FISH.

Patent Strategies for Bioinformatics and Genomics Inventions

April 3, 2024

Housekeeping

- CLE
- Questions
- Materials
  - http://www.fr.com/webinars

Meet the Speakers

Patrick Darno
Principal

darno@fr.com

J. Peter Fasse
Principal

peter.fasse@fr.com

Agenda

- Types of Bioinformatics and Computational Genomics Patents
- Strategies for Patenting Bioinformatics and Computational Genomics Technologies
- The Role of AI in Patentable Inventions
- The Current State of Patent Eligibility for these Technologies in the U.S. and Abroad
- Enablement Issues for Software- and AI- Based Inventions

Types of Bioinformatics and Computational Genomics Patents

Bioinformatics and Computational Genomics Defined

FISH.

Bioinformatics Defined

- **Bioinformatics is a field of technology that uses computer science to understand biology**

- **Using computer science to understand biology is a loaded phrase**
  - Most general sense: computer systems that analyze biological data
  - Further in the weeds: computer systems can apply techniques related to data processing, mathematics, statistical modeling, physics, information engineering, or some combination thereof, that analyze and interpret biological data

- **A broad interdisciplinary technological field**

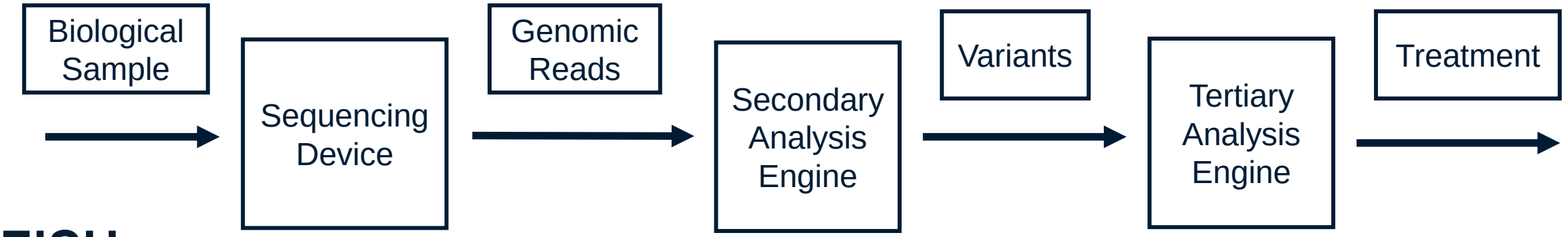
- **Example of a system**
  - Obtaining genomic reads generated by a nucleic acid sequencer and performing one or more computational operations on the obtained genomic reads

Computational Genomics Defined

- **Computational genomics generally relates to using computer science to draw inferences about a person or animal based on a genomic analysis**
- **Computational genomics is a specific subset of bioinformatics**
  - As a result, computational genomics innovations are directed towards computer systems that can apply techniques related to data processing, mathematics, statistical modeling, physics, information engineering, or some combination thereof, that analyze and interpret biological data
- **An interdisciplinary technological field focused on analyzing and interpreting a specific biological data input – i.e., whole genome sequencing data**
- **Given extremely large input data sets, unique challenges arise in managing and processing the large input data sets**
- **For today's discussion:**
  - Computational genomics = bioinformatics
  - Bioinformatics may, but does not necessarily, = computational genomics

The Bioinformatics Pipeline

- **A bioinformatics pipeline can comprise a device, software engine, or combination thereof, that:**
  - Performs one or more operations to obtain or generate biological data
    - *e.g., perform sequencing operations on plant or animal DNA to generate genomic reads*
  - Performs one or more secondary analysis operations on biological data to interpret the biological data
    - *e.g., map genomic reads to a reference sequence, align genomic reads to a reference sequence, determine variants between the genomic reads and the reference sequence*
  - Performs one or more tertiary analysis operations on output from the secondary analysis engine
    - *e.g., generate targeted diagnosis, treatment, or combination thereof based on obtained variants*
  - <u>Example Bioinformatics Pipeline:</u>



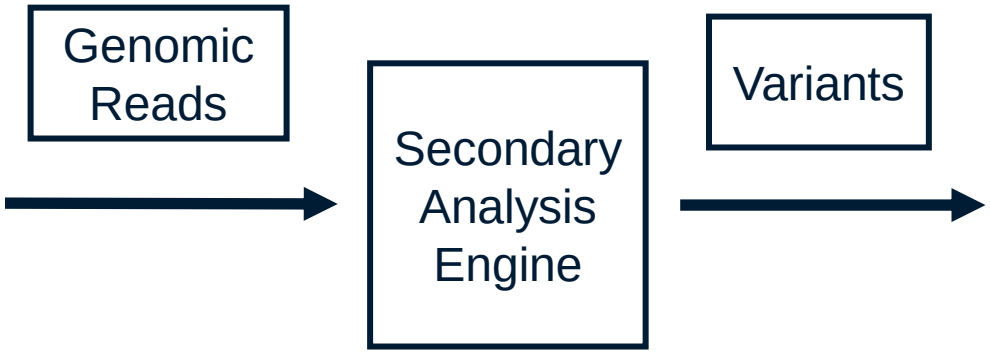
Sequencing Inventions

- **Sequencing inventions generally relate to operations performed by the nucleic acid sequencer**
  - *e.g., sample preparation, nucleic acid sequencing, quality scoring of base calls, read data formatting*

- **Data generated by a sequencing device is often used in bioinformatics inventions**
  - But always ask whether sequencing is ***where*** the invention lies
  - ***Practice Tips:***
    - **Avoid drafting an independent claim to include an active sequencing operation if the novel and/or non-obvious subject matter of the invention is not found at the sequencing stage**
    - **Avoid drafting an independent claim to include an active sequencing operation if the target of the patent claim is not likely to perform sequencing operations**

Secondary Analysis Inventions

- **Secondary analysis inventions generally relate to operations performed on previously generated biological data**
  - *e.g., mapping of genomic reads to a reference sequence, alignment of reads to a reference sequence, determination of variants between aligned reads and a reference sequence*
- **Consider the relationship between the secondary analysis engine to other stages of the bioinformatics pipeline when drafting claims**
  - Would an entity that performs the secondary analysis of generated biological data (e.g., genomic reads):
    - **perform sequencing operations?**
    - **perform any pre-processing operations on genomic reads output by a sequencer?**
    - **perform any post-processing operations on outputs of the secondary analysis engine?**
  - Where is the secondary analysis engine located with respect to the nucleic acid sequencer, database(s) of genomic data, or other input source?
  - Where is the secondary analysis engine going to send the outputs it generates?
  - How will the secondary analysis engine send the outputs it generates?

