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The Legal Challenges Of Standard Essential Patents In The Emerging Smart Healthcare Industry

Dissertation to obtain a Master's Degree in Law, in the specialty of Business Law and Technology

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ABSTRACT

This thesis explores the legal challenges posed by standard-essential patents (SEPs) in the smart health sector, a field that merges medical technology, digital communication, and computer systems. As smart health technologies become increasingly complex, ranging from wearable health trackers to AI-assisted diagnostics and remote monitoring tools, developers face heightened legal and financial uncertainty. This is due in part to fragmented patent ownership, overlapping rights, and poor device interoperability. These challenges risk delaying innovation and increasing costs, particularly for smaller companies and start-ups entering the health technology market.

SEPs are designed to promote interoperability and reduce barriers through licensing on fair, reasonable, and non-discriminatory (FRAND) terms. However, in practice, the lack of a clear, universal definition of FRAND, combined with limited transparency in SEP disclosures, continues to generate litigation and impede licensing negotiations. These issues are particularly pressing in smart health, where regulatory oversight is strict, innovation cycles are slower, and device failures can have life-threatening consequences.

The study mentions traditional strategies, such as vertical integration, early licensing, and adaptable product design, as means to reduce SEP-related risks. However, these safeguards often fall short given the unique demands of the smart health sector. The now-withdrawn EU proposal on SEPs attempted to address these concerns by introducing essentiality checks, FRAND determination procedures, and a centralized register. While well-intentioned, the proposal raised serious concerns over access to justice and procedural fairness.

This thesis argues that the growing role of SEPs in smart health demands a clearer, more transparent legal framework. One that supports innovation without compromising access, safety, or patient welfare. It also highlights the potential role of standard-setting organisations (SSOs) in improving licensing guidance and ensuring more consistent application of FRAND obligations. Ultimately, a balanced and effective SEP framework is essential for advancing smart health technologies, broadening access to life-changing devices, and achieving public health objectives through digital innovation.

Keywords: SEPs, smart health, patent thicket, patent hold-up, FRAND licenses

RESUMO

Esta tese explora os desafios jurídicos colocados pelas Patentes Essenciais a Normas (PEN) no setor da saúde inteligente. Um setor que une tecnologia médica, comunicação digital e sistemas informáticos. À medida que as tecnologias de saúde inteligentes se tornam cada vez mais complexas, desde os rastreadores de níveis de saúde, até aos diagnósticos assistidos por inteligência artificial (IA) e às ferramentas de monitorização remota, os inventores enfrentam uma maior incerteza jurídica e financeira. Isto deve-se, em parte, à fragmentação da propriedade das patentes, à sobreposição de direitos e à fraca interoperabilidade dos dispositivos. Estes desafios correm o risco de atrasar a inovação e aumentar os custos, em especial para as empresas mais pequenas e as empresas que tentam entrar no mercado das tecnologias da saúde.

As PEN promovem a interoperabilidade e reduzem os obstáculos através da concessão de licenças em condições justas, razoáveis e não discriminatórias (FRAND). Contudo, a falta de uma definição clara e universal do que é uma licença FRAND, combinada com uma fraca transparência na divulgação das PEN, continua a gerar litígios e a impedir as negociações de licenciamento. Estas questões são particularmente prementes no domínio de saúde inteligente, onde a supervisão regulamentar é rigorosa, os ciclos de inovação são mais lentos e as falhas dos dispositivos podem ter consequências potencialmente fatais.

O estudo menciona estratégias tradicionais, por exemplo a integração vertical, o licenciamento precoce e o desenvolvimento adaptável dos produtos, como ferramentas para reduzir os riscos relacionados com as PEN. Porém, frequentemente, estes mecanismos são insuficientes, devido às particulares exigências do setor. A proposta atualmente retirada da União Europeia sobre as PEN tentou responder a estes desafios introduzindo controlos de essencialidade, procedimentos de determinação de FRAND e um registo centralizado. Embora com boas intenções, a proposta suscitou sérias preocupações quanto ao acesso à justiça e à equidade processual.

Esta tese defende que o papel crescente das PEN na saúde inteligente exige um quadro jurídico mais claro e transparente. Um quadro que apoie a inovação sem comprometer o acesso, a segurança ou o bem-estar dos doentes. Salienta igualmente o potencial das organismos de harmonização para a melhoria dos desafios mencionados.

Palavras-chave: PENs, saúde inteligente, teia de patentes, retenção de patentes, licenças FRAND

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Chapter 1: Introduction

In this introductory chapter, it will be briefly explained patent protection in the context of the healthcare industry and the increase in patent filings in the corresponding period. Additionally, a literature review will be carried which will explain the research question, as well as a brief mention of the methodology used.

1.1. Patent law and the evolving health industry

A patent is the legal right to exclude others from making, using, selling, or importing the protected invention (a product or a process) without the patent owner's consent. Patent protection is subject to a term of up to twenty years of protection,[1] and it is only valid in the state where it was granted. Since it is a right, the patent owner is not obliged to prevent third-party use of their invention. It is their choice to enforce their right, make licensing agreements, or allow others to freely use the invention.

It is important to stress that the right granted by a patent is a negative right to exclude others from using and profiting from the patent holder's invention. The granting of a patent does not mean that the patent holder can exploit the invention in any way they want. On the contrary, the exploitation of the invention is subject to national regulations.

Applying for a patent has several benefits for the patent owner. As said, it grants them exclusive rights to the technical solution, which is very important for the returns and future investments in research and development, but also as an asset when looking for funding. A patent can also give an advantage over competitors and strengthen a company's position in the market. For example, they can practice higher prices, block competitors from copying, increase market entry barriers, or force competitors to create design arounds. A patent can also be licensed or even sold.[2]

Society accepts this exclusivity because it believes companies will only invest in innovations if they can protect them. Thus, a patent becomes a social contract. In

[1] Article 63 Convention on the Grant of European Patents
(European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC
of 17 December 1991 and the Act revising the EPC of 29 November 2000

[2] Justine Pila and Paul Torremans, *European Intellectual Property Law* (2nd edn, Oxford University Press 2019) <http://www.oxfordlawtrove.com/view/10.1093/he/9780198831280.001.0001/he-9780198831280> accessed 4 April 2024.

exchange for the disclosure of their invention, it is are granted an exclusive right to patent holders. Patents, therefore, incentivize the sharing of information and the development of more and better technical solutions, contributing to society's progress and overall well-being.

Considering the aims of patent protection, Article 52 EPC establishes requirements and exceptions to patentability. An invention must be new, involve an inventive step, be industrially applicable, and not fall within the exceptions of Article 52(2).

An invention is considered "new" if it was not disclosed to the public in any form and anywhere before the date of filing of the application.[3] In other words, the invention shall not be anticipated by the prior art. Article 55 establishes a few exceptions to this principle.

Moreover, an invention must involve an inventive step. It must not be obvious to a person skilled in the art in light of the state of the art.[4] A skilled person in the art is a legal fiction, in this case, an expert with general knowledge in the field (access to the entire state of the art, and ordinary skills, but without inventive skills). Article 54(2) establishes the state of the art. Last, EPO examiners use the "problem/solution" approach: the invention needs to solve a technical problem that could not be solved before.[5]

Medical innovation can be made in three main patent fields, as per the WIPO IPC technology concordance:[6] medical technology, pharmaceuticals, and biotechnology. Medical technology comprises medical instruments for surgery and the diagnosis and treatment of diseases.[7] On the other hand, the pharmaceutical field includes medical, dental, or hygienic preparations,[8] and the field of biotechnology "encompasses peptides, microbiology, and genetic engineering".[9]

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[3] Article 54 EPC
[4] Article 56 EPC
[5] Ibid.
[6] WIPO, 'IPC – Technology Concordance', *WIPO Statistics Database*, 2023, https://www.wipo.int/ipstats/en/docs/ipc_technology.xlsx, (accessed 4 April 2024)
[7] EPO, 'Patent Index 2023, European Patent Applications, Top 10 Technical Fields, Medical Technology', *European Patent Office,* 2024, [https://www.epo.org/en/about-us/statistics/patent-index-2023/statistics-and-indicators/european-patent-applications/top-10-technical-fields/medical-technology] (accessed 4 April 2024)
[8] EPO, 'Patent Index 2023, European Patent Applications, Top 10 Technical Fields, Pharmaceuticals', *European Patent Office,* 2024, [https://www.epo.org/en/about-us/statistics/patent-index-2023/statistics-and-indicators/european-patent-applications/top-10-technical-fields/pharmaceuticals] (accessed 4 April 2024)
[9] EPO, 'Patent Index 2023, European Patent Applications, Top 10 Technical Fields, Biotechnology', *European Patent Office,* 2024,[https://www.epo.org/en/about-us/statistics/patent-index-2023/statistics-

In Europe, the most innovative patent field in the health sector is medical technology.[10] Legitimately, in the field of medical technology, the number of patent applications at the EPO has almost tripled, while in the pharmaceutical and biotechnology fields has remained relatively stagnant.[11] A recent trend in innovation in this type of technology relates to patenting computer-implemented inventions and artificial intelligence (AI), in the definition of the European Patent Office (EPO), smart health.[12] Smart health brings together three of the most innovative fields: medical technology, digital communication, and computer technology. The convergence of all of those technologies has the potential to improve access and quality of care while providing more personalized health care for patients.[13]

The technology poses different challenges that need to be considered when seeking patent protection. Before delving into them, one must make a distinction between computer programs or software as such and computer-implemented inventions. The latter is the only one capable of this kind of protection. A "computer-implemented invention" is an invention that requires the use of a computer, computer network, or other programmable apparatus for it to be implemented. In other words, it is an invention at which point one or more features are realized wholly or partly using a computer program.[14] Therefore, this category includes all software-based AI and machine learning (ML) inventions. Software, on the other hand, as the EPO explains, is "generally understood as the implementation of an algorithm in source or object code, but without distinguishing between technical and non-technical processes".[15]

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and-indicators/european-patent-applications/top-10-technical-fields/biotechnology](accessed 4 April 2024)

[10] EPO, 'Patent Index 2023, Digital and clean-energy technologies driving growth', *European Patent Office,* 2024, [https://www.epo.org/en/about-us/statistics/patent-index-2023] (accessed 4 April 2024)

[11] MedTech Europe, 'The European Medical Technology Industry in figures', *MedTech Europe*, 2023, https://www.medtecheurope.org/wp-content/uploads/2023/10/the-european-medical-technology-industry-in-figures_2023.pdf (accessed 4 April 2024)

[12] EPO, 'Patent Index 2022, Insights into smart health, Smart Health, *European Patent Office,* 2023 [https://report-archive.epo.org/about-us/annual-reports-statistics/statistics/2022/insight-smart-health.html] (accessed 4 April 2024)

[13] Ibid.

[14] European Patent Office, 'Patents for software? European law and practice', *European Patent Office*, 2009, https://ciencias.ulisboa.pt/sites/default/files/fcul/inovacao/PI-Pack-INPI-E-Patents-for-Software-EPO.pdf (accessed 4 April 2024)

[15] Ibid.

