UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.

Petitioner,

v.

UNITED THERAPEUTICS CORPORATION
Patent Owner.

Case IPR2017-01621
Patent 9,358,240

DECLARATION OF DEFOREST MCDUFF, Ph.D.

Mail Stop Patent Board
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

I, DeForest McDuff, Ph.D., declare as follows:

I. Introduction

Qualifications

1. I am a Partner at Insight Economics and an expert in applied business economics, with more than ten years of experience in consulting, finance, and economic research. I provide expert witness testimony and consulting in a variety of areas, including lost profits, reasonable royalties, unjust enrichment, commercial success, irreparable harm, finance, statistics, valuation, and business optimization.

2. My expertise and experience span a variety of topics, including intellectual property, competition, business, antitrust, finance, labor, employment, and class action. My work spans the life sciences (including pharmaceuticals, biotechnology, diagnostics, and medical devices), electronics (including consumer electronics, semiconductors, computers, and telecommunications), and has included projects on a diverse range of other industries.

3. I have significant experience evaluating the economics of the pharmaceuticals industry. I have provided expert analysis and consulting in over 50 cases involving pharmaceuticals and related products, including evaluations of economic damages, competition, commercial success, irreparable harm, and other issues. I have evaluated a number of pharmaceutical product launches, both in a

litigation setting and an advisory role, and have published articles and taught continuing legal education on pharmaceutical topics as well.

4. I earned my Ph.D. in economics from Princeton University. At Princeton, I received a National Science Foundation Graduate Research Fellowship for academic research studying economic and statistical properties of housing markets and financial derivatives. I have published research in several peer-reviewed academic journals. I graduated *summa cum laude* with undergraduate degrees in economics and mathematics from the University of Maryland.

5. My curriculum vitae, provided as Attachment A, contains more details on my background, education, experience, and expert testimony.

Scope of Work

6. In connection with my work on this matter, Insight Economics has been retained by Winston & Strawn LLP on behalf of Watson Laboratories, Inc. ("Watson"). Insight Economics is being compensated at a rate of $700 per hour for my work and at lower rates for time spent by others on my team. The compensation of Insight Economics is not dependent on the substance of my testimony or the outcome of this matter.

7. For this declaration, I was asked to evaluate aspects of commercial success relating to U.S. Patent No. 9,358,240 (Ex. 1001) as it relates to Tyvaso (treprostinil). This declaration is a statement of my opinions in this matter and the

basis and reasons for those opinions.[1] In forming the opinions expressed in this declaration, I have relied upon my education, experience, and knowledge of the subjects discussed.

II. Background

Patent-at-issue

8. I understand that the following patent is at issue in this IPR proceeding: 9,358,240 ("the '240 patent" or "the patent-at-issue").

9. The '240 patent, entitled "Treprostinil Administration by Inhalation," was filed on November 12, 2009 and issued on June 7, 2016. I understand that the '240 patent has the following abstract:

> Treprostinil can be administered using a metered dose inhaler. Such administration provides a greater degree of autonomy to patients. Also disclosed are kits that include a metered dose inhaler containing a pharmaceutical formulation containing treprostinil.

[1] This declaration reflects only my current opinions, which are subject to change based upon additional information, analysis, and/or opinions of other experts.

Pulmonary hypertension

10. Pulmonary hypertension ("PH") is generally defined by high blood pressure in the lungs and the right side of the heart. This can occur when blood is not able to flow freely through arterioles in the lungs. Over time, the heart muscle weakens from the increased effort required to pump blood and may fail. Pulmonary arterial hypertension ("PAH") is known as Group 1 PH, classified by the World Health Organization ("WHO"), and includes PH that is inherited, has no known cause, or is caused by certain drugs or conditions.[2]

11. Patients diagnosed with PH have several treatment options, including medications and surgery. Treatment for PH includes anticoagulants, digoxin, diuretics, and calcium channel blockers ("CCB"), among others. Heart or lung transplants or open heart surgery may be warranted if drug therapy is not successful. For the treatment of PAH, in particular, approved pharmaceuticals

[2] Ex. 1120: Mayo Clinic Website, Pulmonary hypertension, Overview, http://www.mayoclinic.org/diseases-conditions/pulmonary-hypertension/home/ovc-20197480 (accessed 3/22/2017).

