Digital Health Law Update—An Overview of Notable Happenings Affecting Digital Health, Mobile Health, and Telemedicine
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Industry Insights

Are You Ready for Digital-Health Patent Disputes? Getting Strong Patents and Challenging Weak Ones in the Evolving Minefield of U.S. Patent Law

by Douglas H. Pearson, Greg Castanias, Mark Paulson, and Vishal Khatri

With exponential growth occurring in the availability of telemedicine and other digital health products and services, patent disputes are sure to erupt. A recent example is a patent suit between two telemedicine providers, which originally involved one party filing an *inter partes* review ("IPR") petition with the U.S. Patent and Trademark Office ("USPTO") to challenge the validity of the other's patent. Use of the IPR proceeding reflects changes to the U.S. patent law made possible by the America Invents Act, which became effective in 2012.

With the ability to challenge the validity of patents in both federal courts and the USPTO, the need for patent owners to acquire strong patents, and the need for challengers to understand likely areas of weakness, are more important than ever. The terrain is particularly treacherous for computer-implemented inventions (also called software inventions) in light of several recent court decisions addressing, among other things, the subject matter eligible for patenting (*Alice Corporation Pty. Ltd. v. CLS Bank International, et al.*), whether direct infringement must be attributable to a single entity (*Akamai Techs., Inc. v. Limelight Networks, Inc.*), and the effect on patent validity/scope of an unintended

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Detailed Contact Information

UPCOMING EVENTS

American Telemedicine Association Fall Forum
September 16–18, 2015
Washington, D.C.
More Information

September 11, 2015: John Kirsner will speak at Navigant's Clinically Integrated Network Roundtable in Chicago.

October 21, 2015: Maureen Bennett will give a presentation on *International Clinical Research Issues* to the Boston Bar

"means" interpretation (*Williamson v. Citrix Online, LLC*). While the challenges facing digital health patent holders can be significant given these recent court rulings, they can be overcome in many instances with an eye toward good claim drafting for new and pending patent applications and through possible use of the "reissue" process at the USPTO to correct patent claims before asserting the patent in litigation.

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Federal Features

21st Century Cures—On July 10, 2015, the U.S. House of Representatives passed H.R. 6, the 21st Century Cures Act, focused on reducing regulatory obstacles associated with new pharmaceuticals and medical devices and other innovative therapies. The House bill was approved by a vote of 344–77, and although a companion bill is pending in the Senate, it has yet to advance beyond the committee level. The House action follows months of congressional hearings and negotiations among policymakers and related stakeholders, including with respect to digital health measures. The final bill addresses telehealth mostly in the abstract by requiring the Centers for Medicare & Medicaid Services ("CMS") and the Medicare Payment Advisory Committee (known as MedPac) to submit information to congressional committees regarding barriers to the expansion of telehealth services, results of Medicare telehealth pilot projects, and recommendations for diagnosis and treatment codes that should be covered by telehealth reimbursement. In June 2015, the American Telemedicine Association published recommendations in an effort to bolster the bill's telehealth provisions, including proposals to waive Medicare telehealth restrictions for Accountable Care Organizations ("ACOs") and to align CMS's policies for remote patient monitoring with recent developments in chronic care management services, but the final bill did not feature these provisions. Discussion of telehealth policies could resurface if the Senate considers counterpart legislation.

MSSP "Enabling Technologies"—In June 2015, CMS issued a final rule implementing changes to the Medicare Shared Savings Program ("MSSP"). The rule includes data sharing policies to help ACOs more easily access patient data and encourage greater coordination of care. Under the rule, "enabling technologies" may include electronic health records and other health IT tools; telehealth services, such as remote patient monitoring; electronic exchange of health information; and other electronic tools to engage beneficiaries in their care. The changes are effective November 1, 2015.

Telehealth Legislation—Congress has seen a recent flurry of other bills related to telehealth. Last month, Reps. Mike Thompson (D-CA) and Gregg Harper (R-MS) introduced H.R. 2948, the Medicare Telehealth Parity Act of 2015, resurrecting prior proposals by Congress to put telehealth services on a path toward Medicare reimbursement parity with in-person health care. Also, a group led by Reps. Thompson and Morgan Griffith (R-VA) has introduced H.R. 2799, the Furthering Access to Stroke Telemedicine (FAST) Act, aimed at expanding access to telestroke treatments. Companion legislation was introduced in the Senate in May 2015. Additionally, Sens. Mark Warner (D-VA), Johnny Isakson (R-GA), and others have proposed S. 1549, which features proposals for coverage of 24-hour access emergency support via telemedicine or telephone as part of "advanced illness care coordination services."

EHR/EDC Integration Projects—In June 2015, the Food and Drug Administration ("FDA") announced plans for pilot projects aimed at integrating the often "siloed" data systems used in patient care and clinical research. Electronic health records ("EHRs") are the mainstay of health care practitioners, whereas clinical research for pharmaceutical

Association's Health Law Education Committee.