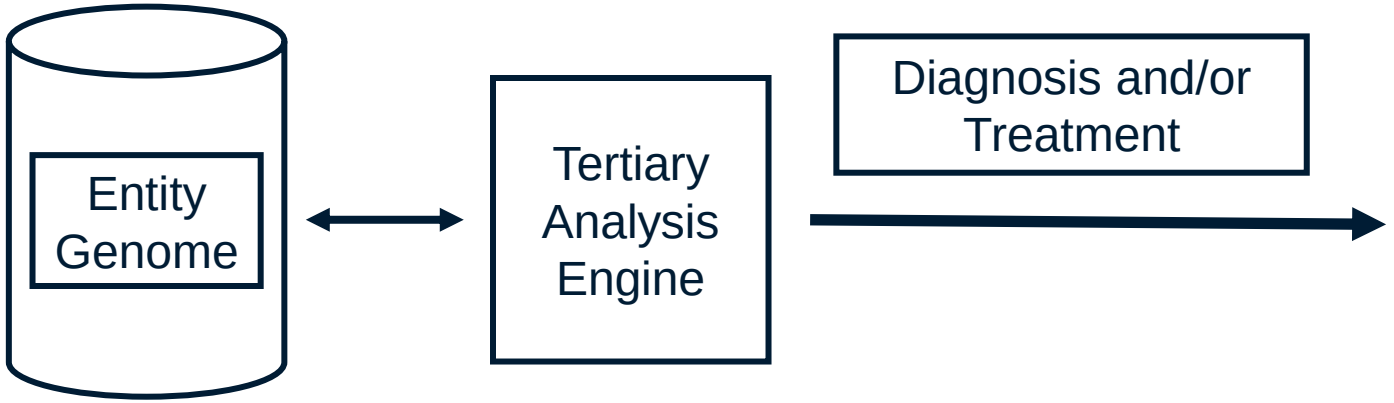


Tertiary Analysis Inventions

- **Tertiary analysis inventions generally relate to operations performed on the output of a secondary analysis engine**
  - *e.g., determination of a diagnosis (e.g., type of cancer), determination of a treatment (e.g., cancer treatment), or a combination thereof*
- **Consider the relationship between the tertiary analysis engine to other stages of the bioinformatics pipeline when drafting claims**
  - Would an entity that performs tertiary analysis of the genomic reads also perform sequencing or secondary analysis?
  - Where is the tertiary analysis engine located with respect to other pipeline devices and/or engines?
  - Will tertiary analysis engine perform pre-processing operations?
  - Where will the tertiary analysis engine transmit generated outputs?
  - Will tertiary analysis engine perform post-processing operations on output before transmitting?
  - Would the entity that performs tertiary analysis to determine a treatment actually administer the treatment?
  - **Practice Tip:** Avoid drafting a claim that administers a treatment, which can be helpful to overcome 35 U.S.C. 101 challenges, ***unless*** target entity actually administers the treatment.

Computational Genomics Inventions

- **Computational Genomics inventions may fall within the tertiary analysis stage of the bioinformatics pipeline**
  - Related to the special case of interpreting an entire genome for an entity
- **Consider relationships with other stages of the bioinformatics pipeline as specified on the tertiary analysis inventions slide**
- **Also consider unique challenges related to processing the large data set of an entity genome**
  - *e.g., storage of genome, access of genome, processing of genome, parallel processing to increase throughput*



Strategies for Patenting Bioinformatics and Computational Genomics Technologies

FISH.

Key Considerations When Framing Patent Strategy

- **Determine *where* the invention fits within the bioinformatics pipeline and *who* is likely to perform the invention**
  - Where: what stage of the bioinformatics pipeline
    - **sample preparation, sequencing, secondary analysis, or tertiary analysis**
    - **other pre-operation processing**
      - *e.g., formatting of reads output by a sequencer, decompression of reads received via a network*
    - **other post operations processing**
      - *e.g., compression of reads generated by a secondary analysis engine, evaluating a diagnosis or treatment generated by a tertiary analysis engine, administering of a treatment generated by a tertiary analysis engine*
  - Who: identify the particular entity that is to perform the stage of the bioinformatics pipeline
    - **an owner of a lab operating a sequencer that performs sequencing operations**
    - **a data analytics company that performs secondary analysis operations in a cloud server**
    - **a pharmaceutical company that runs tertiary analysis software to generate a diagnosis and/or treatment**
    - **a doctor that administers a treatment**
- **Consider how the *where* and *who* may change over time as technology evolves**
- ***Practice Tip:* avoid drafting claims that have divided infringement**

Act ***Now*** To Ensure Your Company Is Not Left Behind

- **Consider current ***and*** future business needs**
  - For example:
    - **Does your company currently have a bioinformatics unit?**
      - If yes, are you taking steps to protect intellectual property rights in your innovations in this space?
      - If no, should your company start a bioinformatics unit?
    - **Thinking about today is important – but also think about tomorrow - where this technology is headed in the next 5, 10, 15, and 20 years**
      - It is always beneficial to evaluate and protect technology that is currently in development and/or can be employed today
      - However, don't sacrifice the future by ***only*** focusing on today
      - There is no requirement for an invention to be reduced to practice to file a patent application
      - Accordingly, perform creative exercises such as identifying innovations that could be achieved assuming an unlimited team and unlimited budget – and then file one or more prophetic patent applications covering those innovations

Strategic Considerations – *A Two-Tiered Approach*

- **The *first tier* of a strategic approach is a look *inwards* at your company's innovations**
- **Identify streams of products and services from which:**
  - Your company derives revenue
  - Your company plans to derive revenue in the future
- **Prepare and file at least one patent family for new and useful "blocking features" of each identified stream of products and/or services**
- **Patent strategy should not only focus on what can currently be done by you for your company**
  - Think about improvements to current products and services
  - Think about new products and services that can launch in the future
- **Monitor public disclosures**
  - Evaluate the subject matter for new and useful "blocking features" and file accordingly
  - Employ strategic uses of NDAs as appropriate

