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Patenting Digital Health Innovations Incorporating AI in View of USPTO's Recent Subject Matter Eligibility Guidance

Patent procurement activity is increasing to protect embedded artificial intelligence ("AI") technologies in a variety of digital healthcare solutions. The United States Patent and Trademark Office ("USPTO") has issued the latest and most far reaching in a series of pro-eligibility revisions to its guidelines for determining subject matter eligibility that should significantly increase the space of eligible subject matter for patenting. The new guidance reveals patent procurement strategies that can potentially increase opportunities for obtaining patents on AI-related inventions and increase the value of associated patent portfolios.

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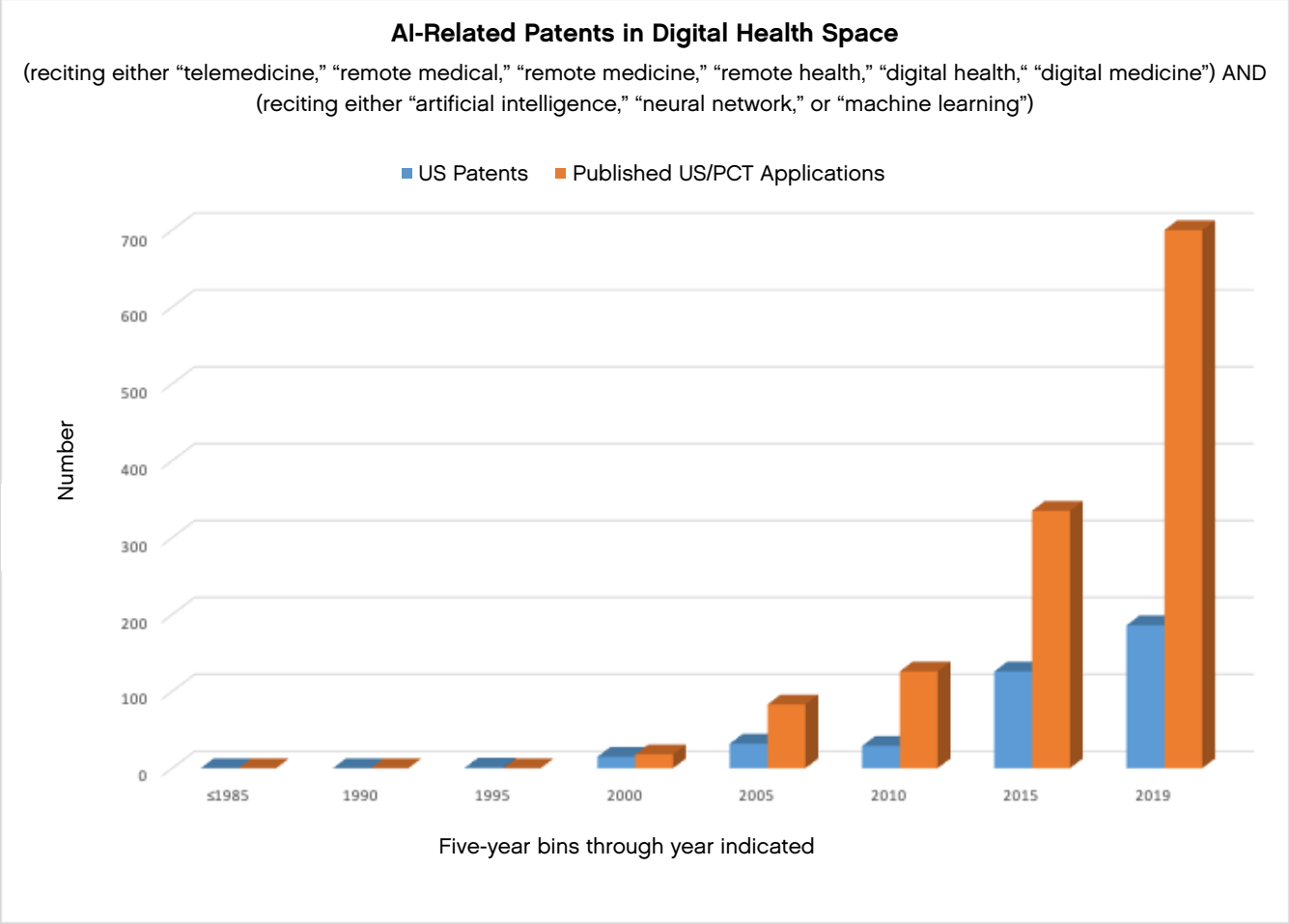
HEIGHTENED ACTIVITY