The first challenge computer-implemented inventions face is patent eligibility. Article 52(1) of the European Patent Convention (EPC)[16] excludes from patentable subject matter inventions that are not in a technical field. When the features of an invention fall into the categories listed in number 2 of the same article, it means that when considered in isolation, those features are not technical. That is the case for "mathematical methods"[17] and "programs for computers",[18] which comprise the technology behind smart health. This particular hurdle can be easily overcome by making sure there is no involvement of a physical step or technical entity, such as a computer.[19] When drafting the patent application, one must consider that claims can contain technical and non-technical features, and it is sufficient that only one of the features of a claim is technical for it to overcome the first challenge: the exclusion of patentability.[20]

Another particularity to consider when patenting smart health regards the patentability of the invention and is the assessment of novelty and inventive step. It is important to note that before this assessment is made, one must filter the features that contribute to the technical character, and only those are considered. One has to consider that there may be features that, even though they are not technical in isolation, can contribute to the technical character of the invention, in which case they should be assessed in the following steps. However, there must be a sufficient causal link between those (in isolation) non-technical features and the technical character.[21] Then the examiner searches for the closest prior art and determines if an invention can be considered new. The next step is to examine whether the invention involves an inventive step. This is the most challenging assessment and requires that the invention solves a problem in a non-obvious way. According to the problem-solution approach by the EPO, the first step is to determine the closest prior art. Then, the objective technical problem to be solved by the invention is established. The follow-up step is to understand what the differentiation factors (or not) are of the solution of the invention. Finally, the patent examiner assesses if the solution to the objective technical problem established before is obvious to a person

[16] Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000
[17] Article 52(2)(a) EPC
[18] Article 52(2)(c) EPC
[19] E-learning centre of the European Patent Academy, 'Advanced lecture series – Medical Technology (MedTech)', *European Patent Office*, 2022, https://e-courses.epo.org/course/view.php?id=315&lang=fr (accessed 4 April 2024)
[20] Ibid.
[21] Ibid.

skilled in the art. A skilled person in the art is a legal fiction, meaning it is an expert with general knowledge in the field (access to the entire state of the art, and ordinary skills, but without inventive skills).[22]

One must not forget that smart health relies on AI and ML, which in turn, also rely on mathematical methods, algorithms, abstract models, or other non-technical features. As previously explained, for an invention that relies on AI or ML to be patented, it must have a technical character. In the words of the EPO, it has to "contribute to producing a technical effect that serves a technical purpose".[23] There are two distinct scenarios where this happens: the invention can have either a technical use or it is adapted to a specific technical implementation, or both. To have a technical use means that the invention can be applied to a field of technology, for example, automatic diagnosis,[24] and it is not mandatory to explicitly state how the output is used; it is sufficient that it is implied.[25] The second case ensues when the invention is "particularly adapted for that implementation in that its design is motivated by technical considerations of the internal functioning of the computer system or network".[26] Considering this, a mathematical method has a technical character when it is used to provide "a medical diagnosis by an automated system processing physiological measurements," but not as a hospital resource management tool.[27]

Once the hurdles regarding the patentability of the invention are overcome, another set of challenges regarding patent acquisition needs to be tackled. As explained above, in exchange for patent protection, the patent holder has to disclose information about their invention, therefore increasing the information available for third parties to build on it. Considering its purpose, it only makes sense that the invention must be disclosed "in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art".[28] When drafting a patent in smart health technology, one must guarantee that the

[22] Justine Pila and Paul Torremans (n 2)
[23] European Patent Office, 'Guidelines for Examination in the European Patent Office, Patentability, Chapter II - Inventions, 3. list of exclusions, 3.3. mathematical methods', *European Patent Office,* 2024 [https://www.epo.org/en/legal/guidelines-epc/2023/g_ii_3_3.html] (accessed 4 April 2024)
[24] E-learning centre of the European Patent Academy (n 19)
[25] European Patent Office (n 23)
[26] Ibid.
[27] Ibid.
[28] Article 83 EPC

main scope of the claim is technical, that all the essential steps of the invention are present and are not described in vague and over-generalized terms.[29]

For certain types of technologies, this requirement can be especially burdensome, as is the case with AI and ML algorithms, crucial tools for smart health. The task becomes increasingly arduous the more complex an algorithm is. Deep learning is a subset of ML based on artificial neural networks capable of creating models that can learn by themselves. However, the increased accuracy achieved by the use of these models comes at the explainability of the outputs. Black-box algorithms are often described as opaque, even to their developers.[30] Given its non-transparent nature, certain inner workings are impossible to describe fully and, thus, comply with the sufficiency of disclosure requirement.[31]

1.2. Literature review

There seems to be a consensus in the literature that even though smart health can be especially beneficial, it also poses a myriad of challenges, particularly when it involves AI. Patent law is no exception. Overall, the literature mostly discusses patentability requirements regarding software in general, and in particular, AI in the field of health. These challenges are generally related to the European Patent Convention (EPC) patentability exclusion criteria, such as computer programs and mathematical methods (article 53, (a) and (c) EPC, respectively), and specifically in the health sector, diagnostic and treatment methods (article 53(c) EPC).[32]

Despite the extensive legal literature debating this subject, these questions have already been clarified by the EPO.[33] Even though software per se cannot be patented, computer-

[29] European Patent Office, 'Guidelines for Examination in the European Patent Office, The European Patent Application, Chapter III – Sufficiency of Disclosure, 1. Sufficiency of Disclosure', *European Patent Office,* 2024, <https://www.epo.org/en/legal/guidelines-epc/2023/f_iii_1.html> (accessed 4 April 2024)

[30] 3 Grégoire Montavon, Wojciech Samek and Klaus-Robert Müller, 'Methods for Interpreting and Understanding Deep Neural Networks' (2018) 73 Digital Signal Processing 1

[31] W Nicholson Price, 'Black-box Medicine' (2023) 28 *Harvard Journal of Law & Technology* 419 <https://jolt.law.harvard.edu/assets/articlePDFs/v28/28HarvJLTech419.pdf> accessed 15 March 2024

[32] Robert Sackin and others, 'Pharma evolution : Digital tech is increasingly impacting the development of pharma patents, say Reddie and Grose's Robert Sackin, Zack Mummery and Duncan Nevett.' *2020 Intellectual Property Magazine* < *https://reddiegrose.wpenginepowered.com/wp-content/uploads/2022/06/Digital-Health-Newsletter-Summer-2022-4.pdf> accessed 15 March 2024*

[33] EPO, 'Guidelines for examination: Part G, Chapter II, List of Exclusions', (epo.org) < https://www.epo.org/en/legal/guidelines-epc/2023/g_ii_3.html > accessed 16 March 2024

implemented inventions can, only if they have a technical character.[34] The question of granted patents lies in careful patent drafting so that it can overcome some of the challenges it may face. Besides, as the state of the art evolves, other topics need discussion.

As technology grows even more complex each day and patent protection around it so grows the risk of patent thickets, as Shapiro explains, it can result in "a dense web of overlapping intellectual property rights that a company must hack its way through to commercialize new technology".[35]

In Europe, this problem is often overcome by resorting to Standard Essential Patents (SEPs). SEPs are "patents that protect a technology incorporated in a standard" and are thus essential as "the implementation of the standard requires the use of the inventions covered by the relevant SEPs".[36]

Moreover, it is also important to highlight the proliferation of different players in the health sector, such as tech and, especially, "Big Tech" companies.[37] In combination with the integration of other types of industry into healthcare, namely digital communications and computer technology,[38] can result in a change in the paradigm of the health market. Are these players bringing them their business models or not? Different question, should they bring these models into the health market?

The healthcare, and especially the pharmaceutical sector, is still very reliant on exclusivity and opts for licensing and enforcing their patent rights on a case-by-case basis. Although there are technical standards applied to pharmaceuticals, they often concern the labeling and packaging and originate from a legal or regulatory source.[39] On the other hand, digital

[34] EPO, 'Patents for software? European law and practice' *2009 European Patent Office* < *https://ciencias.ulisboa.pt/sites/default/files/fcul/inovacao/PI-Pack-INPI-E-Patents-for-Software-EPO.pdf*> *accessed 15 March 2024*

[35] Carl Shapiro, 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting', *2000 Innovation Policy and the Economy*

[36] Tambiama Madiega, 'Standard essential patents regulation', *2023 EPRS | European Parliamentary ResearchService* < *https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/754578/EPRS_BRI(2023)754578_EN.pdf*> *accessed 15 March 2024*

[37] Emarketer, 'Big Tech in Healthcare: Here's who wins and loses as Alphabet, Amazon, Apple, and Microsoft target niche sectors of healthcare', (emarketer.com, January 24, 2023) <https://www.insiderintelligence.com/insights/big-tech-in-healthcare-report/> accessed on 1 March 2024

[38] EPO (n 3)

[39] Robert Sackin and others (n 32)

communication heavily relies on SEPs. Its success is dependent on the cross-licensing of technology.

Recognizing the potential, the crucial role they play in certain industries, and a shift in the market dynamics, the EU came forward with a proposal for a regulation of SEPs. The Proposal has not been without sparking some controversy, with loud dissident voices, such as large communications companies[40] and the President of the EPO,[41] coming forward with various critiques.

According to Chris Smith et al SEPs, it is only a matter of time until SEPs find a more established place in the healthcare sector, and for that reason, pharmaceutical companies need to prepare and embrace themselves to not be left behind in the process. [42] The authors name a few examples where, in their opinion, it is sensible to resort to SEPs and ensure those technologies work in the same way regardless of their origin. However, the claim is only supported by the entry into the health field of tech players, in which business models involve SEPs.

On the same note, Blanca Escribano also highlights the importance of interoperability and technical standards in access to healthcare.[43] The author mentions that the EU "is considering launching sector-specific experiments on standards involving industry, technical community, and public authorities". Nonetheless, it is only mentioned data portability, therefore not discussing the question of standards protected by patents.

Chris Macek et al, on the other hand, claim that the future of healthcare is in "open standards" as they "will foster more innovation and provide more options to global health aid recipients".[44] The authors then list the advantages that an open-standards project will provide without much explanation of those statements. The claim is made in opposition

[40] Foo Yun Chee, 'EU patent rule, disputed by Nokia and Ericsson, gets key EU lawmakers' vote' (reuters.com, January 25, 2024) <https://www.reuters.com/world/europe/eu-patent-rule-disputed-by-nokia-ericsson-gets-key-eu-lawmakers-vote-2024-01-24/> accessed 15 March 2024

[41] Jeremy Fleming-Jones, 'EU Policy. 'Press pause' on SEPs proposal, Patent Office chief urges lawmakers', (euronews.com, February 28, 2024) <https://www.euronews.com/my-europe/2024/02/28/press-pause-on-seps-proposal-patent-office-chief-urges-lawmakers> accessed 15 March

[42] Chris Smith, Robin Ellis and Pete Sadler, 'Standard-essential patents are coming to the pharmaceutical industry' (pharmatimes.com, July/August 2021) < https://pharmatimes.com/magazine/2021/julyaugust_2021/on_the_horizon/> accessed 15 March 2024

[43] Blanca Escribano, 'Digital health: legal challenges in the European Union', *2017 CMS COMMUNICATIONS LAW NEWSLETTER* < https://cms.law/es/content/download/317332 > accessed 15 March 2024

[44] Chris Macek, Brad Cunningham and Nicolas Boillot, 'Open Standard Is the New Open Source' (2022) 12 Journal of Global Health 03042.

to open source, with the main and only real argument for their choice being the fact that open source has not worked until now.

Similarly, Clim analyzes the advantages of standardization in the health sector.[45] The author explains that standardization and interoperability can improve health and diminish disparities by helping the development and implementation of new solutions, including artificial intelligence and precision medicine. In the article, it is also analyzed the subject of open standards. However, Clim delves deeper into the topic and also explains the challenges that need to be overcome to reach its full potential while highlighting the need for a "meticulous calibration" between its benefits and risks.

It is important to note that the considerations made in the last article have not been peer-reviewed at the time of this analysis, since it is a relatively recent article. Given the lack of literature and only recent interest in the subject, I had to widen my research and also take into account other articles.

From the literature review conducted, one can infer that there is a gap in the literature in regards to the application of SEPs in healthcare in Europe. Considering that, as recognized by the EU, certain technologies will be essential in key industries, such as smart health and that there has been a growth in the number of standard essential patent applications,[46] it is crucial to evaluate the role SEPs will take in the health sector in Europe, as well as the impact of this proposal.

First, in light of the literature review, there were not many articles that focused on the subject of SEPs in the specific case of smart health in Europe, and the ones that touched on the subject were insufficient. Second, due to the recent trend of the EU to harmonize and update patent law and regulate SEPs, it is relevant to assess the impact and adequacy of the reform, in particular in the health market. Third, given the increasing complexity of technology and the entry of other technological sectors, such as computer technology and digital communications, into the healthcare field, these industries may introduce their approach to patenting, particularly the use of SEPs.