Ex. 1122: NIH Website; National Heart, Lung, and Blood Institute; Types of Pulmonary Hypertension, https://www.nhlbi.nih.gov/health/health-topics/topics/pah/types (accessed 5/16/2017).

target one of three major biochemical pathways: (1) the endothelin pathway, targeted by endothelin receptor antagonists ("ERAs"); (2) the nitric oxide ("NO") pathway, targeted by phosphodiesterase inhibitors ("PDE-5") and soluble guanylate cyclase stimulators ("GCS"); and (3) the prostacyclin pathway, targeted by prostacyclin analogues and IP receptor antagonists.[3]

Tyvaso (treprostinil)

12. Tyvaso (treprostinil) is a prescription pharmaceutical product sold by UTC that is indicated for treatment of PAH in WHO Group 1 patients to improve exercise ability. Tyvaso was approved by the FDA on July 30, 2009. Tyvaso is available in a 0.6mg/mL solution for inhalation.[4]

[3] Ex. 1120: Mayo Clinic Website, Pulmonary hypertension, Overview, http://www.mayoclinic.org/diseases-conditions/pulmonary-hypertension/home/ovc-20197480 (accessed 3/22/2017).

Ex. 1083: Cowen and Company, "Therapeutic Categories Outlook," 2/2017, at 2249-2250.

[4] Ex. 1140: Tyvaso, FDA Label, 6/2016.

III. Analysis of Commercial Success

Overview

13. Commercial success may provide objective evidence that a patent owner may use to indicate that a patent is not obvious based on the alleged commercial success of a product embodying the invention of the patent. I understand that commercial success can be relevant to the determination of a patent's obviousness based on the presumption that an idea could have been brought to market sooner, in response to market forces, had it been obvious to persons skilled in the art. I further understand that evidence of commercial success may be relevant if there is a nexus between the alleged commercial success and the patentable features of the asserted claims. In other words, I understand that the patent owner must show that the commercial success is attributable to demand for

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Ex. 1120: Mayo Clinic Website, Pulmonary hypertension, Overview, http://www.mayoclinic.org/diseases-conditions/pulmonary-hypertension/home/ovc-20197480 (accessed 3/22/2017).

Ex. 1096: FDA Website, FDA Approved Drug Products, Tyvaso, http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022387 (accessed 5/17/2017).

the alleged benefits of the patented technology relative to demand resulting from other factors.

14. For this declaration, I have been informed that United Therapeutics Corporation made a number of assertions related to the alleged commercial success of Tyvaso as a secondary consideration during the prosecution of the patent-at-issue, or related patents, with the USPTO.[5] Upon review, I find that those assertions of commercial success are based on a skewed market definition (Section III.B) and flawed evaluation of nexus (Section III.C). In addition, my own evaluation of the alleged commercial success indicates only modest commercial performance of Tyvaso (Section III.D) and low or no economic relevance to obviousness of the patent-at-issue (Section III.E). These opinions are discussed in more detail below.

Alleged commercial success based on a skewed market definition

15. I understand that, during patent prosecution, the patent owner made a number of assertions of commercial success based on Tyvaso's alleged market shares among U.S. inhaled prostacyclin drugs compared to Ventavis (iloprost). I understand that the patent owner claimed that Tyvaso earned "the majority of the

[5] *See,* for example, Ex. 1059; Ex.1161; Ex. 1162; Ex. 1163.

US market for inhaled prostacyclins from Ventavis in a single year" and referenced the following chart:[6]

16. However, this purported market share is among only the two inhaled products on the market, and is overstated and unrepresentative of competition in this market because it omits relevant competing products. Substantial evidence indicates competition between Tyvaso and non-inhaled PAH therapies, for example:

a. UTC's CEO stated on an earnings conference call (2010-Q2) that "Roughly speaking about 10% of the patients come on to Tyvaso actually from parenteral therapies. Either Remodulin or Flolan or the other generic parenteral therapies. Maybe a tad less than 10%. About 20% of the patients, maybe a little bit more than

[6] *See,* for example, Ex. 1059 at 8; Ex.1161 at 4; Ex. 1162 at 9; Ex. 1163 at 16.