Artificial intelligence ("AI") is increasingly being embedded in a variety of digital healthcare solutions, ranging from trained machine learning algorithms that detect personalized diagnostic biomarkers and pattern recognition systems that interpret retinal scans, to AI for genetic analysis, AI-enhanced clinical decision making, and virtual doctors that use AI for patient intake triage, just to name a few examples. Along with increased interest and implementation, U.S. patent application filings relating to digital health involving AI have increased substantially since 2005, as shown in the following chart.



Such digital health innovations that utilize AI or machine learning are software-centric, leveraging advanced computer models that are continually updated and trained, including, for example, neural networks and deep learning algorithms. Patent claims for such innovations can face various hurdles at the USPTO during the examination process and/or in courts during enforcement. Here, we discuss recent developments that can impact the ability to obtain robust and enforceable patent protection in this space and discuss various strategy considerations for patent procurement, particularly in light of the USPTO's recent 2019 Revised Patent Subject Matter Eligibility Guidance.

SUBJECT MATTER ELIGIBILITY

As previously reported[1], the *Alice* test for subject matter eligibility established by the Supreme Court involves two steps: (i) determining whether the claims at issue are directed to a patent ineligible concept (i.e., law of nature, natural phenomena, or abstract idea); and (ii) if so, determining whether the claims contain additional element(s) sufficient to ensure that the claims amount to significantly more than the ineligible concept itself.

Navigating *Alice* can be difficult for digital health innovations, particularly those involving AI, since these inventions are

rooted in software, which has, in recent years, been attacked both in district courts and at the USPTO on subject matter eligibility grounds. First, claims rooted in software may fail *Alice* Step 1 if the claim overall reads broadly enough, for example, to cover mental acts or pencil-and-paper processes. AI tends to make heavy use of software algorithms for classification, clustering, regression, dimensionality reduction, and the like, and such activities might be viewed by the USPTO or courts as abstract ideas, even where such is recited in the claim in some detail for execution by a computer and even when such models could not be executed without a computer. In addition, the "intelligence" in AI often consists of computer models trained using empirical data. In some instances involving health-related data, such models may themselves embody empirical patterns extracted from experimental data, for example, models that correlate disease conditions to the presence of specified biomarkers. In these cases, such models might be viewed as simply reflecting laws of nature. *Alice* Step 2 can also be problematic, even for methods having recognized clinical significance.[2] By their nature, AI inventions might be analogized with methods that could otherwise be performed, at least in principle, by a human healthcare provider. Conventional healthcare steps combined in conventional ways around an AI model might be viewed as insufficient to provide the recited "additional element(s)" necessary to overcome *Alice* Step 2.

EVOLVING STANDARDS

In January 2019, the USPTO published the latest and most far-reaching memo in a series of pro-eligibility revisions to its guidelines for determining subject matter eligibility for patenting (referred to here as the "Guidance").[3] These revisions introduce a new two-prong analysis of the Supreme Court's *Alice* Step 1 that should significantly increase the space of eligible subject matter. To avoid confusion, readers should know that the step numbers referred to in the USPTO's Guidance do not match those of the *Alice* test. In the Guidance, "Step 1" of an examiner's analysis involves determining whether the claim is directed to one of the statutory categories (i.e., a process, machine, manufacture, or composition of matter).[4] "Step 2A" of the examiner's analysis corresponds to Step 1 of the *Alice* test.[5] It is this step—Step 2A—for which the USPTO introduces two prongs in the Guidance. In contrast, the Guidance does not amend "Step 2B" of the examiner's analysis, which corresponds to Step 2 of the *Alice* test.

