# The Medicinal Mandate

## Legal and Policy Implications of Compulsory Licensing on Patented Pharmaceuticals in the European Union to Encourage Access to Medicine during Cross Border Health Crises

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# Table of Contents

# Abstract

Patented pharmaceuticals limit medicine access; Compulsory Licensing bridges the gap between Intellectual Property Rights and the Right to Health. The COVID-19 Pandemic sparked debates on medicine access and prompted legal revisions for improved systems. The European Union strives to enhance Intellectual Property Rights and Human Rights, yet current Compulsory Licensing has flaws that hinder medicine access. Respectively, this thesis investigated the efficiency of Compulsory Licensing in the European Union and proposed legal and policy implications to enhance access to medicine during cross-border health crises. This has been carried out with a normative legal method with the support of relevant material such as legal documents and legislations, case law, and scholarly articles. The thesis addressed the need for more harmonization between its Member States, a shaky foundation offered by connecting legal considerations and import and export concerns. It proposed establishing a harmonized and stable framework at the Union level, granting the European Union the authority to generate a Union-based Compulsory Licensing. It emphasized the importance of considering leading factors, such as a more unified patent system and crisis management strategies at the Union level, and improving import and export processes under Compulsory Licensing by setting legal grounds with the ultimate goal of access to medicine within any geography where accessibility is vital.

# Abbreviations

| | |
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| CL | Compulsory Licensing |
| EC | European Commission |
| ECN | European Competition Network |
| ECJ | European Court of Justice |
| EEA | European Economic Area |
| EMA | European Medicines Agency |
| EU | European Union |
| HERA | Health Emergency Preparedness and Response Authority |
| HRs | Human Rights |
| OHCHR | Office of High Commissioner for Human Rights |
| IP | Intellectual Property |
| IPRs | Intellectual Property Rights |
| ICESCR | International Covenant on Economic, Social, and Cultural Rights |
| LDCs | Least Developed Countries |
| MS | Member States |
| OECD | Organization for Economic Co-operation and Development |

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|---|---|
| R&D | Research and Development |
| SMEI | Single Market Emergency Instrument |
| SDGs | Sustainable Development Goals |
| TFEU | Treaty on the Functioning of the European Union |
| TRIPS | Trade-Related Aspects of Intellectual Property Rights |
| UN | United Nations |
| UP | Unitary Patent |
| UPC | Unitary Patent Court |
| VL | Voluntary Licensing |
| WTO | World Trade Organization |

# 1. Introduction

## 1.1 Background

A sea of research criticizes Intellectual Property Rights (IPRs) for being contradictory to Human Rights (HRs). One example is patented pharmaceuticals and their impact on access to medicine.[1]

Granting exclusive rights to patented pharmaceutical producers is crucial. Among other things, pharmaceutical manufacturers spend enormous amounts of time, effort, and resources on their Research and Development (R&D) to introduce novel pharmaceuticals. Consequently, it only seems fair to protect pharmaceutical products with Intellectual Property (IP) law.[2] In substitution for providing information allowing others to "make, use, and sell the product," the owner of the patent is granted the privilege of ownership and control for a set of time.[3] Patented pharmaceuticals are products built on a subtle strategy that rewards the inventor.[4] Respectively, with the lack of an efficient patent system, pharmaceutical companies will only be discouraged from producing novel creations that could potentially be used to save millions of lives.[5]

However, patent protection may hinder and decelerate access to medicine by maximizing costs, lengthening monopolies, and putting off original rivalry. This, in turn, can impair the Right to Health of an individual, which is particularly critical in times of health crisis and emergencies where obtaining medicine is paramount.[6]

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[1] De Campos-Rudinsky, T.C., Intellectual property and essential medicines in the COVID-19 pandemic, *International Affairs*, *97*(2), 2021, p.523.
[2] Lee, S.K., Mahl, S.K., Green, J.J., and Lexchin, J., Multinational Pharmaceutical Companies Shortchange Canada in Research and Development Investments: Is It Time to Pursue Other Options?, *Healthcare Policy, 18*(3), 2023, p.17.
[3] Kumar, A., Kumar, S., and Nanda, A., A review about regulatory status and recent patents of pharmaceutical co-crystals, *Advanced Pharmaceutical Bulletin, 8*(3), 2018, p.355.
[4] Singh, K.K., Patent and Pandemic: Exploring Duties, Obligations, and Responsibilities, *In Relevance of Duties in the Contemporary World: With Special Emphasis on Gandhian Thoug*ht, 2023, p.367.
[5] Holman, C.M., Minssen, T., and Solovy, E.M., Patentability standards for follow-on pharmaceutical innovation, *Biotechnology Law Report, 37*(3), 2018, p.133-134.
[6] Hoen, E., TRIPS, pharmaceutical patents, and access to essential medicines: a long way from Seattle to Doha, *Chicago Journal of International Law, 3*, 2002, p.27.

Access to medicine is paramount for several reasons. First, it is essential to cure the sick and alleviate their symptoms.[7] Second, it is crucial to prevent the spread of diseases.[8] Third, protecting vulnerable groups, such as the elderly and those with preexisting health issues, depends on access to medicine.[9]

Consequently, attempts are being made to find a balance between encouraging innovation by granting patent rights to those that create medicine and providing individuals' Right to Health through access to patented pharmaceuticals. Among the examples of such an effort is a mechanism called Compulsory Licensing (CL) as the last resort.[10] In times of public health emergency and crisis, acquiring CL for utilizing patented items can play a crucial role in ensuring the timely delivery of lifesaving pharmaceuticals.[11] This is because obtaining CL allows governments to give a third party the right to produce, utilize, or market a patented product without authorization from the patent owner under certain conditions. This is crucial, particularly in the context of a health crisis where patented pharmaceuticals can be a burden to the Right to Health.[12]

The mechanism of CL is paramount for the following reasons. The price of patented medications is one area where CL can have a substantial positive impact.[13] It is an adaptable method for addressing local health concerns. To combat an outbreak such as COVID-19 Pandemic, governments may impose CL on the pharmaceutical industry. Countries can respond rapidly and efficiently to public health emergencies without having to haggle with patent holders to access medications. This can help curb further virus transmission and save lives by allowing access to

[7] Boyer, C.A. and Lutfey, K.E., Examining critical health policy issues within and beyond the clinical encounter: patient-provider relationships and help-seeking behaviors, *Journal of Health and Social Behavior, 51*, 2010, p.80-93.
[8] Haldane, V., De Foo, C., Abdalla, S.M., Jung, A.S., Tan, M., Wu, S., Chua, A., Verma, M., Shrestha, P., Singh, S. and Perez, T., Health systems resilience in managing the COVID-19 pandemic: lessons from 28 countries, *Nature Medicine, 27*(6), 2021, p.964-980.
[9] Casola, A., Kelly, E., Smith, K., Kelly, S. and de la Cruz, M.S., Impact of the COVID-19 Pandemic on Medical Students' Perceptions of Health Care for Vulnerable Populations, *Family Medicine*, 2023, p.89-94.
[10] Liu, J., Compulsory Licensing and Anti-Evergreening: interpreting the TRIPS flexibilities in sections 84 and 3 (d) of the Indian Patents Act, *Harvard International Law Journal, 56*, 2015, p.207.
[11] Marques, J.R., Biotechnological Patents, Compulsory Licensing, and SARS-COV-2 in a Pandemic and Epidemic Context, *Blue Planet Law*, 2023, p.253.
[12] Reichman, J.H., Comment: compulsory licensing of patented pharmaceutical inventions: evaluating the options, *Journal of Law, Medicine & Ethics*, *37*(2), 2009, p.247-263.
[13] Stavropoulou, C. and Valletti, T., Compulsory licensing and access to drugs, *The European Journal of Health Economics, 16*, 2015, p.83-94.

medicine.[14] It can as well sustain IPRs by compensating patent owners of the patented pharmaceuticals under the CL.[15]

Initially, CL at the international level was ignited by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the so-called TRIPS Flexibilities following the spark of particular domestic law.[16]

The World Trade Organization (WTO) established the TRIPS Agreement in 1995, where IPRs are mandated at a minimum. Implementing TRIPS's provisions in domestic IP legislation is a prerequisite for all WTO members, including the European Union (EU) and its Member States (MS).[17]

Article 27.1 of the TRIPS Agreement states inventions in any technological area that are novel, comprise an inventive step, and are adaptable to a commercial application are eligible for patent protection.[18] However, this comes with certain exceptions. Respectively, Article 27.2 states that countries can exclude inventions from patentability if preventing their commercial exploitation is required to preserve public morality or maintain public order, such as protecting human health and life.[19]

Consequently, CL has been noted under Article 31 of the TRIPS Agreement and further explored under the Doha Declaration. The CL mechanism, as an example of a TRIPS Flexibilities,[20] allows WTO members to voice unique public health requirements despite existing patent protection.[21] Countries are also allowed and encouraged to go beyond the minimum standards and set legislations that help ease the process under TRIPS-Plus Flexibilities.[22]

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[14] Vawda, Y.A., Compulsory Licenses, and Government Use: Challenges and Opportunities, *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law*, 2022, p.73-104.
[15] Abbas, M.Z., COVID-19 and the Issue of Affordable Access to Innovative Health Technologies: An Analysis of Compulsory Licensing of Patents as a Policy Option, *In Law and Economics of the Coronavirus Crisis*, 2022, p.265-294.
[16] Ruse-Khan, H.G., The international law relation between TRIPS and subsequent TRIPS-plus free trade agreements: towards safeguarding TRIPS flexibilities, *Journal of Intellectual Property Law, 18*, 2010, p.325.
[17] Tenni, B., Moir, H.V., Townsend, B., Kilic, B., Farrell, A.M., Keegel, T., and Gleeson, D., What is the impact of intellectual property rules on access to medicines? *A systematic review. Globalization and health, 18*(1), 2022, p.2.
[18] World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights* (hereinafter TRIPS Agreement), 1994, art.27.1.
[19] ibid., art.27.2.
[20] Other examples of TRIPS Flexibilities: Parallel Import and Transition Period for the Least Developed Countries.
[21] Tenni, op. cit., p.2.
[22] World Trade Organization, *Ministerial Declaration of 14 November 2001* (hereinafter Doha Declaration), 2001, para.4.

