IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THE MEDICINES COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 11-cv-1285
	)	
MYLAN INC., MYLAN PHARMACEUTICALS INC., and BIONICHE PHARMA USA, LLC,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

AMY J. ST. EVE, District Court Judge:

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. In advance of trial, Defendants move to exclude the commercial success opinion of non-retained employee expert Anthony Flammia. For the reasons discussed below, the Court grants the motion.

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 used in patients with unstable angina who are undergoing percutaneous

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

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 Asp^{9}-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 maximum impurity level of Asp^{9}-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.

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 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 Tech., Inc.*, 725 F.3d 753, 765 (7th Cir. 2013); *Power Integrations*, 711 F.3d at 1373; *Pansier*, 576 F.3d at 737.

The Seventh Circuit has repeatedly stated that "genuine expertise may be based on experience or training." *United States v. Conn*, 297 F.3d 548, 556 (7th Cir. 2002) (quoting *Tyus v. Urban Search Mgmt.*, 102 F.3d 256, 263 (7th Cir. 1996)). "[W]hile extensive academic and practical expertise in an area is certainly sufficient to qualify a potential witness as an expert, Rule 702 specifically contemplates the admission of testimony by experts whose knowledge is based on experience." *Trustees of Chicago Painters & Decorators Pension, Health & Welfare, & Deferred Sav. Plan Tr. Funds v. Royal Int'l Drywall & Decorating, Inc.*, 493 F.3d 782, 787-88 (7th Cir. 2007) (citations and quotations omitted). As such, courts "consider a proposed expert's full range of practical experience, as well as academic or technical training, when determining

whether that expert is qualified to render an opinion in a given area." *Id.* (quoting *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000)).

In assessing the admissibility of an expert's testimony, the Court's focus "must be solely on principles and methodology, not on the conclusions they generate.'" *Winters*, 498 F.3d at 742 (quoting *Chapman v. Maytag Corp.*, 297 F.3d 682, 687 (7th Cir. 2002)). *See also Stollings*, 725 F.3d at 765. "The goal of *Daubert* is to assure that experts employ the same 'intellectual rigor' in their courtroom testimony as would be employed by an expert in the relevant field." *Jenkins v. Bartlett*, 487 F.3d 482, 489 (7th Cir. 2007) (quoting *Kumho Tire Co., Ltd. v. Carmichael*,, 526 U.S. 137, 152, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999)). "A *Daubert* inquiry is not designed to have the district judge take the place of the jury to decide ultimate issues of credibility and accuracy." *Lapsley v. Xtek*, Inc., 689 F.3d 802, 805 (7th Cir. 2012).

ANALYSIS

I. Anthony Flammia

Mr. Flammia has worked for TMC since 2003. He currently serves as TMC's Vice President of New Business Ventures. When TMC implemented the new manufacturing process at issue in this case, Mr. Flammia served as TMC's Vice President of Global Manufacturing Supply. In this position, Mr. Flammia had responsibility for contract manufacturing, the commercial clinical supply chain for Angiomax®, attempts to solve Angiomax® batch failures, and the implementation of the new and improved manufacturing process for Angiomax®.

TMC has disclosed Mr. Flammia as its non-retained employee expert on commercial success. In its initial disclosure, TMC provided that "Mr. Flammia may testify regarding the commercial success of The Medicines Company's bivalirudin product, Angiomax®, as a result

of commercial reliability from consistently minimized Asp^9-bivalirudin levels in batches of improved Angiomax®." (R. 359, Declaration of Emily Greb, Ex. 1.)

In its Amended Rule 26(a)(2) expert disclosure, TMC made the following discourse regarding Mr. Flammia's expert opinions:

> Mr. Flammia is expected to testify on the subject matter of the commercial success of Improved Angiomax® as an indicia of nonobviousness. As Vice President, Global Manufacturing and Supply from 2006 to 2010, Mr. Flammia was responsible for the manufacture and supply of The Medicines Company's Angiomax® product. The facts and opinions to which Mr. Flammia is expected to testify are as follows:
>
> > The commercial reliability from consistently minimized Asp^9-bivalirudin levels in batches of Improved Angiomax® is a commercial success.
> >
> > In particular, the original manufacturing process for Angiomax® resulted in pharmaceutical batches with inconsistent and randomly higher levels of impurities, including Asp9-bivalirudin ("Original Angiomax®"). Rejected batches of Original Angiomax® resulted in lost sales. The lost sales ranged as high as approximately $15-20 million per batch.
> >
> > The patents-in-suit disclose minimizing levels of Asp9-bivalirudin. Improved Angiomax® batches with the claimed characteristics of the '727 and '343 patents consistently have lower impurity levels and are less likely to be rejected due to impurity levels.
> >
> > A nexus exists between the commercial success of Improved Angiomax® and the claims of the '727 and '343 patents. The commercial success of Improved Angiomax® can be attributed, in whole or in part, to the claims of the patent, i.e., minimizing levels of Asp9-bivalirudin. The minimization of Asp9-bivalirudin, allows The Medicines Company to avoid lost sales associated with rejected batches. The significance of this can be measured against The Medicines Company's research-and-development ("R&D") budget for Angiomax®. The sales lost (per batch) are approximately the same as The Medicines Company's R&D budget. The Medicines Company allocates approximately $13-22 million annually to R&D for Angiomax®, which represents 15-20% of its total R&D budget. Thus, each failed batch of Angiomax® represents the loss of one year's worth of R&D on Angiomax®.

