What Happened at Theranos and How Does That Impact the Perception of Intellectual Property?

by Barbara Courtney

I. Introduction

Patents and trade secrets are sometimes mentioned in books and movies, and more infrequently, in highly publicized trials. Significant trials that have to do, even tangentially, with intellectual property (IP) issues are typically too arcane and boring to be of popular interest. But not so in the recent federal fraud trial of Elizabeth Holmes, founder and former CEO of Theranos, Inc. (U.S. v Elizabeth Holmes[1]).

The indictment occurred in June 2018 and Holmes was found guilty of four criminal counts in January 2022. This trial in the Federal Courthouse in San Jose, California has garnered a lot of media attention for a variety of reasons, none of which have much to do with IP. Yet, trade secrets and patents have been mentioned in the federal trial (and in the preceding U.S. Securities and Exchange Commission (SEC) action[2] initiated March 2018) in ways that are rather confusing and misleading.

SEC Litigation Release No. 24069 / March 19, 2018,[3] succinctly states the complaints in both the SEC action and later federal criminal trial:

> The complaints allege that Theranos, Holmes, and [former Theranos president] Balwani made numerous false and misleading statements in investor presentations, product demonstrations, and media articles by which they deceived investors into believing that its key product - a portable blood

> analyzer - could conduct comprehensive blood tests from finger drops of blood, revolutionizing the blood testing industry. In truth, according to the SEC's complaint, Theranos' proprietary analyzer could complete only a small number of tests, and the company conducted the vast majority of patient tests on modified and industry-standard commercial analyzers manufactured by others.

In addition, the catastrophic failure of Theranos has, of course, resulted in some finger-pointing. The U.S. Patent and Trademark Office (USPTO) system, the venture capital industry and the culture of Silicon Valley have all come in for a bit of blaming.

This article examines the separate concepts of trade secret protection and patent protection with a goal of deconflicting the two and addressing the confusing information that was documented in trial and deposition testimony in the federal trial, the SEC action and preceding investor lawsuits, such as the first lawsuit filed against Theranos in October 2016 by investor Partner Fund Management LP (PFM).[4]

II. Trade Secret Protection and Patent Protection: What Are They and Why Are They Usually Mutually Exclusive?

A. TRADE SECRETS

Trade secrets cover an aspect of a product or service that the owner chooses not to reveal to anyone. A subject of trade secret protection could be, and often is, an invention. For strategic reasons, the owner believes that keeping the invention secret and foregoing possible licensing fees or opportunities to sue others for the limited term of a patent is less desirable than owning the secret in perpetuity. The recipe for Coca Cola is the classic example of a "secret formula." Machines are usually poor candidates for trade secret protection because they can be reverse-engineered by an expert who can determine how they work.[5]

In the transcripts of depositions in the SEC investigation, and later in testimony in the federal fraud trial, Holmes defended her lies regarding use of third-party devices by characterizing that use as a trade secret. In recorded conversations with potential (or actual) investors and journalists, any questions regarding what the technology actually consisted of or how the "magic" was done were responded to by Holmes with adamant assertions that the technology was "trade secret." In fact, John Carreyrou, the Wall Street Journal writer who penned the article that led to the end of Theranos, was only allowed to interview Holmes with multiple Theranos attorneys present, and they were quite aggressive in using the "trade secret" trope to shut down Carreyrou's questions.

One of the key, constantly repeated lies was eventually discovered by Carreyrou through contact with whistleblower former employees of Theranos. This was that the machine

Theranos claimed could perform a full menu of up to 1,000 blood tests using a single drop of blood was, in fact, only capable of performing a maximum of 12 tests. And those few results were wildly inaccurate.

The extremely attractive attributes of the Theranos machine as presented to the fraud victims included its compact size compared to current, commercially available machines (also referred to as "third-party machines") and its ability to perform tests in a very short time anywhere without having to ship blood samples to a remote lab. The Theranos machine was said to be able to receive the drop of blood and produce complete results almost immediately. Once it was found out that Theranos actually purchased and modified third-party machines in order to perform testing (and the results of that testing were also dangerously inaccurate), the fall of the company began.

Holmes testified in the federal trial in December 2021. On direct examination by her own attorney, Homes admitted that Theranos purchased and modified third-party devices and used them for testing. Holmes said that her attorneys advised her that these actions were trade secret, and an "invention" that should not be revealed lest trade secret protection be lost. Clearly, Holmes legal team was attempting get out ahead of this damaging set of facts and find a way to justify Holmes' actions or shift blame.

