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AI May Help Patent Applicants With Functional Claiming

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For decades, courts addressed the interplay between the enablement and written description requirements of Title 35 of the U.S. Code, Section 112(a)[1] for claims reciting functional language to establish the scope of an invention or a claim element.[2] Functional claims are used in all technologies — from life sciences to high tech. Courts have carefully scrutinized such claims in the life sciences arena.

In May, the U.S. Supreme Court addressed whether claims defining novel antibodies by whether they bind to a specified location of an antigen and block that antigen's activity comply with the enablement requirement.[3] In Amgen Inc. v. Sanofi, the court upheld the U.S. Court of Appeals for the Federal Circuit's invalidation of functional claims, noting that it was consistent with long-established Supreme Court jurisprudence.[4]

Amgen had a substantial impact on patent practitioners, many of whom noted that the Federal Circuit's analyses of Section 112(a) set too high a bar for functional claims. Such a high bar, in the view of some practitioners, negatively affects investment in research.[5]

The concern is that this bar particularly affects biologic drug development, which requires enormous investments. The bar discourages, rather than promotes, development in the useful art of creating and protecting life-saving drugs from copycat drugs; discouraging functional claim elements narrows claim scope and potentially erodes incentive to develop life-saving biologics.

This article addresses the potential interplay between using generative artificial intelligence as a tool and compliance with Section 112(a) for functional claims. It examines suggestions that may allow patent applicants to maximize protection of their research and development efforts through AI disclosures, particularly AI disclosures that address functional features of an invention.

AI enthralled the public for its ability to write short stories, produce images or mimic artistic performances. Aside from the public's interest, these are just a few examples of the potential commercial applications for AI. AI has propelled advances in both the high tech and life sciences arenas by providing tools that can, when prompted, draft source code, predict protein structures based on amino acid sequences, and identify protein mutations implicating health issues, to just name a few.[6]

AI's power to confer advance capabilities into the hands of anyone eager to practice a functionally claimed invention or element may well confer predictability in achieving useful results. AI may thus

alleviate concerns that courts raise when assessing compliance with Section 112(a) — e.g., that patent disclosures require trial-and-error methods to make and use components that achieve a claimed function.[7]

The Supreme Court underscored that functional claims often fall short of Section 112(a) requirements when such claims could monopolize a broad swath of technology. Broad monopolies require disclosures commensurate with their breadth.[8] Unpredictability in achieving results described in functional claims complicates the analysis.[9] Recent and future advances raise questions concerning whether AI could alter functionality analysis, because the power of AI might suffice to predict what was once unpredictable.

When reviewing claims reciting components using functional language, courts developed guidance to determine whether a specification complies with Section 112(a). For enablement, courts look at factors that include the nature of the invention, the scope of the prior art, the level of skill in the art, the level of predictability, the direction provided by the inventors, the number of examples provided, and the quantity of experimentation required.[10]

This often boils down to whether practicing the claims requires undue experimentation. For written description, courts examine the specification for a sufficiently representative number of species that fall within the claimed genus or identification of common structural features shared by genus members.[11]

AI's potential to confer predictability may well affect the analysis courts apply under the above-recited tests. But a prerequisite to successfully influence a court's analysis requires a description of AI in the specification.

The specification should describe the algorithm, the structure of the model and how the model uses data (including block diagrams explaining data flow); identify data types and sources (including training, test and validation data); describe how existing knowledge confirms AI's accuracy; and provide examples of AI output from the model with data establishing accuracy of the many examples disclosed.

The AI disclosure must sufficiently inform a person of skill to practice the claims, and show that a skilled artisan can use AI to identify components that perform a claimed function. The aim is to support the AI component and its output.

But courts examining functional claims may seek more — particularly in the emerging AI art. A court might find that describing the AI used and evidence of success in identifying components that achieve the claimed function is a research plan that requires a person of skill to undertake the same arduous path the inventors traversed,[12] which courts have found lacking in applying enablement and written description jurisprudence.[13]

Because a court might consider simply describing an AI functionality that identifies members of a genus that perform a function insufficient to support broad functional claims, applicants should provide additional disclosure obtained from AI within the specification to seek claim scopes that permit the full enjoyment of the advancement described within the specification.