Additionally, the Doha Declaration[23] of the year 2001 on the TRIPS Agreement reaffirms WTO members' rights to take full advantage of TRIPS Flexibilities to safeguard public health and maximize access to medications.[24]

Under Paragraph 4 of the Doha Declaration, governments agreed that WTO members must defend public health under the TRIPS Agreement and encourage access to medicines. Hence, confirming WTO members' right to use TRIPS Flexibilities for health reasons, allowing WTO members to award CL on any terms they see fit.[25]

The TRIPS Agreement was approved by the EU by Council Decision 94/800/EC,[26] which incorporated the agreement into EU law.[27] Despite the lack of direct effect of WTO Agreements as set out in a European Court of Justice (ECJ) judgment in *Case C-414/11 Daiichi Sankyo*,[28] the agreement serves a significant role and has been interrupted within EU law. Respectively, the basis of the EU's law on CL is derived from the grounds outlined in the TRIPS Agreement.[29]

At the outset of HRs law, access to medicine is under the umbrella of a Fundamental Right; the Right to Health, which is required for leading a life of dignity and is essential for fulfilling many other rights, particularly the Right to Development. The Office of the High Commissioner for Human Rights (OHCHR) has ensured the essence of the Right to Health to the realization of all other HRs; Everyone has the right to the most significant possible level of health that will provide them the chance to live a life with dignity.[30]

The Right to Health can include access to medications in a variety of forms.[31] One notable example is the consequences of financing and pricing structures to ensure that everyone has

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[23] See Appendix A: on the Doha Declaration's legal standing.
[24] Tenni, op. cit., p.2.
[25] Doha Declaration, op. cit., para.4.
[26] European Union, *Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matter within its competence, of the agreements reached in the Uruguay Round multilateral negotiations*, 1994.
[27] European Commission, *Compulsory licensing of intellectual property rights: final study report* (hereinafter European Commission's Study Report), 2023, p.55.
[28] European Court of Justice, *Case C-414/11 Daiichi Sankyo and Sanofi-Aventis Deutschland*, 2013, para.49-83.
[29] European Union, *Regulation (EC) No. 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems* (hereinafter Regulation (EC) No. 816/2006), 2006, rec.1-3.
[30] United Nations Committee on Economic, Social and Cultural Rights, *General Comment No. 14: The Right to the Highest Attainable Standard of Health*, 2000, art.12.
[31] Backman, G., Hunt, P., Khosla, R., Jaramillo-Strouss, C., Fikre, B.M., Rumble, C., Pevalin, D., Páez, D.A., Pineda, M.A., Frisancho, A., and Tarco, D., Health systems and the right to health: an assessment of 194 countries, *The Lancet, 372*(9655), 2008, p.2048.

access to medicines.[32] It is secured under legal HRs instruments such as the International Covenant on Economic, Social, and Cultural Rights (ICESCR);[33] providing an international basis.[34]

Access to medicine and the Right to Health is also evident in 17 Sustainable Development Goals (SDGs)[35] and 169 targets in the 2030 Agenda for Sustainable Development endorsed by the United Nations (UN). SDG 3 expressly guarantees longevity and fosters well-being among individuals of all ages. Section of this is to ensure that everyone has access to crucial healthcare services and vital vaccines and medicines that are both safe and affordable which is essential to the discussion of this thesis.[36]

In aims of balancing IPRs and HRs, CL is typically utilized for different primary objectives, most crucially to help provide individuals the medicine they need so that other public policy goals, such as those for public health, can be met.[37]

As a result of the ongoing COVID-19 Pandemic, there has been a need for access to medications, mainly in the form of vaccines, to treat the COVID-19 virus. Many critics have argued that, among other barriers, unstable grounds presented by CL law have made access to medicine in this critical context difficult. Remarkably, within the EU, numerous debates have taken place, most significantly, the European Commission's (EC) reflection on the current CL legal mechanism in the EU in the form of a report and a proposal. This is because the current system is found inefficient and merely a reflection of the legal grounds set forth for the utilization of CL by the TRIPS Agreement, which is rather broad and not equipped for a high-standard region like the EU.[38]

Respectively, it is argued that certain obstacles within the legal grounds of CL in the EU are crucial to overcoming. Examples of this are not limited to the following: the different degrees of

[32] ibid., p.2049.
[33] United Nations General Assembly, *International Covenant on Economic, Social, and Cultural Rights* (hereinafter ICESCR), 1966.
[34] See Appendix B: the right to health at the outset of legal human rights instruments.
[35] Although SDG is argued to be a political designation, it heavily mentions HRs and international law by creating international policies. Thus, the agenda's political and legal foundation enhances the dialogue on providing the Right to Health.
[36] United Nations, *The 2030 Agenda and the Sustainable Development Goals* (hereinafter SDGs), 2015, g.3.
[37] Lamping, M., Batista, P.H.D., Correa, J.I., Hilty, R., Kim, D., Slowinski, P.R., and Steinhart, M., Revisiting the Framework for Compulsory Licensing of Patents in the European Union, *Max Planck Institute for Innovation & Competition Research Paper,* 2023, p.3-4.
[38] Paquin, S., and Plouffe-Malette, K., The WTO and the Covid-19 "vaccine apartheid": Big pharma and the minefield of patents, *Politics and Governance, 11*(1), 2023, p.261-271.

competence, the effort of utilizing the mechanism, and differences in the legal grounds of MS. This has thus exhibited low usage of the mechanism, resulting in a lack of access to medicine throughout the EU in times of cross-border health crisis and emergencies with the recent example of the COVID-19 Outbreak.[39]

## 1.2 Purpose and Research Question

This thesis aims to investigate CL in the EU to break down the current system's shortcomings and offer legal and policy implications in pursuit of access to medicine in times of cross-border health-related crises and emergencies.

Respectively, the thesis asks the following question:

To what extent is the current CL mechanism efficient, and what legal and policy consequences should be made to strengthen the CL in the EU to pursue access to medicine during cross-border health-related crises and emergencies?

## 1.3 Delimitations

The thesis examines CL's legal mechanism for accessing medicine in cross-border health emergencies in the EU. It examines its TRIPS-related international dimension. It analyzes and interprets the EU's system on the subject matter, particularly Regulation (EC) No 816/2006. It employs the national laws of specific EU MS to illustrate the CL mechanism on patented pharmaceuticals in health emergencies and crises, mainly demonstrating the lack of harmonization across the EU. EC's report and proposal analyze the current situation. It analyzes the system, identifies areas for improvement, and proposes EU CL system improvements.

Overall, the thesis looks at what can be done through the CL mechanism to ease access to medicine within the legal grounds of IPRs. It values the purpose of IPRs in upholding the value of inventions and inventors in cases of health crises and emergencies. Hence, it explores ways to

[39] European Commission's Study Report, op. cit., p.71.

enhance access to medicine under specific health circumstances through the law on CL and the perspective of IPRs.

The thesis does not cover exploring access to medicine through the law and philosophy of HRs. This is a master's thesis on trade law specializing in IP law, not one focusing on HRs. The outset of HR is noted in the introduction only to explain to the reader the cruciality of the right to health and access to medicine in health concerns to understand better the importance of IP law alignment with Fundamental HR.

Specifically, the thesis explores the legal grounds of CL and its effect on access to medicine, not other aspects such as governmental powers, economic gains, and politics. In an ideal world, better governmental wealth, power, and politics go into importing patented pharmaceuticals to feed on access to medicine, allowing the protection of both IPRs and the Right to Health.[40]

Despite different factors that affect access to medicine, such as economic gains and political benefits, this thesis chooses to narrow down the effect of IPRs. It does not state that IPRs are the sole barrier to the Right to Health but rather only chooses to focus on CL which is a small section in the more significant equation that can play a role. Additionally, it does not argue whether IP law hinders access to medicine but instead explores what can be done about it. This allows studying one factor at a time, which is essential for an in-depth study rather than one that superficially examines all factors affecting medicine access.

The thesis is narrowed down to a greater extent by focusing on the CL mechanism within the EU region with a slight effect on how the EU's legal grounds affect access to medicine in other regions, such as those in the Least Developed Countries (LDCs). This helps to further explore the depth of the topic with a more specific instance.

On that note, the grounds of the discussion in the body of the thesis mainly focus on legal documents and scholarly research rather than surveys, statistics, and case studies due to the normative nature of the thesis.

Concerning the dated materials, the thesis looks into sources up to 1 May 2023. This means, with the new proposed regulation (See Chapter 1.4) dated 27 April 2023, gaining excessive insight,

[40] Gold, E.R., What the COVID-19 pandemic revealed about intellectual property, *Nature Biotechnology, 40*(10), 2022, p.1428-1430.

access criticism, and different perspectives from scholars on the matter was not possible due to limited resources concerning the timing of the publication of the proposal and the deadline of the thesis.

Additionally, the thesis covers the subject matter in the context of cross-border health crises and emergencies, where access to medicine is the most vital. It stands by the theory that medication is the most crucial. Hence, it does not argue whether specific medications are effective but instead assumes that medicine is crucial to sustaining health crises.

Respectively, it is crucial to break down essential terminologies such as crisis to understand their significance. A crisis can be categorized as either a national crisis or a cross-border crisis. A national crisis refers to a situation that is publicly proclaimed within a single country.[41] On the other hand, a cross-border crisis occurs when multiple countries or intergovernmental organizations declare a situation as both a national and global crisis.[42]

One specific type of crisis is a national health or global crisis, which encompasses any health concern that has implications at a national or global level.[43] Public health crises often escalate into national and global emergencies. Examples of such crises that extend beyond national borders are epidemics and pandemics, as witnessed during the recent COVID-19 pandemic.[44] The severity and rapid transmission of a disease play a role in determining the level of emergency associated with it. It is important to note that while every emergency is considered a crisis, not all crises require immediate action, as the urgency varies.[45]

The concept of a health crisis is further explored in Regulation (EC) No 816/2006 to address public health issues. Regardless of their definitions, the EC does not differentiate between health crises and health emergencies.[46] For this thesis, the terms health crisis and emergency are used interchangeably.

[41] European Commission's Study Report, op. cit., p.14.
[42] ibid., p.14.
[43] Bayleyegn, T.M., Schnall, A.H., Ballou, S.G., Zane, D.F., Burrer, S.L., Noe, R.S., and Wolkin, A.F., Use of community assessments for public health emergency response to rapidly assess public health issues, *Prehospital and Disaster Medicine, 30*(4), 2015, p.374-381.
[44] Lamping et al, op. cit., p.7-8.
[45] ibid., p.7-8.
[46] European Commission's Study Report, op. cit., p.15.

Consequently, the thesis delves into access to medicine and the role of CL in the context of a public health problem or emergency that affects multiple countries. Health concerns with cross-border effects are considered cross-border health crises, often spanning international borders and necessitating international cooperation to address the situation adequately. Dealing with these complex crises involves coordinating responses across jurisdictions, allocating sufficient resources, sharing relevant data, and implementing effective public health interventions.[47]

The scope of medicine accessibility is examined in these instances for two primary reasons. Firstly, cooperation is essential when addressing any issue with cross-border implications. Secondly, medicine plays a vital role during global outbreaks, as certain illnesses, such as viruses, affect people regardless of socioeconomic status.

Additionally, there are four different categories of products to which a CL may be applied.[48] The COVID-19 vaccines fall under the fourth category, which includes medicines produced rapidly in response to the crisis.[49] When discussing patented pharmaceuticals in the context of access to medicine, this is the specific category referred to under this thesis. Urgent medicines like COVID-19 vaccines are highlighted for their importance in terms of fair and equitable access during critical situations. The identification of the product category is vital for CL because the scope of the CL request is defined based on the product rather than IPRs covering the product.[50]

## 1.4 Methodology

This thesis has conducted a normative legal analysis on CL in the EU, mainly exploring Regulation (EC) No 816/2006 in light of Article 31 of the TRIPS Agreement to provide enhanced legal and policy implications.

[47] Sun, Y., Liu, T., Ye, T., and Shi, P., Coordination and cooperation are essential: a call for a global network to enhance integrated human health risk resilience based on China's COVID-19 Pandemic coping practice, *International Journal of Disaster Risk Science, 12*, 2021, p.593-599.
[48] Different categories of products: the first consists of simple IP items like masks. The second includes breathing apparatus, syringes, or diagnostic testing equipment are all examples of medical devices. Third is that complex products, including biological products, need a license to be used and permission to access secret know-how for which there is no CL mechanism.
[49] European Commission's Study Report, op. cit., p.34.
[50] Liu et al, op. cit., p.315-331.

Normative legal analysis, entail studying the laws and principles of the legal system to see if it meets particular normative criteria such as fairness, justice, or efficiency. It asks the question, "What the law ought to be."[51] Hence, this method of legal inquiry assesses the relevant legal norms and principles to propose changes or enhancements to the law.

