ConnectedHealthInitiative

Healthcare and Standard Essential Patents

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I. Introduction

The integration of standardized technologies into healthcare technology and medical devices has revolutionized the delivery of care, enabling real-time data exchange, seamless interoperability, and improved patient outcomes. From wireless connectivity protocols like Wi-Fi and Bluetooth Low Energy to data exchange frameworks such as FHIR and HL7, standards have become the backbone of modern healthcare systems. However, the adoption of standardized technologies comes with significant challenges, particularly in the realm of standard-essential patents (SEPs). These patents, which become "essential" if the technologies they read on are included in the standard, can create artificially inflated market power that can disrupt competition, stifle innovation, and escalate costs for medical device manufacturers and healthcare providers. The stakes are especially high in healthcare, where delays or inefficiencies in deploying critical devices can directly impact patient care.

II. Technical Standards and Their Applications in Healthcare Technology and Medical Devices

Technical standards allow manufacturers to produce interoperable equipment by defining common protocols and specifications. Standards are ubiquitous in the modern world and include interoperability standards like 5G, Wi-Fi, and Bluetooth. Standards reduce the need for direct coordination during the development process because each participant can design products around the agreed-upon specifications. Standards are developed by standard development organizations (SDOs) which involve broad collaboration from industry stakeholders who work to identify and solve technical challenges necessary to establish uniform interoperability and product compatibility.

A. Function and Development of Standard Essential Patents

Standardization is particularly effective when an industry-wide uniform solution offers greater benefits than rapidly evolving, non-compatible technologies. In situations where the cost of frequent upgrades is high, and the advantages of such upgrades are limited, a stable, standardized

foundation tends to serve the market more effectively.[1] In such cases, the value of the technology is significantly enhanced by the positive network externalities created through standardization—on its own, it may have little standalone utility.[2] By agreeing on these shared specifications, companies can spread the cost of establishing the standard across an industry while mitigating the risk of it not being adopted and reducing redundant development efforts that would arise from parallel development of competing proprietary solutions.[3]

Although the adoption of a standard can slow certain aspects of "upstream" innovation—since radical or non-backward-compatible changes become more cumbersome—it frequently triggers significant "downstream" innovation among manufacturers who compete to utilize that standard.[4] Lower switching costs for consumers mean that they can more easily compare and migrate to products offering the best mix of quality, features, and price. As a result, manufacturers must continuously innovate in non-standardized features to differentiate themselves from rivals. This competitive dynamic drives substantial innovation in areas such as product design, user experience, and cost efficiency—outweighing the potential (and acceptable) impact on innovation of the technology underlying the standard.[5] Over time, the result is a healthier market ecosystem where interoperability, consumer choice, and sustained innovation all thrive.

The electric socket is an example of where standardization can bring significant innovation. The American three-prong configuration has long been the primary plug for most household devices. Even if there was some marginal benefit from changing this configuration, there is significant value and convenience from maintaining uniformity, not to mention the massive costs that would arise from rewiring countless homes. The broad adoption of the standard has enormous obvious downstream advantages: consumers can buy any appliance without worrying whether it will plug in, and they can move homes or apartments without encountering an entirely different socket standard. By settling on a stable design, the industry avoids burdensome hardware overhauls and instead channels its energy toward making better appliances, enhancing competition, and ultimately benefiting consumers with reliable, easy-to-use products.

B. Technical Standards in Healthcare Technology and Medical Devices

Standards are increasingly important in the context of healthcare technology and medical services. Healthcare organizations rely on a diverse array of medical devices and software systems to deliver care efficiently and safely. Standards help ensure these tools work together seamlessly, governing how devices connect, how data is exchanged, and how technology is managed. Connectivity

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[1] *See* Knutt Blind, *Standards and Innovation: What Does the Research Say?*, ISO Research & Innovation Papers at 8 (Jan. 2022), https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100466.pdf
[2] *See id.* at 9.
[3] *See id.*
[4] *See id.* at 8
[5] Raphael De Coninck, Christoph von Muellern, et al, *SEP Royalties, Investment Incentives and Total Welfare* at 3-4, Charles River Associates *prepared for* Fair Standards Alliance

standards—like Wi-Fi, Bluetooth, and cellular—enable real-time data transmission; data exchange standards (HL7, FHIR, DICOM) harmonize the flow of patient information; and management standards (ISO 14971 and IEC 62304) ensure each system is developed, integrated, and maintained with patient safety at the forefront. Continued access to products and services implementing these standards is essential to the modern healthcare ecosystem.

a. Wireless Connectivity Standards

Like most areas of technology, wireless connectivity standards play a critical role in enabling medical devices to capture, share, and analyze patient data in real time. Technologies like Wi-Fi (IEEE 802.11) and Bluetooth Low Energy facilitate secure, near-instant exchange of information from devices such as insulin pumps, heart rate monitors, and implantable cardiac defibrillators. By allowing for continuous data transmission, these standards empower clinicians to make timely decisions, whether they are tracking a patient's vitals from a centralized hospital station or remotely monitoring someone recovering at home. In addition, advanced cellular protocols (e.g., 4G LTE and 5G) allow telehealth solutions to connect seamlessly across large distances, further expanding access to care. Such wireless capabilities are especially beneficial in delivering updates and alerts to care teams, ensuring swift interventions when patients experience changes in their condition. Healthcare technology and medical devices represent a significant share of the emerging internet of things (IoT) sector, with 15% of IoT companies recently reporting that they are developing products in the medical device segment.[6] Wi-Fi provides in-hospital connectivity, enabling devices to transmit real-time patient data with minimal latency. For instance, Philips IntelliVue patient monitoring systems use Wi-Fi to continuously send vital signs and alerts to central stations, ensuring that clinicians can promptly act on changing patient conditions.[7] Similarly, Baxter's Sigma Spectrum infusion pump employs Wi-Fi to log medication dosages and usage data directly into hospital information systems, reducing manual errors and streamlining workflows. [8] Even consumer-oriented devices like the Withings Thermo smart thermometer leverage Wi-Fi to sync temperature readings to mobile apps, supporting at-home monitoring and contributing to an ever-expanding ecosystem of connected health tools.[9]

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[6] European Commission, *Commission Staff Working Document – Impact Assessment Report* (hereinafter Impact Assessment Report) at 133 (Apr. 27, 2023).
[7] Phillips IntelliVue Patient Monitoring System, Philips, https://www.usa.philips.com/healthcare/solutions/patient-monitoring/continuous-patient-monitoring-systems/intellivue (last visited February 25, 2025).
[8] Baxter Spectrum IQ Infusion System, Baxter, https://www.baxter.com/healthcare-professionals/hospital-care/spectrum-iq-infusion-system (last visited February 25, 2025).
[9] Withings Thermo Smart Temporal Thermometer, Withings, https://www.withings.com/us/en/thermo (last visited February 25, 2025).

Bluetooth Low Energy (BLE) addresses the need for secure, low-power data transfer across a wide range of wearable and near-patient devices.[10] Take, for example, the Dexcom G6 Continuous Glucose Monitoring (CGM) system, which uses BLE to send real-time glucose readings to a patient's smartphone or compatible receiver, eliminating the need for frequent fingerstick tests.[11] In clinical and consumer settings alike, Masimo's MightySat pulse oximeter relies on BLE to transmit blood oxygen saturation and pulse rate to mobile apps, allowing both patients and providers to track trends over time.[12] Wearable fitness trackers such as the Fitbit Charge series also harness BLE to sync data like steps and heart rate, making it easier to integrate daily health metrics into broader care plans.[13]

Finally, cellular compliant devices extend connectivity well beyond hospital walls, ensuring that critical data flows no matter where patients are located. Remote patient monitoring devices like the iRhythm Zio patch take advantage of cellular signals to securely transfer cardiac data to healthcare providers, enabling continuous ECG analysis without confining the wearer to a clinical environment.[14] In telehealth scenarios, solutions such as the TytoCare telehealth kit use cellular connections to power remote examinations and consults, bridging the gap between clinicians and patients in any geography.[15] Likewise, GreatCall's Lively Mobile Plus system provides medical alert services via cellular coverage, offering immediate emergency response at the press of a button. By combining broad coverage, speed, and flexibility, cellular connectivity helps maintain uninterrupted, high-quality care and monitoring for patients on the move.[16]

These standards have been broadly recognized as important to national health technology innovation priorities. The UK National Health Services established its Future Connectivity program "to identify health and care sites and match fund installation costs."[17] This project includes supporting connectivity infrastructure in acute care hospitals, are homes, and even ambulances.

