

# Protecting Your Femtech IP

Wednesday, November 30, 2022



# Meet The Speakers

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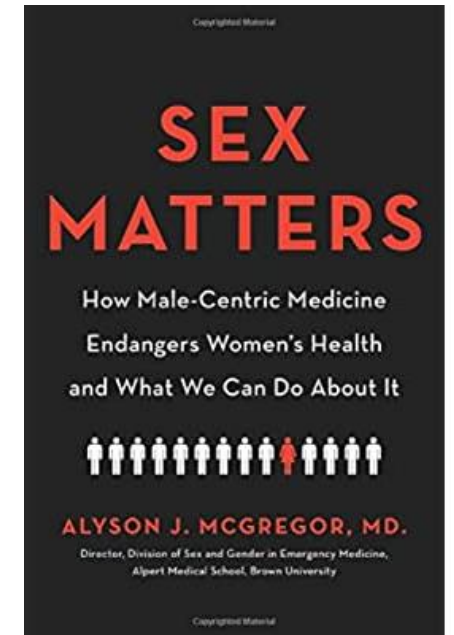
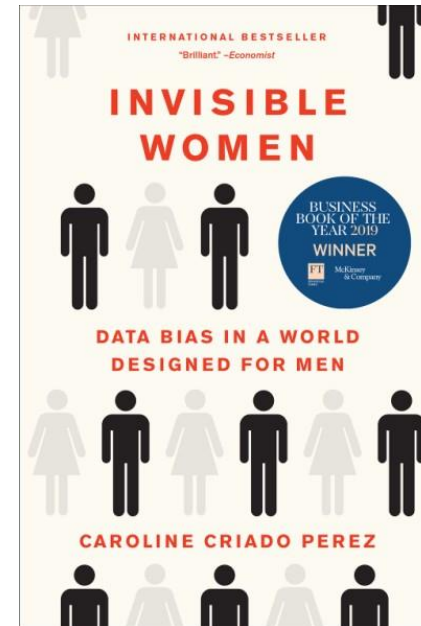


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# Overview

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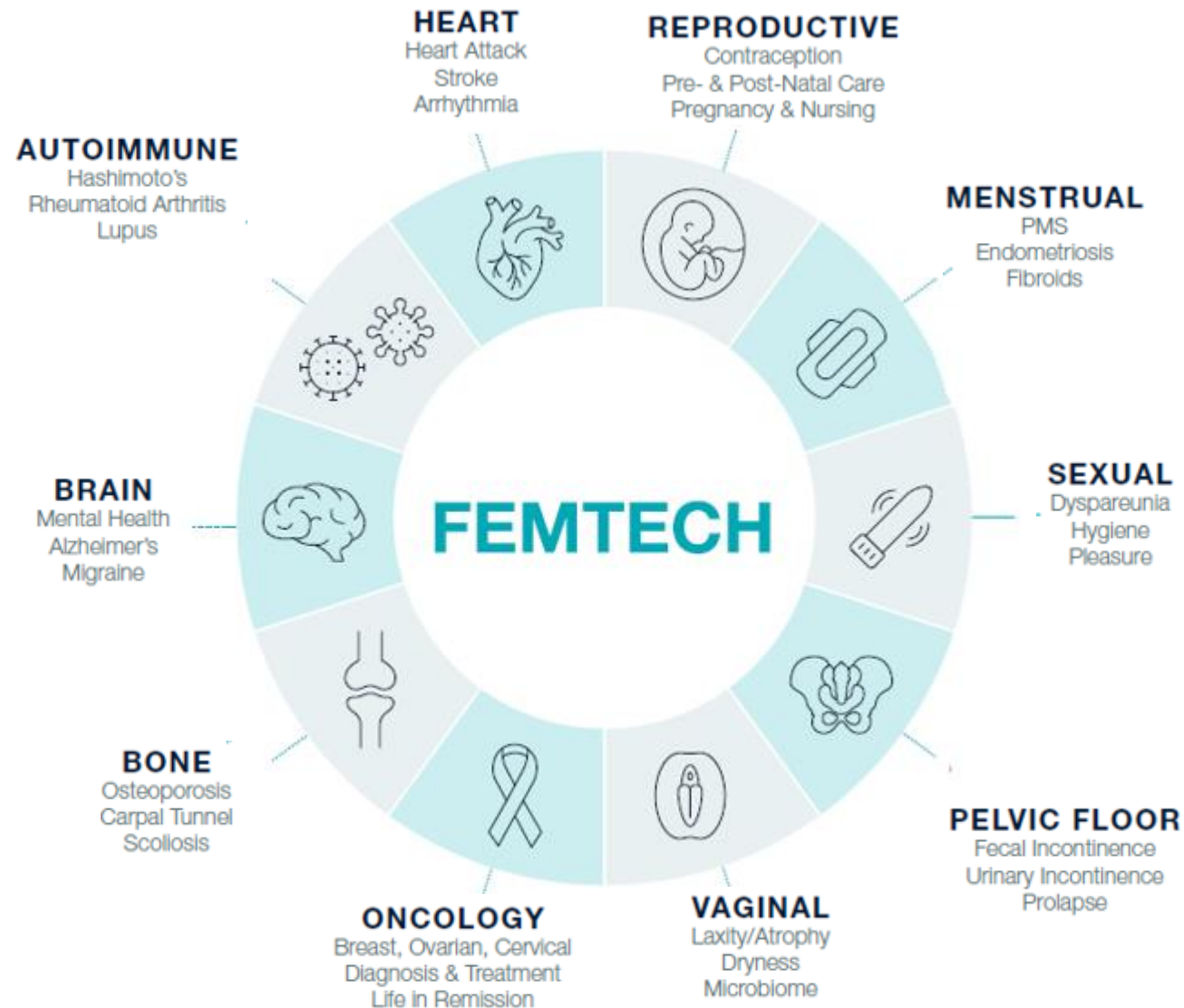
- What is Femtech?
- Investments in Femtech
- Sex Differences Matter
- Protecting Your Femtech
- Where are Women in IP?
- Survey of Femtech IP Landscape 2022
- Questions
- Materials
  - <http://www.fr.com/webinars>





# What is Femtech?

# What is femtech?





# Investments in Femtech

# Economic Outlook of the Industry

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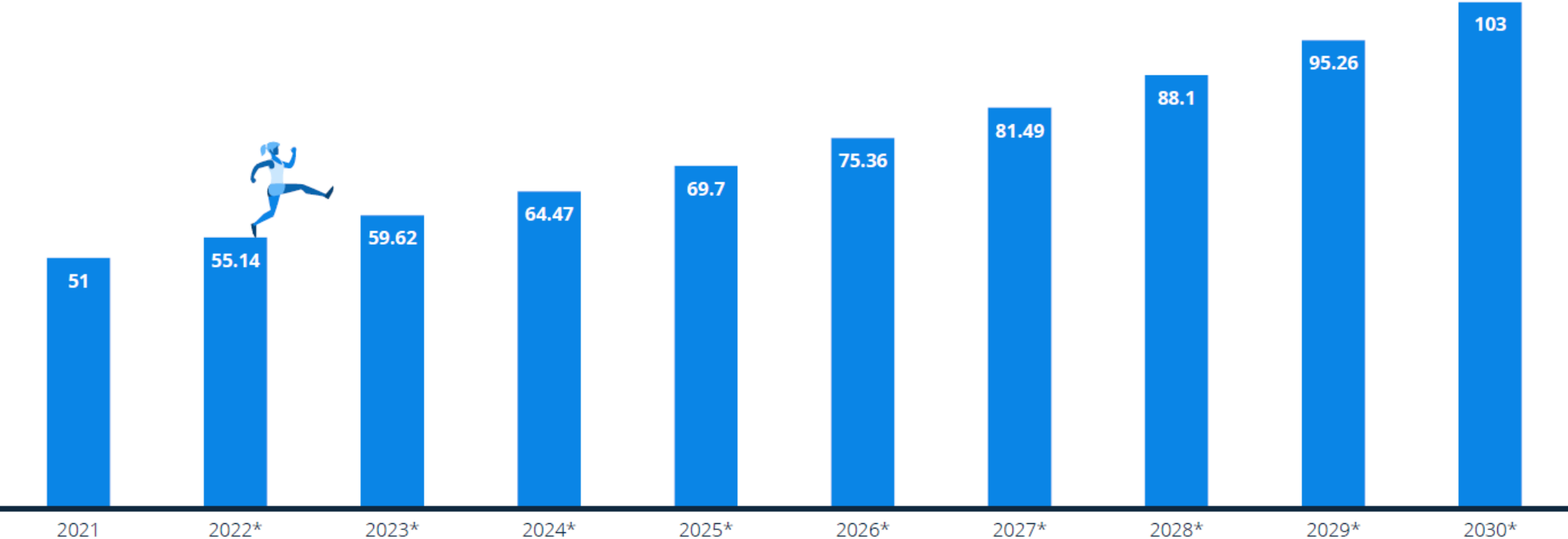
## Market Opportunity

