Litigation Webinar Series: INSIGHTS
Our take on litigation and trial developments across the U.S.

Legal Challenges in Digital Health

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Overview

• Monthly
  • 3rd Wednesday at 1pm ET
  • Key Developments & Trends

• Housekeeping
  • CLE Contact: makarevich@fr.com
  • Questions
  • Materials: fishlitigationblog.com/webinars

• www.fr.com/digital-health
• Next webinar – September 17th
• #fishwebinar

Next in Series
Wednesday, September 17th
1:00 p.m. EST | Webinar
Supreme Court IP Cases
Agenda

• What is “Digital Health”?
• Legal challenges for Digital Health
  • Protection of IP
  • Regulatory issues
  • Privacy concerns
  • Litigation status
• Questions
What is Digital Health?

Medical Care Support

• EHRs / PHRs
• m-Health / e-Health
• HIEs
• Health Care IT

Medical Research and Development

• Analytics: genomics, proteomics, metabolomics
• Databases: public & private
What is Digital Health?

Consumer Devices
- Wearable Devices
- Wireless Sensors

Consumer Services
- Smart Phone and Tablet Apps
- Wellness Programs
- Social Networks
What is Digital Health?

**Medical Care Systems and Services:** Delivery of care, documentation, drug discovery and diagnostics

**Hardware:**
- Sensors
- Wireless
- Wearables

**Software:**
- Databases
- Analytics
- Apps

**Consumer Devices and Services:** Self-monitoring, fitness and wellness, social support, information
What is Digital Health?

Business is Expanding

- Venture funding increasing
- Exponential growth expected
- Technologies expected to be pervasive

Innovation is Everywhere

- Sponsored by computer giants
- Lots of start-up activity
What is Digital Health?

Investment in Digital Health

SOURCE: ROCK HEALTH
What is Digital Health?

Hotbeds for Investment

All data from StartUp Health Insights and infographic compiled by StartUp Health team: Steven McDonald, Polina Hanin, Kiyan Rajabi, Tanner Yager.
What is Digital Health?

Hot Consumer Examples

- Samsung S Health
- SIMBAND
- OWLET
- Q-Medic
- fitbit
- MyBrainSolutions
- 23andMe
- The Future of Corporate Wellness
- stridehealth
- HealthKit
- Chat with a Doctor
- strick

FISH.
What is Digital Health?

Hot Institutional Examples

- McKesson Cardiology™ ECG Management
  Designed to provide anytime, anywhere access and reporting of rest, stress and holter ECGs

- Numerate

- INGENUITY® Systems
  A QIAGEN® Company

- bina TECHNOLOGIES

- rmi Reflectance Medical Inc.

- vitalconnect

- genomic health oncotype DX®
  Breast Cancer Assay

- pacsgear

- practice fusion™
  Free, web-based Electronic Health Records

- proteus DIGITAL HEALTH
Legal Challenges: Protection of IP

Key Issues

• Options
  ✓ Patent
  ✓ Copyright
  ✓ Trade secret
  ✓ Trademark

• Challenges
  › Natural laws and software may not be eligible for patent
  › Software can be copyrighted, but databases cannot
  › Siloing of information limits its utility
  › Reputations unestablished
What is patent eligible subject matter?

- **35 U.S.C. § 101**: Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter ... may obtain a patent therefor ...

Patenting Software

- **In re Bilski**, 130 S.Ct. 3218 (2010)—Claims to methods of hedging risk in commodity trading invalid because directed to an abstract idea
- **Alice Corporation Pty. Ltd. v. CLS Bank International (tbd)**—Whether claims to computer-implemented inventions are directed to patent-eligible subject matter
Patenting Natural Laws

- *Mayo v. Prometheus*, 132 S.Ct. 1289 (March 20, 2012)—Method of monitoring levels of 6-thiopurine in blood, and adjusting dose of same, not patent eligible subject matter

- *Ass’n for Molecular Pathology v. Myriad Genetics*, 133 S.Ct. 2107 (June 13, 2013)—Isolated DNA involving a naturally occurring segment of DNA is not patent eligible subject matter, but synthetically created cDNA is eligible
Legal Challenges: Protection of IP

Protecting Data

  - “Compilations” are “formed by the collection and assembling of preexisting materials or of data that are selected, coordinated, or arranged in such a way that the resulting work as a whole constitutes an original work of authorship”
  - The copyright in a compilation or derivative work extends only to the material contributed by the author of such work, as distinguished from the preexisting material employed in the work
- Protection as a **trade secret** requires reasonable steps to keep the data in the database secret
  - E.g. restricting access by keeping database password-protected
Legal Challenges: Protection of IP