For the context of this thesis, the normative legal analysis has included evaluating the EU's present CL mechanism against its ability to evolve and enable more comprehensive access to medicine during cross-border health concerns. It has worked through what the law on CL ought to be with the objective of access to medicine.

Initially, this has been done by studying CL at an international level, followed by at an EU level, with specific examples of legal grounds at the national level of different MS.

Specifically, Article 31 of the TRIPS Agreement was examined at the international level to set out the basis of CL for members of the agreement, including the EU and its MS.

Two competing principles control the interaction between international law and EU legislation. The EU, on the one hand, is an independent legal system that operates inside a conceptual void between international legislation and nation-state constitutions. That is why EU law makes a point of being distinct from other law systems worldwide. The ECJ stated in its landmark *Case 26/62 Van Gend & Loos* that the Union represents a new legal order.[52] On the other hand, the EU legal system is unwilling to isolate itself from its international law roots while maintaining its independence. That ruling also determined that the Union represents "a new legal order of international law." As a result, the freedom of the legal system of the EU is conditional rather than total. The EU and the ECJ do not seek to operate independently from international law, nor does it permit international law to do so. A typical "monism v dualism" approach cannot adequately convey how international law is absorbed into EU law. This blending occurs in line with a weighing procedure.[53]

It is apparent under the main legal body in the EU that controls CL, Regulation (EC) No 816/2006, that the basis of the secondary law goes back to the TRIPS Agreement. Hence, it

[51] Lieblich, E., How to Do Research in International Law? A Basic Guide for Beginners, *A Basic Guide for Beginners*, 62. 2020, p.46.
[52] European Court of Justice, *Case 26/62 Van Gend & Loos*, 1963.
[53] Lenaerts, K., and Gutiérrez-Fons, J.A., To say what the law of the EU is: methods of interpretation and the European Court of Justice, *Columbia Journal of European Law, 20*, 2013, p.29-30.

seemed crucial to interpret the EU's law per international law, not to understand the complexity of direct effect, but to explore the foundation of the EU's CL system set by international system.

Additionally, concerning the relationship between EU and international law, arguments have been initiated to enhance CL through *Principles of International Law*, such as *Subsidiarity, Territoriality, and Good Faith*. For states and international actors like the EU and its MS, the ability to generate legal arguments based on this was essential for adding legitimacy, consistency, and predictability to viewpoints.

Additionally, studying the EU has primarily included the Regulation (EC) No 816/2006 analysis. Once the EU enacts a regulation, it applies instantly and universally in all EU MS without being transferred into domestic legislation. Hence, all EU MS must comply with them completely.[54] As a result, regulations are on pace with domestic legislative actions. Thus, regulations are among the most potent types of EU legislation, necessitating exceptional accuracy in their development. Any new national laws enacted on the subject have to be compatible with and formed according to the requirements of the regulation. MS are not allowed to obscure the direct effect of regulations, but they are allowed to introduce laws addressing issues that arise as a result of the rule taking effect.[55]

In the case of CL, the present regulation does not provide a detailed and uniform CL mechanism to be utilized at the Union level; therefore, examples of domestic legislation on CL were studied consequently to highlight the difference in approach of the mechanism within the EU. These included examples from Germany, France, Ireland, and Spain.

Following the breaking down of the wording of the stated laws, underlying issues were highlighted in the light of suggesting possible implications. This was done by breaking down the legal grounds and comparing them with the reality of the context in pursuit of reaching the aim of this thesis. The steps included first studying the ability to issue CL at the EU level to ensure harmonized Union on the subject matter. Following that, relevant legal grounds affecting CL in the EU were studied to ensure a smoother foundation to establish more stable grounds of implication for CL. The potential dialogues presented by the EC in aims to enhance the system were studied through the revision of a proposed regulation. Additionally, import and export

[54] European Union, *Treaty of the Functioning of the European Union* (hereinafter TFEU), 2012, art.288.
[55] Davies, K., Van Munster, M., and Düsterhöft, I., *Understanding European Union Law*, 2022, ch.3-5.

matters on patented pharmaceuticals were evaluated in the context of CL. This was to break down the present system's shortcomings further and suggest future implications to enhance access to medicine within the EU and other areas worldwide in cases of absolute necessity during cross-border health crises and emergencies.

This was made possible by studying, alongside the mentioned law, additional legal sources, academic articles, books, and case law.

The EC's report and proposal titled "Compulsory Licensing of Intellectual Property Rights"[56] and the "Proposal for a Regulation of the European Parliament and of the Council on CL for crisis management and amending Regulation (EC) No 816/2006,"[57] respectively, were studied. EC's perspective on CL in the EU helped reach the aim in an accelerated manner. The EC's report helped identify criticism of the current CL mechanism within the Union, and the proposed regulation helped put in place possible steps to be taken by the EU to enhance the current system.

Scholarly articles and books were crucial for establishing context, highlighting key topics, providing contrasting perspectives, and supporting arguments. An example included "Revisiting the Framework for Compulsory Licensing of Patents in the European Union,"[58] which provided an excellent explanation and perspective on the current CL system in the EU. Another example was a paper titled "Intellectual Property and Essential Medicines in the COVID-19 Pandemic,"[59] which helped explore the criticism of the system regarding access to medicine in times of health crisis such as the COVID-19 Outbreak.

Additionally, legal concepts and principles were made clear, precedents were established, legal grounds were identified, and insights into legal thinking were gained through the study of case law. *Case 19/84 Pharmon v. Hoechst*,[60] *Case 78-70 Deutsche Grammophon v. Metro SB*,[61] and *Case 15-74 Centrafarm v. Sterling Drug*[62] were the prominent cases looked to help clarify, establish, and explore legal effects and grounds of EU MS and their connection and relation to the law established at the Union level in terms of CL.

[56] European Commission's Study Report, op. cit.
[57] European Commission, *Proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006* (hereinafter Proposed Regulation on Compulsory Licensing), 2023.
[58] Lamping et al., op. cit.
[59] De Campos-Rudinsky, op. cit.
[60] European Court of Justice, *Case 19/84 Pharmon v. Hoechst*, 1985, para.14-30.
[61] European Court of Justice, *Cases 78-70 Deutsche Grammophon v. Metro SB*, 1971, para.1-19.
[62] European Court of Justice, *Case 15-74 Centrafarm v. Sterling Drug*, 1974, para.1-41.

Hence, by offering a precise and systematic framework for conducting a normative legal analysis thesis, the mentioned types of material strengthened the reliability and validity of the results presented in this thesis. In short, the method and material helped break down the complex topic and recommend reforms to the law on CL to achieve the best possible results regarding access to medicine.

## 1.5 Structure

The thesis begins by examining the legal issues of CL. This entails an analysis of the TRIPS Agreement on CL, the relevant EU law as specified in Regulation (EC) No 816/2006, and select examples of national CL legislation within EU MS. Subsequently, the thesis will provide observations and insights based on the various CL laws.

Furthermore, the thesis delves into underlying issues and potential implications of CL. Firstly, it explores the authority to issue CL at the Union level, considering the absence of a harmonized approach within the EU. Secondly, it investigates other legal factors that impact CL in the EU, emphasizing the importance of uniformity beyond CL. Thirdly, it examines the recently proposed EC regulation on CL to assess the measures taken to enhance the mechanism, identify associated issues, and propose alternative solutions. This is followed by exploring the export and import aspects of the mechanism, aiming to elaborate on the system's current challenges and suggests potential implications. It is worth noting that these discussions align with the primary objective of ensuring access to the medicine during cross-border health crises and emergencies through CL.

The thesis concludes by summarizing the findings, addressing the main research question, and highlighting any limitations of the thesis, together with suggestions for future research.

# 2. The Law on Compulsory Licensing

## 2.1 Introduction

This section covers the legal grounds exploring CL, first at an international level, second at the EU level, and third at the domestic level of EU MS. This includes the studying of the TRIPS Agreement with its supplementary documents, Regulation (EC) No 816/2006, and several references with aspects of domestic law with country examples of Germany, France, Ireland, and Spain.

## 2.2 International Level

### 2.2.1 Introduction

In the context of health-related matters, IPRs are subject to legal permission based on the *Principle of the Common Good*,[63] as IP law is not absolute,[64] enabling occasions of emerging health outbreaks and experiencing a shortage of critical pharmaceuticals in its public health tactics can seek legal permission to bypass patent rights.[65] CL is a method for addressing the shortage of access to medication during health crises, and it is based on Article 31 of the TRIPS Agreement, which describes the requirements for using patented inventions without the rights holder's permission.[66] It allows government-authorized third parties to use the patented invention without the permission of the right owner under specific provisions.[67]

Respectively, this chapter will explain the international dimension of CL presented by the TRIPS Agreement.

[63] Principle of Common Good: all aspects of community life must be integrated to be fully understood, and it originates from the dignity, cooperation, and fairness of all individuals.
[64] Absolute Right: a right that can be limited or restricted under certain circumstances.
[65] De Campos-Rudinsky, op. cit., p.527.
[66] TRIPS Agreement, op. cit., art.31.
[67] ibid., art.31.

### 2.2.2 Agreement on Trade-Related Aspects of Intellectual Property Rights

The provisions within Article 31 of the TRIPS Agreement include the following:

(a) Such permission shall be granted on an individual basis.[68] This means considerations may include the nature of the innovation, the intended use, and the potential effect on the patent owner's business interests. Whether or not such an application is approved depends on each instance case's facts.

(b) CL can be granted only after the intended user has made diligent efforts to obtain permission, typically through Voluntary Licensing (VL),[69] by engaging with the proprietor to negotiate acceptable terms and conditions for the use of the patented invention, but has been incapable of settling the matter promptly. A WTO member can get out of this rule if there is a crisis or some other very urgent situation or if it is for public, non-commercial use.[70] Even if there is a national emergency or a very urgent situation, the right holder should be told as soon as it is reasonable to do so. In the case of public non-commercial use, if the government or any contractor,[71] without doing a patent search, knows or has good reason to believe that a legitimate patent is or will be utilized by or for the benefit of the government, the right holder must be told as soon as possible.[72]

Adding to this, Paragraph 5(c) of the Doha Declaration makes it clear that every WTO member possesses the power to decide what qualifies as a national emergency, crisis, or additional conditions of severe urgency, with the understanding that health emergencies related to any outbreaks may constitute an internal emergency or other conditions of severe urgency.[73]

This is further clarified in Paragraph 3(a) of the Ministerial Decision on the TRIPS Agreement of 17 June 2022.[74] This clarifies the conditions under which eligible members can authorize the use of a patent in a crisis and emergency without the patent owner's consent. It states that the proposed use of the patent does not need to make an effort to obtain authorization from the patent

[68] ibid., art.31(a).
[69] Voluntary Licensing: is a straight-up legal agreement between the patent owner and the third party that wishes to use the patented product.
[70] Non-commercial use: any action that does not directly result in monetary gain.
[71] Any contractor: any party that obtains the permission; subject gains CL to utilize the patented product.
[72] TRIPS Agreement, op. cit., art.31(b).
[73] Doha Declaration, op. cit., art.5(c).
[74] Rutschman, A. Ministerial Decision on the Trips Agreement, *International Legal Materials, 62*(2), 2023, p.289-294.

owner as required by Article 31(b) of the TRIPS Agreement. In other words, if a country has authorized the use of a patented pharmaceutical without the consent of the patent owner, the user of the patent does not need to go through common attempts at license bargaining with the patent owner before using the patent.[75]

(c) The extent and time frame of such utilization shall be restricted to the intent for which it was allowed, and in the instance of semiconductor technology, it can only be used for "public non-commercial use" or to "remedy" an anti-competitive practice found to be anti-competitive following court or administrative procedure.[76] This means granting a green light for the usage of a patented product should only be used for the intended purpose and within a specified time; No alternative considerations bear comparable weight.