20%, come on to our therapy from Ventavis, and then the majority, the large majority, around 70%, come on to our therapy after not really achieving the results desired with either oral or more commonly dual oral therapies. That is PDE5 plus an ETRA. So, that's pretty much as you recall the situation as we reported last year. The majority of patients are coming from the oral therapies rather than at the expense of Ventavis."[7]

b. UTC 10-Ks from 2009 to 2016 indicate that UTC products "compete with many approved products in the United States and the rest of the world," including: Flolan, Veletri, generic epoprostenol; Ventavis and Ilomedin; Tracleer; Letairis; Revatio and generic sildenafil citrate; Opsumit; Adempas; Uptraiv; and drugs in current development. UTC's 10-Ks discuss how various product attributes provide certain competitive advantages and disadvantages within the competition to treat PAH patients:

   i. 2009 to 2013 (Ex. 1151 at 21; Ex. 1152 at 22; Ex. 1153 at 23-24; Ex. 1154 at 23-24; Ex. 1155 at 22-23): "The use

[7] Ex. 1142: UTC, "Q2 2010 United Therapeutics Earnings Conference Call," 7/28/2010, at 4.

of the available oral therapies and Tyvaso, either alone or in combination, could delay the need for infusion therapy for many patients. As a result, the success of other therapies in preventing disease progression affects our commercial products. Furthermore, the commercialization of generic forms of other approved PAH therapies and the development of new PAH therapies may exert downward pressure on the pricing of our products."

ii. 2014 to 2015 (Ex. 1156 at 20-21; Ex. 1157 at 20-21): "We anticipate that [Orenitram] will face competition with existing oral PAH therapies, and will be regarded as a less invasive and more convenient alternative therapy to Tyvaso and Remodulin. The use of available oral therapies could delay many patients' need for inhaled or infused prostacyclin therapy. As a result, the availability of oral therapies affects demand for our inhaled and infused products."

iii. 2016 (Ex. 1158 at 19-20): "…[Orenitram] offers a less invasive and more convenient alternative therapy to

Remodulin and Tyvaso. The use of available oral therapies could delay many patients' need for inhaled or infused prostacyclin therapy. As a result, the availability of oral therapies affects demand for our inhaled and infused products."

c. Third-party analysts:

i. RBC Capital Markets (2011) reports Tyvaso's market share as 7% in 2011 (compared to 13% for Remodulin, 12% for Letairis, 50% for Tracleer, 2% for Adcirca, and 16% for Revatio).[8]

ii. Cowen and Company (2017) reports Tyvaso sales of just 7.4% of major PAH drugs sales worldwide as of 2016.[9]

17. In contrast to the majority share asserted by the patent owner, Tyvaso's sales share as a fraction of competing PAH therapies shows more modest commercial performance. Based on sales data reported by competing companies,

[8] Ex. 1135: RBC Capital Markets, "Untied Therapeutics Corp.," 6/13/2011, at 7.

[9] Ex. 1083: Cowen and Company, "Therapeutic Categories Outlook," 2/2017, at 2248-2250. ($405 million for Tyvaso / $5,456 million total) = 7.4%.

Tyvaso's share of sales among competing PAH therapies has ranged from 0.7% in 2009 up to a peak of 10.4% in 2013 and declining to 7.3% by 2016. *See* Attachment B-9.

Alleged commercial success based on flawed evaluation of nexus

18. I understand that, during patent prosecution, the patent owner made a number of assertions relating to nexus based upon "clinical advantages of Tyvaso® over Ventavis® [being] direct results of: a) dosing regimen of Tyvaso® compared to Ventavis®; and b) the pulsed ultrasonic nebulizer used with Tyvaso® compared to Ventavis®."[10] The patent owner also made assertions as to Tyvaso's "substantially lower share" of sales representatives, at 25.0% share for Tyvaso and 30.7% share for Ventavis.[11]

19. Other than its uncited claim regarding Tyvaso sales representatives compared to Ventavis (which, contrary to patent owner's assertions on market shares, appear to be calculated as shares of a broader PAH market definition), patent owner provides no analysis of other factors that may drive demand for Tyvaso. To my knowledge, patent owner provided no evaluation of other factors commonly evaluated in determining nexus, including actual marketing

[10] *See,* for example, Ex. 1162 at 9–11; Ex. 1163 at 16–18.

