

1 STEPHEN G. DAVIES, D.PHIL.

2 would a person of ordinary skill in the art
3 consider which ingredients had already been
4 used in approved ophthalmic solutions?

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

7 A I think it depends entirely on the
8 material they try to formulate.

9 Q What -- can you give me some examples
10 of what factors it would depend on in terms of
11 whether a person of skill in the art would
12 consider using ingredients that had already
13 been used and approved in ophthalmic solutions?

14 A Well, materials end up being approved
15 because they're put into a formulation that is
16 then approved by the FDA, and then any
17 ingredient gets added to the list. So you can
18 actually use any set of ingredients you like,
19 provided you can persuade -- or provided the
20 FDA are confident in the end that that's a good
21 medication.

22 Q And if a formulator faced with the
23 task of formulating an ophthalmic solution has
24 the choice between two ingredients, one of
25 which has been previously approved in an

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2 ophthalmic formulation by FDA and one which is
3 not, which one would the formulator prefer?

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

6 A I have no idea. I guess it would
7 depend on the formulator and on what they're
8 trying to formulate.

9 Q You would agree, though, that if a
10 formulator faced with the task of formulating
11 an ophthalmic solution has the choice between
12 two ingredients, one of which has been
13 previously approved in an ophthalmic solution
14 and one which has not, there are fewer
15 regulatory hurdles involved in using the
16 ingredient that has been previously approved by
17 the FDA, right?

18 MS. LEBEIS: Objection, asked and
19 answered --

20 A I don't.

21 MS. LEBEIS: -- assumes facts not in
22 evidence, and incomplete hypothetical.

23 A I don't know that's true, that it's
24 easier to get it approved.

25 Q Have you had any experience trying to

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2 get ophthalmic solution formulations approved
3 by FDA?

4 A No.

5 Q Have you had any experience trying to
6 get pharmaceutical formulations approved by
7 FDA?

8 A Is that a different question to the
9 one previously?

10 Q Yes.

11 A Maybe you can repeat them both back
12 to me.

13 Q I think you answered the first one.
14 The second question was have you had any
15 experience trying to get pharmaceutical
16 formulations approved by FDA?

17 A No.

18 Q Have you had any experience trying to
19 get ophthalmic formulations approved by a
20 European regulatory authority?

21 A No.

22 Q Do you know what studies need to be
23 submitted to FDA with respect to ingredients in
24 an ophthalmic pharmaceutical formulation?

25 MS. LEBEIS: Objection. No

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2 foundation. Calls for speculation.

3 A I wasn't asked to consider that, so,
4 no.

5 Q Have you ever published a paper on
6 NSAIDs?

7 A I don't recall. I may well have done
8 it in the 560-plus.

9 Q But you can't recall specifically any
10 paper related to on work on NSAIDs?

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

13 A I can't recall.

14 MS. RAPALINO: I have no further
15 questions.

16 MS. LEBEIS: We have just a few
17 questions on redirect.

18 EXAMINATION BY COUNSEL FOR PLAINTIFFS
19 BY MS. LEBEIS:

20 Q So, Dr. Davies, do you remember that
21 Ms. Rapalino was asking you some questions
22 earlier regarding your definition of a person
23 of ordinary skill in the art?

24 A Yes.

25 Q So let's turn to that section of your

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2 report, which I believe is Davies Exhibit 1.

3 A Okay.

4 Q In particular, paragraph 11.

5 In setting forth your definition of a
6 person of ordinary skill in the art, did you
7 consider the patents-in-suit?

8 MS. RAPALINO: Objection, leading.

9 A I had read the patents-in-suit.
10 That's the first thing I did. So would have
11 considered them when formulating the paragraph
12 on person of ordinary skill in the art.

13 Q And what is your definition of a
14 person of ordinary skill in the art?

15 A It's in paragraph 11. "As of
16 January 21st, 2003, a person of ordinary skill
17 in the art would have had at least a bachelor's
18 degree in a field such as pharmaceutical
19 chemistry, chemistry, or a related discipline
20 with about three to five years of work
21 experience in this area or comparable level of
22 education and training."

23 Q What is a related discipline?

24 A Anything that is relevant to the
25 science being considered. So in this case, it

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2 would be -- since the patents are to do with
3 aqueous liquid formulation, it would be things
4 like formulation. Science would be in there.
5 I guess toxicology would also be in there if
6 there's any toxicological effects. Those sort
7 of areas. Anything that relies on -- anything
8 that relies on chemistry as a part. So
9 formulation science, for example, relies on --
10 significantly on chemistry, as shown in
11 Dr. Lawrence's report.

12 MS. LEBEIS: Thank you. We have no
13 further questions.

14 MS. RAPALINO: Thank you, Dr. Davies.

15 THE VIDEOGRAPHER: We're going off
16 the record at 5:21 p.m.

17
18 (Signature having not been waived, the
19 deposition of Stephen G. DAVIES, D.Phil., was
20 concluded at 5:21 p.m.)

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STEPHEN G. DAVIES, D.PHIL.

J U R A T

I, STEPHEN G. DAVIES, D.PHIL., do hereby certify under penalty of perjury that I have read the foregoing transcript of my deposition taken on February 22, 2016; that I have made such corrections as appear noted herein in ink, initialed by me; that my testimony as contained herein, as corrected, is true and correct.

Signature: _____

Dated: _____

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STEPHEN G. DAVIES, D.PHIL.

C E R T I F I C A T E

DISTRICT OF COLUMBIA:

I, MICHELE E. EDDY, shorthand reporter,
do hereby certify that the witness whose
deposition is hereinbefore set forth was duly
sworn, and that such deposition is a true,
correct, and full record of the testimony
given.

I further certify that I am not related
to any of the parties to this action by blood or
by marriage, and that I am in no way interested
in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set
my hand this 25th day of February, 2016.

Michele E. Eddy

MICHELE E. EDDY, Shorthand Reporter

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STEPHEN G. DAVIES, D.PHIL.

NAME OF CASE: SENJU V. BAUSCH & LOMB, et al.

DATE OF DEPOSITION: February 22, 2016

- 1. To clarify the record.
- 2. To conform to the facts.
- 3. To correct transcription error.

Page _____ Line _____ Reason _____

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STEPHEN G. DAVIES, D.PHIL.

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THIS _____ DAY OF _____, 2016.

(Notary Public) My Commission expires: _____

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