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.

PRESENT:

Appeared on behalf of the Petitioner:

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ALSO PRESENT:

MR. SCOT ZIARKO, Videographer.

REPORTED BY: ANDREA L. KIM,

Illinois CSR No. 84-3722.

I N D E X

I N D E X

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.

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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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

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

Q. Were all of those patent cases?

A. No.

Q. About what percent were patent cases?

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

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

A. Ballpark around half, maybe more.

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

A. I have in one instance, yes.

Q. And what was that?

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

Q. And what role did you play in

that case?

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

Q. So you weren't accused of cheating?

A. Correct.

Q. Okay. Has your testimony ever been excluded?

A. It has in some instances, yes.

Q. Can you describe those instances?

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

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

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testimony was not permitted?

A. Yes, there were two main issues there.

Q. What were those issues?

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

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

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

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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.

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

A. Generally I agree with that, yes.

Q. And that testimony was excluded?

A. That portion was, yes.

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

A. Yes.

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

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

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

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

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

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A. I have, yes.

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

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

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

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patents, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

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

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

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

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

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

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

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

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

Q. Isn't that a double negative?

A. No, not as I think of it.

Q. So is it fair to say that in

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

A. Would you mind reading the question, please.

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

BY THE WITNESS:

A. What do you mean by most?

BY MR. DELAFIELD:

Q. More than 50 percent.

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

Q. Would it be more than 75 percent?

A. I don't know.

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

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

Q. Can you name a couple?

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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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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?

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A. Yes, that's right.

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

Is that fair?

A. I can do that, yes.

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

A. I will do my best to do so.

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

Is that fair?

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

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

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

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

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

Q. So between 20 and 80 hours total?

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

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

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

Q. And what did you talk about with him?

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

Q. Did he write part of your declarations?

A. He may have drafted certain

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

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

A. He did assist with those, yes.

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

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

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

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

Q. And how long has he worked with you?

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

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

A. No, I don't believe so.

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

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

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

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

A. No.

Q. Did you exchange any emails or

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any kind of correspondence with Dr. Donovan?

A. No.

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

BY MR. DELAFIELD:

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

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

BY MR. DELAFIELD:

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

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

A. Yes.

Q. Is this a copy of your declaration?

A. It appears to be, yes.

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

A. Sitting here skimming through

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it, it appears to be, yes.

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

A. It is, yes.

Q. And you signed it June 21, 2017?

A. Yes.

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

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

Q. No one helped you write this declaration?

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

Q. Did anyone else help you draft your declaration?

A. I don't believe so, no.

Q. Counsel didn't help you draft

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the declaration?

A. No.

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

A. I do, yes.

Q. Who found those articles?

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

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

A. Yes.

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

A. It is as of June 2017.

Q. Could you briefly go through your educational background.

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

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

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

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

A. In 2009.

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

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

A. No.

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

A. Yes.

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

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

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

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

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

Q. So the first pharmaceutical

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

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

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

A. Yes.

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

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

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

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

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students to attend colleges and universities.

Q. So it was not related to patents?

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

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

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

Q. Well, it is just yes or no.

Did your Ph.D. dissertation discuss patents?

A. It did not specifically discuss patents.

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

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

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

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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?

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A. No, not as I think of it.

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

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

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

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

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

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

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

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

Q. You are not an expert in

patent law, correct?

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

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

A. I have, yes.

Q. Do you recall an example of that?

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

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

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

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

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

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

Q. Let's say average sales per year.

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

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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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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

correct?

A. Correct, for Tyvaso.

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

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

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

Do you recognize this document?

A. I do.

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

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

So the 1621 declaration here

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

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

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

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

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

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

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BY MR. DELAFIELD:

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

A. It is, yes.

Q. And you signed it June 21, 2017?

A. Yes.

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

A. This one in front of me, no.

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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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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

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.

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.

DEFOREST MCDUFF, Ph.D.

BY MR. DELAFIELD:

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

A. Sitting here, I don't recall.

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

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

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

A. I believe so, yes.

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

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

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

A. Sitting here, I don't recall.

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?

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?

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.

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BY MR. DELAFIELD:

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

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

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

A. That's my understanding.

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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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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.)

DEFOREST MCDUFF, Ph.D.

BY THE WITNESS:

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

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

BY MR. DELAFIELD:

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

MR. MATHAS: Same objection.