[45] Antonio Clim, 'The Future of Digital Healthcare: Integrating Rights, AI and Open Standards' (SSRN 2023) preprint <https://www.ssrn.com/abstract=4576606> accessed 18 March 2024.
[46] IAM, 'Analysis of patents, SEPs and standards in the smart healthcare sector' (iam-media.com, 16 March 2022) <https://www.iam-media.com/article/analysis-of-patents-seps-and-standards-in-the-smart-healthcare-sector> accessed 1 March 2024

1.3. Research question and methodology

In light of the literature review, it is crucial to examine the potential challenges they may encounter within the healthcare sector. To understand this question, it will be necessary to analyze various aspects of patent protection, economic theories behind the challenges, and the Proposal of the EU, among others.

To answer the research question, I plan to explore the legal literature even further. Considering the lack of articles written from the European perspective in particular, I intend to use articles with a broader scope and from jurisdictions outside of the EU and try to apply where it makes sense to the EU, always taking into account the particularities of the jurisdiction.

Additionally, given the economic nature of patents as an incentive to research and development and a way of recouping investment, either monetary or labor, I will also look into non-legal literature. An economic theory behind the challenges and consequences of the current patent system is also necessary to make considerations regarding the future of the legal framework.

Given that the field of innovation and patents is heavily influenced by competition between competitors, and that for SPEs and the FRAND licensing system, competition law is of major importance, I also plan to take into account competition law. Sometimes what may seem to be a question of patents may be a question that should be answered by competition law or both.

Chapter 2 – The need for legal incentives to innovate

Economic theories are crucial in understanding patent protection throughout all the fields of innovation. They explain the reasoning behind the need to create legal incentives, such as a “monopoly” around a certain invention to guarantee that players in the market are incentivized and properly compensated for their effort in creating new technology. It also explains some of the shortcomings of patent protection as it currently is. To understand the challenges of this specific type of patent (SEPs), it is relevant to understand first the economics behind such challenges.

In this chapter, it will be explained different theories that explain the need for patent protection, but also its negative, counterproductive consequences, especially in high-tech sectors, such as smart health.

2.1. The Complements Problem

The "complements problem" is not a new concept in economic theory. Already in 1838, the term was first introduced by the French engineer Augustin Cournot.[47] The author in chapter 9 writes about the "Mutual Relations of Producers," where he studies an example in the brass industry where to produce it, one has to purchase both zinc and copper (complementary goods from a demand viewpoint). In this scenario, there are two monopolists in the market: one who controls the copper and another who controls the zinc market. Cornout uses this situation to demonstrate that each player (the zinc monopolist and the copper monopolist) set a higher price than if there were one monopolist player that controlled both the zinc and the copper market. In this context, the two products are considered complementary when one monopolist sets the price in such a way that an increase in their price leads to a decrease in both demand and profits for the other monopolist.

As explained by Shapiro,[48] the French engineer illustrated that in this scenario, each of the monopolists would be tempted to raise their price above the one that would be in the case of a coordinated monopoly, if the other monopolist was pricing at a reasonable level that maximizes joint profits. This practice would ultimately hurt the consumer. In conclusion, as shown by Cournot, in the case of complementary goods from the perspective of demand, the consumer would be better off if all products were produced by a single monopolist company.

Augustin Cournot's example illustrates a fundamental principle in oligopoly theory. Typically, in oligopoly scenarios involving competition between suppliers of substitute goods, the outcomes are the opposite of those observed in less common oligopoly situations where competition exists between suppliers of complementary goods.

[47] Augustin Cournot, Researches Into the Mathematical Principles of the Theory of Wealth (Nathaniel T. Bacon trans., MacMillan 1987) (1838).
[48] Carl Shapiro, 'Chapter 6 Theories of Oligopoly Behavior', *Handbook of Industrial Organization*, vol 1 (Elsevier 1989) <https://linkinghub.elsevier.com/retrieve/pii/S1573448X89010095> accessed 27 December 2024.

The idea of Cournot's "complements" problem has been further developed over time by numerous different authors in economic theory. Contributing to oligopoly theory, Heller has studied a similar issue, the "tragedy of the anticommons", a term the author coined in 1998.[49] As Heller argues, this theory challenges one of the foundational principles of patent protection and the concept that forms the basis of a private "property" right over an invention: the "tragedy of the commons.". To fully comprehend it first one should first understand the concept the author tries to oppose.

2.2. Tragedy of the Commons

The "tragedy of the commons" was first used by Garrett Hardin,[50] however, the concept can be traced back to Aristotle.[51] The idea behind the metaphor refers to when many individuals have unrestricted access to a limited and valuable resource, such as a pasture, they are likely to overuse it, ultimately leading to its depletion or destruction, thus destroying its value.

Hardin's "tragedy of the commons" is often used as justification for patent protection. Ultimately, a patent is just a form of private ownership over an invention that, without any patent protection, would be considered a common good. If the legal system did not grant the right to the patent owner to exclude others from making use of or profiting from their invention, the likelihood of falling into another "tragedy of the commons" would just be too high. Inventions would likely lose their value altogether, thus hampering progress and innovation. Patents are, therefore, instrumental in solving wasteful overuse and bringing order to the use of an invention.

2.3 Tragedy of the Anticommons

However, like everything, it also comes with its downsides. A patent protects inventions, most with great value to the progress of society. To grant private ownership over those

[49] M.A. Heller, 'The Tragedy of the Anticommons: Property in the Transition from Marx to Markets' (1998) 111 Harvard Law Review 621, 624.

[50] Hardin, G. (1968). The Tragedy of the Commons. *Science*, *162*(3859), 1243–1248. http://www.jstor.org/stable/1724745

[51] "That which is common to the greatest number has the least care bestowed upon it (...) each thinks chiefly of his own, hardly at all of the common interest; and only when he is himself concerned as an individual." Aristotle, The Politics and the Constitution of Athens (S. Everson (ed), B. Jowett (trans) Cambridge: Cambridge UP, 1996) 33.

inventions also means that the decisions regarding the use of inventions will be granted to a private entity only, with its private interests. In the case those private interests do not align with the interests of society, it can be harmful to individuals. As explained by Michael Heller,[52] when privatization goes too far, “it can tip into an anticommons, and again everyone loses”. To support this claim, the author introduces a new situation. In this scenario, every square inch in a common field is privatized to a different shepherd, thus making it impossible for any of the shepherds to graze even a single sheep. Resulting, this time, in the reverse outcome, a wasteful underuse of the common field.

An alternative scenario is also possible. Returning to the parking lot example, if the private owner chooses to install a gate and impose excessively high prices, leaving parkers with no option but to park illegally on the street, this creates a situation that mirrors the very tragedy we initially sought to avoid. Thus, while private ownership, and specifically patent protection in this case, can address the "tragedy of overuse," it can also provoke an opposite effect, leading to "wasteful underuse." As Heller aptly describes, this can result in what is termed the "tragedy of the anticommons".

Moreover, the increased complexity of the technology of today, especially in the case of smart health, where the smart devices include components of digital communication, computer technology, medical technology, and in some cases, biotechnology, exacerbates and brings back into the limelight the so-called “complements problem” at the time or Heller’s “tragedy of the anticommons”. Considering the complexity of the technology, it is expected that in one single smart medical device, there is a myriad of different patent owners, each one holding the potential to block the production of the device and therefore impeding innovation.

The term “tragedy of the anticommons” covers this type of case. As explained by Heller, the term includes “any setting in which too many people can block each other from creating or using a scarce resource”.[53] Nowadays, high-tech and specifically smart health are characterized by devices composed of complementary technology. In layman's terms, to produce one smart health device, it is needed to use technology that operates together and is dependent on each other. This technology is owned by multiple distinct patent owners, and each one of them has to allow for the use of their patented invention. Without

[52] Michael Heller, ‘The Tragedy of the Anticommons: A Concise Introduction and Lexicon’ [2023] SSRN Electronic Journal <https://www.ssrn.com/abstract=4366226> accessed 28 December 2024.
[53] ibid.

this permission, the medical device cannot be made, and innovation will be stalled or even come to a full stop. Given the complexity of the technology and the amount of patented inventions one smart medical device encompasses, producing what could be a "life-changing" medical device becomes more and more difficult and is completely dependent on the will of multiple distinct patent owners. Therefore, coming to a situation that is not desirable for our patent system, and especially for a society that strives for progress and improvement of quality of life. We are now faced with a "free market paradox"[54] that fits Heller's "tragedy of the anticommons" theory. When a resource is controlled by too many owners, it can lead to the disintegration of cooperation, to the erosion of wealth, and society ends up losing all progress and incentive to innovate. Everything that the patent system is against and is trying to avoid. Patent protection aims to incentivize innovation and progress in society.

This "paradox" was already studied and explained by Carl Shapiro in the patent system specifically. In the words of Shapiro, a patent thicket is no more than "a dense web of overlapping intellectual property rights that a company must hack its way through to commercialize new technology".[55] From this description, one can understand that the idea behind a "patent thicket" is no more than the idea of Heller's "Tragedy of the Anticommons," but is now applied to patents in particular. To fight this paradox is a necessity of the patent system for it to be coherent with the aim it strives for: to create the best environment possible for the creation of better and more progressed technology. Hence, it becomes crucial to understand how one can guarantee a balance between commons and anticommons. In this study, the aim is to explore how the patent system can balance the rights of patent holders with the needs of developers who want to build smart health technologies using existing patented innovations.

First, it is needed to dive deeper into the economics of the "tragedy of the anticommons" since it is the concept that best describes this phenomenon. Since Heller first introduced the metaphor in 1998, significant additional research has been conducted to further and more comprehensively develop the topic. In "Symmetric Tragedies: Commons and Anticommons", James Buchanan and Yong Yoon worked on Heller's theory and

[54] ibid.
[55] Carl Shapiro, 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting' [2001] SSRN Electronic Journal <http://www.ssrn.com/abstract=273550> accessed 29 December 2024.

developed a model that illustrates and facilitates the understanding of the phenomenon.[56] According to economists, society derives the greatest total value from a resource (as seen in the parking lot scenario when one single owner governs its use. As more individuals gain independent access to the same resource, its value decreases, demonstrating the already-known "tragedy of the commons". Similarly, as the number of individuals with the ability to restrict access to the resource increases, the value declines symmetrically, representing the "tragedy of the anticommons".

This is true especially in the case of competition for complementary goods, as was the case of the "complements problem" explained above. Putting it simply, "anticommons theory" can be understood as a more modern twist of the previous theory. In theory, when goods are complementary and are used together, the consumer usually wants all or none. As Heller explains[57], in a scenario where to go from one place to it is necessary to use three different railways, those railways are complementary. In this scenario, the fare is set at 9, and each of the railways charges 3 for each ride. One of the railways (railway A) knows that if you want to ride from one place to the other, it is mandatory that you buy its ticket, and it has no incentive to innovate. Railway A raises its price in the hopes that the other two will decrease their price. However, the other two have no incentive to decrease the price. On the contrary, both apply the same logic as A and raise the price to match the price of A's ticket, exceeding the initial price to above the initial 9. What Heller is trying to convey and what Cournot demonstrated previously is that the incentive to innovate in complementary competition is frustrated: when the price of one of the complementary goods decreases, the price of the other complementary goods might just increase.

However, how does this translate into patents? We are faced with the same problem if, instead of railways, we have complementary patents, as it happens in the case of smart medical devices. Each device encompasses a multitude of complementary patented technologies. This takes us back to the notion of "patent thicket". There is great potential to block the production of a device because of too many uncoordinated patent owners with their private interests. Thus, blocking the production of a potentially new resource. Circling back to Cournot's demonstration, in a market dominated by complements, the

[56] James M Buchanan and Yong J Yoon, 'Symmetric Tragedies: Commons and Anticommons' (2000) 43 The Journal of Law and Economics 1.
[57] Heller (n 52).

overall social welfare, in this case, innovation, may be greater if the different patent owners merge. This translates to the current systems of standards and patent pools.

From Michael Heller's point of view, to find a possible solution to this "tragedy," one has to first comprehend the full spectrum of ownership. On one end of the spectrum, there is the "common" ownership. On the other end lies the "anticommons," and between them, in the middle, there is private ownership. The "common" ownership of a resource translates to fully open access for all to use it freely. However, an important distinction must be made between open access and group access. In the latter case, the property is common to insiders but private for outsiders. One cannot ignore, although, that it requires cooperation to achieve the optimal use in this type of case. Moreover, it is also necessary to adapt the solutions to each type of property.

