

SLW Life Sciences Webinar Series

IP Protection for Computational Technologies Used in the Drug Discovery Pipeline

An abstract graphic featuring two pill capsules, one in the foreground and one slightly behind it to the right. Both capsules are rendered with a wireframe mesh overlay, suggesting a digital or computational theme. The background is a deep blue with faint, glowing molecular structures and geometric shapes, creating a high-tech, scientific atmosphere.

June 5, 2025

Speaker



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Topics to be Covered

- Overview of therapeutics development process
- Using patents or trade secrets for IP protection
- Legal framework of patent protection – 35 U.S.C. 101 and 112
- Practical aspects of patent application drafting and prosecution
- Examination insights and case studies

Therapeutic Development Process Overview



Computational Technologies can be Used in Multiple Phases in the Development of Therapeutics

- Target Identification – identify pathways and compounds that are most accessible and provide the most benefit when modulated
- Candidate Discovery – which therapeutics are most likely to interact with target pathways and compounds to alleviate disease/symptoms
- Candidate Optimization – modifications to candidate molecules that improve binding to target and viability in vivo and manufacturing; identify effective delivery methods
- Clinical Trials – identify patients having the most benefit from a therapeutic
- Manufacturing – determine process conditions that provide best yields and maintain efficacy

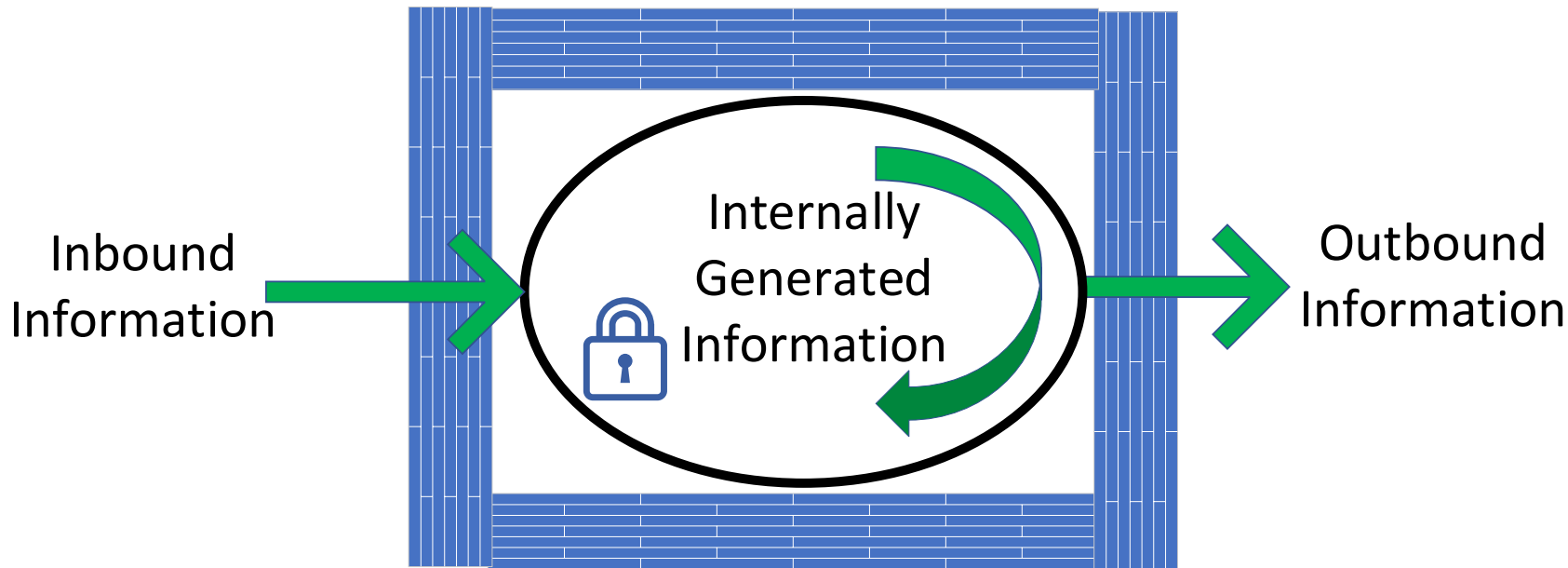
Protection of IP Directed to Computational Technologies Used in Therapeutics Development

Patents or Trade Secrets?

- **Patent** – provides owner with right to exclude others from making, using, or selling the patented subject matter for about 20 years.
 - Requires public disclosure of how to make and use the patented subject matter
 - Examination process can be time consuming, unpredictable, and costly (especially when international protection is being sought)
- **Trade Secret** – provides protection from others using confidential information that has economic value for as long as the confidential information is kept secret
 - Not protectable if the confidential information is reverse engineered or independently discovered by another
 - Disclosure of the confidential information can nullify trade secret protection
 - Must implement reasonable measures to maintain secrecy

Considerations for Choosing Patents or Trade Secrets

- **Public Disclosure of Information**



Considerations for Choosing Patents or Trade Secrets

- Ability of Others to Reverse Engineering
- Detectability of Technology
- Type of Information Being Protected
- Business Considerations
 - How fast is the technological field changing
 - Fund raising and investors interested in IP protection
 - High employee turnover
 - Are other companies patenting their innovation in this space

Legal Framework for Patent Protection – Patent Subject Matter Eligibility Under §101

Patent Eligibility Under 35 U.S. Code §101

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.)

