EXHIBIT 3

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMGEN INC.,)
Plaintiff,)) Chill Assista No. 05 10027 WGW
v.) Civil Action No.: 05-12237 WGY
F. HOFFMANN-LA ROCHE)
LTD., a Swiss Company, ROCHE)
DIAGNOSTICS GmbH, a German Company and HOFFMANN-LA ROCHE)
INC., a New Jersey Corporation,)
Defendants.)
)

EXPERT REPORT OF HARVEY F. LODISH, Ph.D. REGARDING INFRINGEMENT

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117. It is also my opinion that the EPO polypeptide in peg-EPO is equivalent to the claimed EPO polypeptide of the '080 claims because the single-amino-acid difference between the claimed 166-amino-acid glycosylated EPO polypeptide covered by those claims and Roche's 165-amino-acid glycosylated EPO polypeptide is insubstantial as found by this Court in the Amgen v. HMR/TKT lawsuit. Moreover, if there were any relevant differences between Roche's peg-EPO and the claimed EPO products of the other claims of Amgen's Patents, it is my opinion that any such differences would be insubstantial. Roche's peg-EPO and the claimed EPO products of Amgen's Patents perform the same function in the same way to achieve the same result.²⁷

VII. BASES FOR INFRINGEMENT OPINIONS

118. I understand that the parties dispute the meanings of certain terms in the Asserted Claims of Amgen's Patents. For purposes of my analysis, I have applied, where applicable, the claim constructions previously adopted by this Court in the *Amgen v. HMR* lawsuit. Where a term or limitation has not been previously construed by the Court, I have reviewed the claim constructions offered by Amgen to determine whether Amgen's proposed constructions are consistent with how one of ordinary skill in the art in 1983/1984 would have understood the claim terms from a scientific perspective.²⁸ Based upon my review, it is my opinion that Amgen's proposed constructions are consistent with how one of ordinary skill in the art would have understood the meaning of the claim terms. I previously submitted a declaration in support

²⁷ I understand that the Federal Circuit in *Amgen v. HMR/TKT* held Amgen was estopped from claiming equivalents under the '080 patent, but that Amgen is challenging that ruling before the U.S. Supreme Court.

²⁸ As I have previously opined, it is my opinion that a person of ordinary skill in the art in 1983/1984 was a research scientist with a Ph.D. or M.D. and at least two years of postdoctoral research experience in the field of molecular biology, cellular biology, biochemistry, and/or protein expression.

products – activating EPO receptors to initiate the JAK2/STAT5 signaling pathway. Neither peg-EPO's increased half-life in the bloodstream nor its reduced binding affinity represent a significant difference or fundamental change in principle with respect to how peg-EPO functions. MIRCERATM is also a pharmaceutical composition that is not changed in principle from, performs the same function as, and achieves the same result in substantially the same way as the pharmaceutical compositions claimed in the Amgen Patents, because it contains the glycosylated human EPO polypeptide that functions in the same way to achieve the same result as the human EPO claimed in the Amgen Patents.

Executed this 6th day of April, 2007 at Boston, Massachusetts.

HARVEY F LODISH PH D