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ARTIFICIAL INTELLIGENCE/MACHINE LEARNING-BASED MEDICAL DEVICES: REGULATORY AND PATENTABILITY CHALLENGES

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I. INTRODUCTION

From human androids to robot surgeons, a dystopian world with technology dominating every aspect of life may be closer to reality than fiction. For instance, in 2017, Saudi Arabia granted citizenship to a humanoid robot named Sophia for the first time in history.[1] Built by the Hong Kong-based company, Hanson Robotics, Sophia is imbued with artificial intelligence and can reportedly mimic sixty-two human facial expressions.[2] After being given the gift of legal personhood, Sophia has now been condemned to an eternity of working in marketing.[3] Naturally, this event has triggered discussions among scholars and laypeople on the ethics of artificial intelligent humanoids.[4] Another example involves the da Vinci robotic system, introduced by

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[1] Alistair Walsh, *Saudi Arabia Grants Citizenship to Robot Sophia*, DEUTSCHE WELLE (Oct. 28, 2017), https://www.dw.com/en/saudi-arabia-grants-citizenship-to-robot-sophia/a-41150856#:~:text=Saudi%20Arabia%20granted%20citizenship%20to,company%20Hanson%20Robotics%20in%202015.

[2] *Id.*

[3] Emily Reynolds, *The Agony of Sophia, the World's First Robot Citizen Condemned to a Lifeless Career in Marketing*, WIRED (June 1, 2018), https://www.wired.co.uk/article/sophia-robot-citizen-womens-rights-detriot-become-human-hanson-robotics.

[4] *Id.*

Intuitive Surgical in 2000.[5] In the past twenty years, researchers have designed automation builds that can be tacked onto the existing da Vinci system to allow for greater automation during surgical procedures.[6] Currently, these robot surgeons are conducting procedures that include bone cuts and radiation delivery for cancer treatment.[7]

Artificial intelligence and machine learning have already dominated many aspects of human lives, but they often go unnoticed as these applications have integrated so smoothly into human society. Because of the ability of artificial intelligence and machine learning applications to self-learn and imitate the traits of the human mind—like reasoning, problem solving, planning, and optimal decision-making—many industries implementing such technologies have thrived.[8] One of the most significant advancements in this space is in the healthcare industry with the development of software as a medical device (SaMD).[9]

The International Medical Device Regulators Forum (IMDRF) defines the term "software as a medical device" (SaMD) as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."[10] The IMDRF is a voluntary world-wide group of medical device regulators who have come together to harmonize medical device

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5 *About da Vinci Systems*, INTUITIVE, https://www.davincisurgery.com/da-vinci-systems/about-da-vinci-systems (last visited Feb. 6, 2021).

6 *Id.*

7 Elizabeth Svoboda, *Your Robot Surgeon Will See You Now*, NATURE (Sept. 25, 2019), https://www.nature.com/articles/d41586-019-02874-0.

8 Suni Kumar, *Advantages and Disadvantages of Artificial Intelligence*, TOWARDS DATA SCI. (Nov. 25, 2019), https://towardsdatascience.com/advantages-and-disadvantages-of-artificial-intelligence-182a5ef6588c.

9 IMDRF SaMD Working Group, *Software as a Medical Device (SaMD): Key Definitions*, INT'L MED. DEVICE REG. F., 4 (Dec. 9, 2013), http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf.

10 *Id.* at 6.

regulation.[11] IMDRF develops internationally agreed upon documents related to a wide variety of topics affecting medical devices.[12] In 2013, IMDRF formed the Software as a Medical Device Working Group (WG) to "develop guidance supporting innovation and timely access to safe and effective Software as a Medical Device globally."[13]

The U.S. Food and Drug Administration (FDA) and the European Commission (EC) are responsible for promulgating regulations for all types of medical devices.[14] Healthcare industry technology is ever-evolving and inventors are continually innovating new ways to use software as medical devices, specifically artificial intelligence (AI) and machine learning (ML)-based medical devices.[15] These software applications have benefitted the healthcare industry, improving diagnostic efficacy and efficiency in medical monitory and healthcare administration.[16] Although regulatory agencies around the world have adapted to SaMD, the integration of AI/ML algorithms into a medical device is still emerging.

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11 *International Medical Device Regulators Forum (IMDRF)*, U.S. FOOD & DRUG ADMIN. (Aug. 27, 2019), https://www.fda.gov/medical-devices/cdrh-international-programs/international-medical-device-regulators-forum-imdrf.

12 *Id.*

13 *Software as a Medical Device (SaMD)*, U.S. FOOD & DRUG ADMIN. (Dec. 4, 2018), https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd (discussing role of Software as a Medical Device Working Group, chaired by the FDA, to create framework for risk categorization, quality management system, and clinical evaluation of Software as a Medical Device).

14 NATIONAL ACADEMIES PRESS (US), PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS: BALANCING PATIENT SAFETY AND INNOVATION: WORKSHOP REPORT 35-41 (Wizemann T ed., 2010) (providing an introduction to the medical device framework in the European Union and comparing with medical device frameworks in Japan, India, and China).

15 Alicia Phaneuf, *Use of AI in Healthcare & Medicine Is Booming – Here's How the Medical Field Is Benefiting from AI in 2021 and Beyond*, INSIDER (Jan. 29, 2021, 8:47 PM), https://www.businessinsider.com/artificial-intelligence-healthcare#:~:text=save%20them%20money.-,AI%20has%20the%20ability%20to%20analyze%20big%20data%20sets%20%E2%80%93%20pulling,AI%20to%20better%20serve%20patients.

16 Phaneuf, *supra* note 15.

There are two main concerns for AI/ML-based medical device inventions: the lack of regulations in the United States and European Union (EU) and the need for invention novelty to cross the patentability threshold.[17] When implemented appropriately, medical device regulations provide robust protection for public health, which enables the public to have access to safe and effective medical treatment.[18] Also, exclusive patent rights allow inventors to strategically exclude others from making, using, or selling their invention in the issuing country during the life of the patent, allowing patent holders leverage over emerging competition.[19] Both of these considerations are crucial for positive outcomes of AI/MI based inventions in the medical technology industry. Consequently, regulatory bodies have the crucial job of creating AI/ML regulations that will address these concerns.

The FDA does not currently have any final regulations relating to AI/ML in medical devices; the agency only has a proposed regulatory framework published in discussion papers or guidance documents for the industry.[20] For instance, on April 2, 2019, the FDA published a discussion paper and requested feedback on the *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)*.[21] Similarly,

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[17] Christian Johner, *Artificial Intelligence in Medicine*, JOHNER INST. N. AMERICA (Feb. 2, 2019), https://www.johner-institute.com/articles/software-iec-62304/and-more/artificial-intelligence/#:~:text=There%20are%20currently%20no%20laws,performance%20of%20the%20medical%20device.

[18] *Medical Device Regulations: Global Overview and Guiding Principles*, WORLD HEALTH ORG. (2003).

[19] Joseph G. Hadzima, *The Importance of Patents: It Pays to Know Patent Rules*, BOS. BUS. J. (2005), http://web.mit.edu/e-club/hadzima/the-importance-of-patents.html.

[20] Johner, *supra* note 17.

[21] *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)*, U.S. Food and Drug Administration (2019), http://med.a51.nl/sites/default/files/pdf/Proposed_Regulatory_Framework_for_Modifications_to_Artificial_Intelligence_Machine_Learning_%28AI_ML%29-Based_Software_as_a_Medical_Device_%28SaMD%29_-_Discussion_Paper_and_Request_for_Feedback.pdf (last visited Apr 15, 2022) (in the framework described in the discussion paper, the FDA envisions a

the EU has not published any regulations or guidance documents relating to AI/ML in medical devices,[22] which, like those regulations for hardware medical devices, are crucial in determining the device safety and efficacy. Through established regulations, manufacturers and regulators can ensure performance consistency and deliver safe, effective medical devices to consumers. Based upon current guidance documents and literature, this article will propose AI/ML-based medical device regulations for the United States and the EU.[23]

Before discussing needed regulations, this article first discusses the general framework of FDA regulations and the EU regulations. Many countries follow these two regions' lead when designing medical device regulations; thus, understanding their specific frameworks is essential when considering potential harmonization of regulations. Next, the article will compare the FDA medical device regulations with the EU medical device regulations. Understanding and comparing the regulations are critical to comprehend patentability because, in order for medical devices to be cleared for commercialization or approved for market, manufacturers need to use a "substantial equivalence" standard in the United States and an "equivalent device" standard in the EU.[24] These standards impact the U.S. and EU patentability laws

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"predetermined change control plan" in premarket submissions. This plan would include the types of anticipated modifications—referred to as the "Software as a Medical Device Pre-Specifications"—and the associated methodology being used to implement those changes in a controlled manner that manages risks to patients — referred to as the "Algorithm Change Protocol.").

[22] Johner, *supra* note 17.