Strategic Considerations – *A Two-Tiered Approach*

- **The *second tier* of a strategic approach is a look *outwards* at your competitor's innovations**

- **Gather competitor intelligence related to your competitor's products**
  - Determine key features of your competitor's current products and/or services
  - Determine improvements that can be made to your competitor's products and/or services
  - Determine natural technological evolutions to your competitor's current products and/or services

- **File patent applications for "blocking features" related to features of your competitor's products and/or services in any one of the above categories to build an economic moat**

- **Example: By determining how you can improve on a competitor's offering and filing one or more patent applications for the improvement, you can cut off a competitor's revenue stream**

Artificial Intelligence in Bioinformatics Innovations

- **Use of Artificial Intelligence (AI) is rapidly expanding and increasing the pace of innovation**
- **A modern business strategy for Bioinformatics requires a plan to utilize AI to ensure your company is not left behind**
- **Accordingly, when planning your bioinformatics business strategy, the following should be considered:**
  - **Use of AI models to streamline day-to-day operational tasks**
    - **e.g., search engine alternative, creation of *draft* documents or emails, assist with planning schedule**
  - **Applications of AI models to genomic data to draw inferences from the genomic data**
    - **e.g., predict likelihood of a variant given a sample sequence and a reference sequence**
  - **Whether you have the team in place that can effectively use AI in the manners identified above**
- **To the extent innovation occurs in the bioinformatics space using AI, can it be patented?**

The Role of AI in Patentable Inventions

Can Inventions Made Using AI be Patented?

How to Determine Inventorship of Inventions Made Using AI?

FISH.

Can Inventions Made Using AI be Patented?

- **Short Answer – Yes (USPTO Guidance on AI and Patents, issued on February 13, 2024)**
- The use of an AI system by a natural person(s) does not preclude a natural person(s) from qualifying as an inventor(s) if the natural person(s) significantly contributed to the claimed invention
- One can file patent applications for inventions created using AI as a tool, like other tools, but only if a human made a “significant contribution” to the invention
- Such inventions still need to have proper inventorship and meet the requirements for patentability
  - Proper inventorship by human inventors
  - 101 – Patentable Subject Matter
  - 112 – Written Description and Enablement
  - 102/103 – Novelty and Non-Obviousness

Can Inventions Made Using AI be Patented?

- BUT - AI systems and other non-natural persons cannot be listed as inventors on patent applications or patents
- If a machine or AI is listed as an “inventor” the application will be rejected for improper inventorship
  - **Stephen Thaler** filed two US applications (Fractal Container and Neural Flame) listing DABUS (Device for the Autonomous Bootstrapping of Unified Science) as the only inventor
  - **USPTO** held that only “natural persons” – human beings – can be inventors (04-22-2020)
  - **US District Court ED Virginia** agreed with USPTO on summary judgment (09-02-2021)

Can Inventions Made Using AI be Patented?

- ***Thaler v. Vidal,*** 43 F.4th 1207 (Fed. Cir. 2022)
  - **"the Patent Act requires that inventors must be natural persons; that is, human beings"**
  - Supreme Court has held that, when used in statutes, the word "individual" refers to human beings
  - Statutes are often open to multiple reasonable readings. Not so here.
  - "Only a natural person can be an inventor, so AI cannot be."
  - Affirmed District Court, and request for rehearing denied
- **US Supreme Court** denied petition for writ of certiorari (04-24-2023), so for now, AI cannot be an inventor in the US

Can Inventions Made Using AI be Patented?

- Thaler also filed two applications at the EPO, and the applications were refused by the EPO for improper inventorship
- Thaler appealed and was refused by the EPO Boards of Appeal (12-21-2021)
  - Thaler argued that the machine/AI is the inventor, but that he, as the owner of the machine, is the assignee/owner of the IP
  - The EPO and Board disagreed
  - A machine is not an inventor within the meaning of the EPC, because an inventor within the meaning of the EPC must be a natural person
- Thaler lost in Germany - the Federal Patent Court ruled that AI-generated inventions may be patentable, but a natural person must be named as the inventor
- Thaler won in Australia at the Appeal Court level, but lost before the Full Court and the High Court refused to hear the case
- Thaler lost in the UK, NZ, and SK, but received a patent in South Africa

How to Determine Inventorship of Inventions Made Using AI?

- **Follow the USPTO and Court guidance**
- As noted, an inventor must be a “natural person”
- Each named inventor in a patent application or patent (including for AI-assisted inventions), must have made a “significant contribution” to the claimed invention – so must determine:
  - (1) contribute in some significant manner to the conception of the invention,
  - (2) 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, and
  - (3) do more than merely explain well-known concepts and/or the current state of the art” (*Pannu* factors) *Pannu* v. *Iolab Corp.,* 155 F.3d 1344, 1351 (Fed. Cir. 1998)
- A person who uses an AI system to create an invention is required to make a significant contribution to every claim of the invention to be considered a proper inventor
- Attorneys must ask how the AI was used and who was involved at every step
- Inventors must document how they used and trained the AI, and if and how they used and modified any output from the AI

How to Determine Inventorship of Inventions Made Using AI?

- **USPTO Guiding Principles**
  - The natural person can be listed as the inventor or joint inventor if the natural person contributes significantly to the AI-assisted invention
  - A natural person who only presents a problem to an AI system may not be a proper inventor or joint inventor of an invention identified from the output of the AI system
  - A natural person who merely recognizes and appreciates the output of an AI system as an invention, particularly when the properties and utility of the output are apparent to those of ordinary skill, is not necessarily an inventor
  - In some situations, the natural person(s) who designs, builds, or trains an AI system in view of a specific problem to elicit a particular solution could be an inventor, where the designing, building, or training of the AI system is a significant contribution to the invention created with the AI system
  - A person simply owning or overseeing an AI system that is used in the creation of an invention, without providing a significant contribution to the conception of the invention, does not make that person an inventor

How to Determine Inventorship of Inventions Made Using AI?