Heller believes that one of the solutions, often ignored, may be in hybrid systems. The state can sponsor this type of solution and, for example, can claim ownership over certain resources while granting private rights such as licenses.[58] In the opinion of the author, this solution can even go beyond natural resources and reach high-tech innovation.

In conclusion, in the case of open-access resources, it is the role of the State to either directly regulate the use of the resource or establish hybrid property rights, such as implementing quotas. The anticommons equivalent of open access is full exclusion, where an unlimited number of individuals can block each other's access to the resource. To resolve full exclusion, the state must either consolidate fragmented rights through expropriation or create hybrid property regimes that facilitate the consolidation of ownership. Without these interventions, the resource is likely to be underutilized and wasted. However, a key difference between full exclusion and open access is that the issues arising from the anticommons are often not immediately evident; the underuse of the resource must first be identified before addressing the underlying problem.

On the other hand, group access parallel in the anticommons is group exclusion. In this situation, a limited number of owners can obstruct each other's use of the resource. For example, consider a medical device with multiple owners. Whether access is shared among them or limited to certain parties, various approaches, such as contractual agreements, collaborative arrangements, or regulatory frameworks, can be used to manage its use and ownership. Although self-regulation can be particularly difficult in the

[58] ibid.

context of anticommons resources, closely interconnected owners may sometimes coordinate to mitigate the tragedy of the anticommons. Regarding group exclusion resources, regulatory efforts should prioritize the promotion of markets that support ownership consolidation and the removal of obstacles to cooperation.

Heller's contribution in naming and identifying a key phenomenon that many may have hinted at or scratched its surface of, but without being able to pinpoint, fully comprehend, or just put it into words, has been increasingly relevant. Nowadays, and in the context of more high-tech industries, it becomes even more relevant to bring this notion back and discuss it in light of the reality of today. As we move forward and technology becomes more complex, it is important to bear in mind some of Heller's words: "Privatisation can go too far, to the point where it destroys rather than creates wealth. Too many owners paralyze markets because everyone blocks everyone else. Well-functioning private property is a fragile balance poised between the extremes of overuse and underuse".[59]

After the introduction of this theory by Michael Heller, the notion has been subject to multiple studies across different industries. One of those works is again by Heller, now including also Rebecca Eisenberg, about the application of this concept specifically to biomedical research.[60] Furthermore, the tragedy of the anticommons has also been studied in the context of the telecom industry.[61] Finally, Ham Ziedonis has even studied the effects of anticommons in technology patenting.[62] Considering the characteristics of the smart health industry, the type of technology, and the work that has been written in other industries, it is relevant to also study this dilemma in the context of patent protection in the smart health industry.

Drawing loosely from the concept of the "hybrid system" mentioned earlier, one potential solution may involve the use of SEPs, which will be further analyzed below. However, this approach presents its own set of challenges that must be addressed. The following section will explore this "Heller-like" solution in greater detail.

[59] ibid.
[60] Michael A Heller and Rebecca S Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 Science 698.
[61] T.W. Hazlett,'SpectrumTragedies'(2005) 22 Yale Journal of Regulation 242
[62] Rosemarie Ham Ziedonis, 'Don't Fence Me In: Fragmented Markets for Technology and the Patent Acquisition Strategies of Firms' [2003] SSRN Electronic Journal <http://www.ssrn.com/abstract=475601> accessed 30 December 2024.

Chapter 3 - Standard Essential Patents as a legal incentive to foster health technologies

The technology of today is becoming increasingly more complex, and the technology used in the healthcare industry is no exception. With the integration of smart health devices into the industry, interoperability has become a necessity. A technical standard ensures that these devices operate between them, from different providers and at a distance, while also facilitating the development, progress, and diffusion of these technologies with the potential to improve the quality of life of the people. Standards are not a new reality in the high-tech sector. A technical standard is "an agreed or established technical description of an idea, product, service, or way of doing things where you need to share the understanding with others.".[63] They are usually developed by Standard-setting organizations (SSOs), and in Europe, the three main European standards organizations are: the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC), and the European Telecommunications Standards Institute (ETSI).

In the following subchapters, it will be explained what SEPs are, their regulation, and relevant case law for the regulation of this type of patent in the EU.

3.1. SEP Regulation in the EU

A Standard Essential Patent (SEP), on the other hand, is a patent that protects the technology incorporated in a technical standard.[64] In other words, these patents must be disclosed as essential for the implementation of standards.[65] There are a myriad of standards that are based on patented technology. For instance, the Information and Communications Technology (ICT) industry has long been acquainted with them. USB, Wifi networks, 4G, and 5G technology are all great examples of patented technology incorporated in a technical standard. To put it simply, SEPs are "the patents guarding an industry's fundamental technology — the norm that the entire sector must adhere to keep innovating in significant ways. In actuality, SEPs are decided by industry-specific

[63] Intellectual Property Office 'Consultation outcome Standard Essential Patents and Innovation: Call for views' (gov.uk, 5 July 2023) <https://www.gov.uk/government/consultations/standard-essential-patents-and-innovation-call-for-views/standard-essential-patents-and-innovation-call-for-views > accessed 28 August 2024

[64] (Madiega n 36)

[65] Josh Lerner and Jean Tirole, 'Standard-Essential Patents' (2015) 123 Journal of Political Economy 547.

SSOs and are crucial to the standard[66]. Additionally, SEPs often differ from other patents in other aspects. They include more declaration details, such as SEPs often differ from non-SEPs in one aspect as they include more declaration details, such as: "(i) SEPs that have been declared by SSOs will contain a declaration number; (ii) The technology that SEPs cover should be able to be mapped to its stated technical standards or specifications.".[67]

When developing technology that incorporates technical standards and/or needs to comply with a certain standard that is protected by a SEP, the inventor risks infringing the patent owner's rights. For that reason, the patent owner has to give permission, either by not enforcing their negative right or by selling or licensing their technology.

SSOs can play a key role in managing these interactions. Often, a considerable number of these standards are developed through collaborative efforts among market participants within SSOs. Considering the risk of market participants infringing the rights of each other, it is common for these organizations to implement policies that obligate participants to disclose any potentially relevant patents they hold and to commit to licensing them on fair, reasonable, and non-discriminatory (FRAND) terms, if these patents become essential to the standard.

Nevertheless, this is not the only function SSOs perform. As Lerner and Tirole explain, SSOs play a multifunctional role, carrying out three main functions[68]. The first one is the discovery function, and the process involves acquiring knowledge and the evaluation of the value associated with different combinations of functionalities. Secondly, an SSO selects one particular technology out of several options as the technical standard, leading the market expectations towards that technology in particular. Patents that otherwise were not initially considered essential because alternative technologies, which did not depend on them, were competing with the chosen technology, may become, as a result, SEPs ex-post. Lastly, it also regulates the market by establishing that patent owners of SEPs grant FRAND licensing terms.

[66] Prashant and Ashwini Siwal, 'An Introduction to Standard Essential Patents Part –III' (2023) 28 Journal of Intellectual Property Rights <https://or.niscpr.res.in/index.php/JIPR/article/view/1269> accessed 30 December 2024.
[67] ibid.
[68] Lerner and Tirole (n 65).

However, those policies still come with their issues. They are usually loosely determined and relatively broad, and do not provide specific guidance regarding the licensing of SEPs. As a result, SEPs have remained a recurrent subject of legal disputes and regulatory interventions over the past several decades.[69] According to legal literature,[70] it is important to stress and remember in legal disputes that the judgment of what is considered a "fair and reasonable" term should reflect the outcome of competition ex-ante, instead of the ex-post manufactured monopoly scenario.

Patent owners have the right to decide whether, to whom, and under what conditions they wish to license or sell their patents, with or without compensation. However, when these patents are SEPs, the patent holders are obligated to license them on terms that are fair, reasonable, and non-discriminatory (FRAND) to any company that wishes to incorporate the standard into their products or services (referred to as SEP implementers).[71]

So far there has not been any specific European Union (EU) or national legislation about SEPs. They have only been subject to competition law rules.[72] However, to regulate and increase competition in the market, the EU Commission released its Proposal in April 2023 regulating SEPs in its territory.

However, until the new proposed regulation enters into force, in the European Union (EU) standard setting and the corresponding FRAND licensing rules are still determined by the "Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements"[73] and the relevant jurisprudence, such as the ruling of 2015 of the Court of Justice of the European Union (CJEU) "Huawei Technologies Co. Ltd v ZTE Corp and ZTE Deutschland GmbH, C-170/13".[74]

Additionally, standards development organizations (SDOs) also set certain rules that the participants in said organization have to respect.

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[69] Chayanin Wipusanawan, 'Standard-Essential Patents, Innovation, and Competition' (CentER 2023) <https://research.tilburguniversity.edu/en/publications/standard-essential-patents-innovation-and-competition> accessed 30 December 2024.
[70] Richard Schmalensee, 'Standard-Setting, Innovation Specialists And Competition Policy*' (2009) 57 The Journal of Industrial Economics 526.
[71] European Parliament (n 79)
[72] Ibid.
[73] Commission (EC), Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements (Communication) (2023/C 259/01) 21 July 2023
[74] C-170/13 Huawei Technologies Co. Ltd v ZTE Corp., ZTE Deutschland GmbH, [2015] ECR

Patent protection grants the patent holder an exclusive temporary right over an invention to prohibit third parties from using their invention. This allows the patent holder to exploit a potential monopoly position in the market. Standards, on the other hand, exhibit characteristics similar to a classical public good, or at the very least, a club good.[75] Essential information regarding the new invention and, depending on the regime of licensing, the technology itself may be available to other market competitors that have an interest in implementing it. Therefore, standards have the potential to disseminate access, development, and acceptance of the newest technologies.[76] Given this context, what motivates companies to patent their inventions as essential? In other words, what are the benefits of SEPs for inventors?"

First, in the context of the current technology, interoperability is key. Different devices and different technologies must operate together. In the smart health industry, for instance, a medical device must operate with all kinds of systems to transmit health information, even though different hospitals may have different systems to interpret the data. Secondly, it also ensures product substitutability.

Moreover, from a strategic point of view, firms often engage in standardization to gain insights from competitors, access new markets, and influence the development of standards and regulations. However, patenting is primarily employed to safeguard intellectual property rights and maintain market power. By pooling resources, sharing information, and leveraging potential synergies, firms could overcome internal and external resource-related barriers and more effectively implement a holistic strategy.[77]

As explained above, there is still no specific legislation regarding SEPs at the national level or the EU level. It has been subject, usually, to competition law rules. Consequently, jurisprudence plays a key role in guiding and determining the boundaries of SEPs. In this short subchapter, it is going to be summarized two landmark cases of SEP disputes. The first one is the Samsung case, which involves this company and the European Commission. In turn, it is very similar to another one: the Motorola case, so only one of them is going to be explained. The second one, "Huawei," also displays similar

[75] Swann, G. P. (2010). The economics of standardization: An update. *Report for the UK Department of Business, Innovation and Skills (BIS)*.
[76] Knut Blind, 'Explanatory Factors for Participation in Formal Standardisation Processes: Empirical Evidence at Firm Level' (2006) 15 Economics of Innovation and New Technology 157.
[77] Knut Blind, Jakob Pohlisch and Julius Rauber, 'Patenting and Standardization: Similarities and Differences Based on Firms' Strategic Motives and Experienced Barriers' (2022) 65 Journal of Engineering and Technology Management 101699.

circumstances to the first one, however, it went up to the CJUE. The ruling of the Court went a little bit further and established some guidance for SEP licensing negotiations. To further understand the rules currently applicable to SEPs, one cannot leave out jurisprudence. For that reason, it is relevant to also briefly explain the most relevant rules set out in landmark cases in order to fully comprehend the developments and the shortcomings of the current system, which, consequently, have an impact on the smart health sector.

