BEYOND PATENTS: OTHER FORMS OF IP PROTECTION

Learning Objectives

After reading this brief, you will be able to…

I. Understand other methods of protecting health technologies beyond provisional and nonprovisional utility patents
II. Know how to determine which method of IP protection is right for your technology

Getting Started

In the IP Basics toolkit, you learned about provisional and nonprovisional utility patents as mechanisms for protecting your intellectual property (IP). In this brief, we'll explain why these types of patents, which are routinely used to cover traditional medical devices, may not be optimal for protecting other kinds of health technologies, including digital health solutions. Instead, you can use other legal and business strategies that we'll cover in the sections below.

Digital health technologies can take a variety of forms, including telemedicine, data analytics and predictive modeling software, bioinformatics tools, digitized health record platforms, and behavior modification apps, among others.[1] The innovation in these technologies is often in the business model, platform, algorithm, or digital content, which are often not patent eligible, unlike electrical, mechanical, or chemical innovations such as surgical instruments, joint replacements, or bioengineered materials. Due to their digital nature, they're unfortunately also much easier to reproduce than physical devices, which have a higher barrier to manufacture and sell. These forces make IP protection in the digital health space more complicated than in the traditional health tech space.

Why Not Utility Patents?

It's important to understand why pursuing a utility patent on a digital product is not always feasible.

Digital products that collect and analyze data in some way are typically not patent eligible. Neither are claims covering business methods or fundamental economic practices. To be patentable, a digital technology has to do more than take a process previously performed manually and digitize it (e.g., telemedicine). Instead, it must fundamentally solve an internet-based or computer-centric problem (e.g., a method of video compression or method of scanning a computer for viruses), which is often not what digital health solutions seek to do.

Accordingly, some companies with digital-based products have to find entirely different ways to protect their technologies and create barriers to prevent competitors from entering the market. Others are able to use a blended strategy.

Let's consider a real example. 23andMe is a direct-to-consumer genetic testing service. Its primary consumer-facing product is a physical testing kit that allows customers to collect a saliva sample and mail it back to the company. In exchange, customers receive an online report that tells them about their genetic health and ancestry information.

23andMe has been able to secure utility patents on several of its methods – for example, US Pat. No. 8463554, which covers determining a relative relationship between two individuals by comparing their genetic data, calculating a predicted degree of genetic relationship, and advising one if the other individual is likely to be a relation.[2]

However, a lot of the company's valuable intellectual property may not be patent eligible – the web platform, the analysis, and the insights into an individual's health that the company provides after the user sends in their DNA sample. As a result, other forms of IP protection are needed.

Alternative Protections

In addition to understanding what subject matter is patent eligible (see the IP Basics toolkit), it's important to know about the other options available for inventors looking to safeguard their work. In this brief, we'll cover trademarks, design patents, copyrights, and trade secrets, which can be used to protect digital health solutions as well as other less tangible technologies like coatings, finishing processes, or biological/combination devices that make use of novel biochemistry. These protections serve as deterrents to IP thieves and copycat companies, as well as provide legal recourse in the case of infringement or misappropriation.

In this section, we'll discuss these different methods and how a digital health company like 23andMe might use them. More information about each type is available by visiting the links in the citations provided in the text.

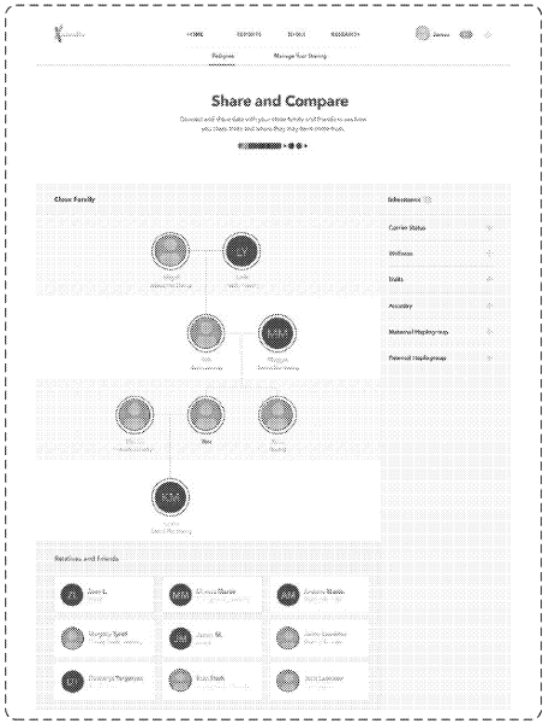
- **Trademark**
  A trademark is a word, phrase, symbol, or design that identifies the goods of one company and differentiates them from the goods of others.[3] Digital health innovators might trademark the names and graphics that are associated with the company and its products in order to build a brand that distinguishes its technology from others. According to their terms of service, 23andMe, Inc., 23andMe, and other 23andMe product and service names and logos, like the one in Figure 1, are all trademarks of the company.[4] Trademark protection lasts for 10 years and can be renewed indefinitely.[5]