Using Trademark

- Marketing, Business, and The Future
  - The Trademark Spectrum – Generic, Descriptive, Suggestive, Arbitrary/Fanciful
  - Software – Don’t forget apps!
- Domain Name vs. Trademark
- New Generic Top-Level Domains
  - YOURBRAND.MEDICAL
  - YOURBRAND.APP
  - Examples: .APP, .MOBILE, .MEDICAL, .HEALTH
Wearable Wireless Devices

Glassware, for Google Glass
* EyeSight, by Prizmne: allows doctors and other medical professionals to transmit live POE video and audio to authorized computers and devices.
* Data translation system, by Augmedica: emerging system that would translate information from Glass’ A/V stream (such as information shared during a patient visit) directly into a patient’s electronic health record.
* A collaboration between Google and Philips aims to provide a patient’s vital signs so a doctor can perform surgery without having to look up and check them; also working on voice-controlled access to patient information while doctors is on the go around the hospital.
* Director, by Wearable Intelligence: a hands-free digital workflow system for performing standardized tests, exams or procedures that can be navigated with voice commands, hand gestures and touch actions.

First Warning System: early screening system for breast cancer that uses a small device placed under a bra to collect breast cell data, which is then run through predictive analytic software.

Wireless Ambulatory ECG, by iHealth: small unit attaches to user’s chest and monitors heart activity; can send data to devices and the cloud.

LifeVest, by Zoll: wearable defibrillator for patients at risk for sudden cardiac arrest.

CloudPhone 3G: wearable smartphone aimed at seniors and children, with voice-controlled dialing, an accelerometer that tracks physical activity throughout the day, transit monitoring, fall and motion detection and conference calling for families.

Dialog, by Artefact: small patch attaches to the body or is worn on a wristband; helps people with epilepsy understand their condition and make more informed decisions about how to take care of themselves.

Google contact lenses: prototype would monitor glucose levels for diabetics through their tears.

Eyes-On Glasses, by Eneva: uses multi-spectral imaging to allow clinicians to see veins below the skin, so they can deliver shots safely and on the first try.

Zen, by Zinc Software: sensor clips on to ear and sends user’s heart information to their smartphone, tablet or PC.

Inner Balance, by HeartMath: device made of an Apple connector and a wire with a sensor, which attaches to user’s ear to pick up their heart rate; also measures heart rate variability.

A small circuit board developed by scientists at the National Taiwan University fits into dentures, crowns, cavities or braces and keeps track of jaw motion. A sensor can figure out how much time a person spends speaking, chewing, drinking, coughing and smoking.

Wireless blood pressure monitor, by Withings: allows patients to take their blood pressure using a cuff and app, which stores all readings, syncs with the Withings Health Cloud and provides feedback on results.

Endotheliometer: device being developed at Lancaster University that measures activity within the endothelium, the layer of cells that coat the inside of the body’s blood vessels, the state of which is indicative of the overall state of the body.

LEGs: wearable sensor system that analyzes the user’s gait using motion capture technology, and generates reports demonstrating the patient’s progress toward measurable goals.

Graphic by Kathleen Keough/IDG News Service; sources: company websites; medcitynews.com; Forbes; modernhealthcare.com; psfk.com
The FDA has discretionary rules

- Medical Device Classifications; 510 (K) v. PMA
- **2007 Wireless Medical Guidance** – updated August 2013 to “nonbinding recommendations”
  
  ✓ Applies to “instrument…article including any component or accessory intended for use in the diagnosis of disease or other condition or in the cure, mitigation, treatment or prevention of disease…or intended to affect the structure or any function of the body…”
  
  ✓ “Accessory” takes on same classification as parent device
Legal Challenges: Regulatory Issues

The FDA has discretionary rules

• Sept. 2013 Guidance on Mobile Medical Apps
  ✓ Who is not regulated?
    o Manufacturers of mobile phones and similar devices not specifically promoted for medical applications
    o Distributors of medical apps who do not write software or engage in other FDA-regulated “manufacturing” activities
    o Creator of original idea of medical app would be regulated as “initial specifications developer,” unless another entity agrees to assume all FDA responsibility
  ✓ What is not a regulated medical device?
    o General fitness, health and wellness
Legal Challenges: Regulatory Issues

- Sept. 2013 Guidance on Mobile Medical Apps
  - What is not regulated under “enforcement discretion”
    - Self-manage disease (coaching/adherence) but no specific treatment suggestions
    - Organize and track patient health information but no recommendations
    - Match specific diagnosis/treatment to reference information to facilitate patient assessment
    - Document or communicate to healthcare providers medical condition
    - Simple calculations routinely used in clinical practice (body mass index, delivery date estimator)
    - Interact with PHR or EHR systems
Legal Challenges: Regulatory Issues

