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Prosecuting Bioinformatics Patent Applications in the United States, Europe, and China

The bioinformatics market is a multi-billion dollar industry, expecting to nearly double in a few years. However, seeking patent protection for bioinformatics innovations can have challenges. The December issue of the Global Patent Prosecution Newsletter explores patent challenges faced by bioinformatics patent applicants in three jurisdictions: the United States, Europe, and China.

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PROSECUTING BIOINFORMATICS PATENT APPLICATIONS IN THE UNITED STATES

By: Todd M. Hopfinger and Christian A. Camarce

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This article discusses challenges in prosecuting bioinformatics patent applications before the United States Patent and Trademark Office (USPTO). Bioinformatics generally refers to an interdisciplinary field in which computer science techniques are applied to biological data to solve biological problems. Because bioinformatics patent applications are oftentimes tied to computer software, they are subject to restrictions on software-focused applications and associated subject-matter eligibility hurdles. The USPTO determines the subject-matter eligibility of bioinformatics patent applications based on *Alice*[1], *Mayo*[2], and its progeny. Four points of concern and consideration related to the subject-matter eligibility of bioinformatics patent applications in the United States are discussed below.

First, the USPTO may incorrectly reject a bioinformatics patent claim as being directed to an abstract idea, such as a mathematical concept or a mental process. For example, in its abstract idea analysis, the USPTO may fail to consider the claim as a whole. But, it is not enough for a portion of the claim to involve an abstract idea; rather, the abstract idea would need to apply to the entire claim. Patent applicants can rebut such incomplete abstract idea analysis during prosecution.

Second, the USPTO may conclusory argue that one or more claim features necessary to solve the biological problem at the heart of the bioinformatics invention are routine and conventional. In response, patent applicants can rebut such conclusory statements by arguing that the USPTO failed to provide sufficient objective evidence to support that the claim features are routine and conventional.[3]

Third, the USPTO may overlook bioinformatics patent applications that improve an existing technological process, which is considered patent-eligible subject matter. While a bioinformatics patent application may not improve the mechanical and/or electrical operations of a computer, the application may improve an existing technological process — namely (1) enabling an existing manual process to be run on a computer[4], or (2) improving the accuracy and effect provided by the computer[5]. Patent applicants can argue that the improvement to the existing technological process can be in terms of improving the result provided by the computer, such as providing a particular step or data structure that enables a manual process to be run on the computer or improving the accuracy and effect provided by the computer.

Fourth, the USPTO may incorrectly reject a bioinformatics patent claim merely because the

claim involves a diagnostic method. For example, a bioinformatics patent claim may be directed to a method for diagnosing whether a particular genetic variant is benign or pathogenic. Such a diagnostic method claim is generally patent ineligible.[6] But, the USPTO may fail to distinguish between diagnostic claims that recite a natural law and means for detection (which are generally considered patent ineligible) and claims directed to the application of natural laws (which are generally considered patent eligible).[7] One way patent applicants can argue that its claims are directed to the application of natural laws is to recite a treatment step that; for example, the claims can recite the effects of a particular treatment or prophylaxis. Patent applicants should be cognizant of reciting a treatment step in its claims because of potential divided infringement issues, especially for bioinformatics patent applications having clinical applications.

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[1] *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014).
[2] *Mayo v. Prometheus*, 566 U.S. 66 (2012).
[3] *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018).
[4] *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1313 (Fed. Cir. 2016).
[5] *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1314 (Fed. Cir. 2016).
[6] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, LLC, 915 F.3d 743, 750 (Fed. Cir. 2019).
[7] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, LLC, 915 F.3d 743, 751 (Fed. Cir. 2019).

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This article discusses challenges in prosecuting bioinformatics patent applications before the European Patent Office (EPO). The EPO determines the subject-matter eligibility of bioinformatics patent applications under Articles 52 and 56 of the European Patent Convention. Article 52 governs what is considered patent eligible subject matter.[1] Article 56 governs whether a bioinformatics patent claim involves an inventive step.[2] While Article 56 is not directly related to eligible subject matter determinations, the EPO uses this Article to screen bioinformatics patent application for eligible subject matter issues. Four points of concern and consideration related to the subject-matter eligibility of bioinformatics patent applications in Europe are discussed below.

First, under Article 52, the EPO may incorrectly reject a bioinformatics patent claim as being directed to (1) discoveries, scientific theories, and mathematical methods, or (2) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers.[3] One way patent applicants can argue that a bioinformatics patent claim is not directed to either category is to explicitly recite a computer or physical step (e.g., tying bioinformatics method claim to specific technical equipment) to support technical character in the claim.

Second, under Article 56, the EPO may overlook a technical purpose of a bioinformatics patent claim. In response, patent applicants can argue that the technical purpose is the biological rationale for performing the bioinformatics analysis. For example, the biological rationale can be related to diagnosing a disease or assessing a particular physical property. Patent applicants should be cognizant that issues may arise when arguing that the features fundamental to solving the biological problem (e.g., aligning gene sequences) are the biological rationale. This is because such features may not be considered by the EPO to sufficiently provide the requisite biological rationale.

