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UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC., )  
Petitioner, ) IPR NO. 2017-01621  
vs. ) IPR NO. 2017-01622  
UNITED THERAPEUTICS CORP., )  
Patent Owner. )

The videotaped deposition of DEFOREST  
MCDUFF, Ph.D., called as a witness for  
examination, taken pursuant to the Federal  
Rules of Civil Procedure of the United States  
District Courts pertaining to the taking of  
depositions, taken before ANDREA L. KIM, a  
Certified Shorthand Reporter of said state, CSR  
No. 84-3722, at Suite 4800, 35 West Wacker  
Drive, Chicago, Illinois, on the 6th day of  
April, A.D. 2018, at 9:37 a.m.

1           **PRESENT:**

2                   **Appeared on behalf of the Petitioner:**

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17  
18                   **-and-**

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ALSO PRESENT:

MR. SCOT ZIARKO, Videographer.

REPORTED BY: ANDREA L. KIM,

Illinois CSR No. 84-3722.

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I N D E X

WITNESS:	PAGE:
DEFOREST MCDUFF, Ph.D.	
EXAM by MR. DELAFIELD.....	6
EXAM by MR. MATHAS.....	240
EXAM by MR. DELAFIELD.....	244
EXAM by MR. MATHAS.....	246
EXAM by MR. DELAFIELD.....	246

I N D E X

EXHIBIT NUMBER	MARKED
Exhibit No. 1 Article titled Thinking Economically about Commercial Success.....	190
Exhibit No. 2 Copy of U.S. Patent 9,550,716..	231
Exhibit No. 3 Copy of U.S. Patent 8,410,121..	234
Exhibit No. 4 Declaration of DeForest McDuff, Ph.D. Case IPR2017-01621.....	243

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DEFOREST MCDUFF, Ph.D.

THE VIDEOGRAPHER: Good morning.

We are on the record. This is the video deposition of Dr. DeForest McDuff in the matter of Watson Laboratories, Inc., versus United Therapeutics Corporation. Today's date is April 6, 2018. The time is now approximately 9:35 a.m.

My name is Scot Ziarko. I am with David Feldman, and I am the videographer. The court reporter is Andrea Kim.

Will counsel please identify yourselves for the record, and will the court reporter please swear in the witness.

MR. DELAFIELD: Bobby Delafield with Wilson Sonsini Goodrich & Rosati for patent owner and United Therapeutics.

MR. MAEBIUS: Stephen Maebius from Foley & Lardner on behalf of patent owner United Therapeutics.

MR. MATHAS: Good morning. Kurt Mathas, Winston & Strawn on behalf of the petitioner Watson Laboratories, Inc., and the witness, Dr. DeForest McDuff.

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DEFOREST MCDUFF, Ph.D.

(WHEREUPON, the witness was duly sworn.)

THE VIDEOGRAPHER: You may begin.

DEFOREST MCDUFF, Ph.D.,

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

EXAMINATION

BY MR. DELAFIELD:

Q. Good morning, Dr. McDuff.

A. Good morning.

Q. Could you please state your full name for the record.

A. Robert DeForest McDuff.

Q. And I know you've been deposed before, but I want to go over just a few ground rules just as a reminder. The court reporter has the task of taking down all of our words, and so for every question I ask, if you could give a verbal response and not a head nod or uh-huh, and also because she has to take down every word, please wait until I finish my question, and I will wait until you finish your answer to ask the next question.

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DEFOREST MCDUFF, Ph.D.

Do you understand?

A. Yes.

Q. Do you understand you are obligated to tell the truth in response to my questions?

A. Yes.

Q. And do you understand that you must answer all of my questions unless your counsel instructs you not to?

A. Yes, that's fine.

Q. If you need to take a break at any point time today, as long as a question is not pending, we can take a break. If for any reason -- is there any reason that would prevent you from giving your best answers in response to my questions today?

A. No.

Q. Are you on any medication that would affect your testimony today?

A. No.

Q. So approximately how many times have you worked as an expert witness in the past?

A. I've submitted more than 50

1                    DEFOREST MCDUFF, Ph.D.

2                    expert reports. I have been deposed around 40  
3                    times, and then there are additional cases  
4                    where I was retained but didn't submit an  
5                    expert report or never got deposed.

6                    Q.                Were all of those patent  
7                    cases?

8                    A.                No.

9                    Q.                About what percent were patent  
10                    cases?

11                    A.                It varies over time. It's  
12                    probably between 50 and 80 percent ballpark.

13                    Q.                And of those cases, about what  
14                    percent were pharmaceutical patent cases?

15                    A.                Ballpark around half, maybe  
16                    more.

17                    Q.                Have you ever been a fact  
18                    witness in a case?

19                    A.                I have in one instance, yes.

20                    Q.                And what was that?

21                    A.                I provided testimony as a fact  
22                    witness in a dispute related to student  
23                    cheating and my role at Academic Integrity  
24                    Seminar.

25                    Q.                And what role did you play in

1                   DEFOREST MCDUFF, Ph.D.

2           that case?

3                   A.           I was a tutor to a student  
4           that was identified as potentially plagiarizing  
5           his answers, and so I provided factual  
6           information about that incident.

7                   Q.           So you weren't accused of  
8           cheating?

9                   A.           Correct.

10                  Q.           Okay. Has your testimony ever  
11           been excluded?

12                  A.           It has in some instances, yes.

13                  Q.           Can you describe those  
14           instances?

15                  A.           There was one instance  
16           relating to a reasonable royalty in an  
17           electronics case where my testimony was not  
18           permitted, and then there have been four or  
19           five instances where my testimony was  
20           challenged on a variety of issues, and most or  
21           at least the majority of my opinions were not  
22           excluded, but there was some aspect of my  
23           opinions that was not permitted.

24                  Q.           So on the reasonable royalty  
25           case you mentioned, do you recall why your

1                    DEFOREST MCDUFF, Ph.D.

2                    testimony was not permitted?

3                    A.                Yes, there were two main  
4                    issues there.

5                    Q.                What were those issues?

6                    A.                The first related to a  
7                    methodology for apportionment related to  
8                    vehicle tracker technology related to a type of  
9                    analysis called content analysis where one  
10                    quantifies apportionment based on how  
11                    frequently something occurs. The Court viewed  
12                    that methodology in the context of that case as  
13                    not appropriate.

14                                       The second issue was a  
15                    methodology in calibration related to  
16                    bargaining -- bargaining models and how parties  
17                    would negotiate in a hypothetical negotiation.  
18                    That was a methodology that was not permitted  
19                    by that Court. It was later challenged in  
20                    subsequent courts and permitted, and I've since  
21                    published peer-reviewed articles on both  
22                    topics. That's a summary of what that was  
23                    about.

24                    Q.                On the apportionment issue,  
25                    was that apportionment of the value of patents?

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DEFOREST MCDUFF, Ph.D.

A. It was apportionment related to a reasonable royalty analysis.

Q. Was the reasonable royalty analysis -- strike that.

Was it a patent case?

A. It was, yes.

Q. So in that case did you provide testimony as to different values for different patents?

A. I don't recall specifically how many patents there were or what the technology was not sitting here.

Q. I am just trying to understand what you meant by apportionment if you were talking about your testimony giving value to certain patents over others.

Is that what you did?

A. Apportionment in a reasonable royalty context is about determining the contribution of a patent in a negotiation relative to other factors and how one goes about quantifying that. So it was a quantification process for determining that contribution.

1                                    DEFOREST MCDUFF, Ph.D.

2                                    Q.                    So you determined the  
3                                    contribution to a reasonable royalty rate of  
4                                    certain patents, correct?

5                                    A.                    Generally I agree with that,  
6                                    yes.

7                                    Q.                    And that testimony was  
8                                    excluded?

9                                    A.                    That portion was, yes.

10                                  Q.                    Now you mentioned you have  
11                                  provided a number of opinions on pharmaceutical  
12                                  patent cases; is that correct?

13                                  A.                    Yes.

14                                  Q.                    How many of those did you find  
15                                  that the pharmaceutical patent was not a  
16                                  commercial success?

17                                  A.                    I don't have a count for you  
18                                  sitting here.

19                                  Q.                    Do you know how many times you  
20                                  found that the pharmaceutical patent was a  
21                                  commercial success?

22                                  A.                    I don't have a count for you.  
23                                  I'm sorry.

24                                  Q.                    Have you ever found that a  
25                                  pharmaceutical patent was a commercial success?

1                                    DEFOREST MCDUFF, Ph.D.

2                    A.            I have, yes.

3                    Q.            Is it fair to say the majority  
4 of the time you provide an opinion that the  
5 patents you are asked to opine about you find  
6 are not commercially successful?

7                    A.            I don't know. It's hard to  
8 summarize in that way because it's not always  
9 an opinion that a certain patent is or isn't  
10 commercially successful. There's often a range  
11 of issues that I am evaluating in a particular  
12 case. I don't know that it's fair to describe  
13 it that way for each patent at issue.

14                   Q.            Is it fair to say that you  
15 have found patents to lack commercial success  
16 more than you have found patents to have  
17 achieved commercial success?

18                   MR. MATHAS: Object to the form.

19 BY THE WITNESS:

20                   A.            I don't really think about it  
21 as patents achieving commercial success or not.  
22 That's not the way I would describe it.

23 BY MR. DELAFIELD:

24                   Q.            You have provided opinion in  
25 this case about the commercial success of two

1                   DEFOREST MCDUFF, Ph.D.

2           patents, correct?

3                   MR. MATHAS: Object to the form.

4           BY THE WITNESS:

5                   A.           I would describe it as  
6           commercial success as a secondary consideration  
7           that relates to non-obviousness of two patents.

8           BY MR. DELAFIELD:

9                   Q.           So isn't that an opinion about  
10          whether or not the patents in this case were  
11          commercially successful?

12                  A.           I just wouldn't describe it  
13          that way. I don't think of patents themselves  
14          being commercially successful or not.  
15          Commercial success of a product and a  
16          technology is one factor that relates to  
17          obviousness of certain patents.

18                  Q.           Let me put it a different way.  
19          Would you agree with me that the majority of  
20          the pharmaceutical patent cases that you have  
21          been involved with you have found that the  
22          secondary consideration of commercial success  
23          favored that the patent was obvious?

24                  A.           I don't typically view my  
25          opinion as weighing that a patent is obvious or

1                    DEFOREST MCDUFF, Ph.D.

2            not. It's more about does the evidence  
3            presented on commercial success as a secondary  
4            consideration support obviousness.

5                    Q.            So is it fair to say that most  
6            pharmaceutical patent cases that you have been  
7            on you have found that the secondary  
8            consideration -- secondary consideration of  
9            commercial success favored obviousness?

10                   A.            I don't think of it that way.  
11            It's not that the evidence favors obviousness.  
12            It's whether -- I perform an evaluation of  
13            whether the evidence should be used in favor of  
14            non-obviousness.

15                   Q.            In this case would you say  
16            that the commercial success of Tyvaso would be  
17            in favor of obviousness?

18                   A.            I don't think of it that way.  
19            I don't think of a lack of commercial success  
20            as a secondary consideration favoring  
21            obviousness. It is just that the secondary  
22            consideration doesn't favor non-obviousness.

23                   Q.            Isn't that a double negative?

24                   A.            No, not as I think of it.

25                   Q.            So is it fair to say that in

1 DEFOREST MCDUFF, Ph.D.

2 the most -- most of the pharmaceutical patent  
3 cases that you have been on, you have found  
4 that the secondary consideration of commercial  
5 success does not favor non-obviousness?

6 A. Would you mind reading the  
7 question, please.

8 (WHEREUPON, the record was read  
9 by the reporter.)

10 BY THE WITNESS:

11 A. What do you mean by most?

12 BY MR. DELAFIELD:

13 Q. More than 50 percent.

14 A. Looking at all of the cases,  
15 that's probably true.

16 Q. Would it be more than 75  
17 percent?

18 A. I don't know.

19 Q. So in all of the  
20 pharmaceutical patent cases you have been on,  
21 how often have you been retained by the brand  
22 side, the patent owner?

23 A. I don't know. I don't have a  
24 specific number for you.

25 Q. Can you name a couple?

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DEFOREST MCDUFF, Ph.D.

A. I mean, I can think of several examples.

Q. Could you provide a couple of examples?

A. So some cases that I have worked on would relate to being retained by the patent owner for the drugs Herceptin, Noxafil, Crestor. Those are some examples that come to mind.

Q. For those three, did you provide an opinion about the commercial success of the patent?

A. I think about it as commercial success as a secondary consideration. In two of the cases I was a consulting economist, and one of the cases I was a testifying expert.

Q. Was your testimony related to commercial success?

A. It was. It was put forth in support of a finding of commercial success as a secondary consideration.

Q. You have been retained by Watson before, correct?

A. Yes.

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DEFOREST MCDUFF, Ph.D.

