

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.

IPR2016-00204¹
Patent RE 38,551

**PETITIONERS' RESPONSE TO MOTION FOR OBSERVATIONS
REGARDING THE CROSS-EXAMINATION OF DEFOREST MCDUFF**

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

Petitioners file this Response to Patent Owner's Motion for Observations on Cross-examination of DeForest McDuff (Paper 68) in accordance with Due Date 5 (Papers 20, 50). Petitioners respectfully disagree that Patent Owner's Observations are relevant or demonstrate inconsistency for the reasons asserted by Patent Owner. Furthermore, several of Patent Owner's Observations are argumentative. Petitioners respectfully reserve their right to present such argument during the oral hearing.

Observation #1: In Exhibit 2193 at 94:6-18, Dr. McDuff testified: "I'm not an attorney and I've not sought to cite court opinions on that topic, yet it is central to what I understand the purpose of commercial success to be. The purpose of commercial success is about economic incentives to bring a product to market sooner. And as an economist, I relate that notion to economic profit and a profit opportunity or commercial opportunity." In Exhibit 2193 at 94:20-95:14, Dr. McDuff also testified: "[T]he purpose of commercial success, as the courts have articulated that purpose, as I understand it, having read cases and working in this area and having discussions with counsel, my interpretation of that as an economist is that they are discussing the notion of economic profit and economic incentives for development." In Ex.2193 at 113:10-18, Dr. McDuff testified: "Dr. Velluro did not analyze [actual operating profit margin for Vimpat] and UCB did not provide it. *I think it's unfortunate and I think it's a significant flaw in Dr.*

Vellturo's work to not consider the costs and profits of Vimpat." (emphasis added).

Observation #2: In Ex.2193, Dr. McDuff testified that Attachment B-3 "clarified" the single-character typo (114:2-4) in the text of the declaration, agreed that the "corrected value to \$1.2 billion correlates on Attachment B-3" (114:12-16), and agreed that his conclusion regarding the lack of commercial success was based on "the \$1.2 billion number" (117:6-10).

Observation #3: In Ex.2193 at 61:22-63:6, Dr. McDuff testified: "I wouldn't seek to characterize [\$2.4 billion in net sales] as significant or insignificant. I think it naturally raises the question relative to what. So without that context, I think it's hard to provide a characterization of that one way or the other." In Ex.2193 at 65:3-9, Dr. McDuff testified that significance of sales depends on the relevant comparator, as one must ask, "Significant relative to what?" In Ex.2193 at 71:3-5, Dr. McDuff testified: "I would not describe Vimpat's market share growth as substantial." In Ex.1086, ¶22, Dr. McDuff testified: "Dr. Vellturo tabulates sales and prescriptions and declares them to be a "success" in some abstract, unexplained sense. However, the Vellturo Declaration fails to provide appropriate context to determine whether those sales are, in fact, successful or large enough to demonstrate a commercial profit opportunity." In Ex.1086, ¶¶20-21, Dr. McDuff testified: "[A] number of AEDs are prescribed

significantly more often than Vimpat.” In Ex.1086, ¶¶23-27, Dr. McDuff listed several AEDs with commercial sales *in a single year* approximately the same or even larger than *cumulative* commercial sales of Vimpat from 2009 into 2016, and he testified that “the Velturo Declaration[‘s] fail[ure] to consider profits of any sort” for Vimpat is “a significant shortcoming of his analysis and calls into question any conclusion of commercial success.”

Observation #4: In Ex.2193 at 66:21-67:21, Dr. McDuff testified: “I agree that the market is more competitive than it would be if generic competition did not exist. I would need to think about ‘difficult.’ I don't have an opinion on that one way or the other sitting here.”

Observation #5: Contrary to Patent Owner’s assertion, Ex.2193 at 75:16-76:11 does not include any question by Counsel for Patent Owner about the time period from FDA approval for which Dr. McDuff reported sales for Lamictal, and Lamictal is not mentioned in Dr. McDuff’s answers to Counsel’s questioning in the transcript. Patent Owner’s argument (Paper 68, ¶5) that *cumulative* Vimpat sales from 2009 into 2016 approach the *single-year* sales figures for Lamictal, Keppra, Neurontin, and Topamax (achieved after as little as eight years of marketing) does not undermine Petitioners’ argument (Paper 52 at 25) that “Even the raw sales figures fall short of other branded AEDs since 1990.”

Observation #6: Patent Owner mischaracterizes Dr. McDuff’s testimony by suggesting that the potential 10-year wait from invention date to FDA approval date and the first commercial sales applies to Dr. McDuff’s testimony that the “numerics” of “cumulative present value” calculation depend on timing to some degree. Paper 68, ¶6. To the contrary, in Ex.2193 at 121:9-122:14, Dr. McDuff testified: “[H]ere I’m referring to the future *relative to the time of the claimed invention*. So if one is contemplating whether there are incentives to pursue a particular invention, one contemplates the fact that one will have to undergo significant development costs in bringing a product to market and then many years into the future, it could be 10 years [from the invention date] *before you earn a single revenue* or a single profit.” (emphases added). Dr. McDuff did not testify that the present value of cumulative net sales should be calculated only after 10 years have passed since FDA approval, or any similar such implication. To the contrary, in Ex.2193 at 116:19-117:21, Dr. McDuff agreed that his calculations evaluated Vimpat’s sales “to date.” In Ex.2193 at 117:22-118:10, Dr. McDuff testified that he calculated net sales of Vimpat through June 2016 and was not aware of Dr. Velluro providing sales data for sales that occurred after that date.

Observation #7: In Ex.2193 at 116:19-117:21, Dr. McDuff agreed that his calculations evaluated Vimpat’s sales “to date.” In Ex.2193 at 117:22-118:10, Dr. McDuff testified that he calculated net sales of Vimpat through June 2016 and was

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