IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

GENENTECH, INC and CITY OF HOPE,))
Plaintiffs,	
V.)
AMGEN INC.,)
Defendant.)

C.A. No. 18-00924-GMS

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS DEFENDANT'S UNENFORCEABILITY COUNTERCLAIMS AND TO STRIKE DEFENDANT'S ELEVENTH AFFIRMATIVE DEFENSE

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Cellectis S.A. v. Precision Biosciences, 883 F. Supp. 2d 526 (D. Del. 2012)
<i>Fowler v. UPMC Shadyside</i> , 578 F.3d 203 (3d Cir. 2009)
<i>Genetic Techs. Ltd. v. Interleukin Genetics Inc.</i> , No. 10-CV-69-BBC, 2010 WL 3362344 (W.D. Wis. Aug. 24, 2010)
Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc., 655 F.3d 1291 (Fed. Cir. 2011)
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<i>IBM v. Priceline Group, Inc.</i> , 2017 U.S. Dist. LEXIS 54285 (D. Del. Apr. 10, 2017)
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I. INTRODUCTION

Amgen has not identified any factual dispute that would prevent the Court from disposing of its unenforceability defenses at the pleadings stage. For the '213 patent, Amgen argues that there is a factual dispute as to whether Genentech's statements to the patent examiner constituted permissible attorney argument or improper material misrepresentations. But Amgen's position cannot be reconciled with long-standing Federal Circuit precedent that an applicant's statements concerning the teachings of the prior art cannot, as a matter of law, support a claim of inequitable conduct so long as the patent examiner was capable of assessing the applicant's arguments on her own. Amgen has not pleaded any facts alleging that the patent examiner here was incapable of fully evaluating Genentech's statements concerning the prior art for herself, and Amgen's unenforceability counterclaim for the '213 patent and related Eleventh Affirmative Defense are therefore legally deficient. Indeed, Amgen does not even engage with the many cases dismissing a defendant's unenforceability counterclaims in exactly these circumstances, and the cases that Amgen does discuss only underscore the need to plead facts alleging that the patent examiner was incapable of evaluating the applicant's arguments (which Amgen has failed to do here).

For the remaining seventeen patents-in-suit, Amgen asserts that it need not meet the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) because there are ways besides inequitable conduct that a patent may be unenforceable. But that does not relieve Amgen of its obligation to plead at least *some* facts supporting its counterclaims, and Amgen does not dispute that it has pleaded none. Instead, Amgen asserts that there are "a number of ways" in which the patents-in-suit might someday become unenforceable—for example, based upon the anticipated expiration of certain patents, or potential future decisions in other proceedings concerning the validity of those patents. But that is pure speculation about future events, and even Amgen cannot say today what its theory of unenforceability for any particular

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