Q. How often have you been retained by Watson?

A. I don't have a specific count for you, several times.

Q. Ten to 15 times?

A. It's probably not that high, no.

Q. Did you meet with counsel in preparation for your deposition today?

A. Yes.

Q. Who did you meet with?

A. I met with Mr. Mathas.

Q. Did you meet with anyone else?

A. No.

Q. For how long did you meet to prepare for your deposition?

A. I met with Mr. Mathas for about three to four hours.

Q. Now, throughout this deposition, you understand that you are here to testify on behalf of two cases, correct?

A. Yes.

Q. And one is IPR 2017-01622, and the other is IPR 2017-01621, correct?

1                                    DEFOREST MCDUFF, Ph.D.

2                                    A.                    Yes, that's right.

3                                    Q.                    So throughout the deposition  
4 unless I specify a specific case or a specific  
5 patent, you understand my question to pertain  
6 to both.

7    Is that fair?

8                                    A.                    I can do that, yes.

9                                    Q.                    And if your answer differs  
10 based on one patent or the other in the two  
11 cases, will you provide different answers?

12                                    A.                    I will do my best to do so.

13                                    Q.                    And if you don't provide a  
14 different answer, your answer will be for both  
15 cases.

16    Is that fair?

17                                    A.                    I don't know how it works  
18 procedurally, but I'll do my best to answer as  
19 applicable to both cases.

20                                    Q.                    Okay. When were you first  
21 retained for these two cases?

22                                    A.                    I believe it was in early  
23 2017. I don't have an exact date.

24                                    Q.                    Approximately how many hours  
25 have you spent on these two cases so far?

1                                    DEFOREST MCDUFF, Ph.D.

2                    A.            I don't have an exact estimate  
3                    for you. It's probably greater than 20 hours,  
4                    less than 80. Somewhere in that range.

5                    Q.            So between 20 and 80 hours  
6                    total?

7                    A.            It's very ballpark. I don't  
8                    have specific recollection, but that seems like  
9                    a likely range to me.

10                  Q.            Other than counsel, have you  
11                  spoken to anyone else about this deposition or  
12                  either of these cases since the time you were  
13                  retained?

14                  A.            Yes, I spoke with a member of  
15                  my staff working at my direction. His name is  
16                  Mr. Noah Brennan.

17                  Q.            And what did you talk about  
18                  with him?

19                  A.            Mr. Brennan and I discussed  
20                  the upcoming deposition, and he also assisted  
21                  with the preparation of my declarations as part  
22                  of our work on the case.

23                  Q.            Did he write part of your  
24                  declarations?

25                  A.            He may have drafted certain

1                    DEFOREST MCDUFF, Ph.D.

2                    portions. Typically -- I don't remember  
3                    exactly what parts he may or may not have  
4                    drafted in these cases, but a typical work  
5                    process would be that someone working at my  
6                    direction may draft parts of the declaration  
7                    that I later review and edit. He may have done  
8                    so here. I simply don't recall.

9                    Q.                Did he do any of the  
10                    calculations that are presented in your  
11                    declarations?

12                    A.                He did assist with those, yes.

13                    Q.                Do you know approximately what  
14                    percent of the calculations he performed?

15                    A.                Mr. Brennan performed the  
16                    majority of the calculations at my direction.  
17                    I don't have a percentage for you, but most of  
18                    the calculations he directly performed working  
19                    with me.

20                    Q.                What is Mr. Brennan's  
21                    educational background?

22                    A.                He has a Bachelor's Degree and  
23                    a Master's Degree in development economics.

24                    Q.                And how long has he worked  
25                    with you?

1                   DEFOREST MCDUFF, Ph.D.

2                   MR. MATHAS: I am going to object  
3 to the form and this whole line of questioning  
4 but go ahead.

5 BY THE WITNESS:

6                   A.           He has worked with me at  
7 Insight Economics for about a year. He and I  
8 have also worked together at a previous  
9 employer for something like three or four years  
10 in addition to the one year at Insight.

11 BY MR. DELAFIELD:

12                  Q.           Did you start work on this  
13 case at your previous employer?

14                  A.           No, I don't believe so.

15                  Q.           Did you talk to any other  
16 expert in this case about -- strike that.

17                               Did you talk to any other  
18 expert retained by Watson about this case?

19                  A.           No. Yet, as indicated in my  
20 declaration, I did review the declaration of  
21 Dr. Donovan.

22                  Q.           But you didn't have any  
23 discussions with her?

24                  A.           No.

25                  Q.           Did you exchange any emails or

1                                    DEFOREST MCDUFF, Ph.D.

2                    any kind of correspondence with Dr. Donovan?

3                    A.            No.

4                                    (WHEREUPON, the document was  
5                                    tendered to the witness.)

6                    BY MR. DELAFIELD:

7                    Q.            You have been handed what's  
8                    been premarked as Exhibit 1055 for IPR  
9                    2017-01622.

10                                    (WHEREUPON, the document was  
11                                    tendered to the witness.)

12                    BY MR. DELAFIELD:

13                    Q.            And you have also been handed  
14                    what's been marked as Exhibit 1055 for IPR  
15                    2017-01621.

16                                    Turning first to the 01622 or  
17                    for the '507 patent, if you understand that, do  
18                    you recognize this document?

19                    A.            Yes.

20                    Q.            Is this a copy of your  
21                    declaration?

22                    A.            It appears to be, yes.

23                    Q.            Is this a complete and  
24                    accurate copy of your declaration?

25                    A.            Sitting here skimming through

1 DEFOREST MCDUFF, Ph.D.

2 it, it appears to be, yes.

3 Q. If you could turn to page 25,  
4 is that your signature on the declaration?

5 A. It is, yes.

6 Q. And you signed it June 21,  
7 2017?

8 A. Yes.

9 Q. Now, you mentioned your  
10 assistant helped you write your declaration; is  
11 that correct?

12 A. I don't believe that was my  
13 testimony, no.

14 Q. No one helped you write this  
15 declaration?

16 A. Well, as I've described, I  
17 don't have specific recollection of whether  
18 Mr. Brennan assisted with the drafting of the  
19 declaration. Often he does when I do work with  
20 him, but I just don't remember whether he did  
21 for this declaration specifically.

22 Q. Did anyone else help you draft  
23 your declaration?

24 A. I don't believe so, no.

25 Q. Counsel didn't help you draft

1 DEFOREST MCDUFF, Ph.D.

2 the declaration?

3 A. No.

4 Q. You cite several articles in  
5 your declaration, correct?

6 A. I do, yes.

7 Q. Who found those articles?

8 A. I did along with research  
9 support from Mr. Brennan.

10 Q. Now, if you turn to page 26 of  
11 your declaration, this is the first page of  
12 your CV; is that correct?

13 A. Yes.

14 Q. And is this a true and  
15 accurate copy of your CV?

16 A. It is as of June 2017.

17 Q. Could you briefly go through  
18 your educational background.

19 A. Yes, I have a Bachelor's  
20 Degree -- I have two Bachelor's Degrees from  
21 the University of Maryland at College Park, one  
22 in economics, and one in mathematics. I would  
23 note that there's a typo here in the CV. It  
24 says a Bachelor's of Arts in Economics and a  
25 Bachelor of Science in Economics. That's since

1 DEFOREST MCDUFF, Ph.D.

2 been corrected. It's a Bachelor of Science in  
3 Mathematics from the University of Maryland.

4 I also have a Master's in  
5 Economics from Princeton University and a Ph.D.  
6 in Economics from Princeton University.

7 Q. And what year did you obtain  
8 your Ph.D.?

9 A. In 2009.

10 Q. I noticed in your declaration  
11 and your CV you did not put the year you  
12 graduated.

13 Is there any reason you didn't  
14 put the year?

15 A. No.

16 Q. So as of 2009, did you  
17 consider yourself to be an expert in economics?

18 A. Yes.

19 Q. Did you consider yourself to  
20 be an expert in economics with respect to  
21 pharmaceutical patents?

22 A. It would depend on what aspect  
23 of economic analysis I was evaluating. Some  
24 aspects definitely, yes. Others I would say I  
25 accumulated experience in the pharmaceutical

1                    DEFOREST MCDUFF, Ph.D.

2                    industry over time in my professional  
3                    experience as a consultant. I don't know at  
4                    what point I would consider myself an expert,  
5                    but certainly for any case where I put myself  
6                    forth as an expert and submitted an expert  
7                    report and I felt qualified at that time.

8                    Q.                Do you recall how long after  
9                    receiving your Ph.D. that you provided expert  
10                   testimony in a pharmaceutical patent case?

11                   A.                Looking at page 34 of Exhibit  
12                   1055 which is the last page of my CV, I do  
13                   remember my first case which didn't relate to  
14                   pharmaceuticals, but I testified as an expert  
15                   with respect to patents. That was in 2009. So  
16                   that was immediately following my graduation  
17                   and earning my Ph.D., and then specifically as  
18                   to pharmaceutical cases, the first one that  
19                   comes to mind is number 34 which is listed on  
20                   the previous page on page 32, UCB versus Teva.  
21                   That would have been in the 2013 to 2014 range.  
22                   I, of course, worked on a number of  
23                   pharmaceutical cases as a consultant prior to  
24                   that time.

25                   Q.                So the first pharmaceutical

1 DEFOREST MCDUFF, Ph.D.

2 patent case in which you provided expert  
3 opinions was in the 2013 to 2014 range?

4 A. As a testifying expert, that's  
5 right. Prior to that, of course, I provided  
6 consulting expertise.

7 Q. So you mentioned that you  
8 considered yourself an expert with respect to  
9 economics at the time you obtained your Ph.D.;  
10 is that correct?

11 A. Yes.

12 Q. So would anyone with a Ph.D.  
13 in economics at the time of their graduation be  
14 an expert?

15 A. I don't know. It depends on  
16 the context probably. It certainly is an  
17 advanced degree that has recognition of  
18 expertise?

19 Q. What was the subject of your  
20 Ph.D. dissertation?

21 A. The field was in applied  
22 micro-economics and financial economics, and  
23 the subject of my Ph.D. research related to  
24 financial markets in housing and real estate  
25 and decisions of -- labor market decisions of

1    DEFOREST MCDUFF, Ph.D.

2                    students to attend colleges and universities.

3                    Q.                    So it was not related to  
4                    patents?

5                    A.                    The scope was not specific to  
6                    patents. Yet certainly the expertise I  
7                    developed does go into my education and  
8                    experience as an expert that allows me to opine  
9                    in patent cases.

10                    Q.                    But your Ph.D. dissertation  
11                    was not related to patents, correct?

12                    A.                    It strikes me as the same  
13                    question. I will provide the same answer.

14                    Q.                    Well, it is just yes or no.  
15    Did your Ph.D. dissertation  
16                    discuss patents?

17                    A.                    It did not specifically  
18                    discuss patents.

19                    Q.                    And your Ph.D. dissertation  
20                    did not discuss pharmaceuticals, correct?

21                    A.                    Not specifically, I don't  
22                    believe so.

23                    Q.                    During your education, did you  
24                    take any courses on pharmaceutical patents --  
25                    related to pharmaceutical patents?

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DEFOREST MCDUFF, Ph.D.

A. Certainly my course work as a Ph.D. student does contribute to my expertise as an economist that I then apply to patent cases, but specifically with respect to pharmaceutical patents, the only class that comes to mind is a second year graduate course in health economics where we discussed, you know, pharmaceutical development and research, and I believe patents came up in that context.

Q. Do you recall if whether a patent is valid or not came up in that context?

A. I don't remember.

Q. Do you recall whether analyzing commercial success of patents came up in that course?

A. I don't believe it did. I don't recall.

Q. You have never worked for a pharmaceutical company as a full-time job, correct?

A. Not as an employee. I have as a consultant.

Q. And you are not an expert in drug formulation, correct?

1                                    DEFOREST MCDUFF, Ph.D.

2                                    A.                    No, not as I think of it.

3                                    Q.                    And you are not an expert in  
4 inhalable drug delivery, correct?

5                                    A.                    Not from a clinical  
6 perspective. I have analyzed aspects of that  
7 from an economic perspective here in this case.

8                                    Q.                    But the technology involved  
9 with inhalable drug delivery, you are not an  
10 expert in the technology, correct?

11                                   A.                    Not as a technical expert. I  
12 perform my work from the perspective of an  
13 economist.

14                                   Q.                    And you are not an expert in  
15 FDA regulations, correct?

16                                   A.                    Not in terms of specific  
17 expertise. It is something that frequently  
18 comes up in my work, and I evaluate from an  
19 economic perspective but not an area that I  
20 would claim independent expertise.

21                                   Q.                    And you are not an expert in  
22 the treatment of pulmonary hypertension?