(*Id.* at Ex. 2.)

Mr. Flammia admitted that he did not see TMC's amended disclosures until the morning of his June 2013 "expert" deposition. (R. 361, 6-3-13 Flammia Dep. at 21.)

II. Mr. Flammia's Testimony Fails to Meet the Mandates of *Daubert*

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 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).

TMC seeks to offer Mr. Flammia's testimony on the commercial success of Angiomax® to support its nonobvious arguments. Defendants challenge it on the grounds that his methodology does not comport with the legal requirements for commercial success.

A. Commercial Success

Mylan first challenges Mr. Flammia's "commercial success" opinions because they are not grounded in Federal Circuit law and fail to follow an accepted methodology. Specifically, Mr. Flammia opines that the '727 patent is a commercial success because it has resulted in fewer

rejected bivarlirudin lots and batches of Angiomax®, and thus it saves TMC certain overhead costs. TMC's assertion fails under the law of commercial success.

The Federal Circuit teaches that "the most probative evidence of commercial success is not overall sales, but whether those sales represent "'a substantial quantity in th[e] market.'" *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*, 719 F.3d 1346, 1356 (Fed. Cir. 2013), (citing *In re Applied Materials, Inc.*, 692 F.3d 1289, 1300 (Fed. Cir. 2012)). In order to establish commercial success, TMC must prove that the product has a substantial share of sales in a definable market. Id. at 1356 n.5; *In re: Applied Materials, Inc.*, 692 F.3d at 1300 ("[T]he more probative evidence of commercial success relates to whether the sales represent a substantial quantity in the market") (citations and quotations omitted); *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996).

Mr. Flammia has failed to identify any evidence that the '727 patent has resulted in increased sales or market share. When asked whether he intended to offer opinions regarding commercial success, he said that he was "prepared to talk about the commercial reliability and robustness of the manufacturing process." (R. 361, 6-3-13 Flammia Dep. at 21.) Furthermore, Mr. Flammia is not offering any opinions or testimony regarding increased sales, market share, or customer demand relating to features claimed in the '727 patent. It was also clear from Mr. Flammia's deposition testimony that he did not have an understanding of the Federal Circuit's definition of commercial success in the context of obviousness. TMC contends that Mr. Flammia's testimony nevertheless establishes commercial success because he opines that the new process in the '727 patent results in fewer rejected batches of Angiomax® thus saving TMC overhead costs. TMC argues that this "commercial reliability" translates to commercial success. TMC, however, has failed to provide any support for its argument that the saving of

manufacturing costs alone is a measure of commercial success. Indeed, in *The Medicines Company v. Hospira, Inc.*, No. 1:09-cv-00750-RGA, another TMC litigation involving the '727 patent, the District Court in Delaware rejected this same argument by TMC. (R. 358, Affidavit of Greb in Support of Defendants' *Daubert* Motions, Ex. 16, Letter to the Honorable Richard G. Andrews from Mary B. Matterer and attached exhibits.)

TMC's reliance on *Litton Systems, Inc. v. Honeywell, Inc.*, 87 F.3d 1559 (Fed. Cir. 1996), *vacated on other grounds*, 520 U.S. 1111 (1997), is misplaced. In *Litton*, the patent at issue claimed a method for coating "a substrate with multiple layers of materials to form an optical component. This method uses ion beams to coat optical material with multiple layers. The result is an almost perfectly reflective mirror." *Id.* at 1563-64. These mirrors are essential components in the manufacturer of ring-laser gyroscopes used for navigational control of aircraft. Honeywell, the defendant and accused infringer, manufactured ring-laser gyroscopes. In addressing the issue of commercial success, the Federal Circuit noted that Litton "enjoyed commercial success with the patented method." *Id.* at 1569. In fact, "Litton captured about seventy percent of the military market for guidance systems." *Id.* Additionally, Honeywell admitted that the invention was critical to its highly successful industry. The Federal Circuit did not suggest in *Litton* that a party can establish commercial success based upon the savings of manufacturing costs.

In addition, TMC's contention that Mylan merely raises a factual issue is simply wrong. Mylan does not challenge the facts underlying Mr. Flammia's opinions. Instead, it seeks to exclude his opinions because he does not apply the correct legal standard for commercial success.

Because Mr. Flammia applies the wrong legal standard regarding commercial success and does not opine on, or consider, TMC's increased sales, market share, or customer demand relating to the '727 patent, his methodology fails to comply with the law on commercial success. Accordingly, the Court strikes his opinions on commercial success because they are legally flawed and will not be helpful to the trier of fact. *United States v. Mire*, 725 F.3d 665, 674 (7th Cir. 2013) (Rule 702 permits expert opinions "provided the testimony is helpful to the trier of fact").

