Exhibit A

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. Claims which describe a product by reference to the source from which the product is obtained are called "source" claims. Claim 1 of the '422 patent is a product claim with a source element. (The "purified from mammalian cells grown in culture" element of '422 Claim 1 "only speaks to the source of the EPO and does not limit the process by which the EPO is expressed.")

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); *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1329 (Fed. Cir. 2003).

XIV.I. ANTICIPATION – EFFECT OF PROCESS OR SOURCE LIMITATIONS [MODIFIED]

A 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 elements help to distinguish the claimed product over prior art. Product claims may include process steps to wholly or partially define the claimed product. A product claim that contains source elements or product-by-process elements must be given the same consideration as claims having traditional product characteristics.

To establish that the source element 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 a product identical to the claimed product previously existed in the prior art. So, for example, Roche must prove by clear and convincing evidence that Dr. Goldwasser's EPO product purified from urine is identical in structure and function to "human EPO purified from mammalian cells grown in culture," as recited in 422 claim 1.

Similarly, to establish that the process elements of claims 3, 7-9, 11, 12 and 14 of the '933 patent do not distinguish the claimed inventions over the prior art, Roche must first prove by clear and convincing evidence that Dr. Goldwasser's EPO product purified from urine is identical in structure and function to the products claimed in each of those claims.

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); *Sinskey 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).