Tests that courts apply to assess compliance with enablement and written description may turn on how many examples the patent specification discloses. Unshackled from human limitations, AI may describe a large number of components — be that software/hardware architecture or proteins features — that achieve a claimed function. A diversity of examples can provide a basis for a patentee to argue that a

sufficiently detailed disclosure supports a genus claim that recites a specific function through an AI component or element.

AI may yet satisfy other overlaps between enablement and written description tests to support functional claims. The Federal Circuit has explained that a patent specification that identifies "structural features commonly possessed by members of the genus that distinguish them from others" that allow a skilled artisan to "visualize or recognize the identity of the members of the genus" can satisfy the written description requirement.[14]

The Supreme Court has articulated a similar concept to comply with the enablement requirement. Hearkening back to its jurisprudence from the 19th century, the Supreme Court explained that a specification may support broad claims if it discloses "a quality common" to the component "peculiarly" adapted to perform the claimed function.[15]

The court's statement in Amgen that "it may suffice to ... disclose[] 'some general quality ... running through' the class that gives it 'a peculiar fitness for the particular purpose'" sounds similar to the common-structural-feature test for written description.[16] And so a properly drafted specification may well support a sufficiently broad claim having an AI component or element.

Though humans may be unable to identity common features of a genus, AI can assess large data sets and recognize key commonalities of species that perform a function, and thus provide a basis to support functional claims. The outcome in Amgen might have been different had the patent specification particularly described a sufficient number of qualities of the species within the genus.

AI's ability to predict the structure of a target protein and its potential to reveal structures that bind and inhibit the target protein might suffice to predict features of hundreds of proteins that bind a target protein at specific binding sites.

Thus, AI might identify common topological binding features, hydrophobic and van der Waals interactions, hydrogen and ionic bonds shared by functionally described genus members. By including such information, an applicant may provide general qualities spanning a genus, or common features allowing a skilled artisan to identify genus members such that the specification complies with the tests for Section 112(a). This is the promise of AI.

Courts, including the Supreme Court, addressing the enablement requirement for antibodies have noted the need to conduct extensive experimentation to identify genus members. With the advent of AI, the level of experimentation necessary to identify members of a covered genus may be substantially reduced. For example, one could focus on structure/function relationships and properties of antibodies (e.g., CDRs) rather than on antigen epitopes.[17]

We suggest that AI may effectively identify species with specifically articulated structural changes to an antibody CDR which satisfy the functional element of a genus claim.

For example, AI can test, in silico, conservative amino acid substitutions in multiple permutations and run each permutation through an antigen or epitope binding process in silico. A person of skill using AI in this manner can rely on AI to provide binding characteristics, or scores, for single or combinations of conservative CDR mutations.

The universe of species that satisfy the functional elements of the claim could be reduced from, e.g.,

tens of thousands to perhaps mere dozens. The likelihood that a court would invalidate a functional claim under Section 112(a) would be minimized. AI may thus traverse the undue experimentation burden on the person of skill. This is but one way that AI may address Section 112(a) threatening innovation in antibody development.

To address uncertainty as to how courts will apply Section 112(a) on AI, an applicant must draft the specification to present evidence consistent with the prongs of the tests applied by courts. Though it may not always be practical to include all data produced by an AI model, including a diverse collection of examples will give patentees a basis to argue that sufficient support exists for functional claims. Similarly, including common features exhibited by diverse examples supports validity.

Applicants seeking allowance of functional claims should claim the invention in multiple ways. Applications should recite claims to the preferred components in the specification to perform a given function. Applications can also use means-plus-function claims to encompass all disclosed components and their equivalents. These strategies will protect against a court concluding that AI-generated disclosures do not address the demonstrable concerns courts have with broad functional claims.

AI may address other critical issues in life sciences, such as product-by-process AI claim elements. Product-by-process claims, in general, are unfavored by patent practitioners because of their narrow scope. But in life sciences, AI-containing claims may enjoy a resurgence.

For example, AI algorithms for identifying improved antibodies can be generated to reproducibly make antibodies with certain desirable functional changes. Such AI algorithms would dictate structural changes the antibodies will have at the end of the process. A patent specification claiming such AI element(s) would disclose both the desired functionality and — critically — the universe of structural changes that confers such functionality.

Such a claim may avoid the undue experimentation trap that results from an unsuitably large genus. A suitably detailed specification coupled with AI-supported functional elements in its claims could provide competitive advantages to patentees desiring to protect innovative methods for antibodies with specified functionality.