[23] Originally, the Medical Device Directive (93/42/EEC) was in effect until the European Commission introduced the EU Medical Device Regulations (EU 2017/745) on May 26, 2017. The European Commission has given the industry three years for full Medical Device Regulations compliance. Even with the new regulations, the EC has not introduced any provisions related to artificial intelligence or machine learning. *Transition Timelines from the Directives to the Regulations*, EUROPEAN COMM'N, https://ec.europa.eu/health/sites/health/files/md_newregulations/docs/md_infographic-timeline_en.pdf (last visited Feb. 11, 2021)

[24] The FDA describes the substantial equivalence standard in an FDA guidance document. See Section II Background for the definition of "substantial equivalence." The EU MDR describing equivalent device. See Section II Background for the definition of "equivalent device." It is also important to note that the substantial equivalence standard is used for Class II medical devices in the United States; and, the equivalent device standard can be applied as long as the device is

because it is unclear whether these medical devices, although ready for commercialization, are novel or inventive enough to get over the threshold for patentability.

After the patentability discussion, the article will employ a comparative analysis of U.S. and EU software as a medical device regulations. Since artificial intelligence and machine learning in the healthcare space are relatively new, there are not many regulations relating to AI/ML-based SaMD. Currently, the FDA only has guidance documents related to AI/ML-based SaMD, but no final promulgated regulations.[25] The EU recently published its new Medical Device Regulations (MDR), but the MDR only has provisions for general SaMD, and has not included any provisions relating specifically to AI/ML-based SaMD.[26]

Part III Section B of this article will propose potential pathways for AI/ML-based SaMD regulations for the U.S. and EU regulatory network. The proposal will be made by comparing the FDA with EC SaMD regulations and extrapolating that to include AI/ML-based SaMD regulations, while discussing clinical validity of a medical device with AI/ML.[27] Because the FDA also does not have any regulations specifically for AI/ML and only guidance documents, the extrapolation for potential regulatory pathways will consider FDA guidance documents and literature as well.

The last central point of the article will connect AI/ML-based SaMD regulations back to the patentability issues in the United States

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used for the same clinical condition or purpose and has the same kind of user. Only these types of devices will be considered in this article as that ties into the issues with patentability.

[25] *Artificial Intelligence and Machine Learning in Software as a Medical Device*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device (last updated Jan. 12, 2021) (draft guidance document published by the FDA to provide information to the industry regarding medical devices that contain artificial intelligence or machine learning).

[26] *Transition Timelines from the Directives to the Regulations*, *supra* note 23.

[27] Although only clinical validity is mentioned there, the medical device pathway to commercialization includes submission of technical documentation. This is further explained in Part II Section C.

and EU, as discussed in Part III Section C. In addition to commercialization success, many manufacturers are interested in obtaining intellectual property rights for their invention. When manufacturers use the substantial equivalence or the equivalent device standard, they generally have a hard time finding a novelty hook to pass the patentability test.[28] This challenge is true for all medical devices, regardless of their mode of operation—hardware or software. This follows that because the functionality, the clinical validity, and the intended use of the AI/ML-based SaMD would still be used to determine whether the device will get cleared or approved for commercialization, the impact on patentability will still be similar. Lastly, this article will conclude by providing proposals on how companies can overcome the challenging patentability hurdle for AI/ML-based SaMD.

II. BACKGROUND

A. Short History of Artificial Intelligence (AI)

Over the past few decades, the terms "artificial intelligence" and "machine learning" have become more colloquial with the technological advancement.[29] Software, or more specifically, a piece of programming algorithm, is a preset, rigid, coded step-by-step instruction that gets executed when it encounters a trigger.[30] On the other hand, artificial intelligence is a group of algorithms that has the capability to modify itself and create new algorithms in response to learned inputs and data.[31] Instead of relying on inputs that the standard algorithm is designed to recognize, "intelligent" algorithms absorb massive amounts of data and "learn" from the data to form new and more efficient pathways, similar to human intelligence.[32] This capability

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[28] 35 U.S.C.A. § 101–3 (West 2021).

[29] AMEET V. JOSHI, MACHINE LEARNING AND ARTIFICIAL INTELLIGENCE 3-7 (1 ed. 2020).

[30] Kaya Ismail, *AI vs. Algorithms: What's the Difference?*, CMS WIRE (Oct. 26, 2018), https://www.cmswire.com/information-management/ai-vs-algorithms-whats-the-difference/.

[31] Ismail, *supra* note 30.

[32] *What Is Artificial Intelligence?*, BUILT IN, https://builtin.com/artificial-intelligence (last visited Oct. 13, 2020).

to change, adapt, and learn based on new data is described as "intelligence."[33]

In 1950, English mathematician Alan Turing, the "Father of Artificial Intelligence," published an academic paper titled "Computing Machinery and Intelligence," which introduced a concept that changed the entire world of computer science.[34] He developed a test (the Turing test) that would evaluate a machine's ability to exhibit intelligent behavior as either equivalent to or indistinguishable from a human.[35] During the test, a human evaluator would judge a natural language conversation between a human and a machine.[36] If the human evaluator was unable to distinguish the human from the machine, the machine was said to have passed the Turing test.[37] This test was only theoretical, but with the increase in computational power over the decades, intelligent machines are slowly becoming a reality.

The term "artificial intelligence" was first coined in 1956 by John McCarthy in an academic conference.[38] John McCarthy, who invented the programming language Lisp (historically LISP), organized a conference with many other experts in the field to discuss the possibility of machines simulating the human way of thinking.[39] Over the next few decades, as computer processing power increased, the machines will become more "intelligent," although expectations for AI have always exceeded reality.[40] While computer software have beaten humans in chess games and complicated board games, AI has not advanced enough to simulate human thinking, and no computer has come close to passing the Turing test.[41] Instead of truly intelligent humanoids as seen in science fiction, AI has a more subtle effect in the

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33 Ismail, *supra* note 30.

34 Chris Smith et al., *The History of Artificial Intelligence*, HISTORY OF COMPUTING (Dec. 2006), https://courses.cs.washington.edu/courses/csep590/06au/projects/history-ai.pdf; Alan Turing, *Computing Machinery and Intelligence*, 59 MIND 433-442 (1950).

35 *Id.* at 433-42.

36 *Id.*

37 *Id.*

38 TOM TAULLI, ARTIFICIAL INTELLIGENCE BASICS 6 (1 ed. 2019).

39 *Id.* at 7.

40 *Id.* at 8; *Id.* at 11.

41 Taulli, *supra* note 38.

real world— mostly through automation of mundane tasks to make human life more efficient.

This is not to say that the field of artificial intelligence is not advancing rapidly— computers are getting higher processing speeds, so the progress of artificial intelligence is also accelerating.[42] Currently, many companies utilize artificial intelligence applications to increase their operations efficiency and reliability. From chatbots to human resource data management, AI is successfully incorporated into various business interfaces to help business owners understand how they receive and interpret data.[43]

B. Merging Artificial Intelligence and Healthcare

Artificial intelligence is rapidly growing in healthcare, significantly impacting every aspect of the industry. Introducing artificial intelligence into the healthcare industry has provided many advantages for primary healthcare providers, including improving efficiency, accuracy, and precision of healthcare services.[44] Advantages can also be seen on the healthcare administration side with patient data management and automating administrative tasks.[45] Thirty percent of healthcare costs are associated with administrative tasks.[46] AI can automate some of these tasks and ease the workload of healthcare professionals to ultimately save them money.[47] Wearable healthcare technology, like smartwatches, also use AI to better serve patients by

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42 Matt Asay, *Where AI Has Made Real Progress*, InfoWorld (2021), https://www.infoworld.com/article/3635489/where-ai-has-made-real-progress.html (last visited Apr 15, 2022).

43 Forbes Technology Council, *15 Business Applications For Artificial Intelligence And Machine Learning*, FORBES (Sep. 27, 2018), https://www.forbes.com/sites/forbestechcouncil/2018/09/27/15-business-applications-for-artificial-intelligence-and-machine-learning/.

44 Amisha et al., *Overview of Artificial Intelligence in Medicine*, 8(7) J. FAM. MED. & PRIMARY CARE 2328, 2329 (2019).

45 *Id.* at 2330.

46 Phaneuf, *supra* note 15.

47 *Id.*

analyzing data to alert users and their healthcare professionals of potential health issues and risks.[48]

Although AI integration has many advantages, many believe that AI will eventually replace human workers.[49] Their fear is not entirely unfounded.[50] Healthcare professionals may be replaced with the increasing intelligence in machines.[51] Radiologists and pathologists may be especially vulnerable as many of the most impressive breakthroughs in AI are happening around medical imaging and diagnostics.[52] Although this fear may be legitimate in certain regions of the world, many countries are experiencing a shortage of healthcare professionals, and AI solutions may be a lifesaving option.[53] AI can likely fill worker shortage gaps by reducing menial tasks that healthcare professionals will have to perform.[54] Additionally, introducing AI to carry out administrative tasks will allow current healthcare professionals to have more face time with their patients and improve the patient care experience.[55]

Data privacy is also one of the most cited concerns regarding AI healthcare integration.[56] The success of AI relies on the wealth of patient data fed into the algorithms.[57] Therefore, data security and privacy will always be a concern.[58] According to a 2017 study completed in the United Kingdom, the three main types of breaches in the health sector were (1) data posted or faxed to an incorrect recipient, (2) loss or theft of paperwork, and (3) data sent by email to

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48 *Id.*

49 Jennifer Bresnick, *Arguing the Pros and Cons of Artificial Intelligence in Healthcare*, HEALTH IT ANALYTICS (Sept. 18, 2018), https://healthitanalytics.com/news/arguing-the-pros-and-cons-of-artificial-intelligence-in-healthcare.