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BY THE WITNESS:

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

BY MR. DELAFIELD:

Q. So it is just speculation?

A. I wouldn't describe it that way.

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

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

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

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patent and the '240 patent?

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

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

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

A. It could be.

Q. But you didn't investigate that?

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

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

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.

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Q. Do you recall that it describes the kit and process used to inhale treprostinil?

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

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

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

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

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

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?

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A. I do.

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

A. Relative to Venativs, as I recall.

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

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

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

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

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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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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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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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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?

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MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

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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 treprostinil 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 treprostinil, 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?

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MR. DELAFIELD: Sure.

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

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

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

BY MR. DELAFIELD:

Q. Welcome back.

A. Thank you.

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

BY MR. DELAFIELD:

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

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

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

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

A. Okay.

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

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

Do you see that?

A. Yes.

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

A. Okay.

Q. Both declarations are very similar, correct?

A. They appear to be, yes.

Q. And specifically if you look

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

Do you see that?

A. Yes.

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

A. I believe so, yes.

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

Do you understand?

A. I do.

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

Do you see that?

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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,

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?

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

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

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

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

Q. If you turn to your

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

A. I'm there.

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

A. Yes.

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

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

Q. But you didn't do that?

A. Correct, not as part of my analysis.

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

MR. MATHAS: Object to the form.

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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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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

differences in dosing regimen and delivery, and I explain in paragraph 20 that based on the opinions of Dr. Donovan, that those differences relate to the differences between the compounds -- between the two products and the different half-lifes.

So in other words, the number of times the patient takes each product is different because the compounds have different half-lifes.

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

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

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

A. Yes.

Q. So looking at 1162 at page 23,

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

Do you see that?

A. Yes.

Q. Do you agree with that statement?

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

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

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

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

A. That's my understanding.

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

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

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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.

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

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

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

Is that fair to say?

A. They appear to be, yes.

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

A. Yes.

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

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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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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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.

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

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

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

Do you see that?

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A. I do.

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

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

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. It is not based just on that,

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no.

BY MR. DELAFIELD:

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't agree with that.

BY MR. DELAFIELD:

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

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

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

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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?

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MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't agree with that.

BY MR. DELAFIELD:

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

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

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

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BY MR. DELAFIELD:

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

Do you agree with that?

A. That's my understanding.

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

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

Do you agree with that?

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

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

A. Yes.

Q. But you don't address whether

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

MR. MATHAS: Object to the form.

BY MR. DELAFIELD:

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't agree with that.

BY MR. DELAFIELD:

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

MR. MATHAS: Asked and answered.

BY THE WITNESS:

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

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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

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Dr. Donovan's opinion, correct?

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

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

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

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

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

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

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of that in that section.

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

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

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

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

A. I don't recall your previous

question being limited to technical aspects. If it was, I apologize.

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

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

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

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

A. Yes, and I reviewed those as well.

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

MR. MATHAS: Object to the form.

BY MR. DELAFIELD:

Q. Is that fair to say?

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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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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.

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BY MR. DELAFIELD:

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

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

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

MR. MATHAS: Asked and answered.

BY THE WITNESS:

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

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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?

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

Are you asking what his counsel told him?

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

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

BY MR. DELAFIELD:

Q. You are not a clinician, correct?

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

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

A. No.

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

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nexus, correct?

MR. MATHAS: Asked and answered.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

MR. MATHAS: Asked and answered.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

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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.

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BY THE WITNESS:

A. I don't agree with that.

BY MR. DELAFIELD:

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

Q. So let's start with paragraph 20.

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

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

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

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

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

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

A. I will give you one example in paragraph 35 where I discuss clinical contributions -- quote: "Clinical 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?

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

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

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

Q. So you don't know?

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

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

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

Q. Clinicians are typically medical doctors, right?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. It's commonly used that way.

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

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

(WHEREUPON, documents were tendered to the witness.)

BY MR. DELAFIELD:

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

Do you recognize this document?

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

Q. Yeah, I was talking about 1140.

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.

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

Do you see that?

A. Yes.

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

A. I agree with that.

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

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

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

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

Q. Now, if you look under Dosage and Administration on that first page, the 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 treprostinil'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 treprostinil exert their effect on pulmonary

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

A. Yes.

Q. And they -- strike that.

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

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

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

A. Okay.

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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

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

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

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

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

BY MR. DELAFIELD:

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, as I understand it, this information from Dr. Zamanian is supposed to go towards nexus. As we talked about, he doesn't use the word nexus in this declaration that I am referring to. This is Exhibit 1162 of case 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?