- Women are 51% of the population
- Women make 80% of the household healthcare decisions
- Women have 75-80% purchasing power
- Women consume approximately 80% of pharmaceuticals in the US<sup>1</sup>

# Economic Outlook of the Industry

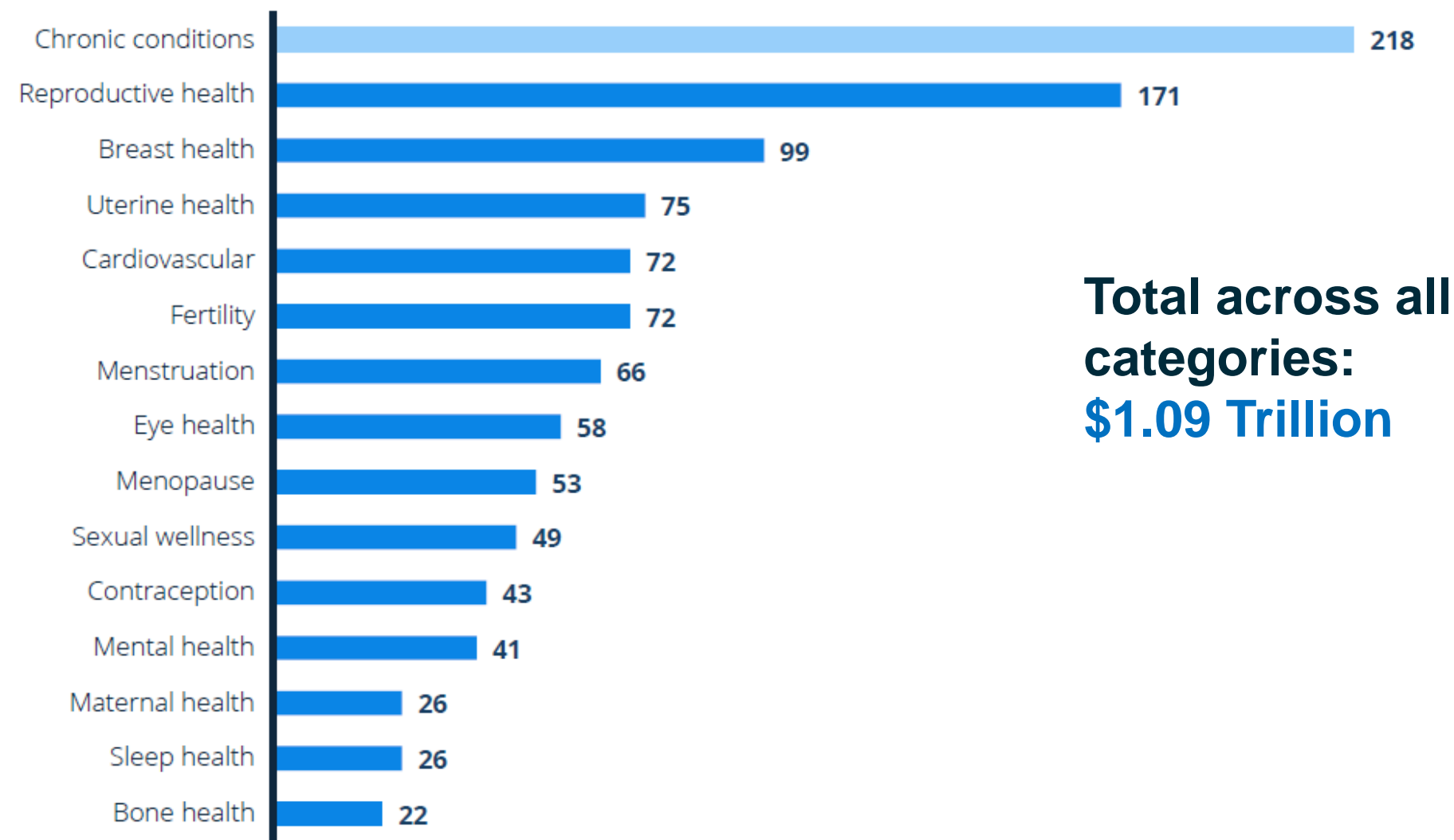
Revenue forecast to reach 103 billion U.S. dollars by 2030

Femtech market size worldwide from 2021 to 2030 (in billion U.S. dollars)

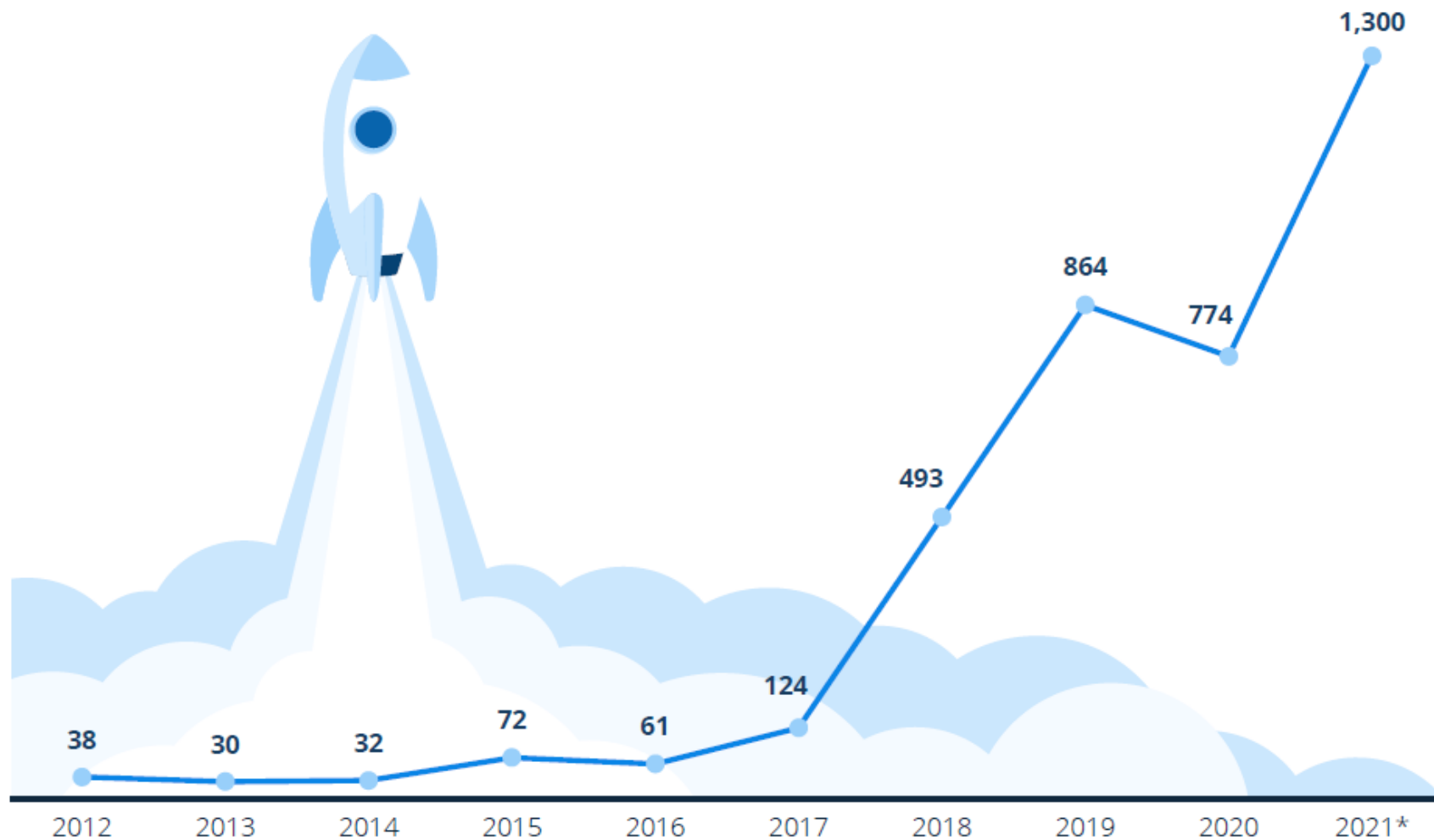




# Forecasted Value of 2027 Worldwide Female Health Market



# Venture Funding in Femtech Companies



Source: Statista Dossierplus on the Global Femtech Industry; Rock Health; ID [1303968](#)

