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Protecting digital health inventions

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Protecting digital health inventions

Over the past decade, changes to patent law have raised challenges concerning protecting advances in digital-based technologies, including digital health. One major change has increased restrictions on the types of innovation that are eligible for patenting under Section 101 of the Patent Code, 35 U.S.C. § 101. Steven J. Corr and Louis Touton of Jones Day explore the issues in the US related to the patentability of digital health technologies, and analyse recent developments which have clarified requirements for patent eligibility.

Historically, three categories of innovation - laws of nature, natural phenomena and abstract ideas - were not considered eligible for patenting under US law. For several decades, lower courts seldom considered invalidating patents because of those eligibility limitations. This changed in a series of Supreme Court decisions beginning with *Bilski v. Kappos*[1] emphasising the need to enforce limitations.

In practice, lower court decisions after *Bilski* have made patents less effective when protecting innovations in digital health. Because digital health advances often blend natural medical phenomena with computer automation, stricter enforcement of the three categories of ineligibility raises the bar for patenting. But even more challenging, the newly invigorated restrictions are both novel and nuanced, so that inventors, technology developers, judges, patent examiners and lawyers must grapple with uncertainties in applying the Supreme Court's decisions.

All this contributes to difficulties for those who want to build a digital health business, which would rely on patents to protect its foundational innovations. However, it seems a corner is being turned. While some degree of uncertainty remains, the lower courts are now settling some important issues, with the result that patent protection is increasingly available for many important types of digital health innovations.

The fog comes in: the Supreme Court's decisions on patent eligibility

The limiting Supreme Court decisions most applicable to digital health innovations are *Mayo Collaborative Services v. Prometheus Lab., Inc.*[2] and *Alice Corp. Pty. Ltd. v. CLS Bank Int'l.*[3]. *Mayo v. Prometheus* involved a patent on natural phenomena, namely how drug concentration in blood indicates therapeutic efficacy. *Alice v. CLS*, on the other hand, involved a patent covering the use of computers to implement the abstract idea of 'intermediated settlement' - the conventional notion of using an independent actor to ensure that buyer and seller perform their financial obligations. These cases mean that the road to patenting digital health innovations must often overcome dual challenges:

1. possible ineligibility of claims to natural phenomena; and
2. potential ineligibility of using computers to implement abstract ideas.

In both these cases, the Supreme Court followed a two-step test for patent eligibility:

1. whether the patent claims are directed to a patent-ineligible concept and, if so;
2. whether the claims do 'significantly more' than simply describe the natural phenomenon or abstract idea.

In both cases, the Supreme Court concluded that the patent claims involved ineligible concepts without doing significantly more in implementation. This legal analysis, however, has proven very difficult for courts and the patent office to apply, since the stated test provides few illustrations to guide how to make the required subjective judgments. By limiting patent eligibility under Section 101 without detailed guidance, these and similar cases caused some lawyers to conclude that patent law was no longer the best way to protect digital health products. In the wake of these, some practitioners suggested innovators should forgo patents and instead rely on trade secret law, even though it is impractical to keep many digital health innovations secret. Others advised how to draft better patent applications generally (e.g. describe in detail the circuitry employed and other tangible features; focus on details rather than generalities; seek various differently written patent claims targeting both hardware and software etc.). While this is good general advice, the new legal environment left entrepreneurs without particular and reliable strategies to protect the innovations they need to build their businesses.

The fog clears: clarifications of patent eligibility in digital health

Fortunately, recent developments have clarified requirements for patent eligibility in the digital health technologies. Although the best strategies for patenting depend on the nature of the specific digital health product involved, there are several recent developments that can help guide digital health innovators in negotiating the twin eligibility hurdles of natural phenomena and abstract ideas. These emerging principles are discussed below.

Treatment methods are usually eligible for patenting

Generally, patent eligibility requirements are more demanding for methods than devices. Methods are more likely to lack the specifics that can provide the

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'substantially more' to convert patent-ineligible natural phenomena or abstract ideas into more concrete innovations that are eligible for patenting.

