

Exhibit A

EXHIBIT A

SUPPLEMENTAL PROPOSED JURY INSTRUCTIONS

XII. C. PROCESS AND SOURCE LIMITATIONS IN PRODUCT CLAIMS

Sometimes a product may best be described by the process by which it is made, or by the source from which it is derived, instead of by describing its structure or chemical characteristics. Claims which describe a product by describing the process by which it is made are called “product-by-process” claims.

Claims 3, 7-9, 11, 12 and 14 of the ‘933 patent are product-by-process claims or depend from product-by-process claims. Claim 1 of the ‘422 patent is not, however, a product-by-process claim; it is a product claim with a source limitation. The “purified from mammalian cells grown in culture” limitation of ‘422 Claim 1 “only speaks to the source of the EPO and does not limit the process by which the EPO is expressed.” *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 13131, 1329 (Fed. Cir. 2003).

SOURCES & AUTHORITIES:

Fed. Cir. Bar Assoc. Model Patent Jury Instructions 7.3; *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372-73 (Fed. Cir. 2000); *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557-58 (Fed. Cir. 1995); *Mentor Corp. v. Coloplast, Inc.*, 998 F.2d 992, 997 (Fed. Cir. 1993); *All. Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 837 (Fed. Cir. 1992), reh’g en Banc denied, 974 F.2d 1279 (Fed. Cir. 1992); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991).

XIV. I. ANTICIPATION – EFFECT OF PROCESS OR SOURCE LIMITATIONS

Where the structure and/or function of a claimed product is novel, in other words new and not found in the prior art, the product may be claimed by reference to the source or process from which it is obtained without regard to the structure of the product if the source or process limitations help to distinguish the claimed product over prior art. Product claims may include process steps to wholly or partially define the claimed product. Similarly, product claims may

include source limitations to wholly or partially define the claimed product. To the extent that these source or process limitations distinguish a novel product over the prior art, they must be given the same consideration as traditional product characteristics.

During prosecution of the '422 and '933 patents, the examiner accepted that the claimed products were novel, and that process or source limitations within the issued claims properly defined the scope of the claimed inventions. To establish that the source limitation of '422 claim 1 does not distinguish the claimed invention over the prior art, Roche must first prove by clear and convincing evidence that the claimed product is not novel. That is, Roche must prove that the identical product previously existed in the prior art. So, for example, Roche must prove by clear and convincing evidence that the claimed product, recombinant EPO purified from mammalian cells grown in culture, is identical to a prior art EPO product, such as Dr. Goldwasser's EPO product purified from urine.

Similarly, to establish that the process limitations of claims 3, 7-9, 11, 12 and 14 of the '933 patent do not distinguish the claim over the prior art, Roche must first prove by clear and convincing evidence that the claimed product in each of those claims is not novel.

SOURCES & AUTHORITIES:

Amgen Inc. v. F. Hoffmann-La Roche, Civ. Action No. 05-12237, Doc. No. 613 July 3, 2007 Memorandum and Order at 18; *In re Luck*, 476 F.2d 650, 653 (C.C.P.A. 1973); *Amgen v. Hoechst Marion Roussel*, 314 F.3d 1313, 1329 (Fed. Cir. 2003); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1304 (Fed. Cir. 2006); *Sandt Technology v. Resco*, 264 F.3d 1344, 1350 (Fed. Cir. 2001); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996) ; *Sinsky v. Pharmacia Ophthalmics, Inc.*, 982 F.2d 494, 498-99 (Fed. Cir. 1992); *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1445 (Fed. Cir. 1984); *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1567 (Fed. Cir. 1983).