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

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

Do you see that?

A. Yes.

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

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

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

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

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

Q. What is the difference --

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

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

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

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pulmonary hypertension.

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

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

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

A. Yes.

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

A. Yes.

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

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

evidence of that competition.

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

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

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

Do you see that?

A. Yes.

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

A. Yes.

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

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

Q. It's Q2, 2010, right?

A. Yes.

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

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but so likely less than a full year, correct?

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

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

Do you see that?

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

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

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

A. Yes.

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

A. Yes.

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

A. Correct.

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

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

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

A. Yes.

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

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

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

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

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

Q. Venativs was approved in 2004, correct?

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

A. I see that, yes.

Q. And Tyvaso was approved in 2009, correct?

A. Yes.

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

A. That's my understanding, yes.

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

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

Q. Can you tell me your understanding of that?

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

associated with that.

Q. What are those advantages?

A. The advantages with respect to competition. Customer recognition is a good thing for competition in the market.

Q. So basically if you are the first on the market, everyone knows about -- strike that.

If you are the first on the market, you are the only drug that people know about, and you have no competition, right, for that specific treatment?

A. For the period of time where you are the only product on the market. Of course, you would still call something a first mover once additional competition comes on to the market.

Q. Would you agree that a second market entrant in the same market segment may face a greater challenge to gain market share?

A. That may be true. It depends on the situation. Sometimes a second mover can have the advantage that a certain type of therapy or practice has been established, and

they benefit positively from that. So it just depends on the situation.

Q. Did you look to see if that was the case in this case?

A. I am not sure what you mean. I am aware that Venativs was launched before Tyvaso if that's what you mean.

Q. You don't provide any opinions about whether it was an advantage or disadvantage for Tyvaso to be the second market entrant into inhaled treatment for pulmonary hypertension, correct?

A. I don't view that as the correct market definition. I wouldn't call Tyvaso the second market entrant here.

Q. Well, assume for this question I am just talking about the inhaled pulmonary hypertension treatments as a market. You don't provide any opinion about the fact that Tyvaso was the second market entrant in that same market, correct?

A. It would be odd for me to draw an opinion on a market that I don't think is correct or relevant, but I agree that I don't

focus on order of market entry between Tyvaso and Venativs. I don't view it as particularly impactful here.

Q. And you agree that Tyvaso has performed better over time than Venativs in terms of sales, correct?

A. It has had greater sales, yes.

Q. Now, moving to the other pulmonary hypertension drugs that are not inhaled that you included in your market definition, earlier we also discussed there are different stages of pulmonary arterial hypertension, correct?

A. Groups I think they are typically referred to. Is that what you mean?

Q. Yes, or -- well, actually let's just -- if you look at the Venativs label, for example, Exhibit 1160, under Indications and Usage, the last sentence says: "Studies establishing effectiveness included predominantly patients with NYHA Functional Class III to IV symptoms and etiologies of idiopathic or heritable pulmonary arterial hypertension or pulmonary arterial hypertension

associated with connective tissue diseases."

Do you see that?

A. Yes.

Q. So there's a couple things here. So -- well, first, do you have an understanding of what NYHA Functional Class symptoms are?

A. I presume they are just a description of symptoms associated with the disease.

Q. Are you aware that there's four classes of symptoms under that?

A. That sounds right.

Q. Is it your understanding that each class of symptoms -- strike that.

Is it your understanding that pulmonary hypertension is a progressive disease?

A. That sounds familiar. I don't recall specifically addressing that in my declaration.

Q. Is it your understanding that the class symptoms increase as the disease progresses?

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A. That's consistent with my experience.

Q. And so, for example, a patient with Class I symptoms may be treated differently than a patient with Class IV symptoms, correct?

A. That may be true. It's not something I have specifically evaluated in my declaration or opined about.

Q. So you don't know if patients with different class symptoms are treated differently with different medications?

A. There may be some nuances with respect to treatment. Some options may be more effective for patients at various difference classes. It's not a distinction that was in the evidence when evaluating the relevant market. So it's not something that I focused on.