Figure 1 – 23andMe Trademarked Logo

- **Design Patents**

  Design patents provide legal protection of unique visual aspects of a product. Designs are valuable because they can improve the effectiveness and functionality of your technology, and build a connection with users. Recognizable designs help build the company image and can become part of the brand. In a digital health app or web tool, or an electronic health record platform, design patents can protect aspects such as the artistic design, user experience, and screen layout. 23andMe has at least six design patents in the public domain on their graphical user interface, filed between 2015 and 2020. Figure 2 is an example of one that protects 23 and Me's "Share and Compare" screen layout.[6] A design patent will protect your designs for 15 years.[7]

Figure 2 – 23andMe Design Patent



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- **Copyright**

  A copyright is an exclusive legal right to publish or distribute literary, artistic, or musical material. Digital health companies who produce online content as a product (e.g., 23andMe, Headspace, WebMD) can copyright that content so that they have full ownership over its sale and distribution. However, copyright protection can apply beyond online content. Although we usually associate copyrights with content like books or videos, copyright protection under US law broadly covers all original works, created using "any tangible medium of expression, now known or later developed" that can be reproduced or communicated "either directly or with the aid of a machine or other device" (17 U.S.C. § 102). This language is important because it covers software code – an authored set of instructions that can be communicated with the aid of a computer. Digital health companies can copyright their code as authored text in order to protect it against being reproduced and sold without their consent. In 23andMe's terms of service, they make clear that they've done just that. All of their downloadable software is the copyrighted work of 23andMe and/or its suppliers.[8] It's a good idea to do this when you begin to sell and distribute a packaged version of your code since, once distributed, downloaded code can sometimes be reverse engineered. A copyright lasts at least 70 years after the death of the original author.[9]

- **Trade Secrets**

  A trade secret is information that has value because it is not widely known. In digital health, this might include information such as algorithms and processes used to manipulate data, software or hardware architecture designs, and curated databases of information. However, information that can be reversed engineered or otherwise independently identified is not a good candidate for trade secret protection. But if a trade secret is misappropriated, or illegally obtained through theft or illegal disclosure, companies can pursue legal action. The beauty of trade secrets is that, unlike patents

and copyrights, this information doesn't have to be disclosed to the public and can theoretically be held by the company forever if they have sufficient security in place. To prevent information leaks, companies might require employees and contractors to sign non-disclosure agreements and be especially clear about what information should be considered confidential. One of the most obvious trade secrets that 23andMe keeps is their database of genetic information, although we can speculate there may be others (such as proprietary analysis algorithms). 23andMe limits information access to essential personnel, based on job function and role. They additionally encrypt sensitive software and information when it is being stored and transmitted.[10] A trade secret's long-term value is contingent on how well it's protected.

Other Sources of Competitive Advantage

Even with the use of trademarks, design patents, copyrights, and trade secrets, it can be challenging for digital health companies to protect their IP because digital information, by its very nature, is easily shared and redistributed. However, IP protection is not the only source of competitive advantage. For instance, companies can gain an edge over their competitors by being first to market, establishing important relationships (e.g., with key opinion leaders who recommend their products), or by forging strategic alliances with well-respected institutions (e.g., a university or professional association that lends credibility to the digital health start-up).

Data is another source of competitive advantage in the digital health field. As an example, 23andMe wards off competitors because part of their value is the network of people who have contributed DNA to their database. The larger the database grows, the more valuable the product becomes to new customers who might want to find DNA relatives or build their family tree. Now, even if 23andMe has its software code or DNA sequencing technology stolen, the data it has amassed would protect its competitive position.

Digital health companies also can pursue regulatory clearance as a source of competitive advantage (see the Regulatory Basics toolkit for more information). Getting a product cleared by the FDA requires the company to invest more time and money to conduct necessary product testing and submit its application. However, once obtained, regulatory clearance allows the company to make specific marketing claims (as designated by the FDA) about the ability of the product to prevent, diagnose, or treat the relevant condition. This lends credibility to the technology as a medical-grade product and allows the company to differentiate it against other digital health solutions that can't make similar claims. That said, see Box 1 for an example of how 23andMe's regulatory strategy initially worked against the company.