Notes: United States; 2012 – August 31, 2021

Notes: Amounts are in million U.S. Dollars



# Sex Differences Matter

# Let's talk about sex (differences), baby!

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There are differences in *every* tissue *and* organ system in the human body

- Mechanical workings of the heart
- Autoimmune disease
- Metabolizing drugs
- Lung capacity
- Reactions to vaccines
- Pain
- Cellular<sup>2</sup>
  - blood-serum bio-markers for autism,
  - proteins,
  - immune cells used to convey pain signals,
  - how cells die following a stroke,
  - Parkinson's disease,
  - brain ischemia,
  - aging of blood vessels,
  - cell response to stress

# Let's talk about sex (differences), baby!

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## Women are Underrepresented in Research

- Until 1993, women of child-bearing age were excluded from participating in clinical drug trials
- In 1993, the US passed the National Institute of Health Revitalization Act to make excluding women in federally funded clinical trials illegal<sup>3</sup>
- 1987-2012, women made up 25% of participants across 31 landmark trials for congestive heart failure<sup>4</sup>
  - Startling because cardiac disease is the #1 killer of women
- In many cases, females aren't included in animal studies on female-prevalent diseases<sup>5</sup>
- Even if female animals are included, no guarantee data will be sex-analyzed – in fact, 2/3 of the time results were not analyzed by sex<sup>6</sup>

# Let's talk about sex (differences), baby!

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## Sex-Specific Drug Efficacy

- A 2005 review found that 79% of pain studies used only male mice<sup>7</sup>
- 2007, of the few studies that did involve rats or mice of both sexes, 54% revealed sex-dependent drug effects<sup>8</sup>
- A 2001 report from the Government Accountability Organization found that out of 10 prescription drugs withdrawn from the market from 1997-2001, 8 were found to pose greater health risks for women<sup>9</sup>
  - 1/3 of which created sudden cardiac death in women not otherwise considered at risk
- Statins are some of the most prescribed drugs in America, yet they appear to have little benefit for the millions of women taking them<sup>10</sup>
- 2002, FDA's Center for Drug Evaluation and Research showed 'statistically significant differences between men and women in bioequivalence for most generic drugs compared with reference drugs.' <sup>11</sup>



# Protecting Your Femtech Assets

# Where there is neglect, there is opportunity

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## White Space in Femtech

- Because of these sex differences, there is enormous opportunity in creating new treatments, diagnostics, and preventative care for various diseases and conditions that affect women
- Not just in health, but opportunity in new designs based on the female body
  - Cars and seatbelts are not designed for women's bodies, resulting in more deaths and serious injuries from car accidents than men
  - Women are more likely to experience motion sickness, generally, and also while using VR
  - PPE, tools, phones, keyboards, speech recognition software, etc.

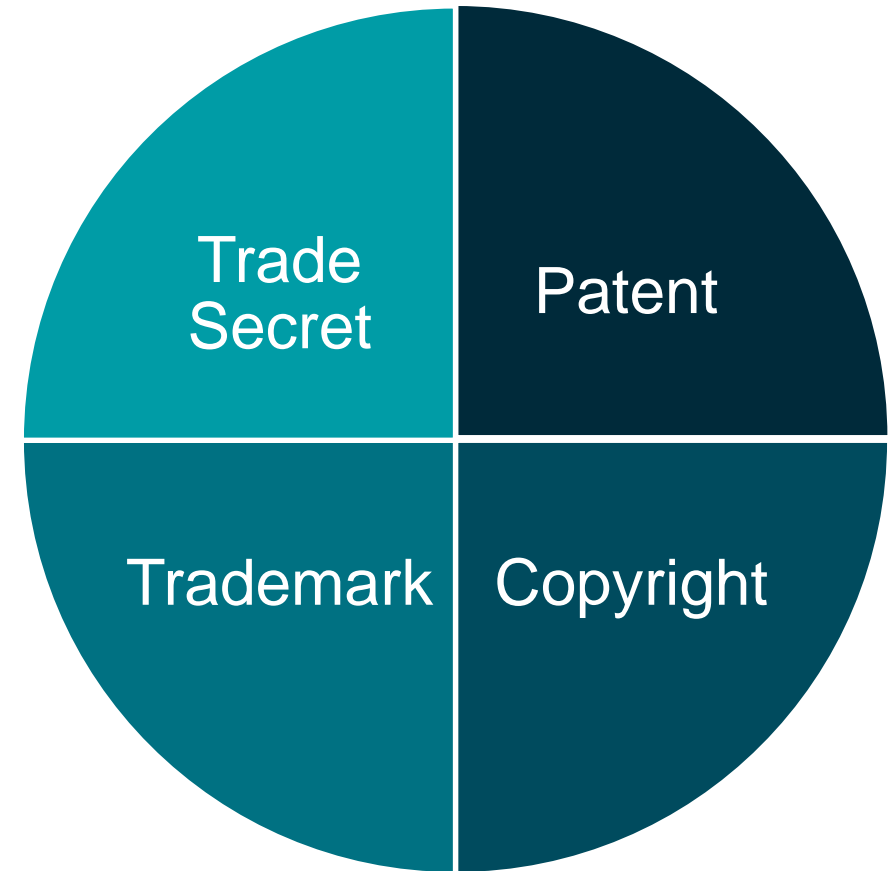


# What is Intellectual Property?

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*“A category of intangible rights protecting commercially valuable products of the human intellect. A commercially valuable product of the human intellect, in a concrete or abstract form.”*

Black's Law Dictionary (11th ed. 2019)



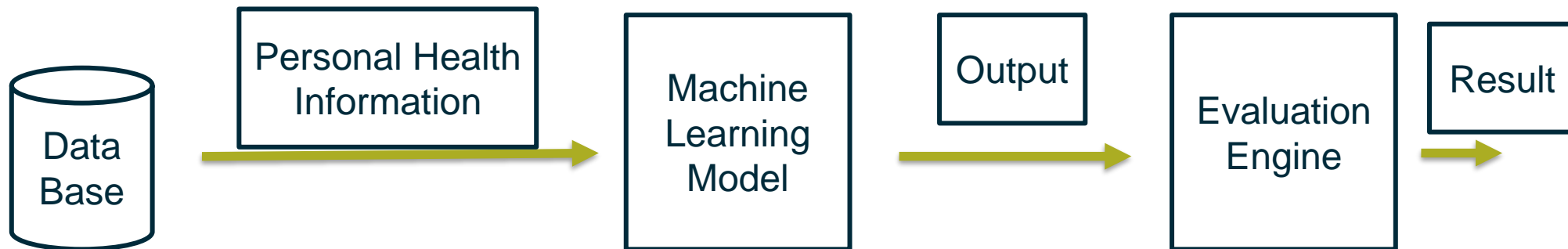
# Patents

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- **The right to exclude others from making, using, selling, offering for sale, and importing your patented invention**
- **General Requirements to Obtain a US Patent**
  - Subject matter eligible
    - “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 therefore...” (35 U.S.C. §101)
    - **Cannot patent law of nature, natural phenomenon, or an abstract idea**
  - New (35 U.S.C. §102)
  - Not obvious to a person having ordinary skill in the art (35 U.S.C. §103)

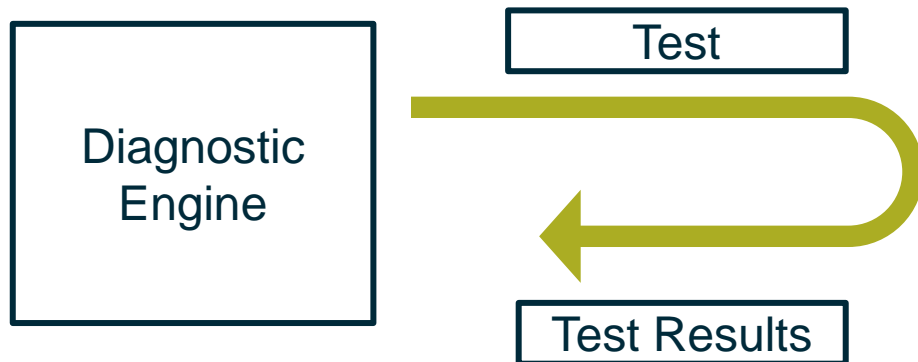
# Utility Patents – Digital Health Technologies