(d) The utilization "shall be non-exclusive."[77] This indicates that if multiple parties have accessed a patented product, all parties can use it, but none can control it.

(e) The utilization of such an act shall not be assigned to an alternate party; "non-assignable," except for the component of the business or reputation that benefits from such use.[78]

(f) The utilization of CL must be primarily allowed for the WTO members permitting it to serve its own domestic market.[79] This indicates that if the use of the patented product is authorized, it should primarily serve the domestic market of the WTO member that grants the authorization.

After the implementation of the Protocol Amending the TRIPS Agreement, this requirement has changed. Members to which the amended TRIPS Agreement applies may derogate and deviate from this obligation concerning pharmaceutical products outlined in Paragraphs 1 and 3 of Article 31bis, Paragraph 2 of the Annex, and the Appendix to the TRIPS Agreement.[80]

Competitors are allowed to manufacture, import, and export generic copies of patented pharmaceuticals according to Article 31bis TRIPS Agreement. Accordingly, WTO members can issue a CL and export the resulting generic medicine for various WTO members in demand. With

[75] World Trade Organization, *Ministerial Decision on the TRIPS Agreement*, 2022, para.3(a).
[76] TRIPS Agreement, op. cit., art.31(c).
[77] ibid., art.31(d).
[78] ibid., art.31(e).
[79] ibid., art.31(f).
[80] ibid., art.31(bis), para.2 to the annex, appendix.

the initial statement of Article 31(f) of the TRIPS Agreement, generic pharmaceuticals manufactured via a CL had to be predominantly to provide the national marketplace; export of generic goods developed under the mechanism was impossible. The modification, though, makes export feasible. The initial export limitation was unfavorable to that WTO member that lacked or needed pharmaceutical production facilities, making it difficult for them to utilize the licensing under the TRIPS Agreement before the amendment to a reasonable extent. In short, a WTO member can bring in generic medicines made in another WTO member via CL thanks to mainly Article 31bis.[81]

The remainder of the article states that if the conditions that first justified CL no longer exist and are extremely unlikely to return, CL can be ended without jeopardizing the interests of those who were granted the privilege.[82] The patent holder should receive a reasonable and sufficient sum of money.[83] The legitimacy of authorized CL can be checked by judicial review or impartial appraisal, and compensation decisions can be checked by courts or independent organizations.[84] When dealing with anti-competitive behavior, members are given leeway and can go against established norms.[85] If comparable situations are expected to arise, authorities can refuse to suspend the permission.[86] When CL is utilized to allow the use of a patent that would infringe upon another, additional constraints such as technical advancement, fair cross-licensing, and restrictions on transferring granted patents apply.[87]

### 2.2.3 Summary

The legal ground provided by the TRIPS Agreement and the supplementary rules provides a sufficient ground for CL. It seeks to ensure the protection of both IPRs and HRs. However, it is flexible and nationally based. This can be good in allowing sovereign states to handle manners to their extent within their territory, respecting the *Principle of Territoriality*.[88] Nevertheless, it creates contentious legislation insufficient to meet specific requirements, particularly cross-border health crises.

[81] De Campos-Rudinsky, op. cit., p.529.
[82] TRIPS Agreement, op. cit., art.31(g).
[83] ibid., art.31(h).
[84] ibid., art.31(i).
[85] ibid., art.31(j).
[86] ibid., art.31(k).
[87] ibid., art.31(l).
[88] Principle of Territoriality: there are distinct territories under the control of each sovereign nation.

Based on the aforementioned legal framework, the following subchapter will examine EU law on CL.

## 2.3 Union Level

### 2.3.1 Introduction

There has yet to be a specific EU-wide CL apparatus. However, there is a CL framework, as outlined in "Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on CL of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems."[89]

### 2.3.2 Regulation (EC) No 816/2006

The scope, definitions of terms, and method for appointing a responsible body are all laid out in Articles 1 to 3 of Regulation (EC) No 816/2006.[90] Article 1 of the regulation sets a system for the award of CL for patents and additional safeguarding credentials for the production and distribution of pharmaceutical goods for export to qualified importers for the sake of tackling public health issues.[91] Article 2 defines key terms: "pharmaceutical product" (manufactured by the industry), "rights-holder" (patent owner or licensee), "importing country" (destination), and "competent authority" (national agency granting CL).[92] Article 3 states that unless an EU MS agrees alternatively, the competent authority should have the authority to approve CL under domestic patent law. The MS's selected competent authority will be communicated to the EC. Additionally, publication in the Official Journal of the EU is required for all notifications.[93]

The determination of the importing nation, the request process for CL, and the terms of the grant, along with other required notifications, are all laid out in Articles 4 through 12 and 16 and 17 of Regulation (EC) No 816/2006. These rules encompass those stipulated in Articles 31 and 31bis of TRIPS to a great extent.[94] Article 9 encompasses prior conciliation with the patent owner, such

[89] Regulation (EC) No 816/2006, op. cit., art.1-20.
[90] European Commission's Study Report, op. cit., p.57.
[91] Regulation (EC) No 816/2006, op. cit., art.1.
[92] ibid., art.2.
[93] ibid., art.3.
[94] European Commission's Study Report, op. cit., p.57.

as those set forth under Article 31 (b) of the TRIPS Agreement.[95] This is crucial as it highlights that CL can be used only when negotiating with the patent holder who has yet to succeed in upholding IPRs.

Furthermore, Articles 19 and 20 of the Regulations address revision and implementation, respectively. There are no significant changes, substitutes, or additions to the TRIPS Agreement in these five articles.[96] The effectiveness and security of pharmaceuticals are planned for in Article 18. A request for CL on a pharmaceutical product may make use of several processes under both EU legislation and national law.[97]

### 2.3.3 Summary

The law suggests that CL is, to a great extent, a matter of domestic law. Respectively, it is argued to be highly fragmented. Each EU MS administers its CL regime, with varying requirements and jurisdictions derived from the vague and non-centralized grounds of the law.

Consequently, examples from different national laws on CL will be studied below, further adding to the ground for discussion in Chapter 3 to highlight underlying issues and possible implications to improve the current system.

## 2.4 National Level

### 2.4.1 Introduction

To meet the requirements of EU MS, national ordinances primarily control CL and should be utilized to fulfill the needs within their local markets. Most MS have codified this process into national law; however, the legal justifications for doing so and the accompanying procedures may vary. For example, most crucially, in the event of a public health emergency, CL may be utilized in specific but not all EU MS.[98]

[95] Regulation (EC) No 816/2006, op. cit., art.9.
[96] European Commission's Study Report, op. cit., p.57.
[97] ibid., p.57.
[98] Bertuzzi, N., Lagalisse, E., Lello, E., Gobo, G. and Sena, B., Politics During and After Covid-19: Science, Health and Social Protest, *Partecipazione E Conflitto, 15*(3), 2023, p.507-529.

### 2.4.2 Member State Specific Examples

Several MS, like Germany, have revised their patent legislation under the COVID-19 Outbreak to make the issuance of CL simpler and more expedient.[99] The issuance of CL for patented innovations is governed by Section 24 of the German Patent Act. The Federal Patent Court has the authority to issue CL in limited circumstances, such as when the public interest requires it.[100] However, to what extent a particular set of conditions or circumstances constitutes a public interest is up to the discretion of the appropriate national body in Germany.[101] In summary, the MS's legislation has a broad provision allowing for CL in the public interest. Still, the exact situations of what falls under the category are left to the national authorities to specify.

Other examples of different MS include more specific reasons for granting CL, and these lists tend to be thorough such as France; its IP Code addresses public health, national defense, and inadequate exploitation head-on to fall under public interest.[102] The French IP Code details the requirements to acquire a CL and the circumstances under which one may be granted.[103]

Ireland, similar to France, is another MS example where CL can be issued for a wide range of reasons, for instance, inadequate profit-making or unmet demand alongside the public's best interest.[104]

There are additionally merged methods, like the one utilized by Spain, which is a more open-ended provision on CL in the public interest and a non-exhaustive list with particular instances, including public health, nutrition, defense, environmental protection, etc. Hence, thanks to the list, the Spanish law on CL to the specific instances given, clarifies for both license applicants and authorities how the phrase 'public interest' should be interpreted.[105]

Like in Spain, a mechanism could be considered in the event of EU-wide harmonization, with an umbrella provision on CL in the public interest and a non-exhaustive list of particular instances,

[99] Oser, A., The COVID-19 Pandemic: Stress Test for Intellectual Property and Pharmaceutical Laws, *GRUR International, 70*(9), 2021, p.846-854.
[100] Maume, P., Compulsory licensing in Germany, *In Compulsory licensing: Practical Experiences and Ways Forward* 2014, p.95-120.
[101] Lamping et al., op. cit., p.5-6.
[102] ibid., p.6.
[103] Jaluzot, B., The Legal Framework Of Intellectual Property Rights In Comparative Law: Japan–France, Dynamics Of Regional Innovation, *The Policy Challenges In Europe And Japan, 10*, 2011, p.149.
[104] Lamping et al., op. cit., p.6.
[105] ibid., p.6.

including public health, nutrition, defense, environmental protection, etc. In addition to the specific instances given, this clarifies for the license,[106] the applicant,[107] and the authority[108] how the term public interest should be interpreted.[109]

### 2.4.3 Summary

There are different grounds to issue CL within different EU MS. This results in the lack of uniformity in managing a health crisis, particularly with cross-border implications.

Despite the differences as stated under Article 3 Regulation (EC) No 816/2006, it is still required for any MS to inform the EC and publication of CL made under the Official Journal of the EU of any national acts in respect to the mechanism. This allows to some extent, the lead back of national law to the EU level; however, with no specific legislation that tells explicitly what MS's domestic law should be is where the problem lies.

## 2.5 Remarks

The fundamental issue is the deficiency of a specific CL at the Union level. Great flexibility is found in Regulation (EC) No 816/2006, which reflects even more flexible legislation, the TRIPS Agreement Article 31. The lack of a rigid legal system of CL stems from further inconsistencies.[110]

Currently, EU CL law is irregular, with varied requirements, goals, and processes imposed by each EU MS. Mainly, national CL mechanisms are tailored to serve the requirements of the individuals living in the issuing MS and to fulfill the public interest of that specific MS alone. National systems exclusively need to prepare to deal with crises that go beyond their territory, like the recent global pandemic. This is because domestic legislation does not have a common ground to operate and cannot depend on cross-border value networks. Hence, the EU, as a

[106] License: a person or group granted permission under CL to use or manufacture the patented innovation.
[107] Applicant: a person or group who wants or applies for a CL to use or manufacture a patented innovation.
[108] Authority: the government entity or agency with the legal authority and jurisdiction to grant CL to use or manufacture patented innovations.
[109] Lamping et al., op. cit., p.6.
[110] Zaheer, M., Pros and cons of compulsory licensing: An analysis of arguments, *International Journal of Social Science and Humanity, 3*(3), 2013, p.254-256.

greater power, needs to initiate a uniform mechanism to increase its adaptability to handle crises, particularly those with cross-border consequences, on accounts of medicine accessibility.[111]

A flawed CL mechanism can have several negative consequences for access to medicine. It may reduce incentives for R&D by increasing ambiguity about the value of patents. A complicated or expensive licensing process may encourage generic medication producers to request licenses, resulting in a drug shortage. Furthermore, indiscriminate or poorly paid licensing by governments might impair the long-term motivation for innovation, resulting in the limited availability of innovative and effective treatments. Most importantly, the flaws can directly result in the lack of access to medications crucial to treating the present health concerns and the lack of efficient grounds to obtain CL. This can have severe consequences for public health, especially in the case of infectious illnesses that necessitate access to medicine and continual innovation.[112]

Consequently, the following chapter will explore the underlying issues with the present mechanism in the EU and explore possible implications for better access to medicine CL mechanism.