[11] *See,* for example, Ex. 1059 at 8; Ex.1161 at 4; Ex. 1162 at 9; Ex. 1163 at 16.

expenditures, marketing messages, pricing, or other attributes contributing to demand for Tyvaso, such as the treprostinil compound (*e.g.*, Ex. 1019: U.S. Patent 4,306,075 ("the '075 patent")) or the application of treprostinil to treating PAH (*e.g.*, Ex. 1025: U.S. Patent No. 5,153,222 ("the '222 patent")). Without evaluating these factors, patent owner does not provide adequate basis to conclude that Tyvaso's commercial performance is driven by the alleged innovative aspects of the patent-at-issue.

20. With respect to specific comparisons between Tyvaso and Ventavis, I understand from Dr. Donovan (Ex. 1002 at ¶ 213) that this difference derives primarily from differences between treprostinil and iloprost rather than any alleged innovative aspects of the patent-at-issue, and thus differences in commercial performance are largely attributable to the '075 patent and '222 patent rather than the patent-at-issue. I understand from Dr. Donovan (Ex. 1002 at ¶ 213) that the less frequent treatment with Tyvaso relates to treprostinil's longer half-life relative to iloprost rather than any differences in the way the Ventavis and Tyvaso are delivered via inhalation.

21. Finally, patent owner's own assertions appear to support the notion that Tyvaso sales were impacted by marketing. Tyvaso's purported 25.0% share of sales representatives compared to a peak market share of just 10.4% indicates above-average marketing relative to competition (*i.e.*, the share of marketing

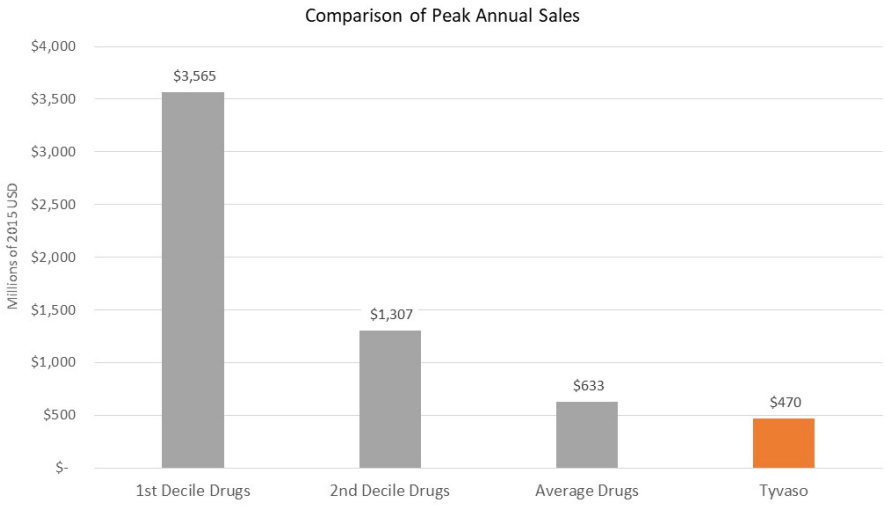
expenditures exceeding the share of revenues). It is difficult to assess further without the underlying analysis provided by patent owner.

Tyvaso sales show only modest commercial performance

22. Contrary to patent owner's assertions, Tyvaso sales show only modest commercial performance, as evidenced by: (1) comparisons to pharmaceutical products generally, and (2) comparisons to competitor PAH products.