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products increasingly involves data collection and analysis through electronic data capture ("EDC") approaches. FDA's notice requests applications from stakeholders interested in participating in the pilot projects and general comments regarding the use of standards-based technology solutions for eliminating duplication in data capturing and transmission, as well as the facilitation of remote monitoring of data to reduce onsite visits. Applications and comments are due **August 10, 2015**.

State Summaries

Interstate Medical Licensure Compact—In July 2015, Illinois officially joined the Interstate Medical License Compact ("Compact"), becoming the 11th state to adopt the policy initiative that relaxes certain administrative requirements of licensure for physicians practicing medicine across state lines. Earlier this summer, Minnesota and Nevada adopted the Compact. Follow the status of these state bills and learn about the Compact at licenseportability.org.

Connecticut—On June 23, 2015, Connecticut's governor signed a new law," Concerning the Facilitation of Telehealth." Effective October 1, 2015, each provider (including physicians and non-physician providers) furnishing services via telehealth to patients in Connecticut must meet certain requirements set out in the statute, including, among others, a specific patient consent, identification of the provider's license number and contact information, and access to the patient's medical record.

Delaware—On July 7, 2015, Delaware enacted a new statute regarding telemedicine services. Effective immediately, the legislation sets out several notable requirements for telemedicine providers, including disclosure of the provider's identity and credentials, patient consent, the provision of a written summary to the patient, and, where the standard of care requires, either an in-person examination or both an audio and visual communication prior to diagnosis and treatment. In contrast to many other similar recent state actions, the Delaware law allows for the prescription of controlled substances through telemedicine in certain circumstances.

Iowa—In June 2015, the Iowa Supreme Court invalidated a recent rule by the state's medical board that had required physicians to conduct in-person examinations prior to administering abortion-inducing drugs. In the opinion, the court held that the rule violates the state constitution by placing an "undue burden" on women located in remote areas, and it also noted that the state already allows telemedicine in other situations.

Maine—In June 2015, the governor of Maine signed a new law allowing the state medical board to register out-of-state licensed physicians to provide medical services via interstate telemedicine to patients located in Maine, if certain requirements are met. The law goes into effect September 15, 2015.

New Hampshire—Effective September 11, 2015, providers delivering telemedicine services in New Hampshire will need to comply with a statute signed into law last month. In particular, the new statute specifies that prescribing without a physician–patient relationship is unprofessional conduct subject to discipline (noting that a physician–patient relationship can be established by either in-person or face-to-face, real-time communication). The statute also limits the prescribing of certain controlled substances based solely on a telemedicine examination.

Reimbursement Review

State Reimbursement—Legislatures in the following states approved telehealth reimbursement measures: Connecticut, Delaware, New Hampshire, Oregon, Texas, and Vermont.

Global Happenings

Data Protection Opinion on Mobile Health
In May 2015, the European Data Protection Supervisor ("EDPS") published an opinion regarding data protection in the age of technological innovation. The opinion aims at drawing attention to the most relevant aspects of data protection for mobile health ("mHealth") that are often, according to the EDPS, overlooked or underestimated. By issuing this opinion, the EDPS hopes to enhance compliance with existing data protection rules and ensure consistent application of such rules. The EDPS makes four key recommendations:

- In future mHealth policymaking, the EU legislator should foster accountability and allocation of responsibility to those involved in the design, supply, and functioning of apps (including designers and device manufacturers);
- App designers and publishers should design devices and apps to increase transparency and information in relation to data processing and avoid collecting more data than necessary to perform the expected function by embedding privacy and data protection settings in the design;
- Industry should utilize "Big Data" in mHealth to benefit app users, as opposed to using it for potentially harmful practices such as discriminatory profiling; and
- The EU legislator should enhance data security and encourage both the application of privacy by design and the development of building blocks and tools.

Finally, the EDPS explains that because the sector is still largely unregulated, data protection principles and guidance are needed to increase legal certainty and trust in mHealth, and such guidance will contribute to the full development of the mHealth sector.

Health Care Sector Comes Out on Top in Data Protection Eurobarometer Survey
On June 24, 2015, the European Commission published the results of its Data Protection Eurobarometer survey, which was conducted in March 2015. During the course of the survey, almost 28,000 face-to-face interviews were carried out across the European Union with the aim of studying the perceptions of EU citizens on data protection. Although the results show public trust in digital environments remains low, with two-thirds of respondents expressing concern about a lack of control over online information, the health care sector is the most trusted of any sector. Nearly three-quarters of respondents said that they trusted hospitals and medical institutions to protect their personal data, although this figure has declined by 4 percent since the 2010 survey. In contrast, six out of 10 respondents say they do not trust phone companies and internet service providers. The results of the survey will be used to finalize the EU data protection reform.

