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# IP Protection for Connected Devices

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# Presenters

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Rabiya Kader is Senior Patent Counsel at Sanofi. She supports Business Development activities for medical devices, including mobile health applications. She also manages prosecution for Sanofi's own device development. In addition, she is responsible for all copyright issues for North America.



Hussein Akhavannik, co-leader of BakerHostetler's Life Sciences team, merges his engineering background with insight as a technologist to strengthen his patent prosecution and portfolio management practice. His services include patent procurement, optimizing patent portfolios for sale, performing freedom-to-operate studies, and serving as an international portfolio manager.

# Overview

- Introduce an example connected device
- Protecting hardware
- Protecting software
- Protecting GUIs
- Trademarks and apps
- HIPPA
- Filing trends

# Drug Delivery and Monitoring Example

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- Drug delivery device first tests blood, then automatically adjusts drug amount, and finally delivers the drug
- Wirelessly transmits blood test results and amount of drug delivered to patient's smart phone
  - Bluetooth



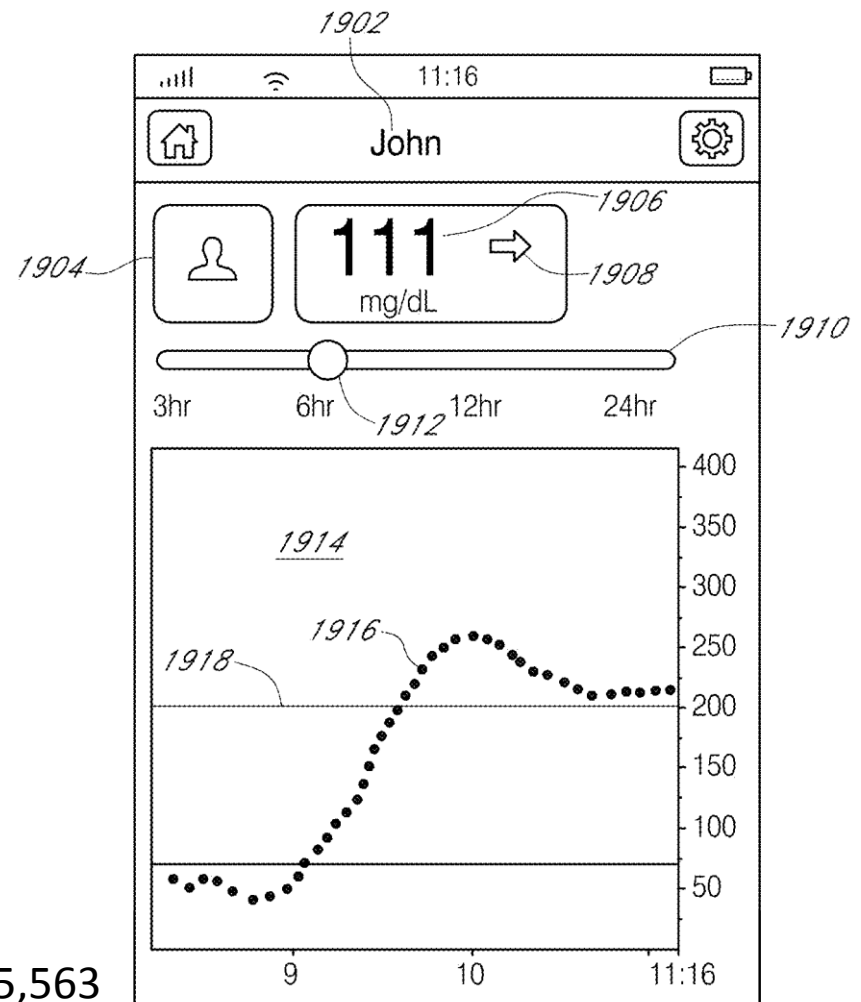
US 9,585,563

# Drug Delivery and Monitoring Example

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- App on phone displays information over time so patient can monitor trends
- App also transmits information to doctor/hospital (w/ ID) and medical device/drug manufacturer (w/o ID)
  - Use information to identify value-based healthcare treatment pathways

