Virtual Roundtable: Intellectual Property
Issues for Bioinformatics and Health Information Management Entrepreneurs
January 24, 2019

Among the most rapidly growing sub-disciplines in the biotechnology industry are the management and manipulation of data, the creation of code for bioinformatics and personalization of medicine, and the creation of apps. Researchers and entrepreneurs are responsible for understanding how this innovation and ownership is protected.

Speakers will address the opportunities and challenges surrounding digital innovation, in which a large portion of the commercial potential is seated in ownership of data, computer code, and apps.

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Research Community Resources

-a borderless initiative mapping the future for regional and international collaboration

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Young Investigators

Rare Disease Symposium

Consortium on Translational Research in the Microbiome

Westchester Biotech Project
Research Community Resources
Thank You to our Community Partners, Alliance Partners, and Participants!
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Intellectual Property Issues for Bioinformatics and Health Information Management Entrepreneurs

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January 24, 2019
Assets Recognized by Competitors and Investors

* Code/Computer Programs
  * Object Code
  * Source Code
  * Sequence, structure and organization
  * APIs
    * application program interface: a set of routines, protocols, and tools for building software applications.

* Data/Databases

```php
<?php
$var = "hello world";
if ($var == "hello world") {
    echo "Correct!";
} else {
    echo "Incorrect.";
}
?>
```

* Methodologies
* Algorithms
* Analytics
* Agreements and relationships
* Digital images
* Graphics
* Website/App look and feel
* Personnel
Intellectual Property is the oil of the 21st Century
-Mark Getty, Getty Images
“Only one thing is impossible for God:
To find any sense in any copyright law on the planet”
- Mark Twain’s Notebook 1902-1903
Copyright Primer

* **Protection for Expression of Ideas**

* **Copyrightable Assets**
  * Computer Code
  * What is created by the code (graphics, Apps)
  * Selection, compilation and organization of data but not data itself

* **Process**
  * Benefits of Registration

* **Notice**
  * Innocent infringers still liable
Copyright Limits

- Facts: medical records
- Medical images
- Independent creation
- High levels of extraction
- Functional features
Permissible Behavior

* Statutory Allowances
  * Additional copy or adapt in order to use/archive
  * Copies made during repair of machine

* Fair use
  * Purpose/character of new work (commercial)
  * Nature of copyrighted work (unpublished/creative)
  * Amount of original work used
  * Effect on market

* Disassembly and Interoperability

* Oracle v. Google
  - Supreme Court?
Defining the Relationship with Programmers

- Non-disclosure agreements (NDAs)
- Work made for hire
- Independent contractor agreements
- Written assignments
- Access to code and passwords
Ownership pitfalls

- Previous employers
- Open Source
- Collaborations w/o contracts
- Crowdsourcing
- Third party rights
The Burdens and Benefits of Trade Secret Protection

* Narrower than confidentiality (Defend Trade Secrets Act)
  * (1) not generally known or readily ascertainable
  * (2) has value as a result of secrecy
  * (3) subject to reasonable efforts to protect

* Remedies
  * Ex parte seizures, actual loss, unjust enrichment, reasonable royalty, double damages, attorneys’ fees
Trade Secrets Risks

* Former Employees
  * Preliminary injunctions - “inevitable disclosure”
  * Non-compete agreements

* Potential Business Partners – The Pinterest Problem
Race to most protective:
- **California**: Consumer Privacy Act of 2018 (to take effect January 1, 2020).
  - Right to know what is collected, sourced, used for, disclosed and sold
  - **Right to opt out of sale of information** — this is not explicit in GDPR
  - Right to have information deleted
  - **Right to equal service even if opting out**
  - De-identification: (1) technical safeguards that prohibit re-identification; (2) business processes that specifically prohibit re-identification; and (3) business process to prevent inadvertent release of de-identified information.