Holmes stated that former Senator Sam Nunn was on the Theranos board and had previously been on the Coca Cola board. She stated that he briefed everyone on what trade secrets were and how to protect them. Bryan Roberts, an experienced healthcare and life sciences investor, was asked what he thought about concealing the use of third-party machines as trade secret. "It's nuts," he said. "Coke can keep their formula a trade secret, but they can't buy a truckload of Pepsi and sell it in Coke cans."[6]

In a 2017 interview in the SEC action, Holmes admitted to knowing in 2014 that purchased third-party machines were being modified.

> In her second interview two days later, [attorney] Chan asked Holmes what, if anything, Theranos told [retail partner] Walgreens.
>
> > **Jessica Chan**: You also don't know whether you or anyone else at Theranos would have disclosed to Walgreens that Theranos was using commercially available machines and modifying the protocols on them?
> >
> > **Elizabeth Holmes**: I don't. I mean we generally considered that implementation of our chemistries to be trade secret and we'd filed nonpublic patent applications on certain parts of it. So, I... I wouldn't expect that we would have gotten into detail on that.

> There it is. Her argument to justify hiding the use of third-party analyzers from Walgreens and everyone else is that the changes Theranos had made to them were trade secrets. I cannot stress this enough: what Elizabeth is claiming here, and what she'll likely claim during the [Federal] trial, is that the tweaks they made to another, is that the tweaks they made to another company's widely used blood-testing machine somehow amounted to a multi- billion-dollar innovation.[7]

In this excerpt of the SEC interviews, Holmes seems to be saying the trade secret was also patented (at least certain parts of it). Holmes also states that "nonpublic" patent applications were filed. But there is technically no such thing as a "nonpublic" patent, as discussed below in II B.

In Balwani's SEC interview two months later, he compounds the confusion:

> This appeared to be the new company line. In his own SEC interview, a month later, Sunny even bragged about Theranos's handiwork.
>
> > **Sunny Balwani**: In general, even today in the lab industry, it is not a common knowledge that you can actually modify a commercial device to run a fingerstick sample. This is considered to be a near impossible problem. We solved that problem and not only solved it, we solved it beautifully and we could scale with that. So even pointing people in that direction, by saying, by the way, [commercially available device] ADVIA 1800, it's possible to modify it for fingerstick, to me was a huge loss. We didn't want anybody to know that.
>
> Sunny's statement is comical. First of all, no one else was trying to solve this supposed problem because no one else saw it as a problem. Second of all, the "beautiful" solution Theranos came up with produced dangerously inaccurate results. And yet, as Elizabeth testified, Theranos even tried to patent the changes it had made to the ADVIA.[8]

When asked by the SEC why Theranos did not file for a patent until May 23, 2016 (almost three years after Theranos began using the supposed invention), Balwani again said that the invention was so great that they did not want anyone to eventually find out about it when the patent published. Balwani also blamed John Carreyrou's WSJ article for "outing" this trade secret and forcing the company to hastily file for patents. One likely problem with that is the "invention/trade secret" was in use for almost two years, making it potentially barred as being in public use before the filing date of the application.

The statements and lies, and their justifications across years of time and in several forums (e.g., press appearances, recorded conversations with actual or potential investors, and

eventually in legal depositions) are difficult to parse. However, as the timeline of the Theranos debacle advanced, one thing that became clearer was that Holmes and Balwani used “trade secrets” and “patents” as sloppily applied terms to suit the situation, and often mischaracterized those concepts in attempts to cover lies.

B. PATENTS

What is a patent and what is the role of the local patent office in examining and granting a patent? A patent conveys a right to exclude others from making, using, selling, offering for sale or importing the invention that the patent claims describe. Patent claims are numbered paragraphs of rather arcane legal language that define what is owned. The term of a patent is currently 20 years from issue. After that time, the invention is in the public domain and can be made, used, sold or imported by anyone.

The source of patent rights is the U.S. Constitution,[9] as interpreted by 35 United States Code, (35 U.S.C, or “the Patent Statute”). Codes of Federal Regulation (CFRs) define how the USPTO (which is under the Department of Commerce) applies the laws. The USPTO examines patent applications that, if granted, convey rights inside the United States only. Any countries that companies could possibly imagine doing business in have their own local patent offices that grant patents in those countries. They do so according to their own laws and regulations, and in most of the world, in accordance with international treaties that were created to somewhat harmonize patent rights among signatory countries for the same inventions. Companies seeking to profit from inventions have significant incentives to obtain patent protection in all countries of commercial interest.