3.2. Settlement Agreement between the European Commission and *Samsung* over FRAND licenses

The European Commission issued on the 29th of April 2014 a press release where it stated that it accepted *Samsung Electronics* legally binding commitments on injunctions of SEPs.[78] According to these commitments, "Samsung will not seek injunctions in Europe based on its SEPs for smartphones and tablets against licensees who sign up to a specified licensing framework".[79] The framework under consideration is the FRAND terms, and it is the responsibility of a court, or an arbitrator in the event of an agreement between the parties, to determine what is deemed fair, reasonable, and non-discriminatory in the context of the specific case.

Samsung's commitment comes after an investigation started in January 2012 by the European Commission and following a statement of objections regarding possible misuse of SEPs on mobile phone technology.[80] The Commission was concerned that Samsung's resort to injunctions against Apple for infringing SEPs that the first held could amount to an abuse of dominant position, prohibited by competition rules, namely article 102 of the Treaty on the Functioning of the European Union (TFUE).

It is important to stress that, although in this case the use of injunctions was considered a potential abuse of dominant position, seeking these actions before the courts is usually a legitimate remedy in the event of patent infringements that patent holders can resort to. In this specific case, however, since SEPs are patents that protect technology it is

[78] European Commission, 'Commission proposes a new framework on Standard Essential Patents' (Press release, 2 July 2014) <https://ec.europa.eu/commission/presscorner/detail/en/ip_14_490> accessed 23 February 2025.
[79] Ibid.
[80] European Commision (n 92)

necessary to develop products that need to comply to a certain standard. To manufacture them is impossible without obtaining a license to use the patented technology. As a result, companies that hold SEPs may own significant market power. For that reason, SEP holders must license their patents on FRAND terms. Injunctions typically involve a prohibition on the sale of products that infringe a patent. When SEP-based injunctions are sought against a willing licensee, there is a risk of excluding products from the market. This potential threat can distort licensing negotiations, resulting in anticompetitive terms that the licensee would not have accepted in the absence of the injunction. Such an outcome would be detrimental to innovation and could have adverse effects on consumers.[81]

In conclusion, given Samsung's market power and *Apple*'s (the licensee) willingness to negotiate a licensing deal to use the essential patented technology, to seek an injunction against *Apple* may have constituted an abuse of dominant position, prohibited by antitrust rules, namely article 102 of the TFUE. For that reason, the European Commission had to act on this case and accepted *Samsung*'s legally binding commitment to "not to seek any injunctions in the European Economic Area (EEA) based on any of its SEPs, present and future, that relate to technologies implemented in smartphones and tablets against any company that agrees to a particular framework for licensing the relevant SEPs.".[82]

3.3. Huawei Technologies Co. Ltd v ZTE Corp., ZTE Deutschland GmbH (Case C-170/13)

On July 16th, 2015, the CJUE landed its ruling on the landmark case of Huawei Technologies Co. Ltd v ZTE Corp., ZTE Deutschland GmbH (Case C-170/13).[83] The Court judged that the holder of a SEP that has committed to license its patent in FRAND licensing terms may violate Competition Law rules, namely Article 102 of the TFUE, if, under certain circumstances, seeks an injunction against a potential licensee.

Huawei, a Chinese mobile network technological corporation brought an action against *ZTE*, also a Chinese technological corporation, before the German Federal Court of Justice for patent infringement and seeking an injunction to prohibit the continuation of the infringement, an order for the rendering of accounts, the recall of products, and an

[81] European Commision (n 73)
[82] Ibid.
[83] European Court of Justice (n 74)

award of damages. *Huawei* claimed *ZTE* was marketing products in Germany that comprised software linked to the 4G "Long Term Evolution" (LTE) standard, in which they held patents protecting the technology used. Despite the efforts to conclude a licensing deal regarding Huawei's patents on FRAND terms, the parties failed to reach an agreement and stopped all negotiations.

On the other hand, ZTE presented a defense arguing that Huawei was abusing its dominant market position, thereby violating Article 102 TFEU. ZTE contended that Huawei was seeking a preliminary injunction despite ZTE's willingness to engage in negotiations for a licensing agreement to use Huawei's patent.

In its decision, the CJUE when adopting a position, had the major goal to try and "strike a balance between maintaining free competition and the requirement to safeguard intellectual property rights and their effective judicial protection, guaranteed by Article 17(2) and Article 47 of the Charter of Fundamental Rights, respectively".[84] In other words, the CJUE's major concern was to protect both the interests of the SEP holder and the interests of the implementers in developing technology that uses the SEP and made efforts to negotiate a licensing deal.

Therefore, the ruling imposed some restrictions on SEP holders that they must follow when enforcing their rights in specific circumstances. Moreover, the CJUE also established certain limitations on the authority of the European Commission to initiate investigations under EU competition law when patent holders have already sought injunctions in the context of patent disputes.

It is already established in EU case law that the exercise of an exclusive right can only, in exceptional circumstances, constitute an abuse of the dominant position. Nevertheless, the CJUE considered this situation to be one of those exceptional circumstances. In the present case, the patent was a SEP, and it was only considered as such because Huawei had committed to ETSI to license it on FRAND terms. This commitment, as a result, created a legitimate expectation on future SEP implementers that the SEP holder would,

[84] Peter Georg Picht, 'Standard-Essential Patents: Limiting Exclusivity for the Sake of Innovation' in Josef Drexl and Anselm Kamperman Sanders (eds), *The Innovation Society and Intellectual Property* (Edward Elgar Publishing 2019) <https://china.elgaronline.com/view/edcoll/9781789902341/9781789902341.00019.xml> accessed 2 January 2025.

when the time came, grant them a license on those terms. Thus, such refusal, in this situation, may constitute an abuse of dominance.

However, the ruling of the CJUE did not stop there. In an attempt to clarify to SEP holders what can be considered an abuse of dominance, it also outlined a series of specific guidelines for negotiations concerning SEP patent licensing. These guidelines also included the steps that a SEP holder must adhere to prevent a request for an injunction from being construed as an abuse of dominance. The outcome of the guidelines is that, while the implementer is obliged to assume the patent's validity, it agrees to either pay the specified or negotiated royalty (or place the difference in escrow) and retains the right to independently challenge the patent's validity.[85]

It is important to note that it is still up to the national courts to judge to what extent a patent holder of a SEP has market power, on a case-by-case basis. Contrary to the opinion of the Advocate General, the CJUE did not hold a position on whether a SEP confers or not a dominant position in the market.

Chapter 4: The potential challenges of Standard Essential Patents in the smart healthcare industry

As was explained until now, standards and SEPs have a lot of benefits, such as guaranteeing interoperability between products, efficiency in the market, and increased probability of substitution between products that ultimately increase consumer welfare. Nonetheless, it also comes with some downsides, especially in high-tech industries, like smart health. Therefore, it is of the utmost importance for this study to understand these challenges and possible ways to overcome them. The European Commission's guidelines on horizontal agreements offer a systematized idea of the concerns with standards and SEPs and how to navigate through them.

[85] Norton Rose Fulbright, 'The EU Court of Justice Judgment in Huawei v ZTE – important confirmation of practical steps to be taken by Standard Essential Patent holders before seeking injunctions' (nortonrosefulbright.com, August 2015) <https://www.nortonrosefulbright.com/en/knowledge/publications/8f90efbd/the-eu-court-of-justice-judgment-in-huawei-v-zte---important-confirmation-of-practical-steps-to-be-taken-by-standard-essential-patent-holders-before-seeking-injunctions> accessed 15 September 2024

4.1 Patent hold-up, hold-out, ambush

During the standardization process, participants in the development of the standard agree on a particular technological solution from a set of (potentially) competing options. This choice can result in the concentration of market power, which may enable the holder of a SEP to exploit this power by imposing unfavorable terms on implementers.[86]

In the following sub-sections, the paper will focus on the patent hold-up (4.1.1.), the patent hold-out (4.1.2.), and the patent ambush (4.1.3).

4.1.1. Patent hold-up

Patent hold-up, as the name suggests, is none other than the use of market power to exploit a technology implementer by refusing to grant a license on competitive terms. As the European Commission explains in the guidelines regarding horizontal agreements, patent hold-up occurs "[w]hen the standard constitutes a barrier to entry, the undertaking could thereby control the product or service market to which the standard relates. This in turn could allow undertakings to behave in anti-competitive ways, for example by refusing to license the necessary IPR or by extracting excess rents by way of discriminatory or excessive (…) royalty fees, thereby preventing effective access to the standard".[87]

However, not all royalty fees can be qualified as excessive. The qualification is subject to competition law rules, namely, it is determined if the conditions of Article 102 of the TFUE and the corresponding case law of the CJUE are met.[88]

4.2. Patent hold-out

Patent hold-out is the reverse situation of patent hold-up. In this case, licensing negotiations are delayed or blocked by the implementer of a SEP, for example, by postponing discussions or refusing to accept and pay a licensing fee under FRAND terms and conditions.[89]

Although both hold-up and hold-out concerns are typically unilateral, they arise from different factors. Specifically, a hold-out occurs when an implementer refuses to take a license, which is not a direct outcome of the standardization but arises because intellectual property rights' (IPRs) holders can only prevent unlicensed use through legal action. The Court of Justice's ruling in Huawei v ZTE, which sets out requirements for implementers

[86] European Commission (n 87)
[87] Ibid.
[88] Ibid.
[89] Ibid.

of standard-essential IPRs to avoid injunctions by national courts, typically offers sufficient protection against hold-out tactics within the EU.[90]

4.3. Patent ambush

A "patent ambush" happens when a company involved in the standard-development process deliberately hides its ownership of essential patents related to the standard. The company then asserts these patents only after the standard is finalized, forcing other companies to adopt it. This type of tactic undermines trust in the standardization process and harms consumer welfare. A transparent and effective development process is essential for fostering technical innovation and the growth of competitive markets, which ultimately benefits consumers.[91]

4.2. Doctrinal debate around patent hold-up

In the essay "The Role of Antitrust in Preventing Patent Holdup",[92] Shapiro and Lemley argue that patent hold-up remains one of the most significant concerns for patent policy in the current system. Despite the efforts to combat the problem and the loud voices that deny its existence in the first place, the consequences and importance of patent hold-up in the innovation system still justify bringing this discussion to the table. Moreover, as previously discussed, economic theories (such as Cournot's "complements problem," Heller's "tragedy of the anticommons," and the more recent concept of "royalty stacking") underscore the systemic inefficiencies in the current SEP framework. These issues are particularly pronounced in socially impactful and innovation-driven sectors like smart health, thereby reinforcing the need for regulatory reform.

As it was briefly previously explained, patent hold-up occurs, in general, "when a patent holder can obtain unreasonably high royalties by asserting its patent against another company's products because that company's most efficient way to develop, make, and sell those target products involves investments that cannot easily be redeployed to non-infringing products".[93] This problem is exacerbated in the case of SEPs, considering that to introduce a standard-compliant product in the market, there is no way to invent around

[90] Ibid.
[91] Ibid.
[92] Carl Shapiro and Mark A Lemley, 'The Role of Antitrust in Preventing Patent Holdup' [2020] SSRN Electronic Journal <https://www.ssrn.com/abstract=3666211> accessed 30 January 2025.
[93] Carl Shapiro and Mark A Lemley, 'The Role of Antitrust in Preventing Patent Holdup' [2020] SSRN Electronic Journal <https://www.ssrn.com/abstract=3666211> accessed 30 January 2025.

that patent, and it is, therefore, necessary to implement said patent. This gives holders of SEPs substantial market power and imposes great potential for monopoly situations. A player in the market can potentially block competition from introducing new standard-compliant products into the market by imposing, for example, unreasonably high royalty rates, resulting in great consumer harm.

Great consumer harm translates to substantial consequences for the quality of life of individuals in industries that are essential to society, such as the healthcare industry. Without entering into the debate regarding whether the right to health is sufficiently protected in the EU, which goes beyond the object of this study, one cannot ignore the relevance of the protection of this right. The patent system can and should play a role in the protection of the right to health. In the EU is acknowledged in various human rights treaties to which EU Member States are signatories, such as Article 12 of the International Covenant on Economic, Social and Cultural Rights and Article 11 of the European Social Charter, in addition to Article 35 of the European Union Charter on Fundamental Rights. A key question is how the patent system, particularly SEPs, can be designed to effectively incentivize innovation and technological development in the healthcare sector.