For treatment methods, rather than diagnosis methods, it is likely that the method's steps will be seen as making the innovation patentable. This is illustrated by comparing *Mayo v. Prometheus* (invalidating a patent) with *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int'l Ltd.*[4] (sustaining a patent). The patent in *Mayo v. Prometheus* concerned a diagnosis method for determining whether a dosage of a thiopurine drug given to a particular patient is adequate. The Supreme Court unanimously held that the method, which was limited to administering the drug and determining the resulting blood concentration, was not eligible for patenting because it sought to patent a natural phenomenon.

Six years later in *Vanda*, the Court of Appeals for the Federal Circuit (responsible for all patent appeals) upheld a patent on a method of treating a patient with iloperidone, by comparing the dosage administered to the resulting blood concentration and depending on that comparison, administering a stated dosage. The Federal Circuit ruled that the patent was valid because the treatment claim in *Vanda* went beyond *Mayo v. Prometheus* to require a specific treatment step, and not just observing natural relationships to be used diagnostically.

Although Supreme Court review is possible, *Vanda* is being treated as authoritative - the U.S. Patent and Trademark Office has instructed patent examiners that methods that include treatment steps should generally be considered patent eligible[5].

In summary, the *Vanda* decision has clarified that digital health-guided treatment methods will likely be patentable, since they will include instructions that specific therapeutic steps be taken, and thus avoid the ruling in *Mayo v. Prometheus*, that standalone diagnostic methods cannot be patented.

Diagnostic innovations can also be eligible for patenting

While the Supreme Court's *Mayo v. Prometheus* decision indicates that lab techniques and other diagnostic methods are vulnerable to being ineligible for patenting, subsequent lower court decisions have indicated that some diagnostic methods are eligible. For example, in *Exergen Corp. v. Kaz USA, Inc.*[6], (2-1 decision, non-precedential), the Federal Circuit considered a patent claiming a method for detecting body temperature involving moving a radiation detector three times over the temporal artery.

The Court found that even though "the patent is directed to the measurement of a natural phenomenon (core body temperature)," it incorporated into its claims the "unconventional method of temperature measurement," involving the temporal artery. Thus, although the claim was "directed to a patent-ineligible concept", it "incorporated an inventive concept[7]." Because it "transformed the process into an inventive application of the formula," the invention was eligible for patenting[8].

Thus, although they will often be considered as directed to natural phenomena, diagnostic methods and devices can be found to be eligible for patenting if they add unconventional ways to employ the phenomena in rendering diagnoses. This is another way in which more recent decisions have provided a more certain framework to obtain patents on digital health advances.

The challenges of patenting the use of computers

As noted above, the Supreme Court's 2014 *Alice v. CLS* decision limited the patentability of computer-based inventions. The field of digital health, of course, includes many innovations arising from using computers to automate tasks previously performed by humans.

Although this decision has sometimes been characterised as the death knell of patenting computer-based operations, it has not been applied nearly so broadly in recent times. While *Alice* held that one cannot patent the use of a computer to perform an underlying abstract idea, e.g. a well-known algorithm, it allowed patenting innovations which have "additional features" that introduce computers in a way which "improve[s] an existing technological process[9]."

In the digital health field, this is an important distinction. Computer technology will often be used to execute algorithms in different ways than would be conventionally employed by humans. These differences can lead to patentability. For example, *McRO, Inc. v. Bandai Namco Games America, Inc.*[10] concerned a patent that automated production of lip synchronised

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three-dimensional animations. The facts showed that the abstract idea of lip synchronisation had long been commonly performed by human animators. But the patent was found to be eligible because the computers implemented a different procedure to achieve synchronisation following formal timing rules (using computers), rather than making aesthetic judgments (using humans). As the computer used a process different than the process conventionally performed by humans, the Federal Circuit ruled that the process was eligible to be patented. This decision is an example of how a patent directed to automating tasks can be patentable, provided it performs the task in a way not conventionally done by humans.