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[10] *See* United Kingdom National Health Service, *Wireless Technologies in Health,* NHS Digital, https://digital.nhs.uk/services/future-connectivity/connectivity-hub/advice-and-guidance/introduction-to-wireless-technologies-in-health/wireless-technologies (last visited Feb. 26, 2025).
[11] Dexcom G6 Continuous Glucose Monitoring System, Dexcom, https://amsldiabetes.com.au/wp-content/uploads/2020/06/PR-100-374-Dexcom-G6-Tech-Sheet-LR.pdf (last visited February 25, 2025).
[12] Masimo MightySat Rx Fingertip Pulse Oximeter, Masimo, https://www.masimo.com/products/monitors/spot-check/mightysatrx/ (last visited February 25, 2025).
[13] Fitbit, Fitbit Charge Product Manual 8, https://staticcs.fitbit.com/content/assets/help/manuals/manual_charge_en_US.pdf (last visited Feb. 25, 2025).
[14] iRhythm Zio Monitor, iRhythm, https://www.irhythmtech.com/ (last visited Feb. 25, 2025).; iRhythm Patient Support FAQs, iRhythm, https://www.irhythmtech.com/patients/myzio/zio-at (last visited Feb. 25, 2025).
[15] TytoCare Medical Exam Kit, Baptist Health, https://baptisthealthdigital.tytocare.com/ (last visited Feb. 25, 2025).
[16] Lively Mobile+ User Guide, Lively 25 (2020), https://www.lively.com/static/adc3a5a585ee2c0aca3f33541b06b204/user-guide-Lively-Mobile-plus.pdf.
[17] NHS Digital**,** *Future Connectivity*, NHS Digital, https://digital.nhs.uk/services/future-connectivity (last visited Feb. 26, 2025).

As part of this effort, the UK government announced in 2024 that it was piloting a trial to integrate wireless capabilities in ambulance bays.[18]

b. Data Exchange Standards

There are also standards specific to healthcare that facilitate data exchange. The healthcare industry's sweeping shift from manual patient files and administrative healthcare tasks to electronic health record (EHR) systems has enabled large amounts of data to be stored in a more efficient way.[19] But a patient's care often requires data to be shared across multiple healthcare servers. The lack of consistent methods of digital data exchange across healthcare systems results in slower approaches, including faxing physical documents, which disrupts workflows, increases incremental costs, and invites significant incompetencies across a patient's routine or critical care.

Healthcare's data exchange layer—encompassing the systems and protocols that make data sharing possible—plays a pivotal role in ensuring that patient records are both broadly accessible and easily shareable among care teams. Whenever a patient has bloodwork done at a lab, undergoes imaging at a diagnostic center, or visits a specialist outside of their primary care network, that information must flow seamlessly back into a central record. If an emergency arises, clinicians need immediate access to everything from past prescriptions to recent lab results. Interoperability standards are what make this possible, transforming fragmented data formats into a cohesive set of records. Coordinating data exchange across numerous clinical systems is no small task, but it is essential for timely, informed decision-making and continuity of care.
In addition to enabling real-time data flow, the data exchange layer must also support portability, ensuring that records move effortlessly when patients switch providers or relocate. Medical records from multiple sources—ranging from small local clinics to major hospital networks—must converge in a user-friendly, standardized format. Likewise, specialists who operate independently of a patient's primary care provider still need to push critical updates back into the patient's central file, preserving a 360-degree view of that person's health status. This open, standardized approach is also critical for innovation, allowing new tools—such as remote patient monitoring devices or telehealth platforms—to integrate without creating information silos. Ultimately, the faster and more reliable the sharing of patient data, the better clinicians can respond, especially in urgent or emergency situations where immediate access to accurate information can save lives.

The Health Level Seven (HL7) International standards organization represents the leading organization in the healthcare industry for interoperability standards that facilitate the secure exchanging, integrating, sharing and retrieving of protected health information (PHI). The HL7

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[18] NHS England, *£1 Million Boost for Wireless Innovations to Improve Patient Care*, NHS England (Feb. 1, 2024), https://www.england.nhs.uk/2024/02/1-million-boost-for-wireless-innovations-to-improve-patient-care/.
[19] *See* Office of the Nat'l Coordinator for Health Info. Tech., *What Are the Advantages of Electronic Health Records?*, HealthIT.gov, https://www.healthit.gov/faq/what-are-advantages-electronic-health-records (last visited Feb. 26, 2025).

standards represent the most relied upon standards in the healthcare space with 95 percent of U.S. healthcare institutions operating on the HL7 V2.x standard for information systems and the standards' adoption across 35 more countries.[20] Standards like the HL7 V2 and its successors (e.g., HL7 V3 and Fast Healthcare Interoperability Resource (FHIR)) have enabled healthcare to be truly digitized and streamlined, opening up opportunities for more personalized patient care and higher chances of administering life-saving medical treatments.

For instance, Epic Systems' EHR platform relies on HL7 messaging to share patient data with other healthcare systems, resulting in more comprehensive patient records.[21] HL7 also supports Cerner's Millennium Laboratory Information System (LIS), facilitating the smooth transmission of lab results to EHRs,[22] and is integral to GE Healthcare's Centricity Radiology Information System, helping unify imaging data with other clinical information.[23]

Meanwhile, FHIR brings a modern, web-based approach to data sharing. Allscripts' Sunrise EHR uses FHIR to enable real-time interoperability between healthcare applications,[24] while the Apple Health app leverages FHIR to consolidate health data from multiple sources.[25] Even advanced clinical decision support tools like Cerner's PowerChart tap into FHIR interfaces to analyze patient data in the moment and provide actionable insights.[26]

Notably, Epic Systems and Oracle Health (Cerner) hold over 50 percent of the domestic HER market share, and they both rely on the HL7 standards. Epic Systems makes up 37.7 percent of the market share in the United States, with its international presence growing in prominent jurisdictions.[27] Cerner follows closely behind Epic Systems with 21.7 percent of the U.S. EHR market share.[28]

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[20] HL7 Version 2 Product Suite, Health Level Seven International, https://www.hl7.org/implement/standards/product_brief.cfm?product_id=185 (last visited Feb. 25, 2025).
[21] Epic Systems' Interoperability Guide for Clinical Information: HL7v2, Epic Systems, https://open.epic.com/clinical/HL7v2 (last visited Feb. 25, 2025).
[22] HL7 WBT, Cerner, https://ulearn.cerner.com/content/uLearn/courses/Cerner_HL7_2_2_WBT_1621367637332/content/pages/HomePage.html (last visited Feb. 25, 2025).
[23] Centricity Enterprise Archive HL7 Conformance Statement, GE Healthcare (2020), https://www.gehealthcare.com/-/jssmedia/documents/us-global/products/interoperability/hl7/gehc-hl7-conformance-enterprisearchive_40-doc1030395_rev11.pdf.
[24] Altera Sunrise Product Solutions, Altera Digital Health, https://www.alterahealth.com/solution/sunrise/ (last visited Feb. 25, 2025).
[25] Apple Health Records, Apple, https://www.apple.com/healthcare/health-records/ (last visited Feb. 25, 2025).
[26] Kevin Shekleton, *Cerner's Open Source Contributions for Interoperability*, Cerner (June 21, 2018), https://engineering.cerner.com/blog/cerners-open-source-contributions-for-interoperability-developers/; SMART on FHIR Tutorial, Cerner, https://engineering.cerner.com/smart-on-fhir-tutorial/.
[27] Maggy Bobek Tieché, *Most Common Inpatient EHR Systems by Market Share*, Definitive Healthcare (Jan. 10, 2024), https://www.definitivehc.com/blog/most-common-inpatient-ehr-systems.
[28] *Id*.