- **GDPR — Europe** (similar idea to CCPA but more detailed)
  - Procedures for data breach
  - Data security implementation
  - Data protection officers
  - Local representatives
  - Cross-border transfers
  - What and how data must be shared with consumer
  - **Requires opt-in**
  - **De-identification vs. “cannot reasonably identify” of CCPA**

- **Cybersecurity** (Malware, Ransomware, Phishing)

- **HIPAA** (Information Portability and Accountability Act of 1996): Protected Health Information (PHI) and exception for de-identified information Rules 164.502(D) AND 164.514(a)-(b). [https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#safeharborguidance](https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#safeharborguidance)
IP Issues on the Internet

- Publicly accessible ≠ publicly available
- Domain names are not trademark rights
- Cybersquatting and typosquatting
- Search Engine Optimization and Google AdWords
- Content vs trade dress: “look and feel”
Virtual Roundtable: **Intellectual Property**

**Issues for Bioinformatics and Health Information Management Entrepreneurs**

**January 24, 2019**

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Patenting Bioinformatic Inventions

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Definitions

Bioinformatics is conceptualizing biology in terms of macromolecules (in the sense of physical-chemistry) and then applying “informatics” techniques (derived from disciplines such as applied maths, computer science, and statistics) to understand and organize the information associated with these molecules, on a large-scale.

Patent Classifications

The International Patent Classification (IPC), established by the Strasbourg Agreement 1971, provides for a hierarchical system of language independent symbols for the classification of patents and utility models according to the different areas of technology to which they pertain.

http://www.wipo.int/classifications/ipc/en/
## Patent Classifications

<table>
<thead>
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<th>Patent Classification</th>
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<tbody>
<tr>
<td>G01</td>
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- **G01**: MEASURING; TESTING
- **G02**: OPTICS
- **G03**: PHOTOGRAPHY; CINEMATOGRAPHY; ANALOGOUS TECHNIQUES USING WAVES OTHER THAN OPTICAL HOLOGRAPHY [4]
- **G04**: HOROLOGY
- **G05**: CONTROLLING; REGULATING
- **G06**: COMPUTING; CALCULATING; COUNTING
- **G07**: CHECKING-DEVICES
- **G08**: SIGNALLING
- **G09**: EDUCATING; CRYPTOGRAPHY; DISPLAY; ADVERTISING; SEALS
- **G10**: MUSICAL INSTRUMENTS; ACOUSTICS
- **G11**: INFORMATION STORAGE
- **G12**: INSTRUMENT DETAILS
- **G16**: INFORMATION AND COMMUNICATION TECHNOLOGY (ICT) SPECIALLY ADAPTED FOR SPECIFIC APPLICAT
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<tr>
<th>Code</th>
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<tbody>
<tr>
<td>G06D</td>
<td>DIGITAL FLUID-PRESSURE COMPUTING DEVICES</td>
</tr>
<tr>
<td>G06E</td>
<td>OPTICAL COMPUTING DEVICES (digital storage using optical elements G11C 13/04) [5]</td>
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<tr>
<td>G06F</td>
<td>ELECTRIC DIGITAL DATA PROCESSING (computer systems based on specific computational models G06N)</td>
</tr>
<tr>
<td>G06G</td>
<td>ANALOGUE COMPUTERS (analogue optical computing devices G06E 3/00; computer systems based on specific computational models G06N)</td>
</tr>
<tr>
<td>G06H</td>
<td>HYBRID COMPUTING ARRANGEMENTS (optical hybrid computing devices G06E 3/00; computer systems based on specific computational models G06N; neural networks for image data processing G06T; analogue/digital conversion, in general H03M 1/00)</td>
</tr>
<tr>
<td>G06K</td>
<td>RECOGNITION OF DATA; PRESENTATION OF DATA; RECORD CARRIERS; HANDLING RECORD CARRIERS (printing per se B41J)</td>
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<tr>
<td>G06M</td>
<td>COUNTING MECHANISMS; COUNTING OF OBJECTS NOT OTHERWISE PROVIDED FOR (counting by measuring volume or weight of articles to be counted G01F; G01G: adaptation of counters to electricity meters in electromechanical arrangements for measuring time integral of electric power or current)</td>
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<th>Code</th>
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<tr>
<td>G06F 17/00</td>
<td>Digital computing or data processing equipment or methods, specially adapted for specific functions [2006.01]</td>
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<tr>
<td>G06F 19/00</td>
<td>Digital computing or data processing equipment or methods, specially adapted for specific applications (specially adapted for specific functions G06F 17/00; data processing systems or methods specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes G06C; healthcare informatics G16H) [2018.01]</td>
</tr>
<tr>
<td>G06F 21/00</td>
<td>Security arrangements for protecting computers, components thereof, programs or data against unauthorised activity [2013.01]</td>
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## Patent Classifications