Wearables

At the forefront of current digital health innovations are medical wearables: devices that incorporate embedded computers which can be worn on the body (or even implanted) to monitor pulse, temperature, blood chemistry and other body characteristics. In some applications, these can even react therapeutically. Therapeutic wearables often gather biometric data and then spring into action based on those measurements. In view of the Federal Circuit's recent *Vanda* decision, these are now generally recognised as eligible for patenting.

The patentability of wholly diagnostic wearables involves more nuance. In the immediate wake of *Alice v. CLS*, some decisions indicated patent protection for diagnostic devices and techniques would be quite limited. More recently, however, decisions have recognised patent eligibility even for wholly diagnostic devices.

The dispute between Fitbit and Jawbone concerning wearable fitness monitors, which sprung up in 2015, indicated that courts might use *Alice* broadly to render diagnostic wearable ineligible for patenting. Jawbone asked the United States International Trade Commission ('USITC') to block Fitbit from importing fitness wearables because they infringed six Jawbone patents[11] and Fitbit asked the USITC to block Jawbone from importing its wearables because they infringed three Fitbit patents[12]. Jawbone and Fitbit each challenged the other's patents under Alice, and in a series of rulings, the USITC judge found all of them ineligible for patenting. Although for many of the patents this was because fitness wearables simply use the same techniques conventionally used by doctors and nurses, some of the rejected patents were directed to improved ways that computers could be employed in this role, such as power-conservation technique, e.g. USITC Investigation No, 337-TA-973, Initial Determination Granting Respondents' Motion for Summary Determination of Invalidity n.13, 19 July 2016.

The Jawbone/Fitbit decisions, which read *Alice* broadly to invalidate patents, even though the covered particular design features were directed to the special requirements of wearables, understandably caused many to question whether patents were of any use at all in protecting wearable innovations. It is one thing to apply *Alice* to say one can't patent using a computer-implemented wearable to mimic the diagnostic techniques of doctors and nurses. It is quite another to deny patents on novel configurations of the computers to allow them to efficiently do the mimicking.

The Federal Circuit decisions such as *McRO, Inc. v. Bandai Namco Games America, Inc*. provide some hope: devices that automate operations previously performed by humans through having computers use different methods than humans conventionally use, are likely eligible for patenting. To the same effect, see *Thales Visonix Inc. v. United States*[13], which allowed a patent on computerised inertial tracking using techniques not conventionally used by humans. Thus, where diagnostic wearables perform their function in a way that is significant different than the humans they replace, good arguments can be made for patent eligibility.

Conclusion

The Supreme Court's decisions in *Mayo v. Prometheus and Alice v. CLS* prohibiting patenting of natural phenomena and abstract ideas, injected significant uncertainty as to whether digital health innovations could be patented. Subsequent lower court rulings have significantly dispelled that uncertainty, so that patents are increasingly viable means of protecting digital health innovations.

1. 561 U.S. 593 (2010).
2. 566 U.S. 66 (2012).
3. 134 S. Ct. 2347 (2014).
4. 887 F.3d 1117 (Fed. Cir. 2018).
5. See Recent Subject Matter Eligibility Decision, *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, 7 June 2018, available at https://www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.PDF
6. 725 Fed. App'x 959, 8 March 2018.
7. 725 Fed. App'x at 966.
8. Ibid.
9. *Alice v. CLS*, 134 S. Ct. at 2357-58.
10. 837 F.3d 1299 (Fed. Cir. 2016).
11. Re Certain Activity Tracking Systems, Devices, and Components Thereof (USITC Docket No. 337-TA-963, instituted 21 August 2015).
12. Re Certain Wearable Activity Tracking Systems, Devices, and Components Thereof (USITC Docket No. 337-TA-973, instituted Dec. 7, 2015.
13. 850 F.3d 1343, 1348-49 (Fed. Cir. 2017).