Under the first prong of the USPTO's Step 2A, the Examiner determines whether the claim recites a patent ineligible concept—in particular, whether the claim recites an abstract idea, law of nature, or natural phenomenon. Notably, the inquiry at this stage is not whether the claim "as a whole" is directed to such (as required by the *Alice* test), but rather simply whether the claim "recites" such. In principle, the second prong of USPTO's Step 2A assesses whether the claim "as a whole" is directed to a judicial exception in compliance with the *Alice* test. Significantly, the "abstract idea" exception in the Guidance has been restricted to three defined groupings: mathematical concepts, certain methods of organizing human activity, and mental processes. Under the Guidance, claims directed to subject matter outside these groupings are now deemed to pass the *Alice* test without being subject to further analysis (except in rare circumstances which require approval by a Technology Center director). Even subject matter that might seem to coincide with one of these groupings can be eligible if crafted to avoid the USPTO's definition for the groupings. For example, the following claim limitation covering a genus of mathematical formulas likely would not be considered to recite a mathematical concept under the Guidance because it does not explicitly recite any mathematical relationship, formula, or calculation:

> "applying one or more transformations to each digital facial image including mirroring, rotating, smoothing, or contrast reduction to create a modified set of digital facial images."[6]

If the claim is not already found eligible under the first prong of USPTO's Step 2A (corresponding to *Alice* Step 1), the second prong of USPTO's Step 2A (still *Alice* Step 1) is applied, and the Examiner is required to assess whether the claim contains additional elements that integrate the exception into a *practical application*. Notably, in determining whether such integration has occurred, examiners are instructed to exclude all consideration of whether claim limitations are well-understood, routine, conventional activity.

The Guidance identifies several categories of integration into a practical application under the second prong that are

particularly relevant to AI. For example, a claim that uses an abstract idea to improve the functioning of a computer should meet the integration requirement, provided there is a technical explanation as to how to implement the invention in the specification, and the claim itself reflects the improvement in technology. As a second example, a claim that applies an abstract idea to effect a particular treatment or prophylaxis for a disease or medical condition can also satisfy the integration requirement. To evaluate whether treatment/prophylaxis limitations are sufficient, the Guidance instructs USPTO personnel to consider whether the limitations are (i) sufficiently particular; (ii) have more than a nominal or insignificant relationship to the exception(s); and (iii) merely extra-solution activity or a field of use.

QUESTIONS REMAIN

While the USPTO's Guidance should increase allowance rates for digital health applications rooted in AI, it remains difficult to predict how the resulting patents will fare when they are pressure-tested in court. In *Cleveland Clinic Foundation v. True Health Diagnostics, LLC*, the Federal Circuit expressly declined to defer to USPTO guidance (in an earlier 2016 memo).[7] Moreover, not all trends are patent-friendly. In *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, for example, the Federal Circuit continued to solidify its precedent disfavoring claims directed to diagnostic biomarker correlations, notwithstanding the sense that such claims should be patent eligible.[8] Indeed, the Federal Circuit recently denied en banc rehearing in *Athena v. Mayo*, in which there were eight separate opinions concurring or dissenting from the order, and which included outright pleas from Federal Circuit judges to either the Supreme Court or Congress to provide a workable framework for the current (broken) subject matter eligibility law.[9] In addition, the U.S. Supreme Court continues to entertain review of relevant patent cases. In January 2019, for example, the Supreme Court asked the U.S. Solicitor General to weigh in on Federal Circuit precedent regarding factual determinations relevant to subject matter eligibility.[10]

Against this backdrop, below are several considerations for application drafting and patent prosecution in view of the USPTO's revised examination guidelines.

TAKEAWAYS FOR PATENTING DIGITAL HEALTH INNOVATIONS INVOLVING AI

- **Beef up the Specification in new applications**. Consider providing detailed technical explanations regarding how to implement analytics and AI features to improve the functioning or results of the technology of the invention, and consider conspicuously describing the practical application(s) of the claimed invention, in an effort to avoid rejections under *Alice* Step 1 in the first instance.