23                                   A.                    Not from a clinical  
24 perspective, no. I am an economist.

25                                   Q.                    You are not an expert in

1                   DEFOREST MCDUFF, Ph.D.

2           patent law, correct?

3                   A.           I'm not an attorney. I  
4           frequently consider issues of patent law from  
5           an economic perspective but not from a legal  
6           perspective.

7                   Q.           Have you ever consulted with a  
8           pharmaceutical company in connection with a  
9           decision of whether or not to launch a  
10          particular drug?

11                  A.           I have, yes.

12                  Q.           Do you recall an example of  
13          that?

14                  A.           I have performed that kind of  
15          consultation on a number of occasions, maybe a  
16          half dozen times. Two types of examples would  
17          be a generic supplier considering to launch a  
18          generic product and how the market would evolve  
19          as a result of that launch. The second type of  
20          example is a company evaluating the launch of a  
21          branded product and how the result of that  
22          launch would be from an economic and market  
23          perspective.

24                  Q.           Have you ever consulted a  
25          pharmaceutical company with respect to pricing

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DEFOREST MCDUFF, Ph.D.

of a pharmaceutical product?

A. Yes.

Q. Would you agree that pricing is a relevant factor to commercial success?

A. It can be. It depends on the context.

Q. Have you yourself used pricing in your analysis of commercial success in any case?

A. I have evaluated pricing in other cases.

Q. What is the relevant time period to examine whether a pharmaceutical product has achieved commercial success?

A. It depends what you mean by relevant time period. Would you mind trying to clarify?

Q. Well, that's what I am asking you.

What is your understanding of the time period needed to be analyzed for commercial success?

A. Well, I can describe how I think about it. We are sitting here today in

1                    DEFOREST MCDUFF, Ph.D.

2                    2018. So this is a relevant time period in the  
3                    sense that this is when we are doing the  
4                    analysis or 2017 is when I performed the  
5                    analysis, and the analysis is applicable to a  
6                    determination of obviousness back around the  
7                    time of the invention. So it would be back  
8                    around the priority dates of the  
9                    patents-at-issue, and just to follow up, of  
10                   course, examining the sales that occurred over  
11                   time, that would be relevant time period as I  
12                   think about it.

13                   Q.                    When you say sales over time,  
14                   would you agree that the average sales over  
15                   time is a relevant factor to consider for  
16                   commercial success?

17                   A.                    It depends what you mean by  
18                   that. I might be open to considering it.

19                   Q.                    Let's say average sales per  
20                   year.

21                   A.                    I would be open to considering  
22                   it. It's not something that is typically  
23                   calculated. More often myself or other experts  
24                   working in this area would simply plot the  
25                   sales over time by year and show the sales over

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DEFOREST MCDUFF, Ph.D.

time, but average sales could be something one could look at.

Q. And total sales is an important factor to consider for commercial success as well, correct?

A. It depends on -- it depends on how one is using it. I would be open to considering it.

Q. When would total sales not be relevant to commercial success?

A. It just depends how one is using it and interpreting it. I typically try to find a summary metric like the ones I have provided in my report or my declarations in this case. For example, peak sales in a given year that's a good way to provide an apples-to-apples comparison between products.

I don't recall providing total sales over time in this declaration because it's often hard to find an apples-to-apples comparison without a determinant. So, again, I am open to considering total sales, but it's not something I believe I calculated or compared here.

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DEFOREST MCDUFF, Ph.D.

Q. If you turn to page 38 of Exhibit 1055 of the '507 patent which is Attachment B-4.

Do you see that?

A. I do, yes.

Q. And it lists PAH Drug Revenues by Year.

Do you see that?

A. I do.

Q. And that's referring to pulmonary arterial hypertension?

A. It is, yes.

Q. And you list Tyvaso as the second entry, correct?

A. Correct.

Q. And that's the drug in which the '507 patent and the '240 patent are listed in the Orange Book for, correct?

A. Correct.

Q. That's the drug you analyzed in both of your declarations, correct?

A. Yes, among other drugs.

Q. And then to the far right, you have a total of \$2.515 billion; is that

1 DEFOREST MCDUFF, Ph.D.

2 correct?

3 A. Correct, for Tyvaso.

4 Q. So you did calculate total  
5 revenue over -- since launch, correct?

6 A. I did. I had forgotten about  
7 this attachment in my previous response. I  
8 don't believe it's referenced in the  
9 declaration text which is what I was thinking  
10 about.

11 Q. Before I forget, if you could  
12 turn to Exhibit 1055 for IPR 2017-10621 for the  
13 '240 patent.

14 Do you recognize this  
15 document?

16 A. I do.

17 Q. And is this a true and  
18 accurate copy of your declaration for the '240  
19 patent?

20 A. I understand that this may  
21 have been a version that was submitted, but  
22 this version does not include my attachment  
23 calculations which can be seen on Exhibit 1055  
24 in the 1622 declaration.

25 So the 1621 declaration here

1                   DEFOREST MCDUFF, Ph.D.

2           in front of me does not provide those  
3           attachment calculations. I understand that  
4           there was a version provided to patent holder  
5           at some point with those attachments.

6                   MR. MATHAS: And for the record,  
7           Bobby, I have copies here. You are welcome to  
8           use them if you would like.

9                   MR. DELAFIELD: For the record, we  
10          object to the use of those declarations. You  
11          submitted this declaration almost a year ago,  
12          and we did not receive those until last night  
13          so.

14                   MR. MATHAS: Do you allege any --  
15          that you suffered any prejudice from this  
16          considering you had the information in the  
17          other declaration?

18                   MR. DELAFIELD: Well, it's not  
19          clear we had the information in the other  
20          declaration. We just got it last night. So we  
21          are still evaluating it.

22                   MR. MATHAS: Well, you are welcome  
23          to ask Mr. McDuff that -- or Dr. McDuff that.  
24          I am sure he can testify about it at some point  
25          today.

1 DEFOREST MCDUFF, Ph.D.

2 BY MR. DELAFIELD:

3 Q. So Exhibit 1055 that shows  
4 page 1 through 25 for IPR 2017-01621, this was  
5 the copy submitted to the patent office in June  
6 of 2017, correct?

7 MR. MATHAS: Object to the form.

8 BY THE WITNESS:

9 A. I would defer to counsel on  
10 that in terms of what was submitted. My  
11 declaration I think of it as including the  
12 declaration as well as attachments. They are  
13 the same as what was provided in my declaration  
14 for 1622.

15 BY MR. DELAFIELD:

16 Q. Well, if you turn to page 25  
17 of the '240 declaration, is that your  
18 signature?

19 A. It is, yes.

20 Q. And you signed it June 21,  
21 2017?

22 A. Yes.

23 Q. And this version doesn't have  
24 any attachments, correct?

25 A. This one in front of me, no.

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DEFOREST MCDUFF, Ph.D.

Q. And, similarly, if you look at paragraph 15, there appears to be a missing chart; is that correct?

A. Yes. My understanding is that this is some sort of printing issue. You can see the corresponding chart that should be there on -- in paragraph 15 of the 1622 declaration, and my understanding is that this chart was included in an updated version of my declaration that was provided to the patent holder at some point. It can also be seen in the underlying documents that are cited here in footnote 6.

Q. At what point did you realize that the declaration for the '240 patent did not contain the attachments?

A. That was yesterday when I was flying from Boston to Chicago in preparation for this deposition.

Q. So since June of 2017, you hadn't noticed that there were no attachments to this declaration?

A. I was not aware that they were omitted until yesterday morning.

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DEFOREST MCDUFF, Ph.D.

Q. Now, other than the absence of attachments and the figure in paragraph 15 in the '240 declaration as well as cites to the different prosecution histories for the '507 patent versus the '240 patent and the different declarations from Dr. Donovan, are you aware of any other differences between these two declarations?

A. This may be a minor point, but the two declarations do reference their respective patents in paragraphs 8 and 9 where describing the patents-at-issue and then other places where they reference the patent. That's the only other difference that comes to mind.

Q. So your opinions with respect to Tyvaso are the same in both declarations.

Is that fair to say?

A. As a summary opinion, I would agree with that. I draw the same conclusions in both declarations.

(WHEREUPON, the document was tendered to the witness.)

BY MR. DELAFIELD:

Q. You have been handed what's

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DEFOREST MCDUFF, Ph.D.

been marked as Exhibit 1001 for IPR 2017-01622.

Do you recognize this document?

A. I do.

Q. This is U.S. Patent 9,339,507, correct?

A. It appears to be, yes.

Q. Have you reviewed this document?

A. Yes.

Q. Is it important to understand the claimed subject matter of the patents to perform your analysis?

A. As a general matter from the perspective of an economist, it's one of the things that I do. I would say it's important to understand from an economic perspective.

Q. Did anyone assist you with understanding the technical aspects of this patent?

A. Yes, I read the patent myself. I discussed the patent and the claimed inventions with counsel. I also reviewed the declaration of Dr. Donovan.

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DEFOREST MCDUFF, Ph.D.

Q. Did you do anything to understand the patent?

A. Yes, I also reviewed the patent prosecution and the documents that I cite in my declaration with respect to the claimed invention and associated benefits.

Q. If you turn to the back page 24, you see a list of claims under column 18. Do you see that?

A. Yes.

Q. Which claims did you analyze for your analysis?

A. My analysis addresses the claims collectively. I don't recall providing a breakdown or differentiation of one claim versus another.

Q. Do you understand that each claim of a patent is its own invention?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I wouldn't purport to provide a legal conclusion or perspective on that. I am familiar with that notion.

1 DEFOREST MCDUFF, Ph.D.

2 BY MR. DELAFIELD:

3 Q. Do you know which claims of  
4 the '507 patent are at issue in this case?

5 A. Sitting here, I don't recall.

6 Q. You don't specify any claims  
7 in your declaration for the '507 patent,  
8 correct?

9 A. I don't believe so. As  
10 indicated, I have addressed the claims  
11 collectively rather than individually.

12 Q. But you agree there are  
13 differences within the claims, right?

14 A. I believe so, yes.

15 Q. But you didn't provide any  
16 separate analysis for any specific claim,  
17 correct?

18 A. As I described, I addressed  
19 the claims collectively. I did not provide a  
20 breakdown or direct analysis of individual  
21 claims compared to other claims.

22 Q. And to clarify, you don't know  
23 which claims are at issue in this case?

24 A. Sitting here, I don't recall.

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DEFOREST MCDUFF, Ph.D.

(WHEREUPON, the document was  
tendered to the witness.)

BY MR. DELAFIELD:

Q. You have been handed what's  
been marked as Exhibit 1001 for IPR 2017-01621  
which is U.S. Patent 9,358,240.

Do you recognize this  
document?

A. I do, yes.

Q. Have you reviewed this  
document?

A. Yes.

Q. Now, the same questions I  
asked for the '507 patent. If you could turn  
to page 24. Did you provide an analysis for  
each -- strike that.

Do you know which claims are  
at issue in this case for the '240 patent?

A. Sitting here, I don't recall.

Q. And like the '540 -- strike  
that.

Like the '507 patent, you only  
provided an analysis of the claims as a whole  
and not individually, correct?

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DEFOREST MCDUFF, Ph.D.

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I wouldn't describe it that way. I do agree that I evaluated the claims collectively rather than providing distinctions of one claim versus another, but as I think of it, my analysis applies to all of the claims as well as the individual claims.

BY MR. DELAFIELD:

Q. So for both patents, you agree that your opinion applies to all of the claims for both patents; is that correct?

A. I agree with that, yes.

Q. And so by that rationale, all of the claims embody Tyvaso, correct -- or strike that -- or Tyvaso would embody all of the claims of both patents, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I haven't provided an opinion on that.

BY MR. DELAFIELD:

Q. Well, your opinion is about Tyvaso primarily, correct?

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DEFOREST MCDUFF, Ph.D.

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. It's about commercial success aspects of Tyvaso, yes.

BY MR. DELAFIELD:

Q. And so if one claim was not covered by Tyvaso, that would change your analysis, right?

A. Sitting here, I don't see how my opinions would be any different if that were true.

Q. What is the difference between these two patents?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I would defer to technical experts to provide technical opinions on the differences. My understanding at a very high level from an economic perspective is that the '507 patent has claims that relate to kits, and the '240 patent has claims that relate to methods, and largely they are similar in aspects as well.

1                                    DEFOREST MCDUFF, Ph.D.

2                    BY MR. DELAFIELD:

3                    Q.            But for your opinion, you did  
4                    not provide different analyses for the two  
5                    patents, correct?

6                    A.            I submitted separate  
7                    declarations one for each patent. Yet as an  
8                    economist, my opinions are the same with  
9                    respect to the '240 patent and the '507 patent.  
10                   I viewed the analysis as appropriately similar  
11                   across the two patents.

