
14 patent is April of 1996, right?

15 A That's correct.

16 Q It's entitled "Enhancement of
17 benzalkonium chloride preservative activity in
18 formulations containing an incompatible drug,"
19 right?

20 A That's what the title says, yes.

21 Q What did you understand incompatible
22 drug to mean in that title?

23 A Well, I didn't know when I read the
24 patent precisely because they don't -- don't
25 they give an example of the -- I'll have to

1 STEPHEN G. DAVIES, D.PHIL.

2 check -- of an incompatible drug?

3 Q Are you familiar with The Merck
4 Index?

5 A Yes.

6 Q Is that a reference that you use in
7 your work?

8 A I have used it, yes. It's on my
9 shelf.

10 Q And is it a reliable reference?

11 MS. LEBEIS: Objection. Calls for
12 speculation.

13 A It's what it is. It gives you a very
14 brief summary of a somewhat random list of
15 properties of biologically active molecules.

16 Q When you say it's on your shelf, is
17 it a book that you consult and rely upon in the
18 course of doing your work?

19 MS. LEBEIS: Objection, asked and
20 answered.

21 A I use it very infrequently. It's on
22 my shelf because they gave it to me.

23 Q Who gave it to you?

24 A Whoever publishes The Merck Index.

25 Q Okay. Is it a -- is it a common

1 STEPHEN G. DAVIES, D.PHIL.

2 reference text for chemists to use?

3 A It used to be before Google arrived.

4 Q As of 2003 -- I guess Google was
5 probably around, but was it something that was
6 in use in around 2003?

7 A I would think so.

8 Q If we look at -- going back now to
9 Exhibit 7, the '113 patent --

10 A Okay.

11 Q -- the abstract of this patent
12 describes the patent as covering a formulation
13 that includes an acceptable drug, including
14 flurbiprofen or ketorolac tromethamine that is
15 interactive with benzalkonium chloride, right?

16 MS. LEBEIS: Objection.

17 Mischaracterizes the document.

18 A Sorry, what was the question that you
19 asked me.

20 Q The abstract of this patent describes
21 the patent as covering a formulation that
22 includes an acceptable drug including
23 flurbiprofen or ketorolac tromethamine that is
24 interactive with benzalkonium chloride, right?

25 A That's what it says in the abstract,

1 STEPHEN G. DAVIES, D.PHIL.

2 but you have to read the body of the patent to
3 see what they're actually doing.

4 Q We'll get there.

5 And the abstract specifies that
6 interactive with benzalkonium chloride means
7 that the drug forms a precipitate with
8 benzalkonium chloride, right?

9 A I don't think they give any evidence
10 that that's the case.

11 Q That's what the abstract says, right?

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

14 A That's what the words in the abstract
15 say. It's meaningless unless there's some
16 evidence produced.

17 Q And then if we look at column 1 of
18 the '113 patent, and I'm looking now starting
19 at line 31 --

20 A Okay.

21 Q -- it says, "Therefore, benzalkonium
22 chloride, which is a quaternary ammonium
23 compound, has been widely used in ophthalmic
24 solutions."

25 Do you see that?

1 STEPHEN G. DAVIES, D.PHIL.

2 A That's what it says.

3 Q That's consistent with prior
4 statements we have seen in other patents we've
5 looked at?

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

8 A The words are consistent, but nowhere
9 is any evidence produced.

10 Q And then it goes on to say, "It is
11 also well-known, however, that benzalkonium
12 chloride is considered incompatible with
13 anionic drugs, forming insoluble complexes
14 which cause the solution to turn cloudy."

15 Do you see that it says that?

16 A The words are there, yes.

17 Q And those words are also consistent
18 with the prior statements we've seen in the
19 other patents we've looked at, right?

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

22 A It's consistent with the words in
23 other patents, but in no case has it been
24 demonstrated that any cloudiness is due to
25 insoluble complexes.

1 STEPHEN G. DAVIES, D.PHIL.

2 Q Then the next paragraph starting at
3 line 37 goes on to say, "This is because of the
4 fact that many anionic drug entities carry a
5 negative charge at physiological pH. In fact,
6 all acidic drug entities will carry a negative
7 charge at all pHs above their PKAs."

8 Do you see that?

9 A I can read that, yes.

10 Q Okay. And you agree that anionic
11 drug entities -- I'm sorry, acidic drug
12 entities will carry a negative charge at all
13 pHs above their PKAs?