When the USPTO receives a patent application, it is tasked with examining it in order to determine whether the invention is new (the novelty requirement) and useful (the utility requirement), or is an improvement of a previous invention, as required by 35 U.S.C. § 101.[10, 11]

Theranos filed over 200 patent applications, and one would assume that the applications dealt with its product and how it was used. The patent applications and any issued patents were not front and center in the SEC action and federal trial. Holmes did not get into trouble by touting the patent applications as a primary hook to defraud investors, business partners or patients. Rather, she got into trouble by citing trade secret protection as a reason for concealing lies.

The problem of improving blood testing has been studied for years. To anyone in the industry, or with knowledge of the industry (including Dr. Phyliss Gardner,[12] one of Holmes’ professors at Stanford University), constructing the purported mini-lab machine was literally as impossible as constructing a Star Trek transporter. Investors with extensive experience in the industry avoided investing in the company.

Fraud victims and former board members testified that if they had known Theranos used third-party devices, they would not have invested or taken board positions.[13, 14]

It seems that before the WSJ article exposed Theranos as a fraud, Holmes was sticking to the story that how the touted results were achieved was just trade secret. However, Theranos filed more than 200 patent applications on its "technology." But something that is held as a trade secret cannot be patented if a product embodying it was made, used, sold or offered for sale for one year or more (even if the trade secret element of a product is not readily discernable by reverse engineering). This is known as the on-sale bar. So, if the true magic sauce was trade secret (as it turned out not to be), are Theranos' patents worth anything?

The Theranos product was its machine, the method of using it and how it worked. If the patents were issued and found to be valid, then those patents would each convey a limited-time monopoly (20 years from issue date) to Theranos, freeing it to use each invention any way it liked, and preventing others from copying the inventions during the term of each patent. Each patent can claim only one "invention." Therefore, it is fair to assume that Theranos filed patents on more than 200 different aspects of the device and/or its method of using one drop of blood.

The mystery here, then, is what could have been held as trade secret? Since Theranos had filed lots of patent applications (presumably before the on-sale bar), it was good to proceed with monopolizing the inventions in the issued patents. If none of those patent applications contained the trade secrets, then what did the trade secrets cover? If any of the patent applications did include trade secrets, trade secret protection would be automatically lost as soon as the applications were made public (which happens whether the applications issue or not).

As noted above, machines typically are not good candidates for long-term trade secret protection because they can be reverse engineered. For example, when Theranos purchased and modified third-party machines to attempt to perform blood drop analysis on them, some reverse engineering of those devices took place. Then, Theranos scrambled to file one or more patent applications on its hack of the commercially available machine. This, in and of itself, does not bar patentability, but again the question of the relative value of the resulting patents suggests itself.

Some writers have criticized the USPTO for "enabling" the whole Theranos debacle.[15] For example, it has been suggested that the USPTO failed to determine whether the applications met the utility requirement or were enabled (in the patent law sense of the word). According to the patent statute, anyone who invents or discovers a new and useful invention, or improvement thereof, may obtain a patent. (See 35 U.S.C. § 101 above). The Manuel of Patent Examination and Procedure (MPEP) is the document that guides patent examiners

in their job. Below is a short excerpt from the MPEP instructions for examiners regarding the utility requirement.

II. EXAMINATION GUIDELINES FOR THE UTILITY REQUIREMENT

Office personnel are to adhere to the following procedures when reviewing patent applications for compliance with the "useful invention" ("utility") requirement of 35 U.S.C. 101 and 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph.

(A) Read the claims and the supporting written description.

- (1) Determine what the applicant has claimed, noting any specific embodiments of the invention.
- (2) Ensure that the claims define statutory subject matter (i.e., a process, machine, manufacture, composition of matter, or improvement thereof).
- (3) If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.

(B) Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible:

- (1) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.
    - (i) A claimed invention must have a specific and substantial utility. This requirement excludes "throw-away," "insubstantial," or "nonspecific" utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. 101.
    - (ii) Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.
- (2) If no assertion of specific and substantial utility for the claimed invention made by the applicant is credible, and the claimed invention

> does not have a readily apparent well-established utility, reject the claim(s) under 35 U.S.C. 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed. The 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, rejection imposed in conjunction with a 35 U.S.C. 101 rejection should incorporate by reference the grounds of the corresponding 35 U.S.C. 101 rejection.[16, 17]

From this glimpse at the utility guidelines, it becomes clear that "utility" is interpreted as having a use. It is sometimes asserted that the USPTO must require proof that the invention actually works in order to satisfy the utility requirement, but that is not strictly true. While the patent office may require proof that the Star Trek transporter works (e.g., by demonstration or affidavit), such cases are rare.

The enablement requirement relates to the way the claimed invention is described in the application. The enablement requirement has nothing to do with whether the claimed invention actually works. Nor does it require a working prototype. An excerpt from the MPEP regarding enablement is quoted below.

