

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

REGENERON PHARMACEUTICALS, INC.,

Plaintiff/Counter-Defendant,

v.

CIVIL NO. 1:22-CV-61  
(KLEEH)

MYLAN PHARMACEUTICALS INC.,

Defendant/Counter-Claimant.

MEMORANDUM OPINION AND ORDER DENYING MYLAN'S SECOND  
MOTION TO AMEND [ECF NO. 505] AND GRANTING REGENERON'S  
MOTION FOR JUDGMENT ON THE PLEADINGS [ECF NO. 175]

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Pending before the Court is Mylan's second motion to amend its answer, defenses, and counterclaims [ECF No. 505], which relates to Regeneron's motion for judgment on the pleadings [ECF No. 175]. For the reasons discussed herein, the Court **DENIES** Mylan's motion and **GRANTS** Regeneron's.

Rule 15 of the Federal Rules of Civil Procedure provides that "a party may amend its pleading only with the opposing party's written consent or the court's leave" and that "[t]he court should freely give leave when justice so requires." Leave to amend "should be denied only when the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would have been futile." Sciolino v. Newport News, 480 F.3d 642, 651 (4th Cir. 2007) (citation omitted). The Court finds that Mylan's proposed amendment would

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be prejudicial to Regeneron due to its untimeliness and the volume of new allegations proposed. For these reasons and the reasons discussed during the pretrial conference on May 30, 2023, the Court **DENIES** Mylan's second motion to amend [ECF No. 505].

As for Regeneron's motion for judgment on the pleadings, the Court agrees with Regeneron that Mylan has failed to adequately plead its inequitable conduct defenses and counterclaims. The judicially-created doctrine of inequitable conduct renders a patent unenforceable when an alleged infringer demonstrates that the patent holder engaged in "egregious affirmative acts of misconduct" intended to deceive the PTO or failed to disclose material information to the PTO in seeking the patent. Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1287 (Fed. Cir. 2011). A party alleging inequitable conduct as either a defense or a counterclaim must plead the circumstances of the conduct with particularity. Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1356-57 (Fed. Cir. 2007). The Federal Circuit requires that the pleading party "identif[y] . . . the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1327 (Fed. Cir. 2009). The pleading party must allege facts supporting

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an inference "that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." Id. at 1328-29.

Specifically, the Court finds that Mylan has failed to plead intent. It has not sufficiently pled the "who, what, when, where, and how." See Exergen, 575 F.3d at 1327. Even if Mylan had satisfied intent, Mylan's allegations also fail because the cited statements were attorney argument. "While the law prohibits genuine misrepresentations of material fact, a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct." Rothman v. Target Corp., 556 F.3d 1310, 1328-29 (Fed. Cir. 2009). As such, Mylan has not sufficiently pled its inequitable conduct defenses and counterclaims, and Regeneron's motion for judgment on the pleadings is **GRANTED** [ECF No. 175].

It is so **ORDERED**.

The Clerk is **DIRECTED** to transmit copies of this Order to counsel of record.

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DATED: June 6, 2023

*Tom S. Klee*

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THOMAS S. KLEE, CHIEF JUDGE  
NORTHERN DISTRICT OF WEST VIRGINIA