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Legal Frameworks for AI in Life Sciences: Patent Law's Adaptation to Technological Innovation

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Speaker

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Overview

- As technology changes at a rapid pace, the law may not keep up with those changes
- Often rely on regulatory agencies to fill in the gaps
- In some situations, this may create a “messy middle”

Overview

- Discuss three of the areas where the regulatory framework for patent protection in the life sciences is adapting to (or not) technology advances
  - Impact of AI usage on inventorship
  - Subject matter eligibility
  - Submission of *in silico* data for enablement purposes

AI and Inventorship

AI and Inventorship

- *Thaler v. Vidal*
  - Stephen Thaler filed two patent applications listing DABUS as the inventor
  - USPTO sent Notice of Missing Parts because no human inventor listed
  - Appealed to district court and then to Federal Circuit. Supreme Court denied *certiorari*
  - Federal Circuit held “individual” in patent statute means natural person/human being
  - Most other jurisdictions throughout the world have made similar decisions

AI and Inventorship

- USPTO Guidance on AI and Inventorship
  - 2024 Guidance – AI-assisted inventions patent eligible if a natural person made a “significant contribution”
  - Provided examples of what may and may not be considered a “significant contribution”
  - Based on *Pannu* case – Discussed how to determine if a natural person was a joint inventor

AI and Inventorship

- USPTO Guidance on AI and Inventorship
  - 2025 Guidance – Rescinded 2024 Guidance
  - Focus should not be on significant contribution because AI is not a natural person
  - Inquiry should be directed to conception of the invention
  - Relies on statements from *Burroughs Wellcome Co. v. Barr Labs, Inc.* (1984) (First-to-Invent related case)

AI and Inventorship

- USPTO 2025 Guidance
  - Conception is “the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.”
  - Conception is complete when “the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan.”
  - The question is whether the natural person possessed knowledge of all the limitations of the claimed invention such that it is so “clearly defined in the inventor’s mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.”

AI and Inventorship

- Possible that USPTO can make inquiries into inventorship
  - Requirements for Information - Examiner makes the request under 37 CFR § 1.105 (MPEP § 704.10)
    - Information need not be material to patentability
  - Examiners may require information when there is a reasonable basis to conclude that a party under 37 CFR 1.56(c) or 1.555(a) has information reasonably necessary to the examination of the application or treatment of some matter
  - Possibility of rejection under 35 U.S.C. 101 if no human conception of claimed features

AI and Inventorship

- Impacts of AI usage in technology development coupled with no AI inventors
  - Increased scrutiny of who conceived of what
  - Enforcement actions may begin to see inventorship challenges regarding AI and inventorship
    - No technical inquiry is involved
  - Not aware of any cases like this yet

AI and Inventorship

- Potential actions to guard against inventorship challenges
  - Documentation of AI usage and human contributions
  - Use of electronic lab notebooks or other documentation tools for AI usage in the technology development process
  - Build AI usage and inventorship inquiry into the invention disclosure process
  - Identify human contributions vs. AI contributions and focus claims on human contributions
  - Use caution when describing AI usage in experimental examples, papers, etc.

Subject Matter Eligibility

Subject Matter Eligibility

- Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- (July 19, 1952, ch. 950, 66 Stat. 797.)

- *Judicial Exception*

- The Court has long held that §101, which defines the subject matter eligible for patent protection, contains an implicit exception for ‘ “[l]aws of nature, natural phenomena, and abstract ideas.’ ” *Association for Molecular Pathology v. Myriad Genetics, Inc*., 569 U. S. 576, 589.

Subject Matter Eligibility

- Based on Supreme Court and Federal Circuit precedent, most computational technologies are examined under the abstract idea exception
  - Recitation of mathematical concept versus being based on or involving mathematical concepts (2106.04)(a)(2)(I)
  - Method of organizing human activity – fundamental economic principles, commercial or legal interactions, managing personal behavior or interactions between people (2106.04)(a)(2)(II)
  - Mental process that can practically be performed in the mind of a human, even though it is possible to use a computer to also perform the process (2106.04)(a)(2)(III)

Subject Matter Eligibility

- MPEP Framework
  - If judicial exception, are claims directed to abstract idea? (Step 2A, Prong One)
  - If abstract idea:
  - Does claims as a whole integrate judicial exception into a practical application? (Step 2A, Prong Two). Evaluate additional elements.
  - Does claim as a whole amount to significantly more than judicial exception?
  - (Step 2B). Do additional elements add an inventive concept?

