IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC, MYLAN PHARMACEUTICALS INC., BRECKENRIDGE PHARMACEUTICAL, INC., AND ALEMBIC PHARMACEUTICALS, LTD.,
Petitioners,

v.

RESEARCH CORPORATION TECHNOLOGIES, INC.,
Patent Owner.

Case No. IPR2016-00204[1]
Patent No. RE 38,551

PATENT OWNER'S MOTION FOR OBSERVATIONS REGARDING THE CROSS-EXAMINATION TESTIMONY OF DEFOREST MCDUFF, Ph.D.

[1] Case IPR2016-01101, Case IPR2016-01242, and Case IPR2016-01245 have been joined with this proceeding.

I. Introduction

In accordance with: (i) The Trial Practice Guide, Federal Register Vol. 77, No. 157, 48756 at 48767–68 and (ii) the Scheduling Order (Paper No. 20) as modified by the Joint Notice of Stipulation Concerning Schedule (Paper No. 50), Patent Owner hereby submits the instant Motion for Observations Regarding the Cross-Examination Testimony of DeForest McDuff, Ph.D., taken on December 8, 2016. The transcript of this testimony has been filed as Exhibit 2193.

Patent Owner requests that the Board enter the instant Motion and consider the observations. Observations 1–8 below pertain to the deposition testimony of DeForest McDuff, obtained on December 8, 2016, after Patent Owner filed its last substantive paper. In addition, and in accordance with the Trial Guide, each of observations 1–8 below provides in a single paragraph a concise statement of the relevance of the precisely identified testimony to a precisely identified argument.

II. Observations

1. In Ex. 2193 at 94:6–95:14, Dr. McDuff testified that "I've not sought to cite court opinions on [economic profit as a factor in commercial success], yet it is central to what I understand the purpose of commercial success to be," and could not identify any court opinion specifically adopting economic profit as he defines it as a factor in commercial success, despite citing to court opinions on other aspects of commercial success. *See* Ex. 1086 ¶32 (discussing commercial success in the

presence of a blocking patent, citing to Ex. 1187 in footnote 33); Ex. 2193 at 95:16-96:2 (Dr. McDuff confirming that Ex. 1187 is a court opinion). This testimony is relevant to the Petitioners' argument that "there's no evidence of profitability." Reply (Paper 52) at 25. This testimony is relevant because it calls into question the acceptance by the courts of Dr. McDuff's "economic profit" as a factor for commercial success, and hence its probative value.

2. In Ex. 2193 at 113:19–115:3, Dr. McDuff testified that paragraph 26 of his declaration contains a "typographical error," insofar as it states that "the net present value of Vimpat sales discounted back to product launch in 2009 . . . is less than $1.2 million," *see* Ex. 1086 ¶26, when it should read "less than $1.2 billion." This testimony is relevant because it corrects a thousand-fold error in Dr. McDuff's declaration.

3. In Ex. 2193 at 61:22–63:6, Dr. McDuff testified that Vimpat had accrued $2.4 billion in net sales from its launch in 2009 through the first six months of 2016, and he also testified that "I wouldn't seek to characterize [Vimpat's sales] as significant or insignificant." This testimony is relevant to Petitioners' claims that "Patent Owner fails to identify any profits from the sale of Vimpat." Reply at 25. This testimony is relevant because it is inconsistent with the findings of the District Court that "Vimpat has generated significant sales totaling

$1.6 billion in the U.S. since its launch in May 2009 through February 2015." Ex. 2193 at 63:8–64:3; *see also* Ex. 2182 ¶208.

4. In Ex. 2193 at 66:21–67:21, Dr. McDuff testified that "I agree that the market is more competitive than it would be if generic competition did not exist," but he also testified that "I don't have an opinion" on whether the generic competition in the AED marketplace makes it more "difficult" for Vimpat to earn prescriptions. This testimony is relevant because in previous testimony Dr. McDuff agreed that "the low cost of generic products and generic competition in the AED marketplace creates a more competitive marketplace and makes it more difficult for Vimpat to earn prescriptions." Ex. 2193 at 68:1–70:9; *see also* Ex. 2196 (McDuff Ex. 2) at 1083:10-14.

5. In Ex. 2193 at 75:16–76:11, Dr. McDuff testified that the time period from approval until the generation of the branded AED sales reported in ¶23 of his declaration for Neurontin "appears to be 10 or 11 years," for Lamictal [sic] and Keppra is "eight years," and for Topamax is "twelve years." This testimony is relevant to Petitioners' argument that "the raw sales figures fall short of other branded AEDs since 1990." Reply at 25. This testimony is relevant because the VIMPAT® drug product, a commercial embodiment of the invention claimed in the '551 patent (Patent Owner Response (Paper 35) at 1), was first launched for sale in

the United Sates in 2009 (Ex. 1086 ¶11), and has not yet been in the marketplace for eight years, much less 10 to 12 years.

6. In Ex. 2193 at 117:14-21, Dr. McDuff testified that his calculation of present value would be different numerically if he had done it through the end of 2014 or if he had done it through the end of 2015. At 122:2-22, Dr. McDuff testified that "it could be 10 years before you earn a single revenue or a single profit" and that "the numerics do depend on timing to some degree." This testimony is relevant to the arguments in Petitioners' Reply that "[t]otal Vimpat sales may not even exceed costs incurred to date; thus, there may be no profit." *See* Reply at 25. This testimony is relevant because it undermines the probative value of Dr. McDuff's calculations, *see* Ex. 1186 B-3, and his "economic profit" approach to commercial success.

7. In Ex. 2193 at 119:6-13 and 120:18–121:7, Dr. McDuff testified that despite having "considered projections of pharmaceutical products in the past," he did not "do any projection of sales based upon the net sales data [he] already [had]." This testimony is relevant to the arguments in Petitioners' Reply that "[t]otal Vimpat sales may not even exceed costs incurred to date; thus, there may be no profit." *See* Reply at 25. This testimony is relevant because it undermines the probative value of Dr. McDuff's calculations, *see* Ex. 1158 B-3, and his "economic profit" approach to commercial success.

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