Successful Strategies for Patenting Bioinformatics and Computational Genomics

October 26, 2022

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Overview

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

- **Topics for Today's Discussion**
  - Definitions
  - Patent Strategy
  - Patent Eligibility
  - Drafting Strategies
  - Foreign Patent Issues

Meet The Speakers

Peter Fasse
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Laying the Groundwork

Bioinformatics and Computational Genomics Defined

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

Initial Stage of Patent Strategy

Defining Boundaries of Technology in a Bioinformatics Pipeline

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*
  - Example Bioinformatics Pipeline:

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 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**

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*

Is *precision treatment* based on an entity's *genome* reality?

- **Volumes of sources seem to suggest that opportunities abound**

Genomic medicine has the capacity to revolutionise the healthcare of an individual with a rare disease or cancer by offering prompt and accurate diagnosis, risk stratification based upon genotype and the capacity for personalised treatments.

-https://www.ncbi.nlm.nih.gov/_pmc/articles/PMC6297695/

Bioinformatics Global Market Report 2022: Rising Demand for Personalized Medicine Presents Opportunities

Research and Markets
October 10, 2022 · 4 min read

[redacted]

-https://finance.yahoo.com/news/bioinformatics-global-market-report-2022-094300853.html?guccounter=1&guce_referrer=aHR0cHM6Ly93d3cuZ29vZ2xlLmNvbS8&guce_referrer_sig=AQAAAE3FAxnC3jdh9Df6zEBb57qnYH--H7Suu5Hv7muXG-UpP79-0W1g5XwNiJ81rfOe01BDOd5UcoPmI6BT9nr39FJ

Personalized medicine is an emerging practice of medicine that uses an individual's genetic profile to guide decisions made in regard to the prevention, diagnosis, and treatment of disease. Knowledge of a patient's genetic profile can help doctors select the proper medication or therapy and administer it using the proper dose or regimen. Personalized medicine is being advanced through data from the Human Genome Project.

-https://www.genome.gov/genetics-glossary/Personalized-Medicine

Precision Medicine and Genomics

Using advanced genetic testing technologies like DNA sequencing is easier and less expensive, making it more accessible than before. The amount of genomic data from individuals that is available to researchers and scientists is rapidly growing. By studying genomic data from different populations, these researchers and scientists in genetics and genomics can better understand how genetic variations contribute to disease. **This understanding can lead to disease treatments and prevention strategies that are needed in a precision medicine approach.** As time goes on, genetics and genomic medicine will play a growing role in healthcare.

https://resources.genomemedical.com/what-is-precision-medicine-in-genomics#:~:text=Precision%20medicine%20uses%20information%20about,genetics%2C%20which%20is%20rapidly%20evolving

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Elephant in the Room

- **Will it be possible to efficiently manage all this data?**
- **Compression is set to play a vital role in the field of Bioinformatics**
  - A human genome comprises 3 billion nucleotides
  - Short-read sequencers output pileups of multiple reads for a single reference location
    - *E.g., a 32x pileup*
  - Each base call of a read generated by a sequencer may have one or more quality scores
  - The field of genomics is poised to become the largest generator of data in the world
    - *Displacing, e.g., Astronomy and YouTube*
- **Accordingly, you MUST consider the role of data compression and decompression**
  - Consider innovative ways to make genomic data files ***smaller***
  - Consider innovative ways to make compression and decompression of genomic data files ***faster***
  - Consider innovative ways to make compression of genomic data files ***lossless***
  - Consider ***data formats*** that enable either of the aforementioned improvements

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**

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Navigating The *Alice* Landmines – Part 1

Are Bioinformatics Inventions Eligible for Patent Protection?

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.

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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.

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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

