

Patent Protection at the Intersection of Life Science & Computer Science

November 9, 2023

Panel



Attorney

Lea Westman

Schwegman Lundberg
& Woessner



Senior Attorney

Trevor Lind

Schwegman Lundberg
& Woessner

Topics today

- Bioinformatics patent landscape
- Scientific and legal frameworks
- Practical aspects of patent application drafting and prosecution

Overview

Software

- Computer driven methods
- Algorithms
- Digital data

Biotech

- Physical methods
- “Wet lab” processes
- Data from biological hosts

Types of Cases

- Medical imaging cases
- Analyzing medical records
- Medical records databases
- Genetic data collection
- Large scale genetic data analysis
- Pathogen analysis
- 3-D shape analysis
- Drug discovery
- Genomic and epigenomic data analysis

... and more!

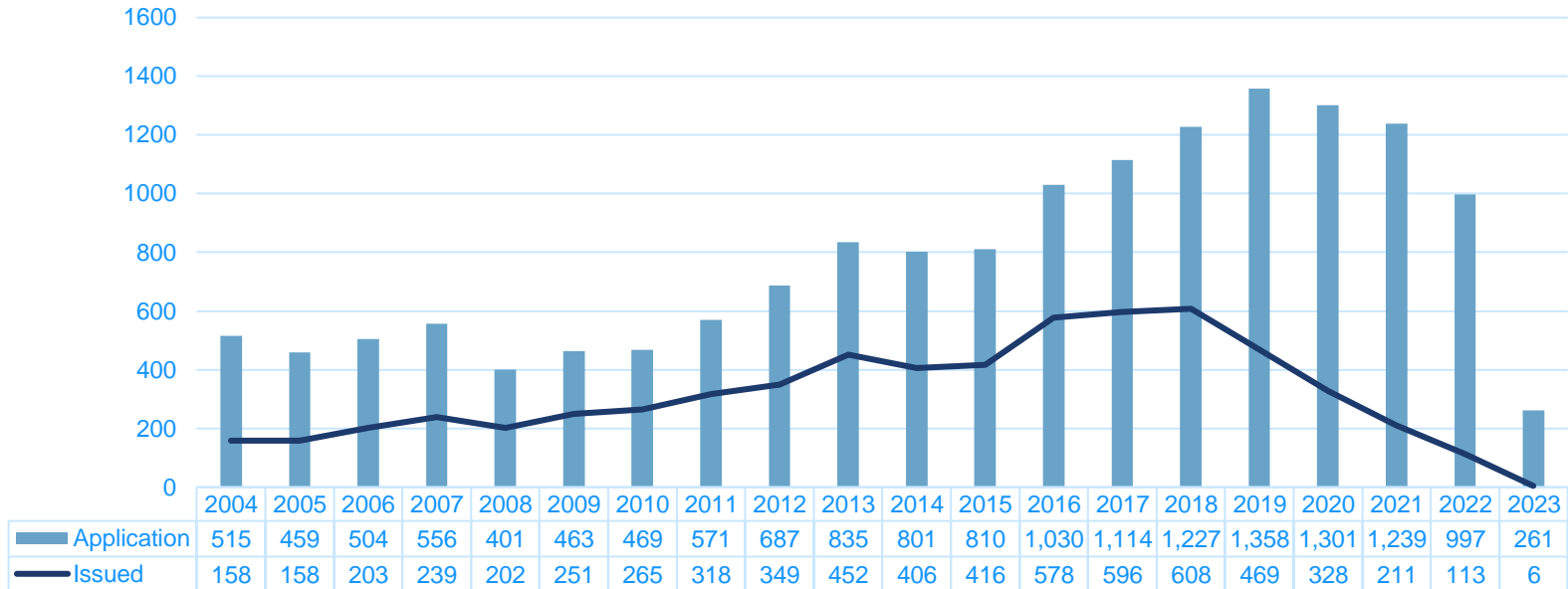


Bioinformatics

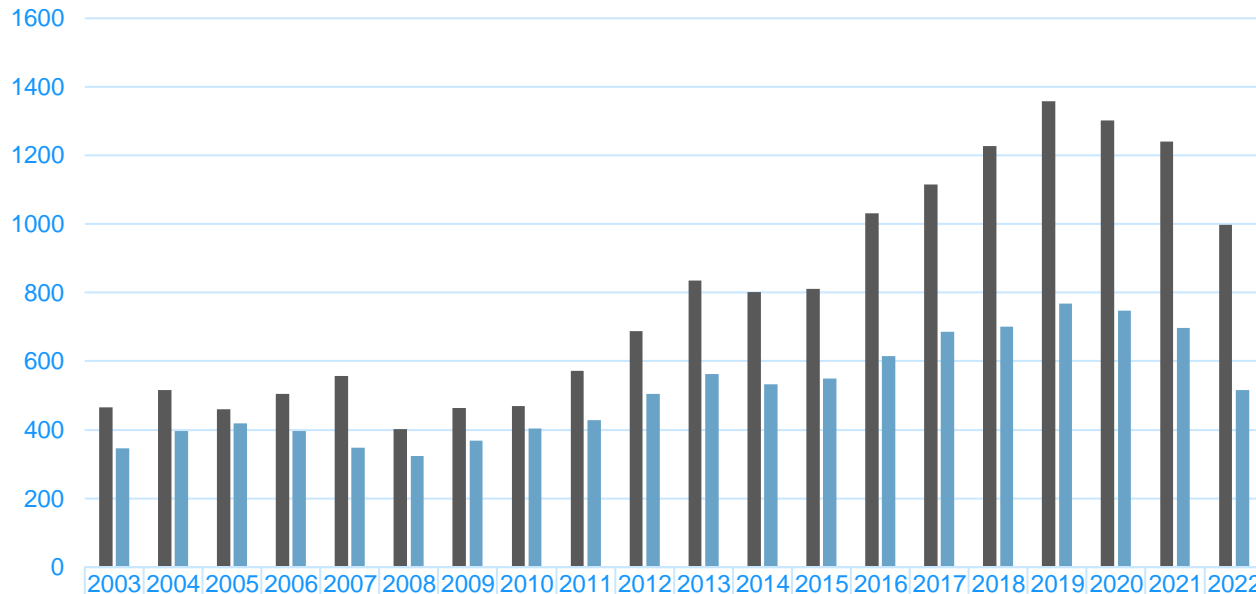
combines biology, computer science, and statistics to analyze biological data

Related: computational biology, computational genomics, computer aided drug design

Filings and Grants by Filing Year



Lifecycle



■ Number of Applications	465	515	459	504	556	401	463	469	571	687	835	801	810	1,030	1,114	1,227	1,358	1,301	1,239	997
