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3 Practice Tips For Patenting Medical Devices In A Digital Age

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Digital technology continues to shake up our health care system, driving innovation and transforming all aspects of health care.

Just recently, for example, we've seen a flood of new software programs and medical devices introduced to market in efforts to aid health care providers in detecting and surveilling different COVID-19 strains.

There has likewise been a surge in the development of digital therapeutic applications that purport to help manage or treat a variety of diseases.

Products include MedRhythms Inc.'s digital platform designed to improve walking in patients with Parkinson's disease or multiple sclerosis; NightWare, a prescription app designed to treat nightmares caused by post-traumatic stress disorder; and AppliedVR's therapeutic virtual reality platform for pain management.

Meanwhile, companies creating and responding to such digital innovation face an array of challenges, including how to protect their technology. This article explores different strategies for patenting medical devices and software.

Best Practices and Pitfalls: How to Make Medical Devices and Software Patentable

1. Remember the basics.

As innovative and transformative as a medical device and its software may be in daily life, the elementary rules of patent eligibility still apply. This point bears repeating because case law is littered with attempts to patent laws of nature, physical or natural phenomena, and abstract ideas that the U.S. Supreme Court clearly held ineligible in the 2010 Bilski v. Kappos decision.[1] Allowing otherwise would risk stifling future innovation and undercutting the purpose of a patent.

How, then, do inventions in the medical device industry that incorporate software that may rely on laws of nature, physical phenomena or abstract ideas successfully obtain patent protections? The simple answer: not easily. An applicant must focus on applications or implementation through a concept that is so inventive that it transforms what would be an otherwise ineligible law, phenomenon or idea into an

eligible one.[2]

Merely introducing generic computerization of an otherwise ineligible abstract idea is not enough to transform a mental concept into a patentable invention. One example of this pitfall was demonstrated in DietGoal Innovations LLC v. Bravo Media LLC,[3] a 2014 case in the U.S. District Court for the Southern District of New York, involving a computerized method and system for meal planning that allowed users to visualize meals and alter them to observe nutritional impact.

The court deemed the abstract idea or mental concept of planning and building meals so "conventional and quotidian" that, without any special method, formula or device, other than a generic computer, this idea was patent-ineligible.[4] The court went on to clarify that the "addition of a computer to perform calculations, retrieve data, and visually display images is nothing more than 'post-solution activity' that cannot render the process patentable."[5]

The lesson from this case is that if an invention rests on an ineligible concept such as natural law, physical phenomena or abstract idea, the patent applicant must take extra caution in specifying its truly inventive application.

2. Claim more than well-organized data, and improve on what exists.

Despite the importance of data and records in medicine, in order to be patent-eligible, an invention must go beyond collecting data and making it accessible. There have been numerous attempts to patent inventions that aggregate and manage patient health records or medical resources and make them accessible or searchable.

However, courts often find the inventors have failed to transform an otherwise ineligible law of nature, physical phenomenon, or abstract idea, or at least to demonstrate in the application that they have done so.

For example, in the 2014 MyMedicalRecords Inc. v. Walgreen Co. decision in the U.S. District Court for the Central District of California, MyMedicalRecords alleged that Walgreens infringed its patent, based on its management of health records and method of secure computer access.[6]

Here, MyMedicalRecords' patent claimed to address very real concerns, such as "the need to provide secure and private communications between healthcare providers and patients in a manner convenient for both parties" and "the need for an individual to access their healthcare records" in a secure location.[7]

Nevertheless, the court held that the abstract idea of record management using nothing more than a conventional computer and internet was not patent-eligible.[8] Similar arguments have been made — and rejected.

Again, merely implementing an abstract idea such as collecting, organizing and displaying data using a generic computer is not considered patent-eligible. In the 2014 Cogent Medicine Inc. v. Elsevier Inc. decision in the U.S. District Court for the Eastern District of California, Cogent Medicine committed a similar error as described above in its attempted infringement claim based on a patent covering a customizable and searchable electronic database for medical literature.[9]

Not surprisingly, the court found this database to be an ineligible abstract concept.[10] In response to

Cogent's claim that its enhanced interface — which automated searching based on prior search history and expert recommendations — made the abstract idea patent-eligible through an inventive concept, the court reinforced that simply computerizing what can ordinarily be done by the human mind is not enough to transform the concept.[11]

There have been successful attempts as well. Patent claims that are based on system improvements or error detection distinguish themselves from those that fail for merely processing data.

For example, in the 2017 U.S. Court of Appeals for the Federal Circuit decision Visual Memory LLC v. NVIDIA Corp., Visual Memory maintained its patent's validity by moving beyond the abstract idea of data storage and actually improving on prior memory systems and creating a new system with "programmable operational characteristics that can be tailored for use with multiple different processors without the accompanying reduction in performance."[12]

Similarly, in the 2018 Federal Circuit decision Koninklijke KPN NV v. Gemalto M2M GmbH, Koninklijke defeated a patent-ineligibility claim regarding its "check data" generator by moving beyond the abstract idea of manipulating data for the purposes of identifying errors in data transmission — common practice for data transmission systems — and introducing a new generator that varies the permutation for each block of check data to prevent systematic errors from going undetected.[13]

3. Claim the new physical device, or improve on what exists.

While physical or tangible components and results of an invention do not guarantee a successful patent claim, they can be highly persuasive.