12                   Q.            So you would agree that the  
13                   equipment and methods described in the claims  
14                   of the '240 patent and the '507 patent are  
15                   required to use Tyvaso, correct?

16                   MR. MATHAS: Object to the form.

17                   BY THE WITNESS:

18                   A.            I don't recall providing an  
19                   opinion on that one way or the other.

20                   BY MR. DELAFIELD:

21                   Q.            Well, that is why you provide  
22                   opinions about Tyvaso because these two patents  
23                   are listed in the Orange Book as being covered  
24                   by Tyvaso, correct?

25                   A.            That's my understanding.

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DEFOREST MCDUFF, Ph.D.

Q. So you would agree that the claims of the '240 patent and the '507 patent are required to use Tyvaso?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't know if I would go so far as to say required. I don't believe I have provided that opinion. I do understand these patents to be listed in the FDA Orange Book. So from an economic perspective, I understand they are alleged to cover Tyvaso.

BY MR. DELAFIELD:

Q. Are you aware of any evidence that a patient can use Tyvaso without the claimed kit and methods described in the '240 patent or the '507 patent?

A. I would have to think more about that to provide a conclusion on that from a global perspective, but I do understand that there are certain limitations here in claims 1 of each patent, and that there are other ways to deliver treprostinil in inhaled form that would not fall under the scope of these patents.

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DEFOREST MCDUFF, Ph.D.

For example, what's listed here in claim 1 about being delivered via a nebulizer or having certain opto-acoustical triggers, for example.

Q. So you are saying you are aware that treprostinil can be delivered in inhaled form not using the technology described in the '240 patent or the '507 patent?

A. That's my understanding. I would defer to a clinician or a technical expert to provide a conclusion or an opinion on that point.

Q. You don't provide any evidence that treprostinil can be used in an inhaled form other than used through the equipment and methods described in the '507 patent and the '240 patent, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Would you mind reading the question, please.

(WHEREUPON, the record was read by the reporter.)

1 DEFOREST MCDUFF, Ph.D.

2 BY THE WITNESS:

3 A. For my purposes, that's not  
4 something I specifically set out to do, nor  
5 have done, but I think looking at the patents,  
6 it's to some degree common sense that the  
7 patents describe delivering treprostinil  
8 through inhaled form. They describe a metered  
9 dose inhaler, but I understand that that is  
10 different than the claims.

11 There are certain limitations  
12 here in claim 1 such as the opto-acoustical  
13 trigger. So, for example, if one wanted to  
14 provide with a different kind of trigger, just  
15 an acoustical trigger, I think it is sensible  
16 that it could be delivered that way, but it's  
17 not something that I am providing a clinical  
18 opinion on. That's just my understanding as an  
19 economist.

20 BY MR. DELAFIELD:

21 Q. But you don't have any  
22 evidence that treprostinil could be used in an  
23 inhaled form other than how it's described in  
24 the '240 patent and the '507 patent, correct?

25 MR. MATHAS: Same objection.

1 DEFOREST MCDUFF, Ph.D.

2 BY THE WITNESS:

3 A. As I have described in my  
4 previous response, that's not a question that I  
5 set out to answer or provide an independent  
6 opinion or conclusion on. Yet I think reading  
7 the patents, that's to some degree clear, and  
8 that's my understanding, but it's not something  
9 I specifically set out to provide evidence or  
10 draw an opinion on.

11 BY MR. DELAFIELD:

12 Q. So it is just speculation?

13 A. I wouldn't describe it that  
14 way.

15 Q. Well, how do you know that  
16 treprostinil could be used in inhaled form in  
17 any other way but those described in these two  
18 patents?

19 A. That's my understanding as an  
20 economist of what is claimed by the patents and  
21 what is described in the patents in the  
22 background in the summary.

23 Q. Are you aware of anyone ever  
24 inhaling treprostinil other than through use of  
25 the kit and methods described in the '507

1 DEFOREST MCDUFF, Ph.D.

2 patent and the '240 patent?

3 A. I don't know. That's not  
4 something I set out to evaluate.

5 Q. So you said you didn't set out  
6 to evaluate.

7 If there was another nebulizer  
8 or process to inhale treprostiniil that was  
9 available on the market, wouldn't that be  
10 relevant as competition for commercial success?

11 A. It could be.

12 Q. But you didn't investigate  
13 that?

14 MR. MATHAS: Object to the form.

15 BY THE WITNESS:

16 A. I did evaluate competition for  
17 Tyvaso. I evaluated a number of PAH drugs. I  
18 don't recall there being a competing product  
19 that delivers treprostiniil in an inhaled form.

20 BY MR. DELAFIELD:

21 Q. So sitting here today, you are  
22 not aware of any other -- strike that.

23 So sitting here today, you are  
24 not aware of any other way to administer  
25 treprostiniil in an inhaled form except for

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DEFOREST MCDUFF, Ph.D.

what's described by the '240 and '507 patents?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't believe that was my testimony, no.

BY MR. DELAFIELD:

Q. You are not aware of a competing product that delivered treprostinil in an inhaled form, correct?

A. Outside of Tyvaso, that's correct.

Q. And so the kit and methods described in the claims of the '240 patent and the '507 patent are necessary to use Tyvaso, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't believe I have provided an opinion on that one way or the other.

BY MR. DELAFIELD:

Q. You have reviewed the label for Tyvaso, correct?

A. I believe so, yes.

1 DEFOREST MCDUFF, Ph.D.

2 Q. Do you recall that it  
3 describes the kit and process used to inhale  
4 treprostiniil?

5 A. I don't recall specifically  
6 what it says with respect to the kit and the  
7 method claimed here in these patents.

8 Q. But is it your understanding  
9 that the kit and methods used to administer  
10 Tyvaso use the technology claimed in the '240  
11 and '507 patents?

12 A. I mean, I do understand that  
13 they are listed in the FDA Orange Book to cover  
14 Tyvaso. So I have that understanding that they  
15 are alleged to cover Tyvaso. Whether all  
16 administration of Tyvaso falls within the scope  
17 of these claims, I am not sure. I didn't set  
18 out to evaluate that.

19 Q. If they don't fall within the  
20 scope of these claims, wouldn't that affect  
21 your opinion on commercial success -- strike  
22 that.

23 So let's say, for example, you  
24 could nebulize and administer treprostiniil  
25 through an inhaled form using a different type

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DEFOREST MCDUFF, Ph.D.

of inhalation process. That would be known as a design around.

Are you familiar with that term?

A. I am familiar with that term.

Q. And so if a design around was available, wouldn't that be relevant to commercial success in terms of what else was available to administer treprostinil?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. It could be relevant, and as discussed in my declaration, I haven't seen any evidence from patent owner that these specific limitations provide benefits relative to an alternative form of delivery that did not have these limitations. That's one of the opinions I provide.

BY MR. DELAFIELD:

Q. You said you reviewed the prosecution history, correct?

A. Yes.

Q. And do you recall the declarations of Dr. Zamanian?

1                                    DEFOREST MCDUFF, Ph.D.

2                                    A.                    I do.

3                                    Q.                    And in those declarations he  
4 provided clinical benefits of Tyvaso over other  
5 inhaled pulmonary hypertension treatments,  
6 right?

7                                    A.                    Relative to Venativs, as I  
8 recall.

9                                    Q.                    Yes. So you have seen  
10 evidence from patent owner that those specific  
11 declarations provide benefits to an alternative  
12 form of delivery, right?

13                                   A.                    I don't agree with that. I  
14 discuss that in my declaration that differences  
15 between Tyvaso and Venativs are largely  
16 attributable to the treprostiniil compound  
17 itself. That's based on review of  
18 Dr. Donovan's declaration.

19                                   Q.                    And you don't have any  
20 independent opinion on that point other than  
21 your reference to Dr. Donovan's declaration; is  
22 that correct?

23                                   A.                    Well, I provide an evaluation  
24 of the economic aspect of that. So if  
25 Dr. Donovan provides the clinical aspect with

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DEFOREST MCDUFF, Ph.D.

respect to the difference between the two products being the chemical compound, I then provide an economic opinion based on that which is, thus, there's no connection based on that comparison between the patents and the commercial performance of Tyvaso.

Q. Assuming that the kit and methods described in the '240 and '507 patents are required to use Tyvaso, then whatever commercial success Tyvaso obtained, part of that success would be attributable to the '240 patent and the '507 patent if those are required, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Could you read the question, please.

(WHEREUPON, the record was read by the reporter.)

BY THE WITNESS:

A. No, I wouldn't agree with that, not as a global conclusion.

BY MR. DELAFIELD:

Q. Why not?

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DEFOREST MCDUFF, Ph.D.

A. Well, one example that comes to mind is if they were required from some FDA regulation perspective that this was one thing that was required by the FDA yet there was another method or another design that would have worked just as easily well, I wouldn't necessarily conclude a nexus between the commercial performance and the patents-at-issue just because it was required from an FDA perspective.

Q. Are you aware of the FDA requiring the specific type of equipment and method used in the '240 and '507 patents in this case?

A. I don't recall sitting here. That's not something I specifically set out to evaluate.

Q. So in general if you are evaluating a product covered by multiple patents and part of that product is covered -- strike that.

For example, if you are considering the commercial success of a car, which is probably covered by thousands of

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DEFOREST MCDUFF, Ph.D.

patents, you would agree that a patent on the wheels would be a required component of that car, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, in that example a specific kind of wheel might be required for a specific kind of car based on some external regulation like a highway regulation or a transportation regulation for the specifics of that car, but you wouldn't necessarily conclude a nexus or a connection to those patents because it's possible that that car could have a different kind of tire and still be a commercially viable car with no difference to demand for the car.

So just because it's required from some sort of regulatory perspective doesn't necessarily mean that there's a nexus or connection to the patent at issue.

BY MR. DELAFIELD:

Q. So in this example are you saying there would still be a demand for a car without wheels?

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DEFOREST MCDUFF, Ph.D.

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. No, that's not what I am saying.

BY MR. DELAFIELD:

Q. Well, going back to Tyvaso, you are not aware of any method of delivering treprostinil through inhalation methods commercially available other than Tyvaso, correct?

A. I'm sorry. Could you read the question again.

(WHEREUPON, the record was read by the reporter.)

BY THE WITNESS:

A. In terms of a competing product, I am not aware of products that compete with Tyvaso that provide inhaled treprostinil. Whether Tyvaso could be administered outside the claims of the patents-at-issue that may be true.

BY MR. DELAFIELD:

Q. But are not aware of any evidence that that is true, correct?

1                   DEFOREST MCDUFF, Ph.D.

2                   MR. MATHAS: Object to the form.

3 BY THE WITNESS:

4                   A.            I don't believe that's  
5 something I specifically sought out to confirm  
6 one way or the other.

7 BY MR. DELAFIELD:

8                   Q.            So you are not aware of any  
9 evidence that that is true, right?

10                  MR. MATHAS: Object to the form.

11 BY THE WITNESS:

12                  A.            Not sitting here as it's not  
13 something that I set out to evaluate. It seems  
14 sensible to me that it could be true given my  
15 understanding of the claims of the patents  
16 here.

17 BY MR. DELAFIELD:

18                  Q.            But, again, you are not aware  
19 of anyone ever administering treprostinil via  
20 inhalation other than through use of the  
21 equipment provided with Tyvaso, correct?

22                  MR. MATHAS: Object to the form.

23 BY THE WITNESS:

24                  A.            If I understand your question,  
25 it's just not something that I have sought to

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DEFOREST MCDUFF, Ph.D.

evaluate or provide a conclusion on one way or the other.

BY MR. DELAFIELD:

Q. Since you didn't seek to evaluate it, you are not aware of any evidence that would show that a person could take treprostiniil in an inhaled form except through using the Tyvaso system, correct?

A. Well, based on my understanding of the claims and the reading of the patents, it seems sensible to me that one could do that, but I have not sought to provide that opinion or evaluate evidence to support that claim.

Q. But are not a technical expert, right?

A. No.

Q. So you don't know if what's not in the claims would work for treprostiniil, correct?

A. I wouldn't purport to provide a clinical or technical opinion on that, no.

THE WITNESS: Maybe now would be a good time for a break?

1                   DEFOREST MCDUFF, Ph.D.

2                   MR. DELAFIELD:    Sure.

3                   THE VIDEOGRAPHER:  The time is  
4  10:52 a.m.  This is the end of media 1.  We are  
5  off the record.

6                               (WHEREUPON, a recess was had at  
7                               10:52 a.m. until 11:03 a.m.)

8                   THE VIDEOGRAPHER:  The time is now  
9  11:03 a.m.  This is the beginning of media 2.  
10 We are back on the record.

11 BY MR. DELAFIELD:

12                   Q.           Welcome back.

13                   A.           Thank you.

14                               (WHEREUPON, the documents were  
15                               tendered to the witness.)

