# Theranos: How a broken patent system sustained its decade-long deception

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> *Elizabeth Holmes, like Benjamin Franklin and Edith Clarke, challenged a basic assumption. Why, she wondered, do doctors and researchers need to take so much blood from a person when running tests? She's proven that they don't. Her innovation—which she has patented—requires the patient to surrender a mere drop of blood, and that small sample is then used for numerous experiments. It's no surprise that the company she founded on this technology is thriving.*
>
> *-USPTO Director Michelle Lee, May 25, 2015*

When Patent Office Director Michelle Lee gave that speech, Theranos appeared to be one of the most impressive companies in Silicon Valley. But later that year, the public learned that Holmes hadn't "proven" anything. Whistleblowers told *The Wall Street Journal* that Theranos wasn't even using its own devices for most of its blood testing. Holmes had apparently spent more than a decade building a company based on unrealistic or outright false claims about its revolutionary technology.

For any disaster as large as Theranos, there's plenty of blame

to go around, of course. Both Holmes and former COO Sunny Balwani now face federal fraud charges. Theranos' star-studded board of directors failed to do adequate oversight. Walgreens ignored warning signs before launching its in-store partnership. Some VCs and journalists were too eager to believe Theranos' unproven claims.

But the patent system also played an important, and often overlooked, role in the situation. The USPTO gave out patents *much* too easily, giving Theranos early credibility it didn't deserve. Theranos then used these patents to attract staff, investors, and business partners. The company would last for 10+ years and burn through half a billion dollars before the truth finally emerged.

## A company "built around patents"

In 2002, an eager Stanford undergraduate named Elizabeth Holmes told a professor about an idea. (New ABC podcast "The Dropout" covers the story in its opening episode.) Holmes approached Professor Phyllis Gardner of Stanford Medical School with a radical suggestion. She wanted to make a microfluidic patch that could test blood for infectious organisms and could deliver antibiotics through the same microfluidic channels. The professor replied that this idea was not remotely viable.

But Holmes found a more receptive audience at the USPTO. She says she spent five straight days at her computer drafting a patent application. The provisional application, filed in September 2003 when Holmes was just 19 years old, describes "medical devices and methods capable of real-time detection of biological activity and the controlled and localized release of appropriate therapeutic agents." This provisional application would mature into many issued patents. In fact, there are patent applications still being prosecuted that claim priority back to Holmes' 2003 submission.

But Holmes' 2003 application was not a "real" invention in any meaningful sense. We know that Theranos spent years and hundreds of millions of dollars trying to develop working diagnostic devices. The tabletop machines Theranos focused on were much *less* ambitious than Holmes' original vision of a patch. Indeed, it's fair to say that Holmes' first patent application was little more than aspirational science fiction written by an eager undergraduate.

So how did Holmes' unrealistic application lead to real patents, like US Patent No. 7,291,497? If you look through that patent's application history, you can see that the examiner did review it closely. The examiner made two non-final rejections and two final rejections before eventually allowing the claims. (At the USPTO, a "final" rejection is not really final). The rejections were based on prior art and other technical grounds. What the examiner did not do, however, was ask whether Holmes' "invention" *actually worked*.

Two legal doctrines are relevant here. The "utility" requirement of patent law requires that the invention work. And the "enablement" requirement means that the application has to describe the invention with enough detail to allow a person in the relevant field to build and use it. If the applicant herself can't build the invention with nearly unlimited time and money, it does not seem like the enablement requirement could possibly be satisfied.

The USPTO generally does a terrible job of ensuring that applications meet the utility and enablement standards. In practice, unless an application claims an obviously impossible device (like a perpetual motion machine), the examiner will not question whether it works. To some extent, this is understandable. Examiners only have a few hours to review each application, and they can hardly be expected to run complex experiments to check the applicants' claims. But this practice can lead to serious errors.

In early 2014, around the same time that Theranos was beginning to grow its profile, the USPTO was criticized for awarding a patent to a Korean researcher for work that was *already* known to be fraudulent. The applicant had even been convicted for falsifying the relevant results. A USPTO spokesperson told *The New York Times* that the agency "operates on an honor code and that patent examiners cannot independently verify claims." In response, Professor James Grimmelmann commented: "The USPTO is an armory handing out legal howitzers on the honor system. What could possibly go wrong?"

To answer Professor Grimmelmann's rhetorical question—Theranos is what could go wrong. Holmes' original patent application became a key part of the company's mythology. For example, an infamous *Fortune* article from 2014 reverently tells the story of Holmes staying up late to write her application and suggests that Theranos was founded on that original vision. And if you had visited Theranos' website in 2014, you would have found an "Our Mission" page that said Holmes left Stanford to "build Theranos around her patents and vision for healthcare."

Yet more than a decade after Holmes' first patent application, Theranos had still not managed to build a reliable blood-testing device. By then the USPTO had granted it *hundreds* of patents. Holmes had been constructing a fantasy world from the minute she started writing her first application, and the agency was perfectly happy to play along.

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