- **USPTO Guidance Example 2 – Developing a Therapeutic Compound for Treating Cancer**
  - **Background**: Marisa researches cancer drugs and discusses with AI expert Raghu methods of using *in silico* drug-target interaction prediction methods in a deep neural network prediction model. Lauren trained and maintains the model. Raghu enters data strings of well-known cancer-related datasets for 20K compounds suggested by Marisa. The model outputted binding affinity numbers. Marisa selected potential drug candidates based on the numbers.
  - **Scenario 1 – Drug optimization using wet-lab experiment**
    - Marisa's post doc Naz synthesized 6 drug candidate compounds and through testing picked one compound has having greatest promise. They discussed unmutated and mutated forms, and adverse effects, and identified structural modifications. Naz found an intermediate compound with higher binding to mutated target, yet with sufficient anti-tumor effect. They together developed a method of using the model to provide drug candidates followed by wet-lab experiments.
    - **Claims** to a specific lead compound and to a method of identifying and synthesizing a lead drug by:
      - providing compound information as inputs to deep neural network, obtain outputs of binding affinity numbers
      - identifying selected drug candidate with high binding
      - synthesizing stable intermediate, and
      - synthesizing lead drug by introducing structural modifications to the stable intermediate

How to Determine Inventorship of Inventions Made Using AI?

- **Who are the inventors of Scenario 1?**
- Marisa and Naz are joint inventors of the method and compound claims
  - Marisa contributed by deciding to create a treatment for prostate cancer by developing new compounds for a specific target, identifying specific datasets of target protein as inputs for the model, identifying top candidates, determining structural modifications, and synthesizing the drug, and recognized the anti-tumor potency and limited side effects
  - Naz contributed by performing wet-lab experiments, identifying lead compounds, determining which structural modifications would work, characterizing lead candidates and synthesizing intermediates that had better efficacy and fewer side effects
- Raghu and Lauren are not inventors of the method or the compound claims
  - Raghu merely provided inputs to the model using standard formats, and this work was “insignificant in quality when measured against the dimensions of the full invention,” because he used only normal skill to input known data suggested by Marisa into a known model
  - Lauren only trained the model on diverse drug sets and targets from prior studies and so her general training and maintenance of the model is not a significant contribution
  - These contributions were not made with a specific problem in mind

How to Determine Inventorship of Inventions Made Using AI?

- **USPTO Guidance Example 2 – Developing a Therapeutic Compound for Treating Cancer**
  - **Scenario 2 – Drug optimization using Molecular Optimizer (different from Scenario 1)**
    - Marisa and Raghu found most of the drug candidates failed during trials due to poor absorption, high excretion and toxicity, so they decided to find other drugs with good binding and fewer side effects
    - Raghu developed a new generative neural network-based AI system, Molecular Optimizer, and Marisa provided the desirable properties and optimal numerical value ranges and a scalar objective function based on the optimal ranges of these good properties
    - Raghu trained a neural network regression model to predict the value of the objective function for a molecule and then trained the Molecular Optimizer, and Marisa synthesized a subset of drug candidates based on outputs of the optimizer and validated the outputs by characterizing and testing these candidates, and Raghu fine-tuned the model
    - Raghu inputted 6 drug candidates with highest binding affinity and model provided modified versions. Marisa synthesized and tested the 6 best candidates, and they claimed the best compound

How to Determine Inventorship of Inventions Made Using AI?

- **Who are the inventors of Scenario 2?**
- Marisa and Raghu are joint inventors of the compound claim
  - Marisa and Raghu contributed by identifying the problems with synthesizing a drug directly as outputted by the original model and set out to find a new way to discover and synthesize new drug candidates that bind well to the target and have low side effects
  - They collaborated to train the new Molecular Optimizer model. The new model generated new drug candidates, and Marisa synthesized them and worked with Raghu to fine-tune the new model. Both contributed significantly to the conception of the claimed compound.
  - Marisa recognized that there was one best drug candidate that could be used to treat prostate cancer.
  - Marisa also developed the scalar objective function and Raghu developed, trained, and refined the new model. These were significant contributions above and beyond just building the new AI model.
- As in Scenario 1, Lauren's work with the original model, which was the starting point for the new work, is not an inventor of the chemical compound, for the same reasons above

The Current State of Patent Eligibility for these Technologies in the U.S. and Abroad

Are Bioinformatics Inventions Eligible for Patent Protection?

FISH.

The *Alice* Question ...

- **General Requirements To Obtain A U.S. Patent**
  - Eligible for patenting
  - Novel
  - Non-obvious
- **Subject matter eligibility is often the most difficult hurdle to overcome for Bioinformatics and Computational Genomics Innovations**
- **Likely to receive "*Alice*" rejection under 35 U.S.C. 101** ***(Alice Corp. v. CLS Bank International, 573 U.S. 208, 2014)***
    - Such rejections allege that a claim is directed to a judicial exception *(e.g., abstract idea, law of nature, or physical phenomena)* to patent eligible subject matter
    - Examiners are likely to allege that bioinformatics claims are directed to an abstract idea
- **The Federal Circuit has considered bioinformatics inventions**
  - *See* ***In re Board of Trustees of Leland Stanford Junior University, 991 F.3d 1245 (2021)***
    - Notably, the Federal Circuit found the claims in this case to be *ineligible* for patent protection
    - A close read of the opinion reveals insights that, if found in a patent application, may have resulted in a different outcome
    - These insights provide us helpful practice tips that we will highlight in the coming slides

In re Board of Trustees of Leland Stanford Junior University

Claim 1 of US Application No. 13/486,982

1. A computerized method for inferring haplotype phase in a collection of unrelated individuals, comprising:

receiving genotype data describing human genotypes for a plurality of individuals and storing the genotype data on a memory of a computer system;

imputing an initial haplotype phase for each individual in the plurality of individuals based on a statistical model and storing the initial haplotype phase for each individual in the plurality of individuals on a computer system comprising a processor a memory;

building a data structure describing a Hidden Markov Model, where the data structure contains:

a set of imputed haplotype phases comprising the imputed initial haplotype phases for each individual in the plurality of individuals;

a set of parameters comprising local recombination rates and mutation rates;

wherein any change to the set of imputed haplotype phases contained within the data structure automatically results in re-computation of the set of parameters comprising local recombination rates and mutation rates contained within the data structure;

repeatedly randomly modifying at least one of the imputed initial haplotype phases in the set of imputed haplotype phases to automatically re-compute a new set of parameters comprising local recombination rates and mutation rates that are stored within the data structure;

automatically replacing an imputed haplotype phase for an individual with a randomly modified haplotype phase within the data structure, when the new set of parameters indicate that the randomly modified haplotype phase is more likely than an existing imputed haplotype phase;

extracting at least one final predicted haplotype phase from the data structure as a phased haplotype for an individual; and

storing the at least one final predicted haplotype phase for the individual on a memory of a computer system.