For example, the 2016 ContourMed Inc. v. American Breast Care LP decision in the U.S. District Court for the Southern District of Texas involved a patent that covered breast imaging using software. The patent also relied on tangible components such as alignment markers and ended in the actual creation of a prosthetic, and it was upheld as valid.[14]

These physical components and results made a meaningful difference in terms of patent eligibility, transforming this into an invention involving more than the mere collection and storage of data — which would make it an ineligible abstract idea.

The strength that physical components lend to a patent claim is good news for inventors of medical devices.

For example, in the 2016 Baxter International Inc. v. CareFusion Corp. decision, in considering the patent eligibility of a medical infusion pump that monitors and alerts health care providers to battery voltage and time remaining, the U.S. District Court for the Northern District of Illinois examined the patent as a whole and emphasized that the invention had a concrete and tangible form — an infusion pump.[15]

Thus, even if measuring and monitoring battery life is an abstract idea, the battery-monitoring infusion pump passed the second prong of the test derived from the 2011 Supreme Court decision Mayo Collaborative Services v. Prometheus Laboratories Inc., in that the pump effectively transformed the claim through its inventive concepts.[16]

Even commonplace physical components that are not independently new or particularly inventive, such as touch pads, can be considered patent-eligible when arranged in a novel way to solve a specific

problem.

For instance, in the 2018 Immersion Corp. v. Fitbit Inc. decision in the U.S. District Court for the Cental District of California, Immersion Corp. maintained patent eligibility for its haptic-feedback touch pads, which, for the first time, used vibrations in touch pads to notify the user of an event's occurrence without visual or audio alerts. Within the same opinion, however, the court deemed the mere transmission of messages to a mobile device too abstract an idea to be patent-eligible.[17]

Notably, patentees have also succeeded when they can demonstrate that their inventions improve existing technological processes and/or provide advantages to prior art. In the 2016 Rapid Litigation Management Ltd. v. CellzDirect Inc. decision, the Federal Circuit upheld the inventors' patent based on its improvements to a previous process, cryopreservation of hepatocytes, based on the law of nature that hepatocytes can be preserved through freezing.[18]

The court explained that:

[T]he claims are simply not directed to the ability of hepatocytes to survive multiple freeze-thaw cycles. Rather, the claims of [U.S. Patent No. 7,604,929] are directed to a new and useful laboratory technique for preserving hepatocytes. This type of constructive process, carried out by an artisan to achieve "a new and useful end," is precisely the type of claim that is eligible for patenting.[19]

With regard to the growing field of medical devices and software, careful analysis of niche case law is required to assess patent eligibility. The basic rules of patent eligibility, excluding laws of nature, physical phenomena and abstract ideas are at play for medical devices and software.

However, inventions may still be eligible for patent protection if they include an inventive concept that is transformative. Specificity regarding the problem that is addressed, the method or device relied on, the physical components or results of the invention, and the improvements offered to existing science and art is essential.

Of course, when arguing for patent eligibility or validity, practitioners should clearly distinguish an invention from past failed attempts in this continuously iterative area of the law. With careful crafting of the patent application, it is possible for the medical device and software to be deemed patent-eligible.

Key Takeaways

- If the invention relies on a natural law, physical phenomenon or abstract idea, it must involve more than mere application by a generic computer. Rather, it should ideally be based on a specialized application method or physical device, and transform the routine into something truly inventive according to patent-eligibility rules.

- If the invention is based on preexisting or naturally occurring phenomena, it must involve specific physical elements or formulas, or improve on existing processes, for example through detection of error. It cannot be based merely on compiling and displaying data.

- If the invention involves medical device technology, it should include the tangible or physical machine itself — not just the use of the device — and/or improve on the existing technology.

- If the invention involves observation of natural law or phenomena, it must improve on existing science and art, or create something new.

For all of the above, the claim should be as specific and well defined as possible.

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[1] Bilski v. Kappos, 561 U.S. 593, 601 (2010); Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[2] Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, (2012); Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 221 (2014).

[3] DietGoal Innovations LLC v. Bravo Media LLC, 33 F. Supp. 3d 271, 288 (S.D.N.Y. 2014), aff'd, 599 F. App'x 956 (Fed. Cir. 2015).

[4] Id. at 284.

[5] Id. at 288 (quoting Parker v. Flook, 437 U.S. at 590 (1978)).

[6] MyMedicalRecords, Inc. v. Walgreen Co. No. 2:13-CV-00631-ODW SH, 2014 WL 7339201, at 3 (C.D. Cal. Dec. 23, 2014).

[7] Id.

[8] Id. at 5.

[9] Cogent Med., Inc. v. Elsevier Inc., 70 F. Supp. 3d 1058 (N.D. Cal. 2014).

[10] Id. at 1063.

[11] Id. at 1065.

[12] Visual Memory LLC v. NVIDIA Corp., 867 F.3d 1253, 1255 (Fed. Cir. 2017).

[13] Koninklijke KPN N.V. v. Gemalto M2M GmbH, 942 F.3d 1143, 1146 (Fed. Cir. 2019).

[14] ContourMed Inc. v. Am. Breast Care L.P., No. CV H-15-2769, 2016 WL 1059531, at 3 (S.D. Tex. Mar. 17, 2016).

[15] Baxter Int'l, Inc. v. Carefusion Corp., No. 15-CV-09986, 2016 WL 2770787, at 9 (N.D. Ill. May 13, 2016).

[16] Id. at 11.

[17] Immersion Corp. v. Fitbit, Inc., 313 F. Supp. 3d 1005, 1024, 1027 (N.D. Cal. 2018).

[18] Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1045 (Fed. Cir. 2016).

[19] Id. at 1048 (quoting and Alice, 573 U.S. at 217).