HL7 standards, and particularly, FHIR, are mandated in many countries. In the United States, Congress updated the 21st Century Cures Act in 2016 to require certified health IT developers to use FHIR Application Programming Interfaces (APIs).[29] While the EU has not mandated FHIR, it promotes the use of standardized data protocols like HL7 standards in the European Health Data Space (EHDS) Regulation, which governs the facilitation of access to electronic health data.[30] EU members states are increasingly adopting FHIR as the de facto or, in some cases, mandated standard due to its strength and reliability across the EU and global medical community. Notably, in 2021, Germany established the ISiK law, which required all German hospitals to implement FHIR-compliant health IT systems by 2023. [31]

DICOM addresses the specialized needs of medical imaging.[32] For example, Siemens Healthineers' MAGNETOM MRI systems use DICOM to ensure that images are stored in a format compatible with various Picture Archiving and Communication Systems (PACS).[33] GE Healthcare's Centricity PACS also employs DICOM to streamline image retrieval and management, improving efficiency and accuracy in radiology workflows. [34] Moreover, Philips IntelliSpace Portal relies on DICOM standards to display and analyze imaging studies, letting radiologists and specialists make diagnostic decisions with access to the same, consistently formatted data.[35] When combined with HL7 or FHIR, DICOM-based imaging data can seamlessly merge into a patient's overall digital health record.

IEEE 11073 extends interoperability to personal health devices, ensuring that data from blood pressure cuffs, weight scales, glucose monitors, and other home-based devices is consistently

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[29] 21st Century Cures Act—Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Fed. Reg. 25510 (May 1, 2020).
[30] Council of the European Union, Regulation Of The European Parliament And Of The Council on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, PE 76/24 Rev-1 INIT (February 11, 2025), https://data.consilium.europa.eu/doc/document/PE-76-2024-INIT/en/pdf.
[31] Andrii Krylov, *ISiK Compliance: Standards, Challenges, Becoming Compliant*, Kodjin (Oct. 15, 2024), https://kodjin.com/blog/isik-compliance/.
[32] Nat'l Electr. Mfrs. Ass'n, *About DICOM*, DICOM Standard, https://www.dicomstandard.org/about-home (last visited Feb. 26, 2025).
[33] Siemens, Siemens DICOM Conformance Statement 6 (2013), https://cdn0.scrvt.com/39b415fb07de4d9656c7b516d8e2d907/1800000001382718/c57cb4975454/mr_dicomconformance_ve60a-01382718_1800000001382718.pdf.
[34] GE Healthcare , GE Healthcare's Centricity PACS-IW DICOM Conformance Statement 11 (May 31, 2024), https://www.gehealthcare.com/-/jssmedia/documents/us-global/products/interoperability/dicom/radiology-pacs-ris/gehc-dicom-conformance_centricitypacs-iw-server5_0-doc1193612_rev4.pdf?rev=-1&hash=602D3CC909A59A83DC590BE4DE2E2976; GE Healthcare, GE Healthcare's Centricity PACS-IW DICOM Conformance Statement 10, https://www.gehealthcare.com/-/jssmedia/documents/us-global/products/interoperability/dicom/radiology-pacs-ris/gehc-dicom-conformance_centricitypacs-iw_3739_doc1148833_rev3.pdf?rev=-1&hash=73B6F6AA2EA0A4405351C252569864CA (last visited Feb. 25, 2025).
[35] Philips, Philips IntelliSpace Portal 13 (December 30, 2023), https://www.documents.philips.com/assets/Instruction%20for%20Use/20240205/61d77240ce0b4be2be0bb10d00a6836f.pdf?feed=ifu_docs_feed.

formatted and communicated.[36] For example, Accu-Chek's blood glucose monitoring system uses IEEE 11073 standards to transmit blood glucose readings to paired devices.[37] Similarly, Nonin's Connect series of pulse oximeters adopt the same protocols for sending oxygen saturation and pulse rate measurements.[38] By adopting IEEE 11073, these manufacturers allow real-time monitoring and seamless integration of patient-generated health data, bridging the gap between clinical environments and everyday life. This approach enables continuous patient oversight, supports proactive intervention, and ultimately improves the quality and timeliness of care.

c. Technology Management Standards

Standards are also essential in healthcare technology management, ensuring that medical devices and health IT systems are developed, integrated, and maintained with safety, efficacy, and security in mind. ISO 14971 addresses risk management across a device's entire lifecycle, guiding manufacturers through the process of identifying, evaluating, and controlling hazards. IEC 62304 sets out rigorous requirements for developing and maintaining the software behind complex medical systems, reducing the likelihood of critical failures that might compromise patient care. Meanwhile, IEC 80001-1 provides a framework for incorporating these devices into broader healthcare IT networks, mitigating potential security threats and technical malfunctions. Collectively, these standards support key regulatory objectives—such as safeguarding sensitive information under HIPAA and promoting seamless data exchange—thereby strengthening the entire continuum of patient care.

Beyond data security, aligning with these standards also streamlines the path toward regulatory approvals, including those from the FDA. Such clearances demand thorough documentation of a product's reliability and performance—an effort eased by demonstrating adherence to ISO 14971 for risk management and IEC 62304 for software lifecycle practices. Remote patient monitoring platforms, telehealth solutions, and electronic health record ( ) systems likewise benefit from these guidelines, which promote continuous uptime and robust fail-safes to protect patient safety. By adopting these internationally recognized benchmarks, healthcare organizations and device manufacturers not only simplify compliance but also advance better patient outcomes and safer clinical environments.

ISO 14971 addresses risk management throughout a device's lifecycle, helping manufacturers identify, assess, and mitigate potential hazards.[39] For example, BD's Alaris System infusion pumps

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[36] IEEE Standards Ass'n, *Personal Health Devices (PHD) Working Group*, IEEE, https://sagroups.ieee.org/11073/phd-wg/ (last visited Feb. 26, 2025).
[37] Roche, Accu-Chek Guide Me Blood Glucose Monitoring System User's Manual 24, 38, https://us.test.accu-chek.com/sites/g/files/iut341/f/accu-chek_guide_me_users_manual_1.pdf (last visited Jan. 19, 2025).
[38] Nonin Med. Inc., *Nonin Medical Inc. Pioneers First Interoperable Wireless Fingertip Pulse Oximeter*, BioSpace (May 15, 2008), https://www.biospace.com/nonin-medical-inc-pioneers-first-interoperable-wireless-fingertip-pulse-oximeter.
[39] Int'l Org. for Standardization, *ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices* (3rd ed. 2019), https://www.iso.org/standard/72704.html.

leverage ISO 14971 processes to ensure safe medication delivery, minimizing risks such as dosage errors or mechanical malfunctions.[40] In respiratory support, Dräger's Evita V600 ventilator employs ISO 14971 principles to spot and control clinical risks, safeguarding patients who rely on mechanical ventilation.[41] Even surgical tools, like Medtronic's transcatheter instruments, integrate ISO 14971 into their design[42] and development to manage risks related to device performance and patient outcomes, ultimately enhancing safety across various procedural settings.

IEC 62304 focuses on the full software development lifecycle for medical devices, outlining how to design, test, and maintain reliable code.[43] For instance, Roche's Cobas IT 1000 software uses IEC 62304 to ensure that laboratory diagnostics run accurately, reducing the likelihood of errors in patient results.[44] In imaging environments, Canon Medical Systems' software follows IEC 62304 to maintain quality standards for CT, MRI, and ultrasound devices, preventing unpredictable software glitches that could disrupt diagnoses.[45]

Layer	Standard	Medical Application
Wireless Connectivity	Wi-Fi	Infusion pumps Smart hospital beds Telehealth hubs
	Bluetooth Low Energy	Wearable ECG Smart glucometers Clinical grade fitness trackers
	Cellular	Remote patient monitoring Connected emergency response systems Med alert devices
Data Exchange Layer	HL7	Hospital information systems Laboratory information systems Pharmacy management

[40] Becton, Dickinson & Co., *BD Alaris System with Guardrails Suite MX*, BD, https://www.bd.com/en-us/about-bd/cybersecurity/bulletin/bd-alaris-system-with-guardrails-suite-mx (last visited Feb. 26, 2025).

[41] U.S. Food & Drug Admin., *510(k) Premarket Notification: K222024* 3 (Dec. 16, 2022), https://www.accessdata.fda.gov/cdrh_docs/pdf22/K222024.pdf (concerning Draegerwerk AG & Co. KGaA's Evita V800 and Evita V600 ventilators).

[42] Medtronic, Inc**.,** *Micra AV Implant Manual: Medical Procedure & EMI Precautions* at 80, (2020), https://wwwp.medtronic.com/crs-upload/letters/401/401_Micra_AV_Implant_Manual_with_Medical_Procedure_and_EMI_Precautions.pdf.

[43] Int'l Org. for Standardization & Int'l Electrotechnical Comm'n**,** *ISO/IEC 62304:2006 – Medical Device Software – Software Life Cycle Processes* (1st ed. 2006, amended 2015), https://www.iso.org/standard/38421.html.

