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Amgen v. Sanofi: Implications for the Enablement Standard

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In 2014, Amgen Inc. sued Sanofi and others for infringement of multiple patents covering technology related to monoclonal antibody therapies for treating high cholesterol. Sanofi et al. argued noninfringement because the claims were not enabled due to being overly broad, despite Amgen's patent disclosure including more than 400 pages describing the genetic and polypeptide sequences for 26 antibodies and providing CDs detailing the X-ray crystallography coordinates for 2 antibodies used in their drug Repatha. The jury for the District Court initially found that Amgen's patents, including the genus claims therein, were not invalid for lack of enablement. However, the Federal Circuit held that the jury instructions regarding enablement were erroneous. On remand, the District Court ruled that Amgen's patents were invalid for lack of enablement, with the Federal Circuit affirming. The Supreme Court granted certiorari and the case was decided in May 2023, with this being the only patent case the Supreme Court heard in 2023.

The Federal Circuit's interpretation of the enablement standard has shifted over the past three decades, especially in regard to the unpredictable arts including chemical, pharmaceutical, and biotechnological arts which have substantially relied on genus claims to protect their innovations. Not long ago, the Federal Circuit upheld broad genus claims in the unpredictable arts, illustrated in cases such as *In re Angstadt*, 537 F.2d 498 (C.C.P.A. 1976), *Atlas Powder Co. v. E.I. du Pont De Neours & Co.,* 750 F.2d 1569 (Fed. Cir. 1984), and *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). However, beginning in the 1990s the Federal Circuit began to require a more commensurate disclosure to uphold broad genus claims, finally requiring a disclosure sufficient to teach a skilled artisan how to distinguish operative embodiments from inoperative embodiments without undue experimentation. Cases such as *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991), *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362 (Fed. Cir. 1999), *Wyeth v. Abbott Laboratories*, 720 F.3d 1380 (Fed. Cir. 2013), and *Idenix Pharms LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019) illustrate this change. Thus, the enablement standard has changed from a test regarding whether the patentee has taught a skilled artisan how to make and use the invention to a test regarding whether the patentee was in possession of the full scope of the invention at the time of filing. Despite these changes, patent drafters have continued to write, and the United States Patent and Trademark Office have continued to grant, broad genus claims for the unpredictable arts.

Ultimately, the Supreme Court affirmed the rulings of the Federal Circuit and District Court, holding that the Amgen's broad genus claims were not sufficiently enabled by the specification and were thus invalid. In so ruling, the Supreme Court has essentially upheld the changes to the enablement standard the Federal Circuit has implemented over the preceding three decades.

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