

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC and CITY OF HOPE,

Plaintiffs,

v.

AMGEN INC.,

Defendant.

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) C.A. No. 18-00924-GMS
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**PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR MOTION
TO DISMISS DEFENDANT'S UNENFORCEABILITY COUNTERCLAIMS
AND TO STRIKE DEFENDANT'S ELEVENTH AFFIRMATIVE DEFENSE**

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I. NATURE AND STAGE OF THE PROCEEDINGS

Plaintiff Genentech, Inc. (“Genentech”) invented and developed the drug Herceptin[®], which is a first-of-its-kind biologic therapy that specifically targets a protein associated with an aggressive form of breast cancer. Seeking to profit from this groundbreaking work, Defendant Amgen, Inc. (“Amgen”) is seeking FDA approval to sell a biosimilar version of Herceptin[®]. Because Amgen’s proposed product infringes patents held by Genentech and Plaintiff City of Hope (collectively, “Plaintiffs”)—including patents covering Herceptin[®], methods of using it, and methods of manufacturing it—Plaintiffs sued Amgen for patent infringement on June 21, 2018. D.I. 1. Plaintiffs amended their complaint shortly thereafter to reduce the number of patents-in-suit to eighteen. D.I. 15.

Amgen filed its answer to the amended complaint on August 2, 2018. D.I. 19. As an Eleventh Affirmative Defense, it asserts that “Plaintiffs’ Complaint, and each of its purported causes of action is barred by Plaintiffs’ unclean hands, in view of at least the reasons relating to Genentech’s inequitable conduct.” D.I. 19, Aff. Defs. ¶ 11. In support of that defense, however, Amgen only identifies alleged conduct with respect to one of the eighteen patents that Genentech has asserted, U.S. Patent No. 6,407,213 (“the ’213 patent”). D.I. 19, Aff. Defs. ¶¶ 11-23. Amgen also asserts counterclaims seeking declaratory judgment of unenforceability for each of the eighteen asserted patents. D.I. 19, Countercls., Counts 1-18. But Amgen’s counterclaims include no factual allegations of their own—they simply incorporate the rest of Amgen’s pleading by reference. *See, e.g., id.* ¶¶ 48-54. The only factual allegations about unenforceability in Amgen’s eighteen counterclaims therefore relate to the ’213 patent.

Plaintiffs now move to strike Amgen’s “unclean hands/inequitable conduct” affirmative defense under Federal Rule of Civil Procedure 12(f) and move to dismiss Amgen’s



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