

Exhibit A**XIII. INFRINGEMENT [MODIFIED]****A. INFRINGEMENT GENERALLY [MODIFIED]**

This is the test for infringement: does the alleged infringing product contain every element of the patent claim? If only one element of the claim is missing from the accused product or process, there is no infringement, even if all the other elements of the claim are present.

If the accused product contains other things beyond the elements of the claim, or if the accused process includes other steps beyond those stated in the claim, it still infringes so long as the accused product or process has every element or step of the claim. If the accused product or process is improved, made better or more sophisticated, it still infringes so long as it has every element or step of the claim. Miss an element and there is no infringement. But add to the elements or make the elements better, and there is still infringement so long as Roche's MIRCERA has every element of an Amgen patent claim.

To prove infringement, it is Amgen's burden to prove by a fair preponderance of the existence that MIRCERA or the process by which MIRCERA is made includes every element of an Amgen product or process claim.

Amgen's burden is not clear and convincing proof. Rather, it is by a fair preponderance of the evidence. On all the evidence you believe does the evidence tend to prove that it is more likely than not that Roche's MIRCERA product infringes every element of the claim? That's infringement.

When you get to the dependent claims, you must consider both the referenced claim and the dependent claim together. If you find that that referenced claim is infringed, you still must separately determine whether the claim which depends from it will also be infringed. You have to go back to the referenced claim, and consider every element of the referenced claim plus the dependent claim.

Sources & Authorities

Ethos Techs., Inc., v. RealNetworks, Inc., No. 02-11324 (4/12/06 Trial Tr. at 2694:21-2697:16; 2710:2-11); *Read Corp.* Instruction, p. 26; Fed. Cir. Bar. Assoc Model Patent Jury Instruction 8.10.

1. Proposed Instruction for Infringement of '933 Claims 3, 7-9, 11 and 12

'933 claims 3, 7-9, 11 and 12 are product-by-process claims or depend from product-by-process claims. A product-by-process claim describes a product by reference to the process by which the product is made, not by reference to the particular structure or function of the claimed product. In order for MIRCERA to infringe a product-by-process claim, you must find that Amgen has proved by a fair preponderance of the evidence that MIRCERA contains the claimed product made by the same process described in the claim. The fact that MIRCERA may contain additional elements, including elements not made by the process recited in the claims, does not mean that MIRCERA does not infringe the claim. Like a product claim, a product-by-process claim is still infringed by a product that meets every element of claim, even if the accused product also contains elements beyond those stated in the claim.

Sources & Authorities:

Fed. Cir. Bar Assoc. Model Patent Jury Instructions 8.9; *Atl. Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 837 (Fed. Cir. 1992); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991); *Northern Telecom Ltd. v. Samsun Elec. Co.*, 215 F.3d 1281 (Fed. Cir. 2000); *Suntiger, Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1336-37 (Fed. Cir. 1999); *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); *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1177-79 (Fed. Cir. 1991)

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).

3. Proposed Instruction for Infringement of '933 Claims 11 and 14

The act of encouraging or inducing others to infringe a patent is called “inducing infringement.” In this case, Amgen asserts that Roche will induce others to infringe the methods of treatment claimed in claims 11 and 14 of the '933 patent as soon as it receives regulatory approval to sell MIRCERA in the United States.

There can be no inducement of infringement unless someone will directly infringe the patent. Thus, in order to prove that Roche will induce another person to infringe '933 claims 11 and 14, Amgen must prove by a fair preponderance of the evidence that another person will directly infringe claims 11 or 14 and that Roche will induce that infringement.

A person induces patent infringement if he or she purposefully causes, urges or encourages another to perform an act that infringes a patent claim and knows or should have known that his or her actions would induce actual infringement. Inducing infringement cannot occur unintentionally.

Amgen asserts that Roche will induce infringement of '933 claims 11 and 14. Amgen must prove by a fair preponderance of the evidence that:

Roche has or will encourage or instruct another person to use the method described in '933 claim 11 or 14.

Roche knows of the '933 patent.

Roche knows or should know that its encouragement or instructions will induce others to use MIRCERA in a manner that will infringe '933 claim 11 or 14.

The other person will use MIRCERA to perform the method described in '933 claim 11 or 14.

Sources & Authorities

Fed. Cir. Bar Assoc. Model Patent Jury Instruction 8.12, 8.12.1; 35 U.S.C. § 271(b) (1984); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 340-41 (1961); *DSU Medical Corp. v. JMS Co., Ltd.*, 471 F.3d 1293 (Fed. Cir. 2006) (en banc); *Arthur A. Collins, Inc. v. N. Telcom Ltd.*, 216 F.3d 1042, 1049 (Fed. Cir. 2000); *Porter v. Farmers Supply Serv., Inc.*, 790 F.2d 882, 884-86 (Fed. Cir. 1986); *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1261 (Fed. Cir. 1999); *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1311-12 (Fed. Cir. 1998); *Joy Tchs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774-76 (Fed. Cir. 1993); *DSU Medical Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006).