So far, the hold-up problem in SEPs is no more than an expression of the various economic theories that were briefly explained in the previous chapters. To put it simply, it arises primarily due to the complementary nature of the goods involved (much like Cournot's economic theory, the "Complements problem" shows) and the necessity for these goods to operate together, which requires interoperability. In the context of smart health products, these technologies are composed of multiple components that often involve numerous patent holders, each of whom can potentially block the others, leading to a "tragedy of the anticommons." Furthermore, because the technologies in question are essential, each patent holder can impose excessive royalty rates, resulting in royalty stacking. This raises the critical question: how can these issues be addressed to encourage investment in advanced technologies and ensure that such technologies reach the market, thereby providing society with access to their benefits?

One potential solution that has been proposed involves the patent system and competition law, specifically through the FRAND licensing framework. While this system alleviates some of the negative consequences associated with SEP-related challenges, as previously discussed, it is not without its issues, particularly legal disputes, and is furthermore insufficient on its own to fully resolve the problem.

Shapiro and Lemley,[94] as well as Heller and Eisenberg,[95] highlighted in their works what they considered one of the pitfalls of patent protection and for that reason, argued for a change in the system. However, it has been argued that there is no “tragedy of the anticommons” and, on the other hand, the real “tragedy, if there is one, is underpayment for technologies that have high social returns, resulting in underinvestment in R&D and lower innovation and growth than society desires”.[96] In his work, David J. Teece recognizes that there might be certain situations where patent thickets, as argued by Heller and Eisenberg, might impede downstream innovation because of the challenges in assembling the necessary intellectual property rights when they are held by multiple parties. Nevertheless, it is not enough to support the argument that there is a systemic problem of patent underuse and excessive payment for their use. To counterargue, the author relies mainly on the fact that patents differ from real property rights in that they are not self-enforcing. Patent holders must rely on courts to issue injunctions, which have become less frequently granted, particularly after the eBay decision. Additionally, courts are often reluctant to recognize the concept of an "infringer’s royalty”. In his point of view, this inability to effectively exclude infringers diminishes the utility of the anticommons thesis as a reliable basis for policy or judicial decision-making.

Facing this argument, one cannot deny the fact that patents are not self-enforcing and, on the contrary, the patent holder, facing an infringement of their patent, has to seek the courts to enforce their right. However, it ignores the deterrent effect the threat of an injunction may have on potential competitors seeking to enter the market. Furthermore, it fails to address a significant issue faced by many market participants: the difficulty in determining which patented technologies they may inadvertently infringe upon when developing new products, due to the complexity of modern high-tech innovations.

Finally, seeking an injunction against an alleged infringer has indeed become more difficult since the eBay case in the United States and, in parallel, since the Huawei ruling in the EU. However, those cases are not enough to conclude, as was concluded by Teece, that there is an inability “to easily or credibly threaten to exclude infringers (especially

[94] ibid.
[95] Heller and Eisenberg (n 60).
[96] David J Teece, ‘THE “TRAGEDY OF THE ANTICOMMONS” FALLACY: A LAW AND ECONOMICS ANALYSIS OF PATENT THICKETS AND FRAND LICENSING’ <https://lawcat.berkeley.edu/record/1128535> accessed 3 February 2025.

difficult today when FRAND commitments have been made)".[97] The eBay ruling[98], to put it simply, tried to balance the rights of both the patent holder and the alleged infringer by determining a four-factor test to be weighed in when granting an injunction. To summarize, the Supreme Court of the United States argued that an injunction should not be automatically granted solely upon a finding of patent infringement, nor should it be denied solely because the plaintiff does not practice the patented invention. Similarly, in the EU, the CJEU did not make it impossible for patent holders to seek an injunction against alleged infringers. On the other hand, in its ruling, it established a set of "guidelines" on which steps to follow in negotiating with the alleged infringer before seeking an injunction against them. In the same way, the primary goal of the Court was to establish a necessary balance to guarantee the respect and protection of the rights of each party. In both rulings, there was no evidence of the balance tipping in favor of the alleged infringer, as Teece suggested.

While the FRAND licensing system helps mitigate the negative effects of patent hold-up, it is not without its significant challenges. As noted earlier, there is no universally agreed-upon method for determining what constitutes a fair, reasonable, and non-discriminatory royalty. This lack of clarity leads to difficult negotiations between parties and, ultimately, extensive litigation, which often lacks consistency. Consequently, it would be incorrect to conclude that the current patent system is incapable of effectively excluding infringers.

Moreover, David J Teece argues that the core issue arises when legal standards do not align with economic realities, leading to infringement being viewed as a "solution" rather than pursuing licensing agreements. This undermines incentives for research and development (R&D) and innovation, exacerbating problems of underinvestment. Eisenberg later acknowledged that "unauthorized use" might serve as a solution, but did not address the distortions this approach creates in terms of investment. The prevalence of unauthorized use and inadequate enforcement mechanisms leads to diminished innovation and erodes the integrity of the intellectual property system.

David Teece further argues in the article that the primary issue lies in the underpayment for high-return technologies, which results in insufficient investment in R&D and consequently lower levels of innovation than society requires. This problem is especially

[97] ibid.
[98] eBay, Inc. v. MercExchange LLC, 401 F.3d 1323 (Fed. Cir. 2005).

evident when patents involve general-purpose technologies. Considering this, the article suggests that the actual tragedy is society's failure to receive the level of innovation it is willing to fund, which Heller and Eisenberg's analysis overlooked.

The author effectively emphasizes the significance of protection and the opportunity to take legal action against those who infringe upon an exclusive right to a particular invention. This mechanism serves as a means to recover investment and encourage further technological advancements that might not otherwise occur in the absence of the prospect of a monopoly on the invention. Ultimately, this argument aligns with the fundamental rationale for patent protection. For this reason, "unauthorized use" should not be a solution for the problem as it would result, as eloquently explained by Teece, in the same outcome it is trying to solve: an underinvestment in R&D, but instead for the opposite reasons.

Despite raising a very good point by highlighting the problem of taking patent infringement lightly and not granting effective protection to patent holders, the article lacks in justifying what it argues is the real issue: the underpayment for the investment in high-tech.

Secondly, as explained above,[99] the threat of an injunction (patent hold-up) can allow a patent holder to secure royalties significantly higher than the patent holder's actual economic contribution, especially when patents cover "a minor feature of a complex product developed independently by the infringing party".[100] These excessive royalty charges effectively act as a tax on new products that incorporate the patented technology, thereby hindering innovation rather than fostering it. This problem is aggravated the more complex the technology is, especially in situations where the technology is considered essential, since there is no way to invent around it. The phenomenon known as "royalty stacking" is not new in legal debate. Lemley and Shapiro, in the article "Patent Hold-Up and Royalty Stacking,"[101] identify this problem, raise some concerns about it, and argue for a change. However, since the publication of the article, several authors[102] have come

[99] Chapter 4, subchapter 4.1, subsection 4.1.1
[100] Mark A Lemley and Carl Shapiro, 'Reply: Patent Holdup and Royalty Stacking' (2007) 85 *Texas L Rev* 2163.
[101] E Elhauge, 'DO PATENT HOLDUP AND ROYALTY STACKING LEAD TO SYSTEMATICALLY EXCESSIVE ROYALTIES?' (2008) 4 Journal of Competition Law and Economics 535.
[102] Lemley, M. A, & Shapiro, C. (2007). Patent Hold-Up and Royalty Stacking. *UC Berkeley: Competition Policy Center*. Retrieved from <https://escholarship.org/uc/item/8638s257> accessed 23 February 2025;

forward to discredit their work and oppose their views. According to this doctrine, patent hold-up and royalty stacking do not necessarily result in excessive royalty rates. This position is supported by the absence of empirical evidence demonstrating that patent holders systematically impose inflated royalty fees.

Similarly, it has also been argued that there is no patent hold-up.[103] Shapiro and Lemley, in their work "The Role of Antitrust in Preventing Patent Holdup,"[104] eloquently explain why that is not the case. Before delving into their arguments, it is important to establish what the so-called "patent hold-up problem" is. To put it simply, this problem occurs when "the owner of a key asset can charge more than the asset is worth ex-ante if the buyer has made asset-specific investments that will be lost unless the parties agree on terms of trade".[105] To counterargue the argument that there is insufficient empirical evidence of hold-up, the authors explain that it is very difficult to measure actual hold-ups, but the simple presence of certain institutions is enough to understand that the problem is "real and significant". Nevertheless, according to the authors, the simultaneous presence of three key indicators provides sufficient evidence of a patent hold-up problem: (1) the firm has independently developed a new product; (2) it has made significant, product-specific investments related to one or more asserted patents; and (3) it lacks protection against the risk of patent hold-up.

Returning to the smart health sector, being a high-tech sector, the presence of the first two telltale signs is very common, which puts considerable weight on the firms to try and develop safeguards against possible hold-up. However, the traditional market solutions do not seem to be sufficient when it comes to patent hold-up. Particularly, in the high-tech sector, and for that reason, the smart health sector, patent law rules such as the ones ruling injunctions and patent damages have shown themselves to be insufficient. Despite the efforts of the system, namely through court decisions, such as Huawei, there is still work to do. For that reason, companies in this type of sector had to resort to other

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Geradin, Damien and Layne-Farrar, Anne and Padilla, Jorge, The Complements Problem within Standard Setting: Assessing the Evidence on Royalty Stacking (January 8, 2008). Boston University Journal of Science and Technology Law, Vol. 14, No. 2, 2008, Available at SSRN: https://ssrn.com/abstract=949599; Sidak, J. Gregory, Holdup, Royalty Stacking, and the Presumption of Injunctive Relief for Patent Infringement: A Reply to Lemley and Shapiro. Minnesota Law Review, Vol. 92, No. 3, pp. 714-748, 2008, Available at SSRN: https://ssrn.com/abstract=988694

[103] Alexander Galetovic, Stephen Haber and Ross Levine, 'An Empirical Examination of Patent Holdup' (2015) 11 Journal of Competition Law and Economics 549.

[104] Shapiro and Lemley (n 93).

[105] Ibid.

strategies. Thus, come into play, SSOs and FRAND commitments and Shapiro and Lemley's strongest argument confirming the existence of a problem of patent hold-up. The almost universally recognized need for such mechanisms confirms that hold-up is seen by companies as a problem to avoid and that they must build safeguards to fight it. Therefore, it is my understanding that patent hold-up is a reality that the current system needs to address and improve its mechanisms to address it.

While it may seem redundant, the case of smart health technology, which is covered by essential patents, is in a particularly sensitive position due to the increased risk of patent hold-up. Consequently, FRAND licensing terms are crucial in this type of sector to mitigate the potential adverse effects of SEP hold-up.

Chapter 5 – Conclusion: a need for specific provisions

Smart health has the potential to increase quality and access to proper, more personalized healthcare. It is therefore, crucial to guarantee access to this type of technology as well as to incentivize the creation and development of better smart medical devices. To balance access and patent protection of smart health devices can be a tricky challenge. Already there is a mechanism in research that aims to find this balance. However, it is only aimed at research purposes and, for that reason, quite limited.

SEPs can also be seen as another mechanism. Nonetheless, they present their own challenges as was explained. For that reason, proper regulation of this type of patents is key to guarantee the benefits of the use of smart medical devices.

This chapter discusses the existing research exemption and examines the Proposal for a Regulation on SEPs, which aims to enhance legal certainty and address previously identified shortcomings in the current system. The Proposal will be analyzed within the context of smart health.

5.1. The research exemption

A mechanism that tries to balance patent protection and access to technology for the development and study of better, more equipped technology used in the healthcare system, and that can also be used in smart health, is the research exemption.

The health sector is an extremely innovative field and is no exception to the digital transformation phenomenon that is occurring across multiple fields. Medical technology, the one where the most patent applications are filed, has seen a trend in applications that combine also digital communications and computer technology, including AI and ML. Even though there may still be a misconception this type of technology cannot be patented, throughout the essay, it was demonstrated that patent law allows for the protection of smart health. However, given the nature of the technology, it comes with its challenges regarding patent eligibility and acquisition. These need to be taken into account when drafting the patent claims to avoid rejection of protection.