B. Nexus

Mylan further challenges Mr. Flammia's commercial success opinions because he has failed to opine or prove that a nexus exists between the novel features of the '727 patent and any alleged commercial success. The Court agrees.

It is well established that "[e]vidence of commercial success . . . is only significant if there is a nexus between the claimed invention and the commercial success." *Galderma Labs., L.P. v. Toulmar, Inc.*, 737 F.3d 731, 740 (Fed. Cir. 2013), quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311–12 (Fed.Cir. 2006). *See also Metso Minerals, Inc. v. Powerscreen Intern. Distribution, Ltd*., 526 Fed.Appx. 988, 998 (Fed. Cir. 2013), quoting *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) ("Our case law clearly establishes that the patentee must establish a nexus between the evidence of commercial success and the patented invention.");

Pregis Corp. v. Kappos, 700 F.3d 1348, 1356 (Fed. Cir. 2012) ("The lack of nexus between the claimed subject matter and the commercial success or purportedly copied features of the EZ I machine renders Free–Flow's proffered objective evidence uninformative to the obviousness determination."). There must be "proof that the sales were a direct result of the unique

characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter." *In re Applied Materials, Inc*. 692 F.3d at 1299 -1300. TMC bears the burden of establishing a nexus between the novel features of the patent and commercial success. *See W. Union Co. v. MoneyGram Payment Sys., Inc.*, 626 F.3d 1361, 1372-73 (Fed. Cir. 2010). Given that TMC has failed to establish the requisite nexus, its "commercial success evidence is not significant." *ArcelorMittal France v. AK Steel Corp.* 700 F.3d 1314, 1326 (Fed. Cir. 2012).

During his deposition, Mr. Flammia testified as follows about the nexus requirement:

Q: What is your understanding of the nexus requirement?

Lawyer: Objection.

A: As I stated earlier I understand my role in general terms of giving the expert opinion for the company on the reliability of manufacturing process and its impact to The Medicines Company.

In broad terms all of these paragraphs and all of these words mean that and I am happy to do so.

Q: Okay. And so as with this phrase indicia of non-obviousness you don't have any understanding of what the nexus requirement is, correct?

Lawyer: Objection. Mischaracterizes testimony.

A. I am not a trained attorney. I am not a legal counsel. I don't understand the legal impacts.

I understand the role that I am playing on this proceeding as an expert witness on the manufacturing reliability and its commercial impact and success to the company. That is my understanding of what I am here for.

(R. 361, 6-3-13 Flammia Dep. at 56-67.) Mr. Flammia did not appear to understand the nexus requirement in this context.

TMC contends that Mr. Flammia's opinions satisfy the nexus requirement because he opines that the minimization of Asp^9-bivalirudin allows TMC to reliably and consistently

produce Angiomax®, and that Angiomax®'s commercial success is due to this commercial reliability. The '727 patent, however, is a "pure product" patent that does not include process-related elements. TMC cannot assert a nexus on a characteristic that is not part of the claim in the '727 patent.

Furthermore, TMC has not informed its customers about the claimed improvement in the '727 patent. (R. 361, 6-3-13 Flammia Dep. at 149-151.) Accordingly, TMC cannot claim that its customers based their purchasing decisions on a feature claimed in the '727 patent about which they were uninformed.

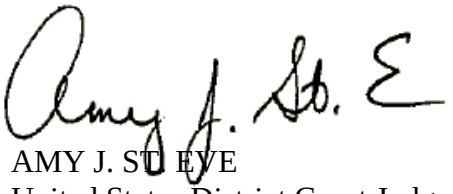
TMC next argues that the nexus is presumed in this case because the product is coextensive with the claimed invention in the '727 patent. It is clear that a presumption of a nexus applies if the commercial product is coextensive with the asserted claims. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363 (Fed. Cir. 2013); *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1129 (Fed. Cir. 2000). A commercially successful product is not "coextensive" with the patented invention when the patented invention is "only a component of a commercially successful machine or process." *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). It is undisputed that Angiomax® is covered by multiple patents, including the '727 patent, the '343 patent and U.S. Patent No. 5,196,404. Moreover, neither TMC nor Mr. Flammia has distinguished the contributions of each patent to the commercial product. Accordingly, the presumption does not apply. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1299 (Fed. Cir. 2010), *vacated for en banc rehearing on inequitable conduct*, 374 Fed. Appx. 35 (Fed. Cir. 2010) (not entitled to presumed nexus where several patents cover marketed product).

Defendant's argument that Mylan's challenges raise factual issues and are better suited for cross-examination fails. Mylan's challenges do not pertain to Mr. Fammia's credibility or the underlying factual predicates for his opinions. Instead, it challenges Mr. Fammia's methodology because he applies a legally incorrect methodology.

CONCLUSION

Because Mr. Fammia's opinions rest on an inaccurate theory of commercial success, his methodology is faulty and his opinions will not assist the trier of fact. Accordingly, the Court grants Mylan's motion to exclude his expert opinions.

Dated: March 25, 2014



AMY J. ST. EVE
United States District Court Judge