One additional source of competitive advantage is reimbursement (see the toolkit called Reimbursement Basics for more information). Companies can gain a positional edge over their competitors by convincing public and/or private health insurers to establish codes and coverage policies to pay for their digital technology. Many people expect their insurance companies to cover health-related technologies and, as a result, favor those that are reimbursed. Once codes are established, it also can be difficult for competitors to use the same ones when they reach the market, or to justify the creation of additional codes in the same disease area.

BOX 1
23andMe's Regulatory Woes

23andMe did not initially pursue regulatory clearance for its consumer-facing genetic test kits. Yet, in its marketing materials, the company positioned the health-related information provided by the tests as a "first step in prevention" that enables users to "take steps toward mitigating serious diseases."

In 2013, the FDA issued a warning letter to 23andMe indicating that the company did not have adequate scientific evidence to support these claims. Additionally, the agency raised concerns that the unsubstantiated genetic information provided by the tests could cause consumers to make unnecessary or even dangerous health decisions.

In response, the company agreed to stop marketing its health-related genetic tests until it generated the required clinical evidence and received regulatory clearance. For roughly two full years, it was only able to offer ancestry testing to its customers. Since then, 23andMe has employed a robust regulatory strategy, backed by clinical evidence, to ensure its marketing claims are substantiated and allowable.[11]

As you think about the most effective way to protect your technology as you move it toward the market, be sure to think beyond traditional utility patents. The case study in Box 2 describes how a company called Cala Health approached its IP strategy, levering a combination of different mechanisms. Additionally, check out the video called Protecting Digital Technology at Emme for some additional pointers surrounding this company's approach.

BOX 2
Cala Health Case Study

Kate Rosenbluth founded Cala Health™ in 2014 after completing the Stanford Biodesign Innovation Fellowship. As a fellow, Rosenbluth was struck by the need for better treatment options for patients suffering from essential tremor. As she described, "I met a man whose hands shook so badly that he could no longer write a letter to his wife or drink a coffee with a friend. He was desperate, and had just learned he was not a candidate for the brain

surgery that he hoped would restore his hand control. He had tried medications, but they didn't provide him relief. As we observed more patients, we saw how they struggled to do tasks that so many of us take for granted, like putting a key in a lock or eating soup with a spoon. We were astonished to learn this condition was nearly eight times more common than Parkinson's disease, with more than 7 million people living with essential tremor in the US alone."[1]

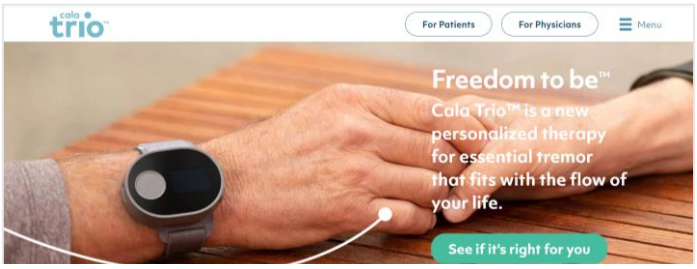
Samuel Hamner, a Stanford PhD, joined Cala Health shortly after its founding as Head of Product, and he helped Rosenbluth and the Cala team develop and launch the first-ever non-invasive stimulation treatment for essential tremor. The Cala Trio™ is a wearable device that delivers surface stimulation via nerves in the wrist to disrupt pathological tremor signals in the brain. This results in a significant short-term reduction of the tremor.[1]

As Hamner's role evolved, he took on the expanded responsibility of managing the company's innovation pipeline, as well as its IP portfolio. When asked to reflect on Cala Health's IP strategy, he started by explaining, "Initially, our core technology and value to patients is a therapeutic device, so the majority of our intellectual property is covered by utility patents. There are three major areas that we have protected in this way. First, Cala devices deliver electricity as a medicine, so we developed a patent family that covers stimulation patterns and how they interact with the nervous system. Second, we have patents describing the physical embodiment of a wrist-worn stimulation device. For example, how to enable fit of the device on the wrist and configure electrodes to target specific nerves. And, finally, Cala devices are built with sensors and a digitally-connected ecosystem, so we have utility patents describing algorithms for remote data monitoring and analysis."

In addition, Hamner described how the company has pursued a variety of other IP protections:

Trademarks

Cala Health has trademarked its company name and the product name for the Cala Trio. The team also sought trademark protection for various tag lines used by the company, including ***Freedom to be™*** (see below for an image from Cala Health's website). "When building a brand, it's essential to protect that with trademarks," Hamner said. In the early days, as a single-product company, he noted, this was fairly straight forward. "But now, as the company matures into a wearable neuromodulation platform with potential to treat other diseases, we are developing a strategy to establish multiple brand lines and protect those with trademark."