[111] European Commission, Questions and Answers on Compulsory Licensing, *European Commission Webpage* (hereinafter European Commission's Question and Answer on Compulsory Licensing), 2023, retrieved from: https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_2456, last access 1 May 2023.
[112] Henry, C. and Stiglitz, J.E., Intellectual property, dissemination of innovation and sustainable development, *Global Policy, 1*(3), 2010, p.237-251.

# 3. Underlying Issues and Possible Implications of Compulsory Licensing

## 3.1 Introduction

This section highlights underlying issues of CL and suggests possible implications in aims to reach the purpose of the thesis. It first highlights the lack of uniformity of CL at the Union level with possible implications to improve it. Following, the legal aspects that connect and relate to CL will be studied to generate a more enhanced system at the Union that serves both CL and other underlying struggles. Additionally, it explores EC's perspective approach to changing the current CL to analyze further and critique what can be done better. Finally, the chapter considers import and export struggles and implications to further connect the legal ground to a better system where the chance to access medicine is more feasible than it already is.

## 3.2 Compulsory Licensing Uniformity Across the Union

### 3.2.1 Introduction

Currently, the EU lacks the authority to issue CL at the Union level. It is required to provide the EU with authority to issue Union-based CL to achieve a legitimate and unified system for the subject matter. Thus, this section will examine the underlying issue concerning the unavailability of an EU-based CL power and suggest possible implications.

### 3.2.1 Authority to Issue Compulsory Licensing Across the Union

According to Article 3 of Regulation (EC) No 816/2006, the authorities competent to award a CL in the context of medicine are the entities capable of doing so according to domestic law on patents and CL.[113] This means that only specific EU MS can issue CL, and more significantly, only inside their territory. This highlights the first issue, in which CL is only feasible for

[113] Regulation (EC) No 816/2006, op. cit., art.3.

domestic use and cannot be used as a weapon to control access to medicine across the region uniformly. This can be problematic in health outbreaks affecting the territory of more than one MS. Take the example of the COVID-19 Outbreak, particularly with the differences in domestic law. This has resulted in an imbalance of medicine distribution and different national legislations leading to a lack of uniformity across the EU.[114]

If looked at the issue through the lens of the *Principle of Subsidiarity*,[115] MS have the authority to decide for their law on the matter.[116] However, this is only ideal when all MS proceed within the same knowledge base. Hence, despite the general acceptance of the principle, the EU may have the potential to harmonize its procedure for CL for medicines to provide at least a more harmonized ground than it already has. This will potentially allow, at least, a more outstanding foundation for MS to start from.[117]

From the perspective of the *Principle of Territoriality*, in the *Case 19/84 Pharmon v. Hoechst*, ECJ stated that activities of the government of EU MS are subject to territoriality.[118] As an act of a governmental entity, a CL in its nature cannot confer rights in the territory of other EU MS. To clarify, a CL given by one MS of the EU is only valid within the territory of that MS and may not be enforced in any other MS. This shines the light on national CL and IPRs legal and policy grounds and shies away from a harmonized one at the EU level, indicating that IPRs are generally national rights.[119]

Nevertheless, in *Case 78-70 Deutsche Grammophon v. Metro SB*[120] and *Case 15-74 Centrafarm v. Sterling Drug*,[121] the ECJ developed its notion of EU-wide exhaustion of IPRs to facilitate the free movement of products between MS of patented product or product directly derived by the patented method. However, this does not cover patented pharmaceuticals achieved through CL, as was discussed in *Case 19/84 Pharmon v. Hoechst*. This is because items generated under a CL

[114] Hu, W., Compulsory licensing and access to future Covcines, *Centre for European Policy Studies*, 2020, p.20.
[115] Principle of Subsidiarity: decisions should be made at the most localized and decentralized level of government or authority feasible.
[116] Fabbrini, F., The principle of subsidiarity, *Oxford Principles of EU Law*, 2016, p.4-24.
[117] Estella de Noriega, A., *The EU principle of subsidiarity and its critique*, Oxford University Press, 2002.
[118] European Court of Justice, *Case 19/84 Pharmon v. Hoechst*, 1985, para.1-30.
[119] European Commission's Study Report, op. cit., p.50.
[120] European Court of Justice, *Cases 78-70 Deutsche Grammophon v. Metro SB,* 1971.
[121] European Court of Justice, *Case 15-74 Centrafarm v. Sterling Drug*, 1974.

are not subject to such EU-wide depletion since the patent owner probably did not consent to the first commercialization of the product.[122]

In summary, Case law has established that after the initial sale, permission for the product to be distributed across the borders in the EU is given.[123] According to the nature of CL, there is no consent from the patent holder when obtaining it. This shies away from cross-border implications to CL. This shows that the present mechanism cannot issue CL across a particular MS's borders. A legal framework at the Union level is needed to enable cross-border CL, establishing a uniform understanding of public interest across the EU. The lack of uniform EU legislation complicates cross-border health crises, so EU MS must work together effectively.[124] Clear legislative frameworks and coordinated responses are essential to effectively handle such crises and ensure public health and safety throughout the region.[125] Patent holders, manufacturers, and potential licensees can all benefit from less time spent negotiating and more certainty in the law if a Union-level CL is issued during a cross-border health crisis.[126] In the event of regional shortages or disruptions in the international value chain, it can also improve access to medicines and communication regarding their availability.[127]

Respectively, the EU could promote greater cooperation and coordination among its MS in the area of CL for pharmaceutical products while still adhering to the *Principle of Subsidiarity* and *Territoriality* and respecting national-level decision-making by employing soft law measures such as guidelines or best practices as a solution.[128] Soft legislation initiatives are critical for the EU to deal with health crises that affect more than one EU MS. This can be attributed to its prompt to conceptualize and deploy flexibility to specific circumstances and encourage consistency and coherence across borders. Soft law measures provide an adaptable structure that can be tailored to local conditions or variances, lowering the danger of ambiguity or conflicting

[122] European Commission's Study Report, op. cit., p.54.
[123] Liu, op. cit., p.16-17.
[124] Lamping et al., op. cit., p.7-9.
[125] Sagan, A., Erin, W., Dheepa, R., Marina, K., and Scott, L.G., Health system resilience during the pandemic: It's mostly about governance, *Euro health, 27*(1), 2021, p.10-15.
[126] Council of the European Union, *Commission staff working document impact assessment report accompanying the document Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006* (hereinafter European Commission's Impact Assessment Report), p.35, 37, 39.
[127] European Commission's Impact Assessment Report, op. cit., p.35-37.
[128] Cygan, A., Regional governance, subsidiarity, and accountability within the EU's multi-level polity, *European Public Law, 19*(1), 2013, p.161-188.

laws.[129] They are a vital tool for the EU to address critical imbalances in shorter periods than is needed to implement hard law like regulations. This might be especially helpful in a sudden and widespread health crisis, where a prompt and coordinated response is of the utmost importance.[130]

The production of a soft law mechanism in cases of a health crisis, in particular one that is abrupt and unpredictable, can be used as a tool to set expectations on the present legal systems in the different MS. Nevertheless, one cannot put aside the adverse effects of soft law, one being its lack of adequate legal grounds to impose the criteria on MS and the other being its unequal implication due to its voluntary effect.[131] Regardless, to tackle the health crisis in a shorter period, only the willingness to cooperate among EU MS can solve the concerns.

Other long-term implications, such as presenting a regulation aiming to create a CL mechanism at the EU level, can be a more efficient tool to employ forward thinking. However, with a rapid and unpredicted health crisis such as the COVID-19 Pandemic, a soft law gathering all EU MS's approaches to one can be a form of guidance for an adequate short-term fixation of the lack of harmonization among them.

## 3.3 Uniformity Beyond Compulsory Licensing

### 3.3.1 Introduction

The underlying issue does not solely arise from Regulation (EC) No 816/2006 but from the broader legal ground contributing to EU patent law and IPRs.

Hence, numerous aspects within the EU's legal grounds could be harmonized besides reaffirming EU-wide exhaustion. This can include the nature of IPRs, their cross-border implications for the sake of an enhanced approach to the EU's goal of a Single Market, and a uniform approach to health crises and emergencies.[132]

[129] Boyle, A., Soft law in international law-making, *International law, 5*, 2014, p.119-137.
[130] European Commission's Study Report, op. cit., p.71.
[131] Klabbers, J., The undesirability of soft law, *Nordic Journal of International Law, 67*, 1998, p.381-391.
[132] European Commission's Study Report, op. cit., p.72-73.

### 3.3.2 Unitary Patent System

To start with the nature of patents and generally IPRs, there is a lack of cross-border implications, as touched upon in the previous chapter. The approach to enhancing the patent system as a whole in the EU is one of the steps that the Union has taken. The rollout of the Unitary Patent (UP) system, scheduled for June 2023, is complementary to the EC's CL pursuits. UP is an official designation that will give uniform protection in a "one-stop-shop," conserving time and resources.[133]

The primary goal of UP protection is to ensure a uniform nature of protection; however, the EU has failed to control CL, which weakens this goal. A patent cannot have a unitary impact if CL is given in a specific MS but not others or if licenses issued in different MS have different terms. The Unitary Patent Court (UPC) also cannot issue a unified ruling for patent infringements involving patents for which a CL has been issued.[134]

Possible fragmentation of the Internal Market and a considerable disadvantage for the applicant for a CL compared to the UP holder result from the absence of a centralized process to apply for a CL with unitary effect. This is because the holder of a UP only has to deal with a single court, UPC, to enforce its patent right. In contrast, the seeker of a CL must navigate the myriad of laws, authorities, and processes of each MS to get what will be, at most, a license with restricted geographic scope.[135]

Granting a CL for a UP to a national authority would violate the unitary nature of protection and the separation of powers between the EU and its MS. The goal of UP protection is to reduce expenses and complications for businesses within the EU; however, this imbalance of power between UP holders and those seeking a CL runs counter to this goal.[136]

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[133] European Commission, Internal Market, Industry, Entrepreneurship, and SMEs, *European Commission's Webpage, 2023*, retrieved from: https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/unitary-patent-system_en#:~:text=The%20unitary%20patent%20is%20a,a%20single%2C%20specialised%20patent%20jurisdiction, last access 1 May 2023.
[134] Lamping et al., op. cit., p.22-24.
[135] ibid., p.23.
[136] ibid., p.24.

Note that the EU's UP system is an attempt to standardize patent protection across the Union.[137] This objective is challenging because MS has wide latitude in deciding whether or not to issue CL. The lack of a centralized method to apply for a CL with unitary effect threatens to divide the Internal Market and unfairly favors the holder of the UP over the applicant for a CL. This contradicts the goal of EU-wide patent protection in reducing administrative burdens and costs for businesses. However, introducing a UP system in the region might also be beneficial in changing the law in the EU to feed on the goal of a Single Market and connection among EU MS, ultimately improving the current CL system.[138]

Hence, it is crucial to argue that bringing the CL mechanism to the same level as the UP system is essential. The changes within the patent system across borders and the issue of CL could go hand in hand and optimistically result in a uniformity of application throughout the EU if they were to run parallel to each other rather than the contrary.[139]

Creating the UP system can go hand in hand with a harmonized CL mechanism at the EU level. The lack of compliance of the current CL system to the goals of UP emphatically requests changes within the CL. This could represent a significant step toward completing the Single Market for Patents. EC's proposed regulation on CL, as will be discussed in Chapter 3.4, thus stands at an intersection amid the various EU crisis mechanisms and the international commitments on IPRs and CL against the framework of the complete Single Market in the EU for patents.[140]

In connection with this, involvement with appropriate stakeholders, including pharmaceutical corporations, medical professionals, coordinated initiatives, political power, and ongoing conversations across EU MS, is crucial to make the system work. Through cooperative efforts, the EU can further increase its citizens' access to medicine and boost their quality of life.

