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Q. And you didn't make any attempt to compare Tyvaso sales only to other orphan drugs, correct?

A. Not specifically to other orphan drugs. That is addressed inherently in paragraph 24 where all of the competing drugs in that paragraph are treatments for PAH. So that is an analysis that takes into account the patient population size, but paragraph 23 is independent of the patient population size.

Q. So just so I am clear, it is your opinion that an orphan drug with potentially less than 200,000 total patients making over 2.5 billion in net sales over a seven-year period is not a commercial success?

A. Could you repeat the question, please.

Q. Well, let me break it down.

Earlier we looked at your Attachment B-4. If you can turn to that on page 38 of 45.

A. Okay.

Q. And for Tyvaso from 2009 to 2016 you totaled revenue at 2.515 billion for

DEFOREST MCDUFF, Ph.D.

Tyvaso, correct?

A. That's right --

Q. And --

A. -- over all years.

Q. Yes. And Tyvaso is an orphan drug meaning that it likely has less than 200,000 patients, correct?

A. I don't know if that's true as of today. There may have been less than 200,000 PAH patients in the U.S. at one point in time.

Q. So is it your opinion that $2.5 billion in sales over a seven-year period for an orphan drug is not a commercial success?

A. It depends. It's a case-by-case analysis. So I couldn't give you an answer to that in a global way that would apply to every drug with that profile, but I have analyzed Tyvaso, and the magnitude of sales here do not demonstrate commercial success.

Q. So in your opinion an orphan drug with 2.5 billion in sales over seven years in this case is not a commercial success?

DEFOREST MCDUFF, Ph.D.

A. It sounds like the same question and the same answer.

Q. It's a yes or no question.

A. I've found that Tyvaso sales do not demonstrate commercial success here.

Q. So an orphan drug with 2.5 billion in sales over a seven-year period is not a commercial success in this case, correct?

A. Maybe I am missing the distinction with the previous question, but it sounds like the same question to me.

Q. Do you agree with that statement?

A. Tyvaso sales, as I have analyzed them here, do not demonstrate commercial success.

Q. And those sales --

A. I agree with that as a summary opinion.

Q. And those sales were 2.5 billion over a seven-year period, correct?

A. Yes.

Q. You provided no opinion regarding gross profits for Tyvaso, correct?

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A. That's correct. I am not aware of that information being available.

Q. Did you try to find that information?

A. I don't believe so. I am not aware of it being available.

Q. Did you ask counsel for that information without disclosing any actual conversations with counsel?

A. I don't recall. It's not the kind of information that's typically available in IPRs in my experience.

Q. And you provided no opinion regarding gross margins for Tyvaso, correct?

A. Similar answers as before. I don't recall that information being available here, but I have not analyzed it as I am not aware of it being available.

Q. Did you attempt to find information about it?

A. I don't recall.

Q. So going back to the top two deciles, why did you consider just the top two deciles as being relevant benchmarks for

DEFOREST MCDUFF, Ph.D.

commercial success analysis of pharmaceutical sales?

A. I don't think that accurately captures my opinion. I don't think they are the only relevant benchmarks.

Q. I didn't say only, but you did specify the top two deciles, correct?

A. Among other things that I compared it to, yes.

Q. So why just the top two deciles?

A. I don't limit my analysis to just the top two deciles.

Q. But you didn't compare to the third decile, right?

A. That's correct. In this literature they don't report on sales for every decile. They report the first decile and second decile an average as I have provided here in this chart on page 16. Had the literature published other deciles, I might have considered those.

Q. Is it your opinion that when compared against top decile drugs, 90 percent

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of approved drugs would not achieve commercial success?

A. I wouldn't describe it that way, no.

Q. So is it your opinion when compared against the top two decile drugs, that 80 percent of approved drugs would not achieve commercial success?

A. I would not put it that way, no.

Q. So a drug could be below the second decile and still be a commercial success, correct?

A. It depends. It's a case-by-case basis and analysis.

Q. But you are not saying that commercial success is limited to the top two decile of drugs, correct?

A. I am not, no.

Q. Do you know how many top decile drugs treat pulmonary arterial hypertension?

A. Not sitting here, no. I don't recall, nor am I aware of that information

being available.

Q. Well, you calculated the total revenue of drugs that treat pulmonary arterial hypertension and also reported the amount needed to reach the top decile, correct?

A. I performed both of those analyses, yes.

Q. And none of the drugs that treat pulmonary arterial hypertension are in the top decile, correct?

A. Well, comparing the graphs on page 16 and page 17 of my declaration, it appears that Tracleer is either first decile or second decile, and Letairis is possibly second decile, possibly not. I am not exactly sure where the cutoffs are that allow one to make that determination.

Q. Are you looking at paragraph 24?

A. Yes.

Q. Well, your previous chart compares the peak annual sales on page 16 shows first decile drugs 3.565 billion, correct?

A. Yes, as an average for first

decile drugs. Some are higher. Some are lower.

Q. But Tracleer is far below that number, correct?

A. Tracleer is between the averages of the first decile and the second decile. So it depends where the cutoff is. The cutoff between the first decile and the second decile is somewhere between 1.3 billion and 3.5 billion as are the sales of Tracleer. So without that additional information, we don't know whether Tracleer will be in the first decile or the second decile. It might be more likely to be in the second decile given that it's closer to the average for second decile, but I can't say for sure.

Q. And given that the average second decile according to your analysis is 1.3 billion, is it fair to say that the vast majority of the drugs you analyzed for pulmonary arterial hypertension do not meet the top two deciles?

A. I would say the majority do not. I think that's sensible in light of 12

drugs being here on -- in paragraph 24 and two out of 12 being near first decile and second decile around 20 percent, 15 to 20 percent. I think that's consistent with the industry, maybe slightly lower.

Q. You did not provide an opinion on the profit obtained by UTC on Tyvaso, correct?

A. Not here. I am not aware of that information being available or provided by UTC.

Q. Did you look for it?

A. Not specifically, nor am I aware of that information being available here. It's typically not.

Q. Would you be surprised if UTC had a high profit margin on their 2.5 billion in net sales of Tyvaso from 2009 to 2016?

A. I don't know. I would evaluate that information if it were available.

Q. Do you consider profit margin to be an important factor in analyzing commercial success?

A. It depends on the situation.

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Sometimes I analyze it if it's available.

Q. So going back to paragraph 23 and your analysis of peak annual sales of Tyvaso compared to first and second decile and average drugs, you rely on a 2002 article by Grabowski as part of your analysis, correct?

A. As part of my analysis as well as the actual Tyvaso sales.

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

BY MR. DELAFIELD:

Q. You have been handed what has been marked as Exhibit 1113 which is an article entitled Returns on Research and Development for 1990s New Drug Introductions, and Exhibit 1113 is the same for both cases.

Do you recognize this document?

A. Yes.

Q. And is this the document that you cite in footnote 12?

A. Yes, it is.

Q. Or one of the documents.

Now, this study analyzes drugs

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launched between 1990 and 1994, correct?

A. Yes.

Q. And then also uses actual sales that those products made through 2000, correct?

A. That sounds right.

Q. So this means that the study only had between seven and 11 years of actual data from 16 years ago, correct?

A. I don't believe that's accurate. This is a paper that's based on a line of research that occurred in the 1970s, 1980s, 1990s, and then 2000s. They use some data on drugs that were launched from 1990 to 1994, and they combined that with older data it's my understanding to get the longer timeframe and project the full sales path.

Q. So instead of relying on actual data, you chose to rely purely on the projections made in the study or some combination of actual sales and projected sales to create your comparison, correct?

MR. MATHAS: Object to the form.

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BY THE WITNESS:

A. I wouldn't describe it that way, no.

BY MR. DELAFIELD:

Q. Well, let's look at the sales page 17 which is one of the pages you cite, page 7 of the exhibit, 17 internal page.

A. Okay.

Q. And at the top Figure 2 shows worldwide sales profiles of 1990 to 1994 new drug introductions.

Do you see that?

