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

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

(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.

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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,

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?

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

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

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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,

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.)

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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,

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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,

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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,

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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?

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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.

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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

DEFOREST MCDUFF, Ph.D.

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