- **Digital Health Innovations:** Computer software and/or hardware innovations that process “medical information” related to an entity (e.g., a person or animal)
  - Machine learning model that has been trained to predict a likelihood of a particular patient characteristic
  - Ex: Using menstrual history data (including symptoms) to determine a daily workout routine



# Utility Patents – Digital Health Technologies

- **Digital Health Diagnostic Innovations:** Computer software and/or hardware innovations that measure an attribute of an entity (e.g., a person or animal)
  - This can include measuring a biological attribute or measuring a change of a biological attribute
  - Ex: Measuring breast tissue composition, comparing to recorded tissue composition, providing test result of changes and instructions to follow up with your doctor for a breast health exam



Shown: Dotplot, source: <https://www.bbc.com/news/technology-62807367>

# Utility Patents – Digital Therapeutics

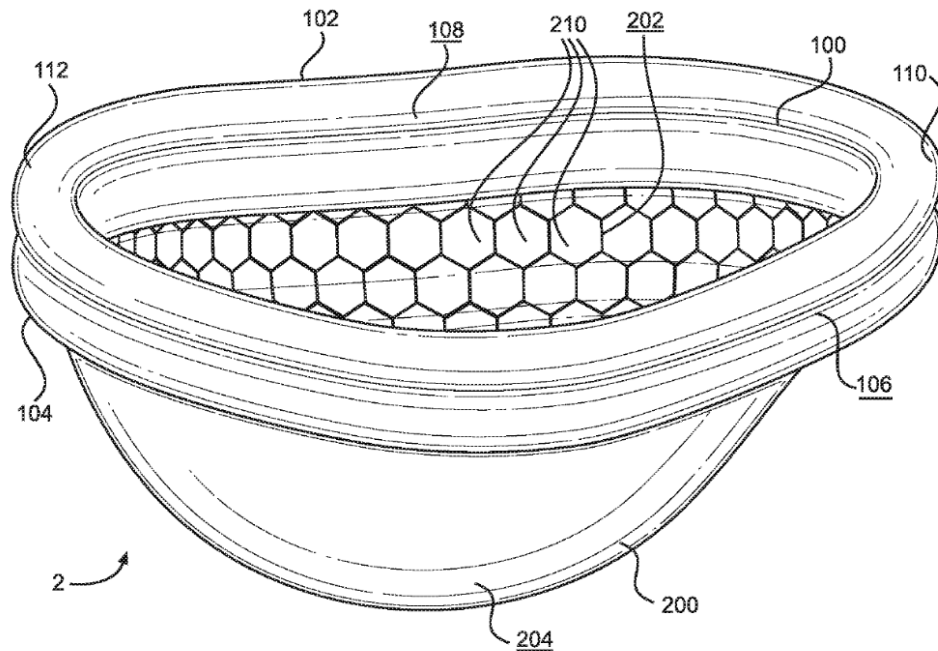
- **Digital Therapeutic Innovations:** Computer software and/or hardware innovations that provide therapeutic content to an entity (e.g., a person or animal) that is configured to treat a symptom of the entity
  - Method of treatment claims (e.g., textual, audio, video content, haptic feedback, or a combination)
  - Example Hybrid System of Digital Therapeutic and Health Innovations: Wearable device that measures heart rhythms and detects symptoms of heart disease and alerts the user



Images from Bloomer Tech

# Utility Patents – Improved Device

- US 10,888,450, Menstrual cups and methods of use



US10888450

1. A menstrual cup, comprising:

a rim having an upper portion, a lower portion, a first end, a second end, and an exterior surface, the rim defining a first lip adjacent the upper portion, the first lip extending along the exterior surface of the rim, the rim comprising silicone; and

a receptacle disposed adjacent and attached to the lower portion of the rim, the receptacle defining an interior surface, the interior surface comprising **a textured pattern**, the receptacle comprising silicone, wherein **a slope of a first end of the receptacle adjacent to the first end of the rim is less than a slope of a second end of the receptacle adjacent to the second end of the rim;**

wherein the first end of the rim extends away from the receptacle.

# Design Patents

- Ornamental appearance of your design

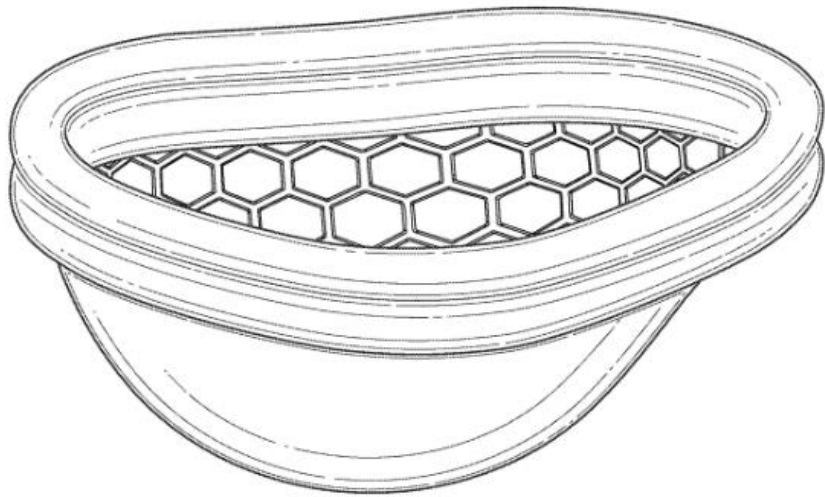


FIG. 1

D837980

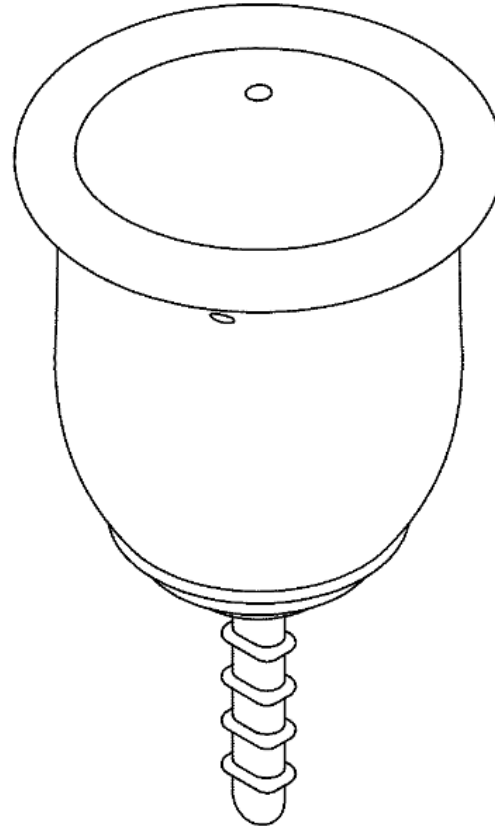


FIG. 1

D746452

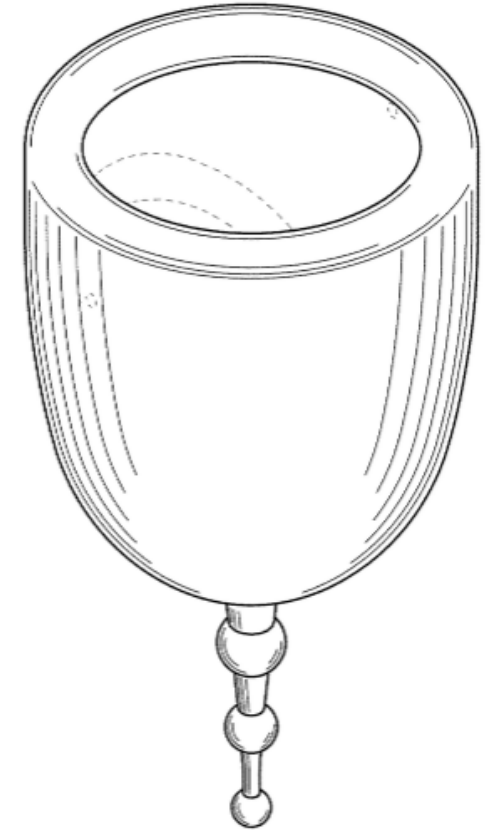


FIG. 2

D832438



# INTIMINA™ Ziggy Cup 2 – patent protected



Roll over image to zoom in



## Intimina Ziggy Cup 2 - New Generation Ultra-Thin Flat-Fit Reusable Menstrual Disc (B)

[Visit the INTIMINA Store](#)

★★★★☆ 98 ratings

Price: \$26.60 (\$26.60 / Count)

**Get a \$200 Gift Card:** Pay \$0.00 ~~\$26.60~~ upon approval for the Amazon Prime Rewards Visa Card. No annual fee.

May be available at a lower price from other sellers, potentially without free Prime shipping.