> The enablement requirement refers to the requirement of 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph that the specification describe how to make and how to use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent.
>
> The purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. However, to comply with 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (an invention directed to a general system to improve the cleaning process for semiconductor wafers was enabled by a disclosure showing improvements in the overall system). Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to

> permit those skilled in the art to make and use the invention. A patent claim is invalid if it is not supported by an enabling disclosure.[18, 19]

Patents are complicated creatures. And no patent system or office is perfect. However, the role of patents as valuable assets in a global economy won't be changing any time soon. Acquiring intellectual property (including trade secrets, patents and trademarks) is one phase of the life of the IP asset. Enforcement of rights in the asset and transfer of the asset are, in themselves, complicated concepts, as well.

In the Theranos case, it is understandable to want to blame it all on a faulty patent system, but that is far too simplistic an answer to the question: "How did this happen?" And there are many different possible answers, no one of which is sufficient to point to one thing that can be fixed in order to ensure that this never happens again. As one example, some observers focus on lack of diligence on the part of participants (including victims and sophisticated attorneys):

> A comprehensive analysis of an IP portfolio as large as that of a company like Theranos is time-consuming and costly. IP diligence is not for the faint of heart, and some have postulated that Theranos investors lacked the life science chops to understand the technology (or lack thereof). (Unfortunately, while many investors may take IP due diligence seriously, prospective board members rarely do. Theranos' name-dropper's paradise of a board included Henry Kissinger, Jim Mattis, George Shultz, William Perry, William Foege, and Richard Kovacevich. A star-studded board can send endorsement signals which delay or undermine proper due diligence.)[20]

The Theranos case provides an opportunity for those who participate in any aspect of IP acquisition and exploitation to better understand what IP is and is not. It also provides encouragement to perform their due diligence with the help of experts at every step of the process.

Resources:

[1] *United States v. Elizabeth A. Holmes*, et al.18-CR-00258-EJD
[2] *Securities and Exchange Commission v. Elizabeth Holmes*, et al., Civil Action No. 5:18-cv-01602
[3] https://www.sec.gov/litigation/litreleases/2018/lr24069.htm
[4] https://techcrunch.com/2017/05/01/theranos-reaches-settlement-with-investor-partner-fund-management/
[5] See also: https://www.wipo.int/tradesecrets/en/
[6] https://podcasts.apple.com/us/podcast/the-dropout/id1449500734
[7] John Carreyrou, Bad Blood: The Final Chapter podcast, Episode 7 and PDF version: https://cdn.smehost.net/threeuncannyfourcom-neonhummediaprod/wp-content/uploads/2021/10/BAD-BLOOD-EP-7-THE-ADVIA-PROJECT.pdf

[8] John Carreyrou, Bad Blood: The Final Chapter podcast, Episode 7 and PDF version: https://cdn.smehost.net/threeuncannyfourcom-neonhummediaprod/wp-content/uploads/2021/10/BAD-BLOOD-EP-7-THE-ADVIA-PROJECT.pdf
[9] U.S. Constitution Article I Section 8 I Clause 8 – Patent and Copyright Clause of the Constitution. [The Congress shall have power] "To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."
[10] § 101 - Inventions Patentable: Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
[11] See also: https://www.uspto.gov/sites/default/files/101_step1_refresher.pdf
[12] Dr Phyllis Gardner, Stanford professor and Theranos critic: "I'll only really feel good if she's convicted" Danny In The Valley Podcast
[13] See for example: https://www.cnbc.com/2021/09/22/james-mattis-testifies-in-elizabeth-holmes-theranos-fraud-trial.html
[14] See: "Grossman told the jury that Holmes never told him the company was using third-party machines to run the blood tests. About his own experience at Walgreens, Grossman said he was surprised to find out that the blood was drawn from his arm and said his test results took longer than four hours."
https://www.cnbc.com/2021/11/16/brian-grossman-says-holmes-lied-about-theranos-finger-prick-tech.html
[15] https://arstechnica.com/tech-policy/2019/03/theranos-how-a-broken-patent-system-sustained-its-decade-long-deception/
[16] https://www.uspto.gov/web/offices/pac/mpep/s2107.html
[17] See also: https://www.ipwatchdog.com/2015/11/07/understanding-the-patent-law-utility-requirement/id=63007/
[18] https://www.uspto.gov/web/offices/pac/mpep/s2164.html
[19] See also https://patentsintegrated.com/what-we-can-learn-from-theranos-patent-portfolio/ Points out that enablement does not mean you have to produce a working prototype.
[20] https://rockridgelaw.com/2021/11/18/3-ip-lessons-to-learn-from-the-theranos-saga/

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