Even though patent protection can be a crucial tool for the development of even greater and more advanced smart health technology, it can also serve as a barrier to access. It is, therefore, crucial to strike a balance. Patent law reaches that balance by allowing its protection with certain limitations. The research exemption is one key limitation, which allows for research to be conducted on the invention with a sense of unraveling more information, without the consent of the patent holder and risk of liability.

An already existing mechanism to find a balance between patent protection and access to technology to further develop life-changing technologies.

However extensive the rights conferred by the patent are, it is not without its limitations. Intellectual Property (IP) tries to strike a balance between innovators' patent rights and protection of other public policies and development goals, namely, access to health. Although there is some discussion around the introduction of the fair use doctrine in patent law,[106] the research exemption remains the most relevant exception in patent law. Smart health is no exception. Although, as it was previously explained can be protected by Patent Law as well, there are still some acts that fall outside of that monopoly and, thus, are permitted.

Considering patent protection's major goal of incentivizing innovation, dissemination of knowledge, and technological breakthroughs, to impede the experimental use of a

[106] O'Rourke, M.A., 'Toward a Doctrine of Fair Use in Patent Law', 100 Columbia Law Review, 2000, 1177-1250.
Geertrui Van Overwalle, 'Fair Use: A Workable Concept in European Patent Law?' in Reto M Hilty Kung-Chung Liu (eds), *Compulsory Licensing*, vol 22 (Springer Berlin Heidelberg 2015) <https://link.springer.com/10.1007/978-3-642-54704-1_20> accessed 2 April 2024.

protected invention would be counterintuitive. Article 3(b) of the Community Patent Convention (CPC) serves as the foundation for all the national laws that will follow.[107]

The scope of the exemption has been subject to extensive debate and will vary from jurisdiction to jurisdiction. The first question relates to the objective of the research, whether it is done for commercial or non-commercial purposes. Research has a non-commercial purpose when the invention is used for "academic research purposes or other not-for-profit or scholarly purposes not involving the use of the inventions of the Licensed Patents or Improvements to perform services for a fee or for the production or manufacture of products for sale to third parties".[108]

However, as highlighted by Evans Misati and Kiyoshi Adachi, in practice, multiple aspects have blurred the line between commercial and non-commercial research and experimentation.[109][110] One key factor is how the research is conducted in Academia nowadays, with academics greatly contributing to patent activity[111] and considering that "applied commercial research relies on basic research done in universities and other research institutions".[112] The distinction, on the other hand, is not significant since the interpretation of Article 31(1) of the CPC includes both acts since the research is conducted with a learning intent about the invention.[113] Once more, the scope of the exemption will depend on the jurisdiction, however, this interpretation has been adopted by multiple European states. In German law, the research exemption does not require that the experimentation is done strictly for non-commercial purposes; it also covers the case in which the research is also conducted for commercial purposes.[114] However, if the research is conducted solely for commercialization purposes and generating revenue, the exception is not applicable.[115] In Portugal, article 103/1, c) of the Industrial Property Code

[107] Pila and Torremans (n 2).
[108] Law Insider, 'Non-Commercial Research Purposes definition' <https://www.lawinsider.com/dictionary/non-commercial-research-purposes> (accessed 4 April 2024)
[109] MISATI, E., and ADACHI, K., "The Research and Examination exemptions in patent law: Jurisdiction variations and the WIPO development agenda", *UNCTAD- ICTSD Project on IPRs and Sustainable Development,* vol. /, March 2010, <https://unctad.org/system/files/official-document/iprs_in20102_en.pdf > (accessed 4 April 2024)
[111] Francesco Lissoni, 'Academic Patenting in Europe: An Overview of Recent Research and New Perspectives' (2012) 34 World Patent Information 197.
[112] Misati and Adachi (n 37)
[113] Pila and Torremans (n 2).
[114] Hans-Rainer Jaenichen and Johann Pitz, 'Research Exemption/Experimental Use in the European Union: Patents Do Not Block the Progress of Science' (2014) 5 Cold Spring Harbor Perspectives in Medicine a020941.
[115] ibid.

explicitly states that the research exemption only covers acts done exclusively for experimental purposes.[116]

Then, it is important to understand which acts are covered by the research exemption. Once again, it will depend on which jurisdiction it is in question. Research can be made "on" the invention or "with" the invention. In other words, the invention can be the subject matter or it can work as a tool to develop other inventions. Typically, in Europe, only the research acts that are done on the invention are permitted, while acts that require the invention as a tool are not permitted without the consent of the patent holder,[117] as is the case in Portuguese law. Article 103/1, c), also explicitly states that acts related to the subject matter of the patented invention are the ones permitted by the research exemption. On the contrary, the Belgian Patent Act establishes a general permission for acts "with" and "on" the patented invention.[118]

5.2. European Commission's Proposal for a Regulation on Standard Essential Patents

Nonetheless, the scope of the research exemption mechanism is very limited. Outside of research, developers and implementers of smart health technology still face the myriad of challenges outlined above.

I contend that the solution to these issues is already embedded within the existing framework of the system, particularly in the context of SEPs. When a technology that is part of a standard is protected by a patent, it seems reasonable to mandate that patent holders grant licenses to market participants wishing to implement that standard and to do so under FRAND terms. This approach could strike a balance between market players, safeguarding the interests of both patent holders and implementers, while mitigating issues such as patent thickets, hold-up, and royalty stacking. However, the current system is insufficient. Despite this, the resolution to these challenges can be found, even though not perfect, within the boundaries of the system.

The first step in that direction was already taken with the ruling of Huawei establishing what could be considered an abuse of dominant position when seeking an injunction

[116] Código de Propriedade Industrial https://diariodarepublica.pt/dr/legislacao-consolidada/decreto-lei/2018-117279941
[117] Misati and Adachi (n 37)
[118] Pila and Torremans (n 2).

against a party "willing" to negotiate a licensing agreement. Nevertheless, it was still not enough. For instance, it did not give relevance to the problem of patent hold-up. In addition, given the scope of the questions that were referred to the CJUE, it was not settled whether holding a SEP granted to the patent holder a dominant position in the market. Regardless, the landmark decision played a key role in highlighting the importance of competition law in relation to patents, especially when it comes to enforcing patents. As demonstrated by the ruling, it is not possible to resolve without the support of competition law and the involvement of both national and European courts.

The EU Commission tried to take another step in that direction, taking into account some of the problems analyzed previously by coming forward with a Proposal for a Regulation on SEPs.[119]

5.2.1. Content and objectives of the proposal

The proposed regulation on SEPs introduces a centralized framework aimed at enhancing transparency, legal certainty, and efficiency in SEP licensing across the EU. Title II of the proposal outlines the establishment of a Competence Centre within the EU Intellectual Property Office (EUIPO). This body would oversee the management of a centralized SEP register, conduct essentiality checks, and facilitate FRAND determinations. SEP holders would be required to register their patents within six months of either the registration process of the standard or the grant date of the patent. Enforcement of SEPs, including claims for royalties or damages, would be prohibited until registration is completed, thereby incentivizing compliance and increasing legal certainty for implementers.

The register would collect detailed information such as patent numbers, countries of validation, associated standards, and technical specifications. Additionally, the Competence Centre would provide training and guidance to small and medium-sized enterprises (SMEs), raise awareness of SEP licensing, and gather data from patent pools, national courts, and global case law to support informed policymaking.

The regulation mandates annual, sample-based essentiality checks for registered SEPs. These assessments, conducted by qualified and impartial evaluators, aim to verify whether declared patents are genuinely essential to a given standard. Evaluations will cover one patent per family and will follow a statistically robust methodology. Although

[119] Proposal for a Regulation of the European Parliament and of the Council on standard essential patents and amending Regulation (EU) 2017/1001, COM(2023) 232 final.

the assessments are non-binding, their results, along with evaluators' reasoned opinions, will be published in the SEP register. Both SEP holders and requesting implementers must pay fees for these evaluations. Importantly, the absence of an essentiality assessment does not preclude licensing negotiations or legal proceedings.

By introducing a SEP register where essentiality checks would be performed on certain registered patents and a procedure to determine FRAND licensing terms as well as aggregate royalties for use of a certain standard, the Commission takes a step in the right direction. Essentiality checks would ensure that patents incorporated into a standard are genuinely essential for its implementation. This process ensures that patent holders who have not genuinely contributed to the standard do not gain excessive market power. It prevents patent holders from exploiting the system by holding weak or non-essential patents, which could otherwise be used to unfairly boost their market power and profits. Fewer SEPs, especially those that are not essential in reality, could result in a lower risk of hold-up. Similarly, fewer SEPs could also diminish the risk of a patent thicket around a given standard technology.

This requirement can have a positive impact on the smart healthcare industry for several reasons. Requiring verification if a declared patented technology is truly essential to a standard ensures that patent implementers (from manufacturers or technology developers that may need to incorporate the standards) know which patents they need to license. This additional step helps reduce the risk that developers and implementers will pay for non-essential technologies or overpay for them. It lowers costs for those aiming to use the technology to create potentially life-changing innovations, thereby encouraging further development. Additionally, it enhances legal certainty and market clarity, which can lead to fewer disputes over questionable patent claims.

Overall, essentiality checks improve transparency, efficiency, and fairness in SEP licensing, characteristics that are crucial for smart health devices that depend on standardized technologies. They support interoperability, lower entry barriers, and guard against unfair licensing, helping to promote innovation in health tech.

Moreover, as explained above, there is no pre-determined universal way to interpret what is considered a FRAND licensing term. Combined with the lack of transparency around

a SEP regarding its scope, validity, ownership, and enforceability,[120] it is very difficult to reach an agreement between the SEP holder and the implementer on FRAND terms, ultimately resulting in lengthy litigation. It is therefore desirable to establish a procedure to determine these FRAND terms to avoid unnecessary litigation and a smooth negotiation between the parties.

On that note, the regulation introduces a pre-litigation procedure for resolving FRAND licensing disputes, administered by the EUIPO's Competence Centre. This process, limited to a maximum of nine months, is intended to provide a "safe harbor" for negotiations and reduce litigation risks. It is mandatory before initiating court actions, except for standards deemed by the Commission to have no significant licensing difficulties. Either party may initiate the procedure, which is overseen by independent conciliators with technical expertise. Should the parties remain at an impasse, the conciliator will issue a non-binding final proposal. Although the process does not produce binding outcomes, the conciliator's report may serve as evidence in subsequent litigation.

5.2.2. Issues and withdrawal

However, despite its good intentions, the current (and now withdrawn) Proposal had the potential to seriously harm fundamental rights, namely the right to access to court.[121] A key issue is that the patentee can only file a court claim after the FRAND determination procedure has been completed.[122] This restriction is lifted only if the responding party expresses its refusal to participate.[123] This limitation can be deemed to restrict the patent holder's right to access the court. Moreover, an implementer has little incentive to expedite the FRAND determination process and may deliberately delay it for the entire nine-month period, thereby extending the period of protection. This delay is argued to unfairly advantage implementers, enabling hold-out behavior.[124]

Arguably, the lack of transparency and the lengthy and costly disputes between the parties required a need for action to make it easier to develop and implement a certain standard

[120] European Commission. Directorate General for Enterprise and Industry., ECORYS., and Technische Universiteit Eindhoven., *Patents and Standards: A Modern Framework for IPR Based Standardization : Final Report.* (Publications Office 2014) <https://data.europa.eu/doi/10.2769/90861> accessed 17 February 2025.
[121] Article 47 of the EU Charter of Fundamental Rights
[122] Article 34(1)(a).
[123] Article 38(3)(b).
[124] Anne Marie Verschuur and others, 'A Critical Analysis of the EC Proposal for SEP Regulation' (patentblog.kluweriplaw.com, 27 February 2024) <https://patentblog.kluweriplaw.com/2024/02/27/a-critical-analysis-of-the-ec-proposal-for-sep-regulation/> accessed 23 January 2025.

and, therefore, drive innovation further to develop more robust and accurate smart health devices. In combination with the essentiality checks, the mechanism proposed by the EU Commission could enhance transparency in FRAND licensing negotiations and avoid unnecessary litigation. The smart health sector is highly regulated, with increasingly strict requirements and interoperability standards. In this context, the approach could support companies, especially start-ups and smaller enterprises, in effectively developing their research and development (R&D) and market entry strategies.