Q. You have said it's not in the evidence that you evaluated?

A. Yes.

Q. If you turn to your declaration Exhibit 1055 for the '507 patent

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with the exhibits attached, and if you look at Attachment B-8 Competing PAH Therapies.

A. Yes.

Q. So, for example, the first drug Remodulin lists effectiveness for patients with Class II to IV symptoms.

Do you see that?

A. Yes.

Q. And Tyvaso is only listed for patients with Class III symptoms, correct?

A. Yes.

Q. Adcirca is for patients with Class II to III symptoms, correct?

A. I see that, yes.

Q. So without going through all of these, each of these drugs have their own uses in terms of patients with certain types of symptoms -- strike that.

Each of these drugs are used for patients with certain types of symptoms, correct?

A. Yes, the indications are not identical. They all relate to pulmonary arterial hypertension. Tyvaso has a narrower

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label. In other words, it's useful in fewer patients, and so it's a more limited commercial opportunity.

Q. Did you account for the fact that other pulmonary hypertension drugs were listed for patients with wider variety of symptoms?

A. Yes, that's reflected in the sales data where a product that has applicability to a wider set of patients because of a broader or narrower indication is able to achieve more sales. So comparison of sales is where that is manifested in the economic data.

Q. If a drug is only used to treat specific symptoms, isn't it fair to compare only other drugs that treat those same symptoms?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. No, not in my opinion. That's not correct here.

BY MR. DELAFIELD:

Q. Why is that?

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A. Because that's the incorrect way to think about competition here. They have -- there are a number of products competing for PAH sales, and they have different attributes and different coverage and different effectiveness, but it's the broader competition that tells you about the market opportunity for treating pulmonary arterial hypertension. Drug submarkets or segments with respect to symptoms is not something that's appropriate or consistent with what I have reviewed.

THE WITNESS: And we have been going for a while. Maybe at some point we should break for lunch.

MR. DELAFIELD: Do you have lunch here yet?

MR. MATHAS: It should be here.

MR. DELAFIELD: Yeah, we can take a break.

THE VIDEOGRAPHER: The time is now 12:35 p.m. This is the end of media 2. We are off the record.

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(WHEREUPON, a recess was had at 12:35 p.m. until 1:26 p.m.)

THE VIDEOGRAPHER: The time is now 1:26 p.m. This is the beginning of media 3. We are back on the record.

BY MR. DELAFIELD:

Q. Welcome back.

A. Thank you.

Q. I think when we left, we were talking about your declaration Exhibit 1055 for the '507 patent and Attachment B-8, and we were discussing how these different drugs have different indications depending on what symptoms they treat, correct?

A. Yes, I recall that.

Q. If you look at page 10 at Adempas, and in the -- under Indication the first bullet point says: "Persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension after surgical treatment or inoperable (CTEPH) to improve exercise capacity and WHO functional class."

Do you see that?

A. Yes.

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Q. And then separately it's also indicated for pulmonary arterial hypertension to improve exercise capacity, improve WHO functional class and to delay clinical worsening.

Do you see that?

A. Yes.

Q. So just as an example, Adempas is specifically prescribed for chronic thromboembolic pulmonary hypertension, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. That's part of the indication.

BY MR. DELAFIELD:

Q. And Tyvaso is not prescribed for that purpose, correct?

A. It's not indicated for that, that's right.

Q. So at least for patients with chronic thromboembolic pulmonary hypertension, Tyvaso doesn't compete in the same market as Adempas for that condition, correct?

MR. MATHAS: Object to the form.

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BY THE WITNESS:

A. I haven't seen evidence that Tyvaso is prescribed for that. I haven't seen evidence of it. I have not specifically evaluated it, though.

BY MR. DELAFIELD:

Q. But you didn't account for the differences in the indications for these drugs being different than Tyvaso in your analysis of the sales and revenue, correct?

A. I don't agree with that. The differences in the indications are reflected in the sales data. So if one drug has a slightly more effective indication than another drug, perhaps that drug has more sales. So it's one of the inputs that is reflected in the economic data.

Q. Well, I am talking about indications not effectiveness. For example, if a drug is indicated to treat three different things -- strike that.

In your opinion if drug A is indicated to treat three conditions and drug B is indicated to treat just one of those three

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conditions, would you say it's fair to compare sales -- total sales of both drugs to each other?

