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Unpredictability In The Art: Amgen v. Sanofi In View Of "Simultaneous Conception And Reduction To Practice"

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After reading the Supreme Court's decision in *Amgen v. Sanofi*, I thought of the doctrine of simultaneous conception and reduction to practice, given both the decision's and the doctrine's focus on unpredictability in the art.

An invention has two parts: conception and reduction to practice. An inventor conceives of claimed subject matter. Reduction to practice typically does not correlate with inventive activity. Simultaneous conception and reduction to practice can occur in unpredictable research areas. According to the doctrine, "there is no conception until the invention has been reduced to practice." *MacMillan v. Moffett*, 432 F.2d 1237, 1234-40; see also *Hitzeman v. Rutter*, 243 F.3d 1345 (Fed. Cir. 2001) (conception simultaneous with reduction to practice where appellant lacked reasonable certainty that yeast's performance of certain intracellular processes would result in the claimed antigen particles). Conception is not complete "if subsequent experimentation reveals factual uncertainty which 'so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice.'" MPEP 2138.04 [citing *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223,

1229 (Fed. Cir. 1994)].

In *Amgen*, the claims were directed to antibodies described by their binding and blocking functions rather than their structure. Whether Amgen's antibodies could have been expected to have particular functionality was unpredictable, as noted in *Amgen*:

> Despite recent advances, aspects of antibody science remain unpredictable. For example, scientists understand that changing even one amino acid in the sequence can alter an antibody's structure and function. [Citation omitted]. But scientists cannot always accurately predict exactly how trading one amino acid for another will affect an antibody's structure and function. [Citation omitted]. As Amgen's expert testified at trial: '[T]he way in which you get from sequence to that three-dimensional structure isn't fully understood today. It's going to get a Nobel Prize for somebody at some point, but translating that sequence into a known three-dimensional structure is still not possible.' [Internal quotation omitted]."

The Supreme Court ruled that Amgen's trial-and-error process of making and then screening antibodies to determine if they possessed the necessary binding and blocking functions did not enable production of the antibodies without undue experimentation. The Court reasoned that forcing scientists to engage in "painstaking experimentation" is not enablement – it is merely a "hunting license."

In the context of simultaneous conception and reduction to practice, Amgen's inventors arguably did not have a "definite and permanent reflection of the **complete** invention" in the claims – could Amgen's inventors have conceived of (invented) antibodies

over the **complete** claim scope defined by functionality if they had not yet reduced antibodies to practice commensurate with such scope? In an unpredictable area such as antibody research, should the inventors have been entitled to patent protection for such non-conceived and non-reduced-to-practice antibodies under these circumstances?

Indeed, as reflected in Amgen's penultimate paragraph, the Supreme Court stated:

> Finally, Amgen warns that an affirmance risks 'destroy[ing] incentives for breakthrough inventions.' [Citation omitted]. But striking the proper balance between incentivizing inventors and ensuring the public receives the full benefit of their innovations is a policy judgment that belongs to Congress. Since 1790, Congress has included an enablement mandate as one feature among many designed to achieve the balance it wishes. Our only duty in this case lies in applying that mandate faithfully.

Would the proper balance have been struck if Amgen's inventors had been granted patent protection for antibodies they had yet to conceive/reduce to practice? Would the public have received the full benefit of the complete invention? Simply stated, if Amgen's inventors had not yet conceived of subject matter, could they properly obtain patent protection for such subject matter?

Examining the *Amgen* decision through the looking glass of conception, in particular simultaneous conception and reduction to practice in an unpredictable area, provides a different vantage point from which to analyze or interpret the decision.

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