

## United States District Court, Northern District of Illinois

<b>Name of Assigned Judge or Magistrate Judge</b>	Amy J. St. Eve	<b>Sitting Judge if Other than Assigned Judge</b>	
<b>CASE NUMBER</b>	11 C 1285	<b>DATE</b>	5/24/2013
<b>CASE TITLE</b>	The Medicines Company vs. Mylan, Inc.		

### DOCKET ENTRY TEXT

The Court denies Plaintiff's Motion to strike Defendants' commercial success contentions or expert report [212]. The depositions of Mr. Flammia and Mr. Hofmann must take place on or before 6/8/13.

■ [ For further details see text below.]

Notices mailed by Judicial staff.

### STATEMENT

Before the Court is Plaintiff's Motion to Strike Defendants' Commercial Success Expert Opinions. (R. 212, Pl.'s Mot.) For the following reasons, the Court denies the Motion.

### BACKGROUND

#### I. Patents-in-Suit

Plaintiff The Medicines Company ("TMC") brought this lawsuit against Defendants Mylan Inc., Mylan Pharmaceuticals Inc., and Bioniche Pharma USA, LLC (collectively, "Mylan" or "Defendants"), asserting that Mylan infringed U.S. Patent Nos. 7,582,727 ("the '727 Patent") and 7,598,343 ("the '343 Patent" and collectively with the '727 Patent, the "patents-in-suit"). The patents-in-suit pertain to pharmaceutical formulations of Bivalirudin and the processes of making Bivalirudin. (R. 1, Compl.) Bivalirudin is the active ingredient in Angiomax®, an anticoagulant drug used in patients with unstable angina who are undergoing percutaneous transluminal coronary angioplasty. (*Id.* ¶¶ 11, 13.) TMC markets Angiomax®. (*Id.* ¶¶ 11, 13.)

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## II. Current Discovery Dispute

On April 29, 2011, Mylan served its initial interrogatories. Interrogatory #2 asked TMC to identify “the factual and legal basis for any objective indicia of nonobviousness” that TMC contended supported the validity of its patents-in-suit. (R. 220, Defs.’ Mem. in Opp. to TMC’s Mot. to Strike, Ex. 1, at 6.) On October 16, 2012, TMC served a supplemental response to Mylan’s Interrogatory #2 indicating its intention to rely on evidence of commercial success as a secondary consideration of nonobviousness. (Defs.’ Mem., Ex. 8, at 12). Two days later, on October 18, 2012, Mylan deposed Mr. Anthony Flammia as a Rule 30(b)(6) witness for TMC, including on TMC’s commercial success contentions. (Pl.’s Mot., Ex. 12, Flammia Dep.)<sup>1</sup> On November 30 and December 14, the parties exchanged “amended final” invalidity and validity contentions, respectively. On November 19, 2012, the Court amended the scheduling order and set the deadlines of February 8, 2013 for opening expert reports, March 8, 2013 for rebuttal expert reports, and April 8, 2013 for reply expert reports. (R. 173, Minute Order.)

During the initial round of expert reports, Mylan served the report of Mr. David Auslander, Ph.D., dated February 4 relating to the invalidity of TMC’s patents-in-suit. (Pl.’s Mem. 4, Ex. 12.) On March 8, TMC responded with the rebuttal expert report of Professor Alexander M. Klibanov and TMC’s Rule 26(a)(2) disclosures, which stated that Mr. Flammia “may testify regarding the commercial success of . . . Angiomax” as a non-retained expert. (Defs.’ Mem. at 3, Ex.11.) Following Mylan’s objection to TMC’s Rule 26(a)(2) disclosure on the basis that TMC failed to disclose the opinions to which Mr. Flammia would testify at trial, TMC served an amended disclosure listing such opinions on March 21, 2013. (R. 214, Ex. 13.) On April 8, 2013—the deadline for the reply round of expert reports,—Mylan served the expert report of Ivan T. Hofmann addressing the issue of commercial success. (Defs.’ Mem., Ex. 12.) Mylan had first disclosed Mr. Hofmann as an expert on February 26, 2013. (Pl.’s Mem., Ex. 4.) The parties met and conferred on March 19 and April 12 in an attempt to resolve the issue over the timing of the disclosure of Mr. Hofmann’s report. TMC filed the present motion on April 17.