A. Yes.

Q. And it goes out to 20 years, right?

A. Yes.

Q. But this paper was published in 2002, and so many of those years are just projections, correct?

A. The later years are projections based on actual historical sales data as I indicated in my previous response.

Q. But it says sales profiles of 1990 to 1994 new drug introductions, right?

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A. I am not sure I understand the question.

Q. Let me rephrase.

So we can agree some of the data in this chart represents actual sales of drugs launch between 1990 and 1994, correct?

A. Yes.

Q. And some of the data used to generate this are projections of where those sales would go after the time of this paper based on prior sales, correct?

A. I agree with that, yes.

Q. So your reliance on this is using both actual and projected sales, right?

A. It's a combination of those. That's the methodology that's described in this paper. This is among the most widely cited literature in pharmaceutical research and development.

Q. And you will notice it says worldwide sales, right?

A. Yes.

Q. Now, in evaluating commercial success of a U.S. patent, you would agree that

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it's appropriate to look at only U.S. sales, correct?

A. I don't agree with that, no.

Q. Well, if it's not protected in other countries, then the commercial success isn't relevant because there's no patent protection, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I am not seeking to provide a legal conclusion on this issue of whether sales outside the U.S. are relevant from a legal perspective, but from an economic perspective, evaluating the commercial opportunity it's common to evaluate sales worldwide.

BY MR. DELAFIELD:

Q. So, for example, if someone patented a product and sold none of it in the United States with the patented -- strike that.

So if someone patented a product in the United States and there were no sales in the United States but they had a lot of sales where there was no patent protection, are you saying that those sales are relevant to

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the commercial success of the patent?

A. I don't think I can provide a global conclusion on that. It would depend on the circumstances. That's not the circumstance here.

Q. Well, you are providing global sales numbers for a U.S. patent, correct?

A. I wouldn't describe it that way. I am analyzing sales both in and outside the U.S. for these comparisons in order to put Tyvaso sales into context so that we can understand what the magnitude of Tyvaso sales means. I think it's fully appropriate.

Q. And you didn't provide any analysis of U.S. only sales, correct?

A. Not here in my declaration. I am not aware of those being readily available. Companies report their worldwide sales in public filings. They typically do not do so for U.S. sales alone.

Q. Did you attempt to determine U.S. sales for any of the drugs that you list in your analysis?

A. No, I did not view that as

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necessary for the conclusions I am drawing.

Q. So you don't know how well Tyvaso has performed in terms of U.S. sales only, correct?

A. I know that their U.S. sales are at least at or below their worldwide sales. So I know the sales are if anything lower than the sales I have analyzed in my report.

Q. I'm sorry. Could you repeat that?

A. In other words, the U.S. sales are certainly no greater than the worldwide sales that I have analyzed. So if anything the U.S. sales are lower than what I have analyzed.

Q. But likewise for every drug and even the top decile drug, those would also be lower, correct?

A. If limiting to U.S. sales only, they could be, yes.

Q. So you don't know how much lower either -- strike that.

You don't know how much lower each drug would sell in the U.S. compared to worldwide sales, correct?

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A. I haven't provided that specific breakdown in my declaration, nor do I view it as necessary. I think one would draw the same conclusions if one looked at U.S. data.

Q. You said one would draw the same conclusions if they looked at U.S. data; is that right?

A. It seems likely to me that one would, yes.

Q. But you didn't look at U.S. data. So how you would know that someone would draw the same conclusions?

A. In my experience doing many cases of this type, typically doing the analysis on a worldwide basis or a U.S. basis provides similar conclusions.

Q. But you don't provide any evidence of that, correct?

A. Again, that's not something I specifically sought to do in my declaration. I did not view it as necessary to draw the opinions or the conclusions that I am drawing here, but I think it's likely that if one did

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the analysis with U.S. sales, one would draw -- or I would draw similar conclusions.

Q. So just to clarify, it is your opinion with respect to analyzing the commercial success of a U.S. patent, the sales in the U.S. are no more relevant than sales in Japan, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I wouldn't put it that way, no.

BY MR. DELAFIELD:

Q. Would you agree that sales in the U.S. are more relevant than sales in other countries with respect to analyzing the commercial success of a U.S. patent?

A. I don't think I have a global opinion or conclusion on that issue. I think what I have done here by comparing Tyvaso sales as publicly reported on a worldwide basis is sufficient for the opinions I have reached.

Q. Are you aware that UTC -- strike that.

Are you aware that United

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Therapeutics holds patents in many different countries on Tyvaso and I believe all of their treprostinil products?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I am aware that they have some international patents.

BY MR. DELAFIELD:

Q. Did you analyze what patents are available in what countries with respect to Tyvaso?

A. I don't believe I did that specifically, no.

Q. So if Tyvaso is patented in the U.S. and Tyvaso is patented in England, would sales in England still be relevant to the commercial success of a U.S. patent or just the patent in England?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't have a global conclusion or opinion on that. I would evaluate it on a case-by-case basis. I think evaluating Tyvaso sales as I have done here is

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appropriate and sufficient for the conclusions I have drawn.

BY MR. DELAFIELD:

Q. In your career have you ever evaluated commercial success of patents from different countries?

A. I don't believe so. I think given that most of my work occurs here in the U.S., all the litigations I have worked on have been for U.S. patents. Of course, sometimes worldwide patents are relevant to the evaluation, but the litigations are specifically about U.S. patents.

Q. And so just to clarify, it is your opinion that sales outside the U.S. are directly relevant to the commercial success of a U.S. patent, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. They can be, yes, from an economic perspective. I understand that's consistent with guidance provided by the U.S. PTO, and it's consistent with what I have done with my work in the past and what other experts

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evaluating commercial success analyze, but it's a case-by-case situation. It depends on what conclusions one is reaching. The worldwide sales that I have analyzed here are sufficient for the conclusions I have drawn.

BY MR. DELAFIELD:

Q. You mentioned guidance from the U.S. PTO. You don't cite any such guidance in your declaration, correct?

A. I don't recall doing so, no.

Q. So looking back at the Grabowski article Exhibit 1113, Figure 2, is -- this is one of the figures you used for your calculations, correct?

A. Which page are you on?

Q. Page 7 of Exhibit 1113, internal page 17.

A. Yes.

Q. Is that a, yes, that was one of the figures you used to base your calculations on?

A. Yes, that's right.

Q. And if you look at page 16 of your report next to that Exhibit 1113, you

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report comparisons for first and second decile and mean or average, correct?

A. Yes, that's right.

Q. And you don't report a comparison of Tyvaso to the median sales of pharmaceuticals, correct?

A. That's correct, because I don't view them as a relevant benchmark for commercially successful pharmaceutical products.

Q. Why is the median not a benchmark for commercially successful pharmaceutical products?

A. As indicated in this literature, median pharmaceutical products tend to lose money. They tend to not be economically profitable. So they are not a benchmark or an example of a commercially successful drug product.

Q. So you don't know whether Tyvaso would be above the median sales because you didn't do that analysis, correct?

A. I haven't calculated it here for my declaration because I don't view it as

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an appropriate benchmark for commercial success.

Q. But you included the mean sales, right?

A. Yes, because I viewed that as a relevant benchmark for evaluation.

Q. But this paper reports both, right?

A. That's correct, and they explain the context for each, and the context that's relevant for commercial success is that average drugs tend to be about break even in terms of profitability, and so when thinking about a commercially successful drug product, the fact that Tyvaso is below average indicates that it's likely not profitable. Whereas, a median drug tends to be not economically profitable, and so it's not a relevant benchmark for evaluating commercial success.

Q. Now, we talked about the fact that this paper uses sales numbers of drugs from 1990 to 1994, correct?

A. Products that were launched over that period, that's right. The sales

occurred over the next seven to 11 years and beyond.

Q. And the beyond we discussed that those are all projections, correct?

A. Projections based on actual data prior to that time period.

Q. So this paper the actual data all occurred prior to 2000, correct?

A. I think it's through 2001 based on the launch dates and length of time they appear to report data.

Q. And so haven't pharmaceuticals changed since pharmaceuticals launched in 1990 and sales of those same products in 2001 since that time?

