

The Court's adjudication that Roche's MIRCERA® meets this limitation is the law of the case.² Further, Rule 56(d) specifies that where there has been a partial adjudication of "facts that appear without substantial controversy Upon the trial of the actions, *the fact so specified shall be deemed established, and the trial shall be conducted accordingly.*"³

The Court's adjudication that MIRCERA® comprises "human erythropoietin" is factually established in this case and the trial should be conducted accordingly. The Court has construed "human erythropoietin" to mean "*a protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine.*"⁴ Thus, the Court determined as a matter of law that the MIRCERA® composition comprises a protein having the amino acid sequence of human EPO.

Roche's graphics for its opening argument show that it is plainly intending to argue that MIRCERA does not comprise human EPO, *i.e.*, a protein having the amino acid sequence of human EPO. Roche is precluded from contradicting the Court's factual determination as a matter of law that MIRCERA® comprises "human erythropoietin." Thus, the trial should be conducted such that Roche may not present any argument, evidence, or witness testimony that MIRCERA® does not contain "human erythropoietin," including the argument (1) that MIRCERA® has a different amino acid sequence than human erythropoietin or (2) that MIRCERA® does not comprise a protein, or (3) that MIRCERA® does not contain a protein having the amino acid sequence of human EPO.

² *United States v. Medina*, 219 Fed. Appx. 20, 21-22 (1st Cir. 2007) (Under the relevant branch of the law of the case doctrine, "a legal decision made at one stage of a civil or criminal proceeding . . . remain[s] the law of that case throughout the litigation, unless and until the decision is modified or overruled by a higher court.") (citing *United States v. Moran*, 393 F. 3d 1, 7 (1st Cir. 2004)).

³ Fed. R. Civ. P. 56(d) (emphasis added).

⁴ *Amgen Inc., v. F.Hoffman-La Roche Ltd.*, 494 F. Supp. 2d 54, 64 (D. Mass. 2007) (the Court's Claim Construction Order). *See also id.* (confirming that "human erythropoietin" is "open" and contemplates that additional molecules may be attached).

If Roche is permitted to present evidence that MIRCERA does not contain a protein having the amino acid sequence of natural EPO, Amgen should be permitted to inform the Jury of the Court's adjudication to the contrary.

DATED: October 2, 2007

Respectfully Submitted,

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