

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,
Plaintiff,
v.
F. HOFFMANN-LA ROCHE LTD, ROCHE
DIAGNOSTICS GmbH, and HOFFMANN-
LA ROCHE INC.,
Defendants.
Civil Action No.: 05 Civ. 12237 WGY
DEFENDANTS' FIRST AMENDED
ANSWER AND
COUNTERCLAIMS TO
PLAINTIFF'S COMPLAINT
DEMAND FOR JURY TRIAL

In response to the Complaint For Declaratory Judgment Of Infringement ("Complaint") filed in this action by Amgen, Inc. ("Amgen"), F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche"), by their attorneys, hereby amend their answer and counterclaims to the Complaint For Declaratory Judgment Of Infringement ("Complaint") of Amgen, Inc. ("Amgen") as follows:

PART I: ROCHE'S ANSWER AND AFFIRMATIVE DEFENSES

In response to the Complaint of Amgen, defendants Roche, by their attorneys, state as follows:

- 1. Roche admits that Amgen is a corporation existing under the laws of the State of Delaware with its principal place of business in Thousand Oaks, California. Roche lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 1 of the Complaint.
2. Admitted.
3. Admitted.
4. Admitted.
5. Roche denies the allegations contained in paragraph 5 of the Complaint.

oral proceedings in Europe. (EP 411 678, EPO Opposition Proceedings , Record of Public Oral Proceedings Before the Opposition Division, dated 12/16/94). Additionally, the claims of the later issued '698, '080, '349 and '422 patents from the same family as the '933 patent, are sufficiently interrelated with the '933 claims and have a substantial relationship with the inequitable acts such that these patents should also be deemed unenforceable under the doctrine of "infectious unenforceability."

Additional Contradictory Statements

84. In addition to the contradictory statements made by Amgen in the 1992 and 1994 Strickland declarations, Amgen and its employees, including even the named inventor of the Amgen EPO Patents, have made numerous statements, in publications and to the FDA, that directly contradict positions Amgen has taken before the PTO during the prosecution of the patents in suit. These additional contradictory statements further evidence Amgen's intent to deceive the PTO. *See Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1319 (Fed. Cir. 2006) ("Intent . . . may be inferred from the totality of the evidence."). Tellingly, Amgen's conduct throughout prosecution reveals a consistent pattern of purposely failing to disclose material information to the examiners. During the prosecution of the '349 and '422 patents, Amgen made no effort to inform the PTO of the then pending litigation against TKT (Civil Act. No. 97-10814-WGY).

85. Lin, the inventor of the patents in suit, reported in a publication that "[r-EPO] has an apparent [molecular weight] of 34,000 when analyzed in an electrophoretic transfer blot." Lin et al, *Cloning and Expression of the Human Erythropoietin Gene*, 82 Proc. Nat'l Acad. Sci., 7580, 7582 (1985). The specification for the '933 patent states that the molecular weight of natural EPO was also "approximately 34,000 dalton." ('933 patent, Col. 5, lines 48-

50). Lin, therefore, knew as of 1985 that the molecular weights of r-EPO and u-EPO were the same, yet, as shown in Example 10 of the '933 patent which issued from an application that was filed in 1995, continued to state that the molecular weight of r-EPO was higher than that of u-EPO.

86. In addition, two Amgen scientists, Dr. Joan Egrie, and Dr. Thomas Strickland, reported in a publication that “Both the purified natural and recombinant EPO preparations were characterized . . . by Western analysis. . . . By Western analysis, the recombinant and human urinary EPO migrate identically.” Egrie et al *Characterization and Biological Effects of Recombinant Human Erythropoietin*, 172 *Immunobiology* 213 (1986). If r-EPO and u-EPO “migrate identically” that means that the two products have the same apparent molecular weight. Therefore, the finding that r-EPO and u-EPO “migrate identically” contradicts Dr. Egrie’s data reported in Example 10 in the '933 patent. This publication, however, was withheld from the Examiner of the '933 patent.

87. Additional internal documents from Dr. Egrie provide evidence regarding glycosylation inconsistent with the positions that Amgen took during prosecution of its patents. (See AM-ITC 00828987-88). This information was never disclosed to the examiner.

88. Another Amgen scientist, Jeff Browne, corroborated the published findings of Egrie and Strickland, stating in a publication that human u-EPO and CHO-cell derived r-EPO migrate identically in SDS-polyacrylamide gels. Browne et al, *Erythropoietin: Gene Cloning, Protein Structure, and Biological Properties*, 51 *Cold Spring Harbor Symposia on Quantitative Biology* 693-702, 698 (1986). This publication also was not disclosed to the Examiner. Additionally, in order to receive approval for its r-EPO drug, Amgen made statements to the FDA that directly contradict the positions Amgen took in arguing patentability

of its EPO claims to the PTO. Significantly, these statements were not submitted to the Examiner of the '933 patent. (*See* Amgen PLA, Vol. 4, pg 762 and Figure 9.C-1 (June 1989)).

EIGHTH DEFENSE - UNCLEAN HANDS

89. The asserted patents are unenforceable due to Amgen's unclean hands.

NINTH DEFENSE - PUBLIC HEALTH AND WELFARE

90. Amgen's request for an injunction precluding Roche from importing into, making, using, or selling CERA in the U.S. is contrary to the public health and welfare.

TENTH DEFENSE - AMGEN IS ESTOPPED FROM SEEKING DAMAGES

91. Amgen has taken the position that it is not seeking damages against Roche related to the accused product in this action.

92. Amgen contends that it is only seeking declaratory and injunctive relief against Roche's alleged acts of infringement.

93. Amgen has alleged that there are current acts of infringement in the United States in connection with the accused product.

94. Based on its decision to forgo damages, Amgen has argued to the Court that Roche is not entitled to a jury trial on Amgen's claims.

95. At the conclusion of the litigation, in the event that Amgen is successful in its claims against Roche and the asserted claims are found to be infringed, valid and enforceable, the Court must undertake an analysis mandated by the United States Supreme Court's decision in *eBay, Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006), to determine if a permanent injunction would be appropriate.

96. Based on Amgen's decision to waive any damages, compensatory or otherwise, as a tactic to deprive Roche of its constitutional right to a jury trial on Amgen's claims (even though Roche contends that they are entitled to a trial by jury), Amgen is estopped and