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<th>Code</th>
<th>Title</th>
<th>Details</th>
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| G06F 19/10 | Bioinformatics, i.e. methods or systems for genetic or protein-related data processing in computational molecular biology (in silico methods of screening virtual chemical libraries C40B 30/02; in silico or mathematical methods of creating virtual chemical libraries C40B 50/02) [2011.01] | Note(s) [2011.01]  
1. This group also covers bioinformatics methods or systems where digital data processing is inherent or implicit, but not explicitly mentioned.  
2. In this group, the following term is used with the meaning indicated:  
   • "systems" includes apparatus.  
3. In this group, the first place priority rule is applied, i.e. at each hierarchical level, in the absence of an indication to the contrary, classification is made in the first appropriate place. |
| G06F 19/12 | for modelling or simulation in systems biology, e.g. probabilistic or dynamic models, gene-regulatory networks, protein interaction networks or metabolic networks [2011.01] |         |
| G06F 19/14 | for phylogeny or evolution, e.g. evolutionarily conserved regions determination or phylogenetic tree construction [2011.01] |         |
| G06F 19/16 | for molecular structure, e.g. structure alignment, structural or functional relations, protein folding, domain topologies, drug targeting using structure data, involving two-dimensional or three-dimensional structures [2011.01] |         |
| G06F 19/18 | for functional genomics or proteomics, e.g. genotype-phenotype associations, linkage disequilibrium, population genetics, binding site identification, mutagenesis, genotyping or genome annotation, protein-protein interactions or protein-nucleic acid interactions [2011.01] |         |
| G06F 19/20 | for hybridisation or gene expression, e.g. microarrays, sequencing by hybridisation, normalisation, profiling, noise correction models, expression ratio estimation, probe design or probe optimisation [2011.01] |         |
| G06F 19/22 | for sequence comparison involving nucleotides or amino acids, e.g. homology search, motif or Single-Nucleotide Polymorphism (SNP) discovery or sequence alignment [2011.01] |         |
| G06F 19/24 | for machine learning, data mining or biostatistics, e.g. pattern finding, knowledge discovery, rule extraction, correlation, clustering or classification [2011.01] |         |
| G06F 19/26 | for data visualisation, e.g. graphics generation, display of maps or networks or other visual representations [2011.01] |         |
| G06F 19/28 | for programming tools or database systems, e.g. ontologies, heterogeneous data integration, data warehousing or computing architectures [2011.01] |         |
Fig. 1. Patent Filing Trend. The year wise patenting activity in relation to bioinformatics related inventions.

Bioinformatics Patents

Patentable Subject Matter

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

35 U.S.C. § 101 (emphasis added)
Patentable Subject Matter

- **Process**: An act, or a series of acts or steps. See *Gottschalk v. Benson* (S. Ct. 1972); *NTP, Inc. v. Research in Motion* (Fed. Cir. 2005); See also 35 U.S.C. § 100(b); *Bilski v. Kappos* (S.Ct. 2010).

- **Databases**: Not patentable under current U.S. law. *In re Warmerdam* (Fed. Cir. 1994); *but see Amdocs (Israel) Ltd. v. Openet Telecom, Inc.* (Fed. Cir. 2016)(“The collection, filtering, aggregating, and completing steps all depend upon the invention's unique distributed architecture”).
**Bilski v. Kappos (S.Ct. 2010)**

- *Bilski* involves claims directed to hedging risk in the field of commodities trading (business method)
- § 101 broadly describes subject matter eligible for patenting (processes, machines, manufactures and compositions of matter)
- Three exceptions: (1) laws of nature
  (2) abstract ideas
  (3) natural phenomena
Bilski v. Kappos (S.Ct. 2010)

- Business methods are not unpatentable under § 101
- Preemption is key factor in analysis of whether method claim is directed to mere abstract idea
- Cannot simply attempt to limit abstract idea to field of use or add token post-solution activity
Mayo Collaborative Services v. Prometheus Labs. (S.Ct. 2012)

- Methods for calibrating the proper dosage of thiopurine drugs
- Correlation between 6–TG blood levels and over/under thiopurine dosage is an unpatentable law of nature because the relation is a consequence of the ways in which thiopurine compounds are metabolized by the body
- Difference between claims to laws of nature themselves (not patent eligible) and claims to specific applications of such laws (patent eligible)
Natural Process + Known Elements = No Patent

- Application of a law of nature is patentable, but “simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.”