50 *Id.*

51 *Id.*

52 *Id.*

53 *Id.*

54 *Id.*

55 *Id.*

56 *Id.*

57 *Id.*

58 *Id.*

an incorrect recipient.[59] This study suggests that data breaches occur as a result of accidental mistakes made during the course of routine care.[60] However, government agencies are rapidly catching up to the advancement of AI technology, and as a result, there has been a surge in new policies and regulations for data privacy and security.[61] The advancement of AI technology has shown to be advantageous to the healthcare industry. Instead of impeding its progress, humans will be forced to learn, change, and adapt, just like artificial intelligent algorithms.

Three major fields present significant trends in AI: chronic diseases management, medical imaging, and AI and the Internet of Things (IoT).[62] Through the implementation of machine learning in AI, companies are able to manage chronic diseases by monitoring the disease with sensors and automating delivery of treatment as needed using connected mobile applications.[63] The field of medical imaging is growing with the integration of AI-driven platforms in medical scanning devices to improve image clarity and clinical outcomes by reducing radiation exposure.[64] Various companies are also integrating AI and IoT to better monitor patient adherence to treatment protocols and to improve clinical outcomes.[65] As discussed above, unfortunately, with the prevalence of improved and automated systems, there arises the concern of decreased job opportunities for humans.[66]

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59 *What Are the Risks Around Patient Data?*, UNDERSTANDING PATIENT DATA, https://understandingpatientdata.org.uk/weighing-up-risks#data-breaches-in-the-health-sector (last visited Jan. 15, 2021).

60 *Id.*

61 Bresnick, *supra* note 49.

62 Kumba Sennaar, *AI in Medical Devices—Three Emerging Industry Applications*, EMERJ, https://emerj.com/ai-sector-overviews/ai-medical-devices-three-emerging-industry-applications/. (last updated Nov. 22, 2019).

63 Sennaar, *supra* note 62.

64 *Id.*

65 The term Internet of Things (IoT) encompasses everything connected to the internet, used to define objects that "talk" to each other. Matt Burgess, *What Is the Internet of Things? WIRED Explains*, WIRED (Feb. 16, 2018), https://www.wired.co.uk/article/internet-of-things-what-is-explained-iot.

66 Amisha et al., *supra* note 44.

Similar to how the private industry adapts to emerging technology, regulatory agencies across the globe are discussing how to implement a regulatory framework for artificial intelligence.[67] Public safety and device efficacy continue to be the priority of many agencies.[68] Regulatory bodies will have to balance safety and efficacy without impeding the innovation efforts of manufacturers. Further, regulators around the world recognize the need for a common regulatory framework and uniform SaMD principles that will promote safe innovation and protect patient safety.[69] With the rapid development of AI, FDA and EU regulations have not kept pace and must be addressed for current and future medical device manufacturers. The FDA and the EU already recognize stand-alone software as a medical device (SaMD), therefore, it is reasonable to envelope artificial intelligence within SaMD regulations.[70]

The United States and EU are two of the five founding members of the Global Harmonization Task Force (GHTF).[71] The GHTF was founded in 1992 in response to a need for ease of medical device commercialization without administrative redundancy like documentation review and repeated safety testing.[72] This voluntary group was comprised originally of representatives from the medical device regulatory authorities of the five founding members: United States, European Union, Japan, Australia, and Canada.[73] Because major software companies like Amazon, Oracle, Google, and Facebook are also based in the United States and the EU, these two regions have a higher stake in designing favorable medical device regulations.[74]

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67 Johner, *supra* note 17.

68 *Id.*

69 *International Medical Device Regulators Forum (IMDRF)*, *supra* note 11.

70 *Software as a Medical Device (SaMD), supra* note 13; Regulation 2017/745 of the European Parliament and of the Council of Apr. 5, 2017, art. 2, 2017 O.J. (L 117) 1 (EU).

71 Susan Lamph, *Regulation of Medical Devices Outside the European Union*, 105(Suppl 1) J. ROYAL SOC'Y MED. S12, S13 (2012).

72 *Id.*

73 *Id.*

74 *Global 100 Software Leaders by Revenue* (2016), PWC (2016), .https://www.pwc.com/gx/en/industries/technology/publications/global-100-software-leaders/explore-the-data.html.

C. United States Food and Drug Administration (FDA) Medical Device Regulation Structure

The U. S. Food and Drug Administration (FDA) is the oldest comprehensive consumer protection government agency.[75] The FDA promotes and protects the health of the citizens of the country by regulating food, cosmetics, drugs (including generic drugs and animal drugs), biologics, and medical devices.[76] The agency is split into various offices that specialize in various product regulation.[77] Each office is responsible for regulating products and ensures that the product is ready for commercialization.[78] FDA's Center for Devices and Radiological Health (CDRH) regulates medical devices in the United States[79] by evaluating the safety and efficacy of medical devices before and after commercialization.[80]

Under Section 201(h) of the Federal Food, Drug, and Cosmetics Act,[81] FDA defines a medical device as "an instrument, apparatus, machine, implant, in vitro reagent, including component, part, or accessory, that diagnoses, cures, mitigates, treats, or prevents disease or condition, affects structure or function of body, and does not achieve that purpose as a drug."[82] The agency classifies devices

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75 Elias Mallis, *An Introduction to FDA's Regulation of Medical Devices*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/123602/download (last visited Oct. 16, 2020).

76 *Id.*

77 *Id.*

78 *Id.*

79 *Id.*.

80 *Id.*

81 Federal Food, Drug, and Cosmetics Act § 201(h), 21 U.S.C. § 321(h).

82 21 U.S.C.A. § 321(h) (West 2021). FDA defines a medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

based on the their description and intended use.[83] The classes of medical devices include Class I, Class II, and Class III; the classes increase with the degree of risk.[84] Devices can also be defined by their three-letter product codes, which designate groups of similar devices and intended use.[85] This article focuses on Class II devices as the substantial equivalence standard is only used for Class II medical devices in the United States; the equivalent device standard can be applied as long as the device is used for the same clinical condition or purpose and has the same kind of user.[86] Only these types of devices will be considered in this article as that ties into the issues with patentability.

Class II medical devices are cleared for commercialization through two different pathways—a 510(k) submission or an exemption.[87] A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device.[88] Manufacturers must compare their device to one or more similar legally marketed devices and make and support their substantial equivalence claims.[89] A device is substantially equivalent if,

> in comparison to a predicate, it has the same intended use as the predicate; has the same technological characteristics as the predicate; or has different technological characteristics but does not raise different questions of safety and effectiveness; and the information submitted to FDA demonstrates that the

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[83] *Classify Your Medical Device*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device (last updated Feb. 7, 2020).

[84] *Id.*

[85] 21 C.F.R. § 807.100 (2020).

[86] *See* note 24.

[87] *Classify Your Medical Device*, *supra* note 83.

[88] Federal Food, Drug, and Cosmetics Act § 513(i)(1)(A).

[89] *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k (last updated Mar. 13, 2020).

> device is as safe and effective as the legally marketed device.[90]

The submission exemption pathway is where devices can be placed on the market without any formal 510(k) submission to the FDA due to their low-risk intended use.[91] This exemption applies if the FDA determines that a 510(k) is not required to provide reasonable assurance of safety and effectiveness for the device.[92] Devices which may be exempt from 510(k) requirements are pre-amendment devices, and Class I and Class II devices specifically exempted by the FDA.[93]

The 510(k) pathway may seem like an attractive pathway for new medical device manufacturers, but several issues have been identified within the industry.[94] The main issue involves the lack of clarity and consistency of the substantial equivalence standard, specifically the definitions of "same intended use" and "same technological characteristics."[95] The intended use of a device and its labeled indication are usually not synonymous.[96] With the absence of a statutory definition of "same intended use," the FDA permits a rather

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[90] The requirements of the 510(k) submission include submission of bench testing data, non-clinical data, technological documentation, verification and validation reports, product labeling, and sometimes clinical data may even be required. *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k (last updated Mar. 13, 2020).

[91] *Classify Your Medical Device*, *supra* note 83.

[92] *Class I / II Exemptions*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-ii-exemptions (last updated July 1, 2019).

[93] Preamendment status can be obtained for a medical device if it was in commercial distribution before May 28, 1976, the date the Medical Device Amendments were signed into law. The FDA requires supporting documentation and a signed affidavit to prove the preamendment status of a device for a specific use. *Preamendment Status*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status (last updated Nov. 15, 2017); *Class I / II Exemptions, supra* note 92.

[94] Jonas Zajac Hines et al., *Left to Their Own Devices: Breakdowns in United States Medical Device Premarket Review*, 7(7) PLOS MED. (2010).

[95] *Id.* at 3.

[96] *Id.*

lenient interpretation of this term.[97] Even though the agency asserts that it possesses the "scientific expertise [that] enables [the agency] to exercise considerable discretion in construing intended uses," the FDA has permitted more novel devices to be reviewed under the 510(k) pathway.[98] Additionally, differences in technological characteristics of a predicate device and a new device do not preclude a determination of substantial equivalence, as long as the differences do not raise new issues of safety or effectiveness.[99]

D. European Union Medical Device Regulation (EU MDR) Structure

For manufacturers interested in the European market, medical devices will not be approved for commercialization without conforming to strict European Commission safety requirements.[100] One of the most important requirements is the affixation of the *Comformité Européenne* (French for 'European conformity') (CE) mark.[101] Instead of a national agency overseeing the regulatory process, the EU medical device regulation responsibility belongs to the Competent Authorities (CA), Notified Bodies (NB), and authorized representatives.[102] Although each member state may have their own regulatory scheme for medical device approval, all member states in the EU accept the CE mark and allow manufacturers to provide minimal documentation to show the safety and efficacy of a device before placing the product on the market.[103]

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97 *Id.*

98 *Id.*

99 *Id.* at 4.