16 BY MR. DELAFIELD:

17                   Q.           I have handed you four  
18 exhibits.  The first being Exhibit 1162 for IPR  
19 2017-01622 which is a Substantive Submission  
20 Under 37 C.F.R. Section 1.114 part of the  
21 prosecution history for the '507 patent.

22                               The second exhibit I have  
23 handed you is Exhibit 1163 for IPR 2017-01622  
24 which is Supplement Amendment and Reply Under  
25 37 CFR 1.111 also from the '507 patent

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DEFOREST MCDUFF, Ph.D.

prosecution history. Let's start with those two.

Do you recognize these documents?

A. I do, yes.

Q. Did you review these documents in preparing your declaration?

A. Yes.

Q. The last two exhibits you have been handed are Exhibit 1162 for IPR 2017-01621 which is also entitled Substantive Submission Under 37 C.F.R. Section 1.114 and is part of the prosecution history for the '240 patent, and Exhibit 1163 for IPR 2017-01621 which is entitled Supplement Amendment and Reply Under 37 CFR 1.111 which is also part of the prosecution history for the '240 patent.

Are you familiar with these two documents?

A. Yes.

Q. And did you review these two documents in preparation of your declaration?

A. Yes.

Q. Okay. I wanted to hand you

1                                    DEFOREST MCDUFF, Ph.D.

2                    all four because they are very similar, and so  
3                    we can go through probably two at a time. I  
4                    assume your answers will likely be the same  
5                    because they are very similar. So let's look  
6                    at Exhibit 1162 for both cases if you kind of  
7                    have them side by side.

8                    A.            Okay.

9                    Q.            And if you turn to page 22 --  
10                   actually, sorry -- if you could turn to page 19  
11                   of both exhibits 1162.

12                                    Do you see this is the start  
13                   of the declaration under 37 C.F.R. Section  
14                   1.132 of Dr. Roham T. Zamanian.

15                                    Do you see that?

16                    A.            Yes.

17                    Q.            Now, if you could just briefly  
18                   look through his declaration until page 8 or  
19                   page 26 of the exhibit in both. I will let you  
20                   take a second to look.

21                    A.            Okay.

22                    Q.            Both declarations are very  
23                   similar, correct?

24                    A.            They appear to be, yes.

25                    Q.            And specifically if you look

1                                    DEFOREST MCDUFF, Ph.D.

2                    at page 22 starting paragraph 18, there's a  
3                    section called Commercial Success of Tyvaso.

4                                    Do you see that?

5                    A.                    Yes.

6                    Q.                    And that section is identical  
7                    between the two declarations, right?

8                    A.                    I believe so, yes.

9                    Q.                    So with that in mind, I am  
10                    just going to refer to Exhibit 1162 for the  
11                    01622 case, but you understand that my  
12                    questions are in reference to both cases  
13                    because we are talking about the exact same  
14                    disclosure.

15                                    Do you understand?

16                    A.                    I do.

17                    Q.                    Okay. So looking at Exhibit  
18                    1162 at page 19, paragraph 1 it says: "I,  
19                    Dr. Roham T. Zamanian, hereby declare I  
20                    received a Bachelor of Science and Doctor of  
21                    Medicine from the University of California  
22                    Irvine, where I also completed my intership,  
23                    residency, and a fellowship in pulmonary  
24                    medicine and critical care."

25                                    Do you see that?

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DEFOREST MCDUFF, Ph.D.

A. Yes.

Q. And through his declaration and attached CV, you would agree that he has treated patients with pulmonary hypertension, correct?

A. I don't see that here, but it seems plausible to me that that's true.

Q. Did you review his CV in preparation for your declaration?

A. Yes.

Q. And that indicates he was involved in several clinical trials involving pulmonary hypertension?

A. That may be true. I don't recall.

Q. You would agree that Dr. Zamanian is familiar with the use of Tyvaso in treating pulmonary hypertension based on his declaration and CV, correct?

A. That's my understanding.

Q. Now, turning to page 22 where he starts the discussion of commercial success of Tyvaso, at paragraph 18 he says:  
"Interestingly, once Tyvaso entered the market,

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DEFOREST MCDUFF, Ph.D.

it was clinically preferred to Venativs."

Do you have any reason to disagree with that statement?

A. Well, I do disagree with his explanation for that. As you can see in the next sentence, that claim appears to be supported by the graph on the following page which is the graph showing a market share calculated among U.S. inhaled prostacyclins which I discuss in my expert report, and I discuss the flaws in that presentation. So I do disagree with how he is explaining it here.

Q. Well, I am asking specifically do you have any reason to disagree that Tyvaso was preferred to Venativs once it entered the market?

A. Well, it's not clear what he means by that. Does he mean preferred by everybody, preferred by some patients, preferred by some physicians? It's not -- certainly not preferred by everyone.

Q. Well, in the graph it shows that the market share increased for Tyvaso and decreased for Venativs, correct, over time?

1                                    DEFOREST MCDUFF, Ph.D.

2                    A.            Well, I see what the graph  
3 purports to show. As I explain in my  
4 declaration, I think it misrepresents the  
5 market. You know, in particular this graph  
6 makes it appear that Tyvaso is taking market  
7 share from Venativs, but the data don't support  
8 that claim.

9                                    If you look at Venativs sales  
10 over time, they actually don't decrease very  
11 much over that period. They are more flat, and  
12 Tyvaso is competing with a broader set of  
13 competitors. I think this misrepresents the  
14 market.

15                    Q.            I understand you have a  
16 different definition of what the market should  
17 be, but in your declaration, you don't disagree  
18 with the data itself presented in paragraphs  
19 18, 19 of Zamanian's declaration, correct?

20                    A.            Well, I don't believe the  
21 underlying data supporting this graph was  
22 provided. I don't know what it's based on. I  
23 didn't calculate an alternative presentation of  
24 this based on different data.

25                    Q.            If you turn to your

1                                    DEFOREST MCDUFF, Ph.D.

2                    declaration Exhibit 1055 for the '507 patent  
3                    Attachment B-4.

4                    A.            I'm there.

5                    Q.            You provide revenues by year  
6                    for Tyvaso and Venativs, correct?

7                    A.            Yes.

8                    Q.            And so using those numbers,  
9                    you could have checked to see if the market  
10                    share analysis done by Dr. Zamanian is correct,  
11                    right?

12                    A.            Well, for the reasons  
13                    discussed in my declaration, I don't view it as  
14                    correct, but if one wanted to try to create  
15                    that graph with the data in Attachment B-4, one  
16                    could do that.

17                    Q.            But you didn't do that?

18                    A.            Correct, not as part of my  
19                    analysis.

20                    Q.            So I understand that you have  
21                    a different analysis, but you don't have any  
22                    reason to doubt that the analysis he performed  
23                    is incorrect in terms of the facts presented,  
24                    correct?

25                    MR. MATHAS: Object to the form.

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DEFOREST MCDUFF, Ph.D.

BY THE WITNESS:

A. For my declaration, it's not something I specifically evaluated, but just eyeballing some of the figures here, they don't appear to line up one for one with the graph. For example, in 2013 if one were to perform that calculation, it looks like you would get less than 80 percent of the share between those two drugs for Tyvaso with the sales being 119 for Venativs and 439 for Tyvaso. Yet here in his graph he has greater than 80 percent for Tyvaso. So, you know, you get different results.

I don't know what figures his data are based on whether it's units or prescriptions or revenues. It doesn't line up one for one, but I haven't sought to provide an alternative based on these revenues not in my declaration.

Q. To clarify, one difference I just realized he is providing U.S. inhaled prostacyclin market share.

Do you see that?

A. Yes.

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DEFOREST MCDUFF, Ph.D.

Q. And your Attachment B-4 is sales throughout the world, correct?

A. Yes, as reported by companies.

Q. So looking at your Attachment B-4, you would agree that Tyvaso sales increased from 2009 to 2014, correct?

A. Yes.

Q. And during that same time, Venativs sales roughly stayed the same, correct?

A. They have been roughly flat, yes.

Q. And you agree that Tyvaso and Venativs are the only two inhaled treatments for pulmonary hypertension, correct?

A. To the best of my recollection, yes.

Q. So what are the clinical benefits of Tyvaso over Venativs?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. This is discussed in my declaration in paragraphs 18 and 20. I understand that patent owner has claimed some

1                   DEFOREST MCDUFF, Ph.D.

2           differences in dosing regimen and delivery, and  
3           I explain in paragraph 20 that based on the  
4           opinions of Dr. Donovan, that those differences  
5           relate to the differences between the  
6           compounds -- between the two products and the  
7           different half-lives.

8                   So in other words, the number  
9           of times the patient takes each product is  
10          different because the compounds have different  
11          half-lives.

12                  Q.           And those are the only  
13          opinions you provided with respect to any  
14          clinical benefit of Tyvaso over Venativs; is  
15          that correct?

16                  A.           Those are the primary  
17          opinions. Paragraph 18 provides the alleged  
18          benefits by patent owner. Paragraph 20  
19          explains them in context with respect to the  
20          opinions of Dr. Donovan.

21                  Q.           Did you consider the rest of  
22          Dr. Zamanian's opinions with respect to  
23          clinical benefits of Tyvaso?

24                  A.           Yes.

25                  Q.           So looking at 1162 at page 23,

1 DEFOREST MCDUFF, Ph.D.

2 paragraph 20, he states: "Because of the  
3 pharmacodynamic differences between iloprost  
4 and treprostinil, Tyvaso does not need to be  
5 administered as frequently as Venativs, leading  
6 to higher patient compliance."

7 Do you see that?

8 A. Yes.

9 Q. Do you agree with that  
10 statement?

11 A. I don't have an agreement or  
12 disagreement with it.

13 Q. Do you have any reason to  
14 disagree with it?

15 A. Not sitting here. It strikes  
16 me as a clinical opinion.

17 Q. So we discussed how  
18 Dr. Zamanian was -- is an M.D. who focuses on  
19 treatment of pulmonary hypertension, correct?

20 A. That's my understanding.

21 Q. Dr. Donovan is not an M.D.,  
22 right?

23 A. I would have to go back and  
24 refresh my memory. I don't recall sitting  
25 here.

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DEFOREST MCDUFF, Ph.D.

Q. I can represent she's not an M.D.

Do you know if Dr. Donovan had experience with treatments for pulmonary hypertension before this case?

A. I don't recall.

Q. So why are you relying on Dr. Donovan's opinion and not Dr. Zamanian's opinion?

A. I am not seeking to provide an opinion on any dispute between Dr. Zamanian and Dr. Donovan. I am simply noting what Dr. Donovan explains as an explanation for those differences. Reading it as an economist, Dr. Zamanian appears to agree based on what he is writing here in terms of the half-life being attributable to the different compounds, but I am not seeking to provide an opinion on which is correct and which is incorrect.

I simply provide the economic implication of Dr. Donovan's clinical opinion which is that there's no nexus between the commercial performance and the patents-at-issue.

1                                    DEFOREST MCDUFF, Ph.D.

2                    Q.            But Dr. Zamanian specifically  
3                    says there is a nexus, correct?

4                    A.            If you are looking at it,  
5                    could you point me to it? I don't see that  
6                    opinion looking through the Zamanian  
7                    declaration here.

8                    Q.            Actually, if you look at -- if  
9                    you turn to Exhibit 1163 starting at page 23,  
10                   and actually like we did for 1162, if you have  
11                   both versions of Exhibit 1163 open to page 23,  
12                   both the second declarations are roughly the  
13                   same.

14                                    Is that fair to say?

15                    A.            They appear to be, yes.

16                    Q.            And did you review these prior  
17                    to your declaration?

18                    A.            Yes.

19                    Q.            So if you turn to paragraph 16  
20                    which is on page 26 of Exhibit 1163, under  
21                    Commercial Success he states: "There is a  
22                    clear nexus between the commercial success of  
23                    Tyvaso and the technical features of the  
24                    pending claims, including the single event  
25                    dosing of 'from 15 micrograms to 90 micrograms

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DEFOREST MCDUFF, Ph.D.

of treprostinil,' the single inhalation event of '18 or less breaths,' and the pulsed ultrasonic nebulizer."

Do you see that?

A. I do.

Q. Did you consider that in forming your opinions?

A. Yes.

Q. And so why do you credit Dr. Donovan's opinion over Dr. Zamanian?

A. I'm not seeking to resolve any dispute between those two experts. I am simply relying on the opinion of Dr. Donovan in explaining the economic implication of that. So if Dr. Donovan is correct that differences between Tyvaso and Venativs derives primarily from differences between treprostinil and iloprost rather than the alleged innovative aspects of the patent-at-issue, then from an economic perspective, there's no nexus between the commercial performance of Tyvaso and the patents-at-issue. So that's the opinion I am providing.