[44] U.S. Food & Drug Admin.**,** *510(k) Premarket Notification: K171655* 14 (Mar. 2, 2018), https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171655.pdf (concerning Roche Diagnostics Hematology, Inc.'s cobas m 511 integrated hematology analyzer).

[45] U.S. Food & Drug Admin., *510(k) Premarket Notification: K232526* 3 (Sept. 12, 2023), https://www.accessdata.fda.gov/cdrh_docs/pdf23/K232526.pdf (concerning Canon Medical Systems Corporation's XIDF-AWS801, Angio Workstation (Alphenix Workstation)).

Layer	Standard	Medical Application
	FHIR	Healthcare portals Wearable integration Telehealth solutions
	DICOM	Medical imaging (MRI, CT, X-ray) AI-driven imaging analytics Picture archive system
	IEEE 11073	Glucometers Pulse oximeters ECG monitors Weighing scales
Technology Management	ISO 14971	Monitoring infusion pumps and dialysis machines Surgical robot analysis Implants and integrated medical sensors
	IEC 62304	Automated medication dispensing software Patient monitoring

III. Standard Essential Patents and Licensing Problems in Healthcare Technology and Medical Devices

While standardization offers many benefits, it is not without risks. While there are typically multiple alternative technical solutions to solve a particular problem prior to standardization, once a specific solution—along with any patented technology that reads on it—is adopted in the standard, competing alternatives are no longer an option.[46] Companies seeking to implement the standard must thus practice these standard essential patents (SEPs). This dynamic gives SEP holders two distinct advantages when negotiating with companies that have chosen to develop products that implement the standard.

First, the patent is able to assert market power beyond the claims of the patent because it intertwines with the value of the entire standard.[47] A SEP holder that refuses to grant a license and seeks to exclude a manufacturer from using the standard is also effectively holding the rest of the standard—including unpatented value and patents held by others—hostage. This could allow the

[46] Expert Report of Friedhelm Hillebrand on behalf of Nokia at ¶ 11, Nokia Corp. v. Qualcomm Inc., 2330-VCS (Del. Ch. May 22, 2008).
[47] Case AT.39985—Motorola—Enforcement of GPRS Standard Essential Patents, Comm'n Decision ¶ 320 (Apr. 29, 2014), https://ec.europa.eu/competition/antitrust/cases/dec_docs/39985/39985_928_16.pDf.

SEP holder to capture value entirely disconnected from what the patented invention is actually entitled to.[48]

Second, standardization can frequently result in depriving a putative licensee from their countervailing buyer power to walk away.[49] Once a standard is broadly adopted, a manufacturer developing a product incorporating the standardized feature frequently has no viable alternative to the standard.[50] Even if the technical contribution of the patent to the standard is de minimis, the manufacturer cannot adopt an alternative solution to accomplish the same task once the patent is incorporated into the standard.[51] The ability to walkaway is further limited because the costs associated with developing a standard compliant products can be significant and abandoning standard can often mean abandoning the product those investments.

This gives SEP holders more leverage when dealing potential licensees than the economic value claimed by the patents themselves or using its intellectual property to exclude competitors from accessing the standard. The risk of exclusion or unreasonable royalty demands after a product goes to market can thus deter product developers from adopting a standard, lowering the likelihood that the standard will ultimately succeed.[52]

A. SDO Licensing Commitments

SDOs have adopted a variety of approaches to mitigate this risk, typically through the creation of intellectual property rights (IPR) policies. The core feature of SDO IPR policies are voluntary assurances from participants limiting how they will enforce any SEPs against other parties implementing the standard. The exact commitment can vary significantly. Some IPR policies take a royalty free approach, and ask SDO participants to commit to grant a license their SEPs to anyone seeking to develop products implementing the standard (often reciprocal on the product developer likewise committing to license on royalty-free terms). Other IPR policies require participants to license their SEPs on fair, reasonable, and non-discriminatory (FRAND) terms. Some SDOs allow participants to choose from a menu of options that can include a commitment to not enforce their SEPs, grant a license on royalty free terms, or grant a license on FRAND terms.

The FRAND commitment represents the most permissive intellectual property rights (IPR) framework that SDOs can allow under competition law. Both the US Supreme Court and European Commission (EC) have indicated that where a group of industry participants pool technology to establish a standard, participants must make licenses available on reasonable terms.[53] The FTC

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[48] *Id*.
[49] *Id*.
[50] Herbert Hovenkamp, *FRAND and Antitrust*, 105 Cornell L. Rev. 1683, 1690 (2020).
[51] Joseph Farrell et al., *Standard Setting, Patents, and Hold-Up*, 74 Berkely Antitrust L. Rev. 607, 608 (2007).
[52] FTC Complaint, *In re Dell Computer Corp.*, 121 F.T.C. 616, 18 (1996).
[53] *Hartford-Empire Co. v. United States*, 324 U.S. 570, 573–74 (1945); Commission of the European Communities*, Communication from the Commission: Horizontal Guidelines on the Application of EU*

has taken action against SEP holders who have attempted to leverage their SEPs to exclude competitors or extract above-FRAND royalties.[54]

While only a minority of standards result in significant patent monetization and licensing disputes, the overwhelming majority of those involve patents subject to a FRAND commitment. The FRAND commitment developed out of a series of antitrust cases in the 20th century and has been adopted by SDOs to mitigate the ability of SEP holders to undermine the standardization process by charging unreasonable royalties or using their SEPs to exclude competitors from a standard.[55] The FRAND commitment requires that SEP holders not only grant a license, but also not pursue royalties that exceed the technical value of their patented technology.[56]

For the FRAND commitment to be effective, the following principles should apply:[57]

- **The FRAND Commitment Means All Can License –** A holder of a FRAND-committed SEP must license that SEP to all companies, organizations, and individuals who use or wish to use the standard on FRAND terms.
- **Prohibitive Orders on FRAND-Committed SEPs Should Only Be Allowed in Rare Circumstances –** Prohibitive orders (federal district court injunctions and U.S. International Trade Commission exclusion orders) should not be sought by SEP holders or allowed for FRAND-committed SEPs except in rare circumstances where monetary remedies are not available.
- **FRAND Royalties –** A reasonable rate for a valid, infringed, and enforceable FRAND-committed SEP should be based on the value of the actual patented invention itself, which is separate from purported value due to its inclusion in the standard, hypothetical uses downstream from the smallest saleable patent practicing unit, or other factors unrelated to invention's value.
- **FRAND-committed SEPs Should Respect Patent Territoriality** – Patents are creatures of domestic law, and national courts should respect the jurisdiction of foreign patent laws to

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Competition Law to Business Agreements, C(2023) 259 final, O.J. C 259, at 1 (July 21, 2023), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=oj:JOC_2023_259_R_0001.

[54] *In re Robert Bosch GmbH*, 2012 WL 5995560 (F.T.C. Jan. 1, 2012).; *In re Motorola Mobility LLC* and Google Inc., 2013 WL 124100 (F.T.C. Jan. 3, 2013).

[55] *See generally* Robert Pocknell & David Djavaherian, *The History of the ETSI IPR Policy: Using the Historical Record to Inform Application of the ETSI FRAND Obligation*, 75 RUTGERS UNIV. L. REV. 977 (2023); Jorge L. Contreras, *A Brief History of FRAND: Analyzing Current Debates in Standard Setting and Antitrust Through a Historical Lens*, 80 Antitrust L.J. 39 (2015).

[56]Commission of the European Communities*, Communication from the Commission: Horizontal Guidelines on the Application of EU Competition Law to Business Agreements,* C(2023) 259 final, O.J. C 259, at 1 (July 21, 2023), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=oj:JOC_2023_259_R_0001; Ericsson, Inc. v. D-Link Sys., Inc.773 F.3d 1201, 1209 (Fed. Cir. 2014).

[57] Principles for Standard Essential Patents, All Things FRAND, https://allthingsfrand.com/about/ (last visited February 25, 2025).

avoid overreach with respect to SEP remedies. Absent agreement by both parties, no court should impose global licensing terms on pain of a national injunction.

- **The FRAND Commitment Prohibits Harmful Tying Practices –** While some licensees may wish to get broader licenses, a SEP holder that has made a FRAND commitment cannot require licensees to take or grant licenses to other patents not essential to the standard, invalid, unenforceable, and/or not infringed.
- **The FRAND Commitment Follows the Transfer of a SEP –** As many jurisdictions have recognized, if a FRAND-committed SEP is transferred, the FRAND commitments follow the SEP in that and all subsequent transfers.