100 *Id.*

101 Regulation 2017/745 of the European Parliament and of the Council of Apr. 5, 2017, art. 20, 2017 O.J. (L 117) (EU).

102 Elaine French-Mowat & Joanne Burnett, *How Are Medical Devices Regulated in the European Union?*, 105(Suppl 1) J. ROYAL SOC'Y MED. S22, S24 (2012).

103 Besides the members states that are part of the EU, countries in the European Economic Area (Norway, Liechtenstein and Iceland), Turkey, and Switzerland are part of the EU single market for medical devices. This means that these countries also accept the CE mark to show that the medical devices are approved for commercialization. *Medical Device Regulations: Global Overview and Guiding Principles*, WORLD HEALTH ORG. (2003).

A Competent Authority is "any person or organization that has the legally delegated or invested authority, capacity, or power to perform a designated function."[104] A Competent Authority designates a Notified Body to ensure that the conformity assessment procedures are completed according to the EU Medical Device Regulations (MDR).[105] The role of a Notified Body is to conduct a conformity assessment under the relevant EU Directives.[106] Another vital player in conformity assessments is the authorized representative. The authorized representative is designated by medical device manufacturers and is legally responsible for compliance with the MDR and serves as the first point of contact for the EU authorities.[107] The Competent Authority, Notified Body, and authorized representatives each have a precise scope of actions and responsibilities, as listed in the EU MDR.[108]

The term "medical device" as defined in the EU MDR is similar to the FDA definition.[109] Like the FDA, the EU regulations place medical devices into four categories: Class I (including Class Is and Im), Class IIa, Class IIb, and Class III. The higher the classification, the greater the level of assessment required by Notified Bodies (NB).[110] The intended purpose of the device determines the

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[104] *Want to Know More About the Notified Body?*, BSI GROUP, https://www.bsigroup.com/globalassets/meddev/localfiles/it-it/documents/bsi-guide_to_notified_body_2019-it.pdf (last visited Apr 15, 2022).

[105] French-Mowat & Burnett, *supra* note 102, at S23.

[106] BSI Group, *supra* note 104.

[107] French-Mowat & Burnett, *supra* note 102, at S23.

[108] Regulation 2017/745 of the European Parliament and of the Council of Apr. 5, 2017, art. 10, 2017 O.J. (L 117) (EU).

[109] Medical device is defined as "any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; investigation, replacement or modification of the anatomy or of a physiological process; control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means." Regulation 2017/745 of the European Parliament and of the Council of Apr. 5, 2017, art. 2, 2017 O.J. (L 117) (EU).

[110] French-Mowat & Burnett, *supra* note 102.

device classification, not the technical characteristics of the device.[111] There are several considerations for device classification, including the duration of contact with the human body, the degree of invasiveness, and local versus systemic effect of the device on the human body.[112]

Manufacturers have the responsibility to ensure that their device complies with the relevant EU legislation's essential requirements.[113] Each medical device class is required to prepare technical documentation that is submitted to the Notified Body for certification as part of the CE marking process.[114] Manufacturers must follow certain conformity assessment procedures, like design verification and validation, human factors engineering studies, or clinical evaluation, depending on the device's risk.[115] The procedures help manufacturers decide how much information is needed to support their claims of the safety and efficacy of their device.[116] The CE mark signifies that the device meets all the appropriate provisions of the relevant legislation,[117] and indicates that the device can be freely marketed anywhere in the European Economic Area (EEA) without further regulatory control.[118]

Similar to FDA regulations for Class II devices, the EU also uses the equivalent device standard.[119] Instead of using this standard for a certain class of devices, the EU MDR allows the show of equivalency for non-clinical and clinical data regardless of the classification of the device.[120] However, unlike the FDA, the EC does not have a unified regulatory body that reviews equivalency of

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111 *Id.*

112 Regulation 2017/745 of the European Parliament and of the Council of Apr. 5, 2017, Annex II, 2017 O.J. (L 117) (EU).

113 Regulation 2017/745 of the European Parliament and of the Council of Apr. 5, 2017, art. 10, 2017 O.J. (L 117) (EU).

114 French-Mowat & Burnett, *supra* note 102, at S23.

115 *Id.*

116 Regulation 2017/745 of the European Parliament and of the Council of Apr. 5, 2017, art. 10, 2017 O.J. (L 117) (EU).

117 *Id.*

118 French-Mowat & Burnett, *supra* note 102, at S23.

119 Regulation 2017/745 of the European Parliament and of the Council of Apr. 5, 2017, art. 5, 2017 O.J. (L 117) 1 (EU).

120 *Id.*

devices.[121] This burden falls on registered notified bodies.[122] Medical device manufacturers are responsible for engaging with a registered notified body before they may commercialize their devices in the European market.[123] Issues identified for FDA's substantial equivalence standard also exist for the EU equivalent device standard, including the lack of clarity and consistency in defining what constitutes an "equivalent device."[124]

E. Intellectual Property Law in the United States and the European Union and Issues with Patentability for Artificial Intelligence-Based Medical Devices

Intellectual property law in the United States, specifically copyright and patent law, is permitted by the U.S. Constitution,[125] which explicitly grants Congress power to "[p]romote the [p]rogress" of the relevant field and the ability to create copyright and patent law.[126] For trademarks and other forms of intellectual property, the federal government only has the authority to make law through the regulation of commerce.[127] It is widely understood that the Framers of the U.S. Constitution grounded the idea of copyright and patent law for the purpose of promoting economic benefit and increasing the amount of innovation and creative works available to the people.[128] Although the federal government is active in intellectual property law, there are still important state regulations.[129]

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121 Travis G. Maak & James D. Wylie, *Medical Device Regulation: A Comparison of the United States and the European Union*, 24 J. AM. ACAD. ORTHOPAEDIC SURGEONS 537, 543 (2016).

122 *Id.* at 539.

123 World Health Organization, *supra* note 103.

124 *Id.*

125 *Outline of the Legal and Regulatory Framework for Intellectual Property in the United States of America*, WIPO IP PORTAL, https://wipolex.wipo.int/en/info/outline/US (last visited Jan. 19, 2020).

126 [The Congress shall have power] "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." U.S. CONST. art. VIII, § 8.

127 *Id.*

128 Legal and Regulatory Framework *supra* note 125.

129 *Id.*

Congress delegated regulatory authority for intellectual property to several agencies.[130] The United States Patent and Trademark Office (USPTO), under the Department of Commerce, grants U.S. patents under the Patent Code, registers trademarks under the Lanham Act, and hears certain disputes through either the Patent Trial and Appeal Board (PTAB) or the Trademark Trial and Appeal Board (TTAB).[131] The Patent Code is contained in Title 35 of the United States Code (USC).[132] Patents are exclusively governed by federal law. There are three types of patents that may be granted: utility patents, design patents, and plant patents.[133] Currently, the utility patent term, starting from the earliest claimed filing date, is twenty years.[134] However, this timeline may be extended to accommodate for delays in the patent office or to obtain FDA approval under the Drug Price Competition and Patent Term Restoration Act.[135]

Fortunately for healthcare manufacturers the Food, Drug, and Cosmetics Act (FDCA) also grants quasi-patent rights in the form of market exclusivities for drugs.[136] For example, the Orphan Drug

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130 *Id.*

131 *About Us*, UNITED STATES PATENT AND TRADEMARK OFF. https://www.uspto.gov/about-us (last visited Jan. 19, 2022).

132 35 U.S.C.A. § 100 (Westlaw through Pub. L. No. 116-259).

133 *Manual of Patent Examining Procedure*, UNITED STATES PATENT AND TRADEMARK OFF., https://www.uspto.gov/patent/laws-and-regulations/manual-patent-examining-procedure (last visited Jan. 19, 2022).

134 35 U.S.C.A. § 154 (Westlaw through Pub. L. No. 116-259).

135 The Drug Price Competition and Patent Restoration Act, also known as the Hatch-Waxman Amendments, established the approval pathway for generic drug products, under which applicants can submit an abbreviated new drug application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). *Hatch-Waxman Letters*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters (last updated July 19, 2018).