23. 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. For example, published research on pharmaceutical product sales indicates that Tyvaso sales are below average for the pharmaceutical industry: compared to Tyvaso's peak annual sales to date of $470 million in 2015, peak annual sales based on published research (normalized to 2015 USD) are $3.6 billion for top-decile drugs (top 10% of drugs), $1.3 billion for 2nd-decile drugs (80-89% percentiles), and $633 million for average drug sales. *See* Attachment B-2. Top-decile and 2nd-decile drugs tend to be the drivers of profitability in the pharmaceutical industry, whereas average drugs tend to be close to break-even in

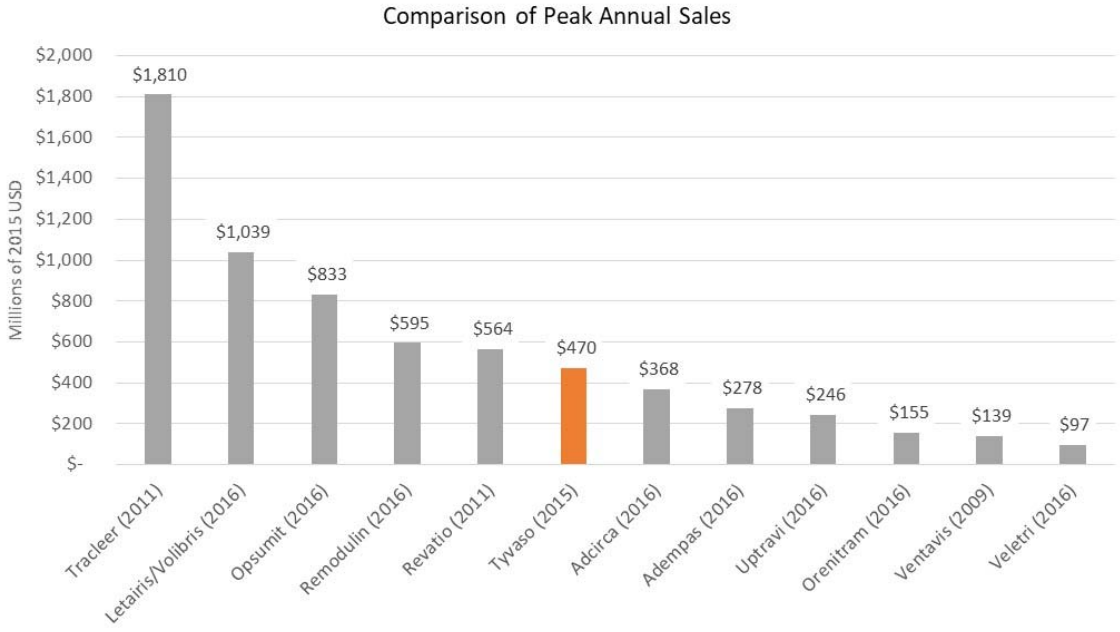
terms of economic profits that account for the economic costs of development.[12] A comparison of Tyvaso sales to these benchmarks can be seen as follows (*see* Attachment B-3):



12 Ex. 1084: DiMasi, Joseph A. and Henry G. Grabowski (2012), "R&D Costs and Returns to New Drug Development: A Review of the Evidence," in Patricia Danzen and Sean Nicholson, ed., *The Oxford Handbook of the Economics of the Biopharmaceuticals Industry*, New York: Oxford University Press, at 43 ("The search for these blockbuster drugs, typically "first in class" or "best in class" compounds, has been a key driver of R&D competition over the past several decades.").

Ex. 1113: Grabowski, Henry, John Vernon, and Joseph A. DiMasi (2002), "Returns on Research and Development for 1990s New Drug Introductions," *Pharmacoeconomics* 20(3): 11–29, at 11, 17, 22-23.

24. Second, as another point of comparison, Tyvaso sales are middle-of-the-pack relative to competing PAH treatments. In comparison to Tyvaso's peak annual sales of $470 million in 2015, peak annual sales of competing PAH treatments include $1.7 billion for Tracleer (2011), $1.1 billion for Letairis/Volibris (2016), $844 million for Opsumit (2016, 4th year on the market), and $602 million for Remodulin (2016). *See* Attachments B-4 and B-5. A comparison of Tyvaso sales to competing PAH drugs can be seen as follows (normalized to 2015 USD, noting that Tyvaso sales have already peaked and started to decline as of 2015 but that other drugs may continue to have even higher peak sales beyond 2016—*see* Attachment B-6):



25. In sum, patent owner provides limited information and no basis for comparison to conclude that Tyvaso was a "tremendous commercial success." By

contrast, an economic evaluation of Tyvaso sales in proper context are only modest by comparison and are not demonstrative of commercial success.