Size: B

A	B
\$31.26	<b>\$28.00</b>
(\$31.26 / Count)	(\$28.00 / Count)

Size	B
Brand	INTIMINA
Color	Dark Pink
Material	Silicone
Item Diameter	14 Centimeters

### About this item

- Upgraded design - made of reinforced, flexible, 100% medical grade silicone, and it comes with an addition; ribbed tab for slip-free removal
- Inclusive sizes - Ziggy Cup 2 now comes in sizes: size A (low cervix, light to medium flow) and size B (higher cervix, light to heavier flow)
- Period protection - Can be worn for up to 8 hours, and you can use it for up to 2 years. A reusable and reliable menstrual cup that can be worn during sex
- Adapts to your body - It's a high-capacity cup with a flexible,



# Femtech in Law

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Intellectual Property

Regulatory

Privacy



# **Where are Women in IP?**

# Where there is neglect, there is opportunity

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## Representation in Inventorship

- 0.4% of issued patents are directed to women's health
- In the field of biomedical patents, patents with women inventors are significantly more likely to focus on female diseases and conditions <sup>12</sup>
- *“Rough calculations suggest that if all the patents invented between 1976 and 2010 had been produced by men and women equally, then there would have been around **6,500 more female-focused inventions.**”*
- Quick Illustration: US Filed Patent Applications - 1515 v. 304
  - **1515** related to penile pumps and implants vs. **304** related to menstrual cups and discs for collecting menstrual blood

# Where there is neglect, there is opportunity

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## Representation in Inventorship

- Data on gender is not collected by the USPTO. Rather, to estimate patents issued to women inventors, the Institute for Women's Policy Research ("IWPR") relied on a commercial name matching software to guess the gender of the inventors in a 2016 report. This 2016 report found that "[i]n 1977 just over 1,500 domestic patents had at least one female inventor, **but by 2010 the number of patents with at least one female inventor increased by 15 times to just under 23,000.**"<sup>13</sup>
- Another IWPR study found that while "the share of patents [in the US] with at least one woman inventor grew from 20.7 percent to 21.9 percent between 2016 and 2019, this improvement is smaller than that of other benchmarks of women's education and employment as scientists and engineers." <sup>14</sup>

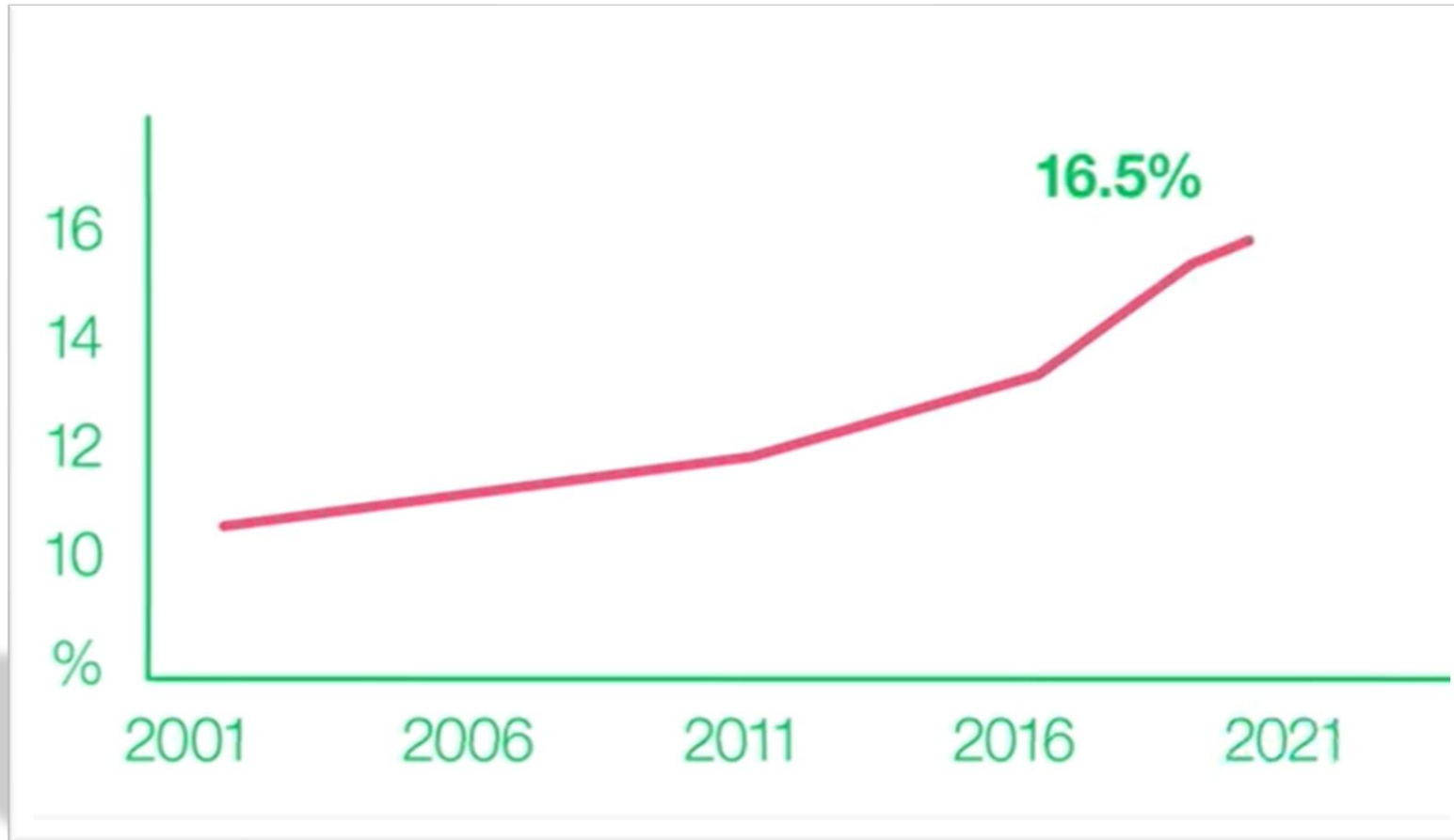
# Women Inventors Stats in U.S. Are Still Behind

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- In 2022, women make up **50.7%** of U.S. college-educated workforce and as of 2020 represented **45%** of STEM majors.
- But, women are only **27%** of U.S. STEM workforce per 2021 census data
- Women inventor rate as of 2019 is **only 13%** in U.S. but as of 2021 is **only 16.5%** internationally

