Westlaw Today
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Insight on U.S. subject-matter eligibility

By Michelle K. Holoubek, Esq., and Todd M. Hopfinger, Esq., Sterne, Kessler, Goldstein & Fox, and Naveed S. Hasan, Esq.

JUNE 27, 2022

In 2021, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) decided two cases[1] involving the subject matter eligibility of bioinformatics patent applications, U.S. Patent Appl. No. 13/486,982 ('982 application) and U.S. Patent Appl. No. 13/445,925 ('925 Application), both owned by the Board of Trustees of the Leland Stanford Junior University (Stanford cases).

While these decisions focus on bioinformatics patent applications, they may also apply to patent applications in other technical fields, including data analytics, artificial intelligence, and machine learning.

In view of these decisions, several points of concern and consideration related to the subject matter eligibility of at least bioinformatics patent applications deserve a closer look.

First, patent applicants may want to consider whether their claimed invention involves a technological improvement or merely a mathematical algorithm improvement. In the Stanford cases, the Federal Circuit considered whether improving the accuracy of haplotype phasing and increasing the number of generated haplotypes was subject matter eligible.

In one of the cases, Stanford argued that the '982 application claims provided a technological improvement because they provided an improvement to the field of haplotype phasing.

Specifically, Stanford argued that the claims provided the technological improvement by increasing the accuracy of haplotype prediction using a PHASE-EM statistical model and a particular type of Hidden Markov Model (HMM).

In the other case, Stanford argued that the '925 application claims provided an improvement to the field of haplotype phasing by factoring in additional data, such as linkage disequilibrium and transition probability data, to identify a greater number of haplotype phases.

Stanford also provided evidence illustrating the improvement provided by the '982 and '925 applications in the field of haplotype phasing.

For example, with respect to the '982 application, Stanford argued that using the PHASE-EM statistical model improves accuracy over existing methods by using a particular type of HMM to predict a haplotype phase.

Further, with respect to the '925 application, Stanford demonstrated that the claims improved the resolution of the haplotype phase to about 98% of all heterozygous positions from a previous maximum of about 80%. The Federal Circuit disagreed with Stanford's arguments in both cases.

Patent applicants may want to consider whether their claimed invention involves a technological improvement or merely a mathematical algorithm improvement.

While the Federal Circuit failed to define the parameters of what qualifies as another technological field and what qualifies as an improvement to that field, the Federal Circuit did clarify that an "enhancement to the abstract mathematical calculation of haplotype phase itself" is not an improvement to another technological field.[2]

Similarly, the Federal Circuit clarified that while identifying "a greater number of haplotype phase predictions, may constitute a new or different use of a mathematical process, [] we are not persuaded that the process is an improved technological process."[3]

That is, just because the *math* is new or different does not necessarily mean that the *technology* itself is improved.

In view of the above, during prosecution, patent applicants may consider arguing that its claims involve more than merely improving the accuracy of a mathematical algorithm itself. Specifically, patent applicants may consider amending its claims such that the application of the mathematical algorithm to a concrete, practical application goes beyond simply storing or outputting data.

For example, patent applicants may consider how the resulting data is being used to effectuate a real-world result. The real-world result may include controlling the execution of a physical process.

For example, in *Diamond v. Diehr*,[4] the U.S. Supreme Court found a process for curing rubber was patent eligible because a computer program controlled the execution of a *physical* process (e.g., curing rubber). In the biomedical field, a treatment step may be an example of invoking a physical process.

However, patent applicants may want to consider potential divided infringement issues before adding a treatment step in the claims.

For example, in the biomedical field, a system may identify a condition and a healthcare professional may treat that condition. But claiming both the identification of a condition and the treatment of the condition may result in potential divided infringement issues because the identification and treatment steps are performed by different actors.

Second, patent applicants may consider arguing that their claims are subject matter eligible for reasons beyond improvements to another technology or technical field.

For example, patent applicants may consider arguing that their claims improve a computer's function. In the Stanford cases, the Federal Circuit did not consider Stanford's argument that the '982 application claims improved computational efficiency — an argument that Stanford did not raise before the USPTO's Patent Trials and Appeals Board (Board) before its appeal to the Federal Circuit.

Patent applicants may consider this cautionary example when prosecuting software-based patent applications in the fields of bioinformatics, machine-learning, and artificial intelligence.

Not only is it a best practice to provide such technological arguments to the examiner for due consideration and potentially avoiding appeal altogether, but it is also important to preserve such arguments for appeal if the examiner nonetheless maintains a subject matter eligibility rejection.

Evidence of computational improvements (e.g., test data) may be provided during prosecution in response to a subject matter eligibility rejection via, for example, a technical expert declaration.

At the drafting stage, in light of the Stanford cases, patent applicants may consider preparing patent applications that detail how the claimed invention involves more than merely improving the accuracy of a mathematical algorithm itself.

Furthermore, patent applicants may consider how the claimed invention improves a computer's function, in addition to how the claimed invention provides an improvement to another technology or technical field. By doing so, these types of descriptions will provide patent applicants additional arguments to address potential subject matter eligibility rejections.

In view of the above, while many questions still remain, the Stanford cases provide further clarity regarding the subject-matter eligibility of patent applications in the fields of bioinformatics, machine-learning, and artificial intelligence.

Patent applicants may use this insight to avoid critical pitfalls when preparing and prosecuting patent applications in these technical fields. In particular, to avoid subject matter eligibility rejections, patent applicants may consider arguing that the claimed invention involves more than merely improving the accuracy of a mathematical algorithm itself.

Furthermore, patent applicants may consider arguing that the claimed invention is subject matter eligible for reasons beyond improvements to another technology or technical field.

Notes

[1] *In Re Board of Trustees of the Leland Stanford Junior University*, No. 20-1288 (Fed. Cir. 2021); *In Re Board of Trustees of the Leland Stanford Junior University*, No. 20-1012 (Fed. Cir. 2021).

[2] *In Re Board of Trustees of the Leland Stanford Junior University*, No. 20-1288 (Fed. Cir. 2021).

[3] *In Re Board of Trustees of the Leland Stanford Junior University*, No. 20-1012 (Fed. Cir. 2021).

[4] 450 U.S. 175 (1981).

About the authors



Michelle K. Holoubek (L) is a director at **Sterne, Kessler, Goldstein & Fox**. She specializes in software, digital health care, bioinformatics and optical technologies. She is based in Washington, D.C., and can be reached at holoubek@sternekessler.com. **Todd M. Hopfinger** (C) is also a director at the firm's Washington office, where he prepares, prosecutes and manages several patent portfolios in the bioinformatics, data analytics, artificial intelligence and machine learning fields. He can be reached at thopfinger@sternekessler.com. **Naveed S. Hasan** (R) is an attorney with substantial experience preparing and prosecuting patent applications in the bioinformatics, data analytics, artificial intelligence and machine learning fields.

This article was first published on Westlaw Today on June 27, 2022.