136 The laws of the United States are organized by subject into the United States Code. The United States Code contains only the currently enacted statutory language. The official United States Code is maintained by the Office of the Law Revision Counsel in the United States House of Representatives. The Office of the Law Revision Counsel reviews enacted laws and determines where the statutory language should be codified related to its topic. The Federal Food, Drug, and Cosmetic Act and subsequent amending statutes are codified into Title 21 Chapter 9 of the United States Code. *Federal Food, Drug, and Cosmetic Act (FD&C Act)*, U U.S. FOOD & DRUG ADMIN., https://www.fda.gov/regulatory-information/laws-

Designation program grants "orphan status" to drugs and biologics, where "orphan status" is defined as "those intended for the treatment, prevention or diagnosis of a rare disease or condition, which is one that affects less than 200,000 persons in the United States or meets cost recovery provisions of the act."[137] Once a drug is designated as an orphan drug, the FDA will grant market exclusivity of the drug due to the drug's intended use of treating rare diseases.[138] For example, from 2014 to 2016, there were eleven cases of ebolavirus infections in the United States.[139] On May 8, 2019, the FDA designated EBANGA™ as an orphan drug intended for the treatment of infection caused by the Zaire ebolavirus in adult and pediatric patients, including neonates born to a mother who is tested positive for the Zaire ebolavirus infection.[140] EBANGA™ received market approval from the FDA on December 21, 2020.[141]

The European Union acts as a single market instead of as a collection of individual countries.[142] As an EU member, each country has a right to transfer and implement the laws and regulations promulgated by the EU.[143] Intellectual property law is included in that regulatory design. The European patent system is considered the home of the world patent system.[144] The European Patent Office (EPO) is

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enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act (last updated Mar. 29, 2018).

137 *Developing Products for Rare Diseases & Conditions*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/developing-products-rare-diseases-conditions (last updated Dec. 20, 2018).

138 *Designating an Orphan Product: Drugs and Biological Products*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products (last updated Apr. 6, 2020).

139 *2014-2016 Ebola Outbreak in West Africa*, CNTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/index.html (last updated Mar. 8, 2019).

140 *Search Orphan Drug Designations and Approvals*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/opdlisting/oopd/listResult.cfm (last visited Jan. 19, 2022).

141 *Id.*

142 *Single Market and Standards*, EUROPEAN COMM'N, https://ec.europa.eu/growth/single-market_en (last visited Jan. 19, 2022).

143 *Id.*

144 *Id.*

responsible for the search, examination, and authorization of European patents.[145] The requirements of patentability are similar to those in the United States insofar as the invention must satisfy several requirements—being novel, involving inventive procedure, being capable of industrial application, and not otherwise being excluded from patentability.[146]

A big concern for manufacturers, both in the United States and the EU, is whether the device passes the novelty threshold to meet patentability requirements.[147] When medical device manufacturers commercialize their device using the substantial equivalence standard in the United States, or equivalent device standard in the EU, manufacturers may not be able to differentiate their device from an existing device enough to have a novelty hook to render the device patentable. On average, manufacturers are expected to spend $31 million to bring a medical device to market through the 510(k) pathway.[148] The time and cost required to bring a device to market is a major incentive for manufacturers to also ensure its patentability to secure exclusive rights of the device for a set patent term.[149] This exclusive right will allow the patent owner to recoup any research and development costs and obtain a return on investment, which allows the manufacturer to gain competitiveness in the market.[150]

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145 *Patent Protection in the EU*, EUROPEAN COMM'N, https://ec.europa.eu/growth/industry/policy/intellectual-property/patents_en (last visited Jan. 19, 2022).

146 *Patentability Requirements*, JUSTIA, https://www.justia.com/intellectual-property/patents/patentability-requirements/ (last updated June 2019).

147 Xirui Zhang et al., *The Interplay Between the FDA Regulatory Process for Medical Devices and Patent Law—Considerations for 510(k) Submission*, FINNEGAN (Aug. 4, 2020), https://www.finnegan.com/en/insights/blogs/ip-fda-blog/the-interplay-between-the-fda-regulatory-process-for-medical-devices-and-patent-law-considerations-for-510k-submission.html.

148 Danielle Kirsh, *Exploring FDA Approval Pathways for Medical Devices*, MASS DEVICE (Sept. 12, 2019), https://www.massdevice.com/exploring-fda-approval-pathways-for-medical-devices/#:~:text=The%20average%20cost%20to%20bring,average%20costs%20of%20%2494%20million.

149 Evoluted New Media, *The Importance of Patents*, LABORATORY NEWS (July 1, 2005), https://www.labnews.co.uk/article/2029687/the_importance_of_patents.

150 *Id.*

Another potential issue is that a 510(k) submission for the device might be considered prior art.[151] Prior art constitutes those references or documents which may be used to determine novelty and non-obviousness of claimed invention in a patent application.[152] Prior art does not need to exist physically or even be commercially available; it is sufficient that someone, somewhere, sometime previously has described or shown or made something that contains a use of technology that is very similar to a manufacturer's device.[153] 35 U.S.C. 102(a) describes prior art as any "claimed invention that was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention."[154] Because a summary of a 510(k) submission is usually published and available on the FDA 510(k) database, it may be considered as prior art.[155]

The third potential issue is that the 510(k) submission of substantial equivalence information could be seen as an admission of infringement.[156] When submitting a 510(k), manufacturers usually identify a predicate device to conduct a substantial equivalence comparison with the manufacturer's own device.[157] Increasing the number of similarities found between the predicate device and the manufacturer's device increases the chances of clearance from the FDA. However, more similarities between the predicate device and the manufacturer's device has the inverse outcome in terms of patentability. Patent infringement rests on "making, using, offering to sell, or selling something that contains every element of a patented

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151 Zhang et al., *supra* note 147.

152 USPTO regularly publishes presentations to explain the process of a patent or trademark application. This presentation describes how to understand prior art and how to use it in determining patentability. Fenn Mathew, *Understanding Prior Art and Its Use in Determining Patentability*, UNITED STATES PATENT AND TRADEMARK OFFICE.
https://www.uspto.gov/sites/default/files/documents/May%20Info%20Chat%20slides%20%28003%29.pdf.(last visited Nov. 17, 2020).

153 *Id.*

154 MPEP § 2152 (9th ed. Rev. 10.2019, June 2020).

155 Zhang et al., *supra* note 147.

156 *Id.*

157 Premarket Notification 510(k), *supra* note 89.

claim or its equivalence while the patent is in effect."[158] Precluding prior permission of the patent owner, manufacturers risk being accused of infringement when their device is equivalent to an existing device.[159]

The EU regulatory field also presents similar issues. According to the EU MDR, manufacturers must identify an equivalent device, but the regulations do not define any parameters for determining equivalence.[160] The EC has published a guidance document to distinctly identify the criteria for evaluation of an equivalence device to be used as clinical evidence.[161] However, manufacturers are still at a loss for the various situations not discussed in the guidance document.[162] In situations where equivalent devices are not CE marked or sold in Europe, comparison of equivalency is generally not accepted.[163] Manufacturers would have to present a strong argument to their Notified Body on the reasons why the data is transferrable to a European population and manufacturers would have to conduct a safety and efficacy analysis for any gaps related to clinical performance.[164]

Additionally, in situations where technological composition is spread across multiple devices or no discussion of any differences between equivalent device and new device, manufacturers might have difficulty in preparing a comprehensive equivalency comparison.[165] Because the MDR mandates that the device being claimed as the equivalent device must share the same technical, biological and clinical characteristics, manufacturers may have difficulty in collecting enough data to support the equivalency comparison.[166] Usually, technical, biological and clinical characteristics are considered confidential

158 35 U.S.C.A. § 271 (Westlaw through Pub. L. No. 116-259).

159 Zhang et al., *supra* note 147.

160 MDCG 2020-5 Clinical Evaluation - Equivalence, EUROPEAN COMMISSION, https://ec.europa.eu/docsroom/documents/40903?locale=en (last visited Apr 15, 2022).

161 *Id.*

162 *Id.*

163 *Id.*

164 *Id.*

165 *Id.*

166 *Id.*

proprietary information of a company that will not be shared between competitors, barring signed intercompany license agreements or mergers and acquisition of companies.[167]

These issues in the United States and the EU are amplified when applied to AI/ML-based SaMD because of the unique features of artificial intelligence. Manufacturers have a strong interest in maximizing their AI property interest and easily commercializing their product to generate revenue. This article will attempt to fill in the gaps of the lack of regulations for AI/ML-based SaMD and to reconcile the interplay between a substantial equivalence or equivalent device standard and potential success for patentability.

III. ANALYSIS

A. Comparative Analysis between the United States and the European Union

1. Medical Device Regulations

To design the most effective commercialization pathways for AI/ML-based SaMD, it is essential recognize the differences in medical device regulation in the United States and the EU to identify any potential gaps in the regulatory framework. In addition to extensive literature comparing these differences, there is also political pressure for a substantial reform of better regulations and further research to understand the effectiveness of both the United States and

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[167] Confidential business information is defined as "information which concerns or relates to the trade secrets, processes, operations, style of works, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, or other information of commercial value, the disclosure of which is likely to have the effect of either impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions, or causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the Commission is required by law to disclose such information. The term 'confidential business information' includes 'proprietary information' . . . " 19 C.F.R. § 201.6 (2020).

EU regulatory systems.[168] Regulations for AI/ML-based SaMD could be the trigger for a regulatory overhaul for both the United States and EU. Because there is a global interest in harmonizing medical device regulations, the proposed regulations in this article will have to take into account that interest.[169] To ensure the success of regulations, global regulators must have foresight into the future of medical technology.

