EXHIBIT F

IN THE UNITED STATES DISTRICT COURT
FOR THE 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-cv-12237 WGY

REDACTED

CONTAINS RESTRICTED ACCESS BLA/IND CONFIDENTIAL INFORMATION

SUBJECT TO PROTECTIVE ORDER

NON-INFRINGEMENT EXPERT REPORT OF RICHARD A. FLAVELL, PH.D.

REDACTED

134. In addition, host cells of the asserted process claims all specify the use of "mammalian host cells" or "vertebrate cells" for the production of a "glycosylated erythropoietin polypeptide" or "erythropoietin." It is possible to use non-mammalian, non-vertebrate host cells to produce the products of the claimed process, however. For example, Hamilton *et al.* describe the creation of yeast cells that express and secrete glycoproteins having human-like glycosylation patterns.[175] These yeast cells could be transformed or transfected with a DNA sequence encoding human erythropoietin to produce a glycosylated erythropoietin polypeptide according to the claims. Importantly, these cells were capable of expressing and secreting a polypeptide with terminal sialic acids intact.[176] In fact, using human erythropoietin as an example of "heavily glycosylated

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[175] Hamilton, S.R., et al. (2006) *Science*, 313: 1441-43.

[176] *Id.* The authors refer to this last step as the "the most complex step of human N-glycosylation."

protein," the authors showed that biologically active human erythropoietin could be expressed in yeast cells.[177] These results demonstrate commercial viability because the work was done with several authors affiliated with Glyco-Fi, Inc. a biotechnology company now a wholly-owned subsidiary of Merck. Because yeast cells are neither vertebrate nor mammalian and, the limitations of the claimed process would not be met and would not infringe.

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[177] *Id.*