[137] Kiesling, K., The European Patent with Unitary Effect-a Unitary Patent Protection for a Unitary Market?, *UCL Journal of Law and Jurisprudence, 2*, 2013, p.87.
[138] Hu, op. cit., p.20.
[139] Lamping et al., op. cit., p.24.
[140] European Commission's Impact Assessment Report, op. cit., p.6.

### 3.3.3 Crisis Management

Another aspect includes the EU's ability to provide a uniform approach to handling health crises.[141]

The main issue lies in various MS health crisis-related CL laws having diverse scopes, granting varying powers to appropriate entities in various scenarios. Most EU MS can issue crisis response CL for use in any health crisis emergencies. These MS rely on the vague concepts of the public's interest to pass their laws. Other MS are typically restricted to the medical sectors. Some MS also appear to lack an overt proficiency in dealing with specific health concerns and emergencies. Hence, public entities cannot issue CL beyond the scope of the law unless they have the authority to do so, in which EU MS are unable to issue CL in the event of a global crisis that affects the EU as a whole.[142]

This is also evident in the examples of domestic law presented in Chapter 2.4. When awarding CL, like in France, specific MS are more detailed concerning what constitutes a public interest than others. In contrast, particular MS, like Germany, gives national authorities greater flexibility to deal with CL during health crises. Regarding CL in the public interest, Spain has an overarching regulation and a non-exhaustive list of specific cases. As a result, harmonizing CL rules at the EU level may help clarify the conditions under which CL may contribute to more excellent uniformity across the EU. This harmonization could start by looking at health concerns and its ability to combat outbreaks with one eye; at the Union level.[143]

Concerning that, there are current crisis tools presented by the EU, such as the proposed Single Market Emergency Instrument (SMEI),[144] Health Emergency Preparedness, and Response

[141] ibid., p.72-73.
[142] ibid., p.24.
[143] Kumar, S., Compulsory licensing of patents during pandemics, *Connecticut Law Review, 54*, 2022, p.57.
[144] European Commission, Crisis-proofing the Single Market: equipping Europe with a robust toolbox to preserve free movement and availability of relevant goods and services, *European Commission's Webpage*, 2022, retrieved from: https://ec.europa.eu/commission/presscorner/detail/en/ip_22_5443, last access 1 May 2023.

Authority (HERA),[145] the proposed Chips Act,[146] and the Regulation (EU) No 2022/2371 on cross-border health threats.[147]

Hence, complementary to CL, approaches like the SMEI, HERA, and the Chips Act enacted during the COVID-19 crisis aim to improve the Union's crisis preparedness by guaranteeing access to essential patented items and technology in times of emergency if VL is unavailable to obtain. This adds significant value to the approach to better create a harmonized Union, mainly when aiming to improve CL.[148]

Taking the example of SMEI, it is an EU Single Market crisis management system. Four parts. First, a governing body will help the Commission handle an EU crisis. Second, an emergency management framework will establish early alerts and crisis procedures to prevent Single Market disruptions. Third, a monitoring system will prevent crises. This structure will monitor strategic commodities and services supply networks and build tactical reserves. Fourth, an EU Single Market crisis framework will include measures to increase openness, restore and promote free movement, and forbid limiting free movement entitlements. The EC grants CL to products that meet exceptional EU harmonized standards during crises.[149]

Consequently, the EC might identify an emergency in public health at the EU level, which would go hand in hand with granting a Union CL by narrowing down to what constitutes a public health concern. Other approaches to enhance the system are crucial. Take the example of the HERA, which is initiated to set strategies to guarantee the availability of crisis-relevant health measures under Regulation (EU) 2022/2372 for "measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at the Union level."[150] Such a

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[145] European Commission, Health Emergency Preparedness and Response Authority, *European Commission's Webpage*, 2022, retrieved from: https://commission.europa.eu/about-european-commission/departments-and-executive-agencies/health-emergency-preparedness-and-response-authority_en, last access 1 May 2023.
[146] European Commission, European Chips Act, European Commission's Webpage, 2022, retrieved from: https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/european-chips-act_en, last access 1 May 2023.
[147] European Union, *Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU*, 2022.
[148] European Commission's Questions and Answers on Compulsory Licensing, op. cit.
[149] European Commission's Impact Assessment Report, op. cit., p.1-130.
[150] European Union, *Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level,* 2022.

step, tackles the issue at the EU level to ensure uniform understanding of the concept of health crisis.[151]

It is under specific provisions at the EU level that define the presence of a crisis or emergency. The EU crisis tools that might trigger an EU CL are enumerated in an Annex to the proposed regulation for the benefit of legal certainty.[152] Therefore, the applicable EU crisis instrument is essential rather than solely changing Regulation (EC) No 816/2006.

These are crucial to acknowledge because, like building a house, one cannot simply place the bricks on the bare ground without establishing a foundation. Hence, it can be argued that within the framework of a UP system and crisis mechanism at the Union level, a CL may be issued more efficiently.[153]

Such steps by the EU seem quite efficient; however, given the relatively recent nature of these findings and their connection to the present pandemic, they have not been subjected to extensive testing to prove their effectiveness. One possible implication side-by-side to this is that regulatory networks of institutions are formed, with open information sharing as a top priority, to deal with the potential coordination challenges caused by different EU MS issuing CL during a crisis; This brings together a dialogue between MS by ensuring cooperation.

The European Competition Network (ECN) and the European Medicines Agency (EMA) are two examples of existing organizations that might be expanded to help harmonize law in the EU on the matter.[154]

The EC and EU MS officials collaborate on fair and open markets through the ECN. This allows for powerful cross-border anti-competitive action challenges. All ECN members use the ECN to implement European competition regulations effectively and uniformly. Competition authorities discuss proposed decisions on the ECN. The ECN lets competition authorities learn from each other's successes and failures. This could be used to handle patented pharmaceuticals granted

[151] European Commission's Questions and Answers on Compulsory Licensing, op. cit.
[152] Proposed Regulation on Compulsory Licensing, op. cit.
[153] European Commission's Questions and Answers on Compulsory Licensing, op. cit.
[154] European Commission's Study Report, op. cit., p.71.

under CL among EU MS, especially during health crises when MS dialogue is crucial to ensure uniformity.[155]

Additionally, medicines in the EU and European Economic Area (EEA) are evaluated and monitored by the EMA, whose mission is to preserve and enhance the well-being of humans and animals. Starting from this mission, access to medicine can be a vital tool to preserve well-being. Hence, the connection of such a system to CL and the right to health through access to medicine in times of crisis is crucial.[156]

Respectively, such regulatory processes among EU MS can benefit from centralizing regulatory tasks at the EU level. Stakeholders and national experts are overwhelmingly in favor of delegating CL administration to expert authorities. One of the many conceivable functions for such an authority can be defined by designating an authority or combination of authorities at the EU level to declare a crisis. Consequently, according to EC's report, MS would benefit from receiving more specific and binding instructions if the EU centralized some areas of crisis response.[157]

Specifically, in times of crisis, where every second counts, the ability to respond swiftly is of the utmost importance.[158] Implementing uniform standards across the EU can achieve more consistent and predictable results, not only in terms of CL but also in any factor affecting the mechanism's effect on access to medicine. It is possible to expedite decision-making and minimize wasted effort by harmonizing regulatory processes across EU MS, consequently feeding back to the discussion under Chapter 3.2.[159]

Assigning a regulatory body, such as the EC, with the authority to issue guidelines for utilizing CL in such situations can be crucial. This would help establish *Principles of Good Faith*,[160] *Best*

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[155] European Commission, Competition Policy, European Competition Network, *European Commission Website*, retrieved from: https://competition-policy.ec.europa.eu/european-competition-network_en, last access 29 April 2023.
[156] European Union, European Medicines Agency, *European Union Website*, retrieved from: https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/ema_en#:~:text=The%20European%20Medicines%20Agency%20, last access 29 April, 2023.
[157] European Commission's Study Report, op. cit., p.73-74.
[158] Ansell, C., Boin, A., and Keller, A., Managing transboundary crises: Identifying the building blocks of an effective response system, *Journal of Contingencies and Crisis Management, 18*(4), 2010, p.195-207.
[159] Soeteman, L.G., Apostolova, M.D., Bekker, C., Dekkers, S., Grafström, R.C., Groenewold, M., Hadzhiyski, Y., Herbeck-Engel, P., Hoehener, K., Karagiozakis, V. and Kelly, S., Safe innovation approach: Towards an agile system for dealing with innovations, *Materials Today Communications, 20*, 2019, p.1-15.
[160] Principle of Good Faith: virtues of honesty, loyalty, and moderation.

*Practices*,[161] and *Fairness*[162] when using a CL at the EU level during times of crisis. This could set out CL's ethical and responsible use, focusing on the public interest. The EU has to establish these criteria to prevent CL from favoring one group or industry over another and ensuring they are only used in times of genuine emergency. This could make MS more at ease using CL as a means of advancing public health and safety, and they may have more faith in the EU's broader regulatory structure.[163]

In general, better coordination and collaboration amongst EU MS during times of crisis can be achieved by centralizing some aspects of crisis response at the EU level. By allowing more detailed legislation, MS avoids competing with one another for limited resources and acting in inconsistent ways. This would allow MS to respond to knot together by coordinating their efforts and resources.[164]

The proposal of a regulatory authority to oversee the use of CL in times of crisis is a reasonable and realistic approach to a difficult subject. Notably, the EC's approach seeks to include individuals, companies, and stakeholders in the process of making decisions; to enhance EU laws in terms of accessibility and effectiveness; to minimize needless costs; and to guarantee that EU policies are grounded in evidence.[165] This, at least in theory, sounds like an effective approach.

The EC has proposed a regulation that will be discussed in the following subchapter.

[161] Principle of Best practice: instruction that takes itself seriously and is therefore thoughtful, well-informed, responsible, and up-to-date.
[162] Principle of Fairness: equality, regard, accountability, and care for the common conditions among mankind.
[163] European Commission's Study Report, op. cit., p.85.
[164] Cavaleri, M., Sweeney, F., Gonzalez-Quevedo, R., and Carr, M., Shaping EU medicines regulation in the post COVID-19 era, *The Lancet Regional Health-Europe, 9*, 2021, p.2-4.
[165] European Commission, Better Regulation: why and how, *European Commission Webpage*, retrieved from: https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation_en#objectives-of-the-better-regulation-agenda, last access 29 April 2023.

## 3.4 Proposed Regulation on Compulsory Licensing

### 3.4.1 Introduction

The EC, under the title "Proposal for a Regulation of the European Parliament and of the Council on Compulsory Licensing for crisis management and Amending Regulation (EC) 816/2006," aims to create a new and harmonized CL in the EU.[166]

### 3.4.2 Insights and Reflections

Article 1 of the proposed regulation states the goal of this regulation is to ensure that the EU has access to crisis-related goods in times of emergency. To facilitate the distribution of patented products to MS, this regulation establishes rules on the process and criteria for the issuance of CL of IPRs at the Union level.[167] These IPRS include those related to patents, among others, as stated in Article 2.[168]

Specifically, Article 3 states that the term EU CL refers to a license given by the Commission for the use of the safeguarded innovation of crisis-related items.[169]

The utilization of an EU CL still entails conditions such as the CL has to be non-exclusive and is not transferable to a different party, except the component of the company or goodwill that benefits from the license as portrayed in Article 5.1 (a).[170] This is crucial in upholding the IP owner's right to use its products to access medicine and nothing else. Such limitations are critical for balancing IPRs and the Right to Health within a law that tries to limit IPRs specifically to feed the necessity of medicinal access.

