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THE MEDICINES COMPANY, Plaintiff, v. MYLAN INC., MYLAN PHARMACEUTICALS INC., and BIONICHE PHARMA USA, LLC, Defendants.

No. 11-cv-1285

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

2014 U.S. Dist. LEXIS 40724

**March 27, 2014, Decided
March 27, 2014, Filed**

SUBSEQUENT HISTORY: Motion granted by, in part, Motion denied by, in part *Meds. Co. v. Mylan Inc., 2014 U.S. Dist. LEXIS 52952 (N.D. Ill., Apr. 17, 2014)*

PRIOR HISTORY: *Meds. Co. v. Mylan Inc., 2014 U.S. Dist. LEXIS 40514 (N.D. Ill., Mar. 27, 2014)*

CORE TERMS: bivalirudin, expert testimony, pharmaceutical, batch, skill, legal standard, subject matter, prior art, trier of fact, offering, training, patent, patent infringement, legal opinions, burden of establishing, nonobviousness, anticoagulant, infringement, compounding, obviousness, reliability, comprising, ingredient, invalidity, gatekeeper, invention, impurity, patented, reliable, maximum

COUNSEL: [*1] For The Medicines Company, Plaintiff: David A. Zwally, Porter F. Fleming, Frommer Lawrence & Haug LLP, New York, NY; John Bostjancich, Patricia Susan Smart, Smart & Bostjancich, Chicago, IL; Mark P Walters, Frommer Lawrence & Haug LLP, Seattle, WA.

For Mylan Inc., Mylan Pharmaceuticals Inc., Bioniche Pharma USA, LLC, Defendants: David E. Jones, LEAD ATTORNEY, PRO HAC VICE, Autumn N. Nero, David J. Harth, Emily J. Greb, PRO HAC VICE, Perkins Coie Llp, Madison, WI; James B Coughlan, Perkins Coie LLP,

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For Bioniche Pharma USA, LLC, Mylan Pharmaceuticals Inc., Mylan Inc., Counter Claimants: David E. Jones, LEAD ATTORNEY, PRO HAC VICE, Autumn N. Nero, David J. Harth, Emily J. Greb, Perkins Coie Llp, Madison, WI; Scott D. Eads, LEAD ATTORNEY, Perkins Coie Llp, Portland, OR; James B Coughlan, Perkins Coie LLP, Chicago, IL; Shannon M. Bloodworth, Perkins Coie Llp, Washington, DC.

For The Medicines Company, Counter Defendant: John Bostjancich, Patricia Susan Smart, Smart & Bostjancich, Chicago, IL; Mark P Walters, Frommer Lawrence & Haug LLP, Seattle, [*2] WA; Porter F. Fleming, Frommer Lawrence & Haug LLP, New York, NY.

JUDGES: AMY J. ST. EVE, United States District Court Judge.

OPINION BY: AMY J. ST. EVE

OPINION

MEMORANDUM OPINION AND ORDER

This is a patent infringement action by The Medicines Company ("TMC") against Defendants Mylan, Inc., Mylan Pharmaceuticals Inc. and Bionche Pharma USA, LLC alleging infringement of *United States Patent No. 7,582,727* (the "'727 patent"),¹ a product patent. TMC has moved to preclude Mylan's expert, Ivan T. Hofmann, from offering opinions regarding the legal requirements for commercial success, including his interpretation of relevant case law. For the reasons set forth below, the Court denies the motion.

1 The Court previously granted Mylan's summary judgment motion as to *United States Patent No. 7,598,343* (the "'343 patent"). (R. 309.)

I. Background

This action arises out of a patent infringement case involving the '727 Patent. The '727 patent "relates to a compounding process for preparing a pharmaceutical batch(es) of a drug product or a pharmaceutical formulation(s) comprising bivalirudin as an active ingredient." ('727 patent at col. 2 ll. 29-32) Bivalirudin is the active ingredient in Angiomax®, which is an anticoagulant drug [*3] used in patients with unstable angina who are undergoing percutaneous transluminal coronary angioplasty. (R. 1, Comp. at ¶¶ 11, 13.) TMC markets Angiomax®. (*Id.* ¶ 13.)

In this case, TMC alleges that Mylan, before the expiration of the patent-in-suit, submitted Abbreviated New Drug Application ("ANDA") No. 202471 to the U.S. Food and Drug Administration ("FDA"), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of its generic Angiomax® product. TMC contends that Mylan's ANDA No. 202471 infringes certain claims of the '727 patent. Specifically, TMC asserts that Mylan has infringed claims 1-3, 7-10 and 17 of the '727 patent. Claim 1 is an independent claim, and the remaining asserted claims depend on Claim 1. Claim 1 states:

Pharmaceutical batches of a drug product comprising bivalirudin (SEQ ID NO: 1) and a pharmaceutically acceptable carrier for use as an anticoagulant in a subject in need thereof, wherein the batches have a maximum impurity level of Asp⁹-bivalirudin that does not exceed about 0.6% as measured by HPLC.