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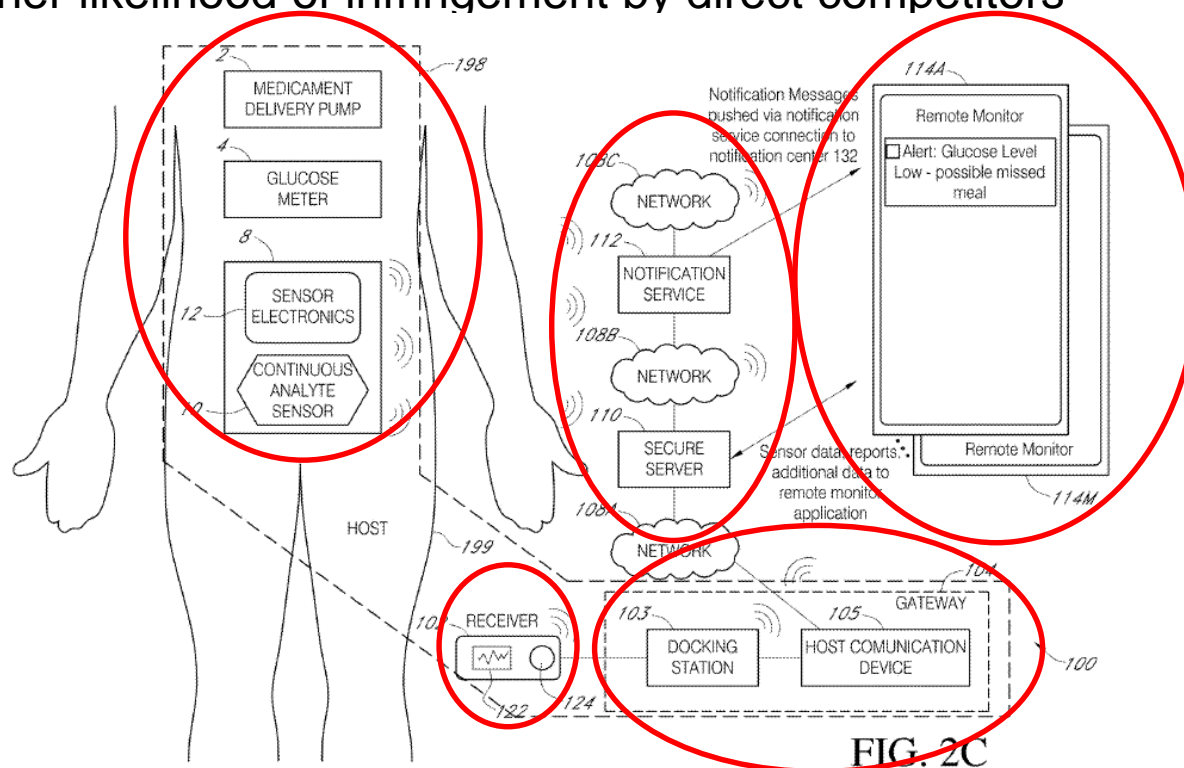
# Protecting the Hardware

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- Hardware claims are the most valuable
  - Protection against manufacturers, distributors, practitioners, and patients
- However, the most challenging for pre-existing devices
- Ensure robust description of changes made to accommodate communication

# Claiming Hardware

- Focus claims on a single actor
  - Devices are connected - ecosystem is inherently a multi-actor
  - Ensures coverage for your system
  - Higher likelihood of infringement by direct competitors



# Protecting the Software

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- Processing and data collected by:
  - Device
  - Gateway (bedside receiver, router, mobile phone, etc.)
  - Server (hospital, manufacturer, or other covered entity)