B. Voluntary Commitment, Timely Disclosure, and Successor Obligations

How and when these commitments attach is equally important. The standardization process could be significantly chilled if participants could have their patented technologies expropriated by the standard merely because they chose to participate in the standard.[58] Companies participating in developing a standard could risk losing the ability to exclude others from using valuable technology that they never intended to share if it was included in the standard. Timely notices by a participant that they do not intend to make licensing commitments does not undermine the standard as it allows alternative solutions to be adopted before the standard is finalized.[59]

But if participants were able to opt-out of making a licensing commitment at any point, then licensing the entire premise of SEP encumbrances could be undermined by late disclosures. Failure to disclose essential—or potentially essential—patents can allow participants in standardization efforts to engage in "patent ambush." Patent ambush occurs when a standardization participant intentionally conceals the existence of essential patents until after the standard is finalized, or "frozen," and then enforces those patents without having made any licensing commitments.[60] The FTC has even conducted multiple investigations leading to consent decrees for these kinds of practices.[61]

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[58] Commission of the European Communities*, Communication from the Commission: Intellectual Property Rights and Standardization,* § 4.3.5, COM (1992) 445 final (Oct. 27, 1992) [hereinafter EC 1992 Standards Communication], https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1992:0445:FIN:EN:PDF.
[59] E.g., ETSI Directive Annex 6 (Dec. 12, 2024), https://portal.etsi.org/directives/50_ETSI_directives_dec_2024.pdf; IEEE-SA Standards Board Bylaws § 6.2 (September 2024), https://standards.ieee.org/about/policies/bylaws/sect6-7/.
[60] Comm'n Decision, Case AT.38636, Rambus Inc., ¶ 27, 2009 O.J. (C 30) 17, https://ec.europa.eu/competition/antitrust/cases/dec_docs/38636/38636_1203_1.pdf.
[61] *See In re Dell Computer Corp.*, 121 F.T.C. 616 (1996); *In re Union Oil Co. of Cal.*, 138 F.T.C. 1 (2004); Rambus Inc. FTC, 522 F.3d 456 (2008).

"It is therefore for standards-making bodies to establish procedures whereby late disclosure or non-disclosure of rights is penalized once actual or presumed knowledge can be established."[62] A participant that breaches its duty to disclose under an SDO's IPR policy implicitly waives its right to enforce the patents against parties using the patent.[63] The scope of the duty to disclose will depend on the particular language and purpose of an IPR policy.[64] Moreover, "[i]mplied waiver is an equitable doctrine, and an equitable doctrine hinges on basic fairness."[65]

Different SDOs have established different mechanisms to trigger the disclosure obligation and request for a voluntary licensing encumbrances. Some standards, like ETSI, require disclosure when an individual participant "to inform ETSI of essential IPR in a timely fashion." [66] In particular, a participant that submits a technical proposal to a standard is required to notify ETSI of any patents "which might be essential if that proposal is adopted."[67] ETSI's IPR disclosure form further states that the participant has a "present belief that the IPR(s) disclosed . . . may be or may become essential" to the standard.[68] The qualifiers —"belief," "might," and "may be"—ensure that the disclosures obligation is overinclusive and captures patents that are merely potentially essential to the standard. Once an ETSI participant makes an IPR disclosure, it has three months to make a licensing commitment.[69] If the participant fails to make a licensing commitment, the ETSI will seek to find a technological alternative that does not practice the withheld technology and, if such an alternative is unavailable, will consider suspending the standardization work until the issue is resolved.[70]

Under IEEE's IPR policy, participants are required to submit letters of assurance (LoAs) if the chair of the relevant standards committee is informed at any time during the standardization process that the use of the standard may require the practice of an essential patent claim.[71] Once an IEEE standard puts out a request for LoAs, a participant may "after Reasonable and Good Faith Inquiry,[72]

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[62] Commission of the European Communities, *Communication from the Commission: Intellectual Property Rights and Standardization,* § 4.4.2, COM (1992) 445 final (Oct. 27, 1992) [hereinafter EC 1992 Standards Communication], https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1992:0445:FIN:EN:PDF.
[63] *Core Wireless Licensing S.A.R.L. v. Apple Inc*., 899 F.3d 1356, 1365 (Fed. Cir. 2018).
[64] *Id*. at 1367.
[65] *Id*. at 1368.
[66] ETSI Directive Annex, s*upra* note 44 at § 4.1.
[67] *Id*.
[68] *Id*. at 53 (IPR Information Statement and Licensing Declaration).
[69] *Id*. at § 6.1.
[70] *Id*. at §§ 6.3, 8.
[71] IEEE-SA Standards Board Bylaws, *supra* note 44 at § 6.2. IEEE-SA, Understanding Patent Issues During IEEE Standards Development, Sept. 2022, https://standards.ieee.org/wp-content/uploads/import/governance/bog/resolutions/september2022- updates-faqs.pdf.
[72] IEEE-SA Standards Board Bylaws, *supra* note 44 at § 6.1 ("'Reasonable and Good Faith Inquiry' includes, but is not limited to, a Submitter using reasonable efforts to identify and contact those individuals who are from, employed by, or otherwise represent the Submitter and who are known to the Submitter to be current or past participants in the development process of the [Proposed] IEEE Standard identified in a Letter of Assurance, including, but not limited to, participation in a Standards Association Ballot or Working Group. If the Submitter did not or does not have any participants, then a Reasonable and Good Faith Inquiry may include,

indicate it is not aware of any Patent Claims that the Submitter may own, control, or have the ability to license that might be or become Essential Patent Claims."[73] If the participant is unable to make such a certification, it can provide a letter of assurance that either disclaim that it will not enforce the essential patents against anyone practicing the SEP in conformance with the standard or commit to license the patents "on a worldwide basis without compensation or under Reasonable Rates, with other reasonable terms and conditions that are demonstrably free of any unfair discrimination."[74] When participant may refuse to provide a letter of assurance, the IEEE Patent Committee will notify the working group who "may wish to consider alternative technologies." Moreover, IEEE "reserves the right to withdraw an approved standard should it be determined that market implementation is being hindered by the assertion of essential patent claims in the absence of an Accepted LOA."[75]

"[L]icensing assurances must be reliable in order to have value in the standards development process."[76] For the commitment to be reliable, it must not only be irrevocable, but it must also survive in the hands of an assignee if the patent is transferred.[77] IPR policies address this by explicitly including language stating that the licensing encumbrance travels with the patent if transferred.

For example, the ETSI IPR policy specifies that the FRAND commitment follows the patent and "bind all successors-in-interest."[78] Those that make a FRAND commitment are obligated to include provisions in any transfer agreement binding the transferee. However, "[t]he undertaking shall be interpreted as binding on successors-in-interest *regardless* of whether such provisions are included in the relevant transfer documents."[79]The IEEE IPR policy also states that the licensing encumbrance follows with the patent if it is transferred or assigned.[80] "The Submitter agrees (a) to provide notice of an Accepted Letter of Assurance either through a Statement of Encumbrance or by binding its assignee or transferee to the terms of such Letter of Assurance; and (b) to require its

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but is not limited to, the Submitter using reasonable efforts to contact individuals who are from, employed by, or represent the Submitter and who the Submitter believes are most likely to have knowledge about the technology covered by the [Proposed] IEEE Standard."). It does not, however, "giv[e] rise toa. Duty to conduct a patent search." *Id.* at ¶ 6.2.

[73] IEEE-SA Standards Board Bylaws, *supra* note 44 at § 6.2.

[74] *Id*.

[75] IEEE-SA, *supra* note 56 at ¶ 14.

[76] *Letter from Donald S. Clark,* Sec'y of the Comm'n, U.S. Fed. Trade Comm'n, to *Judith Gorman,* Managing Dir. of Standards and Secr'y, IEEE Standards Ass'n Board of Governors, In the Matter of Negotiated Data Solutions, LLC, No. 51-94, at 1 (Sep. 22, 2008), https://www.ftc.gov/sites/default/files/documents/cases/2008/09/080923ndslettergormanieeesa.pdf (quoting unpublished IEEE comment to the FTC)

[77] *Id*.

[78] *Id*. at 6.1bis.

[79] *Id*.