Each asserted claim in the '727 patent contains a limitation requiring the pharmaceutical batches at issue to have "a [*4] maximum impurity level of Asp⁹-bivalirudin that does not exceed about 0.6%." No claims in the '727 patent explicitly refer to "efficient mixing" or any other steps in the bivalirudin compounding process.

As a defense to this infringement action, Mylan has asserted that the '727 patent is obvious and thus invalid under 35 U.S.C. § 103. "A patent may not issue 'if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068 (Fed. Cir. 2012) (citing 35 U.S.C. § 103(a) (2006)). "Obviousness is a question of law based on underlying factual findings: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective considerations of nonobviousness." *Id.* Objective considerations of nonobviousness include, among other factors, the "commercial success of the patented invention." *Id.* at 1075. "[T]he [*5] burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *Microsoft Corp. v. i4i Ltd. P'ship*, U.S. , 131 S. Ct. 2238, 2245, 180 L. Ed. 2d 131 (2011) (citing 35 U.S.C. § 282).

Mylan disclosed Mr. Hofmann to opine on the lack of commercial success of the '727 patent.² TMC seeks to exclude certain of Mr. Hofmann's opinions on the grounds that he is giving legal opinions.

2 The Court previously struck the testimony of TMC's expert on commercial success, Mr. Anthony Flammia. (R. 406.)

II. Legal Standard

"The admissibility of expert testimony is governed by *Federal Rule of Evidence 702* and the Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)." *Lewis v. Citgo Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009). *Rule 702*

provides, in relevant part, that "[i]f scientific, technical or other specialized knowledge will assist the trier of fact[,] . . . a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion. . . ." *Id.* See also *Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 824 (7th Cir. 2010).

Under [*6] the expert-testimony framework, courts perform the gatekeeping function of determining whether the expert testimony is both relevant and reliable prior to its admission at trial. See *id.*; *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1373 (Fed. Cir. 2013); *United States v. Pansier*, 576 F.3d 726, 737 (7th Cir. 2009) ("To determine reliability, the court should consider the proposed expert's full range of experience and training, as well as the methodology used to arrive [at] a particular conclusion."). In doing so, courts "make the following inquiries before admitting expert testimony: first, the expert must be qualified as an expert by knowledge, skill, experience, training, or education; second, the proposed expert must assist the trier of fact in determining a relevant fact at issue in the case; third, the expert's testimony must be based on sufficient facts or data and reliable principles and methods; and fourth, the expert must have reliably applied the principles and methods to the facts of the case." *Lees v. Carthage College*, 714 F.3d 516, 521-22 (7th Cir. 2013); see also *Stollings v. Ryobi Techs., Inc.*, 725 F.3d 753, 765 (7th Cir. 2013); *Power Integrations*, 711 F.3d at 1373; [*7] *Pansier*, 576 F.3d at 737. Mylan bears the burden of establishing that Mr. Hofmann's testimony satisfies the mandates of *Daubert* and *Rule 702*. *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009).

III. Analysis

Mylan disclosed Mr. Hofmann as its commercial success expert to opine on the lack of commercial success of the '727 patent. Mr. Hofmann has a bachelor degree in business administration with a double major in

accounting and economics from the University of Notre Dame. He is a certified public accountant and a certified licensing professional. He is not a legal or technical expert.

In the course of offering his opinions on commercial success, Mr. Hofmann references the legal standard upon which he bases his economic analysis and opinions. Contrary to TMC's assertions, Mr. Hoffman is not offering an impermissible legal opinion. Instead, he is merely setting forth his understanding of the legal standards upon which he relies for his opinions. This reference is appropriate and puts his testimony in context. See *A.E. ex rel. Evans v. Indep. Sch. Dist. No. 25*, 936 F.2d 472, 476 (10th Cir. 1991).

Moreover, the trial in this case is a bench trial. The Court is fully aware of [*8] the law of obviousness and commercial success. The Court, as the trier of fact in this case, will not construe Mr. Hoffman's comments or his understanding of the law on which he bases his commercial success opinions as any type of expert opinion on the law. *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 760 (7th Cir. 2010) (observing that "the court in a bench trial need not make reliability determinations before evidence is presented" because "the usual concerns of the rule -- keeping unreliable expert testimony from the jury -- are not present in such a setting"); *United States v. Brown*, 415 F.3d 1257, 1269 (11th Cir. 2005) ("There is less need for the gatekeeper to keep the gate when the gatekeeper is keeping the gate only for himself."). Accordingly, TMC's motion is denied.

Date: March 27, 2014

/s/ Amy J. St. Eve

AMY J. ST. EVE

United States District Court Judge

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