- Concluded that the instructions in the claim add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field; and

- The steps of the method, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.

*Mayo Collaborative Services v. Prometheus Labs. (S.Ct. 2012)*
Alice v. CLS Bank (S.Ct. 2014)

- Computer implemented scheme for mitigating “settlement risk” (i.e., the risk that only one party to a financial transaction will pay what it owes) by using a third-party intermediary.
- Stating an abstract idea while adding the words “apply it” is not enough for patent eligibility.
- The mere recitation of a generic computer cannot transform a patent ineligible abstract idea into a patent eligible invention.
Alice v. CLS Bank (S.Ct. 2014)

- To be patentable, a claim that recites an abstract idea must include “additional features” to ensure “that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].”
- “Nor [does] limiting the use of an abstract idea to a particular technological environment” render a patent ineligible abstract idea a patent eligible invention.
(Step 1) Is the claim to a process, machine, manufacture or composition of matter?

YES

(Step 2A) [Part 1 Mayo test] Is the claim directed to a law of nature, a natural phenomenon, or an abstract idea (judicially recognized exceptions)?

NO

YES

(Step 2B) [Part 2 Mayo test] Does the claim recite additional elements that amount to significantly more than the judicial exception?

YES

Claim qualifies as eligible subject matter under 35 USC 101

NO

Claim is not eligible subject matter under 35 USC 101
STEP 1: Statutory Categories

- Process
- Machine
- Manufacture
- Composition of Matter?
- If the answer is “NO,” NOT ELIGIBLE
STEP 2A: “Directed to” a Judicial Exception

- Abstract Idea
  - Mathematical relationships/formulas
  - Methods of organizing human activities
  - Ideas
  - Fundamental economic practices

- Law of Nature

- Natural Phenomenon

- If the answer is “YES,” proceed to Step 2B
STEP 2B: Does the claim as a whole amount to significantly more than the judicial exception?

- Consider additional elements claimed with the exception, individually AND as an ordered combination
  - Additional elements
  - Meaningful limitations on exception
  - More than a “drafting effort designed to monopolize an exception”
Significantly More?

- Improvements to another technology or technical field
- Improvements to functioning of computer
- Applying the exception with a particular machine
- Effect a transformation or reduction to different state or thing
- Adding a specific limitation that is not “well-understood, routine [or] conventional”
- Other meaningful limitations “beyond generally linking the use of the judicial exception to a particular technological environment”
Can’t simply have a claim that simply states “apply it” to a judicial exception

- Add routine steps
- Add insignificant extra-solution activity (such as data gathering)
- Restrict abstract concept to particular technological environment or field of use
Method of Diagnosis – Abstract ideas

- Algorithm for calculating parameters indicating an abnormal condition (*In re Grams* (Fed. Cir. 1989)).
- Comparing new and stored information and using rules to identify options (*SmartGene v. Advanced Biological Laboratories* (Fed. Cir. 2014)).
Method of Diagnosis – Abstract ideas

- Method whereby information on immunization schedules and the occurrence of chronic disease is “screened” and “compared,” the lower risk schedule is “identified,” and the vaccine is “administered” on that lower risk schedule. *Classen Immunotherapies, Inc. v. Biogen IDEC* (Fed. Cir. 2011).

- Improved method to diagnose Down’s syndrome by measuring known biomarkers and/or ultrasound data taken during both the first and the second trimester of pregnancy, and then subjecting the data to multivariate analysis based on reference parameters to determine the odds that the fetus has Down’s syndrome. *PerkinElmer, Inc. v. Interna Ltd.* (Fed. Cir. 2012).
Methods of Screening – Natural Laws

- Method of screening for BRCA1 mutation by comparing a patient’s gene sequence with a germline BRCA sequence (*Univ. of Utah Research Found. v. Ambry Genetics* (Fed. Cir. 2014)).