14 A That is correct, yes.

15 Q Then the next sentence goes on to
16 say, "In the case of benzalkonium chloride,
17 which is a positively charged preservative,
18 insoluble complexes can be formed with acidic
19 drug entities causing the drug to precipitate
20 out of solution."

21 Do you see that?

22 A I read those words, yes.

23 Q You agree that benzalkonium chloride
24 is a positively charged preservative, right?

25 A Well, it contains the benzalkonium

1 STEPHEN G. DAVIES, D.PHIL.

2 cation that is positively charged, and it's a
3 preservative, I agree with that.

4 Q And given that benzalkonium -- the
5 benzalkonium ion is a positively charged ion
6 and that acidic drug entities will be
7 negatively charged at pHs above their PKAs, you
8 agree that insoluble salts may form between an
9 acidic drug and benzalkonium chloride, causing
10 the drug to precipitate out of solution, right?

11 MS. LEBEIS: Objection to the form of
12 the question, calls for speculation, and to
13 the extent it mischaracterizes the
14 document.

15 A It's possible that a salt could be
16 formed under certain circumstances between
17 anything that has a positive charge and
18 anything that has a negative charge, but I have
19 seen no evidence to suggest that it happens in
20 the cases that are being discussed here.

21 Q And then if we look down to the
22 paragraph that begins just after that chemical
23 structure in column 1, so we're about line
24 57 --

25 A Yes.

1 STEPHEN G. DAVIES, D.PHIL.

2 Q -- it says, "As hereinbefore noted,
3 it is well-known that benzalkonium chloride is
4 generally incompatible with anionic detergents
5 or anionic drug compounds."

6 Do you see that?

7 A That's what the words say there, yes.

8 Q For that proposition, the patent
9 cites The Merck Index, 11th Edition, Merck &
10 Company, Inc., 1989, right?

11 MS. LEBEIS: Objection.

12 Mischaracterizes the document.

13 A It says "See The Merck Index." The
14 Merck Index isn't a primary source of results.
15 So I doubt there's any data in The Merck Index.

16 Q Okay. But it cites The Merck Index
17 for the proposition that BAC is "generally
18 incompatible with anionic detergents or anionic
19 drug compounds," right?

20 MS. LEBEIS: Objection.

21 Mischaracterizes the document.

22 A The Merck Index is cited in that
23 paragraph, yes.

24 MS. RAPALINO: Let's mark as Davies
25 Exhibit 8 U.S. Patent 6,265,444.

1 STEPHEN G. DAVIES, D.PHIL.

2 (Exhibit 8 was marked for identification
3 and attached to the deposition transcript.)

4 BY MS. RAPALINO:

5 Q Exhibit 8 is a U.S. patent that you
6 considered in forming your opinions in this
7 case; is that right?

8 A It is, yes.

9 Q It issued, or the date of the patent
10 is July 2001, right?

11 A The date of the patent is, yes, July
12 2001.

13 Q It's entitled "Ophthalmic
14 composition"?

15 A Yes.

16 Q And it's assigned to InSite Vision,
17 Incorporated, right?

18 A Yes, it is.

19 Q Then if we look at column 2, starting
20 at line 34, the '444 patent at Exhibit 8 says,
21 "Additionally, preserving an ophthalmic
22 composition that contains an NSAID can be
23 problematic."

24 Do you see that?

25 MS. LEBEIS: Objection.

1 STEPHEN G. DAVIES, D.PHIL.

2 Mischaracterizes the document.

3 A That's what it says in the
4 introductory part to this patent without any
5 evidence, yes.

6 Q And then the next sentence goes on to
7 say, "Conventional broad spectrum antimicrobial
8 agents like BAC tend to interact with the NSAID
9 agents over time and thereby reduce the
10 efficacy of the medication."

11 Do you see that?

12 MS. LEBEIS: Objection.

13 Mischaracterizes the document.

14 A That's what it says in this
15 introductory part of the patent without any
16 data to back it up.

17 Q And those statements are consistent
18 with the statements that we've seen in the
19 prior patents that we looked at, right?

20 MS. LEBEIS: Objection to the form of
21 the question. Vague and ambiguous.

22 A We've seen similar statements, but
23 there's never anything to back it up.

24 Q If you look for a moment at the
25 claims of this patent, the '444 patent,

1 STEPHEN G. DAVIES, D.PHIL.

2 starting at column 15 and going on to column
3 16.