[80] IEEE-SA Standards Board Bylaws, *supra* note 44 at § 6.2.

assignee or transferee to (i) agree to similarly provide such notice and (ii) to bind its assignees or transferees to agree to provide such notice as described in (a) and (b)."[81]

IV. Problems in SEP Licensing and Limitations of the FRAND Commitment

Despite the SDO IPR policies and the FRAND commitment, SEP licensing has become increasingly dysfunctional. Many SEP licensors regularly seek to leverage the market power they gain through standardization to extract excessive royalties, often under the threat of injunction.[82] Courts have frequently found SEP licensors demanding royalties orders of magnitude greater than court-determined FRAND rates. The dysfunction in licensing is perpetuated by significant asymmetries in information and negotiating power between licensors and licensees, along with a general failure by courts and competition authorities to enforce the FRAND commitment.

This dysfunction is particularly acute in the context of healthcare technology. The fact that these products are critically important—with lives literally on the line—affords SEP holders even more leverage than they currently possess. Moreover, many of the IPR policies healthcare specific standards fail to adequately address certain issues regarding disclosure and transfer creating a significant cloud over the industry if aggressive monetizers obtain and assert essential patents in the future.

A. General Difficulties in SEP Licensing

SEP licensing takes place under a significant information asymmetry between licensors and licensees. Many SDOs that develop standards don't require SEP holders to specifically disclose which of their patents they believe are essential,[83] making it difficult for a potential licensor to evaluate their potential licensing liability for implementing the entire standard. Moreover, when SEPs are tested in litigation, they are frequently found invalid or not actually essential.[84] Given that some standards can have tens or hundreds of thousands of declared SEPs, with large licensors holding thousands or more of potentially essential patents, the cost for licensees to evaluate

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[81] *Id*.

[82] FTC Commissioner Terrell McSweeny, *Holding the Line on Patent Holdup: Why Antitrust Enforcement Matters* at 4 (Mar. 21, 2018), https://www.ftc.gov/system/files/documents/public_statements/1350033/mcsweeny_-_the_reality_of_patent_hold-up_3-21-18.pdf.

[83] Rudi Bekkers *et al.*, *Disclosure Rules and Declared Essential Patents*, 52(1) Res. Pol'y 104618 at 3 (2023). While some standard setting organizations, like ETSI which develops cellular standards, require contributors to identify which of their patents they believe are essential, this requirement is of limited help as studies show that the vast majority of patents declared essential are not. *See* John Hayes et al., Charles Rivers Assocs., *A Critical Review of 5G SEP Studies*, at 6 (Nov. 8, 2022) (noting studies have found SEP essentiality range from 8–33%)

[84] Matthew G. Rose, Jay Jurata, & Emily Luken, "*Between a Rock and a Hard Place": Unwired Planet v. Huawei and the Dangerous Implications of Worldwide FRAND Licenses*, 84684 Concurrences, at 6 (2017).

whether an offer is actually FRAND can be significant, potentially dwarfing the savings from obtaining a FRAND rate. And while licensors only need to invest in valuing their SEP portfolio once, licensees must make the investment every time they are approached by a licensor. It is thus unsurprising that nearly all licensees report inadequate information regarding FRAND royalties and the SEP landscape as a major problem while only a small fraction of licensors report the same.[85] These inequities are compounded by the fact that many companies purchase standard-enabling components from upstream suppliers and lack the capacity to evaluate the value a SEP portfolio contributes to a standard.[86] This is particularly burdensome on small and emerging business that have limited resources to negotiate.[87] Thirty-eight percent of SEP users reported that the "costs involved in licensing SEPs (search, negotiation and litigation costs)" for start-ups and small and medium sized entities was enough to make them "go out of business/change business."[88]

Additionally, the threat of injunctions gives licensors significant leverage over potential licensees. While standards can provide significant efficiencies and market access to manufacturers, they typically only represent one of many features in the device that goes to market and thus only a small fraction of the value. As a result, the threat of an injunction allows SEP holders to demand significantly more than a FRAND rate based on the value of their underlying patented technology.[89]

While this possibility exists for products involving non standardized technology, it is problematic in the SEP context because the process of standardization removed the viability of switching to a viable alternative that were available prior to standardization. This deprives the licensee of the countervailing buyer power that is normally available during license negotiations, their "ability (or credible threat) to switch to competing suppliers."[90] Given the asymmetric power, licensors are able to demand—and frequently obtain—above FRAND royalties by engaging in these holdup tactics. It is for this reason that licensors who pursue injunctive relief against willing licensees have been broadly recognized as not only breaching their FRAND commitment but also violating competition law.[91]

These asymmetries would not be a significant problem if courts and competition authorities actively enforced the FRAND commitment. The ability of SEP holders to ignore their FRAND

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[85] Impact Assessment Report at 36.
[86] Impact Assessment Report at 20.
[87] Joachim Henkel, *Licensing Standard-Essential Patents in the IoT*, 51(10) Rsch Pol'y 104600 at 1, 6–7 (2022).
[88] Impact Assessment Report at 15.
[89] John Hayes & Assaf Zimring, *Injunctions in Litigation Involving SEPs*, GRUR PATENT 240, 242-43 (June 20, 2024), https://media.crai.com/wp-content/uploads/2024/07/02154935/Hayes-Zimring_GRUR-Patent-2024-240-245_.pdf.
[90] Decision ¶ 243, Case AT.39985—Motorola—Enforcement of GPRS Standard Essential Patents (Eur. Comm'n Apr. 29, 2014).
[91] *See Microsoft Corp. v. Motorola, Inc.*, 696 F.3d 872 (9th Cir. 2012) ("Implicit in [the FRAND] promise is, at least arguably, a guarantee that the patentholder will not take steps to keep would-be users from using the patented material, such as seeking an injunction"); Case C-170/13, Huawei Techs. Co. v. ZTE Corp., ECLI:EU:C:2015:477, ¶ 71 (July 16, 2015).

commitment is ultimately "constrained to an extent by the fact that FRAND is an obligation upon which inter alia courts, arbitral tribunals or competition authorities may rule. In particular, courts are the ultimate decision-makers on whether injunctions should be granted, and any SEP holder needs to convince a court before it can obtain an injunction."[92]

Unfortunately, courts and competition authorities alike have failed to adequately enforce the FRAND commitment. Courts in Germany, Colombia, and Brazil issue injunctions without engaging substantively as to whether the licensor's royalty demand was FRAND in the first instance. And despite SEP holders frequently pursuing injunctive relief in courts around the world, including the US's International Trade Commission, over the past decade, competition authorities have failed to police this conduct through enforcement actions.

B. SEP Licensing Risks in Healthcare Technology and Medical Devices

Healthcare technology and medical devices often require many years—and in some cases more than a decade—to move from initial concept to market release.[93] This protracted timeline stems from extensive research, design, testing, and the fulfillment of stringent regulatory requirements. Once a product's features are determined and submitted for approval, any significant modification can trigger an additional round of costly and time-consuming re-certification.[94] In such an environment, manufacturers need clear information about the costs associated licensing any SEPs early in the development process. Without this certainty, it becomes nearly impossible to accurately gauge whether adopting a particular standardized feature is economically feasible compared to using an alternative, potentially less optimal, technology.

Compounding these concerns is the difficulty of securing SEP licenses long before a product comes to market. Many SEP holders may be unresponsive or unwilling to expend resources on licensing negotiations for a product still under development.[95] Some licensors even adopt a deliberate "wait-and-see" approach, deferring license offers until after standardized features have been widely implemented.[96] At that stage, a manufacturer has far less leverage to negotiate, having already invested considerable time, resources, and regulatory capital into a particular design. This dynamic leaves manufacturers in a precarious position, often forced to commercialize without a licensing agreement, thereby increasing exposure to potential legal and financial challenges later on.

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[92] Case COMP/M.6381 –*Google/Motorola Mobility,* Commission Decision ¶ 113 (Feb. 13, 2012).
[93] Impact Assessment Report at 15-16.
[94] FDA, *Deciding When to Submit a 510(k) for a Change to an Existing Devic*e 25-29 (Oct. 25, 2017), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device.
[95] *See* Björn Lundell, Jonas Gamalielsson, & Andrew Katz, *Implementing IT Standards in Software: Challenges and Recommendations for Organisations Planning Software Development Covering IT Standards*, 10:2 Euro. J. of L. & Tech. at 22-24 (2019) (documenting difficulties in attempt to proactively obtain SEP licenses from 24 licensors).
[96] Impact Assessment Report at 11.