Q. But Dr. Zamanian obviously

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DEFOREST MCDUFF, Ph.D.

disagrees with Dr. Donovan, and I am just trying to understand what basis you have to rely on Dr. Donovan over Dr. Zamanian.

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I would provide the same answer. I am happy to try to do so again, but it's the same answer.

BY MR. DELAFIELD:

Q. Now, sitting here today, you said that you couldn't recall if Dr. Donovan had any experience with pulmonary hypertension or was a doctor, correct?

A. I just don't recall her specific qualifications sitting here. I would need to look at her declaration or CV.

Q. But you do know Dr. Zamanian is an M.D. and treats pulmonary hypertension and is obviously familiar with the use of Tyvaso, correct?

A. He does appear to be an M.D. based on what we have looked at. I don't know the extent to which he personally treats PAH or not.

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DEFOREST MCDUFF, Ph.D.

Q. If you look at paragraph 5 of Exhibit 1163, he says: "Prior to consulting for United Therapeutics, I was a principal investigator in the 'Aspire' registry comparing the incidence of respiratory tract adverse events in patients treated with United Therapeutics' product Tyvaso with other FDA approved pulmonary hypertension therapies."

Do you see that?

A. I do.

Q. So he was involved with patients treated with Tyvaso, correct?

A. It appears so based on this information.

Q. So what basis do you have to conclude that Dr. Donovan is right with respect to her statement regarding the nexus and Dr. Zamanian is wrong with his statement regarding the nexus?

A. Well, in an evaluation of nexus, the idea is to connect the commercial performance to the alleged innovative aspects of the patents-at-issue. I can see what Dr. Zamanian has done.

1                   DEFOREST MCDUFF, Ph.D.

2                   He says that Tyvaso has been  
3                   clinically preferred to Venativs because of its  
4                   clinical advantages, but in his analysis in  
5                   these exhibits that we have reviewed, he  
6                   doesn't appear to tie the commercial  
7                   performance to the patents-at-issue. He, in  
8                   fact, attributes the difference in performance  
9                   to things that are not claimed.

10                  And so I explain Dr. Donovan's  
11                  opinion in that regard from a clinical  
12                  perspective. I am not seeking to resolve a  
13                  dispute between Dr. Zamanian and Dr. Donovan,  
14                  but I do rely on Dr. Donovan and explain the  
15                  economic implication of that.

16                  Q.            In Exhibit 1163 on page 26, we  
17                  just discussed paragraph 16. He states:  
18                  "There is a clear nexus between the commercial  
19                  success of Tyvaso and the technical features of  
20                  the pending claims, including the single event  
21                  dosing of 'from 15 micrograms to 90 micrograms  
22                  of treprostiniil,' the single event of '18 or  
23                  less breaths,' and the pulsed ultrasonic  
24                  nebulizer."

25                  Do you see that?

1 DEFOREST MCDUFF, Ph.D.

2 A. I do.

3 Q. And so he is pointing  
4 specifically to claimed features of the patent  
5 and not the drug substance as contributing or a  
6 nexus to the commercial success of Tyvaso,  
7 correct?

8 MR. MATHAS: Object to the form.

9 BY THE WITNESS:

10 A. In this paragraph he appears  
11 to be making a claim of nexus to the subject  
12 matter. In the previous Exhibit 1162 he does  
13 not appear to.

14 BY MR. DELAFIELD:

15 Q. Do you have any reason to  
16 disagree with paragraph 16 in Exhibit 1163?

17 A. Yes, I do. That's explained  
18 in my declarations. I would be happy to try to  
19 summarize it for you.

20 Q. Is your disagreement just  
21 based on the fact that Dr. Donovan said  
22 something different than what is said here?

23 MR. MATHAS: Object to the form.

24 BY THE WITNESS:

25 A. It is not based just on that,

1                                    DEFOREST MCDUFF, Ph.D.

2                                    no.

3                                    BY MR. DELAFIELD:

4                                    Q.                    You do not provide any  
5                                    evidence in your declaration that demonstrates  
6                                    that paragraph 16 is incorrect, right?

7                                    MR. MATHAS:    Object to the form.

8                                    BY THE WITNESS:

9                                    A.                    I don't agree with that.

10                                   BY MR. DELAFIELD:

11                                   Q.                    Can you point me to anything  
12                                   in your declaration that specifically discusses  
13                                   why there's no nexus to the claim limitations  
14                                   of single event dosing from 15 micrograms to 90  
15                                   micrograms of treprostinil and the single  
16                                   inhalation event of 18 or less breaths and  
17                                   pulsed ultrasonic nebulizer?

18                                   A.                    Sure.    This is a large part of  
19                                   what my declaration is about.    If you turn to  
20                                   page 13 of Exhibit 1055 from the 1622 case, you  
21                                   will see Section C there Alleged commercial  
22                                   success based on a flawed evaluation of nexus.  
23                                   That's in paragraphs 18, 19, 20, and 21.

24                                                                      In addition, if you go to page  
25                                   18 of the same document, you will see the

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DEFOREST MCDUFF, Ph.D.

section header Section E Low or no economic relevance of alleged commercial success, and you can see paragraphs 26 through 37 where I provide a valuation of nexus between commercial performance of Tyvaso and the claimed subject matter.

Q. Okay. My question was specifically to those claim elements.

You don't provide any detail as to why Dr. Zamanian is wrong in his assessment of those specific claim elements with respect to nexus, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I'm not sure what you mean by that. My understanding is that Dr. Zamanian is speaking to a potential nexus between commercial performance of Tyvaso and the aspects of the pending patent claims, and that's what I have addressed in the paragraphs I referenced in my previous response.

BY MR. DELAFIELD:

Q. But you don't address those claim limitations, correct?

1                   DEFOREST MCDUFF, Ph.D.

2                   MR. MATHAS: Object to the form.

3 BY THE WITNESS:

4                   A.           I don't agree with that.

5 BY MR. DELAFIELD:

6                   Q.           Can you show me anywhere in  
7 your report where you discuss a dosing range of  
8 15 micrograms to 90 micrograms or a single  
9 inhalation event of 18 or less breaths?

10                  A.           I mean, I reference those in  
11 summary form in paragraph 18 where I reference  
12 the dosing regimen and the pulsed ultrasonic  
13 nebulizer. Those are the claimed benefits set  
14 forth by the patent owner, as I understand  
15 them. Those are consistent with what  
16 Dr. Zamanian has articulated as claimed  
17 benefits.

18                  Q.           But you don't address whether  
19 those claimed benefits provide a nexus to the  
20 commercial success, correct?

21                  MR. MATHAS: Object to the form.

22 BY THE WITNESS:

23                  A.           I don't agree with that.  
24 That's what these paragraphs in my report are  
25 about.

1                                    DEFOREST MCDUFF, Ph.D.

2                    BY MR. DELAFIELD:

3                    Q.            So let me put it another way.  
4                    So the claims include several different  
5                    elements.

6                                    Do you agree with that?

7                    A.            That's my understanding.

8                    Q.            And you have provided an  
9                    opinion that certain claim elements do not  
10                    contribute to -- strike that.

11                                    That certain claim elements do  
12                    not provide a nexus to the commercial success  
13                    of Tyvaso.

14                                    Do you agree with that?

15                    A.            I am not sure what you mean by  
16                    that. Could you point me to something specific  
17                    in my declaration?

18                    Q.            Well, in the paragraphs you  
19                    mentioned paragraphs 18 through 20. For  
20                    example, in paragraph 20 you reference  
21                    difference in commercial performance are  
22                    largely attributable to the drug substance  
23                    treprostiniil.

24                    A.            Yes.

25                    Q.            But you don't address whether

1                                    DEFOREST MCDUFF, Ph.D.

2                    the other claim elements would provide a nexus  
3                    to the commercial success, right?

4                                    MR. MATHAS: Object to the form.

5                    BY MR. DELAFIELD:

6                                    Q.                    Put it another way. You don't  
7                    do anything to rebut the statement made by  
8                    Dr. Zamanian in paragraph 16 where he claims  
9                    there's a nexus between the dosing and breaths  
10                   to commercial success specifically, right?

11                                   MR. MATHAS: Object to the form.

12                    BY THE WITNESS:

13                                   A.                    I don't agree with that.

14                    BY MR. DELAFIELD:

15                                   Q.                    Where do you address in terms  
16                   of nexus the dosing and number of breaths?

17                                   MR. MATHAS: Asked and answered.

18                    BY THE WITNESS:

19                                   A.                    It's provided in the  
20                   paragraphs citations I gave to you earlier.  
21                   Paragraphs 18 to 21 and paragraphs 26 to 37 of  
22                   my declaration addressing nexus between the  
23                   claimed inventions and commercial performance  
24                   of Tyvaso, and specifically with respect to  
25                   clinical aspects of certain claim limitations.

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DEFOREST MCDUFF, Ph.D.

In paragraph 18 I put forward the claimed clinical benefits of the patents-in-suit as put forward by patent owner. In paragraph 20 I explain that my understanding that those clinical benefits are primarily derived from aspects outside the claimed invention.

Q. But you don't address dosing and number of breaths specifically other than to mention it in paragraph 18 with respect to nexus to commercial success, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I do address it in the paragraphs that I have referenced. I address it by explaining other factors besides the claimed innovative aspects that drive the commercial performance of Tyvaso.

BY MR. DELAFIELD:

Q. And that's based on your reliance on Dr. Donovan, correct?

A. Her declaration is one item that I rely upon.

Q. For nexus, you rely on

1                                    DEFOREST MCDUFF, Ph.D.

2            Dr. Donovan's opinion, correct?

3                            A.            Her declaration is one item I  
4            rely upon. I also rely upon additional  
5            information.

6                            Q.            With respect to whether the  
7            technical aspects of the patents provide a  
8            nexus to commercial success, what other  
9            information besides Dr. Donovan do you rely  
10           upon -- Dr. Donovan's declaration?

11                           A.            I can try to go through it in  
12           summary form if that's helpful.

13                           Q.            Well, can you think of  
14           anything off the top of your head?

15                           A.            Yes. Paragraph 19 where I  
16           discuss other patents covering other aspects of  
17           Tyvaso including the '075 patent and the '222  
18           patent. In paragraph 21 I discuss evidence  
19           related to marketing and the share of sales  
20           representatives for Tyvaso and Venativs  
21           relative to other products on the market.

22                                                      In Section E in paragraph 27,  
23           I explain the notion of blocking patents, and  
24           in paragraph 28 I go over relevant blocking  
25           patents here and explain the economic relevance

1                                    DEFOREST MCDUFF, Ph.D.

2                                    of that in that section.

3                                    In paragraph 31 I examine  
4                                    information on UTC's history and focus on  
5                                    pursuing PAH treatments. I examine information  
6                                    on other companies not being interested in  
7                                    pursuing the claimed -- in pursuing inhaled  
8                                    treprostiniil product, and in paragraphs 35  
9                                    through 37, I rely on similar information as  
10                                    Section C of my declaration.

11                                    So that's the information that  
12                                    I have in mind that you keep asking about with  
13                                    respect to what I examined in seeking to rebut  
14                                    claims of nexus by patent owner and  
15                                    Dr. Zamanian.

16                                    Q.                    Sir, I didn't ask for a  
17                                    summary of your entire opinion. I asked  
18                                    specifically with respect to the technical  
19                                    aspects of the patents in this case and whether  
20                                    or not those technical aspects provide a nexus  
21                                    to commercial success.

22                                    You don't rely on anything  
23                                    else besides Dr. Donovan's declaration with  
24                                    respect to the technical aspects, correct?

25                                    A.                    I don't recall your previous

1                   DEFOREST MCDUFF, Ph.D.

2           question being limited to technical aspects.

3           If it was, I apologize.

4                   With regard to technical  
5           aspects, I rely on my understanding of the  
6           claimed invention and I rely on information  
7           from Dr. Donovan that -- those are the main  
8           sources that I rely upon for technical aspects.

9                   Q.           And why did you rely on  
10          Dr. Donovan?

11                  A.           Because Dr. Donovan was  
12          providing opinions that are relevant to an  
13          economic nexus between the claimed inventions  
14          and Tyvaso's commercial performance.

15                  Q.           But Dr. Zamanian also provided  
16          opinions regarding nexus and commercial  
17          performance, correct?

18                  A.           Yes, and I reviewed those as  
19          well.

20                  Q.           But you rely on Dr. Donovan  
21          and assume she is correct and likewise assume  
22          Dr. Zamanian is incorrect?

23                          MR. MATHAS: Object to the form.

24                          BY MR. DELAFIELD:

25                          Q.           Is that fair to say?

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DEFOREST MCDUFF, Ph.D.

MR. MATHAS: Same objection.

BY THE WITNESS:

A. I wouldn't describe it that way. I would describe it as I have in my previous responses.

BY MR. DELAFIELD:

Q. You disagree with Dr. Zamanian, correct -- strike that.

You disagree with Dr. Zamanian regarding his statement on the nexus between Tyvaso and commercial success, correct?