The differences in device regulations in the United States and the EU fall into six categories: purpose of the regulations, structure of the regulations, funding received, data requirement for device approval, premarket transparency, and the type of post-market device surveillance.[170] While the FDA—a government agency mandated to protect the public's health—clears and approves medical devices for commercialization in the United States, NBs—which are private companies—regulate device approval in the EU.[171] [172] Some experts have questioned whether notified bodies are more interested in getting devices to market rather than in protecting the health and safety of the public because they are privatized,[173] although the FDA also receives its own fair share of criticism. Many critics both inside and outside the agency have said that the FDA's standards have been continually declining.[174] Critics think there are too many prescription drugs and medical devices being approved with too little data on how safe or efficacious they are.[175] Part of the problem is that the agency has too few resources and too little power to fulfill its key responsibilities.[176]

While the FDA regulates device approval and surveillance under one centralized agency, there are more than seventy notified

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168 Maak & Wylie, *supra* note 121 at 543.

169 International Medical Device Regulators Forum (IMDRF), *supra* note 11.

170 Maak & Wylie, *supra* note 121 at 542.

171 *Id.* at 538.

172 Maak & Wylie, *supra* note 121 at 538.

173 *Id.* at 539.

174 *The F.D.A. Is in Trouble. Here's How to Fix It.*, N.Y. TIMES (Feb. 11, 2020). https://www.nytimes.com/2020/01/11/opinion/sunday/fda-commissioner-stephen-hahn.html.

175 *Id.*

176 *Id.*

bodies that regulate device approval in the EU.[177] Notified bodies are also completely funded by private contracts with device manufacturers, while U.S. federal appropriation provides for more than eighty percent of FDA funding.[178] User fees during the application process contribute the remaining twenty percent of FDA funding.[179] Historically, the FDA has been chronically underfunded, leading to issues with the agency being able to meet its statutory responsibilities in a timely and acceptable manner.[180] At its current pace, the FDA would take roughly twenty-seven years to check every international medical device plant.[181] In addition to FDA's existing responsibility, Congress has been passing more than a hundred statutes that have added new responsibilities over the past twenty years without providing enough resources to carry out these tasks; consequently, the FDA has been overwhelmed and falling behind on its duties.[182] Increased FDA funding would likely lead to a more efficient drug, medical device, and food approval process, and enable the agency to better protect public health.[183]

The largest apparent difference between the U.S. and EU systems concerns the substantive part of the regulations.[184] For a device to be cleared or approved in the United States, a device must prove to be substantially equivalent to a predicate device through a 510(k) clearance or prove to be safe and efficacious through the premarket authorization approval.[185] The EU regulations only require proof that the device can perform its intended function and manufacturers are able to use an already CE-marked equivalent device

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177 Maak & Wylie, *supra* note 121, at 539.

178 *Id.* at 542.

179 *Id.*

180 *Federal Funding for the U.S. Food and Drug Administration (FDA)*, ACAD. OF MANAGED CARE & PHARM. (Aug. 2013). https://amcp.org/sites/default/files/2019-02/Federal%20Funding%20for%20FDA_August2013.pdf.

181 *The F.D.A. in Crisis: It Needs More Money and Talent*, N.Y TIMES (Feb. 3, 2008). https://www.nytimes.com/2020/01/11/opinion/sunday/fda-commissioner-stephen-hahn.html.

182 *Id.*

183 Federal Funding for the U.S. Food and Drug Administration (FDA), *supra* note 180.

184 Maak & Wylie, *supra* note 121 at 540.

185 *Id.*

as proof.[186] Manufacturers have an easier pathway to approval in the EU due to the lower standard needed for approval.[187] In addition to an easier pathway, the EU processes also generally take a shorter time from submission to approval.[188] This is generally due to the more personal relationships that manufacturers have with their chosen notified bodies, compared to the lack thereof with the FDA.[189]

Premarket transparency is another important difference between the United States and EU regulatory systems.[190] Many device manufacturers rely on substantial equivalency in the United States to obtain clearance to market their device.[191] Although there are proprietary limits that exist for sharing information of a device, the FDA regularly publishes 510(k) summaries authored by manufacturers.[192] These 510(k) summaries are available on the FDA 510(k) searchable database and manufacturers regularly use these summaries as part of their substantial equivalency analysis.[193] In contrast, approval decisions of the notified bodies are not made public at all.[194] Manufacturers in the EU have to rely on information of equivalent devices that is available on public domain sites to conduct their equivalency analysis, which ties into concerns of patentability as information on public domain sites would be considered prior art.[195]

Lastly, medical device regulation does not just end with premarket review; regulators are responsible for post-market device surveillance as well[196] through mandatory manufacturer reporting to

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186 *Id.*

187 *Id.*

188 Gail A. Van Norman, *Drugs and Devices: Comparison of European and U.S. Approval Processes*, 1(5) J. AM. C. CARDIOLOGY 399, 402 (2016).

189 MAAK & WYLIE, *supra* note 121 at 540.

190 *Id.*

191 *Id.*

192 *Id.*

193 *510(k) Premarket Notification*, U.S. FOOD & DRUG ADMIN, https://www.accessdata.fda.gov/scripts/opdlisting/oopd/listResult.cfm. (last visited Nov. 17, 2020).

194 MAAK & WYLIE, *supra* note 121 at 540.

195 *Id.*; 35 U.S.C.A. § 101–3 (West 2021).

196 MAAK & WYLIE, *supra* note 121 at 540.

the FDA.[197] The FDA can issue public health advisories, safety alerts, and product suspensions or withdrawals through a recall process.[198] In the EU, manufacturers must submit adverse events to competent authorities.[199] Post-market data are shared among competent authorities but not with the public.[200] Competent authorities are responsible for issuing adverse event reports and field safety notices or device recalls.[201]

Understanding the core differences between U.S. and EU medical regulations is vital when developing a new regulatory framework for an upcoming industry like AI/ML-based SaMD. It is a chance for regulators to address existing gaps while developing more efficient regulatory frameworks for the future of medical devices. Because of the political pressure to substantially overhaul the existing regulatory framework, this could also be the first step in creating a harmonized medical device regulation system globally. As far as regulators are concerned, harmonized regulations are needed because they reduce redundant reviews, create an opportunity to share information on product safety, and result in a more efficient regulatory regime.[202] The net result will allow for improved trade in medical devices and safer products for the public.[203]

a. Shortcomings of Current United States and European Union Medical Device Regulations

Unsurprisingly, criticism surrounding the medical device regulations in the United States and in the EU abounds.[204] A recent analysis has revealed an uptick in the number of medical device recalls in the United States and an increase in the number of manufacturer

197 *Id.*

198 *Id.*

199 *Id.*

200 *Id.*

201 *Id.*

202 A. Kaushik et al., *Harmonized Medical Device Regulation: Need, Challenges, and Risks of Not Harmonizing the Regulation in Asia*, 2(1) J. YOUNG PHARMACISTS 101, 104 (2010).

203 *Id.*

204 Carl Heneghan & Mathew Thompson, *Rethinking Medical Device Regulation*, 105(5) J. ROYAL SOC'Y MED. 186, 186 (2012).

field safety notices in the United Kingdom over the past few decades.[205] This situation reflects a very low standard that is currently used to gain regulatory approval.[206] 510(k) pathways do not require any clinical trials; the manufacturer is only required to demonstrate substantial equivalency to another device on the market.[207] The EU also uses the predicate of equivalence for device regulation.[208] The biggest problem is that the definition of "equivalence" is interpreted so loosely that even the FDA admits they need to "clarify the meaning of 'substantial equivalence.'"[209]

A consequence of the loose definition of "substantial equivalence" can be seen with the Medtronic MiniMed Insulin Pump.[210] On February 12, 2020, the FDA issued a Class I recall for the Medtronic MiniMed Insulin Pump because its use had caused serious injuries and even one death.[211] Insulin pumps are Class II devices and Medtronic went through the 510(k) process to obtain market authorization, meaning that Medtronic was able to use the "substantial equivalence" standard to obtain market clearance for commercialization.[212] Without a firm definition of "substantial equivalence," serious injuries—and death—have occurred in these Class II insulin pumps.[213] This small example exemplifies the need for a clear cut definition.

Particularly concerning is that there are many issues with medical devices that go unnoticed by the appropriate agencies.[214] Currently, in the United States and the EU, there is limited ability to trace most medical devices, so when problems or recalls occur, it can

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205 Heneghan & Thompson, *supra* note 204 at 186.

206 *Id.*

207 *Id.*

208 *Id.*

209 *Id.*

210 *Medtronic Recalls MiniMed Insulin Pumps for Incorrect Insulin Dosing*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-minimed-insulin-pumps-incorrect-insulin-dosing (last updated Feb. 12, 2020).

211 *Id.*

212 *Id.*

213 *Id.*

214 *Id.*

be impossible to understand the magnitude of the problem without the appropriate traceability and post-market surveillance activities.[215] The additional requirement of patient data privacy and security will also contribute to the vulnerabilities of the current regulatory framework as the appropriate requirements to ensure safety and efficacy are not established and upheld.[216] Furthermore, the public's demand for accessible and transparent information about devices and the regulatory process has grown in the recent years, and both the United States and EU must take action to improve the exchange of information.[217] These issues can be resolved with a more robust medical device regulation system that is harmonized between the countries.[218] This solution is especially crucial for the formation of AI/ML-based SaMD regulations due to the lack of understanding and transparency of a fully software based medical device.