A. It depends on one's purpose.

Q. What do you mean by that?

A. Perhaps it would be fair in some context but not fair in other context.

Q. Well, in this context there's no indication that Tyvaso is used to treat CTEPH, correct?

MR. MATHAS: Object to form.

BY THE WITNESS:

A. That's my understanding, yes.

BY MR. DELAFIELD:

Q. So sales of the Adempas to treat that form of pulmonary hypertension do not directly compete with sales of Tyvaso, correct?

A. Again, I haven't seen evidence that Tyvaso is prescribed for chronic thromboembolic pulmonary hypertension. Perhaps they don't compete for those prescriptions. Looking through the rest of B-8 and the other one, two, three -- 13 products here, I don't

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see that as being a pervasive issue. It looks specific to Adempas but none of the other products on this list. So while that may be true for Adempas, I don't view this to be an impactful issue.

Q. Other than the separate indication, each drug does have slightly different functional class symptoms that they are designed to treat, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Some may be the same, but there are frequently slight differences. Yes, I agree.

BY MR. DELAFIELD:

Q. Are you aware that patients taking -- strike that.

Are you familiar with Remodulin?

A. Yes.

Q. And Remodulin is taken via IV or subcutaneous, correct?

A. Yes.

Q. Do you understand that

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Remodulin is primarily reserved for patients with pulmonary hypertension that is an advanced stage of pulmonary hypertension?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't see that here in Attachment B-8. It appears to be approved for Classes II to IV symptoms. I don't recall whether it's reserved for advanced stage sitting here.

BY MR. DELAFIELD:

Q. Let me ask it another way. Can all patients with PAH use inhaled formulations?

A. It probably depends on the patient.

Q. Well, I am asking if a patient has pulmonary arterial hypertension, can they use Tyvaso to help alleviate their symptoms no matter what their symptoms are or how severe their pulmonary hypertension is?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. They may be able to. There

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may be varying effectiveness of certain medications on certain types of patients. Physicians evaluate that on a case-by-case basis. That's my understanding.

BY MR. DELAFIELD:

Q. Did you attempt to differentiate the different forms of the drugs in terms of when and how they are used with patients?

A. I am aware of the different forms. You can see that in the Form column on Attachment B-8. So I am aware of those differences across products.

Q. I guess I am trying to understand your basis for your opinion that all forms equally compete against Tyvaso for treatment of pulmonary arterial hypertension.

I guess my question is if a patient can't use a specific form of therapy, it's not a choice to use one pulmonary hypertension therapy over another, correct?

A. I am not sure I follow the question. Could you ask it again?

Q. So let's take, for example, a

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patient takes Orenitram which is an oral form of treprostinil. Are with me?

A. Okay.

Q. And that pill doesn't work at all for them, and then they take Tyvaso and it does work. Would you say that those two products still compete with respect to that patient specifically?

A. Yes, I would. I think that example illustrates the point which is that patients have different options across different forms, and some options may be more effective for certain patients in certain circumstances, and that's the market in which the products compete. There are multiple options, and what we examine in economic data is which products are more successful within that market.

Q. But each indication of all the drugs listed in B-8 specify specifically what class of symptoms they are designed to treat, right?

A. Yes, but indications don't need to be identical to be in the same relevant

market.

Q. If you turn to Attachment B-8, the first page 8 Adcirca.

Do you see that?

A. Yes.

Q. And under Indication it says: "Adcirca is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of pulmonary arterial hypertension to improve exercise ability."

Do you see that?

A. Yes.

Q. Did you account for any differences in Adcirca or any of these drugs in terms of the type of drug compared to Tyvaso?

A. This is the same answer as before. I did indirectly because that manifests itself into the sales data. Different drugs have different active ingredients or classes of ingredients, and they have different level of effectiveness. As a result, that shows up in the economic data in sales, and that's what I have examined.

Q. If you turn back to paragraph

11 in your declaration and the last sentence starting at page 5 states: "For the treatment of PAH, in particular approved pharmaceuticals target one of three major biochemical pathways," and then it lists three pathways.

Do you see that?

A. Yes.

Q. Do you understand each of those pathways?

A. What do you mean by that?

Q. Well, can you explain to me what an endothelin receptor antagonist is?

A. Well, I am an economist, not a clinician, but my understanding is that it targets the endothelin receptors. It's a class of drugs that has that particular mechanism of action.

