Neglect begets opportunity in femtech IP

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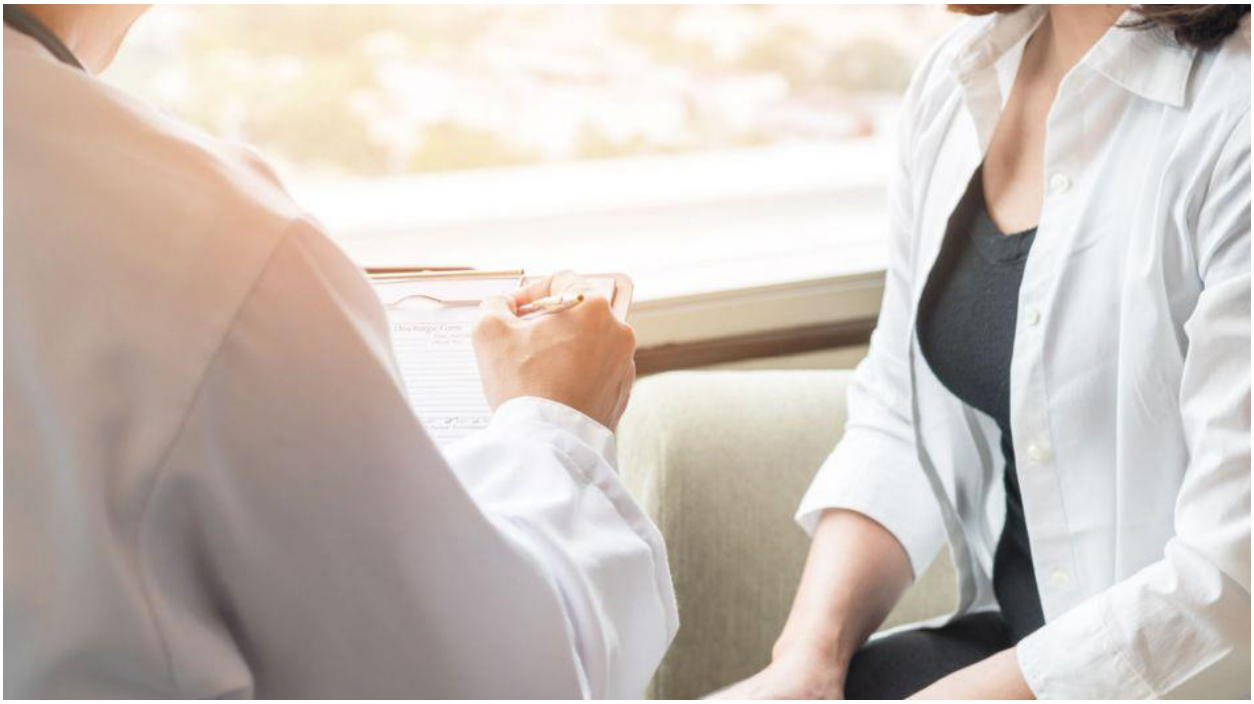

Progress in women's healthcare has historically been inhibited by poor access, few choices, and archaic stigmas. There are sex differences in nearly every tissue and organ system of the human body, yet male physiology is treated as the default in medical research, leading to significantly diminished healthcare outcomes for women.

But with the rise of the internet-of-things, cellular connectivity, smartphone apps, wearable devices, machine learning, and other enabling technologies, women are taking control of their healthcare like never before.

Femtech, a rising force in the women's healthcare industry, aims to harness the power of technology to provide access, expand choice, and end stigmas. Female inventors still lag behind their male counterparts in the innovation economy and intellectual property landscape, but not for long.

The United States Patent and Trademark Office is striving to bridge the gender patenting gap. Meanwhile, femtech entrepreneurs can take advantage of large empty spaces on the patent landscape to secure IP protection for their innovations. This article explores how to best protect those innovations.

What Is Femtech?

Femtech is a growing industry that focuses on building solutions to unmet needs in women's healthcare. Femtech solutions aim to preserve wellness, prevent illness, and close the treatment gap through education and innovations in software, wearables, pharmaceuticals, medical devices, and consumer products. The foundation of femtech as a distinct discipline is the growing recognition of the significant health differences between male and female bodies.

Traditionally, researchers assumed that male and female bodies were essentially identical apart from their sex organs, resulting in male physiology being treated as the default in healthcare research and clinical trials. But sex-based differences are more extensive than were once assumed and manifest in nearly every tissue and organ system in the human body. For example, sex-based differences have been observed in the mechanical workings of the heart, drug metabolization, lung capacity, reactions to vaccines, and the aging of blood vessels, among many other differences.

Femtech initiatives treat healthcare conditions that are unique to women (*e.g.*, endometriosis), predominantly affect women (*e.g.*, autoimmune disorders), or present differently in women (*e.g.*,

cardiovascular disease). Products typically fall into the categories of medical devices, healthcare software, therapeutic drugs, and consumer products, services, and apps. Femtech products address the full range of women's healthcare issues, but some of the most common targets are menstruation, fertility, contraception, menopause, pelvic health, breastfeeding, sexual wellness, bone health, and oncology. Specific examples include cycle tracking apps, breast pumps, diagnostic test kits, intrauterine devices, and wearable fitness trackers.