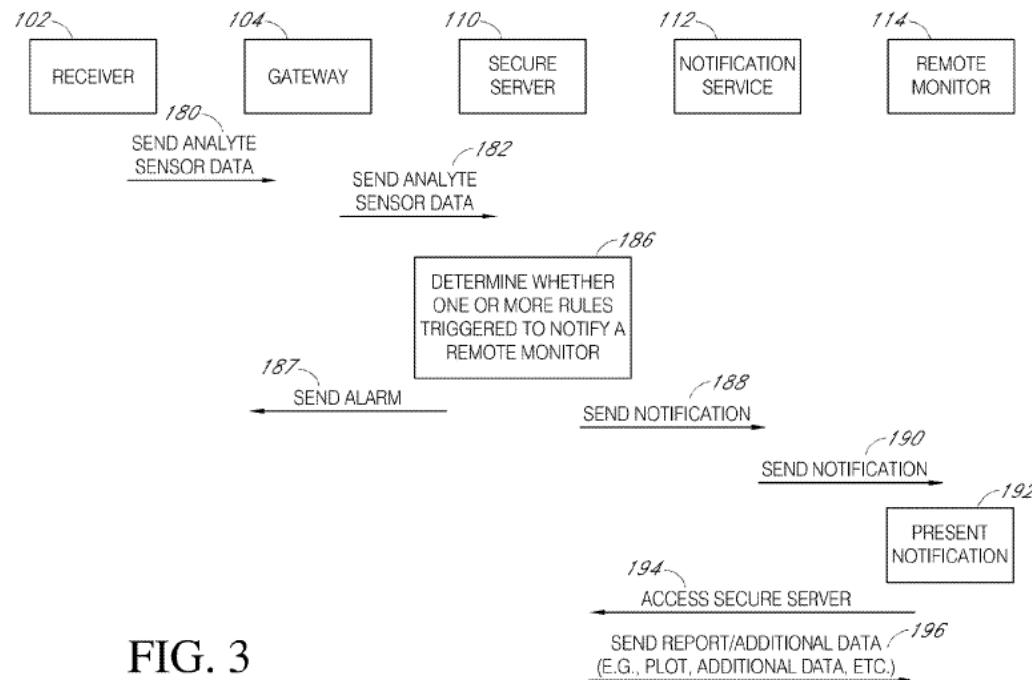


FIG. 3

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# Protecting the Software

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- Software for data collection
- Software for data analytics
  - Account for and analyze bad or unreliable data
  - Determine and transmit insight from data
    - Data visualization to deliver insight from data for hospitals and similarly situated patients
  - Details should be maintained as a trade secret

# What about Alice?

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- Laws changing quickly
  - New USPTO guidelines
- Lower risk than business method patents
  - Not previously done in analog world
- Describe the “practical application” in the specification

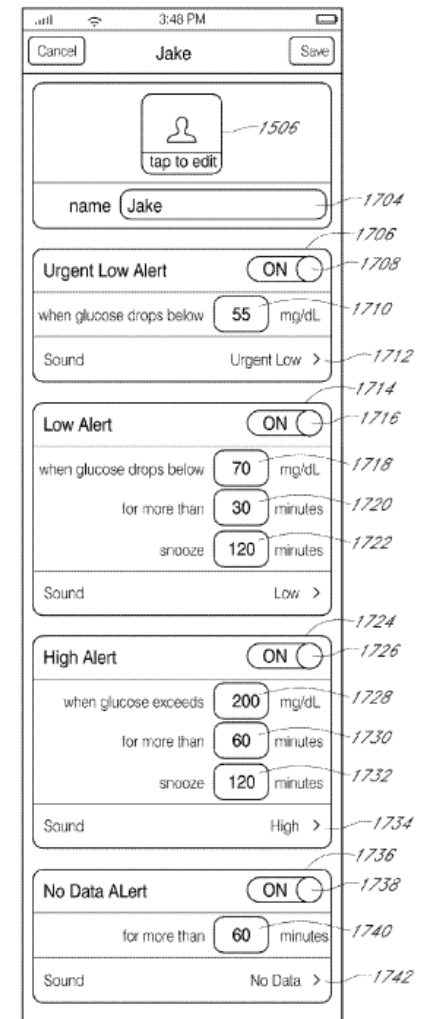
# What about Alice?