Subject Matter Eligibility

- Lots of USPTO Guidance Over the Years
- 49 USPTO Examples (2014-2016 (1-36), twice in 2019 (37-46), 2024 (47-49))
- Recent Memos
  - Reminders on evaluating subject matter eligibility of claims (August 4, 2025)
  - 132 Declarations for subject matter eligibility (December 4, 2025)
  - Notice of change to MPEP in light of *Ex Parte Desjardins* (December 5, 2025)

Subject Matter Eligibility

- Examples that can be helpful for arguing subject matter eligibility for AI applications in the life sciences
- Example 39 – training a neural network for facial detection
- Examples 43 and 49 – determine patient condition and provide treatment (specificity of treatment)
- Example 45 (and 46?) – controller for injection molding (bioprocess applications)
- Examples 47 and 48 – anomaly detection and speech analysis (practical application/improvements)(caution on mathematical concepts)

Subject Matter Eligibility: Case Law

- *RECENTIVE ANALYTICS, INC. v. FOX CORP*., No. 2023-2437 (Fed. Cir. Apr. 18, 2025)
  - Two sets of patents: one directed to scheduling live events and the other directed to mapping live events to television stations
  - Claims are directed to using and training machine learning models at a relatively high level
  - Both specifications state that “any suitable machine learning technique” can be used
  - From the Conclusion:
    - “Machine learning is a burgeoning and increasingly important field and may lead to patent-eligible improvements in technology. Today, we hold only that patents that do no more than claim the application of generic machine learning to new data environments, without disclosing improvements to the machine learning models to be applied, are patent ineligible under § 101.”

Subject Matter Eligibility: Case Law

- *23ANDME, INC. v. ANCESTRY.COM DNA, LLC* , No. 19-1222 (Fed. Cir. 2019)
  - Directed to determining relationships between users having a common ancestor
  - Computer appears to be involved, but not a lot of details
  - Court found that claims included elements of laws of nature and abstract ideas, but were more focused on laws of nature
  - Court held that the claims were too close to the intrinsic nature of DNA and that the inheritance by descent methods used were well-established

Subject Matter Eligibility: Case Law

- *IN RE BOARD OF TRUSTEES OF LELAND STANFORD JR. UNIV.*, 989 F. 3d 1367
  - Claims are directed to using a Hidden Markov Model to determine an inheritance state for allele information and using a computer system to determine the haplotype phase based on the inheritance state among other types of information
  - Most claim elements were directed to receiving, storing and providing steps
  - The application did describe improvements: “While the `trio' method may be able to provide long-range haplotype phasing for approximately 80% of heterozygous positions, the method of the present invention provides accurate, long-range phasing at 97.9% of all heterozygous positions.”
  - The Court held that “The claimed advance proffered by Stanford, that the process yields a greater number of haplotype phase predictions, may constitute a new or different use of a mathematical process, but we are not persuaded that the process is an improved technological process.”

Subject Matter Eligibility: Mental Process Practical Strategies

- MPEP 2106.04(a)(2)(III)(A) Claims do not recite a mental process when they do not contain limitations that can practically be performed in the human mind, for instance when the human mind is not equipped to perform the claim limitations. See *SRI Int'l, Inc. v. Cisco Systems, Inc.,* 930 F.3d 1295, 1304 (Fed. Cir. 2019)

  - Describe the complexity of the inventive concepts in the specification, such as the training process and/or the amount or type of data being processed by the models
  - Include claim elements focused on machine learning architectures that have been adapted for specific implementations
  - Consider features that can only be generated by or processed by a computing device and not a human

Subject Matter Eligibility: Mathematical Concepts Practical Strategies

- MPEP 2106.04(a)(2)(I) A claim does not recite a mathematical concept (i.e., the claim limitations do not fall within the mathematical concept grouping), if it is only based on or involves a mathematical concept. See, e.g., *Thales Visionix, Inc. v. United States*, 850 F.3d 1343, 1348-49, 121 USPQ2d 1898, 1902-03 (Fed. Cir. 2017)

  - Example 39 (A computer-implemented method of training a neural network for facial detection)
    - … the claim does not recite any mathematical relationships, formulas, or calculations. While some of the limitations may be based on mathematical concepts, the mathematical concepts are not recited in the claims.
  - Excluding equations from claims can be helpful, but still possible to overcome 101 rejections with them
  - When possible, avoid language involving simple mathematical operations: sum, average, etc.

Subject Matter Eligibility: Practical Strategies (Improvements)

- Argue features of the claims that cause an improvement in the functioning of a computer, or an improvement to other technology or technical field
- Sometimes improvements have been found to be persuasive under step 2A, Prong One (*Enfish*, *McRo*) and other times under step 2A, Prong Two or step 2B
- Discuss features of the invention that improve computing device/system performance in the specification. Connect the claim features to the improvement.
- Include data in the application showing improvements over previously known technologies
- But improvements may not be enough without more (*23andMe*, *Stanford*)

Subject Matter Eligibility: Drafting

- Consider claim features related to treatment that meet *Vanda* requirements
- In manufacturing context, providing control signals that cause equipment to operate in a particular way can be persuasive
- Include embodiments where non-computational aspects are involved (e.g., synthesis, sequencing, library prep, etc.). But caution on divided infringement.
- Detailed examples in the specification: provide details in components used, process steps, and architecture
- Avoid language characterizing certain aspects as being conventional or typical (*Stanford*)
- Technical problem-solution approach from European practice can be helpful with some modifications
- Draft robust specifications incorporating multiple strategies for overcoming 101 rejections
- Include specific rules or frameworks that are part of the invention (*McRo*)

In silico Data and Enablement

In Silico Data and Enablement

- 35 U.S.C. 112(a): The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same . . . .”
- In re *Wands* factors can be used to determine if enablement is satisfied:

  (A) breadth of the claims, (B) nature of the invention, (C) state of the prior art, (D) level of one of ordinary skill, (E) level of predictability in the art, (F) amount of direction provided by the inventor, (G) existence of working examples, and (H) quantity of experimentation needed to make and use the invention based on the content of the disclosure.