A. Not to my knowledge, not in a way that would make these results inapplicable. I followed this literature over time, and there have been more recent publications, but no publications are as complete that provide the kind of drug sales distribution information that this paper provides.

For example, these authors who are among the most widely cited authors in

pharmaceutical R&D research published a book chapter in 2010 where they report on this same research as being applicable today. So I have no reason to doubt its validity here.

Q. Did you look for more recent papers that analyzed drug sales?

A. I have. I do that on an ongoing basis.

Q. And isn't it possible that the model from 20 to 30 years ago has changed significantly over that time?

A. No, not in my opinion. This literature has continued and this is the highest cited paper of any paper in this genre, and the most recent papers have the same model and the same structure and way of thinking about it economically as these authors did in 2002.

Q. Are you aware that both the number of drugs and the number of drug patents has dramatically increased since 2000?

A. It depends what you mean by dramatically. I am aware that they have increased.

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Q. And so if there are more drugs and more patents out there, you don't believe that the trends may have been changed due to that fact?

A. Not in a way that would make the results inapplicable.

Q. There were no commercially available treatments for pulmonary arterial hypertension as of 2001, correct?

A. I think that's right at or around that time they started being released.

Q. So in the analysis that Grabowski does, there are no drugs that were used to treat pulmonary arterial hypertension, correct?

A. Not in this data set to my knowledge. That's not the intention of using this data set.

Q. Are you aware of any criticisms of the DiMasi and Grabowski studies that you relied on for your opinion?

A. I am aware of some criticisms from special interest groups. Yet the peer-reviewed literature on the topic is widely

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accepting of this literature and of this paper specifically.

Q. Do you recall what those criticisms were?

A. Not sitting here. I believe they are methodological or data critiques that people have articulated and have been evaluated and discredited by the academic literature.

Q. When you say discredited by the academic literature, have you seen academic literature that specifically addresses the criticisms of Grabowski and DiMasi?

A. I guess I would say that there are a number of peer-reviewed publications that have evaluated the methodologies in Grabowski and DiMasi and have confirmed their correctness. That's how I could describe that.

Q. But given the criticisms, it's fair to say that not everyone agrees with the analysis that Grabowski and DiMasi provide with respect to trends in pharmaceutical sales, correct?

MR. MATHAS: Object to the form.

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BY THE WITNESS:

A. Everyone in the world?

BY MR. DELAFIELD:

Q. Well, is it fair to say that other economists disagree with the analysis provided by DiMasi and Grabowski?

A. There may be some who disagree with it, but as I indicated earlier, the majority of the peer-reviewed literature accepts this as the gold standard research on this topic.

Q. And you didn't cite any documents that cite it as the gold standard, correct?

A. Not here in this declaration, but I am aware of more than a dozen papers over the last decade that evaluate this topic and cite to this paper specifically as foundational, and this is among the most widely cited papers in pharmaceutical economics overall.

Q. But you don't cite any evidence of that either in your declaration, correct?

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A. No, but it's true.

Q. How do you know it's the most cited? How would you determine that?

A. I have seen rank lists of paper citations that is something that's tracked in order to evaluate impact of papers, and this paper has shown up at the top of those lists.

Q. Would you agree that it is the overall context rather than the particular market share that defines whether market share are interpreted as persuasive evidence of commercial success?

A. I think that's a fair statement. I think context matters.

Q. You did not provide any opinion regarding Tyvaso's contribution to UTC's overall profitability, correct?

A. No, I don't believe so.

Q. Did you look into that?

A. No, I don't think so. I don't view it as particularly relevant.

Q. So if Tyvaso contributed significantly to UTC's overall profitability,

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you don't think that would be significant to commercial success?

A. I don't. For example, if there were a small company that sold a product versus a large company that sold an identical product, I don't think one would draw different conclusions about their commercial success based on what share of the company they represent if they were identical in other ways.

Q. I am not sure I understand that answer.

So within UTC, you don't think it's relevant if Tyvaso's contribution to its overall profitability compared to other drugs at UTC, you don't think that's relevant to commercial success?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Not as a general matter. I am open to considering it, but it's not something I looked into, nor do I view as particularly relevant here.

BY MR. DELAFIELD:

Q. Do you agree that United

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Therapeutics has been recognized as a valuable and fast growing company since the time of Tyvaso's launch?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't know. Is that an excerpt you are reading from from one of the documents I have cited?

BY MR. DELAFIELD:

Q. I am just asking have you looked into the profitability or market share of United Therapeutics since Tyvaso's launch?

MR. MATHAS: I am going to object to the form, and I think it would be fair to characterize the question as being in this proceeding because obviously Dr. McDuff has been involved in other proceedings related to Tyvaso.

BY MR. DELAFIELD:

Q. In this proceeding?

A. Would you mind just repeating the question.

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

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BY THE WITNESS:

A. For my analysis here, I didn't investigate that, no.

BY MR. DELAFIELD:

Q. And you provided no opinion regarding United Therapeutics' market capitalization since Tyvaso's launch, correct, in this case?

A. I did not, no.

Q. Would it surprise you to know that United Therapeutics' market capitalization has more than doubled since 2009?

A. Not particularly.

Q. Isn't it relevant to consider that the market capitalization more than doubling during a time when Tyvaso's revenues made up a significant amount of UTC's revenues and profits?

A. I'm sorry. Is that a question?

Q. Is market capitalization -- UTC's market capitalization since Tyvaso's launch relevant to consider for commercial success?

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A. Sitting here, I don't see why it would be particularly relevant.

Q. So if United Therapeutics' market capitalization went up as Tyvaso sales went up, you don't think that would be a relevant factor to consider for commercial success?

A. It depends on what the information looked like. I didn't analyze that information here. I don't have a conclusion on it sitting here.

Q. Now, the DiMasi paper projected sales based on prior sales for I think 20 years. You did not project Tyvaso sales through the expiration date of the patents-in-suit, correct?

A. That's correct, because they have already started to decline. In other words, they have already reached their peak sales in 2015 and have declined in 2016 and 2017.

Q. Even if there is a decline, isn't it possible that their sales could go back up?

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A. It's possible but it's not likely.

Q. So you don't know for sure that they have already reached peak sales, correct?

A. It's very likely that they have. I have seen very few examples of drugs that reach a peak sales, decline, and then grow to beyond what they have already reached. In light of the competition in this market, I don't think it's likely that they will be greater again. It's certainly possible just not likely.

Q. So it is possible?

A. It's certainly possible, but I don't view it as likely.

Q. In past cases where you have offered an opinion on commercial success, did you project sales through patent expiration?

A. It depends on the circumstances. I have in some instances and haven't in others.

Q. Why didn't you here -- strike that.

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Is the fact that you believe Tyvaso has already reached peak sales the only reason you did not project sales through patent expiration in this case?

A. That's one reason. Another reason is that future sales are inherently less objective evidence of commercial success given that they haven't occurred yet. They may occur. They may not occur. We don't know. So I put less weight on them.

And I guess the third reason is I think that I didn't need to project future sales in order to draw the conclusions that I have drawn in this declaration.

Q. So you agree that projected sales have less weight than actual sales because you don't know if those would occur, correct?

A. I wouldn't describe it as a global conclusion as you have that would apply to every situation. I don't think it applies to every situation, but I think in terms of evaluating commercial success as a secondary consideration based on sales that have already

occurred, I think future sales are less relevant than past sales.

Q. But in your analysis of comparing Tyvaso to the top two deciles from the DiMasi paper, the majority of those sales for those deciles were projected sales, correct?

A. I don't agree with that.

Q. Well, we discussed how some of the sales are actual sales and some of them are projected, correct?

A. Yes, but the primary results aren't influenced heavily by the projections. You can see in the Grabowski, DiMasi paper that most of the sales profile has been achieved already by years seven to 11. So the projections don't change the results that much.

Q. But there were several years that are just projected sales, correct?

A. Well, they are projected based on the actual sales path. So they are doing their best to program over the full life cycle of a product, but the projections aren't impactful on the result. It wouldn't change my

conclusion.

