Standard-Essential Patent Licensing Comes to Medtech

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Connected technology products are a part of daily life. Connectivity standards – such as 5G and Wi-Fi – provide a common language that allows products from different manufacturers to communicate with each other. But beyond the mundane household tasks of your refrigerator alerting your smartphone that you are out of milk, such standards are increasingly being used to facilitate medical care, including, for example, in wearable or implanted devices that can report patient information to healthcare providers in real time, telehealth appointments with medical professionals, and remote surgical proceedings. This network of medical devices, hardware, and software that are interconnected through the internet (often by way of connectivity standards) is referred to as the Internet of Medical Things (IoMT) – a subset of the Internet of Things (IoT) to which your talking refrigerator belongs.

The increasing use of connectivity standards in the development of the IoMT promises to improve the quality of health care. Patients, for example, can benefit by having access to a wider array of caregivers when geography is not a limiting factor. Patient outcomes can also improve when health data is continuously monitored to aid in preventative care and early diagnosis of medical problems, as well as identifying a drug's optimum dosing regimen for a patient.

But for the potential benefits, adopting connectivity standards in a new IoMT product is not without risk to companies. As happened with smartphones and more recently with the automotive industry, the convergence of connectivity standards – particularly cellular – with new technology can lead to conflict and litigation. Incumbent cellular companies and patent assertion entities holding patents that are claimed to be "essential" to using industry standards can employ costly and disruptive tactics in pursuing licensing royalties for their patents. Understanding these dynamics is critical to ensure important IoMT products can be brought to market, and importantly, stay on the market for the benefit of patients.

This article provides background on patent issues that arise with using connectivity standards, explores the growth of using such standards in medical care, and concludes with an overview of issues that those in the medical industry should have in mind as they begin to use standards.

STANDARD SETTING AND STANDARD ESSENTIAL PATENTS

Industry standards are generally set through a process in which members of a standard-setting organization (SSO) propose technology for inclusion in the standard. Companies making proposals have often sought patent protection covering the technology they propose to be included in the standard. When technology is chosen for the standard, it becomes "essential" or necessary to using the standard. Accordingly, patents covering standardized technology are referred to as "standard essential patents" or SEPs.

Even if essential to using a standard, SEPs do not necessarily cover important inventions. As the U.S. Court of Appeals for the Federal Circuit has observed, "[w]hen a technology is incorporated into a standard, it is typically chosen from among different options. Once incorporated and widely adopted, that technology is not always used because it is the best or the only option; it is used because its use is necessary to comply with the standard."[1] But no matter their technological significance, SEPs nonetheless gain importance by virtue of the leverage the standard can confer on their owners. Previously available alternative technologies are eliminated through the process of standardization, as users of a standard can only use the standardized technology. Users of a standard then become dependent on being able to practice SEPs. After patented

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technology is incorporated into a standard, "the patent holder is in a position to 'hold up' industry participants from implementing the standard."[2] SEP holders can exploit the substantial investments that potential licensees have made in developing products that use standards to obtain unreasonable licensing terms. To thwart such conduct and seek to enhance competition, many SSOs adopt intellectual property rights policies under which a SEP holder voluntarily agrees to license its SEPs on "fair, reasonable, and non-discriminatory" or FRAND terms and conditions to licensees. Making this FRAND commitment is the quid pro quo of being able to have technology selected for inclusion in the standard, a development that benefits licensors by dramatically increasing their pool of potential licensees.[3]

Even with the existence of FRAND commitments, though, there continues to be significant SEP litigation about what constitutes FRAND terms, with often starkly divergent views between SEP holders and licensees. Moreover, despite making commitments to license on FRAND terms, some SEP holders seek to enjoin potential licensees to increase their leverage in negotiations.