Understudied, Underrepresented, & Underreported

The Office of Research on Women's Health at the National Institutes of Health refers to women and women's health issues as "**understudied, underrepresented, and underreported**." Indeed, estimates of the share of R&D invested in women's health vary from about **1%** to **4%**, despite women accounting for roughly half of the population. A **recent study** of NIH disease research funding found that in about three-quarters of cases where a disease affected primarily one sex, the funding pattern favored males. Conditions that predominantly affected males were consistently overfunded, while conditions that predominantly affected females were consistently underfunded.

The underrepresentation of women in healthcare research is longstanding. In 1977, the **U.S. Food and Drug Administration** issued guidance banning most women of child-bearing age from participating in clinical drug trials due to fears of certain drugs causing birth defects. While that policy was rescinded and reversed in 1993, women continue to be underrepresented in clinical trials. A **2005 review** showed that 79% of animal studies for pain used only male mice. Between 1987 and 2012, women made up only **25%** of participants across 31 landmark trials for congestive heart failure, despite cardiac disease being the top killer of women. A 2020 **study of sex differences in pharmacokinetics** found that when females are given the same dosage of a drug as males, they are nearly twice as likely to have an adverse drug reaction. Even in **a study released just last year**,

researchers concluded that U.S. COVID trials also under-enrolled women, among other groups.

This underrepresentation has real-world implications for women's healthcare outcomes. Heart attacks, for example, affect both men and women but often present differently in both sexes. Women do not always experience chest pain when having a heart attack and often present other symptoms such as fatigue, shortness of breath, nausea and vomiting, and back or jaw pain. But because most diagnostic methods for diagnosing heart attacks are based on male symptoms, women experiencing heart attacks are more likely to be misdiagnosed and sent home from the emergency room than men (often with an anti-anxiety medication).

Such outcomes are not limited to healthcare. According to the **National Highway Traffic Safety Administration**, female drivers and right front passengers are about 17% more likely to be killed in a car crash than male occupants of the same age. One possible explanation for this discrepancy is that crash test dummies are typically based on a 171-pound, 5-foot-9-inch "**50th percentile male**" rather than both an average male and an average female. Women also tend to experience **motion sickness** at higher rates than men, which may explain higher rates of "**cybersickness**" among women when using virtual reality applications. Similar discrepancies exist in personal protective equipment, tools, phones, keyboards, and speech recognition software, all of which are based on male physiology.

Opportunities Abound

The historical neglect of female-specific and female-predominant healthcare issues creates new opportunities in women's health, and a new multidisciplinary industry of entrepreneurs, investors, researchers, and healthcare professionals is working to address various needs in women's health. In addition to accounting for half the population, researchers estimate that women make **80% of household healthcare**

decisions and consume about **80% of the pharmaceuticals** in the U.S. Far from a niche market, women's healthcare is a major untapped field, and innovators are increasingly focusing their efforts on developing lifesaving solutions for female-focused conditions. As of 2022, the size of the femtech market was estimated to be about **$55 billion**, with revenue forecasted to reach $103 billion by 2030. Investors also seem to be taking notice of the potential for growth in the femtech sector; venture funding for femtech companies stood at about **$61 million** in 2016 but rocketed to about $1.3 billion by 2021. After decades of neglect, the healthcare industry is finally responding to two truths: women want choices when it comes to healthcare, and women will buy solutions to improve their health.

Protecting Femtech IP

The best way for femtech companies to secure a piece of the femtech market is to obtain IP protection for their innovations. This includes healthcare-related innovations – such as treatments, diagnostics, and preventative care – but also innovations in products designed for the female body. Such IP protection can include both utility and design patents, as well as soft IP assets like trademarks, copyrights, and trade secrets.

The Femtech IP Landscape

Because women's health issues have traditionally been understudied, underfunded, and underrepresented, enormous white space exists in the IP landscape for femtech innovations. In established healthcare industries, such as cardiology, innovators often are faced with well-developed prior art and existing patents that limit their ability to patent and monetize their innovations. This is not the case in the femtech IP space, where the prior art is less extensive and only a handful of patents related to addressing a certain health condition may exist.

To illustrate, an IP landscape analysis of 81 femtech companies conducted by the authors in 2022 revealed only 1,622 patents and

published applications and 1,559 trademark registrations worldwide. Of those 81 companies, only 48% had patents or patent applications. Patenting activity in femtech even lags behind niche innovations in the men's healthcare space; a search of U.S. patent applications conducted by the authors in 2022 revealed 1,515 patent applications related to penile pumps and implants, but only 304 related to menstrual cups and discs for collecting menstrual blood. There is clearly room for innovation in femtech IP.