For the sake of this balance, the proposal in Article 9 takes into account remuneration in which Union level CL mandates compensation to the IP owner, which is set at 4% of total gross income and is assessed by the Commission according to economic worth, public endorsement,

[166] Proposed Regulation on Compulsory Licensing, op. cit., art.1-23.
[167] ibid., art.1.
[168] ibid., art.2.
[169] ibid., art.3.
[170] ibid., art.5.

accumulated costs of development, and humanitarian conditions.[171] This is quite an advancement because Regulation (EC) No 816/2006 does not explicitly mention compensation to patent owners. After all, IP is still a property and requires compensation when being used.[172]

Additionally, the Commission may amend the license to contain a comprehensive list of rights and IPR owner, agree on further steps to accomplish its goal and good partnership, and cancel out CL if conditions change and if requirements are not met as seen in Article 14.[173] This further advances and ensures IPRs while aiming to access medicine under health concerns.

These new conditions do not completely remove the right to national law to set forth its domestic CL stance. Consequently, each EU MS must inform the Commission if it issues a national CL. Objectives, legal justification, particulars, relevant items, rights holders, compensation, and the number of goods to be provided should all be included in the notification as shown under Article 22 of the proposal.[174]

Respectively, it suggests a new article that allows the Commission to issue a CL covering the entire EU in situations when production and sales for export occur in several MS. Specifically, Article 23 of the proposal is the revised version of Article 18 of Regulation (EC) No 816/2006 and it adds Article 18a and Article 18b to the original rule.[175]

Article 18 (a) establishes guidelines for issuing an EU CL to facilitate the export of medicines. Without the patent holder's consent, the EU can now issue licenses authorizing the export of medical devices to nations with public health difficulties. The article further specifies that an Implementing Act (conditions under which the law is implemented) is required for the EU to issue a CL. The EC uses Implementing Act to ensure that EU regulations are followed uniformly across all MS.[176]

Article 18 (b) has a link to Regulation (EU) No 182/2011 and a committee reference. The EU MS is represented on the committee, which assists the EC in enforcing EU law. Implementing actions are governed by Regulation (EU) No 182/2011 to facilitate the implementation of EU

[171] ibid., art.9.
[172] Easterbrook, F.H., Intellectual property is still property, *Harvard Journal of Law and Public Policy, 13*, 1990, p.108.
[173] Proposed Regulation on Compulsory Licensing, op. cit., art.14.
[174] ibid., art.22.
[175] ibid., art.23.
[176] ibid., art.23.

regulations. Since this regulation is referred to, its rules for carrying out Article 18 (a) of Regulation (EC) No 816/2006 will also apply.[177]

Per Articles 34 and 35 of the Treaty on the Functioning of the European Union (TFEU), guarantee the free flow of products within the Single Market. Nevertheless, there are limitations to its use.[178] The need to safeguard intellectual and financial assets, as enshrined under Article 36 of the TFEU, provides a legal basis for these measures.[179] The ECJ has sought to strike a fair balance between competing interests in its area of authority by, on the one hand, permitting the unrestricted movement of patented products if publicity occurred with the permission of the proprietor of the patent where there is EU-Wide exhaustion. On the other hand, limiting free movement in the absence of this permission, as in the present instance of a CL, shows the lack of EU-wide exhaustion. In the event of cross-border health crises, given that a particular MS rely on the resources of others, the absence of a Single Market for these products and their impact becomes an essential obstacle to cross-border accessibility.[180]

Respectively, the proposal serves excellent value as it shows that the EC recognizes the importance of IPRs, particularly patent rights and the utilization of CL, in providing access to medication, especially during times of public health crisis and emergencies. It is an improvement toward a unified CL across the EU, feeding the goal of the EU Single Market.

Despite the positive aspects it brings towards the goal of harmonization of the EU to feed the Single Market, it needs to acknowledge the needs of nations who may need help getting pharmaceutical products at the Union level. The EU should make this effort in the spirit of collaboration and recognition of the Right to Health when necessary, particularly with it fascinating legal order and strength. This point will be further discussed in the following subchapter in the face of CL concerning the import and export of patented pharmaceuticals under the mechanism.

[177] ibid., art.23.
[178] TFEU, op. cit., art.34-45.
[179] ibid., art.36.
[180] European Commission's Impact Assessment Report, op. cit., p.137.

## 3.5 Import and Export Under Compulsory Licensing

### 3.5.1 Introduction

There are underlying issues with the export and import of products issued under CL. First, import under CL to EU MS is made difficult by the region's decision to opt out of the benefits Article 31bis of the TRIPS Agreement set forth, which limits access to medicine. Second, exporting under CL into other EU MS and third countries is difficult due to the vague legal ground. Respectively, this section will explore the underlying issues with import and export under CL and suggest possible implications.

### 5.5.2 Import

The EU and its MS, like many developed regions in the world, has given up, in other words, opting out, its ability to import pharmaceuticals under Article 31bis in the event of an unexpected health crisis. The export ban on drugs made under CL was lifted in 2017 according to a revision to Article 31bis of the TRIPS as stated under Chapter 2.2. However, due to opting out, the EU and its MS cannot import pharmaceuticals issued under CL.[181]

Organizations and specialists urged concerned WTO MS to inform the WTO that it has modified its stance. Additionally, it currently contemplates itself as a permitted importing country and employs anything that legal avenues based on CL are accessible to end the opt-out as importing nations for products made with a CL by 2020 with the start of the COVID-19 Pandemic.[182]

Although the EU and its MS have a robust pharmaceutical sector, it is not immune to health crises. There are instances where the import of certain patented pharmaceuticals is required into the Union. However, under the present state, the EU and its MS lack sufficient authority to import medicines under Article 31bis TRIPS in the event of an unexpected health crisis because they have removed their right to import any goods generated under the mechanism.[183]

[181] De Campos-Rudinsky, op.cit., p.531.
[182] ibid., p.531-532.
[183] European Commission's Study Report, op. cit., p.69.

As a result, the EU MS cannot import essential pharmaceutics and vaccines under the mechanism of CL during an unexpected health crisis like the COVID-19 Pandemic. Consequently, a lack of essential medicines would threaten public health if it continues.[184]

Hence, nations who notified the WTO of their intention not to utilize the Article 31bis mechanism, taking the example of EU MS, may need to opt back and reconsider due to limited industrial capacity in developing and developed nations within the context of the pandemics.[185] The COVID-19 Outbreak has affected every nation regardless of its economic status.[186] Respectively, high-income nations are using CL to negotiate lower pharmaceutical costs and address supply constraints.[187]

The medicine production capability of a high-income country that opted out of the mechanism may not be sufficient in the face of unexpectedly high demand, as was the case during the COVID-19 Outbreak.[188] This shows that regardless of the status of developed nations, they still require access to medicine.

In summary, access to medication in import cases under CL has been limited in the EU. This needs to change to initiate receiving generic copies of the said-to-be effective patented pharmaceutical in cases of a health crisis. This is particularly crucial in cases where the EU would not be able to hold its ability of medicine innovation or when access to CL and the production of the generic copy of the patented medicine is made difficult due to the legal and policy restrictions.[189]

### 5.5.3 Export

Several parts of the TRIPS Agreement allow exporting of items manufactured under a CL. One such provision is Article 31bis of the TRIPS Agreement, which authorizes the export of items manufactured under a CL to countries with little or no capacity to manufacture the item in issue.

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[184] Tariq, M.U., Future Health Care and Medical Entrepreneurship in the Age of Pandemic, *In Medical Entrepreneurship: Trends and Prospects in the Digital Age*, 2023, p. 133-149.
[185] Gurgula, O., Compulsory licensing vs. the IP waiver: what is the best way to end the COVID-19 pandemic?, *Policy Brief*, *104*, 2021, p.4.
[186] Villa, S., Lombardi, A., Mangioni, D., Bozzi, G., Bandera, A., Gori, A. and Raviglione, M.C., The COVID-19 pandemic preparedness... or lack thereof: from China to Italy, *Global Health & Medicine, 2*(2), 2020, p.73-77.
[187] Perehudoff, K., Hoen, E.T. and Boulet, P., Overriding drug and medical technology patents for pandemic recovery: a legitimate move for high-income countries, too, *BMJ Global Health, 6*(4), 2021, p.1.
[188] De Campos-Rudinsky, op. cit., p. 11.
[189] Gurgula, op. cit., p.8.

It should be emphasized, however, that there are other choices. A CL may be issued under Article 31(f) of the TRIPS Agreement for the predominant supply of an item in the domestic market of the WTO member awarding the CL. This indicates that a non-predominant part[190] of the items produced under the CL may be exported.[191]

Additionally, If the WTO member of exportation patents the patented pharmaceutical authorized by the CL, a CL must also be granted in that country. Specifically, Paragraph 1 (b) of the Annex to Article 31bis highlights that at any time, a member can announce whether it plans to utilize CL in its whole or merely under limited circumstances, such as at times of national crisis or other essential significance, or for public non-commercial usage.[192]

Regardless, there are restrictions on the export of goods manufactured under a CL within the EU. In particular, EU authorities often need more competence to award cross-border CL for providing all or a subset of EU MS, as stated in the earlier subchapters. Given that there is no EU-wide exhaustion for national CL, the non-predominant part of pharmaceuticals for export outside the EU can solely be specified concerning the nation's market for which a national CL is granted.[193]

Hence, in addition to what is mentioned in Article 31bis of TRIPS, the EU Regulation (EC) No 816/2006 contains no further rules. Nonetheless, the rule can be clearer to promote using the CL for export mechanisms. Potential importers may need clarification on the variety of authorities across MS competent to grant CL under national patent law, as defined in Article 3 of Regulation (EC) No 2006/816. Verification methods may also be made more difficult by Section 2 of Article 10 of the regulation, which requires licensees to consider the total amount of product manufactured under all CL held by the licensee. Therefore, minimal coordination between EU MS could facilitate the implementation of the present procedure for CL for export and import and alleviate challenges created by different practices between MS.[194]

In essence, the existing EU rule on export can be problematic because, while it complies with the TRIPS Agreement's standards, it does not offer any further provisions or guidance.

[190] Non-predominant part: a measure to guarantee that the bulk of the items manufactured under the CLs is consumed in the issuing country's domestic market.
[191] European Commission's Study Report, op. cit., p.68-69.
[192] ibid., p.60.
[193] ibid., p.69.
[194] ibid., p.87.

The provisions set forth by the EC, as discussed in Chapter 3.4, allow for a Single Market. This encourages the transfer of patented pharmaceuticals between EU MS by encouraging export and importing within the EU to be easier through a harmonized CL mechanism throughout the Union. Hence, the initiative by the EC aims to change Regulation (EC) No 816/2006 to allow cross-border manufacturers to use EU CL. This would eventually allow for easier access to medicine throughout the borders of individual MS without the necessity of the law of export and import between MS.

