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. BINGHE WANG

[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. Binghe Wang, taken on December 10, 2016. The transcript of this testimony has been filed as Exhibit 2194.

Patent Owner requests that the Board enter the instant Motion and consider the observations. Observations 1–27 below pertain to the deposition testimony of Dr. Binghe Wang, obtained on December 10, 2016, after Patent Owner filed its last substantive paper. In addition, and in accordance with the Trial Guide, each of observations 1–27 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. 2194 at 198:7-15, Dr. Wang agreed that the nitrogens in methoxyamino groups were defined by Dr. Kohn in Exhibit 2055 as "basic C alpha amino group[s]." At 198:1-6, Dr. Wang acknowledged that Dr. Kohn expressly taught that "excellent protection against MES-induced seizures by 1 can be achieved by incorporation of a basic C alpha amino substituent." At 192:9-19 (emphasis added), Dr. Wang testified that "having a basic functional group at the

alpha position ***indeed helped to improve activity***." This testimony is relevant because it contradicts Petitioners' assertion that a POSA would expect the replacement of -NH- with -CH_2- in compound 3l to "maintain[] high potency." *See* Petition ("Pet.," Paper 2) at 46; *see also* Ex. 1084 ¶ 229 (arguing that a POSA would have been "motivated to improve Compound 3l by modifying the methoxyamino group to the methoxymethyl group").

2. In Ex. 2194 at 151:22-152:16, Dr. Wang confirmed after reviewing his first declaration that it did not discuss the '301 patent in any paragraphs other than paragraphs 44 to 49 and 123. *See also* Ex. 1084 ¶ 26 (response declaration citing only those paragraphs). This testimony is relevant to Patent Owner's position that arguments relating to the '301 patent as rationale to support Kohn 1991 compound 3l are new arguments beyond the scope of a proper reply. Paper 57 at 1-2. This testimony is relevant because none of paragraphs 44 to 49 and 123 in Dr. Wang's first declaration (Ex. 1002) discusses the '301 patent disclosing or claiming the methoxyamino compound 3l.

3. In Ex. 2194 at 193:21-22, Dr. Wang explained that "the methoxyamino group is different from an amino itself." This testimony is relevant to Petitioners' argument that "a POSA would utilize the well-known concept of bioisosterism and bioisosteric replacements" and substitute the "secondary amino group (-NH-)" with a "methylene group (-CH_2-)" in compound 3l of Kohn 1991. Pet. at 45. This

testimony is also relevant to Patent Owner's argument that the "bioisosteres" for substitution are not nitrogen and carbon, but rather, methoxyamino and methoxymethyl. *See* Patent Owner's Response ("POR," Paper 35) at 28-30, 35-36. This testimony is relevant because compound 3l includes a methoxyamino group, not an amino group (Pet. at 44; *see also* Ex. 1012, Table 1), and the Petition addresses only substituting an ***amino*** group. *See, e.g.*, Pet. at 45 ("it was well known that a methylene group (-CH_2-) is a bioisosteric replacement for a secondary amino group (-NH-)").

4. In Ex. 2194 at 115:17-21, Dr. Wang testified that a compound with a methoxyimino group is "very different" from a compound with a methoxyamino group, even though those functional groups have minor structural differences. At 116:13-21, Dr. Wang affirmed that "looking at the differences between functional groups is important." This testimony is relevant to Petitioners' argument that "a POSA would utilize the well-known concept of bioisosterism and bioisosteric replacements" and substitute the "secondary amino group (-NH-)" with a "methylene group (-CH_2-)" in compound 3l of Kohn 1991. Pet. at 45. This testimony is also relevant to Patent Owner's argument that the "bioisosteres" for substitution are not nitrogen and carbon, but rather, methoxyamino and methoxymethyl. *See* POR at 28-30, 35-36. This testimony is relevant because it shows that a POSA would consider the entire functional group when making a

bioisosteric change. The entire functional group in compound 3l is a methoxyamino group, not an amino group (Pet. at 44; *see also* Ex. 1012, Table 1), and the Petition addresses only substituting an ***amino*** group. *See, e.g.*, Pet. at 45 ("it was well known that a methylene group (-CH_2-) is a bioisosteric replacement for a secondary amino group (-NH-)").

5. In Ex. 2194 at 177:5-22, Dr. Wang explained that his predicted "12- to 36-fold increase in activity," described in ¶ 146 of his second declaration, was calculated using the "experimental number" of 8.3 for ED_{50} of "racemic lacosamide," which he confirmed was from the '551 patent itself (*id*. at 179:3-22) and not available to a person of ordinary skill in the art in 1996 (*id.* at 182:21-183:4). At 178:3-9, Dr. Wang further testified, "So in doing the calculation, I did not want to use the experimental number as the way to do the calculation, right? … And then I wanted to avoid that particular number." This testimony is relevant to the expected increase in activity and reasonable expectation of success from the modification of compound 3l. *See, e.g.*, Ex. 1084, ¶¶ 143-147; Pet. at 46; Reply at 13; *see also* POR at 42-43. This testimony is relevant because Dr. Wang admitted that his prediction in ¶ 146 of his second declaration incorrectly relied on data from the '551 patent itself, which was not in the prior art or known to a POSA.

6. In Ex. 2194 at 157:17-158:14, Dr. Wang testified that one would consider ED_{50}'s in the MES test that differ by 23% to be "essentially the same."

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