- **Craft claims to avoid the "abstract idea" groupings**. To reduce the likelihood of rejections under *Alice* Step 1, consider avoiding, where appropriate, claims that read on the three groups of abstract ideas listed in the Guidance, i.e., mathematical concepts, certain methods of organizing human activity, and steps that can be viewed as reading on mental processes. In addition, as explained in our earlier post[1] on AI claiming, consider including claim limitations related to interaction/manipulation/control of hardware and transformations of data in an effort to better position the patent claims for *Alice* Step 2.

- **Craft claims to qualify under one of the "integration" examples provided in the Guidance**. Consider crafting claims that satisfy one of the integration examples, by reciting a use of AI to, for example, affect a particular modification to a pre-existing treatment regimen, since these may fare well under the USPTO's revised Step 2A.

- **Keep patent families open**. Given the fluid state of law, consider using continuation practice to keep subject matter alive to (i) obtain claims of suitable scope (narrower or broader) consistent with the current state of subject matter eligibility law; and (ii) pursue different types of claims if new case law raises concerns over the validity of existing patents.

- **Pursue multiple avenues to overcome Examiner rejections**. Since overcoming subject matter eligibility rejections by heavy reliance on recent case law could lead to unpredictable results should the law thereafter change, consider pursuing additional claims of different scope by amending the claims to overcome subject matter eligibility rejections, in addition to pursuing broader claims by invoking case

law arguments. This approach can help to insulate patent coverage in the event the law relied upon changes, which is a real possibility given recent Congressional attention to the problem of subject matter eligibility in U.S. patents. [11]

- **Don't rely on the Guidance alone.** When responding to a subject matter eligibility rejection, in addition to explaining how the claims are eligible in view of the Guidance, consider also explaining how those claims are eligible under the *Alice* test apart from the Guidance, since courts are not bound by the Guidance. This may help insulate patent claims against later challenges in district court that the claims are not entitled to much deference on the USPTO's view of subject matter eligibility if the applicant only argued eligibility for those claims under the Guidance.

CONCLUSION

After a difficult run for patent prosecution under the USPTO's earlier approaches to implementing the *Alice* test, the recent Guidance marks a new phase in subject matter eligibility. While patent applicants and patent owners should remain prudent and cautious (courts are not bound by the Guidance), patent applicants and patent owners, including those developing innovations involving AI and machine learning in digital health technologies, can potentially increase the value of their patent portfolios by applying strategies that leverage and exploit this Guidance.

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ENDNOTES

1 (https://www.jonesday.com/protecting-artificial-intelligence-and-big-data-innovations-through-patents-subject-matter-eligibility-03-12-2018/)

2 *See, e.g.*, *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, LLC, 915 F.3d 743, 757 (Fed. Cir. 2019) (Newman, dissenting from holding of invalidity) ("Until discovery of the diagnostic method . . . some 20% of patients suffering from the neurological disorder Myasthenia Gravis were not capable of being diagnosed.").

3 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 4, 51 (Jan. 7, 2019), *available at* https://www.govinfo.gov/content/pkg/FR-2019-01-07/pdf/2018-28282.pdf.

4 Id. at 53, 54.

5 Id.

6 USPTO, "2019 Revised Patent Subject Matter Eligibility Guidance - Advanced Module," p. 110. *Available at* https://www.uspto.gov/sites/default/files/documents/2019peg__advanced__module__05mar2019.pptx.

7 *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 Fed. Appx. 1013, 1020 (Fed. Cir. 2019) ("[w]hile we greatly respect the PTO's expertise . . . we are not bound by its guidance [and], especially regarding the issue of patent eligibility . . . we are mindful of the need for consistent application of our case law.").

8 *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 754 (Fed. Cir. 2019) ("We cannot hold that performing standard techniques in a standard way to observe a newly discovered natural law provides an inventive concept").

9 *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 2019 U.S. App. LEXIS 19979 (Fed. Cir., July 3, 2019).

10 *HP, Inc. v. Berkheimer*, SCOTUSblog (January 7, 2019), https://www.scotusblog.com/case-files/cases/hp-inc-v-berkheimer/.

11 (https://www.jonesday.com/en/insights/2019/06/alices-last-birthday)