Q. Well, aren't all projected sales based on prior sales? That's how you do a projection?

A. Yes.

Q. And you didn't do that for Tyvaso here, correct?

A. I did not, that's correct.

Q. And you do not provide an opinion regarding the relationship between United Therapeutics' gross margin and Tyvaso's gross margin, correct?

A. I think that's true, yes. I am not aware of that information being provided by UTC.

Q. Did you check to see if it was available?

A. I don't recall. It's typically not available in IPRs in my experience.

Q. So you don't remember checking to see if it's available?

A. I don't recall one way or the other.

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Q. You also did not provide an opinion regarding the economic costs for launching Tyvaso, correct?

A. Correct.

Q. But economic costs are an important factor to consider for commercial success, correct?

A. They can be. It depends on the circumstance.

Q. You did not account for preclinical expenses for Tyvaso, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Not in this declaration, no.

BY MR. DELAFIELD:

Q. Do you agree that a patented invention should be considered a commercial success if it can be shown to have earned or can reasonably be expected to earn a positive net return on invested capital after accounting for all relevant costs associated with development and commercialization?

A. I think that's one factor one could analyze.

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Q. Well, do you agree with that statement?

A. I don't agree that that's the only factor or that that's a sole consideration, no.

Q. But you agree that if a patented invention meets those criteria, it should be considered a commercial success?

A. It depends on the circumstance.

(WHEREUPON, a certain document was marked McDuff Deposition Exhibit No. 1, for identification, as of 4/6/18.)

BY MR. DELAFIELD:

Q. You have been handed what's been marked as McDuff Exhibit 1 which is a paper entitled Thinking Economically about Commercial Success.

Do you recognize this paper?

A. Yes.

Q. You are the primary author of this paper, right?

A. I am one of three authors.

DEFOREST MCDUFF, Ph.D.

Q. Do you recall writing this paper?

A. Yes, with contributions from my co-authors.

Q. So if you turn to page 3 at the top the first full sentence: "Rather, commercial success should inform on whether sales and profits provide objective evidence on whether material economic incentives (i.e., 'market forces') would have incentivized others to bring product to market had the invention been obvious."

And then it goes on to say: "Other economists and scholars agree that this is, in essence, the fundamental purpose of commercial success analysis."

Do you see that?

A. Yes.

Q. And then it has an endnote 10 for that statement, and you cite a paper by Jesse David and Marion Stewart and quote: "A patented invention should be considered a commercial success if it can be shown to have earned, or can reasonably be expected to earn,

a positive net return on invested capital after accounting for all relevant costs associated with development and commercialization."

Do you see that?

A. I do.

Q. Do you agree with that statement?

A. Well, those aren't my words. Those are their words. I think that there's some validity to what they are saying. I don't think it's the only thing one should examine in evaluating commercial success.

Q. Well, in your paper in your words where you cite that paper, you say: "This is, in essence, the fundamental purpose of commercial success analysis," and then you cite that quote, correct?

A. I think that's a mischaracterization of what I have written here. The full sentence is: "Other economists and scholars agree that this is, in essence, the fundamental purpose of commercial success analysis," and I am describing the previous sentence which are my words about material

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economic incentives.

Q. So you don't think it's a fundamental purpose of commercial success analysis?

A. I don't think what is a fundamental purpose of commercial success?

Q. The whether a product has earned or can reasonably be expected to earn a positive net return on invested capital after accounting for all relevant costs associated with development and commercialization?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, as I have already explained, that's an excerpt from other economists. I think there's some validity to what they are saying, but I would describe it as I have on page 3 of the article.

BY MR. DELAFIELD:

Q. Would you agree that profit is an important factor to consider in analyzing commercial success?

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

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Q. Well, according to your paper on page 3 the last sentence of the first paragraph: "Said another way, ideas are brought to market when there is a profit opportunity, not merely when sales or market shares are 'high' or 'substantial' in some abstract sense."

Do you agree with that?

A. I do. I think that's consistent with what I have evaluated here.

Q. And so profit is an important factor to consider for commercial success, right?

A. It depends what you mean by that.

Q. Well, I am just looking at your paper. You are talking about the importance of a profit opportunity, correct?

A. What is your question?

Q. Do you agree that profit is an important factor to consider for commercial success?

A. I think it can be. Conceptually we are thinking about a market

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opportunity, and profit is, of course, an element of that. Does one have to analyze profit specifically? Sometimes, yes. Sometimes, no. It depends on the context, but fundamentally we are thinking about an economic incentive to bring a product to market.

Q. Have you ever provided an opinion that a patented product was a commercial success that was not profitable?

A. I don't recall.

Q. Do you recall providing any opinions on commercial success of a patented product that was not profitable as a factor of why it was not a commercial success?

A. Could you read that back or ask it again.

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

BY THE WITNESS:

A. Yes, I think if a product is unprofitable, that weighs against commercial success.

BY MR. DELAFIELD:

Q. And in this case you didn't

analyze cost or positive net return for Tyvaso, correct?

A. Not specifically. Here for the IPR, there's very limited information. I am not aware of UTC providing profit information for its Tyvaso product. Had they done so, I would have been open to considering it.

Q. Did you look for that information?

A. I don't recall. It's not typically available, and my understanding is that it's not available here.

Q. But you don't know because you didn't look, right?

A. I looked at the case information, and I didn't see profit information provided by UTC. Perhaps I overlooked it, but I don't think so. They certainly did not do so in their prosecution history which I did examine.

Q. But other than their 10-Ks and prosecution history, you didn't look elsewhere for profits, prices, or costs associated with

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Tyvaso?

A. I don't know where else I would look. That kind of information is typically confidential and proprietary. UTC would often have that information on a confidential basis but would not make it publicly available.

Q. Do you agree that premium pricing can be an indicator of commercial success?

A. It depends on the circumstance.

Q. In this case if Tyvaso had premium pricing, would that affect your opinion regarding Tyvaso's commercial success?

A. I think having a greater price can be one indicator of some product differentiation, but I don't think it's the only factor that is relevant for evaluation in commercial success.

Q. But it's one factor, correct?

A. It could be.

Q. Have you used that before in your analysis of commercial success of other

products?

A. I have analyzed price, yes.

Q. You do not provide any analysis of number of prescriptions in your declaration, correct?

A. That's correct. I focused on revenues.

Q. Did you look into that information?

A. I don't recall specifically.

Q. Have you ever used IMS data before?

A. I have, yes.

Q. And they typically provide prescription information?

A. That's one type of data you can purchase.

Q. So it's publicly available?

A. Publicly available but not freely available.

Q. And you didn't look at prescriptions for Tyvaso or any of the other drugs for your analysis, correct?

A. I did not. I did not view it

as necessary to do so. IMS health data is expensive, and it didn't seem necessary given the conclusions that I am drawing based on what I have examined here.

Q. Well, it would be relevant if, for example, Tyvaso's price was much higher than competitor price and sold fewer units compared to sales of other -- strike that.

For example, prescriptions may be relevant if they are not indicative of the sales compared to other drugs?

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

Q. If more people were prescribed Tyvaso than other drugs, would that influence your decision on commercial success?

A. Sitting here, it doesn't seem likely that it would change my opinions. I would be open to considering it if it were available, but it is not something that I have analyzed here, nor do I view it as necessary to have done so.

Q. But it is available. You just didn't get it, right?

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A. Well, as I explained, it's not freely available. It can be expensive, and given the information that I saw and the conclusions that I have drawn, I don't view it as necessary to have obtained IMS health data or some other prescription metric.

Q. In a commercial success analysis, it's important to consider the fact that commercial and government payers consider the benefits of Tyvaso to be important enough to justify paying for it, correct?

A. Could you repeat the question.

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

BY THE WITNESS:

A. I don't think I have a global opinion on that that would apply to every situation.

BY MR. DELAFIELD:

Q. So, for example, if an insurer or government payer included a very expensive drug in its formulary coverage, then they would have to provide substantial benefits to the user over other drugs in order to be covered,

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correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Not necessarily. I don't have a global opinion on that that would apply to every situation.

