MOBILE HEALTH TECHNOLOGIES FACE A CHANGING REGULATORY AND PATENT LANDSCAPE

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Electronic health and mobile health technologies represent important and rapidly growing segments of the medical device industry, with point-of-care diagnostics and personalized mobile applications becoming increasingly more common in clinical settings. As the technologies expand, the challenge of navigating the US Food and Drug Administration (FDA) regulatory environment becomes a necessary task for mobile health innovators looking to break into the market. Mobile medical technologies that perform functions such as diagnosing medical conditions, prescribing drugs, or ordering laboratory tests fall within the FDA regulatory framework and require FDA clearance prior to marketing. Developers of mobile health products must also establish a competitive edge with a strategic patent portfolio that protects core technology while exploring new patent areas and securing worldwide patent protection. Mobile health technology innovations will revolutionize the health care system, but companies hoping to capitalize on this boom must carefully navigate the changing regulatory and patent landscape.

Overview of eHealth and mHealth Technologies and Markets

Electronic health (eHealth) and mobile health are two relatively new terms. Generally, eHealth is the intersection of health care services and computer-based technology. eHealth has become the buzzword to describe anything related to health or health care that uses computers, mobile technology, or the Internet. Electronic health technologies are rapidly penetrating the US and global health care systems, and investments in software and digital health continue to increase annually.

Mobile health (mHealth) is a more specific term describing the use of apps and devices as a platform to provide electronic health care services. Common examples of mHealth devices include smartphones, tablets, next-generation watches, wearable medical devices, and any portable device capable of running medical software applications. Major smartphones such as the iPhone, Android phones, and BlackBerry feature apps covering a wide spectrum of health care services, from fitness and nutrition, to medical imaging, medication compliance, and physician-patient communication.

The foundation of the current mHealth market is software and apps developed for mobile platforms such as smartphones, as both providers and consumers seek more information, better health care delivery, and constant connectivity through mobile devices already in routine use. Physicians now use apps on tablets and their phones to access electronic health records and reference drug data to improve patient outcomes. Consumers also use mHealth technology to keep track of their individual health metrics, and more and more patients monitor their chronic conditions with mHealth technology. In addition to apps for preexisting devices, experts predict that related services and accessories, like sensors, medical watches, and wearable medical technology, will also become a significant revenue stream in the coming

years. The United States leads the world in the mHealth market, with Europe and Asia following closely.

Trends in Mobile Health Technologies

The recent growth and adoption of mobile health technologies has led to a number of notable trends including electronic bracelets or other monitors that track vital signs and upload information to a fitness data aggregator, electronic health record sharing platforms used across different medical specialties, and mail-in genetic testing tools that report results electronically. As mobile health technologies expand to cover more aspects of health care, some areas of eHealth and mHealth development poised for significant growth include health consumer engagement, personal health tools, health care practice management, and big data analytics.

Health consumer engagement technologies assist consumers trying to navigate the health care industry. The technology generally presents the consumer with questions and ultimately selects the best insurance or care option for that individual based on the user's responses to the questions. By empowering the consumer to compare costs and quality of health care services, the technology seeks to improve quality of care and help reduce overall health care costs. Other variants give consumers access to expert physicians to assist patients with their health care decisions, including selecting a doctor and choosing a course of treatment.

Personal health care tools give consumers access to data regarding their own health status. These tools include a wide array of offerings, ranging from body mass index calculators, calorie counters, and pedometers, to much more sophisticated options merging software with hardware accessories. Some of these gadgets, considered combination devices, combine a computer program or app with a physical device to measure glucose levels, blood pressure, and other vital data. Ideally, the technologies help consumers to be better informed regarding their health and well-being, promote healthier lifestyles, and help medical professionals manage and track their patients' chronic conditions to improve treatment compliance and medication adherence.