Source: calatrio.com

Copyright

Copyright is considered another necessity, especially to protect software developed internally at the company. “We definitely copyright all of our code,” Hamner said. “We also copyright all of our manuals and other labeling that accompanies the device. For us, copyrighting these materials a best practice.”

Trade Secrets

Cala Health uses trade secrets to protect technologies and/or methods that the company is not yet ready to teach the world. “A key principle in seeking a utility patent,” Hamner explained, “is that you have to disclose how to make and use the invention in sufficient detail that someone of relevant skill could replicate the invention after reading your description. But sometimes you might prefer to keep that information secret.” He offered an example. “Our device initially used standard hydrogel electrodes. But they were sticky and users didn't like them. We couldn’t identify a good off-the-shelf solution, so we invented a new material. There are aspects of the new electrodes covered by utility patents, but other techniques for processing and manufacturing the material are kept as trade secrets because it provides us with a greater advantage this way.”

To determine what concepts can be kept as a trade secret, Cala Health also assesses how feasible it might be to reverse engineer the final product. Hamner explained, “If someone can reverse engineer your product, it likely can’t be kept as a trade secret.” Trade secrets are then protected using a series of confidentiality and non-disclosure agreements with employees, consultants, and suppliers.

Design Patents

According to Hamner, the company had not yet secured any design patents, and is considering this as a move for the near future. “A design has to be prevalent and distinct for it to be defensible,” he said, “like what Apple has done with its

products. We’re not there yet, and will consider design patents as we offer enhancements such as a patient portal with a unique user interface.” He continued, “To some extent, use of design patents corresponds to the stage of the company. Now that we’re getting bigger and more people are becoming familiar with our technology, now is probably the time.”

Above and beyond these approaches, Hamner noted that the company continues to think creatively about other strategies beyond utility patents. As an example, he said, “We’ve intentionally decided not to patent some of our data and data science insights. For instance, we needed to show that measuring tremor with motion sensors is on par with a physician assessment because that’s the gold standard. To do this, we completed the world's largest study in people with essential tremor, used that data to show the correlation, and published the results. With this approach, the data became immediately available and we were able to demonstrate that we're leaders in this field.” This first-in-class strategy is another way Cala Health is differentiating itself from companies, especially those that aren't as scientifically focused.

Credits

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Notes

[1] Ronquillo Y, Meyers A, Korvek SJ, "Digital Health," StatPearls [Internet], StatPearls Publishing, January 2020, https://www.ncbi.nlm.nih.gov/books/NBK470260/.

[2] Finding Relatives in a Database, US Pat. No. 8463554, https://patents.google.com/patent/US8463554B2/en (August 11 2020).

[3] US Trademark Law, 15 U.S.C. § 1052, https://www.uspto.gov/sites/default/files/trademarks/law/Trademark_Statutes.pdf (August 8, 2020).

[4] Terms of Service, 23andMe, https://www.23andme.com/about/tos/ (August 8, 2020). Note that the 23andMe logo is used here without explicit permission from the company. Informational uses of a trademark do not require permission from the owner if the purpose is to educate or express opinions protected under the First Amendment of the US constitution.

[5] Post-Registration Timeline, USPTO, https://www.uspto.gov/trademark/trademark-timelines/post-registration-timeline-all-registrations-except-madrid-protocol#:~:text=Within%20one%20year%20before%20the,9%20and%20pay%20applicable%20fees (August 8, 2020).

[6] Display Screen or Portion Thereof with Graphical User Interface, USD798322S1, https://patents.google.com/patent/USD798322S1/en?oq=USD798322S1 (August 8, 2020). Note that the drawing from design patent is included here without permission from 23andMe because, as part of the terms of granting the patent to the inventor, patents are published into the public domain.

[7] Term of Design Patent, USPTO, https://www.uspto.gov/web/offices/pac/mpep/s1505.html (August 8, 2020).

[8] Terms of Service, op. cit.

[9] Trademark, Patent, or Copyright? USPTO, https://www.uspto.gov/trademarks-getting-started/trademark-basics/trademark-patent-or-copyright (August 8, 2020).

[10] Privacy Highlights, 23andMe, https://www.23andme.com/about/privacy/ (August 8, 2020).

[11] Example drawn from Yock, et al., *Biodesign: The Process of Innovating Medical Technologies*, 2015, Cambridge University Press.

[12] "Individualized, Non-Invasive Therapy for Essential Tremor – An Interview with Kate Rosenbluth of Cala Health," Stanford Biodesign, https://biodesign.stanford.edu/our-impact/technologies/cala-health.html (September 22, 2020).

[13] Ibid.