BY MR. DELAFIELD:

Q. Do you agree that would be relevant to commercial success?

A. It depends on the circumstances, I suppose. I didn't see information on -- that would make that relevant here.

Q. Did you look into whether that was the case for Tyvaso?

A. I don't recall.

Q. Are you aware that Tyvaso can only be obtained through specialty pharmacies?

A. That sounds familiar.

Q. Did you consider that in your analysis the availability of Tyvaso compared to the other drugs?

A. It's a factor that's inherently considered when one looks at the

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sales data. If one drug is harder to obtain and another drug is easier to obtain, that will show up in sales, but it's not a factor that I focused on.

Q. So if a drug is harder to obtain, they might have less sales not because of any patented features, but just because of the availability of the drug, correct?

A. There could be lower sales due to lack of availability. I think that represents a smaller commercial opportunity. In other words, a less successful product.

Q. Well, you would have to consider it in light of the fact that it can only be provided by specialty pharmacies, correct?

A. I don't know what you mean by that.

Q. The commercial success of a product in relation to the patented features have nothing to do with availability, but the total sales could have something to do with availability, correct?

MR. MATHAS: Object to the form.

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BY THE WITNESS:

A. Well, there are various attributes of a product. Some that may relate to a patent and some may not relate to a patent could contribute to its availability. All else being equal, more effective drugs are more available.

BY MR. DELAFIELD:

Q. Did you look into what drugs are only available at specialty pharmacies other than Tyvaso in your list of drugs?

A. I don't think I performed that specific analysis, no. I don't view it as particularly relevant here.

Q. And you provided no other opinions on any other secondary consideration other than commercial success, correct?

A. That's correct in terms of my analysis and conclusions. Although, my declaration may be cited towards other secondary considerations, but I did not draw conclusions on other secondary considerations.

Q. So you were only asked to provide opinions on commercial success,

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correct?

A. That's correct, but I don't have the full scope of what my declaration will be used to support or rebut.

Q. So it's your opinion that the '075 patent and the '222 patent are patents that would -- are blocking patents in this case; is that correct?

A. Yes.

THE WITNESS: Maybe if you are shifting gears, we could take a break.

MR. DELAFIELD: Sure.

THE VIDEOGRAPHER: The time is now 3:03 p.m. This is the end of media 3. We are off the record.

(WHEREUPON, a recess was had at 3:03 p.m. until 3:13 p.m.)

THE VIDEOGRAPHER: The time is now 3:13 p.m. This is the beginning of media 4. We are back on the record.

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

BY MR. DELAFIELD:

Q. You have been handed four

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documents. The first of which is Exhibit 1019 which is U.S. Patent 4,306,075, and it's Exhibit 1019 in both cases.

Do recognize that document?

A. Yes.

Q. The next exhibit is Exhibit 1025 which is the same exhibit number for both cases, and is a copy of U.S. Patent 5,153,222.

Do you recognize this document?

A. Yes.

Q. The third document is Exhibit 1018 which is labeled 1018 in both cases, and it is a copy of U.S. Patent 6,521,212.

Are you familiar with this document?

A. Yes.

Q. And then finally Exhibit 1057 which is the same exhibit number for both cases and is a copy of U.S. Patent 6,756,033.

Are you familiar with this document?

A. Yes.

Q. Have you reviewed all of these

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documents in preparing your declaration?

A. Yes.

Q. So let's start with the '075 patent which is Exhibit 1019.

A. Okay.

Q. Do you know if Watson sought to license this patent from United Therapeutics?

A. I don't know one way or the other.

Q. Or from the Upjohn Company, the original assignee?

A. Did you mean to ask about Watson?

Q. Yes.

A. I don't know.

Q. But it was available to be licensed, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't know what you mean by that, not as I think of it.

BY MR. DELAFIELD:

Q. Well, generally all patents

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are capable of being licensed to someone else, correct?

A. What do you mean by capable of? You can license a patent.

Q. And like that example this patent could be licensed, correct?

A. Without more specifics, I am not sure what you are getting at. Could be licensed to whom, under what circumstances?

Q. Well, this is one of the patents that you designated as a blocking patent; is that correct?

A. Yes.

Q. And a blocking patent, according to your analysis, a patent that effectively blocks others from making, selling, or using the product without the use of the invention claimed in the patent, correct?

A. Yes.

Q. Or put another way, a blocking patent prevents practicing another patent, correct?

A. I am not sure I agree with that last characterization.

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Q. So a blocking patent doesn't necessarily prevent practicing another patent?

A. A blocking patent doesn't present -- prevent practicing another patent? I am just not sure what you mean.

Q. So you have a blocking patent that according to your definition blocks others from making, using, or selling a product without the use of the invention claimed in that patent?

A. Yes.

Q. So if someone wants to patent something else using that product, would you agree a blocking patent prevents obtaining another patent that uses that technology?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. No, that's not how I think about it. A blocking patent blocks commercialization and sales activities, and it disincentivizes development of other technologies.

BY MR. DELAFIELD:

Q. You agree, though, a blocking

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patent is one that effectively blocks others from making, selling, or using a product without use of the invention purportedly claimed in that patent, correct?

A. Yes, that's a sentence from my declaration.

Q. And making or using a product doesn't necessarily mean selling the product, right?

A. What do you mean?

Q. Well, earlier I asked you if a blocking patent would prevent others from patenting something else that includes the invention that's part of that blocking patent, and you said that's not how you think of it, correct?

A. That question is very confusing to me.

Q. Is it your opinion that blocking patents would prevent others from patenting similar technology that uses the invention in the blocking patent?

A. It would disincentivize development of other technologies because, as I

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explain in paragraph 27, other entities would have strong disincentives not to develop technology that they would be blocked from utilizing or implementing in the marketplace.

So if I am entity considering developing a technology, if another patent would block me from bringing my technology to market, I am not going to pursue that as an economic incentive.

Q. But pursuing another patent on related technology that uses that would be part of making or using the blocking patent, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

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

BY MR. DELAFIELD:

Q. Is it your position that the '075 patent is a blocking patent as to the '240 and '507 patents?

A. Yes, along with the other patents listed in paragraph 28.

Q. Now, with respect to the '075

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patent, it was filed in 1980, correct?

A. Yes.

Q. Do you know when it expired?

A. I believe it was sometime in the late 1990s or around 2000.

Q. And the '240 and '507 patents weren't filed until 2006, correct?

A. Correct.

Q. So this patent had expired and wasn't blocking anything as of 2006, correct?

A. In 2006 the '075 patent wouldn't be a blocking patent, but in the period of time leading up to 2006, it was a blocking patent. Again, it's the collection of patents here that provides the blocking disincentive, not just the '075 patent.

Q. But right now I just talking about the '075 patent.

You would agree that given the '075 patent had expired years before the '507 or '240 patents had even been filed, that it was not a blocking patent for those patents, correct?

MR. MATHAS: Object to the form.

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BY THE WITNESS:

A. I don't agree with that. I agree that the '075 patent was not a blocking patent in 2006, but it was prior to 2006.

BY MR. DELAFIELD:

Q. Why does it matter prior to 2006?

A. Because we are contemplating the idea of an invention potentially being developed sooner in response to market forces had it been obvious, and so sooner means before when it was actually submitted. So prior to 2006.

Q. So this patent expired I believe in 1999. I could be wrong about that, but assuming it was 1999, it expired a full seven years before either the '240 or '507 patent had been filed, correct?

A. If it expired in 1999, that's correct.

Q. And that's before anybody had thought of -- strike that.

Do you know when research on the '240 and '507 patents began?

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A. I expect it was the period leading up to the filing of the patent applications in 2006, around that time.

Q. So around 2006?

A. The period leading up to 2006.

Q. So to your knowledge, the '075 patent is not a blocking patent with respect to the '240 or '507 patent given that it had expired several years before those patents had been filed, correct?

MR. MATHAS: Asked and answered.

BY THE WITNESS:

A. I don't agree with that as explained earlier.

BY MR. DELAFIELD:

Q. If a patent is expired, it's not blocking anyone, correct?

A. It depends what time period you are talking about.

Q. After expiration.

A. I agree that it's not a blocking patent after expiration, but it still can be relevant for thinking about whether an invention would have been developed sooner.

