Exhibit A

XIII. INFRINGEMENT [MODIFIED]

A. 2. Proposed Instruction for Infringement of '868 Claims 1-2, '698 Claims 6-9, and '349 Claim 7

'868 claims 1 and 2, '698 claims 6-9, and '349 claim 7 are process claims. Amgen contends that Roche will infringe the asserted process claims by practicing these patented processes for making EPO in Germany, and then importing the EPO product produced by those processes into the United States.

To determine infringement of the asserted process claims, you must first determine whether Roche's process for making EPO in Germany satisfies all of the elements of the asserted process claims. The fact that MIRCERA may contain elements beyond those contained in the product of Amgen's claimed process, or that Roche uses steps beyond those recited in a patented process claim to produce MIRCERA, does not mean that Roche's process does not satisfy all of the elements of an asserted process claim. An accused process that uses every step of the claimed process infringes the claim regardless of whether other steps are used as well, or the imported product contains additional elements or features beyond those produced by the claimed process.

If you find that Roche's process for making EPO satisfies every element of an asserted process claim, you must then determine whether the EPO product of the claimed process is materially changed by Roche prior to its importation of MIRCERA into the United States. If you find, for example, that the EPO product contained in MIRCERA is materially changed by the attachment of polyethylene glycol, then Roche will not infringe the asserted process claim. A material change is a significant change to the structure and properties of the EPO product, which changes the basic utility of the EPO product. The attachment of additional structure to the EPO product of the claimed process is not a material change to the product of the process unless it changes the structure and properties of the EPO product in a way that alters the basic utility of the EPO product. Even a significant change to the structure and properties of the EPO product

will not be a "material change" if it would not be possible or commercially viable to make MIRCERA but for the use of Amgen's patented process.

You must also determine whether the EPO contained in MIRCERA is a trivial and non-essential component of MIRCERA. If you find that it is, then Roche will not infringe the asserted process claim.

Therefore, in order to find that Roche will infringe an asserted process claim, you must find that (1) Roche's process for making MIRCERA in Germany includes every element of an asserted process claim, (2) the EPO product of the claimed process is not materially changed by Roche, and (3) the EPO product in MIRCERA is not a trivial and non-essential component of MIRCERA.

Sources & Authorities

35 U.S.C. 271(g); *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703 (Fed. Cir. 1983); *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482-83 (Fed. Cir. 1984); *Oki America, Inc. v. Advanced Micro Devices, Inc*. No. C-04-3171, 2006 WL 2711555 (N.D. Ca., Sept. 21, 2006); *Eli Lilly & Co. v. American Cyanamid*, 82 F.3d 1568, 1571, 1573, 1575 (Fed. Cir. 1996).