• Sept. 2013 Guidance on Mobile Medical Apps
  ✓ Categories of Regulated Software
    o Medical Device Data Systems
    o Transforms platform into regulated device
    o Controls another medical device
    o Perform patient-specific analysis and provide patient-specific diagnosis or treatment recommendations
Legal Challenges: Regulatory Issues

The FCC requirements

• Regulates radio communications, EMC, radiation safety, wireless power transfer
  ✓ Licensed: PCS/Cellular; private mobile; fixed microwave
  ✓ Unlicensed: WMTS, BTS, MDRS, UWB (medical imaging), MBAN, MMP (movement & control), WiFi / Bluetooth/ Zigbee, General Part 15
  ✓ Tradeoffs

• Test Procedures and Equipment Authorization require certification/verification

• Activities may be subject to marketing rules and enforcement, and may require waivers
EU Regulatory Programs

EU Spectrum Regulation

• R&TTE Directive (radio communications, EMC/Susceptibility, safety)
  ✓ Licensed transmitters
  ✓ Unlicensed short range devices (ERC Rec 70-03)
  ✓ CENELEC and ETSI standards
  ✓ Harmonization Issues

• Equipment Authorization
  ✓ Notified Body Testing
  ✓ Manufacturer DOC

• Enforcement
  ✓ R&TTE Safeguard Procedure ("substantial harm")
EU Regulatory Programs

EU Medical Device Regulation

- Medical Device Directive (93/42/EEC); Implantable Medical Device Directive (90/385/EEC)
- CEN and CENELEC Standards
- Equipment Authorization
  - Notified Body
  - DOC
- Mobile Medical Apps
  - EU medical device definition broader than FDA ("investigation of physiological process")
Legal Challenges: Privacy Concerns

Sensitive Health Data

• Increasing concerns with health data and new technologies, e.g., mobile and wearable devices, health software applications, storage in the cloud etc.
• Various federal and state laws protect medical data
• HIPAA
  ✓ Protected Health Information (PHI)
  ✓ Privacy Rule
  ✓ Security Rule
  ✓ Breach Notification
  ✓ Increasing Enforcement
• A company may not be a “covered entity” subject to HIPAA, but may be a “business associate” under HITECH
Legal Challenges: Privacy Concerns

Business Associates

• Business associates perform certain functions for or serve covered entities involving the use or disclosure of PHI
  • Data analysis, billing, benefit management, legal, financial etc.
• HITECH imposes HIPAA requirements on business associates
• Business associate contracts required, with specific provisions
• Your targeted buyers or partners might consider you a business associate and require HIPAA compliance
• Privacy and security “by design” – analyze these issues at the design stage
  ✓ Who are you sharing PHI with and who is sharing PHI with you?
  ✓ How are you and your business associates protecting PHI?
Legal Challenges: Litigation Status

Litigation is Happening Now

- Business litigation
  - trademark cases, unfair competition claims, and class actions
- Patent litigation
  - Competitors are getting and asserting patents
  - Many software patents foreshadow innovations that are now being developed and commercialized, and are being asserted by monetization entities
Legal Challenges: Litigation Status

Business Litigation

- **Fitbug Limited v. Fitbit, Inc.** (N.D.Cal., 3/29/2013) – alleging trademark infringement, as well as unfair competition and unfair business practices, for use of similar mark; trial just set for 2/9/15

- **Tompkins v. 23andMe, Inc. and others** (N.D.Cal., 11/27/2013) – class actions seeking damages for allegedly misleading claims about the tests’ ability to provide genetic information about diseases; motion to compel arbitration pending hearing
Legal Challenges: Litigation Status

Patent Litigation by Competitors

• **Ariosa v. Sequenom** (N.D. Cal., Oct. 30, 2013)—patents for detecting a paternally inherited nucleic acid of fetal origin in a maternal serum or plasma sample from a pregnant female; found invalid because *patent ineligible*

• **Adidas v. Under Armour** (D. Del., Feb. 2014)—patents on technology for location-aware fitness with information about routes and the user, including movement

• **MyMedicalRecords v. Allscripts** (C.D. Cal. 9/24/2013)—patents on methods for accessing private health records
Legal Challenges: Litigation Status

Patent Litigation by NPEs

• *iLife cases* (N.D. Tex., 12/6/2013)—multiple patents filed as early as 1999 on fall detection technology; asserted against 4 companies

• *My Health cases* (E.D. Texas, 4/2012, 2/2013, 6/2014)—patent providing information to remote user for monitoring and treating a health condition; asserted against 1, then 6, and now 18 defendants

• *Presqriber cases* (E.D. Texas, 5/8/2014)—patent filed 1995 on an interactive medication ordering system; asserted against 26 healthcare and/or software companies
Questions?
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Mark your calendar!

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Please send your NY CLE forms or questions about the webinar to Ellen at makarevich@fr.com.

A replay of the webinar will be available for viewing at http://fishlitigationblog.com.