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Q. So as of the expiration date of the '075 patent, it was not a blocking patent for the '240 or '507 patent, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Could you read the question back.

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

BY THE WITNESS:

A. After the '075 patent expired, it would no longer be a blocking patent, but it was a blocking patent for the period up to expiration.

BY MR. DELAFIELD:

Q. So in your analysis of what is and isn't a blocking patent, did you consider whether the patent actually worked?

A. I don't know what you mean by that.

Q. Well, let's look at the '075 patent.

Can you point out what specifically in the '075 patent you consider to

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be blocking with respect to Tyvaso?

A. My understanding is that the '075 patent covers the compound treprostinil.

Q. Can you --

A. And that's why it's a blocking patent.

Q. Can you point me to where it discloses treprostinil?

A. I believe that's what the patent is about. What are you looking for?

Q. I am just asking for you to identify the treprostinil disclosure that you are claiming the '075 patent discloses?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, I am not a chemist. So I wouldn't purport to wade through all of the chemistry explanation here, but my understanding is that the '075 patent covers the treprostinil compound.

BY MR. DELAFIELD:

Q. Is that based solely on Dr. Donovan's declaration?

A. I believe it is, yes.

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Q. Have you ever identified the structure of treprostinil in the '075 patent?

A. What do you mean by that?

Q. Well, you are claiming it's a blocking patent because it discloses treprostinil, and I am just wondering have you ever satisfied yourself that treprostinil is, in fact, disclosed in the '075 patent?

A. That's my understanding based on information from Dr. Donovan. I don't have any reason to question that.

Q. Do you know if the process described in making treprostinil in this patent actually works?

A. What do you mean by actually works?

Q. Well, do you know whether someone following this patent could actually make treprostinil based on this patent?

A. I have not waded into these technical issues for the purposes of my declaration. My understanding is that this patent covers treprostinil. I understand that Dr. Donovan has provided that opinion.

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Q. And so your opinion that this patent discloses treprostinil is solely based on the fact that Dr. Donovan said that it discloses treprostinil, correct?

A. I believe that's correct. It's based on my understanding and discussion with counsel as well.

Q. You would agree with me that the first commercially available form of treprostinil was Remodulin, correct?

A. I believe that's correct, yes.

Q. And that was launched in 2002; is that correct?

A. 2001 or 2002, around then.

Q. And so the '075 patent was filed in 1980. So for 22 years, nobody had commercialized the compound treprostinil, correct?

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

Q. But it is your opinion that it is the compound that is responsible for the commercial success or at least in part of Tyvaso -- strike that.

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It's your opinion that it is the compound treprostinil that is responsible for whatever success was obtained by Tyvaso?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I would point you to paragraph 35 in my report. I think it is stated best there. I write quote: "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.

My understanding is that that relates to the '075 patent and the '222 patent.

BY MR. DELAFIELD:

Q. So do you have any understanding as to why treprostinil was apparently known since 1980 and yet not commercially available until 2002 if the commercial success is due specifically to the drug itself?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I think it's consistent with a

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limited market opportunity and a small patient population and a lack of commercial incentives for development.

BY MR. DELAFIELD:

Q. Because the '075 patent expired before any commercial use of treprostinil, it actually was not a blocking patent during -- strike that.

It was not a blocking patent at the time that treprostinil was first commercially sold, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. If you are limiting to 2001 onward, which it sounds like you are, I agree that the '075 patent was not a blocking patent for that period of time after it expired. It was a blocking patent before expiration.

BY MR. DELAFIELD:

Q. So if you would look at Exhibit 1025, and this is patent number 5,153,222. Now, can you point out treprostinil in this patent?

A. Like with the '075 patent, I

don't have an independent interpretation of the chemistry here, but my understanding is that this patent covers method of treating pulmonary hypertension with treprostinil.

Q. And so your understanding that this patent discloses treprostinil is based on Dr. Donovan's declaration that states that this discloses treprostinil, correct?

A. Yes, as well as this patent being listed in the FDA Orange Book for Tyvaso which has treprostinil as the active ingredient.

Q. So if you look on the first page of the '222 patent, you see that it was filed in 1991.

Do you see that?

A. Yes.

Q. And in references cited, it lists the '075 patent.

Do you see that?

A. I do.

Q. So if you also compare the '075 and the '222 patent, they are different inventors and different assignees, correct?

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A. I see that, yes.

Q. So the '075 patent didn't block Burroughs Wellcome from developing the '222 patent, correct?

A. Well, as we discussed earlier, the notion of a blocking patent doesn't block someone from performing scientific research. Rather it reduces economic incentives for bringing products to market, but this did occur over the time period where the '075 patent had not yet expired.

Q. So even though the '075 patent had not expired, Burroughs Wellcome was able to patent the use of treprostinil for treating pulmonary hypertension, correct?

A. That's my understanding, yes.

Q. And so they were not blocked from making or using treprostinil that was disclosed in the '075 patent, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, as we discussed earlier, the scientific research itself may not be blocked. Had Burroughs Wellcome brought a

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product to market, perhaps they would have been sued or prevented from doing so by the owner of the '075 patent.

BY MR. DELAFIELD:

Q. So you mentioned economic disincentives. It takes a good amount of money to get an issued patent, correct?

MR. MATHAS: Object to the form.

MR. DELAFIELD: We can ask Steve.

BY MR. DELAFIELD:

Q. Would you agree that it takes a lot of money to get an issued patent?

MR. MATHAS: Same objection.

BY THE WITNESS:

A. I understand there's a range. Some patents are less expensive than others.

BY MR. DELAFIELD:

Q. But in order to obtain a patent, there must be some sort of economic incentive to do so, correct?

A. I would agree with that. It wouldn't necessarily be a big incentive or one that's shared with the broader market, but there may be some incentives for some

scientific researchers.

Q. Now, you mentioned that for scientific research that the inventors of the '222 patent may not have been blocked from doing research on treprostinil by the '075 patent.

Is that fair to say?

A. Not in terms of not being permitted to perform the research.

Q. So I am not sure what you mean by that.

Are you saying you agree that the '075 patent didn't prevent Burroughs Wellcome from performing research on treprostinil?

A. That's my understanding. I am not aware of any prevention or litigation that occurred. That doesn't mean it didn't. Just sitting here I am not aware of it.

Q. Are you familiar with the safe harbor provision in the FDA?

A. I am, yes.

Q. And generally speaking, that provision allows generics and other companies

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to make and use but not sell certain patented inventions, correct?

A. It applies to certain types of scientific research which are permitted even if there's patent protection.

Q. So, for example, a generic company can make and use and put into clinical trials a patented drug. They just can't go sell the drug, correct?

A. As one example, yes.

Q. And if they want to sell the drug, then they can challenge the patent and have a litigation, correct?

A. They can, yes.

Q. Do you know when the '222 patent expired?

A. I don't recall the exact year. Although, the '222 patent was listed in the FDA Orange Book for Tyvaso in 2009 or 2010 so after that. Sometime in the early 2010s would be my best guess sitting here.

Q. So both of these patents despite the fact they may disclose treprostinil, a company could still have made

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and used treprostinil and not have been blocked from doing so, correct?

A. Scientific research may have been permitted under the safe harbor provision as we discussed, but that misses the notion of blocking patents. Blocking patent is about the economic disincentive to perform that research if one would be later prevented from commercializing a product that resulted from that research. So it's about the economic incentive or disincentive to perform research on which one can't later commercialize.

Q. But in that analysis, wouldn't part of the analysis be to look at the blocking patents and whether they can be performed and whether they are valid themselves?

A. I am not sure what you mean.

Q. Well, for the purposes of your declaration, you are assuming that the '222 patent and the '075 patent where both valid and enabled or worked for the purpose that it was used, correct?

A. I don't believe I have made such an assumption.

DEFOREST MCDUFF, Ph.D.

Q. Well, if the patent is invalid, it's not blocking anyone, correct?

A. Well, it could be until it's shown to be invalid. If it hasn't been shown one way or the other, one could face a lawsuit if one tries to sell the product that falls under the scope of the patent. We don't know whether it's invalid at that time.