Q. And what's an endothelin receptor?

A. I don't recall specifically sitting here.

Q. And for this paragraph, you put footnote 3.

Do you see that?

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A. Yes.

Q. And you don't cite Dr. Donovan for that paragraph, correct?

A. Correct.

Q. So in general do these three pathways treat pulmonary arterial hypertension in different ways?

A. If you are asking for a clinical opinion, then that question is probably better for a clinical or technical expert. My understanding is that these are different mechanism of action -- different mechanisms of action that treat a similar set of symptoms.

So patients have a similar set of symptoms, and there are different classes of products that have different mechanisms for improving those symptoms and treating the disease. So that's my understanding of how the different pathways work as an economist.

Q. So for your economic analysis, you didn't differentiate between these three pathways in terms of what would and would not compete with Tyvaso, correct?

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A. I am aware of these differences. I took them into account by analyzing the sales data, but I did not define submarkets according to these distinctions. I don't view that as appropriate or consistent with the evidence I have seen. The evidence I have seen supports competition across these pathways.

Q. And so you don't know how Tyvaso compares to other drugs that have the same biochemical pathway, correct?

A. I am not sure what you mean by that.

Q. You didn't do an analysis of the subgroups, correct?

A. I did not create submarkets based on these pathways, nor do I think that's appropriate here.

Q. And you didn't create submarkets based on drug form either, correct?

A. Correct, nor do I agree that's appropriate.

Q. And you didn't create submarkets based on the symptoms listed in the

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indication, correct?

A. Correct. I don't view that as appropriate in light of the evidence I reviewed.

Q. You also did not consider in your analysis how long each of the products were on the market before reaching their peak sales, correct?

A. I don't agree with that.

Q. Well, let's turn to your Exhibit -- or Attachment B-5.

A. Okay.

Q. And this is a comparison to PAH drug revenues showing sales for peak years for each of the drugs; is that correct?

A. Yes.

Q. And in this attachment you don't specify when the drug was first launched, correct?

A. Not in this attachment, but one can see it in Attachment B-4 on the previous page.

Q. But in your conclusions regarding peak sales, you don't provide any

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analysis of what effect, if any, the year the peak sales came about based on the year the drug was launched, right?

A. I don't agree with that, and in particular I would point you to paragraph 24 where I indicate what the impact of different drugs being on the market for different lengths of time has which is that we know Tyvaso has already achieved peak sales because its sales have already started declining from 2015 to 2016 and then from 2016 to 2017 based on the most recent data reported by UTC. Whereas, other drugs are continuing to increase. They have not already hit peak sales.

So this comparison will look even more favorable to the other drugs and less favorable to Tyvaso into the future. So that's the sense in which I am thinking about how long the drugs have been on the market and whether their sales will continue to increase.

Q. So if a drug had a particularly good year and had extremely high peak sales one year and low sales before and after that, do you still think that peak annual

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sales are a relevant factor to consider?

A. That's not a typical situation that occurs in pharmaceuticals. Sales tend to be more similar from year to year or increasing or decreasing on a more regular basis. It's not frequently the case that sales vary wildly from one year to the next.

Q. Well, I am asking hypothetically if a product has one really good year for whatever reason and before and after have low sales, doesn't that mean that peak sales for that year are not really indicative of commercial success?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. That's a theoretical situation that could be true in some circumstances. It's not true generally in pharmaceuticals, and it's not true based on the evidence I have reviewed here in this case. I have reviewed sales across all years, and peak sales are the good summary statistic for comparing across products based on that analysis.

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BY MR. DELAFIELD:

Q. For your peak sale analysis, did you -- strike that.

Your declaration does not disclose any analysis for peak sales of the various drugs in relation to factors that may affect that year's sales that are unique to the drug, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I am not sure what you have in mind. Could you explain?

BY MR. DELAFIELD:

Q. So, for example, if a brand drug comes on the market and for some reason the very next year a generic comes on the market, their peak sales might be the first year.

Is that a fair assessment? Apologies.

A. That doesn't tend to happen but it could.

Q. So external factors such as the launch of a generic can affect sales for

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any given year, correct?

A. They can. Sales can decline after generics come on the market. That's frequently what happens.

Q. And, similarly, if a drug comes on the market with the same indication and is followed quickly by another drug with the exact same indication, their peak sale year may be different just based on the fact of the timing of the competition, correct?