4 A Yes.

5 Q Do you see that this patent is
6 generally directed to compositions that are
7 suspensions?

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

10 A Where do I see that?

11 Q So, for example, if we look at claim
12 1, it talks about compositions wherein from
13 "about 80 mole percent to less than 100 mole
14 percent of said agent is in the form of a
15 precipitate."

16 Do you see that?

17 A I see that, yes.

18 Q And do you understand that to be a
19 suspension formulation?

20 A Not without reading the bulk of the
21 patent.

22 Q Do you see, in claim 29 at column 16,
23 that the composition being claimed explicitly
24 describes it as an aqueous suspension?

25 A Well, it says, "An ophthalmic

1 STEPHEN G. DAVIES, D.PHIL.

2 composition comprising an aqueous suspension of
3 a crosslinked carboxyl-containing polymer,
4 solid diclofenac in free acid form, dissolved
5 diclofenac, and dissolved magnesium two plus or
6 calcium two plus cations." So that says it's a
7 suspension.

8 Q Okay.

9 Then if you look at column 7 of the
10 '444 patent at line 55.

11 A Line what, say, 65?

12 Q Line 55.

13 A 55.

14 Q Do you see that the patent says, "It
15 should be noted that BAC was found to be
16 unexpectedly compatible with diclofenac in the
17 present ophthalmic composition"?

18 A That's what it says, so that means,
19 presumably, there was no complex or precipitate
20 formed.

21 Q Could you point me to the
22 experimental data that shows that in this
23 patent.

24 A I'm just reading the words you just
25 read to me.

1 STEPHEN G. DAVIES, D.PHIL.

2 Q Okay. So in this instance you feel
3 that you can just read the words without the
4 experimental data?

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

8 A Well, as I read it, it implies --
9 well, I better look at the -- read the whole
10 thing again. But it says it's unexpectedly
11 compatible, presuming nothing untoward is going
12 on. So there's no adverse event.

13 Q So when it says that -- when the
14 statement in the patent is that it was
15 unexpectedly compatible, you just take that at
16 face value, but statements that say that
17 benzalkonium chloride and NSAIDs are
18 incompatible, for those you would need some
19 experimental data? Is that your position?

20 MS. LEBEIS: Objection to the extent
21 it mischaracterizes prior testimony,
22 argumentative, and asked and answered.

23 A This is in -- I'm reading it in the
24 Detailed Description of the Invention.

25 Q Oh, so because it's in the section

1 STEPHEN G. DAVIES, D.PHIL.

2 "Detailed Description of the Invention," you
3 don't need experimental data to believe it; is
4 that right?

5 MS. LEBEIS: Objection to the extent
6 that it mischaracterizes prior testimony,
7 argumentative, and asked and answered.

8 A Well, I think there's a difference
9 between assuming there's a problem in some
10 instances and being told there is no problem in
11 another instance. That's different.

12 Q Is there any difference between being
13 told there is a problem and being told there
14 isn't a problem?

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

18 A I would say there's no -- there's
19 only a problem when you encounter one. If you
20 don't encounter a problem, that's fine.

21 Q And you'd take at face value a
22 statement that no problem was encountered, but
23 you wouldn't take at face value a statement
24 that a problem was encountered? Is that your
25 view?

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STEPHEN G. DAVIES, D.PHIL.

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

A I've seen no evidence that a problem exists with an acid precipitating or causing turbidity with benzalkonium salts whereas this is describing a nonproblem.

Q So to believe a statement about a nonproblem, you don't need experimental data to show that?

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

A A problem only exists when it occurs. If something works the way it is supposed to work and there is no problem, why invent one.

Q What do you understand the authors to mean when they say that BAC was unexpectedly compatible with diclofenac? What do you understand to be unexpected about that?

MS. LEBEIS: Objection to the extent it calls for speculation. Mischaracterizes the document.

A I don't know is the answer, but what

1 STEPHEN G. DAVIES, D.PHIL.

2 you take out of that is BAC is compatible with
3 diclofenac.

4 Q And you don't take out of that that
5 the authors didn't expect BAC to be compatible
6 with diclofenac?

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

10 A The sentence says what it says. What
11 I take out of it is that BAC is compatible with
12 diclofenac. What they're expecting or not is
13 irrelevant to the fact that BAC is compatible
14 with diclofenac. It does not precipitate.

15 Q Now, the authors of this patent
16 hypothesize a theory as to why this -- why BAC
17 is unexpectedly compatible with diclofenac in
18 the formulations discussed in this patent,
19 right?