THE GROWTH OF MEDTECH AND THE IoMT

As described above, there are myriad ways in which the use of connectivity standards is increasing in medical care. The COVID-19 pandemic both highlighted the benefits and hastened the adoption of increased connectivity in medical care. For example, one study found that telehealth appointments jumped from 0.3% of medical contacts from March to June in 2019 to 23.6% of contacts for the same months in 2020.[4]

Already the market for connected medical devices is huge and only expected to increase over time. Estimates vary, but one assessment suggests the IoMT grew from $64.48 billion in 2023 to $79.64 billion in 2024, and is forecast to grow to $192.02 billion in 2028.[5] Not surprisingly given the figures involved and the expected growth, there have already been significant efforts in patenting focused on connectivity standards and medtech. One analysis found that patents declared as essential or potentially essential to SSOs that described healthcare applications increased tenfold from 2016 to 2021, with a total of over 4,000 such declarations in 2021.[6]

CONVERGENCE CAUSES DISPUTES

The convergence of the medical industry with connectivity standards – particularly cellular – is not without risk for the medical industry. The convergence of cellular technology with a new industry has repeatedly led to disputes and extensive litigation because of conflict between competing business practices.

The smartphone patent wars that occurred for much of the 2010s arose because of the advent of smartphones that used cellular technology in new products. These disputes often pitted incumbent cellular companies against new cellular entrants with backgrounds in computing. The conflict created by this convergence of industries was profound. Incumbent cellular phone companies lost sales to new entrants that used non-standardized innovations in their products. Falling behind in product sales, the incumbent cellular companies looked to apply old patent licensing practices to the new entrants that were met with significant resistance. While charging a royalty rate for cellular SEPs based on the percentage of the price of a "dumb" phone may have been sufficiently tied to the value of cellular connectivity, smartphone suppliers resisted a similar approach for more expensive products with many innovations that were not cellular dependent. And these tensions played out with huge sums at stake as smartphone sales exploded, leading to extensive litigation in courts around the world.

More recently, as the use of cellular communications in cars has become widespread, this convergence has again led to significant disputes. The automotive industry has come into conflict with many of the same incumbent cellular SEP licensors over the amounts that they seek to charge for their SEPs and their refusal to license the component suppliers that provide the baseband chips that provide cellular functionality to car manufacturers rather than car manufacturers themselves. As with the smartphone wars, these disputes have led to significant litigation. Many of these disputes have involved SEP holders seeking injunctions against car manufacturers in Germany, where the courts have taken a permissive approach to granting SEP injunctions notwithstanding that FRAND commitments should limit the availability of injunctive relief.

MEDTECH APPEARS POISED FOR INCREASED LICENSING DISPUTES

The use of connectivity standards, such as cellular and Wi-Fi, in medical devices appears poised to create the same conflict as occurred with smartphones and in the automotive industry. As before, a new industry is adopting technology into converged products and services, which will engender disputes about the appropriate means to determine FRAND royalties. In particular, just as with smartphones and cars, there will undoubtedly be fights about how much value a cellular connection brings to a given product and how much value is independent of the ability to connect. Likewise, there are bound to be disputes about whether component suppliers – such as providers of baseband chips that supply cellular functionality – should be licensed or whether end product suppliers are appropriate licensees.

One potential difference from the experience with smartphones and cars is that the IoMT will involve not just large and established medical companies but also smaller and medium enterprises (SMEs). Such SMEs may be less well equipped to handle aggressive demands and strategies of SEP licensors than larger players that have greater resources to devote to understanding SEP licensing and litigation. A study of SEP licensing conducted for the European Commission highlights the challenges they face. As one example, a supplier of medical devices that wanted to use cellular connectivity for remote patient monitoring needed certainty about the cost of cellular SEP licenses to evaluate whether to use cellular connectivity before making the lengthy and costly investments in product development, performing clinical trials, and obtaining regulatory approval.[7] The company reported concerns about its ability to determine aggregate costs for cellular SEPs, negotiate licenses for these patents, and also the disruptive impact that an injunction could have on its product launch.