Navigating The *Alice* Landmines – Part 2

Practice Tips for Drafting Patent Application for Bioinformatics Inventions

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:**

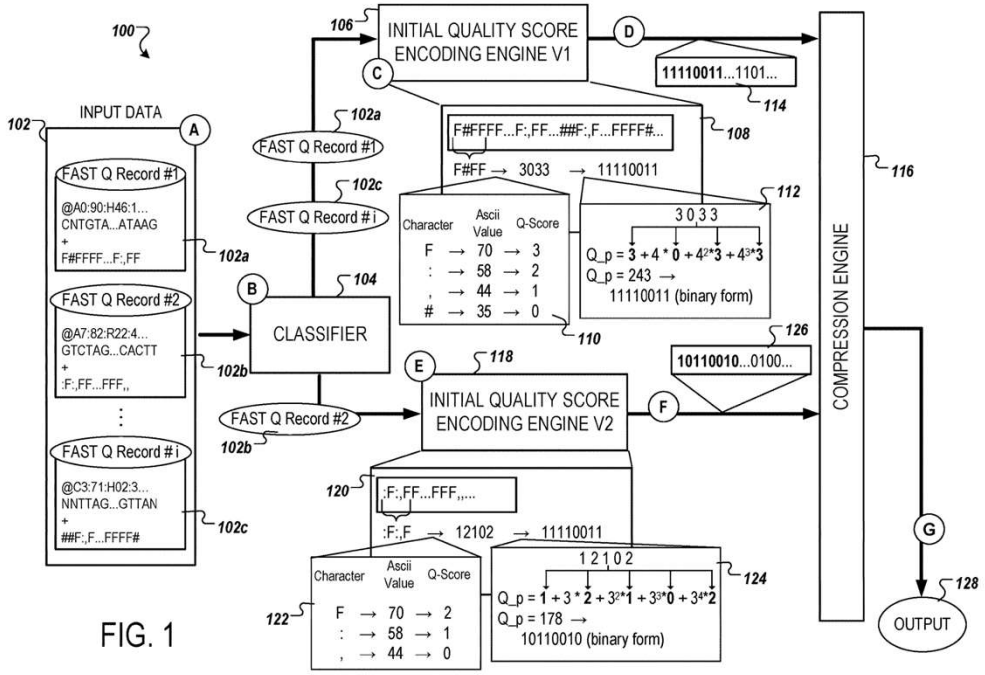

FIG. 1

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

It’s A Small World

Patenting Bioinformatics Inventions Outside the US

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

Common Patent Issues Outside the US: Europe

- **Decision from the Enlarged Board (G 1/19) (March 10, 2021)**
  - Computer-implemented inventions cannot be *a priori* excluded from patent protection
  - A claim directed to a computer-implemented invention avoids exclusion from patentability by referring to the use of a computer, a computer-readable storage medium, or other technical means
  - However, mere possibility of using an unspecified computer for performing a claimed method is not sufficient to establish "technical means"
- **Computer-implemented methods that interact with an external physical aspect, e.g., with an input or output, may have a technical effect/means**
  - *e.g., a computer-implemented method that uses measurements or data as input or produces control signals for a machine as output*
- **Purely numerical methods without an input/output, but having a direct link with physical reality may still solve a technical problem by reciting an *intended* technical use of data**
  - *e.g., resulting data is specifically adapted for controlling a process in an actual drug discovery/genome mapping process*

Common Patent Issues Outside the US: Japan

- Patent eligibility can be satisfied if a claimed information processing invention is based on biological properties (e.g., a relation between gene sequence and expression of a trait in a living body)
- Patent eligibility can also be satisfied if a claim recites specific information processing depending on intended use through cooperation of software and hardware elements
- A “computer program” and its equivalent (such as neural network) (as an intangible object) are deemed to be a “product” under Japanese Patent Law, and an act of providing a computer program through the Internet is deemed to be working of a patented invention

Common Patent Issues Outside the US: Australia

- **When an invention lies in an improvement in a technical field outside of a computer, it will generally be considered patent eligible**
- **Important to provide details and examples in the application of how the invention is applied and the technical benefits achieved**
- **Key aspect for examiner is to determine the "contribution" beyond the prior art**
- **Patentability questions raised for bioinformatics and computational genomics technologies:**
  - Is the contribution technical in nature or does it solve a technical problem?
  - Does the method produce a practical and useful result?
  - Is there ingenuity in the way in which the computer is used?
  - Does the invention include steps that are foreign to the normal use of computers?
  - Does the invention lie in the generation, presentation, or arrangement of information?

Common Patent Issues Outside the US: New Zealand

- **Computer-implemented methods that are new and improve technology can be patentable**
- **Must assess invention as a whole as to whether it makes an advance that is not solely a computer program**
- **Does the "actual contribution" lie in the method or in the computer program per se?**
  - If the former, then may be patentable, if the latter, then not
- **How to determine patentability?**
  - Properly construe the claim,
  - Identify the actual contribution, and
  - Ask whether the actual contribution falls solely within excluded subject matter
- **Key is that you do not need to show that the contribution is “technical” in nature in New Zealand as you do in Australia**

Common Patent Issues Outside the US: Canada

- **Claims to known analytic techniques (e.g., machine learning technique or otherwise) using data organized in a known or obvious manner are not patentable**
- **Specific organization of bioinformatic or genomic data is difficult to patent**
- **Claims to correlations between novel organization of data and a physical attribute may be patentable**
- **For success, include claim elements that correspond to a physical item or attribute**
  - Result of a computing process that corresponds to a physical attribute of a living thing
  - Correlation between computed results and the physical attribute
  - Process that is exclusively implemented in a computing system
  - Practical and commercial benefits of the invention
- **If the invention is a new computing method, such as a new ML analytic technique or a new method of analyzing genome data**
  - Claim improved system for processing data
  - Claim methods that recite physical elements or tie output to subsequent physical steps

Common Patent Issues Outside the US: China

- **Art. 25.1(3) states that methods for diagnosis or treatment of diseases shall not be granted patent rights**
  - However, instruments or apparatus for implementing these methods of diagnosis or treatment, or substances or materials for use in such methods are patentable subject matter
- **Article 25.1(2) specifies that a claim must contain technical features**
  - claim to an abstract algorithm or a pure business rule and method without any technical feature is a mental act that is not patentable subject matter
  - claim that contains technical features in addition to features of algorithms or business rules and methods, is patentable subject matter
- **AI claims that relate to improvements of AI model structures (such as arrangements of layers or nodes) and/or training method and/or learning method and/or data structure, should recite an application to a specific technical field (such as image processing, data processing, text processing) to be patentable**

Common Patent Issues Outside the US: South Korea

- A computer program as such is not patentable (as an abstract idea)
- Claims to computer-related inventions can be patented if the claim recites a computer-readable recording medium containing a computer program that causes a computer to execute certain steps
- A method comprising "a step … using a computer" is not patentable if the step is merely conducted by a human being using a computer
- Each step should clearly indicate execution by hardware (e.g., computer-implemented, used by server) and not by a human

Questions?

Thank You!

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Any questions about the webinar, contact Makayla Mainini at mainini@fr.com

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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.

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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.

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