FISH.

In re Board of Trustees of Leland Stanford Junior University

- **PTAB affirmed examiner's rejection of ineligibility as an abstract idea**

  - The PTAB explained that Stanford ***failed to identify any specific disclosures in the specification asserting that claim 1 results in improved computer functionality***

  - The PTAB distinguished the *McRO* case, because the process used there ***combined order specific rules that render information into a specific format that is then used and applied to create desired results***: a sequence of synchronized, animated characters

  - The PTAB acknowledged claim 1 may be useful in medical or population genetics studies … but … is ***devoid of a specific step that the claimed calculations are 'integrated' into a practical application***

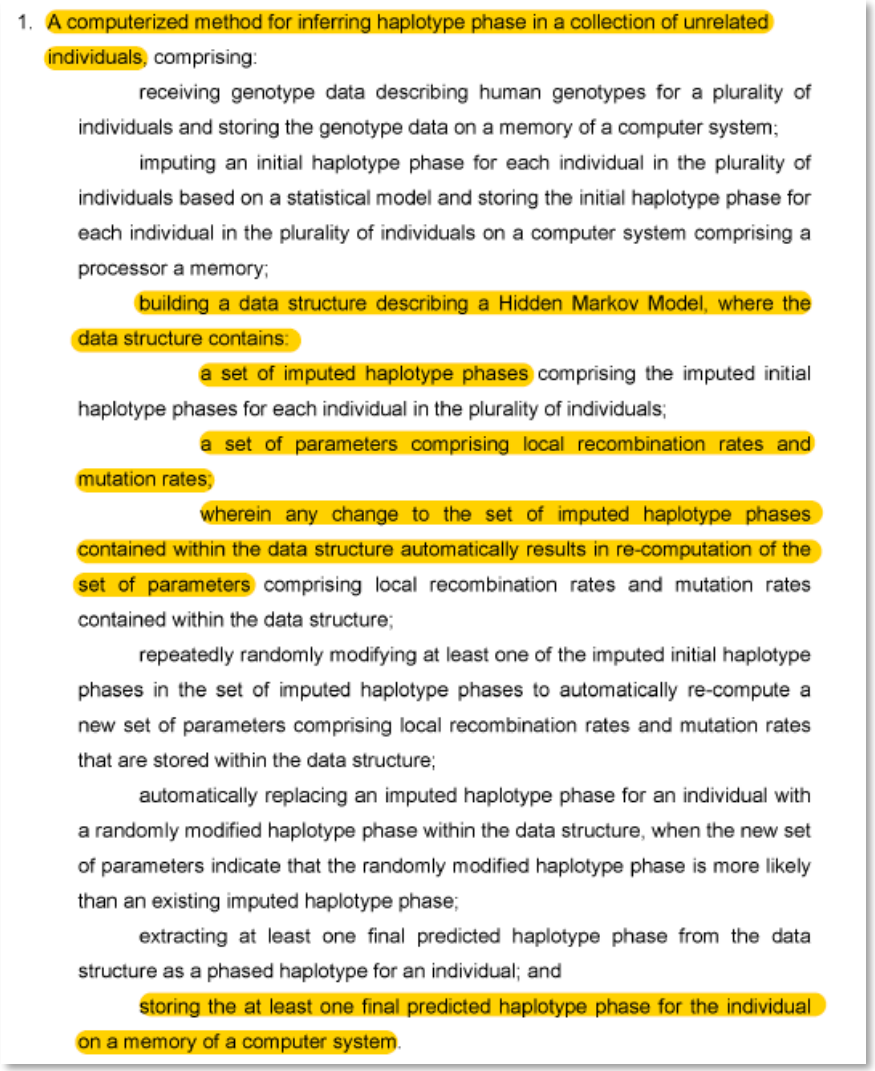
In re Board of Trustees of Leland Stanford Junior University

- **Federal circuit affirmed the PTAB's decision**
  - The Federal Circuit determined that the claims are directed to an abstract idea
  - Stanford argued that the claim steps result in a ***more accurate haplotype prediction***
  - The Federal Circuit pointed out that the written description recited that the mathematical steps were ***conventional and well understood***
  - The Federal Circuit explained that ***the alleged increase in computational accuracy does not qualify as an improvement to a technological process; rather, it is merely an enhanced abstract mathematical calculation of haplotype phase***

In re Board of Trustees of Leland Stanford Junior University

- **Interesting insights:**
  - PTAB noted that Stanford ***did not identify specific disclosures in specification*** asserting that claim 1 results in improved computer functionality
  - Federal Circuit rejected the argument that the claim ***allegedly*** made the mathematical algorithm for haplotype predictions ***more accurate,*** because this was not considered to be a technological improvement
    - **Another signal that the specification was deficient**
  - Federal Circuit pointed out that ***Claim 1 recites no application, concrete or otherwise, beyond storing*** the haplotype phase

Claim 1 of US App. No. 13/486,982



1. A computerized method for inferring haplotype phase in a collection of unrelated individuals, comprising:

receiving genotype data describing human genotypes for a plurality of individuals and storing the genotype data on a memory of a computer system;

imputing an initial haplotype phase for each individual in the plurality of individuals based on a statistical model and storing the initial haplotype phase for each individual in the plurality of individuals on a computer system comprising a processor a memory;

building a data structure describing a Hidden Markov Model, where the data structure contains:

a set of imputed haplotype phases comprising the imputed initial haplotype phases for each individual in the plurality of individuals;

a set of parameters comprising local recombination rates and mutation rates;

wherein any change to the set of imputed haplotype phases contained within the data structure automatically results in re-computation of the set of parameters comprising local recombination rates and mutation rates contained within the data structure;

repeatedly randomly modifying at least one of the imputed initial haplotype phases in the set of imputed haplotype phases to automatically re-compute a new set of parameters comprising local recombination rates and mutation rates that are stored within the data structure;

automatically replacing an imputed haplotype phase for an individual with a randomly modified haplotype phase within the data structure, when the new set of parameters indicate that the randomly modified haplotype phase is more likely than an existing imputed haplotype phase;

extracting at least one final predicted haplotype phase from the data structure as a phased haplotype for an individual; and

storing the at least one final predicted haplotype phase for the individual on a memory of a computer system.