PRACTICAL CONSIDERATIONS FOR MEDTECH COMPANIES USING STANDARDS

As medical technology companies begin using connectivity standards, the following are some practical considerations about how they can prepare for SEP disputes:

- *Inventory Standards in Use in Current Products or Services and Understand IP Obligations or Benefits From Suppliers*. It pays to begin preparing early for SEP assertions by understanding what standards are being used or will be used in future products. Further, it is important to understand the extent to which suppliers of components that provide standardized functionality – e.g., cellular baseband chips – provide indemnification rights or may pass through patent rights to customers by virtue of license agreements with SEP holders.

- *Push for Transparency in FRAND Terms to Overcome Information Asymmetry*. SEP holders can claim that they have standard FRAND rates that they charge all licensees. Litigation has revealed that is often not the case, and there may be one royalty rate charged to smaller, less sophisticated players and lower rates charged to larger, more sophisticated licensees.[8] SEP holders will also claim that confidentiality obligations prevent them from providing information about their license terms, apart from describing their standard terms. It is critical to push SEP holders to demonstrate that the rates they are seeking are FRAND, both by providing a cogent explanation for how the rates are derived and comply with FRAND and by offering tangible proof they are the prevailing rates paid by similarly-situated licensees. While confidentiality obligations may prevent SEP holders from providing copies of licenses to potential licensees, there can be creative ways to use anonymized information to provide such confirmation.

- *Understand the Impact of Negotiation Conduct on Litigation*. The SEP negotiation record and licensing conduct is often crucial to establish a licensee's "willingness" to enter a FRAND license, which some courts consider as a requirement for potential licensees to defend against injunction threats. Demonstrating proactive engagement and responsiveness during negotiations, as well as developing a justifiable and reasoned counteroffer is key in this effort.

- *Keep Up With the Changing Global SEP Landscape*. As a corollary to the point above, it is important to understand how different jurisdictions around

the world are addressing SEP disputes to properly calibrate interactions during negotiations – e.g., how different courts assess "willingness." Such an understanding is also critical to understand the likely litigation strategy of SEP holders and to determine a counterstrategy, which may include proactive litigation or contributing your own SEPs to the standardization process.

- *Recognize the Future Implications of Any License Signed Today*. Licensees must recognize that the SEP licenses they enter into today can become crucial evidence in future litigation to help courts assess what is FRAND. Accordingly, licenses cannot be viewed on a one-off basis and instead must also be assessed for how the rate paid translates when viewed against all the potential SEPs for a given standard.

Notes

1. Ericsson, Inc. v. D-Link Sys., Inc., 773 F.3d 1201, 1233 (Fed. Cir. 2014).
2. Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 310 (3d Cir. 2007).
3. U.S. FTC Commissioner Rebecca Kelly Slaughter, SEPs, Antitrust, and the FTC at 3-4 (Oct. 29, 2021), available at https://www.ftc.gov/system/files/documents/public_statements/1598103/commissioner_slaughter_ansi_102921_final_to_pdf.pdf.
4. Jonathan Weiner et al., In-Person and Telehealth Ambulatory Contacts and Costs in a Large US Insured Cohort Before and During the COVID-19 Pandemic, JAMA Netw Open, Mar. 1, 2021.
5. The Business Research Company, Global Internet of Medical Things Iomt Market Size 2024, Forecast to 2033, available at https://www.thebusinessresearchcompany.com/market-insights/internet-of-medical-things-iomt-market-2024.
6. Tim Pohlmann, Analysis of patents, SEPs and standards in the smart healthcare sector, IAM, Mar. 16, 2022.
7. European Commission, Commission Staff Working Document – Impact Assessment Report at 15 (Apr. 27, 2023).
8. E.g., InterDigital Technology Corp. v. Lenovo Group Ltd. ¶ 516 [2023] EWHC 539 (Pat.) (finding that "InterDigital's 'program rates' . . . were paid only by the smallest and least sophisticated licensees," while others obtained "volume discounts" that significantly decreased the rates they paid).