Paper No. 56
Filed: February 14, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEPTUNE GENERICS, LLC,
APOTEX INC., APOTEX CORP., TEVA PHARMACEUTICALS,
FRESENIUS KABI USA, LLC, and
WOCKHARDT BIO AG,

PETITIONERS,

V.

ELI LILLY & COMPANY,

PATENT OWNER.

Case IPR2016-00240[1]
Patent 7,772,209

PETITIONER'S MOTION TO EXCLUDE PATENT OWNER'S EVIDENCE PURSUANT TO 37 C.F.R. § 42.64(c)

[1] Cases IPR2016-01191, IPR2016-01337 and IPR2016-01343 have been joined with the instant proceeding.

In accordance with 37 C.F.R. § 42.62 and the Federal Rules of Evidence, and for the reasons stated below, Petitioner respectfully requests that the Board exclude Patent Owner's Exhibit Numbers 2120 and 2116.

I. THE BOARD SHOULD EXCLUDE EXHIBIT 2120 AS UNRELIABLE UNDER FRE 702 AND 703.

On October 7, 2016, Neptune timely objected to Exhibit 2120, which consists of the declaration testimony of Dr. Bruce Chabner. (Paper 35). Pursuant to FRE 702, "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (U.S. 1993). "Expert testimony is not admissible if it includes unsubstantiated speculation and subjective beliefs." *Sport Dimension, Inc. v. Coleman Co.*, 820 F.3d 1316, 1323 (Fed. Cir. 2016) (quotation omitted). Expert opinions are also "inadmissible [if] they are based on incorrect legal standards." *Am. Med. Sys. v. Laser Peripherals, LLC*, 712 F. Supp. 2d 885, 901 (D. Minn. 2010) (citing *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1117 (Fed. Cir. 1996)). Dr. Chabner's opinions are all of the above—unsubstantiated, and based on subjective beliefs and incorrect legal standards.

A. Dr. Chabner applies subjective beliefs and incorrect legal standards to reach his opinions.

When Dr. Chabner, was asked what methodology he used to distinguish between his knowledge acquired over 50 years and a POSA's knowledge in June

1999, he testified that he "really can't answer that question," and admitted he did not "employ methodologies" because he used "his own personal experience" and did not conduct his analysis based on a POSA "less informed than myself." (Ex. 1075- 233:15-234:12, 228:11-229:3.)

When asked how he applied the reasonable expectation of success standard in his declaration, Dr. Chabner testified, "I looked at what I knew as of 1999, and what the literature said and what was publicly available, and I concluded that it was not obvious that – that using these vitamins would make a difference, would improve therapy." (*Id.* at 88:25-89:8.) When asked what criteria he employed, he testified, "I think, you know, it's like pornography. When it's reasonable, you understand it when you see it. Scientifically, I was skeptical about it." (*Id*. at 1075-89:20-25.)

When pressed to explain how reasonably successful the claimed combination needed to be for obviousness, Dr. Chabner testified, "I think it would need to be something that I could endorse"— admitting "my standard for saying what's obvious and reasonable is ***my personal standard***. And that's why I have 50 years in the field." (*Id*. at 90:19-94:3 (emphasis added).)

Dr. Chabner's failure to opine from a POSA's perspective renders his opinions unreliable and inadmissible. *See Amazon.com, Inc. v. Barnesandnoble.com*, 239 F.3d 1343, 1364 (Fed. Cir. 2001) (what an expert "did

or did not personally realize at the time based on his actual knowledge is irrelevant"); *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 962 (Fed. Cir. 1986) (inquiry is whether challenged claims are obvious to a POSA, "not to the judge, or to a layman . . . or to geniuses in the art."); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991) (noting the "importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry. Instead of ascertaining what was subjectively obvious …, the court must ascertain what would have been objectively obvious...").

Separately, Dr. Chabner admitted that his personal standard for a reasonable expectation of success required "evidence that it worked in the clinical setting" and that "what was really needed was clinical evidence" of success. (Ex. 1075-214:9-215:4.) But "[c]onclusive proof of efficacy is not necessary to show obviousness. All that is required is a reasonable expectation of success." *Hoffman-LaRoche Inc. v. Apotex, Inc.*, 748 F.3d 1326, 1331 (Fed. Cir. 2014). Because Dr. Chabner did not use the proper standard for determining whether a POSA would have a reasonable expectation of success, his opinions should be excluded.

Dr. Chabner further opines that rather than administering folic acid and B_{12} to address pemetrexed's known toxicity to patients with elevated homocysteine, a POSA would have instead attempted alternative interventions to address toxicity. (Ex. 1075-149:18-152:4.) Dr. Chabner testified that he would have been "very

encouraged to undertake further investigation [of these alternatives]." (Ex. 1075-136:2-6.) When asked, with respect to these alternatives, "[d]oes being encouraged to undertake further investigation satisfy your understanding and application of a reasonable expectation of success?"—Dr. Chabner answered "Yes." (*Id*., 136:7-13.) Dr. Chabner's use of a lower standard (encouraged to undertake investigation) for a reasonable expectation of success for his alternatives—and a heightened standard (proof from clinical data) when evaluating reasonable expectation of success for the claimed folic acid/B_{12} pretreatment—should result in the exclusion of his opinions.

B. Dr. Chabner's Opinions are Unsubstantiated.

The Supreme Court has held that courts should not admit expert testimony that "is connected to existing data only by the ipse dixit of the expert." *Gen. Elec. v. Joiner*, 522 US 136, 146 (1997). That is what Dr. Chabner's opinions entail. Three documents demonstrate that Dr. Chabner's opinions are unsubstantiated and so inadmissible, or at a minimum entitled to no weight. Lilly has produced two documents it submitted to the FDA prior to the earliest effective filing date of the '209 Patent. (Exs. 2103 and 2017.) These documents constitute party admissions concerning the content of the prior art from a POSA's perspective. Fed. R. Evid. 801(d)(2); *In re Copaxone Consol. Cases*, 2017 U.S. Dist. LEXIS 12168 at *78 (D. Del. Jan. 30, 2017) (holding that non-prior art "statements that [Patent Owner]

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