■ Number of Assignees	345	397	418	396	348	324	369	404	428	504	563	532	549	615	686	701	767	748	697	516

Art Unit & Examiner Considerations



Example Art Units

TC 1600

- Biotechnology

TC 2600

- Communications

TC 3600

- Transportation, Construction, Electronic Commerce, Agriculture, National Security and License and Review

TC 2100

- Computer Architecture and Software

TC 2800

- Semiconductors/Memory, Circuits/Measuring and Testing, Optics/Photocopying, Printing/Measuring and Testing

TC 3700

- Mechanical Engineering, Manufacturing and Medical Devices/Processes

Tech Center 1600 — Biotechnology

Group	Description	3YGR
1610	Organic Compounds: Bio-affecting, Body Treating, Drug Delivery, Steroids, Herbicides, Pesticides, Cosmetics, and Drugs	50%
1620	Organic Chemistry	70%
1630	Molecular Biology, Bioinformatics, Nucleic Acids, Recombinant DNA and RNA, Gene Regulation, Nucleic Acid Amplification, Animals and Plants, Combinatorial/ Computational Chemistry	53%
1640	Immunology, Receptor/Ligands, Cytokines Recombinant Hormones, and Molecular Biology	58%
1650	Fermentation, Microbiology, Isolated and Recombinant Proteins/Enzymes	59%
1660	Plants	87%
1670	Unknown new group	52%
1690	Search and Classification	62%

Art Units in Group 1670 – New Group!