As a final caveat, applicants should address potential concerns courts may have about the interplay between the different requirements of patent laws. AI's ability to provide a disclosure that meets Section 112(a) requirements may raise hurdles concerning inventorship and nonobviousness arguments.

Certainly, under current U.S. patent laws AI cannot be a sole inventor, and an ambiguity exists as to AI's contribution rising to the level of joint inventorship.[18] Similarly, uncertainty remains concerning AI's impact on obviousness analysis — which requires assessing motivation to combine and reasonable expectation of success. Applicants must balance these concerns with arguments presented to show compliance with Section 112(a).

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[1] Under the pre-AIA statute, the section was referenced as 35 U.S.C. § 112, ¶ 1.

[2] McRO Inc. v. Bandai Namco Games America Inc., 959 F.3d 1091, 1100 (Fed. Cir. 2020); Amgen Inc. v. Sanofi Aventisub LLC, 987 F.3d 1080, 1084 (Fed. Cir. 2021); Ariad Pharms. Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010); Juno Therapeutics Inc. v. Kite Pharma Inc., 10 F.4th 1330, 1335 (Fed. Cir. 2021).

[3] Amgen v. Sanofi, 598 U.S. 594, 1254 (2023) (confirming that the specification must enable the full scope of the claims).

[4] Id.

[5] See amicus briefs filed with the U.S. Supreme Court in Amgen v Sanofi, No. 21-757, including Brief of Amici Curia of Intellectual Property Professors filed Dec. 22, 2021, Brief of Amici Curia Association of University Technology Mangers Inc. filed Dec. 22, 2021; Westlaw Today, "Practical Insights Commentaries," Adam Mossoff and Matthew Dowd, 2023 PRINDBFRF 0100 (March 1, 2023).

[6] See GitHub Co-Pilot (source code), AlphaFold (protein structure), RoseTTAFold (protein structure), and AlphaMissense (predicting pathogenicity based upon on DNA mutation that results in introduction of a different amino acid).

[7] Amgen, 598 U.S. at 1256; AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech Inc., 759 F.3d 1285, 1300 (Fed. Cir. 2014); Teva Pharmaceuticals Int'l GmbH v. Eli Lilly and Co., 18-cv-12029-ADB, 2023 WL 6282898 *19 (D. Mass. Sept. 26, 2023).

[8] Amgen, 598 U.S. at 1256.

[9] Amgen, 598 U.S. at 1249; other citations.

[10] In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988); Teva Pharmaceuticals, 18-cv-12029-ADB, 2023 WL 6282898 *20 (D. Mass. Oct. 26, 2023).

[11] AbbVie, 759 F.3d at 1299; Teva Pharmaceuticals Int'l GmbH, 18-cv-12029-ADB, 2023 WL 6282898 *8 (D. Mass. Sept. 26, 2023).

[12] Amgen, 598 U.S. at 1256; Ariad Pharmaceuticals, 598 F.3d 1336, 1353-1354 (Fed. Cir. 2010); Baxalta Inc. v. Genentech Inc., 2022-1461, 2023 WL 6135930 *3 (Fed. Cir. Sept. 20, 2023).

[13] Teva Pharmaceuticals Int'l GmbH, 18-cv-12029-ADB, 2023 WL 6282898 *22 (D. Mass. Sept. 26, 2023).

[14] GlaxoSmithKline LLC v. Banner Pharmacaps Inc., 744 F.3d 725, 730 (Fed. Cir. 2014); Regents of the Univ. of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997).

[15] Amgen, 598 U.S. at 1253-1254, citing Consol. Elec. Light Co. v. McKeesport Light Co. (The Incandescent Lamp Patent), 159 U.S. 465, 472 (1895).

[16] Amgen, 598 U.S. at 1254.

[17] Kevin E. Noonan, "In the Wake of the Supreme Court's Amgen v. Sanofi decision: What's Next for Biotechnology Claims?" Patent Docs, Oct. 2, 2023, https://www.patentdocs.org/2023/10/in-the-wake-of-the-supreme-courts-amgen-v-sanofi-decision-whats-next-for-biotechnology-claims.html.

[18] Thaler v. Vidal, 43 F.4th 1207 (Fed. Cir. 2022).