The lack of a finalized licensing agreement before going to market puts medical device manufacturers at risk of holdup. Once a product is being sold—and is used by patients and healthcare providers—SEP holders can use the threat of injunctions or exclusion orders to extract above FRAND royalties. The high stakes of a threatened product withdrawal, particularly in the healthcare context, amplify the licensor's bargaining power. Manufacturers face a stark choice: agree to pay royalty rates that may far exceed FRAND terms or pull life-saving products from the market. Switching to an alternative technical solution is rarely straightforward; any material change to a regulated medical device requires time-consuming, costly approval processes that can span months or years.[97] With patients' well-being on the line, manufacturers are effectively left with no real choice but to concede to inflated royalties, which can in turn increase overall healthcare costs and limit the ability to invest in future product improvements.

A product's forced removal from the market not only disrupts the manufacturer's operations but also can directly compromise patient care.[98] Healthcare institutions are highly sensitive to interruptions in the supply of critical devices,[99] and even the possibility that a device might be unavailable due to licensing disputes can deter hospitals from adopting it. Moreover, switching to another manufacturer's device—even one promising the same core features—introduces new risks: every device is accompanied by its own interface, usage protocols, and maintenance requirements. In urgent medical scenarios, the additional cognitive and training burdens placed on clinicians trying to operate unfamiliar equipment can increase the chance of error.[100] This underscores the importance of consistency and standardization in healthcare, where even slight variances in device design or workflow can lead to safety risks and inefficiencies.

The ripple effects of above-FRAND royalties extend well beyond individual manufacturers. Excessive licensing costs can deter smaller or emerging companies from incorporating advanced standardized features, suppressing competition and slowing innovation. Companies, wary of uncertain or prohibitive royalty burdens, might also opt for older or proprietary technologies simply to avoid potential legal entanglements.[101] This limits the range of available solutions and can stall the advancement of next-generation medical devices that could otherwise improve patient outcomes. When standardized technologies are subject to unpredictable and inflated fees, the

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[97] FDA, *supra* note 94; Tyler Panian, *How Long Does a 510(k) Approval Actually Take? 2021 Edition*, Ontogen MedTech (Aug. 2021), https://www.ontogenmedtech.com/news-articles/how-long-does-510k-approval-take-2021.

[98] *Certain Fluidized Supporting Apparatus and Components*, Inv. No. 337-TA-182/188 (Oct. 1984) (declining to institute exclusionary relief because the accused beds were sold, rented and leased to hospitals for the treatment of burn patients).

[99] *Cordis Corp. v. Boston Scientific Corp.*, No. CIV.A.03-027-SLR, 2003 WL 22843072, at *2 (D. Del. Nov. 21, 2003), aff'd, 99 F. App'x 928 (Fed. Cir. 2004) (denying preliminary injunction for infringed drug-eluting stents due to public health risks posed by inadequate supply).

[100] *Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff*, FDA (Feb. 3, 2016) at 9, https://www.fda.gov/media/80481/download .

[101] *See e.g.,* Impact Assessment Report at 67-68.

entire healthcare ecosystem suffers—from developers and clinicians to patients and payers—through more expensive products and less innovation.

These risks are real and are already impacting companies that supply components to IoT companies, including those that produce healthcare technologies and medical devices.[102] In recent years, difficulties in SEP licensing have put significant pressure on the component and module manufacturers that service health technologies.[103] In December 2024, an IP executive from u-blox, testified before Congress that the inability to obtain licenses on FRAND terms were putting significant pressure on the company.[104] Less than a month later, u-blox announced that it was exiting the market despite industry recognition that u-blox modules were a competitive product.[105]

C. Inadequate SDO IPR Policies in Healthcare Technology Standards

In addition to the acute asymmetry in healthcare technology licensing, the IPR policies in some of the healthcare specific standards—notably HL7 (which also govern FHIR) and DICOM—are ambiguous or silent with regards to disclosure obligations and encumbrances in future transfer. The disclosure duties in both the HL7 and DICOM IPR policies present significant uncertainty as to when a participant's obligation to disclose essential claims has arisen. The language of these policies forms part of the analysis

HL7 requires participants to submit a letter of assurance identifying "any patents or patent applications felt to be applicable to the HL7 Protocol Specification."[106] Meanwhile, DICOM imposes an "affirmative duty" to disclose "any patents or patent applications . . . owned by the Member . . . and known to the Member that practicing one or more of the patent claims is required

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[102] *See, e.g.*, HL Deb. (Nov. 27, 2024) (UK) (statement of Lord Lansley, discussing the Product Regulation and Metrology Bill), available at https://hansard.parliament.uk/lords/2024-11-27/debates/46D3158D-BD1D-4C10-8EAE-9C929C1CCD01/ProductRegulationAndMetrologyBill(HL) ("I have been talking to Tunstall Healthcare, which I know well from its role in providing connectivity, particularly for people who require care at home; it looks after more than 100,000 of them. In order to access licences for 4G and wifi connectivity, it needs to negotiate many licences and to identify where they exist."); Tim Pohlmann, *Analysis of Patents, SEPs and Standards in the Smart Healthcare Sector*, IAM (Mar. 16, 2022) https://www.iam-media.com/article/analysis-of-patents-seps-and-standards-in-the-smart-healthcare-sector (identifying the proliferation of SEP declarations that describe healthcare application of connectivity).

[103] Impact Assessment Report at 68.

[104] IP and Strategic Competition with China: Part IV – Patents, Standards, and Lawfare: Hearing Before the Subcomm. on Cts., Intell. Prop. & the Internet of the H. Comm. on the Judiciary, 118th Cong. (2024) (statement of Kent D. Baker, u-blox America, Inc.) https://docs.house.gov/meetings/JU/JU03/20241218/117764/HHRG-118-JU03-Wstate-BakerK-20241218-U6.pdf.

[105] James Blackman, *Module Maker u-blox Quits Cellular IoT–'the Writing Was on the Wall'*, RCR Wireless News (Jan. 15, 2025), https://www.rcrwireless.com/20250115/internet-of-things/u-blox-quits-cellular-iot.

[106] Health Level Seven Int'l, *HL7 Governance and Operations Manual* § 09.03.01 (Mar. 20, 2023), http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf.

to implement any portion of the DICOM Standard."[107] Thus, under both HL7 and DICOM, the gravamen on triggering a disclosure obligation is based on a feeling or knowledge that the patent is actually essential. But knowing whether a patent is actually essential is no trivial task. Even SEPs asserted in litigation are frequently found to be not actually essential.[108] There is thus a significant gulf between a patent potentially being essential and actually being essential. It is for this reason that both ETSI and IEEE's disclosure obligation is predicated on whether a patent "may be" or "may become" essential. Thus, it is foreseeable even if there may have been an affirmative duty to disclose under ETSI or IEEE, such a duty may not arise under HL7 or DICOM[109] narrowing the effectiveness of a *Core Wireless* waiver defense. This is problematic as neither standard appears to have had significant disclosures made to date. HL7 has only had three IPR disclosures—with the last having been made in 2006—raising the possibility that there exists significant amounts of undeclared HL7 essential patents in existence.[110] Meanwhile, DICOM does not appear to have any publicly available database of disclosed IPR or licensing commitments.[111]

Additionally, while HL7 and DICOM both require disclosures (albeit under narrower triggers than, say, ETSI), these requirements do not necessarily ensure that transferred patents—even those previously disclosed—will continue to be subject to fair licensing. But HL7 and DICOM IPR policies contain no explicit requirement that a FRAND or royalty-free obligation must "travel" with a patent when it is sold or otherwise transferred. Without a binding "successor-in-interest" clause, the transferee is not expressly constrained by the original owner's assurances. Thus, even if a participant binds itself to fair and reasonable licensing terms, there is no clear mechanism ensuring that any assignee or subsequent transferee of that patent remains bound by those same commitments. The omission of such language in HL7 and DICOM heightens the uncertainty for implementers of these healthcare standards: a participant could transfer ownership of its patent to another entity (e.g., a non-practicing entity) that never agreed to HL7 or DICOM's IPR terms, thus raising the specter of more aggressive or opportunistic licensing demands.

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[107] Nat'l Electr. Mfrs. Ass'n, *DICOM Policies and Procedures* § 9.1 (Oct. 2022), https://www.dicomstandard.org/docs/librariesprovider2/dicomdocuments/documents/dicom-policies-and-procedures-2022-october-updates.pdf?sfvrsn=d04262df_3.