Health care practice management technologies help health care organizations improve and track their operational efficiency and quality of care. Examples of health care practice management technologies include time-tabling and scheduling software, and communication tools that link physicians and patients online or through mobile devices. Recently, electronic health records (EHR) are becoming more prevalent and an industry standard due to the Medicare and Medicaid EHR Incentive Programs and the Affordable Care Act (ACA). Clinical analytics is a growing field, as physicians, epidemiologists, and other professionals realize the value of collecting massive amounts of data during the Big Data revolution. Health care providers will continue to expand the use of electronic analytics tools and information databases to improve health care and lower costs.

US Regulatory Challenges

As eHealth and mHealth technologies quickly grew in complexity and prevalence, federal regulation of some of these evolving technologies by the FDA was lagging and unsettled. On September 25, 2013, the FDA issued its long-awaited Final Guidance for the introduction of mobile medical applications into the market. The FDA Final Guidance laid out a regulatory pathway regarding the applicability of the FDA regulatory review process and FDA enforcement to certain mHealth technologies. Developers of mobile medical apps should seek legal counsel to determine if their product requires FDA regulatory clearance before marketing, or if the app can be commercialized without clearance, as it may be in a category where the FDA intends to exercise enforcement discretion.

The FDA will require premarketing clearance or approval prior to commercialization for mobile apps that (1) qualify as medical devices in Class I and Class II requiring premarket clearance and for Class III as premarket approval, and (2) whose functionality includes potential risks to patient safety. Examples of mHealth apps that require FDA clearance include those apps that change a mobile device into a regulated medical device by adding attachments, display screens, sensors, or other hardware; or that function as an accessory to an existing medical device. The mobile app becomes a regulated medical device in that instance and must be cleared in accordance with the device classification of the transformed platform. FDA clearance is also required for mobile apps that connect to a medical device to control, display, store, analyze, or transmit patient-specific medical data. Finally, FDA clearance is required for mobile apps that conduct patient-specific analysis and offer patient-specific diagnosis and/or treatment recommendations, as these apps technically fall under the definition of a medical device and will receive a software classification. Standalone software used to analyze medical device data or transmit such information from a medical device will continue to be regulated by the FDA as an accessory to a medical device or as medical device software.

For the majority of mHealth apps, the FDA has chosen to exercise its enforcement discretion and will not subject most mobile apps to preclearance requirements. Mobile apps that do not offer direct diagnosis or treatments will not require FDA clearance, but will be subject to enforcement and recalls after the apps enter the market. For example, apps that help patients with information on how to manage chronic diseases or conditions (like asthma, diabetes, hypertension, and kidney disease, among others) without giving patient-specific diagnoses and treatments will not require FDA clearance prior to marketing. Apps that simply organize and track user health information, conditions, or treatments also will not require clearance by the FDA. Additionally, the FDA will not require clearance for apps that automate routine tasks for health care providers, or apps that allow patients or physicians to access Personal Health Record (PHR) or Electronic Health Record (EHR) systems.

If a mobile medical app falls within the agency's purview, the FDA recommends the app's manufacturers and developers comply with the Quality System 2 regulations, including good manufacturing practices, when developing and designing

the app. Just as with any regulated medical device, manufacturers should issue timely corrections to prevent patient and user harm due to errors or malfunctions. Manufacturers creating medical mobile apps that fall under an enforced FDA classification must comply with the applicable FDA device classification regulations.

Security and Privacy Concerns in Mobile Health

In addition to potential regulatory requirements, mobile health apps and mobile devices present a vast array of security and privacy concerns. On an individual level, mobile devices are often lost or stolen, setting up a potential security breach involving personal information including health data. Furthermore, mobile devices often use unsecured networks, which may allow unauthorized access or download malware, both of which increase security risks.

Health care providers are also not immune to the risks of security breaches. Although mobile health devices can make the health care system run more smoothly by providing lab results and images sooner and allowing providers to monitor their patients more efficiently, hospital systems and clinicians' mobile devices can become compromised through hacking, malware, or other means.

