

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AMGEN INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS LLC,
et al.,

Defendants.

C.A. No. 16-853 (MSG)
(CONSOLIDATED)

AMGEN INC.,

Plaintiff,

v.

ZYDUS PHARMACEUTICALS (USA)
INC., et al.,

Defendants.

C.A. 17-183 (MSG)

FINAL JUDGMENT [PROPOSED]

This is a consolidated patent infringement action whereby Plaintiff Amgen Inc. (“Amgen”) asserted claims of infringement against Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York LLC (collectively, “Amneal”), Piramal Healthcare UK Ltd. (“Piramal”), Watson Laboratories, Inc., and Actavis Pharma, Inc. (collectively, “Watson”), and Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively “Zydus”).

The Court held a four-day bench trial on infringement between March 5, 2018 and March 9, 2018. (D.I. 375). On July 27, 2018, the Court issued a trial opinion and order holding that

Amneal, Piramal and Watson did not infringe United States Patent No. 9,375,405 (“the ‘405 patent”). (D.I. 375, D.I. 376). The outcome for Zydus, however, was different. The Court held that Zydus did not infringe claims 18 and 20 of the ‘405 patent, but did infringe claims 1-4, 6, 8-9, 15-17, and 19. (D.I. 376).

On August 24, 2018 the Court issued an order and entered judgment of non-infringement of claims 1-4, 6, 8-12, and 14-18 of the ‘405 patent in favor of Amneal and against Amgen, of non-infringement of claims 1-6 and 8-20 of the ‘405 patent in favor of Piramal and against Amgen, and of non-infringement of claims 1-6 and 8-20 of the ‘405 patent in favor of Watson and against Amgen. (D.I. 384, 386).

During trial, Zydus filed a Motion for Judgment Pursuant to Fed. R. Civ. P. 52(c) (“Motion for Judgment”) (D.I. 337). After receiving the Court’s trial opinion, Zydus filed a Motion to Amend the Findings and Judgment of Infringement pursuant to Fed. R. Civ. P. 52(b), 59(e) and 60(b) (“Motion for Reconsideration”). (D.I. 379). The Court has not yet held trial on Zydus’ bifurcated invalidity counterclaims and defenses. Zydus subsequently withdrew its Motion for Judgment and Motion for Reconsideration. (D.I.402,403). An invalidity trial will be scheduled by this Court if necessary following disposition of appeal proceedings.

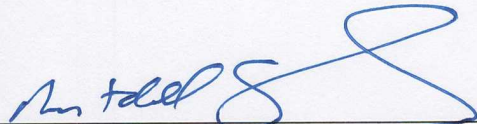
NOW THEREORE, IT IS HEREBY ORDERED that:

1. The invalidity counterclaims and defenses of Zydus (D.I. 99) are DISMISSED without prejudice.
2. In accordance with and for the reasons stated in the Court’s Memorandum Opinion of July 27, 2018 [D.I. 375], judgment is entered in favor of Plaintiff and against Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively, “Zydus”) on Plaintiff’s claim of infringement of claims 1-4, 6, 8-9, 15-17 and 19 of U.S. Patent No.

9,375,405 (“the ’405 patent”) by the cinacalcet HCl tablets, 30mg, 60g, and 90mg, that are the subject of Abbreviated New Drug Application (“ANDA”) No. 208971.

3. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of ANDA No. 208971 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date not earlier than the date of expiration of the ’405 patent, including any extensions and/or additional periods of exclusivity to which Amgen is or becomes entitled. Currently the ’405 patent expires on September 22, 2026.
4. Pursuant to 35 U.S.C. § 271(e)(4)(B), Zydus and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, are hereby enjoined from the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the product that is the subject of ANDA No. 208971 until the expiration date of the ’405 patent.
5. This Judgment as to infringement of the ’405 patent is final and appealable.

Dated: October 9, 2018


UNITED STATES DISTRICT COURT JUDGE