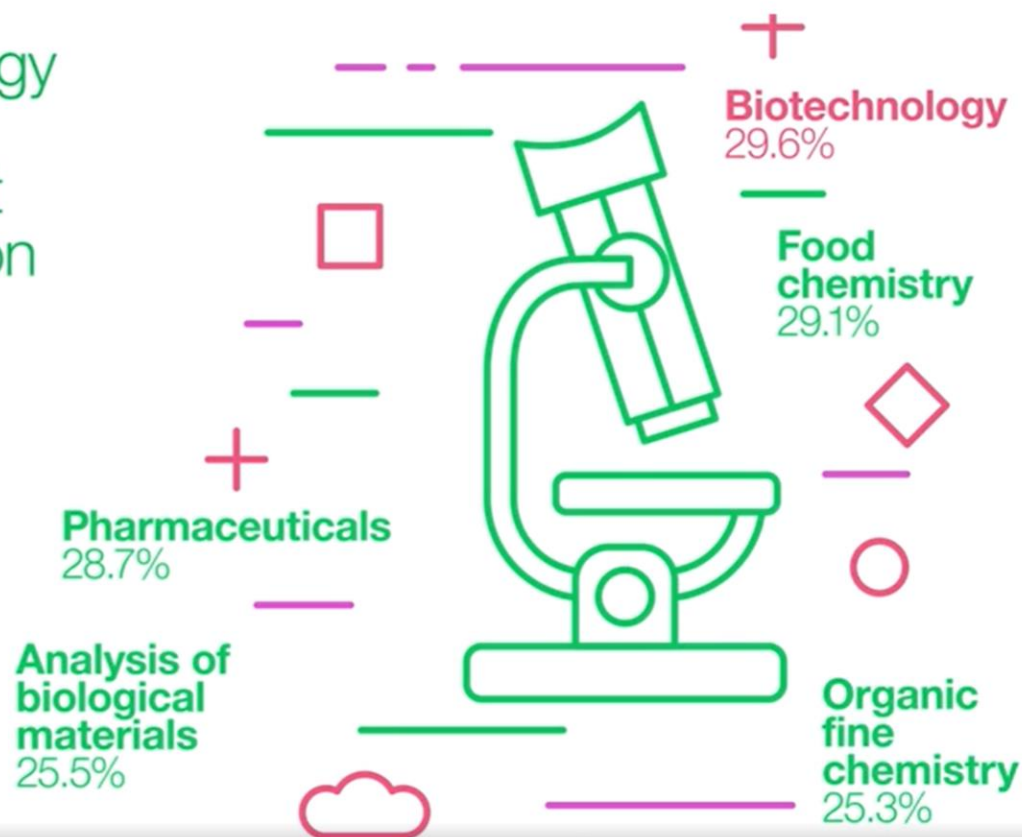
# Women Inventors Worldwide

- **Share of Women Inventors among all PCT Applications from 2001 – 2021**
  - *Data from WIPO IP Statistics Data Center, International Women's Day 2022 Presentation*



# Women Inventors Worldwide

In 2021, biotechnology was the technology field with the highest women's participation

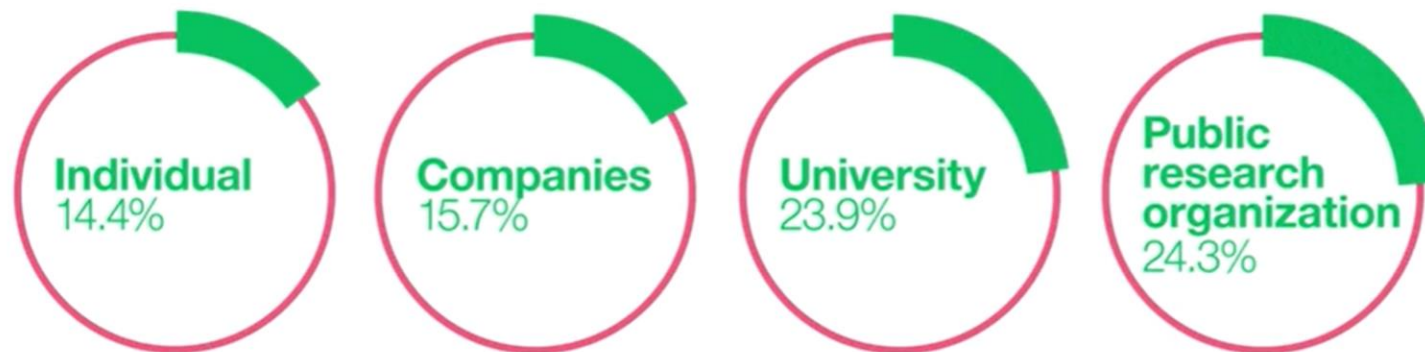


*Data from WIPO IP Statistics Data Center, International Women's Day 2022 Presentation*

# Women Inventors Worldwide

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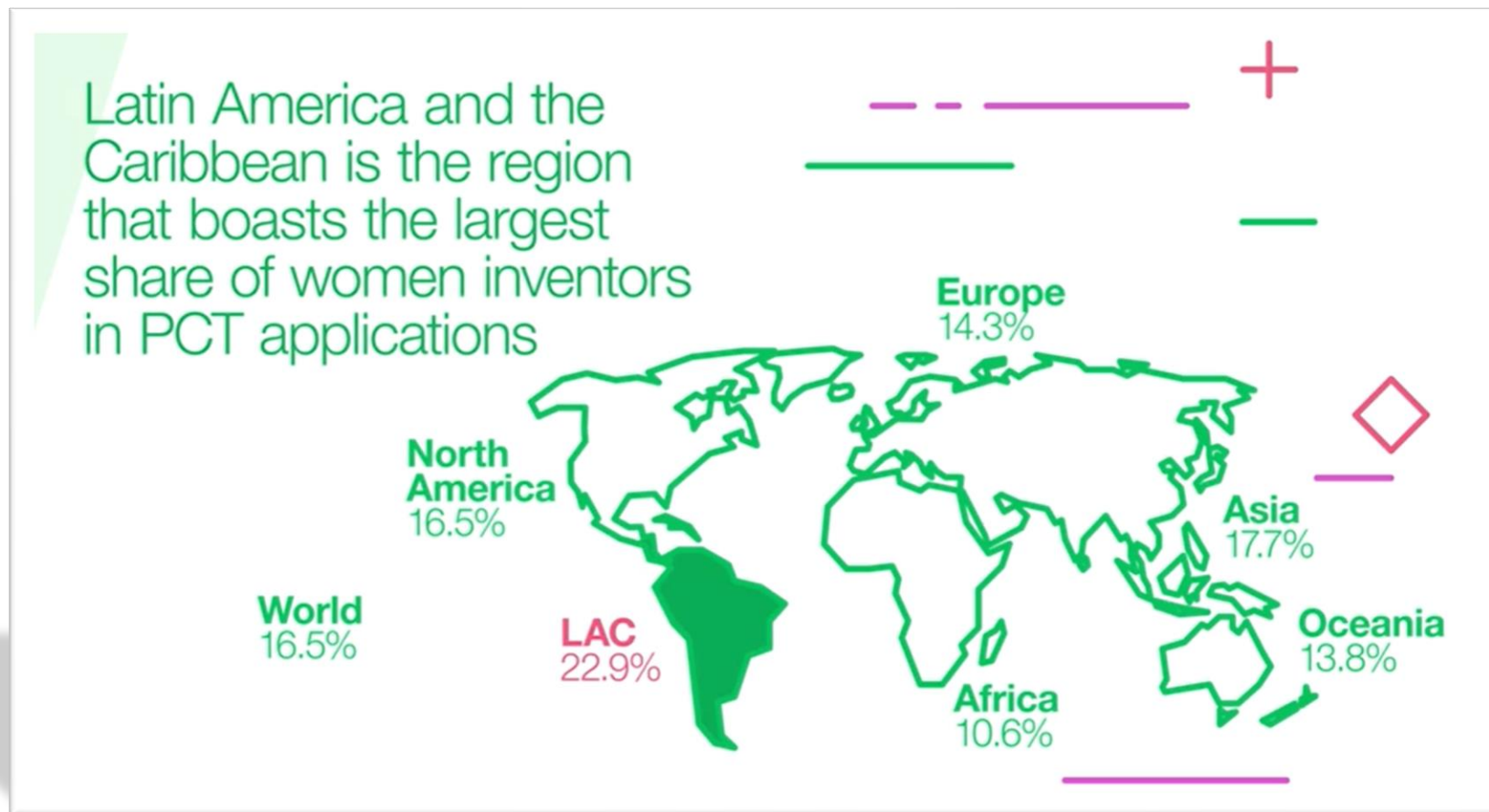
Applications by public research organizations and academia have the highest share of women inventors



*Data from WIPO IP Statistics Data Center, International Women's Day 2022 Presentation*



# Women Inventors Worldwide



*Data from WIPO IP Statistics Data Center, International Women's Day 2022 Presentation*



# **Survey of femtech IP landscape 2022**

# IP Landscape Survey

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- **81 femtech companies**
  - Includes companies based in U.S., Canada, United Kingdom, EU, and Israel
- **Sectors analyzed:**
  - Menstruation products
  - Menopause products
  - Digital health communities
  - Apps
  - Women-focused mechanical devices
  - Egg freezing/IVF/fertility services
  - Diagnostic/testing devices
  - Birth control/nursing delivery
  - Fertility/breastfeeding products
  - Benefits platforms
  - Biotech drug products
  - Sexual and maternal health

