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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**

cannot add new written description, whether in the specification or in the claims themselves, to describe a particular equivalent that became foreseeable after the application date but before the date of an amendment. The applicant is constrained by the original written description and drawings that were in the application at the filing date.¹¹ To subsequently add a description of the later-discovered equivalent — in this case, the fact that the product of example 10 has only 165 amino acids — would violate the statutory prohibition against adding new matter to the application. That is why it is the date of the application, not the date of the amendment, that is the appropriate point in time at which to judge whether the applicant could have foreseen, and therefore could have described, a particular equivalent.¹²

Here, as shown in Amgen's motion and as explained at the July 28 hearing, the record indisputably establishes that at the time Dr. Lin filed his application, neither he nor anyone of ordinary skill could have foreseen that the mature human erythropoietin glycoprotein produced in Example 10 would contain only the 1-165 amino acid sequence of Figure 6. Defendants do not dispute this fact. Amgen's Rule 52(c) motion can be granted on this ground alone.

The fact that 165 human EPO was not foreseeable at the date of the application, and therefore not literally described in Amgen's specification, also explains why, even under Defendant's test, Amgen could not reasonably have been expected to submit a claim amendment

¹¹ See, e.g., M.P.E.P §§ 608.01(g) and (o), 2163(B) and 2163.05-.06.

¹² Defendants' fall-back position, that foreseeability should be judged as of the June 6, 1995 filing date of the '556 application that issued as the '080 patent, should also be rejected. Under 35 U.S.C. § 120, the effective filing date, *i.e.*, "time of the application," for the '556 application is at least as early as the filing date of the last priority application from which it is a direct continuation, *i.e.*, the November 30, 1984 filing date of application Ser. No. 06/675,298 ("An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application. . . .").

Dated: August 18, 2003

For the Plaintiff, AMGEN INC.

By:



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