- Recite hardware in the claim
  - Device, processor, receiver, etc.
- Output more than saving data
  - Provide a report, alarm, change in sensitivity or modality, change in dose, etc.
- Claim scope matters

# Protecting the GUI

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- Utility patent for GUI
  - Federal Circuit has recently found many claims to a GUI to be eligible.
  - What is displayed
  - What happens when selected



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# Protecting the GUI

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- Design patents can claim static structure
  - Does not include the dynamic data (dashed out)
  - Bedside monitor
  - App for monitoring

Patricia Jones : West 4A 03:00 12/29/2009 (1:10)

<b>NIBP **</b> <b>120/80</b> SYS/DIA mmHg ( MAP 93 )	<b>STOP</b> <b>SYN</b> 160 90 <b>DIA</b> 90 50	<b>PULSE RATE</b> <b>110</b> 120 50 ♥/MIN Source = NIBP		
<b>SpO2 **</b> <b>97%</b> ( PI 19.3 )	<b>25</b> 100 95	<b>TEMPERATURE</b> <b>101.5°</b> °F ( 38.6° C ) 102 88		
<b>PATIENT</b> Adult	<b>HEIGHT</b> 72 inches	<b>WEIGHT</b> 197 lb	<b>PAIN</b> 3 <b>RR</b> 15 Br/M	<b>Save</b>

Home Patients Alarms Review Settings

# Method of Manufacturing and Use

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- Method of manufacturing claims are patent eligible worldwide
  - But difficult to police, so trade secret
- Methods of surgery and medical treatment
  - Patentable in the United States and Australia
  - Not in Europe, Japan, South Korea, or Canada
  - Sometimes can covert to “use” claims without mentioning human body
    - Manipulate device in novel way

# Trademarks

- Trademarks are registered to give competitors notice and prevent market confusion
- Should perform trademark search before worldwide filing
- Not all words are eligible
  - Descriptive – “GlucoseMonitor”
- Colors
  - Applications

# Trademarks

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- **Fanciful.** Made up words (e. g., Google, Xerox, Lego)
- **Arbitrary.** Common word that has no relation to the product. A relationship is formed through extensive marketing. (e.g., Apple, Subway, Tide, Amazon, Converse, Target)
- **Suggestive.** These are made up words or existing words that suggest some feature or benefit of the product. (e.g., EZMonitor)
- **Superlatives.** These are common words that imply excellence or some other positive image. (e.g., IntellegentRemote)

# HIPAA - Overview

- Who Should be in Compliance?
  - Does the device transmit Protected Health Information?
    - Individually identifiable
    - Consists of data regarding individual's health
  - Is entity subject to compliance with HIPAA?
    - Covered entities – health plans, health care clearinghouses, health care providers
    - Business associates – third party that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity

Covered Entity

Device Manufacturer

Other Third Parties  
(e.g., subcontractors)

# HIPAA – Compliance Requirements

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- Covered entity and business associate required to execute a business associate contract
  - Describe the permitted and required uses of PHI by the business associate;
  - Provide that the business associate will not use or disclose the PHI other than as permitted or required by the contract; and
  - Require the business associate to use appropriate safeguards to prevent a use or disclosure of the PHI
- Key issues:
  - Privacy
  - Security (also ties in FDA)