Patentability of Therapeutics When AI is Used to Develop Them

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.

- Thaler v. Vidal, 43 F.4th 1207 (Fed. Cir. 2022)
 - Thaler named DABUS (collection of source code or programming and a software program) as inventor on two patent applications
 - Patent applications were found by USPTO to be incomplete because no valid inventor
 - Federal Circuit held that “inventor” is limited to natural persons and does not include AI

Patentability of Therapeutics When AI is Used to Develop Them

- USPTO's 2024 Inventorship Guidance for AI-assisted Inventions
 - Pannu factors (Pannu v. Iolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998))
 - Contribute in some significant manner to the conception or reduction to practice of the invention
 - Make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention
 - Do more than merely explain to the real inventors well-known concepts and/or the current state of the art

Patentability of Therapeutics When AI is Used to Develop Them

- Current computational methods used in the drug development process will likely avoid this issue
- Therapeutic sequences and structures developed solely by AI may be problematic
 - Doctrine of simultaneous conception and reduction to practice (Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991))
 - Applies to situations where synthesizing a compound is unpredictable
- Consider documentation of human contributions to therapeutics development when AI is used

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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.

Patent Eligibility Under 35 U.S. Code §101 – USPTO Guidance (MPEP 2106)

Based on Supreme Court and Federal Circuit holdings, 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)
- Improvements to functioning of computer and improvements to a technology or technical field can be considered patent eligible in some cases

Patent Eligibility Under 35 U.S. Code §101 – 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.”

Patent Eligibility Under 35 U.S. Code §101 – 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

Patent Eligibility Under 35 U.S. Code §101 – 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.”

Common 101 Rejections, Arguments, and Drafting Considerations

Step 2A: Mental Process Rejection

- 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

Step 2A: Mathematical Concepts Rejection

- 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)
- Arguments Based on Subject Matter Eligibility 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.

Step 2A & 2B: Practical Application

Limitations the courts have found indicative that an additional element (or combination of elements) may have integrated the exception into a practical application include:

- An improvement in the functioning of a computer, or an improvement to other technology or technical field,
- Applying or using a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition
- Implementing a judicial exception with, or using a judicial exception in conjunction with, a particular machine or manufacture that is integral to the claim
- Effecting a transformation or reduction of a particular article to a different state or thing,
- Applying or using the judicial exception in some other meaningful way beyond generally linking the use of the judicial exception to a particular technological environment, such that the claim as a whole is more than a drafting effort designed to monopolize the exception

Practical Application Continued

- 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 (Enfish, McRo) and other times under 2B (Alice)
- Discuss features of the invention that improve computing device/system performance in the specification. Connect the claim features to the improvements when possible
- Include data in the application showing improvements over previously known technologies
- Claiming the improvement itself may not be successful without tying the improvement to specific claim operations
- But improvements may not be enough without more (23andMe, Stanford)
- 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

Drafting & Prosecution Considerations

- Consider claiming computational aspects and life science aspects separately (but caveat regarding 101)
- Draft computational aspects from the point of view of a computing device performing the algorithm's operations
- Draft claims that cover the core uses or embodiments
- Detailed examples in the specification: provide details in components used, process steps, and architecture

Other Drafting & Prosecution Considerations

- What parts of the technology pipeline are unconventional? Include these in the specification to help with potential 101 rejections during prosecution.

Case law examples: Unconventional + improvement – Amdocs

Unconventional - Bascom

- 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)
- Consider tying computational aspects to physical manifestations of the system's operations

Legal Framework for Patent Protection - Enablement Considerations under § 112

35 U.S.C. §112

Patent Application Requirements

- 35 U.S.C. 112(a) - Specification
 - Written Description
 - Enablement
 - Best Mode
- 35 U.S.C. 112(b)-(e) Claims
- 35 U.S.C. 112(f) – Means plus function

Today, we will focus on enablement:

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”

Predictable Arts v. Unpredictable Arts

- Computer science innovation is generally interpreted as being predictable. See *McRO, Inc. (Planet Blue) v. Bandai Namco Games* (Fed. Cir. 2020).
- Life science innovation is generally interpreted as being unpredictable. See *Amgen, Inc. et al. v. Sanofi et al.* (S. Ct. 2023).

Enablement Requirement – Case Law

McRO, Inc. v. Bandai Namco Games America, Inc., No. 19-1557 (Fed. Cir. 2020)

- Developers provided evidence of non-enablement of some techniques described in McRo's patent application
- Federal Circuit found that although there may have been non-enablement for some features described in the specification, those features were not claimed.
- Federal Circuit held claimed features were enabled

“An ‘artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art,’ AK Steel, 344 F.3d at 1244, and a ‘patent need not teach, and preferably omits, what is well known in the art,’ Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534 (Fed. Cir. 1987). Here, the district court explained that ‘both experts apparently agree that the state of computer animation overall and the development of rules for animation was well-developed in other contexts.’ Enablement Opinion at *17; see J.A. 4945 (McRO's expert); J.A. 5772 (the Developers' expert).”