TMC contends that because Mylan bears the burden of proof on invalidity and obviousness, Mylan should have disclosed its expert report concerning commercial success as an indicia of nonobviousness with its initial round of experts reports on February 8 pursuant to Northern District of Illinois Local Patent Rule 5.1, which provides that within a certain time frame “each party shall make its initial expert witness disclosures required by Federal Rule of Civil Procedure 26 on issues for which it bears the burden of proof.” L.P.R. 5.1. TMC additionally contends that Mylan’s failure to disclose the report by the opening report deadline was willful and prejudicial. TMC seeks for the Court to strike Mr. Hofmann’s opinions regarding commercial success, to preclude him from testifying about such issues at trial, and to prohibit Mylan from presenting any evidence related to commercial success. (Pl.’s Mem. 12.)

In response, Mylan argues that TMC has misinterpreted Federal Circuit precedent on the burden of production on commercial success as an indicia of non-obviousness as it relates to the order of disclosure of expert reports. Mylan further argues that TMC has played “hide-and seek” with its commercial success contentions and expert witness throughout the discovery process. Finally, Mylan asserts that any failure to timely disclose Mr. Hofmann’s report was harmless pursuant to Federal Rule of Civil Procedure (“Rule”) 37. (R. 219,

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<sup>1</sup> In Mr. Flammia’s deposition, Counsel for Mylan stated in relevant part that because “TMC supplemented its response on Tuesday to interrogatory number 2 to provide its first contentions concerning commercial success as a factor of secondary considerations of nonobviousness . . . we don’t have any questions about these contentions but we are reserving the right to question a TMC witness on the subject of commercial success should it supplement or change its contentions . . . at a later time.” (Pl.’s Mem., Ex. 11, Flammia Dep. 217.)

## LEGAL STANDARD

### I. Obviousness

“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*, 131 S. Ct. 2238, 2245, 180 L. Ed. 2d 131 (2011) (citing 35 U.S.C. § 282).

### II. Federal Rule of Civil Procedure 37

Rule 37(c)(1) provides that “[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence . . . at a trial, unless the failure was substantially justified or is harmless.” Fed. R. Civ. P. 37(c)(1). Rule 26(a)(1) requires parties to disclose, among other things, “the name . . . of each individual likely to have discoverable information—along with the subjects of that information—that the disclosing party may use to support its claims or defenses . . . .” Fed. R. Civ. P. 26(a)(1)(A). Pursuant to Rule 26(e)(1)(A), “a party who has made a disclosure under Rule 26(a)—or who has responded to an interrogatory, request for production, or request for admission—must supplement or correct its disclosure or response in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect . . . .” Fed. R. Civ. P. 26(e)(1)(A). The exclusion of the untimely disclosed evidence is automatic unless the party seeking to present the evidence can meet its burden that the untimely disclosure was substantially justified or harmless. *Tribble v. Evangelides*, 670 F.3d 753, 759 (7th Cir. 2012). The following factors are relevant to a court’s determination of whether the failure was “substantially justified” or “harmless”: (1) the prejudice or surprise to the party against whom the evidence is offered; the ability of the party to cure the prejudice; (3) the likelihood of disruption to the trial; and (4) the bad faith or willfulness involved in not disclosing the evidence at an earlier date. *Id.* at 760.

## ANALYSIS

In disputing whether Mylan’s disclosure of the Hofmann report was timely, the parties debate whether Mylan or TMC bears the burden of production on commercial success as an “objective” or “secondary” consideration of nonobviousness under Supreme Court and Federal Circuit precedent. TMC argues that the Federal Circuit’s decision in *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063 (Fed. Cir. 2012) upholds the long-standing proposition that the alleged infringer always bears the burden on invalidity defenses. Thus, according to TMC, under Local Patent Rule 5.1, Mylan’s failure to disclose its expert report on commercial success in the initial round of expert reports was untimely. TMC in response contends that *In re Cyclobenzaprine*, as well later Federal Circuit precedent acknowledges that, notwithstanding this allocation of the burden of persuasion, traditionally, the patentee initially bears the burden of production on the issue of commercial success. Because these cases do not precisely address the sequence of expert reports and the issue of whether the timing of Mylan’s disclosure is substantially justified pursuant to Rule 37 is dispositive of the Motion, the Court need not resolve any ambiguity in the interpretation of these cases at this stage.

