Functional Claiming[1]

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Biotech Enablement

Amgen Inc. v. Sanofi, 598 U.S. 594 (May 18, 2023)

In this appeal from the District of Delaware, the Federal Circuit affirmed that the disputed claims were invalid under the enablement requirement because they were broad functional claims with little guidance on how to recreate the invention without undue experimentation.[5] The Supreme Court affirmed.

Amgen's '165 and '741 patents describe antibodies which bind to proprotein convertase subtilisin/kexin type 9 enzymes ("PCSK9") and prevent them from binding to low-density lipoprotein ("LDL") receptors with the goal of lowering LDL cholesterol levels.[6] The specification lists amino acid sequences for twenty-six antibodies and claims antibodies that bind at least one of fifteen amino acids on the PCSK9 protein.[7] At trial, the jury found Sanofi had not proven the patents invalid.[8] The court, however, ultimately granted Sanofi's motion for judgment as a matter of law for lack of enablement.[9] The Federal Circuit affirmed.

The Supreme Court unanimously affirmed the Federal Circuit's requirement that a genus claim must enable the full scope of the genus. While Amgen had disclosed several hundred working examples, the claim potentially covered millions of antibodies. The Court found that the disclosed methods for making unspecified antibodies were nothing more than "research assignments" which would force scientists to engage in lengthy trial-and-error to discover working alternatives beyond the twenty-six disclosed examples.[10] The Court concluded that these trial-and-error methods posed too heavy an experimentation burden to enable Amgen's genus claim.[11]

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[5] *Amgen Inc. v. Sanofi*, 987 F.3d 1080 (Fed. Cir. 2021).
[6] *Id.* at 1083 (citing U.S. Patent Nos. 8,859,741 and 8,829,165).
[7] *Id*
[8] *Id*.
[9] *Id.*
[10] *Id.* at 614.
[11] *Id.*

***United Therapeutics Corporation v. Liquidia Technologies, Inc.*, 74 F.4th 1360 (Fed. Cir. July 24, 2023)**

In this appeal from the District of Delaware, the Federal Circuit affirmed a finding that several claims in United Therapeutics' patent directed to an inhaled solution for the treatment of pulmonary hypertension ("PH") were enabled by the patent's specification.[12] Medical experts consider there to be five subgroups of PH, and Liquidia contended that the specification did not explain how Group 2 PH patients would benefit from the disclosed treatment and even indicated the treatment would be unsafe for this group, therefore forcing a skilled artisan to engage in undue experimentation to properly treat Group 2 PH patients.[13] However, the court found sufficient evidence to conclude that, despite safety concerns, Group 2 PH patients could have their blood pressure reduced by the treatment.[14] The Federal Circuit concluded this was enough to affirm the finding of enablement, given that the parties had agreed that "an improvement in a patient's hemodynamics (reduced PAP or PVP)" was all that was required of an effective dose and that any safety concerns were irrelevant to the patent analysis, although they may be important for the FDA.[15]

***Baxalta Incorporated v. Genentech, Inc.*, 81 F.4th 1362 (Fed. Cir. Sept. 20, 2023)**

In this appeal from the District of Delaware, the Federal Circuit affirmed a finding that several claims in appellant Baxalta's patent directed to a treatment for Hemophilia A were not enabled.[16] The district court had granted summary judgment of invalidity due to lack of enablement because it found the specification would require a skilled artisan to undergo undue experimentation to obtain the full scope of claimed antibodies.[17] Baxalta argued its claims were enabled because it had disclosed screening techniques for "mak[ing] and identify[ing] new claimed antibodies."[18] However, the court relied on the recent Supreme Court decision in *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023), which held that merely outlining a trial-and-error method for discovering new antibodies does not enable a genus claim of all antibodies with the desired purpose, to reject Baxalta's argument.[19] It found that, just as in *Amgen*, Baxalta had merely described a trial-and-error screening process without identifying any commonalities

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[12] United Therapeutics Corporation v. Liquidia Technologies, Inc., 74 F.4th 1360 (Fed. Cir. 2023).
[13] *Id.* at 1368-69.
[14] *Id.* at 1270.
[15] *Id.*
[16] Baxalta Incorporated v. Genentech, Inc., 81 F.4th 1362 (Fed. Cir. 2023).
[17] *Id.* at 1365.
[18] *Id.*
[19] *Id.*

between functional antibodies that could help narrow down the screening search.[20] Therefore, the district court's finding that Baxalta's patent failed to teach a skilled artisan how to use the full scope of the claimed antibodies was affirmed.[21]

Software Indefiniteness

***Dyfan, LLC v. Target Corp.*, 28 F.4th 1360 (Fed. Cir. Mar. 24, 2022)**

On this appeal from the Western District of Texas, the Federal Circuit held that disputed claim language was not drafted in means-plus-function format and reversed the district court's finding of invalidity on that ground.[22] Two pieces of claim language were disputed: "said code, when executed, further configured to [list of things the code does]" and "wherein the system is configured such that [list of system configurations]."[23] For each limitation, the Court started by noting that the word "means" was not present so there was a presumption that 112 ¶ 6 did not apply.[24] For the "code" limitation, the Court held that the lower court erred by ignoring unrebutted testimony from the defendant's own expert that "code" and the similarly situated "application" were understood as structures to people of ordinary skill in the art ("a bunch of software instructions" and "a computer program intended to provide some service to a user," respectively).[25] The Federal Circuit referenced its decision in *Zeroclick*, where it held that "program" and "user interface code" were not black box recitations subject to 112 ¶ 6.[26] It continued to describe that software is in many ways special: code is partly defined by its function, so courts must look beyond the initial term to see if a person of ordinary skill would understand the claim limitation as a whole to sufficiently describe a definite structure.[27] For both limitations present here, there were descriptions of operations and enough functional language that a PHOSITA would understand the terms to connote structure.[28] These cases are pretty clearly inconsistent with the Federal Circuit's en banc decision in *Williamson v. Citrix*, which held that "nonce words" like "mechanism" can't satisfy the structure requirement.

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[20] *Id.* at 1366.
[21] *Id.* at 1367.
[22] Dyfan, LLC v. Target Corp., 28 F.4th 1360 (Fed. Cir. 2022)
[23] *Id.* at 1363.
[24] *Id.* at 1365.
[25] *Id.* at 1367-68.
[26] *Id.* at 1368.
[27] *Id.*
[28] *Id.* at 1369.

Title search: Functional Claiming

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