Third, under Article 56, the EPO may incorrectly reject a bioinformatics patent claim because the claim does not have a sufficient number of claim features that contribute to the claim's biological rationale. This can occur when the EPO incorrectly excludes claim features as part of the inventive step analysis. For example, the EPO can exclude claim features that (1) do not serve the biological rationale, (2) are not functionally limited to the biological rationale, (3) are defined at a high level of generality, and (4) are not considered technical by the EPO, such as presentation of information, conceptual aspects of software design and development, and/or

mathematical algorithms. Patent applicants can rebut the EPO's exclusions by explicitly reciting features (with an appropriate level of detail) that define how the biological rationale is achieved.

Fourth, the EPO may incorrectly reject a bioinformatics patent claim because the claim involves a diagnostic method. For example, a bioinformatics patent claim may be directed to a method for diagnosing whether a particular genetic variant is benign or pathogenic. But, the EPO may not distinguish between diagnostic claims where all technical steps are practiced on a human or animal body (which are generally considered patent ineligible)[4] and claims where a portion of the technical steps are not practiced on a human or animal body (which are generally considered patent eligible). One way patent applicants can argue that a claim is directed to a patent eligible diagnostic method is to recite a technical step that is, for example, performed *in vitro*. Patent applicants should be cognizant of reciting an *in vitro* step in claims because of potential infringement issues, especially for bioinformatics patent applications having clinical applications.

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[1] Article 52 EPC, www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar52.html

[2] Article 56 EPC, www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar56.html

[3] Article 52(2) EPC, www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar52.html

[4] EPO Guidance G01/04

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PROSECUTING BIOINFORMATICS PATENT APPLICATIONS IN CHINA

By: Todd M. Hopfinger and Christian A. Camarce

This article discusses challenges in prosecuting bioinformatics patent applications before the China National Intellectual Property Administration (CNIPA). The CNIPA determines the subject-matter eligibility of bioinformatics patent applications under Articles 2 and 25 of the Patent Law of the People's Republic of China. Article 2 requires that a claim involve a set of technical means that adopt laws of nature for solving a technical problem or producing a technical effect (collectively a "technical solution").[1] Article 25 excludes a claim directed to (1) scientific discoveries, (2) rules and methods for intellectual activities, (3) methods for the diagnosis or treatment of diseases, (4) animal or plant varieties, (5) substances obtained by means of nuclear transformation, and (6) designs mainly directed to marking the pattern, color or the combination of the two of prints.[2] Four points of concern and consideration related to the subject-matter eligibility of bioinformatics patent applications in China are discussed below.

First, under Article 2, the CNIPA may incorrectly reject a bioinformatics patent claim because the claim does not solve a technical problem or produce a technical effect. In response, patent applicants can argue that the technical problem or technical effect is the biological rationale for performing the bioinformatics analysis. For example, the technical effect can be the assessment of a biological entity's physical property.

Second, under Article 2, the CNIPA may incorrectly reject a bioinformatics patent claim because the claim does not have technical claim features that contribute to solving the technical problem or producing the technical effect. This may occur if the CNIPA incorrectly excluded claim features as being non-technical. Patent applicants can rebut this argument by explicitly reciting features (e.g., aligning gene sequences) that define how the technical problem is solved or the technical effect is produced. Such rebuttal should be argued from the perspective of a person of ordinary skill in the art.

Third, under Article 25, the CNIPA may incorrectly reject a bioinformatics patent claim because the claim involves a diagnostic method. For example, a bioinformatics patent claim may be directed to a method for diagnosing whether a particular genetic variant is benign or pathogenic. But, the CNIPA may fail to distinguish between different types of diagnostic claims. A diagnostic claim (1) practiced on a human or animal body, or (2) where its immediate purpose is to obtain a diagnostic result of a disease or health condition is patent ineligible. On the other hand, a diagnostic claim is patent eligible where a portion of the recited technical steps are not practiced on a human or animal body and its immediate purpose is not to obtain a

diagnostic result. One way patent applicants can argue that a claim involving a diagnostic method is patent eligible is to recite a technical step that is, for example, performed *in vitro*. Patent applicants should be cognizant that reciting an *in vitro* step may give rise to potential divided infringement issues, especially for bioinformatics patent applications having clinical applications.

Fourth, under Article 25, the CNIPA may incorrectly reject a bioinformatics patent claim because the claim has been mischaracterized as being directed to a diagnostic method. The CNIPA may fail to distinguish between a "true" diagnostic method claim (which is generally considered patent ineligible) and a claim related to a diagnostic method (which is generally considered patent eligible). For example, a claim involving instruments or apparatuses for implementing diagnostic methods or treatment, or substances/materials used in such methods, is patent eligible. Thus, one way patent applicants can argue that a bioinformatics claim related to a diagnostic method is patent eligible is to recite the instruments or apparatuses for implementing the diagnostic method or the substances or materials used in the diagnostic method.

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[1] Article 2 of the Patent Law, www.wipo.int/edocs/lexdocs/laws/en/cn/cn028en.pdf

[2] Article 25 of the Patent law, www.wipo.int/edocs/lexdocs/laws/en/cn/cn028en.pdf