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Bioinformatics – Eligibility Challenges for Inventions at the Intersection of Biology and Software

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(Part 1 of a 2 Part Series)

The application of innovative data driven approaches such as bioinformatics and artificial intelligence to the life science sector has brought about a change in way that biological inventions can be protected by patent laws. Using patent filing and prosecution strategies developed in the fields of computer science and business methods, patent applicants now seek to protect certain aspects of their data driven innovations, which include computer-implemented tools, methods of doing business, and uses of insights discovered from data as well as more traditional biotechnological products and processes. This Four-Part Series examines eligibility challenges of filing and prosecution data driven innovations and provides practical tips for addressing some of these challenges.

Patent Eligible Subject Matter

Filing and prosecution of data driven innovations absolutely necessitates that you preemptively address subject matter eligibility concerns (this is not something you want to wing it on). In order to do this, you must have a good understanding of patent subject matter eligibility requirements as interpreted by both the Courts and the USPTO, which differ slightly.

- Case Law (two-step *Alice/Mayo* test for eligibility):
  - Step 1: Determine whether the claimed invention falls under one of the four statutory categories. 35 U.S.C. § 101 defines the four categories of invention that Congress deemed to be the appropriate subject matter of a patent: processes, machines, manufactures and compositions of matter.
  - Step 2A: Determine whether the claimed invention is directed to one of the judicial exceptions—laws of nature, natural phenomena, and abstract ideas.
  - Step 2B: If it is directed to one of the patent-ineligible concepts, the applicant must establish that the elements of the claimed invention transform the nature of the claims into a patent-eligible application. In other words, the applicant must establish an "inventive concept" such that the claims amount to significantly more than a claim on the ineligible concept itself. (*Mayo Collaborative Servs. v. Prometheus Laby's, Inc.* , 566 U.S. 66, 72 (2012) (citation omitted); *Alice Corp. Pty. Ltd. v. CLS Bank*

Int'l , 473 U.S. 208, 217-18 (2014) (quoting Mayo, 566 U.S. at 72-73)).

- USPTO Guidance (2019) (Non-binding):
  - Step 1: Determine whether the claimed invention falls under one of the four statutory categories. 35 U.S.C. § 101 defines the four categories of invention that Congress deemed to be the appropriate subject matter of a patent: processes, machines, manufactures, and compositions of matter.
  - Step 2A: (Prong 1) Determine whether the claims recite a judicial exception, such as a law of nature or abstract idea, and (Prong 2) if so, whether the claims recite additional elements that integrate the judicial exception into a practical application.
  - Step 2B: Determine whether the claim adds a specific limitation beyond the judicial exception that is not "well-understood, routine, [or] conventional" in the field—i.e., additional elements significantly more than exception. (*In re Rudy*, 956 F.3d 1379, 1386 (Fed. Cir. 2020); MPEP § 2106 Patent Subject Matter Eligibility [R-10.2019]).

Once you have good understanding of the patent subject matter eligibility requirements, you should focus on four key aspects for putting your patent application in the best light to satisfy these requirements: (i) provide as much detail as possible (this is not the time to hide the ball), (ii) specify any improvements achieved by the claimed invention, (iii) draft claims to avoid abstract features without significantly more, and (iv) phrase the title, abstract, and claims so that the application is routed to a certain art unit if at all possible. This post addresses the detail aspects while subsequent posts will address aspects (ii)-(iv).

Addressing the Details

- Make sure you have a discussion with the inventors and completely understand the details and nuances of how the invention works.
  - One of the biggest issues raised in PTAB and federal circuit cases with an eligibility question is the level of detail provided not only in the claims but also the specification. *Intell. Ventures I LLC v. Erie Indem. Co.*, 850 F.3d 1315 (Fed. Cir. 2017); *Nice Ltd. v. CallMiner, Inc.*, No. 18-2024-RGA-SRF, 2020 U.S. Dist. LEXIS 20516, at *18 (D. Del. Feb. 3, 2020), *report and recommendation adopted*, No. 18-cv-2024-RGA, 2020 WL 1502290 (D. Del. Mar. 30, 2020); *Affinity Labs of Tex., LLC v. DirecTV, LLC*, 838 F.3d 1253 (Fed. Cir. 2016); *In re Board of Trs. of Leland Stanford Junior Univ.*, 989 F.3d 1367 (Fed. Cir. 2021); *Apple, Inc. v. Ameranth, Inc.*, 842 F.3d 1229 (Fed. Cir. 2016).
  - If you don't understand the invention you cannot hope to draft a detailed enough specification to support a reasonable claim scope.
  - The details are what you can use to claim additional limitations that capture and utilize the abstract idea in a meaningful manner, they can demonstrate a technological improvement, or claim additional limitations that are significantly more than the abstract idea.
- Next try to describe, in text and illustrations, all physical elements involved in implementing the algorithms

and the specific role each physical element plays in the system or process.
    - For example, describe the data structure being manipulated by the algorithm and the data storage device being used to store the data structure, if the algorithm is orchestrated using a container system describe the system and how various components execute the algorithm, if the algorithm is implemented using quantum computing talk about the qubits, if the algorithm works in conjunction with a sequencer talk about how it interfaces with components of the sequencer, etc.—you want to make sure that you tie the algorithm to as many physical elements as possible.
- In addition to any physical elements you want to provide as much detail as possible about any algorithm that is or may be claimed.
    - For example, describe the purpose, the data structure manipulated by the algorithm, the instructions and order of instruction used to produce the desired result, conditions such as if then statements or Boolean expressions, and any iterations performed.
    - Pay careful attention to the level of abstraction. You do not want to describe everything in gory detail or at the code level but you also don't want to explain everything as a black box either. If every step you describe is determine X based on Y, and you are not describing at some level how X is determined from Y, then you are probably not at the level that you need to be.
- You should also include some description on the requirements for how the desired result is achieved.
    - For example, if your result is the classification of patients for a specific disease using a phenotype algorithm, you want to focus on the specific steps of the phenotype algorithm (hopefully novel steps) that allow for the classification, you don't want to get lost in the weeds and describe steps that are ancillary to achieving the result such as natural language processing steps used for extracting information from the input.
- Lastly, be sure to tie the algorithms to real world solutions/practical applications (not just helpful for the U.S. but required in other jurisdictions such as the EPO). (*Kaavo Inc. v. Amazon.com Inc.*, 323 F. Supp. 3d 630 (D. Del. 2018); *Ex Parte Olson*, Appeal 2017-006489, 2019 WL 4297780 (P.T.A.B. July 1, 2019), *Ex Parte Kimizuka*, Appeal 2018-001081, 2019 WL 2244784 (P.T.A.B. May 13, 2019); Convention on the Grant of European Patents arts. 52, 56, Oct. 5, 1973, 1065 U.N.T.S. 199 [*European Patent Convention* (EPC 1973)]).
    - For example, you don't want to end the description with "we predicted a gene or protein structure or function." Instead, you want to provide real world application of that knowledge achieved from the data processing, for example, manufacturing a pharmacological agent using the predicted protein structure, editing a gene using the predicted gene structure, controlling gene expression based on the predicted gene function, etc.—you want to include at least in the specification some practical application of your data output.

Link to Part 2 of this series.