Strategies for Patenting Femtech Digital Health and Therapeutic Innovations

Many femtech innovations fall into the categories of digital health and digital therapeutics. Digital health generally refers to computer software or hardware that processes medical information related to an entity (*e.g.*, a person or animal), while digital therapeutics generally refer to computer software or hardware that provides therapeutic content to an entity that is configured to treat a symptom of the entity. Digital health innovations can also include digital diagnostics, which use computer software or hardware to measure an attribute of an entity. Applications of digital health and digital therapeutics in femtech commonly include wearables, medical devices, and healthcare software.

Femtech companies seeking patent protection may choose to focus either on the software aspect or the therapeutic aspect of their innovations. In patent prosecution, a focus on the software aspect tends to invite greater scrutiny under 35 U.S.C. § 101 *(i.e.,* whether the claimed subject matter is patent eligible) and less scrutiny under section § 112 (*i.e.*, whether there is sufficient evidentiary support of efficacy in the written description). A focus on the therapeutic aspect tends to have the opposite effect – greater scrutiny under § 112 and less scrutiny under § 101.

Regardless of whether a femtech applicant focuses on software or therapeutics, patent eligibility (commonly known in the U.S. as a "§ 101 rejection") for digital health and therapeutics is typically the most difficult hurdle to overcome at the patent office. Under *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014), certain processes, machines, manufactures, compositions of matter, or improvements thereof are not patentable in the U.S. if they are directed to a judicial exception unless the claimed subject matter provides a technological solution that is something significantly more than the alleged judicial exception. The difficulty in rebutting this rejection is convincing the patent examiner either that the claim at issue is *not* directed to a judicial exception or that the claim provides a technological solution that is *something significantly more* than the judicial exception. What constitutes "significantly more" may be determined on a case-by-case basis.

In addition to the standard rebuttals to § 101 rejections, femtech patent applicants have other strategies available to them. One of the most effective is to frame digital therapeutics claims as methods of treatment claims—*e.g.*, digital therapeutics deliver therapeutic content to an entity to treat a specific disorder. Such claims were found to be patent eligible in *Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International, Limited*, 887 F.3d 1117 (2018). Another strategy is to frame diagnostics innovations as unconventional diagnostics methods, which were found to be patent eligible in *Exergen Corp. v. KAZ USA, Inc.*, 2016-2315 (Fed. Cir. Mar. 8, 2018). The key with this strategy is to explain how the process to perform the diagnostic method is different than that conventionally performed by a human.

Women in IP

The white space in the IP landscape for femtech innovations begs the question – with so many opportunities, why haven't more innovators seized them? Other than lack of funding in women's health, one

possible explanation is that, despite the progress they have made in recent years, women continue to be underrepresented in inventorship. Even more, women inventorship is not tracked by the USPTO—though efforts to change that are underway in Congress. Since the 1970s, the **share of biomedical patents with women inventors** increased from about 12% to 35%, while the proportion of female-focused biomedical patents increased from about 10% to 14%. However, one would expect those numbers to be higher given that women now account for over half (50.7%) of the **college-educated labor force in the U.S.** Even more troubling, women account for only **27% of the STEM labor force** in the U.S., despite making up **53% of STEM degrees at the bachelor's level** and 60% at the master's level. Overall, women account for just **13% of inventor-patentees** in the U.S.

Some research suggests that increased participation of women in the innovation economy will result in increased outputs of female-focused healthcare advances. A **2019 Harvard Business School working paper** found that in the biomedical field, patents with women as named inventors are significantly more likely to focus on female diseases and conditions. Research teams with women are also 19% more likely to produce patents that focus on women, while that percentage increases to 26% when female researchers lead their teams. Rough calculations suggest that if all patents granted between 1976 and 2010 had had equal numbers of male and female inventors, there would have been around 6,500 more female-focused inventions.
The USPTO, under the leadership of Director Kathi Vidal, has made closing the innovation gap a priority. In 2022, the USPTO and the Department of Commerce launched the **Women's Entrepreneurship initiative**, a "community-focused, collaborative, and creative initiative to inspire women and tap their potential to meaningfully increase equity, job creation, and economic prosperity." While IP protection is a key consideration for entrepreneurs, many women struggle to gain access to the capital necessary to obtain IP protection and attract investment. Accordingly, the initiative provides resources for women entrepreneurs

to secure funding and build and maintain a professional network in addition to obtaining IP protection. The Women's Entrepreneurship initiative is just one of many such public-private initiatives aimed at achieving innovation equity.

Every Little Change Counts

Whether you are the potential patentee, the in-house patent counsel, or outside counsel retained to build an IP portfolio, diversify your ideas by taking femtech IP into account. Where is your invention making strides in historically underrepresented fields of research? Where can you make a difference in increasing the percentage of women inventorship? How can you bring parity to the disparity we see in the marketplace vis-a-vis traditional fields of innovation? Under a new lens – one that acknowledges the historical deficiencies in understanding women in science – the IP landscape is both ready and has room to make way for new technologies in this space.