2. Patent Law

Intellectual property law in the United States and the EU includes applications for hardware and software products. Software patents are notoriously difficult to obtain.[219] The USPTO and the EPO do not see software-related patents in the same way, creating another layer of complexity for AI/ML-based SaMD.[220] According to the European Patent Convention (EPC), a patent can be granted in any field.[221] However, the EPC does not consider computer programs to be inventions if they are claimed as such, and methods for performing

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215 *Id.*

216 Andy Hua, *Regulatory Challenges of Software as a Medical Device (SaMD) Supporting Innovation and Safety*, DIAGLOBAL. https://globalforum.diaglobal.org/issue/december-2019/regulatory-challenges-of-software-as-a-medical-device-samd/ (last visited Nov. 17, 2020).

217 Corinna Sorenson & Michael Drummond, *Improving Medical Device Regulation: The United States and Europe in Perspective*, 92(1) MILLBANK Q. 114 (2014).

218 Heneghan & Thompson, *supra* note 204, at 187.

219 Marta Alvarez Guede & Katelyn Bernier, *The Six Big Ways the US and Europe Differ on Software Patents*, IAM (Feb. 10, 2020), https://www.iam-media.com/law-policy/six-big-ways-us-and-europe-differ-software-patents#:~:text=According%20to%20the%20European%20Patent,are%20excluded%20from%20patentability%20altogether.

220 *Id.*

221 *Id.*

mental acts, playing games, doing business and presenting information are excluded from patentability altogether.[222] However, under this approach, a claim directed to a computer program will not be excluded from patentability under Article 52 of the EPC if it contains at least one feature considered to have technical character.[223] Therefore, it is sufficient that a claim is directed to a device or a method implemented in a computer to avoid exclusion from patentability.[224] The non-technical features of such a claim will be ignored when assessing an inventive step.[225]

The EPC provides no general definition of what is considered technical, but relevant case law before the EPO Board of Appeals gives some indication of what constitutes "technical character."[226] For example, a claim to a computer program running in a computer is not considered excluded from patentability if it provides further technical effect going beyond the computer's normal capabilities.[227] Similarly, data encoding schemes contained in physical mediums are traditionally considered to have "technical character."[228] But "technical character" should refer to more functional data, which serves to control the operation of device, rather than cognitive data, the content and meaning of which are relevant to human users only.[229] Ultimately, the technical assessment is highly subjective and has been subject to substantial patent agent and examiner arguments.[230]

In contrast with the U.S. patent system, patent protection for software-related inventions differ significantly from the EPO approach, both in terms of scope of eligibility and in how the

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222 *Id.*
223 *Id.*
224 *Id.*
225 *Id.*
226 *Id.*
227 *Id.*
228 *Id.*
229 *Id.*
230 Gregory "Lars" Gunnerson, *Comparing United States and European Patent Law for Software*, LEXOLOGY (June 18, 2019), https://www.lexology.com/library/detail.aspx?g=2d3ec6ff-b129-4bae-8dc2-c1b66334f4f5.

determination is made.[231] The threshold requirement for patent protection is set out in 35 U.S.C. § 101, which defines "patentable subject matter."[232] Depending on how the patent claim is framed, a software-related invention could easily fall into one or more of the patentable subject matter categories.[233] For example, a claim for software, presented as a process claim, would pass the baseline for patent eligibility.[234] The United States Supreme Court has further outlined the breadth of patentable subject matter and its exceptions.[235] Judicial exceptions include abstract ideas, natural phenomena, and laws of nature.[236] Applications supposedly involving a judicial exception are seemingly subject to more front-end scrutiny during the examination process, meaning much more emphasis seems to be placed on the analysis of whether applications are patentable subject matter rather than the evaluation of other requirements of patentability.[237]

As an example, the U.S. Supreme Court decision in *Alice v. CLS Bank* serves as a foundation for determining whether a software-related invention is considered an "abstract idea."[238] Using the *Alice* test, it is first determined whether the invention at issue is directed at a patent-ineligible concept and then determined whether the invention's elements, considered both individually and as an ordered combination, transform the nature of the claims into an eligible patent.[239] This assessment focuses on patentable subject matter, as opposed to other patentability doctrines. In 2019, USPTO Director Andrei Iancu issued guidelines more favorable to patent applicants with software-related inventions.[240] The guidelines separated the first part of the *Alice* test into two prongs.[241] The first prong is to determine if the patent claim is actually a judicial exception.[242] Where the claim is

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231 Guede & Bernier, *supra* note 219.
232 35 U.S.C.A. § 271 (Westlaw through Pub. L. No. 116-259).
233 Guede & Bernier, *supra* note 219.
234 *Id.*
235 *Id.*
236 *Id.*
237 *Id.*
238 Gunnerson, *supra* note 230.
239 *Id.*
240 *Id.*
241 *Id.*
242 *Id.*

a judicial exception, the second prong then determines whether the judicial exception is used for a practical application, and if so, the claim is still patent eligible.[243] Even if the patent elements do not transform the nature of the claim and the claim is considered to be well-understood, routine, or conventional, the invention is still patent eligible as long as there is a practical application.[244]

The key difference between EPO and the USPTO is that the EPO requires further technical effect for software-related inventions.[245] Contrasting that idea with the USPTO, if an abstract idea is claimed in the United States, it must be tied to a practical application of the idea.[246] Additionally, improvements in the function of a computer that are not understood, routine, or conventional in the industry may be evidence that the invention is patent eligible in the United States.[247] The differences between EPO and USPTO can cause confusion for applicants looking to patent their AI/ML-based SaMD, especially manufacturers interested in expanding their business and protecting their intellectual property globally.

a. Shortcomings of Current United States and European Union Intellectual Property Law, Specifically Patent Law

Even though the EPO and the USPTO differ on several key measures, when it comes to patent prosecution, these two systems share basic features common to all patent systems internationally.[248] Notably, these two governmental agencies grant exclusive property-like rights.[249] These rights are privately enforced and rely on national courts and agencies to assist with the interpretation of the system and rules for enforcement.[250] Infringement issues are also dealt through the court system that may conduct a full investigation into patent

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243 *Id.*

244 *Id.*

245 Guede & Bernier, *supra* note 219.

246 *Id.*

247 *Id.*

248 Susana Borras & Brian Kahin, *Patent reform in Europe and the US*, 36 SCIENCE AND PUBLIC POLICY 631–640 (2009).

249 *Id.*

250 *Id.*

validity.[251] Both the EPO and the USPTO systems are considered to be "unitary" to the extent that the law does not normally distinguish among different types of technology.[252]

Given the similar foundation of the structure for both patent systems, it is not surprising that these two system share the same fundamental issues.[253] While the goal of the patent system is to propagate innovation and stimulate the economy, the patent administration and practice is considered to be legal and process-orientated.[254] This creates a tension when trying to completely overhaul the patent system to accommodate the emerging field of artificial intelligence.[255] The technical nature of patent law and the private nature of patent enforcement causes difficulty for non-practitioners to contribute to policy developments, leaving those who manage the process to retain control of evolving rules and regulations.[256] Although the patent office claims no responsibility for how patents work after they have been issued, policymakers routinely look to the patent office for policy advice.[257] The office then tends to turn to patent professionals and applicants for substantive policy and patent administration advice.[258] Therefore, patent system reform generally would favor interests and perspectives of the industries most benefitted by patents or by the largest customers that hold huge patent portfolios.[259]

Another issue is related to the gap between socio-economic goals of the patent system and its legal-procedural structure.[260] Unlike other regulatory regimes, patent policy development remains oriented to application of the already established case law in individual cases.[261] The eligibility of software has been rarely addressed in the courts or in

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251 *Id.*
252 *Id.*
253 *Id.*
254 *Id.*
255 *Id.*
256 *Id.*
257 *Id.*
258 *Id.*
259 *Id.*
260 *Id.*
261 *Id.*

legislation, creating unclear expectations for inventors when trying to pursue a patent.[262] Issues will undoubtedly arise when AI/ML-based SaMD manufacturers attempt to obtain a patent on their software while pursuing market authorization from regulatory bodies. Because agencies that regulate medical devices have an underlying goal to improve the safety and efficacy of medical products for the public,[263] decisions made by regulatory agencies are intertwined with socio-economic implications, while patent systems are not.[264] Therefore, the disjoint between the patent systems and the regulatory systems may create complications for manufacturers when determining requirements needed for a commercialization pathway.

B. Proposal for New Regulations for Artificial Intelligence/Machine Learning-Based Software as a Medical Device in the United States and the European Union

Despite the differences between the U.S. and the EU medical device regulatory framework, both jurisdictions could benefit from similar solutions to produce a more effective medical device regulation to remedy three key issues: inconsistent evidence requirements during the application process, lack of proper traceability and post-market surveillance requirements, and lack of transparent and accessible device information to the public.[265]

U.S. and EU medical device regulations have historically created the wrong incentives for manufacturers to generate the evidence needed to better understand and evaluate the benefits and risks of new devices.[266] On average, depending on the level of risk for the medical device, a clinical study would cost manufacturers approximately $12 million.[267] Considering the equivalency standard used in both jurisdictions, many manufacturers would be

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262 Gunnerson, *supra* note 230.

263 *Medical Device Regulations: Global Overview and Guiding Principles,* WORLD HEALTH ORG. (2003).