A. Yes, that's right.

Q. But you agree with Dr. Donovan's statement regarding a lack of nexus between the patents and commercial success of Tyvaso, correct?

A. I don't recall whether she provides that specific opinion or conclusion on nexus. She's providing clinical information or clinical opinions that I rely upon, and then I draw an opinion with respect to economic connection or economic nexus.

Q. Well, she provides an opinion on the technical aspects of -- for part of that

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DEFOREST MCDUFF, Ph.D.

nexus. So -- strike that.

So a nexus means a connection between technical aspects and commercial success.

Is that a fair description?

A. I wouldn't describe it that way, no. It's related but I wouldn't summarize it like that.

Q. You wouldn't describe a nexus in this situation as finding a relationship between the technical aspects of the patent to the commercial success of the product of the patent?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. It's related but it's not exclusively limited to technical aspects. For example, I examine information on marking. I examine information on blocking patents. I examine information on other market incentives. Those are non-technical aspects that go towards nexus. So I just mean to clarify that it's not limited to technical aspects.

1 DEFOREST MCDUFF, Ph.D.

2 BY MR. DELAFIELD:

3 Q. But for the technical aspects  
4 in this case, you rely on Dr. Donovan, correct?

5 A. I do as well as my own  
6 understanding of what the claimed technology  
7 is.

8 Q. Do you have any reason to  
9 believe why Dr. Donovan would know more or have  
10 better experience with respect to the use of  
11 Tyvaso to treat pulmonary hypertension than  
12 Dr. Zamanian?

13 MR. MATHAS: Object to the form.

14 BY THE WITNESS:

15 A. No, I have not sought to  
16 provide that evaluation.

17 BY MR. DELAFIELD:

18 Q. So why do you agree with  
19 Dr. Donovan and disagree with Dr. Zamanian?

20 MR. MATHAS: Asked and answered.

21 BY THE WITNESS:

22 A. I'm not seeking to resolve a  
23 dispute between them or decide who is more  
24 credible. I am simply relying on Dr. Donovan  
25 in explaining economic implications of that,

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DEFOREST MCDUFF, Ph.D.

and I view the opinions that she is providing here in paragraph 20 of my declaration and elsewhere as consistent with some of the information that Dr. Zamanian puts forward that clinical advantages of Tyvaso over Venativs appear to relate to the difference between the compounds.

BY MR. DELAFIELD:

Q. But they clearly disagree on whether or not there's a nexus between the commercial success of Tyvaso and the technical features of the claims, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I would defer to Dr. Donovan for any opinions she has on nexus.

BY MR. DELAFIELD:

Q. Did you have any input in terms of identifying a technical aspect -- expert in this case?

A. No.

Q. So you were provided Dr. Donovan's opinion and told to rely upon it, correct?

1                   DEFOREST MCDUFF, Ph.D.

2                   MR. MATHAS: I am going to object  
3 to the form. Also whatever he would be told by  
4 counsel would be privileged. Maybe you can  
5 rephrase the question in a way that's not  
6 objectionable if possible.

7                   Are you asking what his counsel  
8 told him?

9                   MR. DELAFIELD: No, I am not  
10 seeking privileged information.

11                  MR. MATHAS: Maybe move on or ask  
12 it differently then, please.

13 BY MR. DELAFIELD:

14                  Q.            You are not a clinician,  
15 correct?

16                  A.            That's right. I am an  
17 economist.

18                  Q.            And you are not a technical  
19 expert with respect to pulmonary hypertension  
20 or inhaled devices, correct?

21                  A.            No.

22                  Q.            So sitting here today, you  
23 don't have a reason to know whether Dr. Donovan  
24 is correct in her analysis of nexus or whether  
25 Dr. Zamanian is correct in his analysis of

1                   DEFOREST MCDUFF, Ph.D.

2           nexus, correct?

3                   MR. MATHAS:   Asked and answered.

4           BY THE WITNESS:

5                   A.           I don't recall what specific  
6           conclusions Dr. Donovan is drawing with respect  
7           to nexus.  I don't rely on her conclusion of  
8           nexus or no nexus.  I simply rely on her  
9           conclusions on clinical aspects of what's  
10          driving differences between Tyvaso and  
11          Venativs, and I use that information as part of  
12          my analysis and evaluation of economic nexus.

13          BY MR. DELAFIELD:

14                  Q.           For Dr. Zamanian's opinion  
15          regarding nexus, given that you are not a  
16          technical expert, you have no reason sitting  
17          here today to believe that that opinion is  
18          incorrect, right?

19                  MR. MATHAS:   Asked and answered.

20          BY THE WITNESS:

21                  A.           What is your question?  
22          There's multiple parts there.

23          BY MR. DELAFIELD:

24                  Q.           Other than the fact  
25          Dr. Donovan has provided different opinions

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DEFOREST MCDUFF, Ph.D.

regarding the alleged connection between the claims and commercial success, you don't have any opinion as to whether Dr. Zamanian's opinion regarding nexus is incorrect?

A. I don't agree with that.

Q. But you don't describe his opinions other than the chart comparing market share in your declaration, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't agree with that. They are also described in summary form in paragraph 18 where I describe the alleged clinical advantages as put forth by patent owner.

BY MR. DELAFIELD:

Q. So you do rebut some of what Dr. Zamanian has presented in the prosecution of both patents, correct?

A. Yes.

Q. But specifically you don't provide a rebuttal to paragraph 16 where he addresses nexus specifically?

MR. MATHAS: Object to the form.

1                                    DEFOREST MCDUFF, Ph.D.

2                    BY THE WITNESS:

3                    A.            I don't agree with that.

4                    BY MR. DELAFIELD:

5                    Q.            Other than paragraph 18 that  
6                    we have discussed a few times now mentioning  
7                    dosing and number of breaths, you don't  
8                    specifically address dosing or number of  
9                    breaths with respect to nexus in your  
10                    declaration, correct?

11                    MR. MATHAS: Object to the form.

12                    BY THE WITNESS:

13                    A.            I don't agree. Those are also  
14                    discussed in paragraphs 20 and paragraphs 35  
15                    and 36 and 37.

16                    BY MR. DELAFIELD:

17                    Q.            So let's start with paragraph  
18                    20.

19                                    Where in paragraph 20 does it  
20                    talk about dosing or number of breaths?

21                    A.            Where it's talking about the  
22                    alleged innovative aspects of the  
23                    patents-in-suit.

24                    Q.            But that does not specifically  
25                    say dosing or number of breaths, correct?

1                                    DEFOREST MCDUFF, Ph.D.

2                    A.            Correct, but those are among  
3 the innovative aspects as alleged as I  
4 understand it.

5                    Q.            So I am asking you  
6 specifically is there any other place -- strike  
7 that.

8                                    Other than in paragraph 18  
9 with respect to nexus, you do not address  
10 specifically the number of breaths or dosing of  
11 Tyvaso, correct?

12                                    MR. MATHAS: Object to the form.

13 BY THE WITNESS:

14                    A.            I don't know how else to  
15 answer it other than the previous responses I  
16 have provided to you.

17 BY MR. DELAFIELD:

18                    Q.            Well, I am asking specifically  
19 where do you talk about those in specific  
20 detail, not a summary of alleged innovative  
21 aspects?

22                    A.            I will give you one example in  
23 paragraph 35 where I discuss clinical  
24 contributions -- quote: "Clinical  
25 contributions of alleged novel device and

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dosing regimen are limited and that, by contrast, the vast majority of the clinical benefit of Tyvaso comes from the treprostinil compound itself and the application of that compound to treating PAH" end quote.

That's one example in one of the paragraphs that I referenced.

Q. But that doesn't address the specific claim elements that Dr. Zamanian addresses being the specific dosing and number of breaths, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, dosing regimen is specifically there in the excerpt I just read, and clinical contributions of the novel device, as I think about that, that's related to the number of breaths and how it's administered.

BY MR. DELAFIELD:

Q. Going back to the analysis comparing Venativs and Tyvaso that Dr. Zamanian performed, to clarify, Venativs and Tyvaso are the only two inhaled pulmonary hypertension therapies on the market, correct?

1                                    DEFOREST MCDUFF, Ph.D.

2                                    A.                    To the best of my  
3                                    recollection, that's true.

4                                    Q.                    And Venativs and Tyvaso both  
5                                    use stable prostacyclin analogs, right?

6                                    A.                    That may be true. That  
7                                    question seems more directed toward a clinician  
8                                    than an economist.

9                                    Q.                    So you don't know?

10                                   A.                    That may be right, but in  
11                                   terms of the technical terminology, I would  
12                                   defer to a clinician to provide opinions on  
13                                   that.

14                                   Q.                    And when you say clinician,  
15                                   what do you mean by that?

16                                   A.                    Here I am referring to someone  
17                                   that is qualified to provide opinions or  
18                                   information on clinical or technical aspects  
19                                   using the term broadly just to describe someone  
20                                   with technical expertise.

21                                   Q.                    Clinicians are typically  
22                                   medical doctors, right?

23                                   MR. MATHAS: Object to the form.

24                                   BY THE WITNESS:

25                                   A.                    It's commonly used that way.

1                                    DEFOREST MCDUFF, Ph.D.

2                    In this context I'm trying to refer to someone  
3                    with technical expertise.

4                    Q.            Are you aware if Dr. Donovan  
5                    has any clinical experience?

6                    MR. MATHAS:    Object to the form.

7                    BY THE WITNESS:

8                    A.            Sitting here, I don't recall.  
9                    I would have to look at her CV or I would defer  
10                   to Dr. Donovan for that question.

11                                    (WHEREUPON, documents were  
12                                    tendered to the witness.)

13                    BY MR. DELAFIELD:

14                    Q.            So you have been handed what  
15                    has been marked as Exhibit 1140 which is a copy  
16                    of the Tyvaso label, and it's Exhibit 1140 in  
17                    both cases.

18                                    Do you recognize this  
19                    document?

20                    A.            Did you mean to hand me a copy  
21                    of a 1140?    I have a copy of 1160 and a copy of  
22                    1140.

23                    Q.            Yeah, I was talking about  
24                    1140.

25                    A.            Okay.    You handed me two

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documents.

Q. Yeah, I was going to get to 1160.

A. Okay. I see Exhibit 1140.

Q. Are you familiar with this document?

A. Yes.

Q. Now earlier I asked if Ventavis and Tyvaso were prostacyclins.

Under Indications and Usage at the top it says: "Tyvaso is a prostacyclin vasodilator."

Do you see that?

A. Yes.

Q. So you agree Tyvaso is a prostacyclin?

A. Yes, I agree with that.

Q. Then looking at 1160, which is a copy of the label for Venativs, it's Exhibit 1160 in both cases.

Are you familiar with this document?

A. Yes, it appears to be the Venativs label.

1                                    DEFOREST MCDUFF, Ph.D.

2                                    Q.                    And at the top left under  
3                                    Indications and Usage it says: "Venativs is a  
4                                    synthetic analog of prostacyclin."

5    Do you see that?

6                                    A.                    Yes.

7                                    Q.                    So both Venativs and Tyvaso  
8                                    are prostacyclin or prostacyclin analogs,  
9                                    correct?

10                                    A.                    I agree with that.

11                                    Q.                    And Venativs and Tyvaso are  
12                                    both approved for the same indication, correct?

13                                    A.                    They are not identical. You  
14                                    can see here in the two exhibits that they  
15                                    don't have identical language on indication,  
16                                    but they both do generally relate to treatment  
17                                    of pulmonary arterial hypertension.

18                                    Q.                    So they are both used to treat  
19                                    NYHA Functional Class III symptoms of pulmonary  
20                                    hypertension, correct?

21                                    A.                    That appears to be accurate  
22                                    looking at these indications, yes.

23                                    Q.                    Now, if you look under Dosage  
24                                    and Administration on that first page, the  
25                                    dosages differ between Venativs and Tyvaso,

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correct?

A. They appear to, yes.

Q. So keeping that open, if you turn back to your declaration at paragraph 37, in paragraph 37 you state: "I understand from Dr. Donovan that the less frequent treatment with Tyvaso relates to treprostiniil's longer half-life relative to iloprost rather than any differences in the way the Venativs and Tyvaso are delivered via inhalation."

Do you see that?

A. Yes.

Q. Why does circulatory half-life matter?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I would defer to Dr. Donovan for a technical description of that. My understanding is that if the half-life is longer, it has to be administered less frequently to have similar coverage.

BY MR. DELAFIELD:

Q. So do iloprost and treprostiniil exert their effect on pulmonary

1                   DEFOREST MCDUFF, Ph.D.

2           hypertension based on circulating through the  
3           blood or based on direct action in the lungs  
4           where they deposited after inhalation?