Even assuming that Mylan's disclosure of its commercial success expert report was untimely, such failure was "substantially justified." TMC contends that it has suffered prejudice because the Hofman report was the "first notice . . . of Mylan's commercial success contentions" and thus TMC "ha[d] been preparing its case with the understanding that Mylan was not addressing commercial success as an indication of nonobviousness." (Pls.' Mem. 10.) Although TMC first indicated in October of 2012 its intention to rely on "commercial success" evidence as an indicia of non-obviousness, TMC did not disclose its expert's opinions on this issue until March 21, 2013, following the Court's deadline for initial and rebuttal expert reports. While TMC is correct that counsel for Mylan indicated at Mr. Flammia's deposition that he did not have any questions on commercial success, TMC had not yet disclosed Mr. Flammia's commercial success opinions. In addition, Mylan's counsel reserved its right to ask such questions at a later time, given that TMC had disclosed its contentions on commercial success only two days earlier.

Moreover, TMC's claim of unfair surprise by the report is unpersuasive. Given TMC's argument that the burden to establish invalidity rests with the alleged infringer at all times, TMC's "understanding [in preparing its case] that Mylan was not addressing commercial success as an indication of nonobviousness" in spite of TMC's indication of its intent to present evidence on this very issue seems questionable, at best. (Pl.'s Mem. 10.) Moreover, any prejudice to TMC from the timing of the disclosure is curable. The Court has already indicated its willingness to allow the parties to conduct the depositions of Mr. Flammia and Mr. Hofmann beyond the May 8 expert discovery cut-off. (R. 233, Minute Order.) Furthermore, the record does not show any evidence of bad faith by Mylan. Indeed, Mylan cites to correspondence showing its attempts to schedule a deposition for Mr. Hofmann and TMC's refusal to do so based upon on the timeliness objections set forth in the Motion. (Defs.' Mem., Ex. 14.) Mylan also served the expert report by the reply expert report deadline of April 8, within the schedule set by the Court for exchange of expert reports. Accordingly, in light of the procedural history of this case, any failure by Mylan to timely serve the report was "substantially justified." See *Sys. Dev. Integration, LLC v. Computer Sciences Corp.*, No. 09-CV-4008, 2012 WL 2953063, at \*3 (N.D. Ill. July 19, 2012) (no substantial justification for untimely disclosure where party failed to "provide any detail regarding when it learned of the new information" or why it failed to disclose the information earlier).

In addition, TMC's reliance on *Sanofi-Aventis v. Barr Labs. Inc.*, 598 F. Supp. 2d 632 (D.N.J. 2009) and the Court's ruling in *Sloan Valve Co. v. Zurn*, No. 10 C 204, Dkt. #490 (N.D. Ill. Mar. 25, 2013) is misplaced. The circumstances in both of these cases are readily distinguishable from those here based upon the sequence of the parties' disclosures and lack of prejudice to TMC. In *Sanofi-Aventis*, for example, the district court—prior to the submission of any expert reports—declined to permit the defendant to address secondary considerations in its reply rather than opening report where the plaintiffs had already provided defendants with "a detailed statement of the factual and legal basis for their respective invalidity and/or non-infringement opinions." *Sanofi-Aventis*, 598 F. Supp. 2d at 637-638. The court further noted that while a defendant should address secondary considerations in an opening report as a general matter, a situation could arise requiring a different outcome where the plaintiff raised an issue in its rebuttal report that it failed to adequately disclose beforehand. *Sanofi-Aventis*, 598 F. Supp. 2d at 637-638. *Sloan* is similarly inapposite. In *Sloan*, the Court struck portions of an amended expert report submitted by Sloan where Sloan failed to seek leave to file an amended report that went beyond a prior ruling by the Court, the amendments were not due to any delay on the part of the opposing party, and the opposing party demonstrated substantial and uncontested evidence of prejudice from the amendments. Thus, TMC's invocation of *Sloan* and *Sanofi-Aventis* in favor of exclusion of the report is unpersuasive.

## **CONCLUSION**

For the foregoing reasons, the Court denies TMC's Motion to strike Mylan's commercial success contentions or expert report. The depositions of Mr. Flammia and Mr. Hofmann must take place on or before June 8, 2013.