Certainly, the '222 patent and other patents here like the '212 and the '333 patent being listed in the FDA Orange Book are a pretty clear sign of patent protection that will be asserted if one tries to go to market.

Q. Again, it wouldn't block generics, for example, from making or using to prepare a product as long as they don't sell it, correct?

A. My understanding is that they are not blocked from research and preparation but they would be from selling a product.

Q. And that research and preparation typically takes years, correct?

A. It can. It depends on the circumstance.

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Q. And the '222 patent like the '075 patent could have been licensed by interested parties if they wanted to develop treprostinil or products that were within the claims of the '222 patent, correct?

A. I haven't seen any evidence of that patent being available for license in a general way. Certainly by the time UTC took an exclusive license in the mid '90s, it would be unavailable from that point forward. So unavailable because UTC held a license to those patents from the mid 1990s to 2006.

Q. You said until 2006?

A. Yes, the priority date of the patents-at-issue here.

Q. And your position that the '222 patent is a blocking patent for the '507 patent and the '240 patent is based on Dr. Donovan's discussion of the technical aspects of the patents, correct?

A. It's based on that as well as my experience evaluating patents where composition patents and method of treatment patents often are blocking patents. It's also

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further confirmed by the '222 patent, '212 patent, and '033 patent being listed in the FDA Orange Book for Tyvaso.

Q. If you could look at Exhibit 1018 which is a copy of U.S. Patent 6,521,212, and it's the same exhibit number for both cases.

Are you familiar with this document?

A. Yes, this is the '212 patent referenced in my declaration.

Q. Now, this patent does not claim any device to administer treprostinil, correct?

A. That strikes me as a technical issue. I would defer to others on the exact scope. As a general matter, I understand this patent to be covering methods of treating PAH via inhaled treprostinil.

Q. But the patent doesn't cover any kit or use of a kit, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. That strikes me as a technical

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issue. I would defer to others on that.

BY MR. DELAFIELD:

Q. So you don't know?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. It is just not something I have evaluated in my role as an economist here.

BY MR. DELAFIELD:

Q. If you could look at Exhibit 1057 which is U.S. Patent 6,756,033, and for both cases, it's Exhibit 1057.

The same question. This patent also does not claim a kit or method of using a kit to administer treprostinil, correct?

A. It strikes me as a technical issue and not one that I have drawn a conclusion on. At a general level, my understanding is that this provides methods for treating PAH via inhalation.

Q. But it doesn't specify the kit or technology used to administer, correct?

A. That's not something I have drawn a conclusion on or sought to.

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Q. Well, that's what the patents-in-suit cover, right?

A. Well, as we discussed, I provided a summary of the patents-in-suit. I wouldn't want to wade into technical issues of what's covered and what's not covered, but at a general level it describes methods and kits associated with nebulizer delivery with certain limitations and certain aspects and attributes.

Q. And -- strike that.

So in your investigation of blocking patents, did you look to see if others had patented treprostinil or processes of making treprostinil to see if people were actually being blocked by these patents?

A. I don't recall performing that analysis.

Q. For example, if several patents were out there to other companies other than United Therapeutics that claimed treprostinil or processes for making it or use of treprostinil with something else, wouldn't that indicate they were not blocked by the patents that you have identified?

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MR. MATHAS: Object to the form.

BY THE WITNESS:

A. It depends. I am not aware of any of those.

(WHEREUPON, a certain document was marked McDuff Deposition Exhibit No. 2, for identification, as of 4/6/18.)

BY MR. DELAFIELD:

Q. You have been handed what's been marked as Exhibit 2 which is a copy of U.S. Patent 9,550,716.

Have you seen this patent?

A. I don't believe so, no.

Q. If you will notice the title of the patent is Process For Treprostinil Salt Preparation.

Do you see that?

A. I do, yes.

Q. And the assignee is Eon Labs, correct?

A. I see that, yes.

Q. And this has an earliest priority date of 2010.

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Do you see that?

A. I do, yes.

Q. And in the abstract it says: "Disclosed is a process for preparing a treprostinil salt," correct?

A. Yes.

Q. So Eon Labs and the inventors of the '716 patent were not blocked from developing a patent that provides a way of making a treprostinil salt, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, we have discussed the safe harbor provision. So I wouldn't expect any blocking of scientific research to have occurred. I don't see any evidence sitting here, although I have just taken a brief look, of this being specific to treating pulmonary arterial hypertension. So I don't know how related it is to the other patents. It's just related to the '075 patent and treprostinil compound that expired in 1999.

BY MR. DELAFIELD:

Q. And the '222 patent expired

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after this was filed though, correct?

A. That's my understanding, yes.

Q. So this patent was filed before the '222 patent had expired. Yet it discloses a process for preparing a treprostinil salt, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I mean, I see that in the title. I wouldn't provide a technical interpretation of what this covers, but the title is Process For Treprostinil Salt Preparation.

BY MR. DELAFIELD:

Q. Now, you mentioned scientific research. This is a patent, though, which is designed to prevent others from making or using the idea you came up with, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. It's a patent. It provides the right to exclude.

BY MR. DELAFIELD:

Q. And so Eon Labs had at least

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some commercial incentive to patent this technology, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. They had some reason for doing so. I don't know what commercial incentive that would be.

BY MR. DELAFIELD:

Q. Wasn't there at least some commercial incentive to obtaining a patent given the expense?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. They must have had some reason for pursuing this. Again, I don't know what that would be. I have not evaluated this patent until just now.

(WHEREUPON, a certain document was marked McDuff Deposition Exhibit No. 3, for identification, as of 4/6/18.)

BY MR. DELAFIELD:

Q. So if you could also look at Exhibit 3 which is a copy of U.S. Patent No.

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8,410,121.

Have you seen this document?

A. I don't believe so, no.

Q. You see that it's assigned to Lexicon Pharmaceuticals, correct?

A. Yes.

Q. And the original -- strike that.

The earliest filing date is July 11, 2007.

Do you see that?

A. I do, yes.

Q. And it says Methods of Treating -- strike that.

If you look at the abstract on the first page, it says: "Methods of treating pulmonary hypertension are disclosed. Particular methods comprise the administration of a tryptophan hydroxylase inhibitor and a prostacyclin."

Do you see that?

A. Yes.

Q. And if you turn to the claims on the last page, for example, claim 12 it

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says: "A method of treating pulmonary hypertension, which comprises administering to a patient in need thereof therapeutically effective amounts of a prostacyclin and" -- I won't read that long word -- "or a pharmaceutically acceptable salt thereof."

And then in claim 3 -- 13, it says: "The method of claim 12, wherein the prostacyclin is epoprostenol, iloprost or treprostinil."

Do you see that?

A. Yes.

Q. So this patent is claiming the use of treprostinil with another agent, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I wouldn't purport to provide a technical interpretation of this, but I see what you are referring to here in claims 12 and 13. It appears to indicate a prostacyclin and another agent.

BY MR. DELAFIELD:

Q. And so claim 13 includes the

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use of treprostinil in this combination therapy, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. You know understanding that I am an economist just reading this, I mean, I see treprostinil here in claim 13 as one potential option.

BY MR. DELAFIELD:

Q. And that includes the use of treprostinil for the treatment of pulmonary hypertension, correct?

MR. MATHAS: Same objection.

BY THE WITNESS:

A. Just reading this as an economist, I see that, yes.

BY MR. DELAFIELD:

Q. And so Lexicon Pharmaceuticals was able to file and obtain a patent starting in 2007 on a way of using treprostinil to treat pulmonary hypertension, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, this is some sort of

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combination of compounds. I would want to give this some more thought. This is the first time I have seen this patent.

BY MR. DELAFIELD:

Q. But given that the patent issued and the claims do specify the use of treprostinil for treatment of pulmonary hypertension, you would agree that at least Lexicon Pharmaceuticals was not blocked by any of the patents you have referenced in your declaration, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Well, as we have discussed earlier, safe harbor provisions allow for scientific research to occur. You are not blocking them performing research. It's about commercialization that provides disincentives for development. So any alleged commercial success is less informative on market-wide incentives because of the presence of blocking patents.

