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DUANE MORRIS BOSTON

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**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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AMGEN INC.,

Plaintiff,

v.

HOECHST MARION ROUSSEL, INC.

and

TRANSKARYOTIC THERAPIES, INC.,

Defendants.

Civil Action

No. 97-10814-WGY

U.S. DISTRICT COURT
DISTRICT OF MASS.

**AMGEN INC.'S POST-HEARING MEMORANDUM IN SUPPORT
OF ITS FED. R. CIV. P. 52(C) MOTION THAT '080 CLAIMS 2-4 ARE
INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS**

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I. INTRODUCTION

Prosecution history estoppel does not bar Amgen's claims for infringement of its '080 patent under the Doctrine of Equivalents. Amgen "could not reasonably be expected to have described the insubstantial substitute in question," either in its application as originally filed or in any claim amendment. In addition, the rationale underlying Amgen's amendment of its claims — to avoid a double-patenting rejection over the EPO glycoprotein claims in its '933 patent — bears "no more than a tangential relation" to the particular 165 amino acid equivalent in question. Finally, the record demonstrates that Amgen did not intend the sequence amendment to exclude or distinguish over EPO having the 1-165 amino acid sequence of Figure 6 ("165 human EPO"). For all of these reasons, the presumption of estoppel has been rebutted.

During the July 28 hearing, the Court questioned whether Amgen could have amended its '080 claims to expressly recite the 1-165 amino acid sequence of Figure 6.¹ As Amgen's counsel stated at the hearing, the answer to that question is no. When Amgen drafted and filed its patent application, it was unknown and unforeseeable that the human EPO product of example 10 in the patent had 165 amino acids rather than the deduced 166 amino acid sequence shown in Figure 6. Because this fact was unknown in 1984 when the written description of Amgen's specification was drafted and submitted, the specification did not expressly recite an EPO having the 1-165 sequence. As explained more fully in Section II(A) below, the absence of an express description of that specific sequence in Amgen's application made a later claim amendment reciting that specific sequence impermissible.

¹ See, e.g., 7/31/03 Hearing Transcript at p. 81, lines 4-9.

CERTIFICATE OF SERVICE

I, Michael R. Gottfried, hereby certify that on August 18, 2003, I caused a copy of the following document:

- a) Amgen Inc.'s Post-Hearing Memorandum in Support of its Fed. R. Civ. P. 52(C) Motion that '080 Claims 2-4 are Infringed Under the Doctrine of Equivalents.

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