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

22 A You'll have to show me where that is.

23 Q I'm looking at column 7, starting at
24 line 57.

25 A Well, they're basically saying they

1 STEPHEN G. DAVIES, D.PHIL.

2 haven't got a clue because they say "the
3 reasons are not entirely clear, and without
4 wishing to be bound by any theory, the presence
5 of the divalent cation is believed to prevent
6 BAC from complexing the diclofenac out of the
7 system." There's no basis for that.

8 Q So what is the theory they're
9 proposing here as to why the BAC here is
10 unexpectedly compatible with diclofenac?

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

13 A They haven't really got one. They're
14 just basically saying that because there's some
15 divalent cations in there, maybe that's got
16 something to do with it, but they don't want to
17 be bound by it at all because they have no
18 experimental evidence that that's true.

19 Q Right. So they're just proposing a
20 theory as to what might be preventing the BAC
21 from complexing with the NSAID, right?

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

24 A They're not really proposing a theory
25 because they say they don't want to be bound by

1 STEPHEN G. DAVIES, D.PHIL.

2 it.

3 Q Right. But they say that's what they
4 believe is happening.

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

7 A You have to read the whole sentence.
8 It's obvious that they are completely unsure
9 what's going on.

10 Q Right. They're not sure, but they
11 say "the presence of the divalent cation is
12 believed to prevent the BAC from complexing the
13 diclofenac out of the system," right?

14 MS. LEBEIS: Objection to the extent
15 it mischaracterizes the document. Asked
16 and answered.

17 A A person of ordinary skill reading
18 that sentence would understand they don't know
19 what's going on.

20 Q Right. And a person of skill in the
21 art would understand that they believe that the
22 presence of the divalent cation is preventing
23 the BAC from complexing the diclofenac out of
24 the system, right?

25 MS. LEBEIS: Objection to the extent

1 STEPHEN G. DAVIES, D.PHIL.

2 it mischaracterizes the document and to the
3 extent it mischaracterizes prior testimony,
4 asked and answered.

5 A If you read the whole sentence, it's
6 clear they don't know what's going on.

7 Q They don't know for certain what's
8 going on, right?

9 MS. LEBEIS: Objection, asked and
10 answered.

11 A They don't know what's going on, and
12 that's why they say that they don't want --
13 that it's not clear and they don't want to be
14 bound by anything they're talking about.

15 Q But then they postulate a theory,
16 right?

17 MS. LEBEIS: Objection, asked and
18 answered.

19 A If you read the whole sentence, as I
20 read the whole sentence, it's clear they don't
21 know what's going on.

22 Q You haven't seen any prior art
23 bromfenac formulations that contain magnesium
24 chloride or calcium chloride, have you?

25 MS. LEBEIS: Objection. Calls for

1 STEPHEN G. DAVIES, D.PHIL.

2 speculation. Vague and ambiguous.

3 A I don't recall any.

4 MS. LEBEIS: I think it might be a
5 good time for a break. We've been going
6 for about an hour and a half. Short break?

7 MS. RAPALINO: Sure, take a break.

8 THE VIDEOGRAPHER: We're going off
9 the record at 2:41 p.m.

10 (A brief recess was taken.)

11 THE VIDEOGRAPHER: We're going back
12 on the record at 2:51 p.m. This is the
13 start of disc number 5 in the deposition of
14 Stephen Davies.

15 MS. RAPALINO: Let's mark as Davies
16 Exhibit 9 U.S. Patent 5,597,560.

17 (Exhibit 9 was marked for identification
18 and attached to the deposition transcript.)

19 BY MS. RAPALINO:

20 Q Is this a patent you considered in
21 forming your opinions in this case?

22 A Yes.

23 Q The date of the patent is January of
24 1997, right?

25 A That's correct.

1 STEPHEN G. DAVIES, D.PHIL.

2 Q It's entitled, "Diclofenac and
3 tobramycin formulations for ophthalmic and otic
4 topical use," right?

5 A Yes.

6 Q If we look at column 2, starting at
7 line 18 --

8 A Yes.

9 Q -- do you see that the patent
10 describes that "Fu, et al., reports that the
11 use of nonionic surface active agents,
12 especially polyoxyethylene alkylphenol
13 surfactants, avoids the unacceptable
14 interactions between NSAID and quaternary
15 ammonium compounds, wherein the NSAID and
16 quaternary ammonium compound form a complex
17 that is either insoluble or retards the
18 absorption of the NSAID"?

19 A That's what it says there, yes.

20 Q This reference to "unacceptable
21 interactions between NSAID and quaternary
22 ammonium compounds" is consistent with the
23 statements we've seen in the other patents we
24 looked at regarding those interactions, right?