# Security

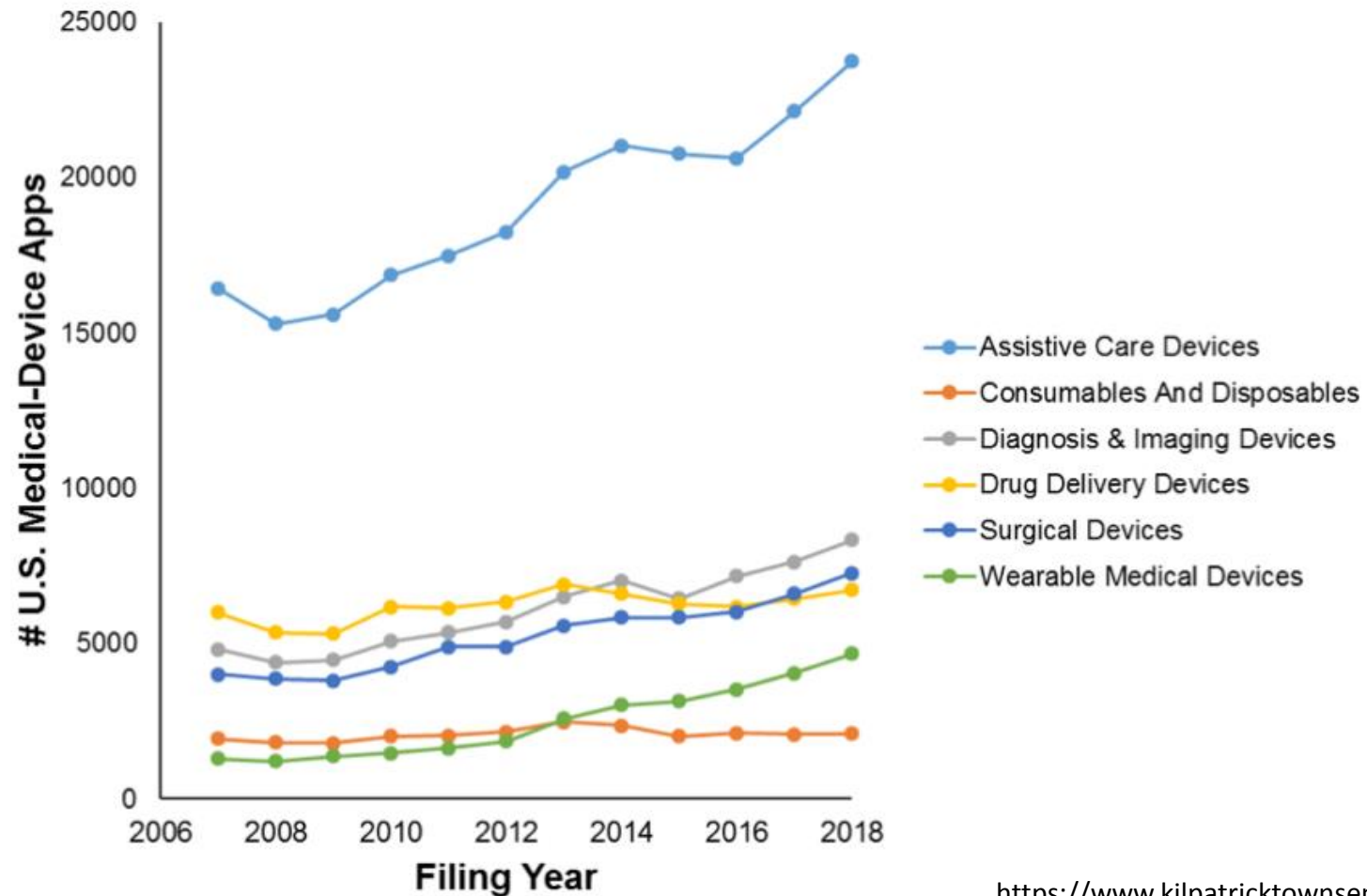
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## *HIPAA and FDA regulated*

- Connected medical devices incorporate software that is vulnerable to threats
- When medical device vulnerabilities are not addressed, this can serve as access points for entry into healthcare networks
  - Data confidentiality
  - Data integrity
  - Data availability
- Shared responsibility between healthcare facilities and providers and medical device manufacturers

# Increased Patent Filings

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<https://www.kilpatricktownsend.com/en/Insights/Publications/2019/4/PatentingTrendsStudy>

# Questions?

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# About BakerHostetler

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- About 950 attorneys in 14 domestic offices
- About 150 IP attorneys
  - More than 100 registered patent attorneys and agents
    - Including many former examiners, SPEs, and an APJ
  - Majority of about 4,000 applications filed per year for domestic clients
- Represent a broad range of companies and institutions, including pharmaceutical, medical device, communication, cloud computing, and manufacturing corporations.

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