A. It could be. That's how competition works.

Q. So peak annual sales could be the result of external factors such as other drugs coming on or off the market or other drugs becoming genericized, correct?

A. Well, you described them as external factors, but they are relevant factors. They are relevant factors for competition, and it's the set of factors -- the set of competitive factors that determines how well a products does. So it's relevant to the analysis.

Q. But for commercial success,

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there must be a nexus to the patented elements, correct?

A. Generally, yes, there must be a nexus.

Q. And so if sales are really good or really bad based on factors that are not related to the patent, then they would be external factors, correct?

A. You don't frequently hear that term, but I see what you are saying. That's not the way it's typically described.

Q. If you could turn to paragraph 33 of your declaration.

A. I'm there.

Q. And the second sentence says: "For example, Tyvaso's designation as an orphan drug (reserved for products with low commercial opportunity and/or fewer than 200,000 U.S. patients) indicates limited economic opportunity."

Do you see that?

A. Yes.

Q. So you understand Tyvaso is an orphan drug, right?

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A. Yes.

Q. And there are fewer than 200,000 U.S. patients, correct, according to your definition here?

A. Well, orphan drug status can be granted based on a low commercial opportunity or fewer than 200,000 patients. I don't recall which prong was met for Tyvaso, and I don't recall whether the current count of PAH treatment is less than 200,000. I would have to go back and check.

Q. Do you know how many people in the U.S. approximately have pulmonary hypertension?

A. I believe it's in the hundreds of thousands, but I would have to go back and look to confirm.

Q. So it could be fewer than 200,000, correct?

A. It could be, and I believe it was at one point in time.

Q. Orphan drug status is specific to number of patients because the FDA requires less to get their approval simply because

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there's not enough people for clinical trials.

Have you heard that? Are you familiar with that concept?

A. I don't believe that's the primary economic rationale for granting orphan drug status. I believe it has to do with limited commercial opportunity and wanting to provide incentives for development where there otherwise would not be.

Q. But to your knowledge, the FDA designates whether or not a drug is an orphan drug, correct?

A. Yes, I believe so.

Q. And the FDA doesn't care about commercial opportunity. Just whether or not there's enough patients to qualify for the required clinical testing, right?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. That may be one factor that they consider. Again, there are two prongs under which a drug can qualify for orphan drug status: The number of patients and also a lack of commercial opportunity.

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BY MR. DELAFIELD:

Q. But it's your opinion that at most patients with pulmonary hypertension are in the hundreds of thousands, correct?

A. As I indicated earlier, that's my best recollection, but to be sure, I would have to go back and confirm. I don't recall the specific figure sitting here.

Q. There's approximately 325 million people in the U.S.

Do you agree with that?

A. More or less.

Q. So even if the full 200,000 patients had pulmonary hypertension, that would be far less than 1 percent of the U.S. population, correct?

A. Yes.

Q. Now, if you turn to paragraph 23, you say: "First, Tyvaso's annual sales ranging from $152 million to $470 million are not exceptional or even above average in the context of pharmaceutical product sales."

Do you see that?

A. Yes.

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Q. And then you go on to analyze the first -- strike that.

You go on to analyze the top two decile percentages for drugs, correct?

A. As well as the averages, yes.

Q. Now, do you know how many drugs are in the top decile in terms of sales that are orphan drugs?

A. I don't know the number. I do know that orphan drugs can and do have sales at that magnitude.

Q. Other than pulmonary hypertension, can you think of any other indication that's an orphan -- orphan -- treated with orphan drugs that is in the top decile?

A. There's a number of cancer drugs that are orphan drugs that have sales in the billions. There's various cancer indications that qualify.

Q. Do you know if the majority of the drugs in the top two deciles are prescribed for -- strike that.

Would you agree that the drugs

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in the top two deciles of sales are typically blockbuster drugs that have millions of patients?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't know that that's generally true.

BY MR. DELAFIELD:

Q. Well, isn't it relevant to know how many patients there are before you compare to the largest sales across all drugs?

A. One could look at that information, but it's not needed for my analysis here of putting Tyvaso sales into context relative to the industry.

Q. But you are putting orphan drug sales in the context of all drug sales, correct?

A. I wouldn't describe it that way. I agree with you that Tyvaso is an orphan drug, and in paragraph 23 I compare it to the range of sales in the industry, and then in paragraph 24 I compare it to other PAH drugs specifically.