Key Take Aways From *Stanford* To Transform Your Practice

- **Drafting a patent application to survive patent eligibility challenges is a multi-faceted approach**
  1. A claim must be drafted to capture a practical application of a process resulting in a technology improvement, ***and***
  2. A specification must be drafted to explain this technological improvement

- **Technological improvements cannot be *alleged***
  - Federal Circuit and PTAB rejected arguments of ***alleged*** increased accuracy while also highlighting lack of specification support for such increased accuracy; or, more bluntly, indicating that the specification said the mathematics was conventional
    - **Thought for further consideration:** ***would the outcome have been different if the specification described unconventional processes or mathematics for achieving the increased accuracy that was alleged?***

Key Take Aways From *Stanford* To Transform Your Practice

- **Execution of a computer process on a data structure should be claimed and described at an appropriate level of detail**
  - E.g., a level of detail that recites how the process executed on the data structure creates a formatted data result that improves computer functionality

- **Draft claims in manner that brings a process executed to achieve a technological improvement to a conclusion that achieves a practical application of the claimed process**
  - E.g., do not merely generate and store data

Practice Tips For Effective Use of Detailed Description

- **Draft detailed description that explains a process having a practical application and technological improvement**
  - Do not leave the practical application and/or technological improvement undefined
- **Create a drafting routine that will ensure you always include a description of a practical application and technological improvement**
  - Practice Tip: Always use first paragraph of the detailed description to create a one-paragraph summary of the invention, practical application, and technological improvement
    - **You will never forget to include this helpful disclosure**
    - **You will always know where to find this helpful disclosure – even years later when it is time to prosecute the application**
- **Include experimental results, when practicable, to provide evidentiary support for technological improvement**
  - Example: invention is compression of genomic quality scores
    - **provide bar graphs showing compression file sizes and/or compression speed of the claimed method on test data relative to conventional compression algorithms performed on the same test data**

Alice Strategies - Effective Claim Drafting

- **<u>Goal:</u> Claim compression of nucleic acid sequence data using multi-stage encoding**
- **Claim 1 states a *practical application***
- Claim 1 claims a *first technical improvement* reduces the size of input data to a second encoding process
- Claim 1 recites a *conclusory step* that completes the process and achieves faster compression speeds and higher compression ratios by compressing the input data of reduced size

<u>Hypothetical Claim 1</u>

1. A method for compressing nucleic acid sequence data, the method comprising:

obtaining, by one or more computers, nucleic acid sequence data; determining, by one or more computers, whether the read sequence data satisfies a first criteria;

based on a determination that the read sequence does not satisfy the first criteria, generating, by one or more computers, a first encoded data set to reduce size of the nucleic acid sequence data; and

using, by one or more computers, a second encoding process to encode the first encoded data set, thereby compressing the obtained nucleic acid sequence data.

Practice Tips To Enhance Description Using Drawings

- **Make creative use of drawings to highlight technical features of your invention**

- **US Pub. No. 2022/0139502 uses FIG. 1 an example of the technical operation of the process of Claim 1:**

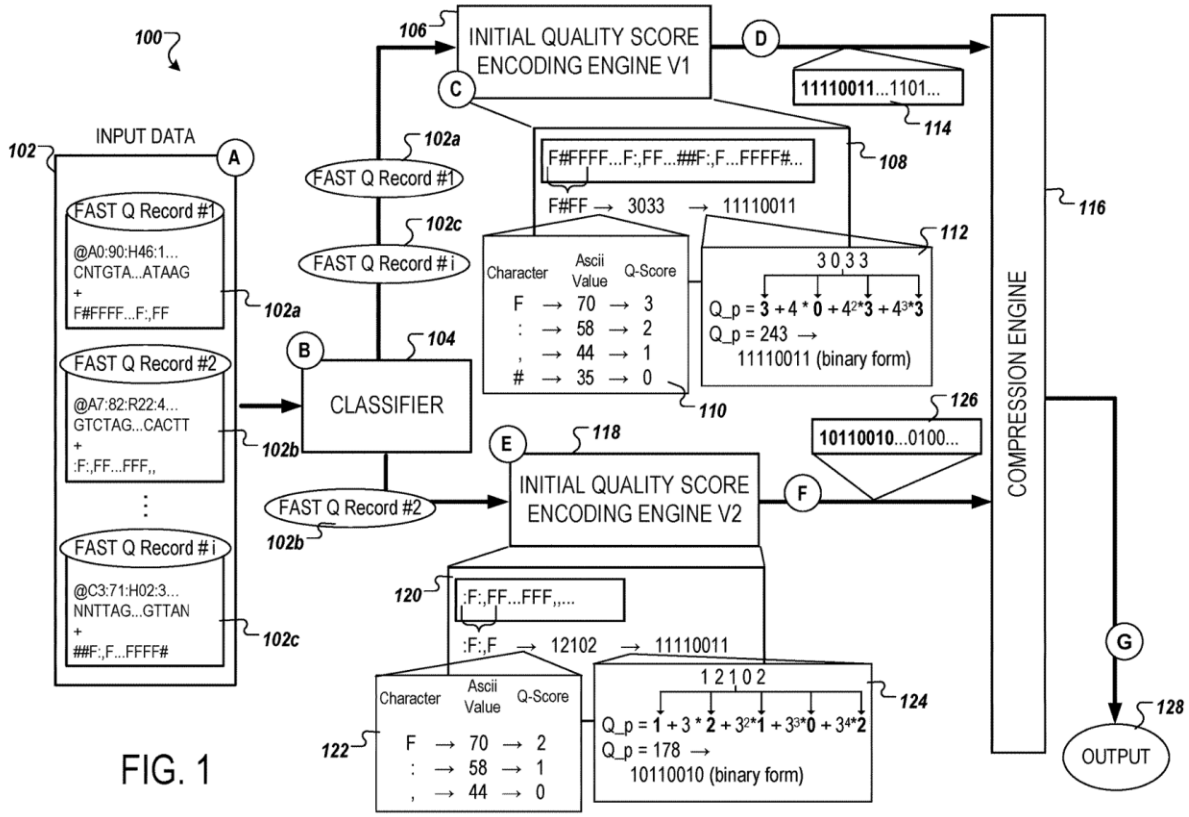


FIG. 1

Summary of Practice Tips Gleaned From Stanford

- **Use detailed description to describe a practical application of the inventive process that achieves a technological solution**
- **Use detailed description to describe the technological solution achieved**
- **Provide evidence of the technological solution so that the technological solution cannot be cast aside as an *alleged* technological solution**
- **Draft claims that include a practical application, a technological solution, and a series of steps that concludes with a step that achieves the technological solution**
- **Creatively prepare drawings to enhance the technical description of the specification**