5                   MR. MATHAS: Object to the form.

6           BY THE WITNESS:

7                   A.           That strikes me as a clinical  
8           question. I don't have an opinion on that  
9           sitting here.

10           BY MR. DELAFIELD:

11                   Q.           Well, you understand that both  
12           drugs are inhaled directly into the lungs,  
13           correct?

14                   A.           Yes.

15                   Q.           And they -- strike that.

16                                They do make their way to the  
17           bloodstream, but they first enter the lungs and  
18           are deposited there, correct?

19                   A.           That's consistent with my  
20           understanding, yes.

21                   Q.           And so I am just trying to  
22           understand whether you understand what  
23           Dr. Donovan meant by half-life and why it  
24           matters in this context.

25                   A.           Okay.

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DEFOREST MCDUFF, Ph.D.

Q. Do you -- can you explain why circulatory half-life matters in this context?

MR. MATHAS: Asked and answered.

BY THE WITNESS:

A. I would defer to Dr. Donovan on specific technical aspects of that. Yet my understanding is that if a drug has a longer half-life, it remains effective in the body for a longer period of time and, thus, less frequent administration needs to occur in order to have effective treatment in the body.

BY MR. DELAFIELD:

Q. Do you know if that's the case for inhaled therapies?

A. That's my understanding sitting here. Yet it does strike me as a clinical question or a technical question.

Q. Because it's a technical question, you don't know, correct?

A. You know, these are questions about technical or clinical aspects, and you are asking for my understanding, and I give you my understanding, and then when you follow up and say, well, are you sure, are you sure that

1                   DEFOREST MCDUFF, Ph.D.

2           that's correct, well, it's my understanding as  
3           an economist, but it's not my area of  
4           expertise. So I can't give you full  
5           confirmation that it's correct.

6                   Q.           Would it change your opinion  
7           if Dr. Donovan was incorrect about her opinion  
8           regarding half-life and the reason for less  
9           frequent treatment?

10                   MR. MATHAS: Object to the form.

11           BY THE WITNESS:

12                   A.           I don't know. I would have to  
13           give that some thought. I don't have an  
14           opinion on it sitting here.

15           BY MR. DELAFIELD:

16                   Q.           So more generally if  
17           Dr. Donovan was incorrect in her opinions  
18           regarding the reasoning for less frequent  
19           treatment with Tyvaso, you can't say that that  
20           would not change your opinion with respect to  
21           nexus?

22                   MR. MATHAS: Object to the form.

23           BY THE WITNESS:

24                   A.           I just am not aware of what a  
25           different opinion would look like from

1                                    DEFOREST MCDUFF, Ph.D.

2            Dr. Donovan. As I review Dr. Zamanian's  
3            declaration sitting here, he acknowledges the  
4            difference in half-life between the two  
5            compounds. He acknowledges that the longer  
6            half-life of Tyvaso allows for less frequent  
7            administration. So regardless of the mechanism  
8            through which that occurs, it seems like  
9            Dr. Donovan and Dr. Zamanian both agree on that  
10           point.

11                                  I don't know how my opinion  
12           would change if there were some nuance that was  
13           incorrect. It would depend I suppose.

14           BY MR. DELAFIELD:

15                                  Q.            The declaration you are  
16           referring to from Dr. Zamanian with respect to  
17           half-life, he doesn't discuss nexus, correct?

18                                  MR. MATHAS: Object to the form.

19           BY THE WITNESS:

20                                  A.            Well, as I understand it, this  
21           information from Dr. Zamanian is supposed to go  
22           towards nexus. As we talked about, he doesn't  
23           use the word nexus in this declaration that I  
24           am referring to. This is Exhibit 1162 of case  
25           1622. But my understanding is that this does

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go towards nexus. That's the purpose behind it.

BY MR. DELAFIELD:

Q. Well, the only time he actually uses the word nexus is in Exhibit 1163 discussing the dosing and number of breaths, correct?

A. He does discuss nexus there. I don't know if that's the only time he discusses it.

Q. Well, earlier you looked through 1162 and said that you don't see any discussion of nexus.

Do you recall that?

A. I don't recall that being my testimony. I indicated he didn't draw a conclusion with respect to nexus which I agree. I haven't seen that conclusion here in 1162, but this information goes towards a connection or a nexus between aspects of Tyvaso and commercial performance.

Q. The only declaration on which he does draw a conclusion specifically about nexus is in 1163, correct?

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MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't know if there are other declarations out there, but of the two that we have looked at today, that's the one where I see him drawing a conclusion and using the word nexus. I agree with that.

BY MR. DELAFIELD:

Q. If we can look back at your declaration Exhibit 1055 at paragraph 16, you state that -- in paragraph 16: "The purported market share is among only the two inhaled products on the market, and is overstated and underrepresentative of competition in this market because it omits relevant competing products."

Do you see that?

A. Yes.

Q. And according to you, the market for Tyvaso competes with several other products besides Venativs; is that correct?

A. Yes.

Q. Does it compete with all other medications that treat pulmonary hypertension?

1 DEFOREST MCDUFF, Ph.D.

2 A. Yes. It's a matter of degree,  
3 of course.

4 Q. So looking back at paragraph  
5 11, you say: "Patients diagnosed with  
6 pulmonary hypertension have several treatment  
7 options, including medications and surgery.  
8 Treatments for pulmonary hypertension include  
9 anticoagulants, digoxin, diuretics, and calcium  
10 channel blockers among others."

11 Do you see that?

12 A. Yes.

13 Q. Several of those you don't  
14 include in your market for competition with  
15 Tyvaso, correct?

16 A. Maybe you could be more  
17 specific. I am not sure what you are referring  
18 to.

19 Q. Well, earlier I asked does it  
20 compete with all other medications that treat  
21 pulmonary hypertension, and you said, yes, it's  
22 a matter of degree, of course, and so I am  
23 asking why did you not include the list of  
24 treatments in Exhibit 11 in your market  
25 analysis?

1                    DEFOREST MCDUFF, Ph.D.

2                    A.            I'm not seeking to omit  
3                    specific drugs that would be applicable. I've  
4                    based my list of drugs based on products I know  
5                    to be approved for pulmonary arterial  
6                    hypertension, and specifically those that are  
7                    listed in third-party market research reports  
8                    as comprising the PAH market as well as  
9                    identified by UTC as competitors in their form  
10                   10-Ks.

11                                    I would note that this  
12                    specific sentence is related to pulmonary  
13                    hypertension and not specifically pulmonary  
14                    arterial hypertension. So perhaps that's one  
15                    item that's driving the difference --

16                    Q.            What is the difference --

17                    A.            -- but I am not seeking to  
18                    exclude relevant products.

19                    Q.            What is the difference between  
20                    pulmonary hypertension and pulmonary arterial  
21                    hypertension?

22                    A.            Pulmonary arterial  
23                    hypertension is known as Group I. Pulmonary  
24                    hypertension that's described in the previous  
25                    paragraph so it relates to a subset of

1                                    DEFOREST MCDUFF, Ph.D.

2                    pulmonary hypertension.

3                    Q.            Do you know what the technical  
4                    difference between pulmonary arterial  
5                    hypertension and pulmonary hypertension is?

6                    A.            Well, my understanding as just  
7                    explained is that pulmonary arterial  
8                    hypertension is a subset of pulmonary  
9                    hypertension. It's Group I. The world  
10                    class -- the World Health Organization has  
11                    different groups associated with pulmonary  
12                    hypertension, and PAH is one of those groups.

13                    Q.            So I guess to step back a  
14                    second. There's different types of pulmonary  
15                    hypertension, correct?

16                    A.            Yes.

17                    Q.            And there are different  
18                    treatments for different types of pulmonary  
19                    hypertension, correct?

20                    A.            Yes.

21                    Q.            And because of that, not all  
22                    products used to treat pulmonary hypertension  
23                    necessarily compete with Tyvaso such as  
24                    digoxin, correct?

25                    A.            That's right. I haven't seen

1                                    DEFOREST MCDUFF, Ph.D.

2                    evidence of that competition.

3                    Q.            Did you look to see if digoxin  
4                    is approved for use in pulmonary hypertension?

5                    A.            I don't recall specifically  
6                    doing that, no.

7                    Q.            Turning back to paragraph 16,  
8                    and under 16a you report a quote from UTC's CEO  
9                    on an earnings call from 2010.

10                                    Do you see that?

11                    A.            Yes.

12                    Q.            And that's in support of your  
13                    statement that substantial evidence indicates  
14                    competition between Tyvaso and non-inhaled PAH  
15                    therapies and then, for example?

16                    A.            Yes.

17                    Q.            Now, how long after the launch  
18                    of Tyvaso was that statement made?

19                    A.            It appears to be in the  
20                    following year. Tyvaso was launched in 2009.  
21                    This statement is from 2010.

22                    Q.            It's Q2, 2010, right?

23                    A.            Yes.

24                    Q.            So Tyvaso I believe was  
25                    launched in July of 2009. I could be wrong,

1                   DEFOREST MCDUFF, Ph.D.

2           but so likely less than a full year, correct?

3                   A.           Almost a year is probably a  
4           good guess from July through what would be the  
5           end of the second quarter. That would be June  
6           or July of the next year.

7                   Q.           And in this statement it says  
8           that many new patients switched to Tyvaso from  
9           oral therapies, correct?

10                   MR. MATHAS: Object to the form.

11           BY THE WITNESS:

12                   A.           I don't see that excerpt, but  
13           I see that notion here in substance.

14           BY MR. DELAFIELD:

15                   Q.           Well, if you look at page 10  
16           starting with: "And then the majority, the  
17           large majority, around 70 percent come on to  
18           our therapy after not really achieving the  
19           results desired with either oral or more  
20           commonly dual oral therapies."

21                                   Do you see that?

22                   A.           Yes, that's what I was  
23           referring to as well.

24                   Q.           So in total in this first year  
25           if you add up the percentages listed, roughly

1                                    DEFOREST MCDUFF, Ph.D.

2                    90 percent of patients taking Tyvaso switched  
3                    to Tyvaso from a different pulmonary  
4                    hypertension medicine, correct?

5                                    MR. MATHAS: Object to the form.

6                    BY THE WITNESS:

7                                    A.            I'm not sure I follow. It  
8                    appears here he is describing all of the other  
9                    medications from which Tyvaso patients  
10                    originate.

11                    BY MR. DELAFIELD:

12                                    Q.            Yes, that's what I meant. So  
13                    the statement says 10 percent of patients come  
14                    on Tyvaso from parenteral therapies, correct?

15                                    A.            Yes.

16                                    Q.            And about 20 percent of  
17                    patients, maybe a little bit more than 20  
18                    percent come on to a therapy from Venativs,  
19                    correct?

20                                    A.            Yes.

21                                    Q.            And 70 percent come on to our  
22                    therapy after not really achieving the results  
23                    desired in either oral or more commonly dual  
24                    oral therapies, correct?

25                                    A.            Correct.

1                   DEFOREST MCDUFF, Ph.D.

2                   Q.           So if you add up those  
3 percentages, 90 percent of Tyvaso patients in  
4 the first year switched from another pulmonary  
5 hypertension drug to Tyvaso, correct?

6                   MR. MATHAS: Object to the form.

7 BY THE WITNESS:

8                   A.           I may be missing your point,  
9 but 70 percent plus 20 percent plus 10 percent  
10 is the full 100 percent.

11 BY MR. DELAFIELD:

12                  Q.           I'm sorry. I'm sorry. I  
13 meant 90 percent came from Venativs or oral  
14 therapies, correct?

15                  A.           Yes.

16                  Q.           And so you agree 20 percent  
17 switched from Venativs to Tyvaso according to  
18 this statement, correct?

19                  A.           That appears to be what this  
20 statement is saying.

21                  Q.           So Tyvaso took market share  
22 from Venativs, correct?

23                  A.           That may be true to some  
24 degree in the first year. Venativs sales  
25 didn't decline very much, just 8 million in

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2 2009 to 2010. So perhaps to a small degree,  
3 that's true.

4 Q. Venativs was approved in 2004,  
5 correct?

6 If you need to look at Exhibit  
7 1160 the label for Venativs in the upper left,  
8 it says initial U.S. approval 2004.

9 A. I see that, yes.

10 Q. And Tyvaso was approved in  
11 2009, correct?

12 A. Yes.

13 Q. And as we have stated before,  
14 those are the only two inhaled therapies for  
15 pulmonary hypertension, correct?

16 A. That's my understanding, yes.

17 Q. In terms of pharmaceutical  
18 sales, have you heard of first mover advantage?

19 A. I have heard of the term  
20 generally, yes.

21 Q. Can you tell me your  
22 understanding of that?

23 A. First mover advantage is a  
24 term that describes customer recognition of the  
25 first product on the market and the advantages