Art Unit	Description	3YGR
1671	Organic compounds -- part of the class 532-570 series	40%
1672	Data processing: measuring, calibrating, or testing	47%
1675	Drug, bio-affecting and body treating compositions	55%
1677	Chemistry: molecular biology and microbiology	54%
1678	Chemistry: molecular biology and microbiology	56%

*Statistics courtesy of PatentBots

Tech Center 3600

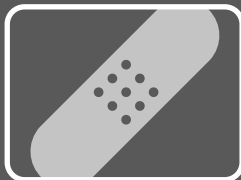
Group	Description	3YGR
3610	Surface Transportation	81%
3620	Business Methods - Incentive Programs, Coupons; Operations Research; Electronic Shopping; Health Care ; Point of Sale, Inventory, Accounting; Cost/Price, Reservations, Shipping and Transportation; Business Processing	33%
3630	Static Structures, Supports and Furniture	74%
3640	Aeronautics, Agriculture, Fishing, Trapping, Vermin Destroying, Plant and Animal Husbandry, Weaponry, Nuclear Systems, and License and Review	73%
3650	Material and Article Handling	81%
3660	Computerized Vehicle Controls and Navigation, Radio Wave, Optical and Acoustic Wave Communication, Robotics, and Nuclear Systems	81%
3670	Wells, Earth Boring/Moving/Working, Excavating, Mining, Harvesters, Bridges, Roads, Petroleum, Closures, Connections, and Hardware	75%
3680	Business Methods - Incentive Programs, Coupons; Electronic Shopping; Business Cryptography, Voting; Health Care ; Point of Sale, Inventory, Accounting; Business Processing, Electronic Negotiation	35%
3690	Business Methods – Finance/Banking/Insurance	35%

But ... if you are assigned an examiner in Art Unit 2125, allowance rate is 77%

Class Number	Description
706	Data processing: artificial intelligence
700	Data processing: generic control systems or specific applications
712	Electrical computers and digital processing systems: processing architectures and instruction processing (e.g., processors)
713	Electrical computers and digital processing systems: support
707	Data processing: database and file management or data structures
705	Data processing: financial, business practice, management, or cost/price determination
703	Data processing: structural design, modeling, simulation, and emulation
709	Electrical computers and digital processing systems: multicomputer data transferring
382	Image Analysis
600	Surgery

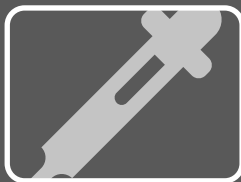
Frameworks for Drafting and Prosecution

Scientific Framework



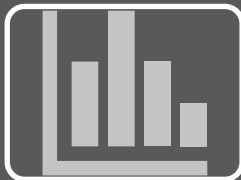
Manifestation of Biological Condition

- Biochemical Process Disruptions
- Disease



Sample Collection and Data Generation

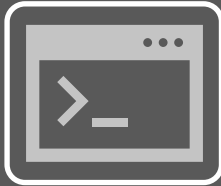
- Sequencing
- Imaging
- Molecule characterization



Data Analysis

- Bioinformatics
- Machine Learning
- Statistics

Legal Framework



§112

- Predictable Arts
- Unpredictable Arts



§101

- Patentable Subject Matter
- Abstract Idea
- Natural Phenomenon





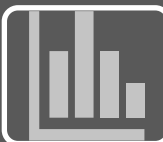
§102, §103

- Novelty & Inventiveness

Enablement & Written Description Considerations under § 112

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).