Enablement Requirement – Case Law

Amgen Inc. et al.v. Sanofi et al., 143 S. Ct. 1243 (2023)

- Amgen’s patent recited broad “genus” claims
- 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.
- Unpredictability in the Art was a Factor in Decision

“Despite recent advances, aspects of antibody science remain unpredictable ...”

USPTO Guidelines on Enablement after *Amgen*

The United States Patent and Trademark Office (USPTO) is publishing guidelines for USPTO employees to use, regardless of the technology, for ascertaining compliance with the enablement requirement ...

- Mainly reaffirms that *Wands* factors will continue to be used with respect to enablement (In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988)):
 - (A) the breadth of the claims, (B) the nature of the invention, (C) the state of the prior art, (D) the level of one of ordinary skill, (E) the level of predictability in the art, (F) the amount of direction provided by the inventor, (G) the existence of working examples, and (H) the quantity of experimentation needed to make and use the invention based on the content of the disclosure.
- Guidelines may have been a reaction to Supreme Court not explicitly using *Wands* factors to determine lack of enablement

Enablement - Drafting and Prosecution Considerations

- Although computational technologies are often subject to a less rigorous standard for enablement, some art units that are more life science oriented can be stricter about satisfying the enablement than others
- Enablement can be brought up in litigation (also reference enablement discussion in McRO)
- Some drafting considerations to address potential enablement issues include:
 - Robust specifications that include details about the training process for models
 - Some details about machine learning architectures
 - Working examples
 - Make sure claim features are sufficiently described

Case Study

Compounds in Clinical Trials Developed Using AI

- Kp Jayatunga M, Ayers M, Bruens L, Jayanth D, Meier C. How successful are AI-discovered drugs in clinical trials? A first analysis and emerging lessons. Drug Discov Today. 2024 Jun;29(6):104009.
- Discuss aspects of a company's patent portfolio that used AI to develop an anti-fibrotic small molecule inhibitor for treatment of idiopathic pulmonary fibrosis

Differences in Examination Between Art Units

Deep transcriptomic markers of human biological aging and methods of determining a biological aging clock (applied to patients with pre-senescent, senescent fibrotic conditions ...)

US 16/104,391 (10,325,673)	US 16/883,205 (CIP of '673 patent)
1. A method of creating a biological aging clock for a subject, the method comprising: (a) receiving a biological data signature derived from a tissue or organ of the subject; (b) creating input vectors based on the biological data signature; (c) inputting the input vectors into a machine learning platform; (d) generating a predicted biological aging clock of the tissue or organ based on the input vectors by the machine learning platform, wherein the biological aging clock is specific to the tissue or organ; and (e) preparing a report that includes the biological aging clock that identifies a predicted biological age of the tissue or organ.	1. A method of creating a biological aging clock for a subject, the method comprising: (a) receiving a proteome signature derived from a tissue or organ of the subject; (b) creating input vectors based on the proteome signature; (c) inputting the input vectors into a machine learning platform; (d) generating a predicted biological aging clock of the tissue or organ based on the input vectors by the machine learning platform, wherein the biological aging clock is specific to the tissue or organ; and (e) preparing a report that includes the biological aging clock that identifies a predicted biological age of the tissue or organ.

Prosecution History Overview

US 16/104,391 (10,325,673)	US 16/883,205
Art Unit 2883	Art Unit 1686
First Action Allowance	112(b) – mostly antecedent basis 101 Non-Statutory Double Patenting Abandoned

But ... Differences in Examination Within Art Units Also

Entangled conditional adversarial autoencoder for drug discovery - U.S. 11,680,063

- Art Unit 2857
- 101 and 102 rejections
- Detailed claim amendments directed to the machine learning architecture resulted in Notice of Allowance:
 - creating a trained model with the machine learning platform that is trained with the plurality of objects and object properties, wherein the trained model is an entangled conditional adversarial autoencoder that is configured to:
 - include an encoder that encodes a distribution of latent code to a latent space;
 - a predictor model configured to extract object property data from latent code and updating the encoder to eliminate extracted object property data from the latent code;
 - include a discriminator model that forces a distribution on the latent code to match a prior distribution, wherein the discriminator model discriminates between samples of the distribution of the latent code in the latent space and the prior distribution ... reparameterizing the latent codes into reparameterized latent codes with the object properties;

Observations From the Portfolio

- Computational Methods examined in art units 2800, 2400, 2100, 1600, RD00
- Specifications were robust including some with comparative examples
- Details of computing architectures were described (and claimed in some instances)
- Portfolio also included composition of matter and treatment related patent applications
- Not able to identify any manufacturing related patent applications

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Thank you for your interest.

Questions?