Common Patent Issues Outside the US

- **We polled patent counsel in numerous countries on the issues they face in patenting bioinformatics and computational genomics inventions in their respective countries**
  - Their responses were surprisingly similar
    - **There is very little or no legal precedent yet in these fields**
    - **The Patent Office guidance specific to bioinformatics and computational genomics is sparse**
    - **Claims are analyzed in the same way as other claims for other software-based inventions**
    - **Patent examiners are often overwhelmed by the combination of biology and software information**

- **The good news is that claims drafted for US or EP standards are generally useful in other countries**

Common Patent Issues Outside the US

- **Useful claim formats**
  - Computer-implemented method
  - Computer system
  - Software in a machine-readable form causing a computer to operate in a specific way
  - Computer programmed with executable code to operate in a particular way
    - **module, library**
    - **neural network, support vector machine, trained model**
  - Information equivalent to a computer program in a machine-readable format
    - **data structures**

Common Patent Issues Outside the US

- **Generally NOT patent eligible**
  - Computer programs “as such” or “per se”
  - Methods that can be performed in the human mind
  - Known methods executed within a general purpose computer
  - Known analytic technique (e.g., machine learning) applied to data organized in a known manner
  - Methods of surgery, treatment, or diagnosis of humans
- **Generally patent eligible**
  - Inventions in an improvement in a technical field outside of a computer
  - Computer-readable recording medium containing computer program that causes a computer to execute certain new steps
  - Diagnostic methods using isolated samples AND do not involve "clinical determination"
  - Devices, systems, and compositions used for diagnostic methods

Enablement Issues for Software- and AI-Based Inventions

Are Bioinformatics Inventions at Risk for Lack of Enablement Rejections?

FISH.

Enablement Issues for Software- and AI-Based Inventions

- *35 USC 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, or with which it is most nearly connected, to make and use the same**, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention

Enablement Issues for Software- and AI-Based Inventions

- ***Amgen v. Sanofi***, 598 U.S. 594 (US Supreme Court - May 18, 2023)
  - Amgen's two patents relate to antibodies that reduce high cholesterol, claimed only by their binding and inhibiting functions to a specific target protein, which was the main invention
  - Broad, functional claims, with no structure
  - The claims cover "a vast number" (millions) of antibodies, but the patents provided details for only 26
  - Court unanimously held Amgen's broad functional claims **invalid** for lack of enablement
  - "If a patent claims an entire class of **processes, machines, manufactures, or compositions of matter**, the patent's specification **must enable a person skilled in the art to make and use the entire class**. In other words, the specification must enable the full scope of the invention as defined by its claims. **The more one claims, the more one must enable.**"

Enablement Issues for Software- and AI-Based Inventions

- ***Amgen v. Sanofi***, 598 U.S. 594 (US Supreme Court - May 18, 2023)
  - **The Court cited several very old Supreme Court decisions all relating to mechanical, chemical, and electronic inventions**
  - "if our cases teach anything, it is that the more a party claims, the broader the monopoly it demands, the more it must enable. That holds true whether the case involves telegraphs devised in the 19th century, glues invented in the 20th, or antibody treatments developed in the 21st.'
  - **Thus, this case applies to all types of inventions, not just antibodies**

Enablement Issues for Software- and AI-Based Inventions

- ***Amgen v. Sanofi***, 598 U.S. 594 (US Supreme Court - May 18, 2023)
  - Supreme Court clarified that the specification does not always need to "describe with particularity how to make and use every single embodiment within a claimed class"
  - The specification may require a reasonable amount of experimentation to make and use the invention
  - What is reasonable will depend on the nature of the invention and the underlying art
    - "it may suffice to give an example (or a few examples) if the specification also discloses some general quality . . . running through the class that gives it a peculiar fitness for the particular purpose"
    - "disclosing that general quality may reliably enable a person skilled in the art to make and use all of what is claimed, not merely a subset."

Enablement Issues for Software- and AI-Based Inventions

- **How does the *Amgen* case apply to software or AI-based inventions?**

- ***Ex Parte William Henry Starrett Jr.*** (PTAB, April 15, 2o22)[Pro se Applicant]
  - Methods of maintaining augmented telepathic data
  - Claims to a non-transitory computer readable medium containing data representing either of or both data structures and program instructions for generating, analyzing, extending, communicating, integrating, storing, converting, editing, encoding, or maintaining said data structures representing: [a long list of categories] and "using at least on machine learning task"
  - Claim 1 contains forty-seven alternatives ("or" clauses) (i.e., more than 140 trillion embodiments)

Enablement Issues for Software- and AI-Based Inventions

- **How does the *Amgen* case apply to software or AI-based inventions?**

- ***Ex Parte William Henry Starrett Jr.*** (PTAB, April 15, 2o22)[Pro se Applicant]
  - Each independent claim contains numerous alternatives ("or" clauses) (i.e., tens of thousands of embodiments)
  - Rejected for lack of enablement (written description, 101, and 103)
  - Each of the *Wands* factors mitigates against enablement
    - Application is lacking in any details
    - Applicant argues that if an apparatus is well-known then any function that applicant claims for that apparatus is fully enabled
  - **PTAB affirmed all of the examiner's rejections**

Enablement Issues for Software- and AI-Based Inventions

- ***In re William Henry Starrett Jr.***, 2023 WL 3881360 (**Fed. Cir.,** June 8, 2o23)
  - The claimed inventions allegedly maintain data structures representing categories of signals in a body such as “Nervous System” and “Sensory System”
  - the Board treated representative claim 1 as a genus claim with forty-seven “or” clauses, thereby allowing it to cover over 140 trillion embodiments
  - Cited the *Amgen* decision:
    - If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent’s specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable

Enablement Issues for Software- and AI-Based Inventions

- ***In re William Henry Starrett Jr.***, 2023 WL 3881360 (Fed. Cir., June 8, 2023)
  - Here, much is claimed, and little is enabled
  - Starrett's contentions were merely conclusory
  - The application's disclosure of a broad and abstract organizational structure used to accomplish the maintenance of augmented telepathic data amounts to little more than a "research assignment" requiring a skilled artisan to undertake undue experimentation to discover what types of devices are encompassed by the claim limitations and how they would function
  - Claim 1, as with other claims in the application, is rife with broad, vague concepts
  - Starrett's arguments on appeal do not address how the disclosure enables the allegedly novel functions of allegedly well-known components
  - Starrett fails to address any of the other Wands factors
  - Accordingly, we affirm the Board's rejection of lack of enablement under § 112(a)

Enablement Issues for Software- and AI-Based Inventions

- **USPTO Enablement Guidance (01-10-2024)**
  - Issued in response to the *Amgen* decision
  - The PTO Guidance reviews the Fed Cir and Supreme Court *Amgen* decisions
  - Also reviews recent Fed Cir decisions, including *In re Starrett*
  - In reliance on *Amgen*, the Federal Circuit stated
    - "[a]lthough a finding of enablement is not precluded by a skilled artisan's need[ ] to engage in some measure of experimentation, the extent of that experimentation must be reasonable."
  - The Federal Circuit endorsed using the *Wands* factors to determine whether the amount of experimentation required in *Starrett* was reasonable when it stated that "[t]he determination as to whether the extent of experimentation is undue or reasonable is informed by the eight *Wands* factors."

Enablement Issues for Software- and AI-Based Inventions

- **USPTO Enablement Guidance (01-10-2024)**
  - Based on these decisions, the PTO will use the ***In re Wands*** factors to determine ‘‘Reasonableness of Experimentation’’
  - The *Wands* factors include, but are not limited to (MPEP 2164.01(a)):
    - (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
    - (H) the quantity of experimentation needed to make and use the invention based on the content of the disclosure

Enablement Issues for Software- and AI-Based Inventions

- **USPTO Enablement Guidance (01-10-2024)**
- **Conclusion**
- Consistent with *Amgen* and the Federal Circuit's post-Amgen decisions of *Baxalta, Medytox*, and *Starrett*, when assessing whether the claims in a utility patent application or patent are enabled, regardless of the technology, USPTO personnel will continue to use the *Wands* factors to ascertain whether the experimentation required to enable the full scope of the claimed invention is reasonable
- Given this conclusion, and the very few court decisions applying *Amgen* to software or AI cases, we need to monitor this issue

Enablement Issues for Software- and AI-Based Inventions

- **Drafting Takeaways**
  - Try to avoid having only functional language in claims
  - Such claims are judged more harshly under enablement after the *Amgen* decision
  - Draft claims to recite specific details of specific method steps
  - Avoid drafting claims too broadly, as the scope of enablement must meet the full scope of the claims (do not “monopolize” a genus)
  - Make sure that the specification includes clear guidance on how to make and use all steps of the claimed invention
  - It is not sufficient to merely recite the method steps in the specification without further details of how to make and use the underlying software, or AI model, to enable the claims
  - When possible, include examples of actual use of an AI model with an actual set of input data and output data

Questions?

FISH.

Patrick Darno

Principal
darno@fr.com

J. Peter Fasse

Principal
peter.fasse@fr.com

Thank You!

- **Please send your NY/NJ CLE forms to mcleteam@fr.com**
- **Any questions about the webinar, contact the Events team at eventsteam@fr.com**
- **A replay of the webinar will be available for viewing at fr.com/insights/webinars**

FISH.

Peter Fasse

J. Peter Fasse
Principal

617-521-7802
fasse@fr.com

Peter Fasse is a Principal in the Boston office of Fish & Richardson.

With well over 30 years of experience, Peter's practice emphasizes client counseling and patent prosecution in a wide variety of technologies, with an emphasis on healthcare, medical devices, and other biological and medical fields as well as various "green" technologies.

Peter helps clients from start-ups to multinationals to develop competitive worldwide patent strategies and to establish solid and defensible patent portfolios. He performs competitive patent analyses, identifies third-party patent risks, and provides patentability and freedom-to-operate opinions. Peter also has experience in opposing and defending patents before the European Patent Office and in U.S. litigation and post-grant proceedings.

Peter has experience in medical therapeutics, diagnostics, devices, and imaging, microfluidic systems, liquid biopsy, nucleic acid sequence analysis systems and software, cell culturing and bioprocessing, molecular biology, complex biomedical systems, optics, machine tools, and lasers.

Specific applications include, e.g., cancer antibodies, engineered AAV systems, microfluidic analysis of circulating tumor and fetal cells, cell-free DNA analysis, next generation sequence analysis, dendritic cell- and DNA- based vaccines, nanoparticle and vector-based delivery, blood analysis systems, nucleic acid probes, tissue engineering, infusion pumps, biochips, laser systems, green energy systems, and diagnostic and therapeutic methods for, e.g., AIDS, cancer, autism, diabetes, psoriasis, and arthritis.

FISH.

Patrick Darno

Patrick Darno
Principal

202-626-7726
darno@fr.com

Patrick Darno is a Principal in the D.C. office of Fish & Richardson.

Patrick's practice focuses on patent prosecution and counseling related to matters before the U.S. Patent and Trademark Office (USPTO). Patrick's technical background reflects his extensive history working with companies in the fields of bioinformatics and telecommunication networks.

Patrick has gained substantial experience preparing and prosecuting patent applications in a number of other bioinformatics-related technologies, including technologies in the fields of digital health and digital therapeutics. A routine part of Patrick's practice in the bioinformatics technology space includes advising clients on prosecution strategies that can be used to prepare and prosecute patent applications that will survive subject matter patent eligibility challenges under 35 U.S.C. 101.

Throughout his career, Patrick has worked with large multinational technology companies on patent applications involving a variety of other technologies, including databases, data search and retrieval, query optimization, data mining, search engines, cloud computing, web services, e-commerce, internet-based applications, mobile applications, mobile communication networks, digital rights management, file management, database management, data retention policies, data integrity, network management, load balancing, data structures, electronic messaging, financial transactions, and other types of business methods.

Prior to his time in private practice, Patrick was a patent examiner for more than 6 years in an art unit dedicated to examination of inventions in the database, data structure, and file system technology space.

FISH.