[108] *See* Matthew G. Rose, Jay Jurata, Emily Luken, "*Between a Rock and a Hard Place" Unwired Planet v. Huawei and the Dangerous Implications of Worldwide FRAND Licenses*, Concurrences 84684 at 11 (showing that half of asserted SEPs that are not withdrawn are found to be infringed, implying they are not essential to the standard).

[109] The mental state of "knowledge" required to trigger a disclosure obligation at DICOM is also greater than that of ETSI. "Knowledge and belief are very different mental states; knowledge implies a much higher degree of certainty." *United States v. Golomb*, 811 F.2d 787, 792 (2d Cir. 1987). Given the difficulty in assessing actual essentiality, it may be difficult for a defendant to show the existence of such a duty absence a smoking gun.

[110] Health Level Seven Int'l, *HL7 Essential Patent Information Policy*, HL7, https://www.hl7.org/legal/patentinfo.cfm (last visited Feb. 26, 2025).

[111] The authors contacted DICOM regarding IPR licensing commitments, but did not hear back in time for publication.

SDO	Disclosure Obligation	Transfer Encumbrance
ETSI	"[I]t is the Declarant's . . . present belief that the IPR(s) disclosed in the attached IPR Information Statement Annex may be or may become essential"[112]	"FRAND licensing undertakings made pursuant to Clause 6 shall be interpreted as encumbrances that bind all successors-in-interest. . . . Declarant . . . who transfers ownership of ESSENTIAL IPR that is subject to such undertaking shall include appropriate provisions . . . ensure that the undertaking is binding on the transferee and . . . The undertaking shall be interpreted as binding on successors-in-interest regardless of whether such provisions are included in the relevant transfer documents."[113]
IEEE	"The Submitter of a Letter of Assurance may, after Reasonable and Good Faith Inquiry, indicate it is not aware of any Patent Claims that the Submitter may own, control, or have the ability to license that might be or become Essential Patent Claims."[114]	"An Accepted Letter of Assurance is intended to be binding upon any and all assignees and transferees of any Essential Patent Claim covered by such LOA. The Submitter agrees (a) to provide notice of an Accepted Letter of Assurance either through a Statement of Encumbrance or by binding its assignee or transferee to the terms of such Letter of Assurance; and (b) to require its assignee or transferee to (i) agree to similarly provide such notice and (ii) to bind its assignees or transferees to agree to provide such notice as described in (a) and (b)."
HL7	"All participants shall identify to HL7 Headquarters, through the issuance of a letter of assurance, any patents or patent applications felt to be applicable to the HL7 Protocol Specifications"[115]	No provision
DICOM	"Members have an affirmative duty . . . to bring to the attention of the Committee any patents or patent	No provision

[112] ETSI Directive Annex 6 at 53 (Nov. 29-30, 2022) https://www.etsi.org/images/files/IPR/etsi-ipr-policy.pdf.
[113] ETSI Directive Annex 6 § 6.1bis (Nov. 29-30, 2022) https://www.etsi.org/images/files/IPR/etsi-ipr-policy.pdf.
[114] IEEE SA, Standards Board Bylaws at § 6.2, https://standards.ieee.org/about/policies/bylaws/sect6-7/ (last visited Feb. 25, 2026).
[115] Health Level Seven International, Governance and Operations Manual § 09.03 (Jan. 14, 2025), http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf.

SDO	Disclosure Obligation	Transfer Encumbrance
	applications . . . owned by the Member . . . and known to the Member that practicing one or more claims of a patent or patent application is required to implement any portion of the DICOM Standard or a revision thereof that is proposed for adoption."[116]	

These two defects in the HL7 and DICOM IPR policies—the high threshold for triggering disclosure and the absence of any requirement that FRAND or royalty-free assurances travel with transferred patents—take on elevated risk precisely because these standards underpin much of today's healthcare data exchange. If hidden patents surface or if a licensing commitment is lost through transfer, entire healthcare ecosystems that rely on seamless data sharing—across hospitals, EHR platforms, and global health networks—could be blindsided by sudden unconstrained licensing demands. A sudden licensing war—as has already occurred in smartphones[117] and appears to be occurring in streaming services[118]—would jeopardizes not only the financial stability of companies providing critical healthcare technology, but also the continuous access to patient information. Furthermore, the fact that HL7, FHIR and DICOM are increasingly mandated or widely adopted in multiple jurisdictions intensifies the impact of these potential pitfalls. A single patent dispute or unencumbered transfer could affect countless providers and patients across national healthcare systems, undercutting the cost savings and interoperability goals that drove widespread HL7, FHIR, and DICOM adoption in the first place. Without clearer safeguards in the underlying IPR policies, the very standards designed to foster open, integrated healthcare risk becoming chokepoints for opportunistic patent enforcement.

[116] Procedures for the DICOM Standards Committee, DICOM § 9.03 (November 16, 2017), https://dicom.nema.org/dicom/geninfo/procedures.pdf.

[117] *See generally* Jonathan Radcliffe and Gillian Sproul, *FRAND and the Smartphone Wars*, December 2011/January 2012 Intellectual Property Magazine 45 (2011-12), https://www.mayerbrown.com/Files/Publication/477a076f-dd7e-408c-8321-64edf33c190e/Presentation/PublicationAttachment/5b202a76-bc80-4467-b286-7a3b8e90e06d/Frand_Smartphone_Sproul.pdf.

[118] Nisha Shetty, *Nokia and Ericsson Executives Shine Light on Video Streaming Licensing Strategies*, IAM (Oct. 16, 2024), https://www.iam-media.com/article/nokia-and-ericsson-executives-shine-light-video-streaming-licensing-strategies; Angela Morris, *InterDigital Announces Streaming Licensing Programme and $1 Billion Revenue Target*, IAM (Sept 18, 2024), https://www.iam-media.com/article/interdigital-announces-streaming-licensing-programme-and-1b-revenue-target.

V. Protecting Innovation Through Balanced SEP licensing Ecosystem in Healthcare Standards

In order to mitigate these risks, policy makers and stakeholders related to healthcare technologies and medical devices should work together to advance policies that preserve and advance the FRAND commitment.

In addition to these broad policies that extend beyond the health context, policy makers should take several steps to ensure continued investment in innovative products in healthcare technology and medical devices. By implementing these recommendations, policymakers across competition, patent, and healthcare domains can address the systemic risks posed by abusive SEP licensing practices. These measures will ensure that the healthcare technology market remains competitive, fosters innovation, and delivers interoperable solutions that enhance patient outcomes.

A. Enhancing Antitrust Enforcement Against Predatory SEP Licensing Practices

To safeguard competition and innovation in healthcare technology markets, competition policymakers should take immediate action to address predatory behavior by SEP licensors. These actions include enforcing antitrust laws against licensors that commit to licensing SEPs on FRAND terms but later exploit their position to distort competition. Such practices undermine market efficiency, inflate healthcare costs, and stifle the development of cutting-edge medical technologies. Policymakers should also collaborate with SDOs to modernize their IPR policies, ensuring they deter abusive SEP licensing practices and support a balanced ecosystem where innovation and consumer access are prioritized.

B. Strengthening National Patent Policies for Medical Devices

Congress should take targeted steps to reduce the impact of SEP licensing disputes on healthcare delivery. A critical measure would be precluding ITC jurisdiction over FDA approved medical devices by establishing a statutory presumption of a public interest against exclusion orders for these devices. This policy would mitigate the risk of supply disruptions caused by exclusion orders and ensure that life-saving medical devices remain available to healthcare providers and patients. By protecting regulated medical technologies from excessive legal entanglements, policymakers can foster an environment that supports continuous innovation while maintaining patient care standards.

C. Promoting Health Data Interoperability and Innovation Through Licensing Reforms

National health policymakers play a vital role in ensuring health data interoperability and reducing barriers to technological advancement. Policymakers should require that contractors and grantees working with healthcare technologies adopt robust licensing practices for SEPs, particularly for standards such as HL7 and DICOM, on clear FRAND terms and make specific declarations as to

what patents they believe are essential. This requirement will align licensing practices with the intended meaning of FRAND commitments and prevent exploitation by SEP holders.
Moreover, health policymakers should investigate SDOs IPR policies and encourage updates addressing deficiencies to prevent abusive practices that inhibit competition and innovation. These efforts should prioritize protecting medical device markets from SEP holders seeking to undermine the very standards designed to promote interoperability and efficiency. Policymakers should also take direct steps to enforce FRAND commitments for technologies that regulatory bodies incorporate or endorse, ensuring compliance and reducing licensing disputes.