# IP Landscape Survey

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# IP Landscape Survey

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**1,622**

**Total Patents and  
Published Applications**

Worldwide, includes  
expired patents



**1559**

**Total Trademark  
Registrations**

Worldwide, includes  
abandoned registrations



**17**

**Total Copyright  
Registrations**

U.S. only

# IP Landscape Survey

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## Breakdown by Companies

48%

have patents or  
patent applications

88%

have registered  
trademarks

7%

Have registered  
U.S. copyrights

## Breakdown by Sectors

### Patents

Companies in biotech drug products, mechanical devices, and menstruation products were more likely to have *patents*

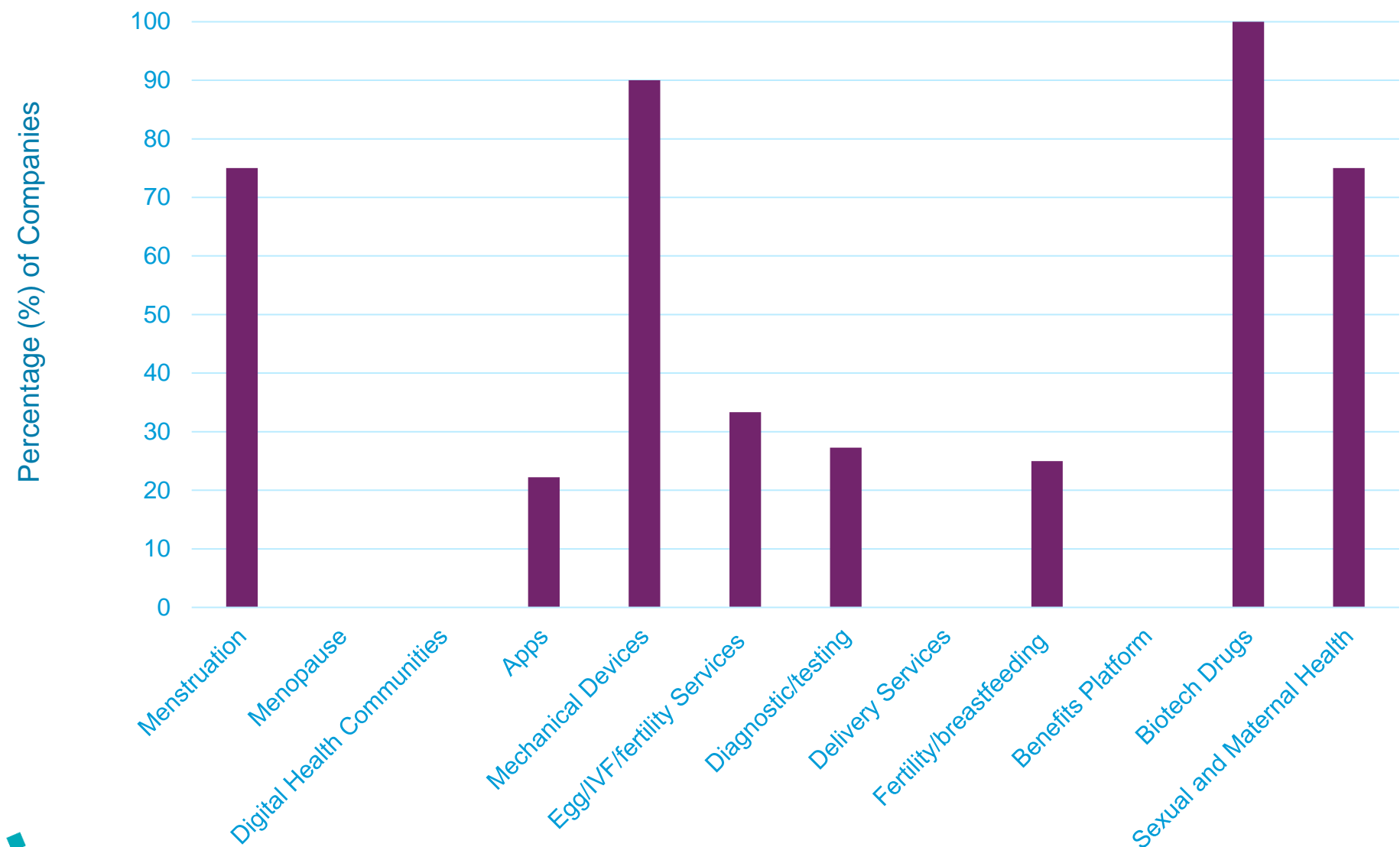
### Trademarks

All sectors had companies registering *trademarks*

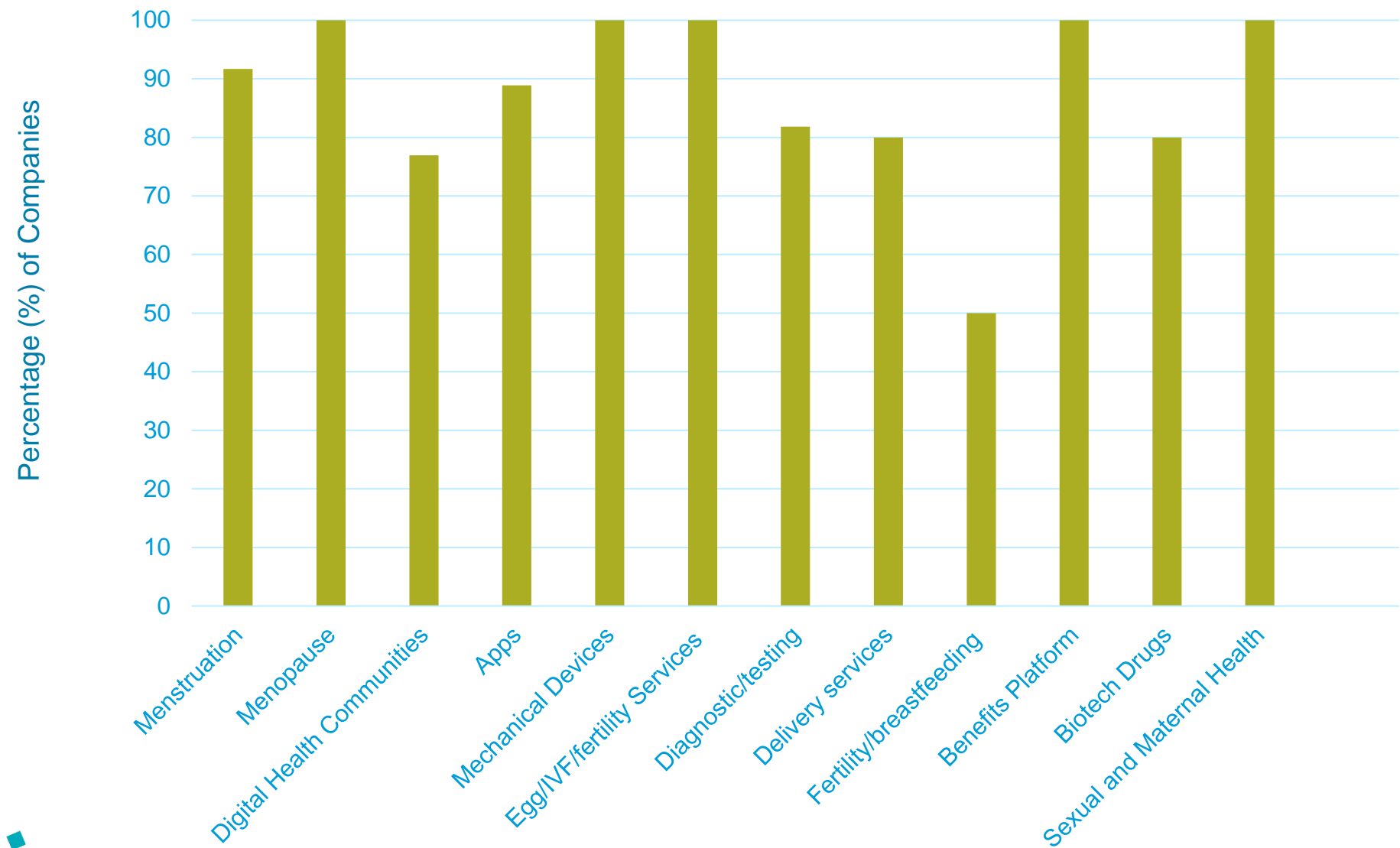
### Copyrights

All sectors less likely to have registered *copyrights* (U.S.)