Low or no economic relevance of alleged commercial success

26. Contrary to patent owner's assertions, there is actually low or no economics relevance of any alleged commercial success, for several reasons, including: (1) blocking patents and regulatory exclusivity, (2) UTC's specialization in PAH, and (3) contributions of the patent-at-issue.

Blocking patents and regulatory exclusivity

27. First, early patents covering Tyvaso and marketing exclusivity granted by the FDA reduce the economic relevance of any alleged commercial success due to blocking disincentives. A blocking patent is one that effectively blocks others from making, selling, or using a product without use of the invention purportedly claimed in that patent. Courts have found that, in the presence of blocking patents and market exclusivity, the existence of commercial success provides little probative value on whether a claimed technology is obvious. For example, in *Merck v. Teva*, the Federal Circuit found that Merck's ability to prevent market entry by others via blocking patents and statutory exclusivity weakened any probative value of commercial success in evaluating non-obviousness of the

patent-at-issue.[13] This makes sense, economically, since other entities would have strong disincentives not to develop technology that they would be blocked from utilizing or implementing in the marketplace.

28. In the case of Tyvaso, there are several patents that have been alleged to cover Tyvaso before the patent-at-issue in this case (*e.g.*, in the FDA Orange Book or described as relating to treprostinil more broadly[14]):

a. U.S. Patent No. 4,306,075 provides the composition and production of stable prostacyclin analogs, including UT-15 (*i.e.*, treprostinil), with approximate priority in or around 1980 and issuing in December 1981.[15]

[13] Ex. 1121: *Merck& Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1376–77 (Fed. Cir. 2005).

[14] Ex. 1085: FDA Orange Book, 2010, at ADA 189 of 197.

Ex. 1086: FDA Orange Book, 2017, at ADA 229 of 237.

[15] Ex. 1019: Composition and Process, U.S. Patent No. 4,306,075 (filed 12/22/1980, issued 12/15/1981).

b. U.S. Patent No. 5,143,222 provides the use of treprostinil for pulmonary hypertension and congestive failure, with approximate priority in or around 1988 and issuing in October 1992.[16]

c. U.S. Patent No. 6,521,212 provides methods for treating PAH via inhalation, with approximate priority in or around 1999 and issuing in February 2003.[17]

d. U.S. Patent No. 6,756,033 provides methods for treating PAH via inhalation, with approximate priority in or around 1999 and issuing in June 2004.[18]

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[16] Ex. 1025: Method of Treating Pulmonary Hypertension with Benzidine Prostaglandins, U.S. Patent No. 5,153,222 (filed 6/14/1991, issued 10/6/1992).

[17] Ex. 1018: Method for Treating Peripheral Vascular Disease by Administering Benzindene Prostaglandins by Inhalation, U.S. Patent No. 6,521,212 (filed 3/15/2000, issued 2/18/2003).

[18] Ex. 1057: Method for Delivering Benzindene Prostaglandins by Inhalation, U.S. Patent No. 6,756,033 (filed 8/6/2002, issued 6/29/2004).

29. In addition, UTC was granted orphan drug exclusivity of 7 years through July 2016, providing it with market exclusivity following launch in 2009.[19]

30. Accordingly, UTC's exclusive license to the '075 and '222 patents and its market exclusivity for Tyvaso provides strong disincentives for other companies to develop and commercialize the technology of the patent-at-issue, even if those alleged innovations had been obvious. Moreover, I am not aware of any evidence that a license to those patents was offered to or pursued by other companies, and thus they represent a disincentive for development. In other words, *even if* there were a compelling commercial opportunity to be inferred by the alleged commercial success of Tyvaso, that alleged success would not be economically relevant to obviousness of the patent-at-issue since other companies would have been blocked from commercializing those technologies.