25 MS. LEBEIS: Objection to the form of

1 STEPHEN G. DAVIES, D.PHIL.

2 the question. Vague and ambiguous.

3 A It's consistent with some of the
4 other things we've seen, but yet again, there's
5 no evidence that the problem actually exists.

6 Q This statement also refers to the use
7 of polyoxyethylene alkylphenol surfactants as a
8 way of avoiding unacceptable interactions. Do
9 you see that?

10 A Well, it's -- that's what it said,
11 but since we haven't seen any evidence that
12 there are unacceptable interactions between an
13 NSAID and quaternary ammonium compounds, it's
14 hard to see what's been avoided.

15 Q Then if we look at column 6,
16 comparative example C, toward the bottom -- do
17 you see that?

18 A Yes.

19 Q And it describes in comparative
20 example C that two comparative controls were
21 prepared, one with sodium diclofenac as the
22 active and the other with tobramycin as the
23 active ingredient. Do you see that?

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

1 STEPHEN G. DAVIES, D.PHIL.

2 A That's what it says.

3 Q And those were compared to another
4 formulation that had diclofenac, tobramycin,
5 benzalkonium chloride, and octoxynol 40, right?
6 I'm just reading at the beginning of
7 comparative example C now.

8 A Oh.

9 Okay, yes.

10 Q So then you would agree with me the
11 comparative controls were the same as that
12 formulation of sodium diclofenac, tobramycin,
13 benzalkonium chloride, octylphenol 40, but just
14 each of those controls had just a single active
15 ingredient, right?

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

18 A (Document review.)

19 I'm sorry, what was the question,
20 please?

21 Q I'm just trying to make sure we
22 both -- we're on the same page in terms of what
23 they're doing in comparative example C.

24 A Yes.

25 Q So you would agree that there was one

1 STEPHEN G. DAVIES, D.PHIL.

2 formulation that contained sodium diclofenac,
3 tobramycin, BAC, and octoxynol 40, right?

4 A Yes.

5 Q Then there were two controls, each of
6 which contained either diclofenac or tobramycin
7 along with those other ingredients that were in
8 that first formulation, right?

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

11 Dr. Davies, you should feel free to
12 read the entirety of comparative example C
13 and not just the portions that counsel has
14 directed you to.

15 A (Document review.)

16 It doesn't specifically say that all
17 of the other components were the same.

18 Q Is that your understanding of what a
19 control is?

20 A I guess in this case we can take
21 that.

22 Q And you would agree that the
23 formulation that contains diclofenac, BAC, and
24 tyloxapol after 41 days at 4 degrees did not
25 develop a precipitate, right?

1 STEPHEN G. DAVIES, D.PHIL.

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

4 A Repeat the question --

5 Q Sure.

6 A -- please.

7 Q The control formulation containing
8 diclofenac, BAC, and octoxynol 40 did not
9 develop a precipitate after storage for 41 days
10 at 4 degrees, right?

11 A After 41 days they didn't develop a
12 precipitate.

13 Q Right.

14 You agree with that?

15 A That -- I agree with that, yes.

16 I note that a precipitate that was
17 formed isn't anything to do with BAC.

18 Q Right. There was a precipitate that
19 formed in the presence of octoxynol 40, but
20 that was a precipitate between the two active
21 ingredients, right?

22 A Right. So BAC isn't involved, wasn't
23 involved.

24 Q Right. So octoxynol 40 successfully
25 prevented the precipitate -- any precipitate

1 STEPHEN G. DAVIES, D.PHIL.

2 from forming in the formulation of diclofenac,
3 BAC, and octoxynol 40, right?

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

6 A I wouldn't come to that conclusion
7 because -- well, there was no precipitate, but
8 you don't know that it -- anything is
9 preventing the formation of a precipitate.
10 It's not evidence that a precipitate would have
11 been formed between BAC and either of the
12 active ingredients.

13 Q If you keep this Exhibit 9 open in
14 front of you but also pull out Exhibit 4, which
15 is the EP '984 patent.

16 A Okay.

17 Q If you would turn to page 9 of the EP
18 '984 patent, Exhibit 4.

19 A Okay.

20 Q You would agree that in Exhibit 9,
21 the '560 patent, we see a report of no
22 precipitate in a formulation of diclofenac,
23 BAC, and octoxynol 40, right?

24 A Where do I see that?

25 Q We're looking now back at the '560