European Code Related to Privacy and Security in mHealth
The European Commission recently announced plans for a Europe-wide, industry-led Code of Conduct for privacy and security in the mHealth sector. The objective of the Code is to foster citizens' trust in mHealth apps and raise awareness of and facilitate compliance with European data protection rules for app developers. The Code is part of a number of ongoing initiatives from the European Commission in mHealth following a recent industry-wide consultation. Cristiana Spontoni and Indradeep Bhattacharya recently participated in a Q&A with the journal *E-health Law and Policy*, discussing the Code and what it could mean for the mHealth sector across Europe.

Announcements

The American Bar Association recently published a book titled *What Is Telemedicine?*, coauthored by Jones Day partner Alexis Gilroy.

In June 2015, Jones Day partners Rebekah Plowman and Gerry Griffith and associate Michele Goodman wrote an article discussing the Department of Health and Human Services, Office of Inspector General's recent fraud alert concerning medical directorships and other compensation arrangements for physicians.

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Abstract Ideas. In *Alice Corporation Pty. Ltd. v. CLS Bank International, et al*., the U.S. Supreme Court set out in June 2014 a two-part test for whether subject matter is eligible for patenting in the first place, which is different from the more commonly known hurdles of novelty and nonobviousness. The test has been applied with devastating effect by district courts and the USPTO to invalidate patents or reject patent claims on grounds that they claim no more than general computer implementations of abstract ideas. With little guidance from the upper courts on (i) what constitutes an "abstract idea" and (ii) what constitutes "significantly more" than the abstract idea under the two-part test, lower courts and the USPTO have struggled. As a practical matter, if the patent claims are not

sufficiently technical and are not rooted in computer technology, and instead recite mere implementation of well-known concepts with a general-purpose computer, the claims are likely vulnerable under *Alice*. While this presents a challenge for those trying to get patent applications on software inventions granted by the USPTO, many issues can be overcome with careful claim drafting. *Alice* issues can be devastating, however, to patents that were granted before *Alice* and its recent predecessor cases, and these patents may be candidates for the "reissue" process at the USPTO to have patent claims corrected and reissued before assertion in litigation.

Divided Infringement. The Federal Circuit ruled in May 2015 in *Akamai Techs., Inc. v. Limelight Networks, Inc*. that direct infringement does not exist where the accused acts are not *attributable to a single entity*, i.e., are not carried by a single actor, or are not carried out by multiple actors in an agency relationship, contractual relationship, or joint venture. This ruling followed the Supreme Court's decision in June 2014 in *Limelight Networks, Inc. v. Akamai Technologies, Inc*., where the Supreme Court refused to find indirect patent infringement where there was no underlying direct patent infringement *attributable to a single entity*. In this case, Akamai had sued Limelight for induced infringement based on the *aggregate* activities of Limelight and its customers, and although it initially won at the district court and the Federal Circuit, it ultimately lost based on the two subsequent decisions noted above. The cases underscore the importance of drafting patent claims in a manner to be attributable to a single entity, which is certainly possible in digital health and telemedicine contexts where the inventions may involve the acts of multiple entities. Granted patents that may suffer from divided infringement issues may be candidates for reissue prior to assertion in litigation.

"Means" Interpretation. Under longstanding precedent, when a patent claim has recited in a claim element "means" for carrying out a particular function, there has been a rebuttable presumption that the claim element should be interpreted as a "means-plus-function" element, which by statute limits the scope of the element to the specific structure disclosed in the patent specification for carrying out the claimed function and to equivalents of the disclosed structure. Likewise, there has been a strong presumption that this statutory claim interpretation did *not* apply where the claim did not recite the word "means." In June 2015 in *Williamson v. Citrix Online, LLC*, the Federal Circuit overruled precedent regarding the latter and held that the standard is whether "the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure." Where a claim element is found to not satisfy the standard (because it recites primarily functional, as opposed to structural, subject matter), the statutory "means" construction applies even if the claim element does not use the word "means." This ruling could have significant impact for digital-health patents and applications where the claim elements are often recited in very functional terms (as opposed to structural terms). On one hand, it could result in certain claim elements being interpreted more narrowly than intended. On the other, it could result in some claims being held invalid as indefinite on grounds that the patent specification does not disclose sufficient structure for carrying out the claimed function. While potential issues may be remedied for patent applications that are pending, patents that have already been granted and that are believed to be vulnerable may be candidates for reissue.

For additional information, see other Jones Day *Alerts* and *Commentaries*:

Alice Corp. v. CLS Bank: Did the Supreme Court Sign the Warrant for the "Death of Hundreds of Thousands of Patents"?

Software Inventions—Keeping it Eligible

Divided Federal Circuit Panel Stands by the Single Entity Rule for Direct Patent Infringement

Federal Circuit Upends Presumption for Means-Plus-Function Claiming

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