In Silico Data and Enablement

- Some cases and the MPEP give flexibility with respect to whether or not working examples are required
- MPEP 2164.02
  - An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved … When considering the factors relating to a determination of non-enablement, if all the other factors point toward enablement, then the absence of working examples will not by itself render the invention non-enabled.
- *Allergan v. Sandoz* (2015) - some leniency in supporting enablement without specific experimental examples. But, after *Amgen* the holding may not be broadly applicable.

In Silico Data and Enablement

- *Amgen Inc. et al.v. Sanofi et al.,*143 S. Ct. 1243 (2023)
  - Amgen claimed “the entire genus” of antibodies that: “bind to specific amino acid residues on PCSK9,” and “block PCSK9 from binding to [LDL receptors].”
  - The Court invalidated Amgen’s Claim under enablement finding that:
    - Broad “genus claims” would require a person of skill in the art to engage in undue experimentation to make each species of antibody claimed
    - A “genus claim” is not enabled unless every species in that genus is described in the patent, OR the genus is described in sufficient structural detail.
- "The more a party claims…the more it must enable."
- “Amgen offers persons skilled in the art little more than advice to engage in ‘trial and error.’”

In Silico Data and Enablement

- USPTO Guidelines post Amgen (2024)
  - “USPTO personnel will continue to use the *In re Wands* factors to ascertain whether the amount of experimentation required to enable the full scope of the claimed invention is reasonable”
  - “intended to inform USPTO personnel and the public on the USPTO's implementation of the Supreme Court decision in *Amgen Inc. et al. v. Sanofi et al.*, 143 S. Ct. 1243 (2023)" but "are not intended to announce any major changes to USPTO practice or procedure."
- Guidelines may have been a reaction to Supreme Court not explicitly using *Wands* factors to determine lack of enablement

In Silico Data and Enablement

- Can AI help alleviate the undue experimentation burden?
  - AI may be able to predict compounds within a claimed genus. If a predicted compound is shown to have the functionality of other members of the genus, how far can that go to reducing the amount of experimentation needed to claim the genus? (e.g., using AI tools to model antibodies with varying CDR compositions binding to an antigen).
  - For example, can AI be used to show that the knowledge of those skilled in the art has increased or that some technology areas are now more predictable?
  - How much detail would be needed about the model in the specification to support the claims?

In Silico Data and Enablement

- EPO appears to have at least some openness to the idea of using *in silico* data to support enablement
  - Sufficiency standard - the application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person.
  - If a claim recites a specific technical effect, the effect must also be achieved across the whole scope of the claim.
  - With respect to sufficiency, EPO Board of Appeals in T 801/06 stated that a “claimed therapeutic effect may be proven by any kind of data as long as they clearly and unambiguously reflect the therapeutic effect.”

In Silico Data and Enablement

- In a case that dealt with industrial applicability (898/05), the EPO was more direct:

  "…The fact that the putative function of the Zcytor1 receptor was assigned in the examples based on computer-assisted methods, rather than on the basis of traditional wet-lab techniques, does not mean that it has to be automatically disregarded or excluded from a careful and critical examination. There is no "all-encompassing" approach, and certainly not a "throw-into-the-bin" approach, for these in-silico examples.

- With regard to inventive step, the decision in T 2517/19 stated that experimental results for antibodies could be "credibly be extrapolated" to corresponding antibody-drug conjugates to support inventive step, based on an *in silico* study."

In Silico Data and Enablement

- Relying only on *in silico* data for enablement/sufficiency purposes would be risky
- Support for claims needs to come from working example (e.g., *in vivo*, *in vitro* data)
- Although doubtful at this point, at least the potential exists to expand the claim scope in some situations
- Perhaps as technology advances and the accuracy of predicting events that are otherwise unpredictable increases, patent offices around the world will be more willing to accept in silico data for enablement/sufficiency purposes

In Silico Data and Enablement

- In contrast to patents, the FDA appears to have embraced this idea (April 10, 2025):
  - **FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs**
  - **“**The FDA’s animal testing requirement will be reduced, refined, or potentially replaced using a range of approaches, including AI-based computational models of toxicity and cell lines and organoid toxicity testing in a laboratory setting (so-called New Approach Methodologies or NAMs data).”
  - “By leveraging AI-based computational modeling, human organ model-based lab testing, and real-world human data, we can get safer treatments to patients faster and more reliably, while also reducing R&D costs and drug prices. It is a win-win for public health and ethics.”

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