- Method for detecting a small fraction of paternally inherited cfDNA in maternal plasma or serum to determine certain fetal characteristics, such as gender (*Ariosa Diagnostics, Inc. v. Sequenom* (Fed. Cir. 2015))
Association for Molecular Pathology v. Myriad Genetics, Inc. (S.Ct. 2013)

- Naturally occurring DNA segment is a nonpatentable product of nature
- cDNA - an artificial product designed to mirror the coding parts of genes - is eligible for patent protection because it is not naturally occurring
- Claim must cover product that is “markedly different” (e.g., have a distinctive chemical identity and nature) from molecules that exist in nature
Example of Rejection Overcome

(12) United States Patent
Shiroyama et al.

(54) CELL ANALYZER AND CELL ANALYSIS METHOD

(75) Inventors: Takahiro Shiroyama, Tokyo (JP); Akane Suzuki, Tokyo (JP); Sunao Takeda, Tokyo (JP)

(73) Assignee: Nihon Kohden Corporation, Tokyo (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1787 days.

(21) Appl. No.: 13/217,338
(22) Filed: Aug. 25, 2011

(65) Prior Publication Data

(50) Foreign Application Priority Data
Aug. 26, 2010 (JP) 2010-189920

(51) Int. Cl.
G01N 33/48 (2006.01)
G01N 21/64 (2006.01)
G01N 15/14 (2006.01)
G01N 15/19 (2006.01)

(52) U.S. Cl.
CPC ... G01N 21/6429 (2013.01); G01N 15/1459 (2013.01); G01N 2013/1006 (2013.01); G01N 2015/1402 (2013.01); G01N 2015/1488 (2013.01)

(20) Field of Classification Search

(10) Patent No.: US 9,970,872 B2
(45) Date of Patent: May 15, 2018


FOREIGN PATENT DOCUMENTS
JP 7-146289 A 6/1995
JP 2005-530772 A 12/2005

OTHER PUBLICATIONS

Primary Examiner — Jenny Lin
(74) Attorney, Agent, or Firm — Sughrue Mion, PLLC

ABSTRACT

A cell analyzer includes: a measuring portion which measures cells that are nucleus stained; a displaying portion which displays a histogram of the nomenclature indicate the
Example of Rejection Overcome

**FIG. 8**

- **S21**: Produce histogram of fluorescence intensity.
- **S22**: Detect peak of normal cells from histogram data.
- **S23**: Obtain number of strong-area cells which are distributed in area where fluorescence intensity is stronger than normal cells.
- **S24**: Obtain total cell number A.
- **S25**: Compare ratio of strong-area cell number S to total cell number A with threshold TH to obtain malignancy grade, and output it.
What is claimed is:
1. A cell analyzer comprising:
a cytometric device which measures cells that are nuclear stained;
a display which displays a histogram of a fluorescence intensity by using a result of the measurement by the cytometric device; and
a computer comprising at least one processor configured to obtain a number of strong-area cells that are distributed in an area where the fluorescence intensity is stronger than normal cells, and determine a malignancy grade of cancer using the number of strong-area cells and the histogram.

5. A cell analysis method comprising:
measuring, by a cytometric device, cells that are nuclear stained, to obtain a histogram of a fluorescence intensity;
detecting a peak of normal cells from data of the histogram;
obtaining, by a computer comprising at least one processor, a number of strong-area cells that are distributed in an area where the fluorescence intensity is stronger than the peak of the normal cells; and
determining a malignancy grade of cancer using the obtained number of strong-area cells and the histogram.
Example of Rejection Overcome

*Ex Parte* Shioyama (PTAB Oct. 10, 2017):

Examiner rejected claim as patent ineligible: (1) directed to *abstract idea* of determining the malignancy of a sample by analyzing a histogram; (2) the additional elements in the claims amount to “no more than the recitation of a generic computer structure that serves to perform generic computer functions” (*routine and conventional*) and (3) using a cytometric device is a *data-gathering step*.

PTAB reversed, finding that (1) the claim was directed to an *abstract idea* of configuring a conventional processor, but the examiner’s rejection was not “supported by sufficient objective evidence that the claimed steps of determining the malignancy grade of a sample by obtaining a number of strong area cells that are distributed in an area where the fluorescence intensity is stronger than normal cells, and determining the malignancy grade using the number of strong-area cells and the histogram, are *routine and conventional*.”
Questions?

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-Westchester Biotech Project
Research Community Resources

-a borderless initiative mapping the future for regional and international collaboration