Patients' health information is governed by the 1996 Health Insurance Portability and Accountability Act (HIPAA), which sets forth standards for the use and disclosure of protected health information in addition to delineating civil penalties for violations. Entities covered by HIPAA include hospitals, doctors, medical billing services, and "business associates" who may receive access to protected health information. Covered entities must comply with the administrative, technical, and physical protective measures required by HIPAA to maintain the confidentiality and integrity of protected health information. In order to protect personal data, health care providers are using passwords, regularly updating their security software, installing remote wiping applications, and using secure networks to send and receive health information.

Consumers should take many of the same security measures to protect personal information, health or otherwise, on their mobile devices. Prudent medical app developers should keep data privacy in mind when creating new apps and ensure that adequate digital security is in place to protect consumer medical data.

Patent Protection Strategies

Mobile medical innovations emerge quickly and evolve rapidly, presenting challenges for obtaining patent protection. In order to stay ahead of competitors, mobile medical companies must pursue strategic patent protection for their innovations. The patent portfolio should protect the core technology of the innovation so that the innovator can secure funding and enjoy a competitive advantage in the market. Mobile medical devices present a special challenge because they often are used for the same purpose as their larger predecessors. Patent applications, therefore, need to focus on the novel, improved, and different features that allow the device or app to be mobile. It is also prudent to investigate ways to patent "white space," or areas not already covered by patents. By leveraging patent white space, mHealth developers can implement patent strategy for building core technology, future expansion, and design-around opportunities. Mobile technology is becoming more international in scope, so companies should also consider filing international patent applications both in countries with large markets and in countries containing competitors' manufacturing facilities.

Cross-licensing with competitors is another valuable option for many mobile device companies. When two or more companies have mutually overlapping patents, meaning that practicing each invention necessarily infringes the other, it makes sense to cross-license so the companies can market their own inventions without a fear of legal action.

Impact of Patent Reform

Patent reform is sweeping the United States and Europe, and mHealth companies must adapt their patent strategies to secure intellectual property protection. In 2013, multiple new provisions of the America Invents Act (AIA), the first major reform to patent law within the United States since 1952, changed the patent system from first to invent to first inventor to file. Thus, mHealth developers should file patent applications early in the development process before any public disclosure. The dramatic revisions of the AIA along with the future changes of the anticipated 2015 launch of Europe's Unitary Patent and Unified Patent Court are closing the gap between the two regions' patent laws. Such fundamental alterations in intellectual property protection have companies reevaluating how to best protect and enforce mHealth innovations. Developers of mobile health technologies should work with strategic patent counsel early in the development process to maximize patent protection in the United

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States and around the world.

Watch Out for Patent Trolls

With the growing success of eHealth and mHealth technologies, patent trolls will not be far behind. Also known as patent assertion entities or nonpracticing entities (NPEs), patent trolls are businesses that acquire patents for the purpose of collecting royalties from companies whose products or practices allegedly infringe patents owned by the NPE. In 2013, patent trolls invaded the medical technology industry, filing numerous patent infringement lawsuits against medical device companies. As the funding and profits in the mobile health technology sector increase, so will the unwanted attention of patent trolls.

By taking careful steps to protect mobile medical technology innovations through patents, companies can reap the financial and legal rewards of a successful strategy and minimize the potential losses caused by patent trolls. Securing patent protection is a key to success in the rapidly evolving mobile health technology market.

Conclusion

The mobile health and electronic health technology markets are exploding with new innovations that face a changing regulatory and patent environment. In the coming years, mobile medical technology will grow substantially as health and medical apps become more prevalent, refined, and user-friendly. Investments in mHealth and eHealth and are also increasing as both medical providers and the general public seek efficient ways to maintain and monitor health and improve the health care system. The recent FDA Final Guidance provides greater certainty on the regulatory requirements of mobile medical technologies. Additionally, mobile medical app developers should pursue strategic patent protection amid patent reform for notable innovations and improvements. Electronic and mobile health technologies are a fertile space for forward-thinking companies, and careful navigation of the evolving regulatory and patent landscape is crucial to maintain a competitive edge. ◆