The proposed regulation allows stakeholders, such as contributors and implementers, to request non-binding expert opinions on the aggregate royalty applicable to a standard. A panel of three conciliators will assess these requests, considering their impact across the value chain. Interested parties may participate by demonstrating a legitimate interest. While the opinions are not enforceable, they are intended to inform and guide individual licensing negotiations.

The smart healthcare sector is a highly patented industry. A single product, such as a wearable ECG with wireless connectivity, integrates multiple standards, which translates into an enhanced risk of royalty stacking. As it was explained, in a single developed product, multiple SEP holders cumulate royalties, sometimes even demanding a price over their market value. The proposed non-binding and non-biased expert opinion would help the developers and manufacturers of smart health devices, especially small and medium enterprises (SMEs), better plan their budgets and anticipate the costs, therefore reducing financial uncertainty at the moment of investment.

Moreover, the more predictable and less excessive licensing costs facilitated by the proposed mechanism could translate into lower prices for the consumers of the smart health market. This reduced cost broadens access to these devices, making smart health more accessible to the public, supporting public health goals like better remote check-ups, early illness prevention, and fair access to digital healthcare.

Despite the EU Commission's attempt, the legislative proposal was dropped amid countless criticisms from across different backgrounds, such as from different governments of the EU, patent attorneys and lawyers, legal professors, prominent Unified

Patent Court (UPC) judges, leading SEP holders,[125] and even the President of the EPO.[126] The Proposal was controversial, to say the least, and fell short of achieving the results it desired. On the contrary, while the objective of creating a fair, balanced, predictable, and transparent licensing framework may seem just, the application of the current draft could, ultimately, produce the opposite effect by disincentivizing innovation and harming fundamental rights.

In conclusion, it is crucial to emphasize the importance of an effective legislative proposal to address patent hold-up and patent thickets. The Commission was correct in acknowledging the need for essentiality checks, in its efforts to establish a more transparent system for SEPs, and in seeking to resolve issues related to FRAND negotiations and reduce litigation. It is therefore essential to determine a universal mechanism to understand what is considered a "reasonable royalty". However, the approach taken was not the most appropriate. While the overall direction is sound, the mechanisms require further refinement, especially when applicable to such a highly-regulated sector as the healthcare sector.

Finally, one cannot forget the role of SSOs. For change to happen, SSOs have to be involved. As stated by Lemley and Shapiro, in an ideal scenario, SSOs would provide comprehensive guidance on what qualifies as a reasonable royalty for a portfolio of SEPs.[127] Moreover, as explained by Picht, SSOs could also take a more active role in litigation and procedure.[128]

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[125] European Commission, 'Intellectual Property: New Framework for Standard Essential Patents' (Staff Working Document) SWD(2023) 343 final, 1–10 <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13109-Intellectual-property-new-framework-for-standard-essential-patents/F3434468_en> accessed 30 January 2025.
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[126] European Patent Office, 'Letter to IAM Regarding SEP Issues' (October 2023) https://files.lbr.cloud/public/2023-10/EPO%20Letter%20IAM.pdf?VersionId=Xk2GKKPZ.qRisb5bU4BFaeiLe44oIuGB accessed 30 January 2025.

[127] Mark A Lemley and Carl Shapiro, 'A Simple Approach to Setting Reasonable Royalties for Standard-Essential Patents' [2013] SSRN Electronic Journal <http://www.ssrn.com/abstract=2243026> accessed 19 February 2025.

[128] Peter Georg Picht, 'Standard-Essential Patents: Limiting Exclusivity for the Sake of Innovation' in Josef Drexl and Anselm Kamperman Sanders (eds), *The Innovation Society and Intellectual Property* (Edward Elgar Publishing 2019) <https://china.elgaronline.com/view/edcoll/9781789902341/9781789902341.00019.xml> accessed 2 January 2025.

5.3 Conclusion

During the dissertation, it was explained that the system, despite its efforts, has been lacking in dealing with the problem of patent thickets, especially in high-tech industries, such as the one object of the study: smart health. The reasons for such difficulties have been explained and counterargued extensively in the literature with the development and increase of complexity of the technology. First, the "complements problem" introduced this idea, then the "theory of the anticommons" came to reinforce and apply it to more modern technologies, and lastly, the notion of patent hold-up was introduced and studied. Despite criticisms and efforts to downplay or dismiss these issues, the problems persist. While the system acknowledges its shortcomings and has taken steps to address them, these efforts have thus fallen short of achieving the necessary effectiveness. One of those attempts to mitigate the problem is in a special type of patent, SEPs. Considering the importance and essentiality of the technology to the market, to avoid patent thickets, hold-up, or abuses by the patent holder, it is required to license the patented technology under FRAND terms. However, as it was explained, currently, FRAND licensing terms are not enough to prevent and mitigate the negative consequences of the systems' problems. There is no universal objective designation of what is considered a FRAND term, and consequently, the licensing contracts are subject to lengthy and costly litigation, frequently with no coherent and harmonized decisions on the topic.

It is, therefore, crucial that companies in the smart health sector figure out a way to safeguard themselves against all these flaws in the system. There are three main safeguards that companies can take ideally before the start of the development process, according to Shapiro and Lemley.[129] First, the firm could choose to vertically integrate, meaning it would acquire the relevant patents to avoid patent hold-up. Second, the firm could enter into a long-term contract, such as a licensing agreement with the patent holder, before starting to develop the product. Lastly, the firm could design its product with enough flexibility, allowing for easy product adjustments to avoid patent infringement if necessary. Nevertheless, until now, these mechanisms have shown themselves to be insufficient to avoid the aforementioned problems for several reasons.[130] Many patents feature broad claims with ambiguous boundaries, making it difficult to determine whether

[129] Shapiro and Lemley (n 93).
[130] Lemley, Mark A. and Shapiro, Carl, Patent Holdup and Royalty Stacking. 85 Texas Law Review 1991 (2007), Stanford Law and Economics Olin Working Paper No. 324, Available at SSRN: https://ssrn.com/abstract=923468

a new product will infringe upon them. Additionally, during the development of a new product, a company may not fully understand all its features or anticipate how it will evolve until later stages of the process. As a result, even if the company initially aims to avoid patent infringement, it may still inadvertently infringe on patents as the design of the product becomes more defined. Even if the product is independently developed, the company could still face accusations of patent infringement. Furthermore, many patents are of questionable quality and may not have warranted approval in the first place. Despite recognizing a weak patent, companies remain vulnerable to patent hold-up because the threat of litigation exists, even if the patent would likely fail in court. Additionally, the long duration between a patent's filing and issuance, coupled with the possibility of modifications to patent claims during the approval process, increases the risk of hold-up. Lastly, due to the complexity of modern technology, a single product may be subject to numerous patents, often owned by different parties.

Traditionally, this was a particularly difficult problem for the information technology and telecommunications industries. On the contrary, pharmaceutical and medical devices companies, to avoid possible patent hold-up, would solely identify significantly fewer and more certain owners of potentially critical patents and negotiate a license before starting to develop the product or modify its design in an attempt to avoid a possible patent hold-up.[131] With the introduction of information technology, telecommunications, and computer technology into the more traditional industry of medical devices, this will likely not be the case anymore, and the smart health industry will encounter the same problem. Again, smart health will have to find a safeguard to deal with patent hold-up and navigate the patent thicket.

Avoiding both of these issues is especially tricky for companies developing complex technologies, such as smart health devices. Identifying all relevant patents can be nearly impossible, and many patents may not even be granted until after development has started. To make it even more difficult, the patents that a company may potentially infringe may be held by multiple different patent holders, raising the aforementioned issue of royalty stacking. Even if the first obstacle of identifying the relevant patents in advance is overcome, the previously mentioned typical safeguards may not be enough.

[131] Ibid.

The field of smart health is likelty to encounter great challenges as patenting activity in this sector continues to grow and as technology protected by SEPs becomes increasingly integrated. Consequently, it is imperative to identify effective safeguards to address the interconnected issues of patent hold-up, patent thickets, and royalty stacking, particularly concerning SEPs.

Dismissing the existence of these problems would represent an extreme position. Conversely, advocating for the infringement of patent rights is equally undesirable, as it undermines the core principles of the patent system. The former position risks granting excessive bargaining power to patent holders, potentially stalling innovation, while the latter disregards the rights of patent holders and diminishes the incentives for further innovation.

SEPs can play a key role in smart health by supporting secure, compatible, and scalable technologies. They make it easier to develop tools like remote patient monitoring and AI-based diagnostics, helping to reduce technical obstacles, improve efficiency, and encourage innovation in digital healthcare around the world. Additionally, they can help ensure interoperability between smart medical devices, dissemination of knowledge, collaborative work to develop more advanced devices, and broaden access to potential life-changing inventions. A robust, sound, and clear legal framework is, thus, crucial in this highly regulated sector.

Concerning smart health, SEPs pose even greater challenges given the sensitive and risky nature of the sector in itself. A malfunctioning device can lead to great consequences and change people's lives. For that reason, special attention must be put into the integration of new patented technology into a standard.

When applying SEPs to smart health, one has to take into account several particularities present in such a particular and sensitive field in comparison to other fields more accustomed to SEPs. First, given its nature and the consequences of an error, smart health is a heavily regulated industry. For example, given the sensitivity of health information, the safety regulations, and the ethical considerations studied before a new product enters the market. Second, as it was hinted before, the impact a malfunctioning device can have on human life. Third, given the need for clinical validation, safety regulations, regulatory approval, and ethical considerations, the innovation cycle is slower compared to other industries.

Another important aspect of SEP use in the smart health sector relates to technological interoperability. Medical devices and digital health platforms frequently operate on different operating systems, firmware, and communication protocols, leading to a highly fragmented technological landscape. This lack of standardization often hinders seamless integration and compatibility between devices. For instance, a glucose monitor, a personal fitness tracker, and hospital equipment may not function together without custom integration. Achieving such compatibility typically requires the use of intermediary systems or software, which increases both complexity and ongoing maintenance costs.

Finally, due to the specific characteristics of the smart health sector, developers and implementers often continue to rely on proprietary ecosystems, resulting in devices that are locked into specific platforms. For example, even a basic wearable such as a smartwatch (now recognized as a smart health device) typically functions within a closed platform. *Apple* uses *Apple Health*, while other companies offer alternatives such as *Fitbit, Samsung Health*, or hospital-based monitoring systems. These platforms are generally not interoperable, creating a fragmented ecosystem that limits seamless data exchange and integration across devices and services.

There is a reason for this. Given the particularities already mentioned, such as heavy regulation, safety concerns, sensitivity of health data, and ethical concerns, companies may choose to develop their own platforms and keep the data and technology in-house for fear of infringing regulations. However, this comes at a cost. The possibility of device compatibility and interoperability could lead to better, more personalized healthcare. SEPs can become the mechanism that facilitates technology interoperability and improves the smart health industry. A clear and robust legal framework becomes even more relevant.

In conclusion, a reform of the system is essential, particularly in high-tech industries. Since SEPs are only regulated by competition law, a specific regulation as the one proposed by the Commission, could be beneficial to increase legal certainty in the system. The risks are amplified in the context of SEPs and sectors vital to society. Although existing mechanisms have been introduced to address current shortcomings, they remain inadequate. This undermines critical industries, such as smart health, which holds significant potential to enhance quality of life. Efforts to resolve issues such as patent hold-up, patent thickets, and royalty stacking have largely been unsuccessful. Moving forward, any changes must be approached with caution to avoid unintended consequences

that could undermine one of the core principles of patent law: ensuring that inventors are adequately compensated for their investment, thus fostering further innovation. The golden rule lies in striking the right balance between granting access to other players in the smart health market to a SEP while ensuring that patent holders are rightfully compensated for their effort, investment, and contribution to better healthcare.

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