# Patents by Sector - 2022

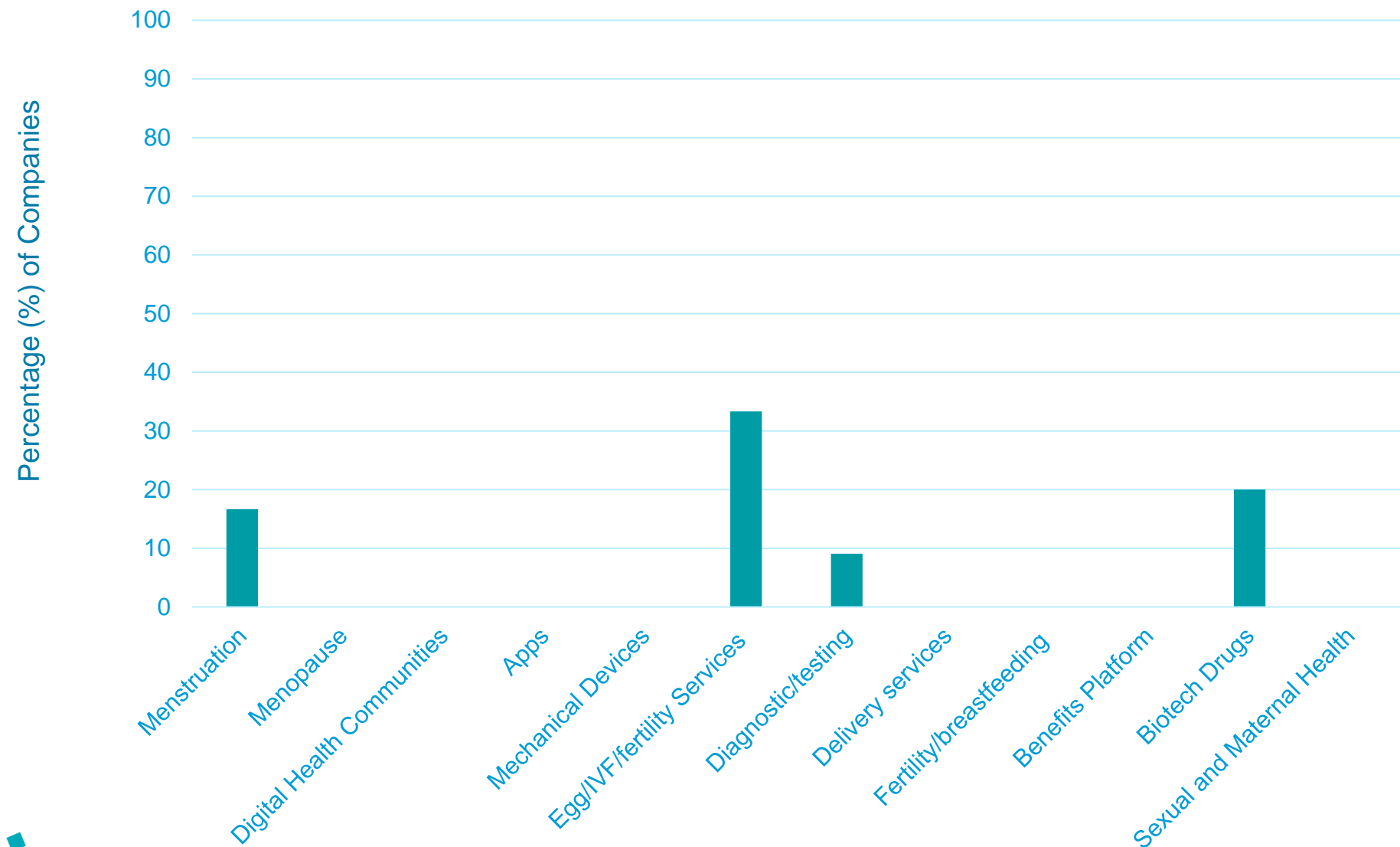


# Trademarks by Sector - 2022





# Copyrights by Sector - 2022



# “Soft IP” Revisited

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## 1) Business assets that grow with company

- a) Registered ® and © gives you more teeth than unregistered rights
- b) Can copyright source code, websites, and most written content and trademark designs



US Reg. No. [2,184,128](#)

## 2) Start early! Trademarks are “first come, first serve”

CLEAR → FILE → USE → POLICE



US Reg. No. [3,936,105](#)

# “Soft IP” Revisited

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- **Keep your protections broad**
  - Example:
    - **Do - Class 9: downloadable podcasts in the field of business, entrepreneurship, health, wellness, and travel**
    - **Don't - Class 9: downloadable podcasts in the field of business, entrepreneurship, personal development, health, wellness, and travel *for women***

# Litigation Trends

- **Patent**

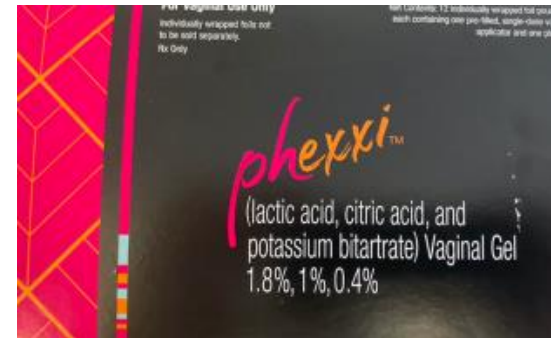
- *Coretek Licensing LLC v. Maven Clinic Co.*, Case No. 1:22-cv-08109 (S.D.N.Y.)
- *Novoluto GmbH v. Uccellini LLC*, Case No. 6:20-cv-02284 (D. Or.)
- *Sportbrain Holdings LLC v. Bellabeat Inc.*, Case No. 1:17-cv-04281 (N.D. Ill.)

- **Trademark**

- *NeighborFavor Inc. v. Hey Favor, Inc.*, Case No. 1:22-cv-00618 (W.D. Tex.)
- *TherapeuticsMD, Inc. v. Evofem Biosciences, Inc.*, Case No. 9:20-cv-82296 (S.D. Fla.)



vs.



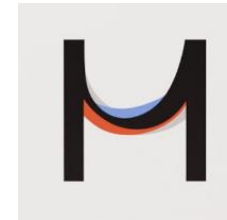
- *Kythera Biopharmaceuticals Inc. v. Lithera Inc.*, Case No. 2:13-cv-06338 (C.D. Cal.)

# M&A Trends

- 8 of the 81 are companies surveyed were acquired by/merged with:



Thinx!



NURX.

- Proctor & Gamble (This is L. - 2019)
- Kimberly-Clark (Thinx – 2022)
- Unified Women’s Healthcare (Gennev – 2022)
- Apricity (WOOM – 2022)
- Femtec Health (Ava – 2022)
- Ro (Modern Fertility – 2022)
- Bayer (kaNDy Therapeutics – 2020)
- Thirty Madison (Nurx – 2022)
- Everly Health (Natalist – 2021)

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- 11. McGregor, Alyson J. (2017), 'The Effects of Sex and Gender on Pharmacological Toxicity: Implications for Clinical Therapy,' *Clinical Therapeutics*, 39:1.
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- 14. <https://www.newm.cam.ac.uk/about/history/biographies/>
- 15. *Invisible Women*, p. 17.
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- <https://fortune.com/2022/06/10/world-built-for-men-women-bodies-gender-gap-health-research-medicine-care-jain-bruzek/>
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- <https://www.census.gov/library/stories/2021/01/women-making-gains-in-stem-occupations-but-still-underrepresented.html>
- <https://www.forbes.com/sites/markkantrowitz/2022/04/07/women-achieve-gains-in-stem-fields/?sh=68d179145ac5>
- <https://ipwatchdog.com/2022/07/27/uspto-expand-initiatives-resourced-inventors-first-time-filers/id=150440/#>
- [https://www.wipo.int/women-and-ip/en/news/2022/news\\_0001.html](https://www.wipo.int/women-and-ip/en/news/2022/news_0001.html)
- <https://www.uspto.gov/sites/default/files/documents/OCE-DH-Progress-Potential-2020.pdf>
- <https://pitchbook.com/news/articles/femtech-sector-venture-capital-weekend-analysis>
- <https://www3.wipo.int/ipstats/pmhbarchart>



# Questions?

# Thank You!



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