Limited Market Interest

31. Second, as discussed, commercial success may be relevant to obviousness based on the idea that a product or technology may have been developed sooner, in response to market forces, had it been obvious. In the case of Tyvaso, UTC had unique specialization in developing PAH treatments (and particularly drugs utilizing treprostinil as an active ingredient) that would not have

[19] Ex. 1152: UTC, Form 10-K, 2010, at 19, 24.

been shared by the broader market. This further weakens any nexus and economic inference between the alleged commercial success and the patent-at-issue.

32. UTC has a history of pursuing and focusing on PAH treatments, including Remodulin, Tyvaso, Adcirca, and Orenitram,[20] and has a specialization in PAH that is not shared by the broader market. Additionally, I understand that UTC was founded and originally existed in response to the CEO seeking to find a cure for PAH for her daughter and her dissatisfaction with options available on the market.[21] As of present day and dating back to approximate patent priority dates, there have been only a few other companies with PAH drugs on the market. *See* Attachment B-8.

33. Additionally, the evidence suggests a limited commercial opportunity and lack of market-wide interest in developing an inhaled treprostinil product. 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 a

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20 Ex. 1158: UTC, Form 10-K, 2016, at 4.

21 Ex. 1079: CNBC, "Highest Paid Female CEO: Race to Save My Daughter," 5/19/2015, http://www.cnbc.com/2015/05/19/highest-paid-female-ceo-race-to-save-my-daughter.html.

limited economic opportunity.[22] The limited opportunity is further confirmed by Pharmacia & Upjohn Company and Glaxo Wellcome Inc. licensing early treprostinil patents to UTC rather than seeking to develop their own products.[23]

34. In other words, market-wide development of PAH drugs appears to have been limited, and other developers would not have UTC's motivation, experience, and resources in developing PAH treatments. This provides yet another hurdle for market-wide incentives for development that, all else being equal, further limits any inference of non-obviousness from the alleged commercial success of Tyvaso.

Contributions of the patent-at-issue

35. Third, I am not aware of the patent owner providing an evaluation of the contributions of the patent-at-issue relative to earlier Tyvaso patents described above. Based on the opinions of Dr. Donovan (Ex. 1002 at ¶ 213), I understand that the clinical contributions of alleged novel device and dosing regimen are limited and that, by contrast, the vast majority of the clinical benefit of Tyvaso comes from the treprostinil compound itself and the application of that compound

[22] Ex. 1152: UTC, Form 10-K, 2010, at 8, 24.

[23] Ex. 1143: UTC, Form 10-K, 2000, at 6.

to treating PAH. Accordingly, for the purpose of a nexus to the commercial performance of Tyvaso, there is very weak nexus (if any at all) to the ’240 patent.

36. With respect to the claimed novelty of the patents, I understand from Dr. Donovan (Ex. 1002 at ¶ 208-213) that all of the alleged benefits over the prior art were known from publicly available nebulizers, were in the prior art, and allowed for the claimed dosing regimen. Thus, the alleged benefits of the claimed invention are unrelated to any advantages over prior art. Further, I have seen no evidence (and have no reason to believe) that Tyvaso’s commercial performance would be any different if it used a different (nonclaimed type of nebulizer or a different (nonclaimed) dosing regimen.

37. Finally, as discussed, with respect to specific comparisons between Tyvaso and Ventavis, I understand from Dr. Donovan (Ex. 1002 at ¶ 213) that this difference derives primarily from differences between treprostinil and iloprost rather than any alleged innovative aspects of the patent-at-issue, and thus differences in commercial performance are largely attributable to the ’075 patent and ’222 patent rather than the patent-at-issue. I understand from Dr. Donovan (Ex. 1002 at ¶ 213) that the less frequent treatment with Tyvaso relates to treprostinil’s longer half-life relative to iloprost rather than any differences in the way the Ventavis and Tyvaso are delivered via inhalation.

IV. Signature

38. I declare that my statements based on my knowledge are true and those based on information and belief I believe to be true. I made all my statements in this declaration with the knowledge that willful false statements and the like are punishable by fine, imprisonment or both pursuant to 18 U.S.C. 1001.

39. I understand that this declaration is to be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

R. D. McDuff

DeForest McDuff, Ph.D.

June 21, 2017