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 DR. KATHRYN A. DAVIS

[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 20) as modified by the Joint Notice of Stipulation Concerning Schedule (Paper 50), Patent Owner hereby submits the instant Motion for Observations Regarding the Cross-Examination Testimony of Dr. Kathryn A. Davis, taken on December 14, 2016. The transcript of this testimony has been filed as Exhibit 2195.

Patent Owner requests that the Board enter the instant Motion and consider the observations. Observations 1–16 below pertain to the deposition testimony of Dr. Kathryn Davis, obtained on December 14, 2016, after Patent Owner filed its last substantive paper. In addition, and in accordance with the Trial Guide, each of observations 1–16 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. 2195 at 38:12–41:18, Dr. Davis could not confirm the relevant date at which she "determined whether there was a long-felt need with respect to the '551 patent." She explained that, "[a]lthough the patent was filed in 1996, the drug [lacosamide] did not become available for clinical use until 2009, and there were many other drugs and compounds that received patent prior and then were released in the interim before the lacosamide was clinically available for use." *Id.*

at 39:8–15. This testimony is relevant to Petitioners' argument that levetiracetam (Keppra) meets the unmet need identified by Dr. Bazil. Reply (Paper 52) at 21–22. This testimony is also relevant to Patent Owner's position that Petitioners' argument identifying Keppra (a product approved post-1996) as a product that satisfied the long-felt need is a new argument beyond the proper scope of Petitioners' Reply. *See* Paper 57 at 2. This testimony is relevant because it is inconsistent with Dr. Davis' declaration, in which she states that she "understand[s] that the year 1996 is the relevant time in determining the alleged obviousness of the claims of the '551 patent." *See* Ex. 1087 (Davis Decl.), ¶ 14.

2. In Ex. 2195 at 124:18–125:15 and 127:1–12, Dr. Davis agreed that, as of 1996, levetiracetam was not FDA-approved for any indication and was not being used clinically. In addition, at 125:17–126:25, Dr. Davis could not confirm that as of 1996, epileptologists considered levetiracetam "to be an effective AED that controlled seizures for many patients whose epileptic seizures previously were not controlled by other AEDs," that levetiracetam was considered "a generally well-tolerated drug with minimal adverse effects," or that "levetiracetam [was] known to lack any clinically significant interactions with other medications." And at 127:14–23, Dr. Davis agreed that "as of 1996, levetiracetam was not available as an IV formulation." This testimony is relevant to Petitioners' argument that levetiracetam (Keppra) meets the unmet need identified by Dr. Bazil. Reply at 21–

22. This testimony is relevant because it undercuts Petitioners' arguments, and contradicts Dr. Davis' assertion that Keppra "was known to have favorable anticonvulsant properties years before" 1999. Ex. 1087 (Davis Decl.), ¶ 46. The testimony is also relevant because it contradicts her assertion that "levetiracetam has the properties of a so-called 'ideal' AED, and was available and used before lacosamide" (*id.* at ¶ 117), to the extent "before lacosamide" means before the relevant date of 1996 (*see id.* at ¶ 14).

3. In Ex. 2195 at 127:25–137:1, Dr. Davis agreed that Exs. 1097, 1098, 1099, 1100, 1101, and 1103, which she cites in paragraphs 43–44 of her declaration (Ex. 1087), are all reports of animal studies relating to levetiracetam that did not involve humans. At 259:23–261:11, she also agreed that an abstract cited in Ex. 1103 is not cited in her declaration (counsel for Petitioner Argentum pointed to this abstract during redirect questioning, *see* Ex. 2195 at 244:14–245:11). In addition, at 138:14–142:24, Dr. Davis agreed that the other exhibits cited in paragraphs 44–45 of her declaration (Ex. 1087)—Exs. 1105, 1106, and 1102—are human studies conducted with "small" sample sizes. She also agreed that Ex. 1106 concludes that double-blind controlled and long-term studies are required to evaluate the efficacy and safety of levetiracetam (Ex. 2195 at 139:10–22), and similarly that Ex. 1102 states that double-blind controlled and long-term studies are planned to evaluate the efficacy and safety of levetiracetam (*id.* at

141:21–142:24). This testimony is relevant to, and inconsistent with, Dr. Davis' and Petitioners' argument that levetiracetam satisfied the "unmet need identified by Patent Owner," which is an AED that, among other things, has "efficacy" and "minimal side effects" in humans suffering from epilepsy. Reply at 20–21; *see also* Ex. 1087 (Davis Decl.), ¶¶ 40–46, 99. The testimony is relevant because it undercuts Petitioners' arguments that, as of 1996, levetiracetam satisfied any unmet need.

4. In Ex. 2195 at 49:24–50:3, Dr. Davis explained that her decision-making process for choosing an AED for any given patient is "complex and has to do with the individual patient characteristics and also the type of epilepsy they have." At 50:4–17, she agreed that there is not a "one size-fits-all in terms of an antiepileptic drug across the epilepsy population." This testimony is relevant to Petitioners' argument that, to satisfy an unmet need, an AED must be suitable for a large proportion of epileptic patients, and that meeting the need in at least some patients is not enough. *See* Reply at 19–20 (arguing Vimpat did not satisfy the unmet need and noting "Vimpat has no more than 3.7% of prescriptions in the AED market," and that "Vimpat is not among Dr. Bazil's top three AEDs he prescribes"). This testimony is relevant because it is inconsistent with Petitioners' argument, and it supports Dr. Bazil's statements that epilepsy "is an extremely heterogeneous disorder" and "treatment is highly individualized," such that "there

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