IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs and Counterclaim Defendants, v. PFIZER INC., Defendant and Counterclaim Plaintiff.	C.A. No. 19-638-CFC [redacted] PUBLIC VERSION FILED - June 14, 2019
PFIZER INC., Counterclaim Plaintiff, v. HOFFMANN-LA ROCHE, INC., Counterclaim Defendant.	

PLAINTIFFS AND COUNTERCLAIM DEFENDANTS' REPLY BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS DEFENDANT'S COUNTERCLAIMS AND TO STRIKE CERTAIN AFFIRMATIVE DEFENSES

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I. INTRODUCTION[1]

The BPCIA establishes a "patent dance" by which biosimilar applicants and reference product sponsors can narrow the scope of patent litigation. In the patent dance, the reference product sponsor must rely on the information the biosimilar applicant provides to decide on which patents to bring suit. Pfizer, by way of its counterclaims and affirmative defenses, wants to change the positions it took, and on which Genentech relied, now that the parties are in litigation. At the same time, Pfizer seeks to avoid the penalties associated with its failure to comply with the patent dance. Instead, Pfizer wants this Court to condone its failure to produce its entire aBLA—a fact ***admitted by Pfizer*** that it now affirmatively ignores—and permit it to assert counterclaims, which themselves assert new invalidity and unenforceability theories that exceed the scope of what Pfizer disclosed in the patent dance. Pfizer also seeks to drop "the atomic bomb of patent law," *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (*en banc*), rendering an issued patent unenforceable for inequitable conduct, for a non-actionable statement, and without pleading the necessary deceptive intent or but-for materiality.

Pfizer's Opposition, D.I. 22, does nothing to address the serious deficiencies raised in Plaintiffs and Counterclaim Defendants' Opening Brief, D.I. 20. Pfizer ignores its own allegations, the case law, and inconvenient facts. Plaintiffs and Counterclaim Defendants' requested relief should be granted, for the reasons provided in D.I. 20 and herein.

II. ARGUMENT

A. Pfizer's Counterclaims Are Barred Due to Non-Compliance with the BPCIA.

1. Pfizer's failure to comply with the requirements of 42 U.S.C. § 262(*l*)(2)(A) are proper grounds for this motion.

Pfizer ignores its own admissions in its Answer by arguing that it "disputes that its

[1] All abbreviations used herein are the same as in D.I. 20.

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