

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 15-61631-CIV-COHN/SELTZER
(CONSOLIDATED WITH 15-62081-CIV-COHN/SELTZER)

AMGEN INC. and AMGEN
MANUFACTURING LIMITED,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

FINAL JUDGMENT

THIS CAUSE came before the Court in a nonjury trial on July 11, 2016 through July 18, 2016, after which the Court found that Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") have not infringed claims 1–3, 6, 7, 13, 15–17, and 22–23 (the "Asserted Claims") of U.S. Patent No. 8,952,138 ("the '138 Patent") held by Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively, "Amgen"). The Court entered separately its Findings of Fact and Conclusions of Law [DE 267].

Pursuant to Federal Rule of Civil Procedure 58, it is hereby

ORDERED AND ADJUDGED as follows:

1. Judgment is entered in favor of Apotex and against Amgen on:
 - a. Amgen's claims of infringement under 35 U.S.C. § 271(e)(2)(C)(i):
Amgen's First Count in each of Amgen's Complaints in this consolidated action [DE 1 in Case No. 15-62081; DE 1 in Case No. 15-61631];

- b. Amgen's claims seeking declaratory judgments of infringement under 35 U.S.C. § 271(g): Amgen's Second Count of Amgen's Filgrastim Complaint [DE 1 in Case No. 15-62081] and Amgen's Third Count of Amgen's Pegfilgrastim Complaint [DE 1 in Case No. 15-61631]; and
 - c. Apotex's counterclaims regarding non-infringement of the '138 Patent: First Counterclaim (Declaratory Judgment of Non-Infringement of the '138 Patent) in each of Apotex's Answers, Affirmative Defenses, and Counterclaims in this consolidated action [DE 47 (incorporating DE 35) in Case No. 15-61631; DE 64 in Case No. 15-61631].
2. Judgment is entered in favor of Amgen and against Apotex on the following issues based on the Court's previous decision on December 9, 2015 [DE 71], the relevant part of which was affirmed by the United States Court of Appeals for the Federal Circuit on July 5, 2016 [DE 259]:
- a. Amgen's claims for Declaratory Judgment that Apotex's Notice of Commercial Marketing Violates 42 U.S.C. § 262(l)(8)(A): Amgen's Fourth Count in each of Amgen's Complaints in this consolidated action [DE 1 in Case No. 15-62081; DE 1 in Case No. 15-61631];
 - b. Apotex's counterclaims for Declaratory Judgment that Subsection (k) Applicants Who Have Complied with 42 U.S.C. § 262(l)(2)(A) May Elect Not to Provide Notice of Commercial Marketing to the Reference Product Sponsor, Subject to the Consequences Set Forth in 42 U.S.C. § 262(l)(9)(B): Apotex's Fifth Counterclaim in Apotex's Pegfilgrastim Counterclaims [DE 47 (incorporating DE 35) in Case No. 15-61631] and

Apotex's second Seventh Counterclaim in Apotex's Filgrastim

Counterclaims [DE 64 in Case No. 15-61631]; and

- c. Apotex's counterclaims for Declaratory Judgment of No Injunctive Relief Under BPCIA: Apotex's Sixth Counterclaim in Apotex's Pegfilgrastim Counterclaims [DE 47 (incorporating DE 35) in Case No. 15-61631] and Apotex's Eighth Counterclaim in Apotex's Filgrastim Counterclaims [DE 64 in Case No. 15-61631].


3. In addition, consistent with the Court's grant of a preliminary injunction in favor of Amgen on December 9, 2015 [DE 71], affirmed by the United States Court of Appeals for the Federal Circuit on July 5, 2016 [DE 259], permanent injunctive relief is appropriate. If the FDA approves Apotex's aBLA for its Pegfilgrastim Product, Apotex must provide Amgen with at least 180 days' notice before the date of the first commercial marketing of the biological product approved by the FDA. 42 U.S.C. § 262(l)(8)(A). Apotex and those acting in concert with it are enjoined from any commercial marketing of Apotex's Pegfilgrastim Product, including selling that product or offering it for sale for use in the United States, until Apotex gives Amgen proper notice, at least 180 days before first commercial marketing but not before Apotex's Pegfilgrastim Product is licensed by the FDA, and the 180-day notice period is exhausted.
4. Likewise, if the FDA approves Apotex's aBLA for its Filgrastim Product, Apotex must provide Amgen with at least 180 days' notice before the date of the first commercial marketing of the biological product approved by the FDA. 42 U.S.C. § 262(l)(8)(A). Apotex and those acting in concert with it are enjoined from any

commercial marketing of Apotex's Filgrastim Product, including selling that product or offering it for sale for use in the United States, until Apotex gives Amgen proper notice, at least 180 days before first commercial marketing but not before Apotex's Filgrastim Product is licensed by the FDA, and the 180-day notice period is exhausted.

5. In addition, judgment is hereby entered in favor of Amgen and against Apotex on Apotex's counterclaim for Declaratory Judgment of Unenforceability of the '138 Patent for Patent Misuse: Apotex's Fourth Counterclaim in Apotex's Pegfilgrastim Counterclaims [DE 47 (incorporating DE 35) in Case No. 15-61631] and Apotex's Sixth Counterclaim in Apotex's Filgrastim Counterclaims [DE 64 in Case No. 15-61631]. Apotex neither provided evidence on this counterclaim at trial nor identified it as a trial issue in the parties' Joint Pretrial Stipulation [DE 217].
6. Apotex's counterclaims regarding invalidity of the '138 Patent for lack of enablement¹—Apotex's Fifth Affirmative Defense (Invalidity) and Second Counterclaim (Declaratory Judgment on Invalidity of the '138 Patent) in each of Apotex's Answers, Affirmative Defenses, and Counterclaims in this consolidated action [DE 47 (incorporating DE 35) in Case No. 15-61631; DE 64 in Case No. 15-61631] —are **DISMISSED without prejudice**.
7. The Clerk of Court is directed to **CLOSE** these cases and **DENY as moot** any pending motions.

¹ The Court previously entered judgment in favor of Amgen and against Apotex on Apotex's Fifth Affirmative Defense and Second Counterclaim in each of Apotex's Answers, Affirmative Defenses, and Counterclaims in this consolidation action [DE 47 (incorporating DE 35) in Case No. 15-61631; DE 64 in Case No. 15-61631] solely with respect to (i) anticipation, (ii) lack of written description, (iii) indefiniteness, and (iv) obviousness. See DE 245.

DONE AND ORDERED in Chambers at Fort Lauderdale, Broward County,
Florida, this 6th day of September, 2016.



JAMES I. COHN
United States District Judge

Copies provided to:
Counsel of record via CM/ECF