264 Johner, *supra* note 17.

265 *Id.*

266 *Id.*

267 Patricio Ledesma, *How Much Does a Clinical Trial Cost?*, SOFPROMED (Jan. 2, 2020). https://www.sofpromed.com/how-much-does-a-clinical-trial-cost/.

understandably reluctant to undertake new clinical studies when they can rely on already cleared devices to establish equivalency to a predicate device.[268] This suggests that when a medical device enters the market, the information about its safety and efficacy is limited, at best.

Once the device enters the market, manufacturers are technically responsible for conducting proper traceability and post-market surveillance activities to ensure that their device does not create any adverse events.[269] Manufacturers are required by law to report any serious adverse events or deaths, but they are not required to do so if they have justification that the events are unrelated to their device.[270] Without systemic post-market data collection, it is extremely difficult for health professionals and regulatory agencies to understand where the device is located and what the actual outcome of the device is once they are on the market.[271]

Consequently, achieving an open and accessible information exchange between the public and the regulatory agencies is still intangible.[272] Manufacturers' applications for a new device remains confidential, as well as information regarding the reasons why devices are not cleared or approved.[273] Moreover, in the EU, Notified Bodies are not required to publish their decision-making processes, any evidence provided by manufacturers, or the basis on which a CE mark was granted.[274] Post-market data is also not shared with the public.[275] Adequate and transparent information on the benefits and risks of new devices must be assured so the public can become more informed on the use of new devices.[276]

To step into the right direction of medical device regulatory reform and to include the AI/ML-based SaMD industry, regulators should look to other regulatory agencies for guidance. For example, in

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268 Sorenson & Drummond, *supra* note 217.
269 *Id.*
270 *Id.*
271 *Id.*
272 *Id.*
273 *Id.*
274 *Id.*
275 *Id.*
276 *Id.*

2018, the U.S. Federal Communications Commission (FCC) was proactively looking into applications of AI/ML in the industry.[277] At that time, FCC Chairman Ajit Pai introduced a series of forums on artificial intelligence and machine learning in hopes of learning more about the advancement of the technology and its effects on the communications industry.[278] Similarly, the EU has gathered an expert group on artificial intelligence to advise on challenges and opportunities during the legislative process.[279] Not only do the U.S. and EU medical device regulators need to design a more robust medical device regulatory framework based on the inadequacy of the current system, both jurisdictions could also benefit from looking laterally into other industries for guidance.

C. Jumping Over the Patentability Hurdle for Artificial Intelligence/Machine Learning-Based Software as a Medical Device

Besides identifying the most efficient commercialization pathway for devices, manufacturers generally have a strong interest in protecting their intellectual property.[280] Medical device manufacturers face an interesting dichotomy when it comes to protecting their proprietary information and receiving market authorization for their devices. On one hand, manufacturers need to keep their proprietary information to prevent infringement from others; on the other hand, manufacturers need to balance the level of information provided to regulatory agencies to make sure there is sufficient evidence for market authorization.[281] However, before manufacturers can make these business strategy decisions, they would still have to overcome the patentability hurdle for AI/ML-based SaMD.

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[277] Alex Hickey, *Why the FCC, EU Are Convening AI Experts*, CIODIVE (June 15, 2018). https://www.ciodive.com/news/fcc-eu-artificial-intelligence-ajit-pai/525758/.

[278] *Id.*

[279] *Id.*

[280] *Why You Need to Protect Your Intellectual Property?*, BRITISH LIBRARY. https://www.bl.uk/business-and-ip-centre/articles/why-you-need-to-protect-your-intellectual-property# (last visited Feb. 2, 2020).

[281] Maak & Wylie, *supra* note 121 at 540.

Due to the established jurisprudence of patentable subject matter, the abstraction of an idea presents one of the particular challenges manufacturers of software-related inventions face (in terms of whether the invention or claim qualifies as patent-eligible).[282] Both the EU and the United States have subjective views on which inventions are considered patentable.[283] Although interpretive case law exists, many confusing discussions regarding patentability are still held during the assessment for software inventions.[284] In the EU, EPO requires that the subject matter have a technical character and is first assessed without reference to prior art.[285] In the United States, the U.S. Supreme Court's test in *Alice* serves as the foundation for all software-related patent eligibility inquiries to determine whether the invention is considered an "abstract idea."[286]

Both jurisdictions do not have well-established definitions on what kind of software is considered to be patent eligible, therefore, more conversations between legislators are required to reform the patent system to include AI/ML.[287] The EPO took a step in the right direction in late 2018 when the Office amended its examination guidelines to include a specific section on how patent examination principles apply to inventions relating to AI/ML.[288] The guidance emphasized that a mathematical method may contribute to technical effect serving a technical purpose by application to a field of technology or by adaptation to specific technical implementation.[289] Furthermore, if computation models can be "trained" to serve a technical purpose, the steps to generate the training set may also contribute to the technical character of the invention, hence, making the invention patent eligible.[290] Similarly, in the United States, the

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282 Guede & Bernier, *supra* note 219.

283 Gunnerson, *supra* note 230.

284 *Id.*

285 *Id.*

286 *Id.*

287 John Richards, *Issues Surrounding Patenting of Inventions Relating to Artificial Intelligence in the US and Europe*, FINANCIER WORLDWIDE (Mar. 2019). https://www.financierworldwide.com/issues-surrounding-patenting-of-inventions-relating-to-artificial-intelligence-in-the-us-and-europe.

288 *Id.*

289 *Id.*

290 *Id.*

USPTO provided guidance in 2019 on inventions relating to mathematical models, organization of human activity methodology, and human mental processes.[291] This guidance encompasses inventions relating to AI/ML as well and the USPTO advises manufacturers to make sure that patent applications have clear, real world technical applications to meet the patent eligibility threshold.[292]

D. A Glimpse into the Future for Artificial Intelligence/Machine Learning-Based Software as a Medical Device in the United States and the European Union

It is encouraging for manufacturers that the United States and the EU are slowly ramping up discussions relating to AI/ML-based inventions and adapting to the evolving field. In order to truly allow for the expansion of the artificial intelligence industry, legislators and industry professionals will need to gain better insight into the requirements and goals of the overall patent system.[293] Additionally, legislators should consider the economic impact of patent decisions, similar to how the medical device regulatory agencies operate.[294] Seeing how interconnected the medical device regulatory system and the patent system are, it is in the best interest of legislators to integrate intellectual property considerations into the medical device regulatory framework, and vice versa. Finally, utilizing the role of IMDRF, legislators globally can convene in one central forum to discuss the reforming process of the current regulatory framework with the help of experts in the artificial intelligence industry.

IV. CONCLUSION

On both sides of the Atlantic Ocean, the United States and EU have an established history of medical device regulations. Understanding and comparing the regulations are critical to comprehending patentability because, in order for medical devices to be cleared for commercialization or approved for market,

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291 *Id.*

292 *Id.*

293 Borrás & Kahin, *supra* note 248.

294 *Id.*

manufacturers need to use a "substantial equivalence" standard in the United States and an "equivalent device" standard in the EU.[295] These standards impact the United States and EU patentability laws because it is unclear whether these medical devices, although ready for commercialization, are novel or inventive enough to clear the threshold for patentability.

Since artificial intelligence and machine learning in the healthcare space are relatively new, there are not many regulations relating to AI/ML-based SaMD. Currently, the FDA only has guidance documents related to AI/ML-based SaMD, but no final promulgated regulations.[296] The EC recently published its new Medical Device Regulations (MDR),[297] but the MDR only has provisions for general SaMD and has not included any provisions related specifically to AI/ML-based SaMD.

There are several potential pathways for AI/ML-based SaMD regulations to address the specific issues currently posed by the U.S. and EU regulatory network. Regulators need to determine clear and adequate evidence requirements during the application process, proper traceability and post-market surveillance requirements, and transparent and accessible device information to the public.[298] Furthermore, both the EU and the United States have subjective views on what invention is considered to be patentable in their patent system.[299] Although there is case law to show judicial opinion, many confusing discussions are still held during the assessment for software inventions.[300] More conversations between legislators are required for a patent system reform for inclusion of AI/ML and realignment of the overall purpose of the patent system based on economic analysis.[301]

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295 Regulation 2017/745 of the European Parliament and of the Council of Apr. 5, 2017, art. 5, 2017 O.J. (L 117) 1 (EU).

296 Artificial Intelligence and Machine Learning in Software as a Medical Device, *supra* note 25.

297 Transition Timelines from the Directives to the Regulations, *supra* note 23.

298 Sorenson & Drummond, *supra* note 217.

299 Gunnerson, *supra* note 230.

300 *Id.*

301 Richards, *supra* note 287.

On top of commercialization success, many manufacturers are interested in obtaining intellectual property rights for their invention. When manufacturers use the substantial equivalence standard, manufacturers generally have a hard time finding a novelty hook to pass the patentability test.[302] This challenge is true for all medical devices, hardware-based or software-based. Because like every medical device, the functionality, the clinical validity, and the intended use of the AI/ML-based SaMD would still be used to determine whether the device will get cleared for commercialization, the impact on patentability will still be similar. In conclusion, taking advantage of the IMDRF forum, legislators from around the globe should feel encouraged for a medical device regulatory reform with the integration of intellectual property considerations for AI/ML-based SaMD.

[302] 35 U.S.C.A. § 101–3 (West 2021); 35 U.S.C.A. § 102 (West 2021); 35 U.S.C.A. § 103 (West 2021).