

Exhibit C
Amgen's Legal Standards and Burden of Proof

VI. ISSUES OF LAW, INCLUDING EVIDENTIARY QUESTIONS, TOGETHER WITH SUPPORTING AUTHORITY

A. Amgen's Position

1. Legal Standards and Burden of Proof¹

Infringement. Amgen must prove, by a preponderance of the evidence, that Roche's manufacture, use, sale, offer to sell, or importation of glycosylated recombinant human erythropoietin, glycosylated recombinant human erythropoietin-containing products, "RO0503821," "Ro 050-3821," "R744," "Continuous Erythropoiesis Receptor Activator," "CERA," "pegserepoetin alfa," "methoxy polyethylene glycol-epoetin beta," or "MIRCERA®" (hereinafter referred to as "peg-EPO") will satisfy every limitation of the claims-in-suit either literally or under the Doctrine of Equivalents. *See* 35 U.S.C. § 271; *Cross Med. Prods. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310 (Fed. Cir. 2005).

Invalidity. The patents-in-suit are presumed valid. *See* 35 U.S.C. § 282. Roche must prove, by clear and convincing evidence, that the patents-in-suit are invalid. *See Robotic Vision Sys. V. View Eng'g, Inc.*, 189 F.3d 1370, 1377 (Fed. Cir. 1999). Section 282 states: "Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims . . ." Therefore, the invalidity of each claim must be proved independently, and "a party challenging the validity of a claim . . . must submit evidence supporting a conclusion of invalidity of each claim the challenger seeks to destroy."

¹ Amgen disagrees with numerous mischaracterizations of the law in Roche's Issues of Law statement. Amgen intends to file bench memos identifying and correcting these mischaracterizations.

Shelcore, Inc. v. Durham Indus., Inc., 745 F.2d 621, 625 (Fed. Cir. 1984); *see also Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.2d 1358, 1370-1371 (Fed. Cir. 2003).

Unenforceability. To establish that the patents-in-suit are unenforceable based on inequitable conduct, Roche must prove, by clear and convincing evidence, the misrepresentation or withholding of a material fact from the Patent Office with an intent to deceive. *See FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987); *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988).