-  Manifestation of Biological Condition
 - Biochemical Process Disruptions
-  Sample Collection and Data Generation
 - Sequencing
 - Imaging
-  Data Analysis
 - Bioinformatics
 - Machine Learning

Amgen v. Sanofi

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]."



Amgen v. Sanofi

The Court invalidated Amgen's Claim under enablement

- 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**.

Amgen v. Sanofi

Unpredictability in the Art was a Factor in Decision

*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. See *id.*, at 14. But scientists cannot always accurately predict exactly how trading one amino acid for another will affect an antibody's structure and function. *Ibid.* 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.” *Id.*, at 14–15. (emphasis added)*

Drafting 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
- Carefully crafted claims
- Draft claims that cover the core uses or embodiments.

Drafting Considerations

- Provide deep support in specification for broad claims, both in figures and in examples.
- Detailed examples in the specification: provide details in components used, process steps, and architecture of experiments and analyses.
- For life science features, consider citations to known techniques for certain processes, such as sequencing or molecule synthesis, that are not part of the claims/invention.

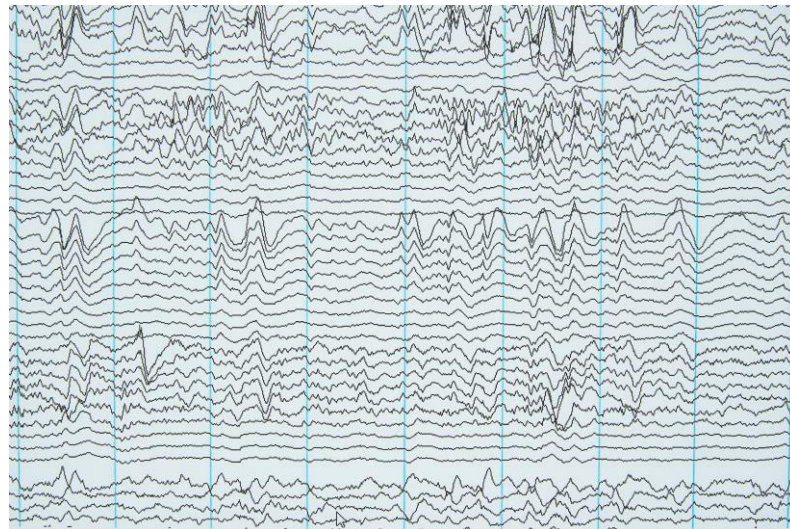
Illustrative Examples, Flow Charts, or Both?

- The intersection of technology areas creates interesting approaches to biotechnology drafting
- Biotech and chemical practitioners rely on **Examples** and **Data**
- Software practitioners often use **Flow Charts** and other **Figures**
- **In the bioinformatics realm, both may be desired to fulfill patent drafting requirements such as enablement, written description, and others.**

Patentable Subject Matter Considerations under § 101

Alice, Mayo... or both?

- Certain bioinformatics cases implicate **abstract subject matter** analysis under *Alice*
- Depending on the case, **diagnostic methods** may also be present, involving the *Mayo* analysis



23andMe Inc. v. Ancestry.com

23andMe sued *Ancestry.com* for **infringement** of the '554 patent

The '554 Patent

- Directed to analyzing recombinable DNA to identify related individuals in a database
- Using “**Identical By Descent**” or “**IBD**” regions
- Claims directed to sequencing the **whole genome** or **identifying certain markers** in relation to **IBD regions**
- Determining a predicted degree of relative relationship between two users based on a threshold overlap of IBD regions in the users.

23andMe Inc. v. Ancestry.com

Ancestry.com argued the '554 invalid over §101



Software
component

- Abstract idea
- Determining a relative relationship by comparing similarities between DNA



Biological
component

- Law of nature
- People who share similar DNA are related

23andMe Inc. v. Ancestry.com

The Court sided with Ancestry.com

- The Court decided to proceed under *Mayo* and determined that the claims did not pass the *Mayo* test.
- Claims of the '554 patent were too close to the intrinsic nature of DNA. The improvements were not enough.
- IBD analysis relied on well-established concepts
- IBD analysis was not novel or obvious

Ariosa Diagnostics, Inc. v. Sequenom, Inc.