BY MR. DELAFIELD:

Q. But you would agree that

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obtaining a patent in general has some economic incentive to it, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. Sometimes, yes; sometimes, no. There are reasons for developing it. Some of which can be to commercialize a product.

BY MR. DELAFIELD:

Q. So assuming the '121 patent and '716 patent inventors wanted to use their invention, why would they file a patent and have it issued knowing that they can't even use their own patent if it was blocked by other patents?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't know the specific motivations of these companies. I haven't analyzed them as part of my declaration in this case.

MR. DELAFIELD: Can we take a short break?

MR. MATHAS: Sure.

THE VIDEOGRAPHER: The time is

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4:01. We are off the record.

(WHEREUPON, a recess was had at 4:01 p.m. until 4:10 p.m.)

THE VIDEOGRAPHER: The time is now 4:10. We are back on the record.

MR. DELAFIELD: Welcome back. I have no further questions.

EXAMINATION

BY MR. MATHAS:

Q. Dr. McDuff, I have a couple of questions for you.

First of all, in performing your analysis in this case, did you have access to any internal United Therapeutics' financial information?

A. I did not, no.

Q. And you have had access to such information in connection with your work on the district court proceeding between the parties; is that correct?

A. Yes, that's right.

Q. And for purposes of your opinions in this case, you did not access any of that information in forming your opinions

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for the declarations in the IPR cases, correct?

A. Yes, that's correct.

Q. All right. Now, there was a question or some questions at the start of the deposition about the contents of your respective declarations, and so if you have those with you, they were Exhibit 1055 which was your declaration in the 1622 case and Exhibit 1055 which was your exhibit in the 1621 case.

Now, I believe there was some testimony about some omissions in the 1621 case from your declaration. Can you tell us what the omissions were?

A. Yes. As submitted and in the version in front of me, there was a chart on page 9 that appears to have been omitted for a printing issue and the attachments from page 26 to page 45 which are present in Exhibit 1055 in the 1622 case are not present in my declaration in Exhibit 1055 in the 1621 case. Yet the attachments are identical to those in the 1622 case.

Q. Okay. So the 1622 case at the

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end of paragraph 15 has a chart in it; is that right?

A. Yes.

Q. And that chart is omitted in the 1621 case?

A. In the declaration there, yes.

Q. But it should have been the identical chart is that correct?

A. Yes.

MR. DELAFIELD: Objection.

BY MR. MATHAS:

Q. All right. What chart should have been there?

MR. DELAFIELD: Same objection.

BY THE WITNESS:

A. The same chart that is in the 1622 declaration as well as in the underlying materials cited in footnote 6 in the 1621 declaration.

BY MR. MATHAS:

Q. All right. And the exhibits that were omitted in the 1621 case, how, if at all, were they different from the exhibits submitted in the 1622 case?

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A. They were identical.

MR. MATHAS: All right. Can we mark this as Exhibit 3, please -- or 4 for the record, please.

MR. DELAFIELD: I am going to object to this exhibit.

MR. MATHAS: Fine, I am making a record.

(WHEREUPON, a certain document was marked McDuff Deposition Exhibit No. 4, for identification, as of 4/6/18.)

BY MR. MATHAS:

Q. Dr. McDuff, the court reporter has handed you what's been marked for identification purposes as McDuff Exhibit 4 which I will represent to you is a corrected version of Exhibit 1055 that was sent to counsel for the patent owner last evening. This has not been filed in the IPR proceeding as of today.

Would you turn with me, please, to page 9 the end of paragraph 15. Does paragraph 15 in Exhibit 4 that I just

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handed you correctly show the chart that was omitted from your original Exhibit 1055 and 1621?

A. Yes.

Q. And if you will turn with me to page 26 through 45 of this Exhibit 4 that I have handed you, do pages 26 through 45 of Exhibit 4 correctly reflect the omitted exhibit from the original Exhibit 1055?

A. Yes.

Q. Are you aware of any other differences between the document I have handed you as Exhibit 4 and the document that was filed as Exhibit 1055 in IPR 1621?

A. No, I am not.

MR. MATHAS: I have no further questions.

FURTHER EXAMINATION

BY MR. DELAFIELD:

Q. I have a couple of questions.

So this new declaration that we received yesterday, do you see at the bottom it says page 1 of 25?

A. I do.

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Q. But there's 45 pages, correct?

A. Yes, there are 45 pages in the declaration including the declaration and the attachments.

Q. So the page numbering is off for the first 25 pages with respect to how many total pages, correct?

A. Yes, I suppose that could say page 1 of 45, and it would say 45 consistently throughout as it does in the attachments.

Q. Did you --

A. Either way I think it represents the full declaration.

Q. Did you yourself prepare this replacement declaration?

A. I did not do so personally. I did so through discussion and assistance from counsel.

Q. And you said you first noticed the missing exhibits and graph yesterday as well?

A. Yes.

MR. DELAFIELD: Okay. I have no further questions.

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MR. MATHAS: One follow up.

FURTHER EXAMINATION

BY MR. MATHAS:

Q. Dr. McDuff, do the -- does the additional information in Exhibit 4 or the absence of the information in Exhibit 4 change your opinions with respect to the '240 patent in case 1621?

A. No, they are all the same either way regardless of whether it's the full document with all of the attachments and chart or the abridged document that omits those.

MR. MATHAS: Thank you. I have no further questions.

FURTHER EXAMINATION

BY MR. DELAFIELD:

Q. One question. You were asked if the information in Exhibit 4 or the absence of information of Exhibit 4 would change your opinions with respect to the '240 patent, correct?

A. More or less.

Q. So if your declaration did not have any of the exhibits or the chart, then you

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couldn't rely on those in your declaration or cite them, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. I don't agree with that. The most relevant charts from my attachments are in both copies of the declaration. The charts themselves are in line in paragraphs 24 and 25 -- sorry -- 23 and 24, and the attachments simply provide the supporting calculations underlying those charts, but the fundamental opinions are the same.

BY MR. DELAFIELD:

Q. And so without the attachments, there would be no supporting calculations for the '240 declaration, correct?

MR. MATHAS: Object to the form.

BY THE WITNESS:

A. There would be no details underlying how the calculations were performed. However, they are described in the declaration itself.

MR. DELAFIELD: Okay. I have no further questions.

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MR. MATHAS: Thank you, Dr. McDuff.

THE VIDEOGRAPHER: The time is now 4:18 p.m. This is the end of media 4. This concludes this deposition. We are off the record.

(WHEREUPON, the deposition was concluded at 4:18 p.m.)

STATE OF _____)
) :ss
COUNTY OF _____)

I, DEFOREST MCDUFF, the witness herein, having read the foregoing testimony of the pages of this deposition, do hereby certify it to be a true and correct transcript, subject to the corrections, if any, shown on the attached page.

_____
DEFOREST MCDUFF

Sworn and subscribed to before me,
this _____ day of _____, 2018.

_____
Notary Public

CERTIFICATE

OF

CERTIFIED SHORTHAND REPORTER

I, ANDREA L. KIM, a State of Illinois Licensed Certified Shorthand Reporter, License number 84-3722, do hereby certify:

That previous to the commencement of the examination of the aforesaid witness, the witness was duly sworn or affirmed to testify the whole truth concerning the matters herein;

That the foregoing deposition transcript was reported stenographically by me, was thereafter reduced to typewriting under my personal direction and constitutes a true and accurate record of the testimony given and the proceedings had at the aforesaid deposition;

That the said deposition was taken before me at the time and place specified;

That I am not a relative or employee or attorney or counsel for any of the parties herein, nor a relative or employee of

such attorney or counsel for any of the parties hereto, nor am I interested directly or indirectly in the outcome of this action.

IN WITNESS WHEREOF, I do hereunto set my hand and affix my seal of office at Chicago, Illinois, this 9th day of April, 2018.

Andrea L. Kim

ANDREA L. KIM, CSR
License No. 84-3722.

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After doing so, please sign the errata sheet and date it.

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I wish to make the following changes, for the following reasons:

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(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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