Ariosa alleged *Seuqnom's* claim was invalid under §101

The '540 Patent

1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises:
 - amplifying a paternally inherited nucleic acid from the serum or plasma sample and
 - detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

Ariosa Diagnostics, Inc. v. Sequenom, Inc.

The Federal Circuit applied the *Mayo* test.

- The patent failed the *Mayo* test, as the method “**begins and ends**” **with a natural phenomenon**.
- “[f]or process claims that encompass natural phenomen[a], the process steps . . . **must be new and useful**.” The inventors added “well-understood, routine, and conventional activity”
- Rejected Sequenom's argument that "implies that the inventive concept lies in the discovery of cffDNA in plasma or serum."

In Re: Board of Trustees of the Leland Stanford Junior University

PTAB found claims to be not patent eligible

- The application did describe improvements to a technology field:

“The written description also explains that, in the prior art, methods of determining haplotype phase based on in-heredity state yielded an incomplete number of the alleles’ haplotypes ... The claimed methods allegedly increase the number of possible haplotype phase predictions.”
- However, claim 1 only had two “determining” operations. All others were “receiving” or “providing” operations. One “determining” operation was described in the specification as being part of the prior art.

In Re: Board of Trustees of the Leland Stanford Junior University

The Federal Circuit 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.

The written description makes clear that the mathematical steps performed, and the types of data received, as claimed, are conventional and well understood in the prior art.

In Re: Board of Trustees of the Leland Stanford Junior University

The Federal Circuit also cautioned against simply adding a diagnosis or treatment step

Dependent claims 8–10 and 18–20 contain limitations drawn to making non-specific determinations of a “diagnosis,” “drug treatment,” and “prognosis” based on the haplotype phase calculation. Without further limitations, these claims do nothing more than recite the haplotype phase algorithm and instruct, “apply it,” as the Supreme Court has prohibited.

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 and maybe add a claim element directed to complexity:
 - # sequences analyzed or generated
 - amount of data stored or processed
 - number of iterations in training process

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 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

Natural Phenomena Rejection and sometimes Abstract Idea Rejection

- Argue applying or using a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition
- Include treatment options in the specification to meet Vanda requirements, if possible

Practical Application Continued

Abstract Idea Rejection

- 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)

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)

Other Drafting & Prosecution Considerations

- For natural phenomenon rejections, possibly tie diagnostic steps into treatment, molecule expression, computational operations features
- 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)

Novelty & Obviousness

Considerations under § § 102, 103

Drafting Considerations

Where is the novelty?

- Sample collection and processing
- Data generating operations
- Data preprocessing
- Computational architecture
- System output

How does the biology impact the computational architecture?

How does the type of data analyzed impact preprocessing and/or the computational techniques implemented?



Manifestation of Biological Condition

- Biochemical Process Disruptions
- Disease



Sample Collection and Data Generation

- Sequencing
- Imaging
- Molecule characterization



Data Analysis

- Bioinformatics
- Machine Learning
- Statistics

Divided Infringement

- Nature of bioinformatics involves both physical and software processes and systems
- Claims can include both
- **Who is the intended infringer?**



132 Declarations

- **Declarations** or **affidavits** can be used to submit evidence in front of an Examiner that is not included in the specification
- Can be used to rebut obviousness rejections, lack of enablement rejections, and subject matter eligibility rejections
- Evidence can include scientific data, expert statements, support for unexpected results, commercial success, inoperability of the prior art, solution to a long-felt need, attribution of a cited reference to the Applicant, prior public disclosure of subject matter derived from an inventor

Thank you for your interest.

Questions?



These materials are for general informational purposes only. They are not intended to be legal advice, and should not be taken as legal advice. They do not establish an attorney-client relationship.



Schwegman Lundberg & Woessner | slwip.com