Specifically, under the proposed regulation, Article 1 emphasizes that EU MS are provided with accessible medication in times of crisis.[195] Additionally, the proposal in Article 11 completely prohibits the export under CL without further justification for any exemptions.[196] This can be positive by limiting access to the patented pharmaceutical only to the CL holder, upholding IPRs. However, it can also be problematic in the sense that while this restriction may not affect the availability and use of CL in the EU, it does block imports of inexpensive supplies by other nations that might not have the appropriate manufacturing capabilities or means of access to medications, particularly in times of crisis. The EU should consider the potential of allowing exports to nations that can only sometimes create or produce their crisis-related pharmaceuticals.

The EU has previously standardized the procedures for the CL of pharmaceuticals to be exported to nations outside the EU with health hazards. Countries qualified for utilizing CL under Article 4 of Regulation (EC) No 816/2006 consist of LDCs, WTO members that have notified the Council for TRIPS of their intent to employ CL as an importer, and non-WTO countries that have been identified as low-income nations by the Organisation for Economic Co-operation and Development (OECD) Committee and have notified the EC of their intent to employ CL as an importer.[197] Consequently, several nations outside the EU currently possess medicinal products through CL. The proposed regulation ensures that pharmaceuticals can be exported with an EU-level CL. Thus, the scope is narrowed to encompass these items for export reasons.

However, when exporting a product to a country other than EU MS, the scope remains vague under the proposed regulation. This is because export matters to non-EU countries remain under domestically.

[195] Proposed Regulation on Compulsory Licensing, op. cit., art.1.
[196] ibid., art.11.
[197] Regulation (EC) No 2006/816, op. cit., art.4.

The persistent criticism from authorities of more economically stable nations, which are often more sympathetic to the objectives of pharmaceutical firms, is, in fact, one of the most challenging elements for countries with poor economies seeking to embrace flexibilities like CL. Specifically, the authorities of advanced nations such as the EU MS have taken action or warned of reprisals towards countries trying to implement flexibilities, generally in response to pressure from the marketing of pharmaceutical corporations.[198]

To address this, it may be required to include express authorization for exporting crisis-related pharmaceuticals to nations that legitimately require them during times of health concern in the proposed legislation to a greater extent at the EU level. Necessary medications typically outpace availability amid a crisis, such as the recent COVID-19 Pandemic, which has resulted in shortfalls and uneven reach to required pharmaceuticals to treat the virus. Specifically for LDCs and nations with low economies with a possibly small capacity to create or import these necessary medicines, this has proven especially problematic.[199]

The EU may assist in addressing these gaps and ensuring that every nation has access to crisis-related medicine by permitting the transfer of the products to countries that cannot obtain their own. This could promote the international collaboration and compassion necessary for tackling global health problems, specifically to reach SDG 3 and save lives. This is highly crucial, as developed nations, including all EU MS, to promote the SDGs and actively work towards achieving them.[200]

Additionally, by opening up new markets and possibilities for pharmaceutical firms to develop and supply vital goods, authorizing the export of crisis-related medications can support R&D in the pharmaceutical sector. This would further allow space for more efforts to be made to tackle health crises with more solitude from the EU.[201]

Respectively, it is crucial for the EC to first tackle and solve the issues within its border. It is only fair if it prioritizes its law before providing accessibility beyond its borders. This solitude can be in legislation that stands side by side with this regulation or, in a way, include the SDG

[198] Kumar, op. cit., p.57.
[199] Kumar et al., op. cit., p.68-87.
[200] Sakeena, M.H.F., Bennett, A.A. and McLachlan, A.J., Enhancing pharmacists' role in developing countries to overcome the challenge of antimicrobial resistance: a narrative review, *Antimicrobial Resistance & Infection Control, 7*(1), 2018, p.1-11.
[201] Bagley, M.A., The morality of compulsory licensing as an access to medicines tool, *Minnesota Law Review, 102*, 2017, p.2463.

efforts into the presented proposal for equity within the international arena. Henceforth, it is crucial to have a unified set of rules that explore where access to medicine is vital and work towards bridging the gap between the presence of pharmaceutical products with countries that genuinely need it, whether it is an EU MS or a country outside the EU.[202]

It is time to step back from generating individual gains, especially in cases of crisis and crucial requirements of medication.[203] Ultimately, the EU can provide a directive asking particular EU MS that have the potential capabilities to distribute patented pharmaceuticals under CL in areas where access to the specific pharmaceuticals is vital. The reason for suggesting a directive instead of a regulation goes back to the definition and purpose of the specific secondary law. Directives can be targeted to specific EU MS based on specific conditions that require implementation of rules into their domestic law, unlike regulation.[204] Hence, obtaining a directive that ensures access to medicine is vital for specific countries with a better possibility of affording medication. A directive requesting MS like France, as an example of an MS that can create top pharmaceutical innovations, to obtain medication under CL in cases of crisis is essential to further support the accessibility of medicine by the EU.[205]

## 3.6 Summary

The EU CL mechanism lacks harmonization, making medicine access difficult across the Union. It cannot issue CL at the Union level because EU MS obtains and run CL based on domestic law. This is problematic in a Single Market region. One way to address this is the EU might consolidate its CL procedures to create a common framework. In short, a harmonized CL system at the EU level is required to permit cross-border CL ramifications and overcome national rights limits.

[202] Xiao, Y., Norris, C.B., Lenzen, M., Norris, G. and Murray, J., How social footprints of nations can assist in achieving the sustainable development goals, *Ecological economics, 135*, 2017, p.55-65.
[203] Birdsall, N., Rodrik, D. and Subramanian, A., How to help poor countries, *Foreign Affairs*, 2005, p.136-152.
[204] Duina, F., Explaining legal implementation in the European Union, *International Journal of the Sociology of law*, 25(2), 1997, p.155-179.
[205] Boly, V., Morel, L., and Camargo, M., Evaluating innovative processes in French firms: Methodological proposition for firm innovation capacity evaluation, *Research Policy, 43*(3), 2014, p.608-622.

On that note, soft law measures like recommendations or best practices can encourage CL cooperation across MS. These initiatives would clarify laws and enable consistent health crisis responses. Soft law can temporarily address a lack of harmonization, especially in unexpected health risks requiring a quick response.

Additionally, a crisis requires unified action. Another solution can boost the EU's crisis response speed and cohesion. The EU should improve its IPR system and crisis management to improve CL's foundation. The EU's patent system's lack of uniformity and crisis management mechanism worsens the CL mechanism. Harmonizing several EU legal reasons, such as the UP system and EU-level crisis management, can solve these issues. First, the lack of a unified process for awarding CL with unitary effect undermines the goal of reducing administrative costs and disadvantages CL applicants compared to UP holders. Second, a health crisis law must clarify and help achieve results to be effective. This can be done by improving dialogue and connection between legal tools like CL for medicine access and crisis management.

Thus, if the EU centralizes some crisis response areas, it may be able to issue more specific and enforceable laws directing MS response activities. MS can improve their response by pooling resources and working together. Centralized regulation can streamline processes, reduce duplication, and spread best practices across the EU.

Centralizing regulatory activities and appointing a regulatory authority to establish CL use standards helps improve collaboration and assure fairness. Participation of stakeholders and the growth of existing organizations such as the ECN and the EMA can provide harmonization. In this context, the EC's proposed legislation intends to increase the accessibility and efficacy of EU laws.

However, centralization may have negative consequences, such as stifling the independence of individual MS and raising the EU's administrative load. However, with proper preparation and execution, a harmonized strategy for responding to crises may be an efficient means of enhancing harmonization at the Union level.

Respectively, the EC's proposed regulation ensures EU-level work. The proposed EU crisis management CL mechanism will ensure emergency access to essential products. It outlines Union-level CL requirements. Under the EU CL, the EC would license crisis-related product

innovation non-exclusively. Patent owners are compensated and can update, collaborate, and revoke CL. The proposal lets the EC issue EU-wide CL. IPRs and CLs help emergency patients get medication. Despite the general positivity the proposed regulation brings, it does not necessarily consider access to medicine in times of crisis for countries outside the EU that would require it.

The EU has limitations and needs improvement in importing and exporting under CL. The EU and its MS have opted out of importing pharmaceuticals during health emergencies under Article 31bis of the TRIPS Agreement, limiting their access to medications provided under CL. In the case of an unanticipated catastrophe, this constraint endangers public health. Due to limited industrial capacity and the worldwide effect of health problems like the COVID-19 Pandemic, nations, including the EU MS, must reevaluate their opt-out posture.

Similarly, MS collaboration is needed to speed up EU CL-manufactured exports. The EU needs more transparency to encourage CL pharmaceutical exports and enable shipments to nations with access to medicine requirements. The proposed EU-wide CL system would simplify medication access across MS without export and import regulations. Before exporting pharmaceuticals, the EU must resolve internal issues. EU exports of crisis-related pharmaceuticals may save lives, improve international collaboration, and aid pharmaceutical research and development. The SDGs are relevant, so the EU should prioritize its problems while closing the global medication gap. Directives targeting MS with enhanced capacities can provide medicine in critical locations and disasters.

# 4. Summary and Conclusion

This thesis examined EU CL and TRIPS Agreement rules. Results showed the Union's CL mechanism's shortcomings. Respectively, it suggested legal and policy changes to make health-related medication more accessible.

Two main points were gathered to answer the thesis's leading question. First, the current CL mechanism is efficient to a certain extent with quite vague and non-centralized grounds. This is because it lacks uniformity between EU MS, the legal grounds that drive parallel to CL are not as efficient, and there are issues with import and export. Despite that, efforts are being made; however, they are insufficient and require more time and resources. Second, the legal and policy implications that should be made to strengthen the CL mechanism for better medicine accessibility in times of crisis can be summarized as the following.

Initially, during a health crisis, Union-level soft law can address the lack of harmonization. This can collect EU MS and provide a target for an immediate crisis that may require a quick solution, like the COVID-19 Pandemic. This can facilitate cooperation and dialogue between MS without affecting their laws and policies. Long-term, this could be less efficient. Thus, enacting a binding law like regulation is crucial to improving the legal system.

Importantly, access to medicine is a top priority in health crises and emergencies, and that to ensure a unified legal system across the EU; it is necessary to set aside certain principles like the *Principle of Subsidiarity* and acknowledge the importance of union in times of absolute necessity. A harmonized platform beyond CL is needed to ensure EU MS union and uniformity. This includes better and more encouraging IPRs and patents across the EU, enhanced crisis management at the Union level, and the importance of centralizing power to the EU to establish a Single Market and ensure compliance of EU MS to better grounds presented to MS. The EU has taken effective steps to improve its system, including those with CL, such as the UP system, which will be implemented by June 2023 and improve the patent application, accessibility, and use across EU MS; Fixing one system requires fixing the other.

The new proposed regulation seeks to harmonize and issue EU-wide CLs. This significant advance addresses many long-term issues. It has flaws. One example is the lack of notice to export under CL to non-EU MS, WTO members, or other countries needing medicine.

This can be problematic. Initially, the EU has uncertainty with import and export under the mechanism. It is opted out to use any product issued by CL to be imported to any EU MS. This decision was made before the recent pandemic. The aftermath evidence of the pandemic initiated them to opt back in because a health crisis does not know of the type of economic state it is in. Because EU MS are developed, countries do not mean they are not affected by health crises.

Respectively, it is crucial to use this right and allow the movement of products to any place where medicine is an absolute necessity in times of crisis. This goes the other way around to export outside the EU of pharmaceuticals. When a health crisis strikes, LDCs, and economically challenging countries might not have the economic grounds to obtain medicine or their capability of resources and medical innovation, hindering medicine access negatively.

Thus, improving EU law requires prioritizing access to medicine over legal grounds that benefit the EU alone. This does not mean the EU should not advance its law and only start a medicine access system outside the Union. Instead, it must strengthen its legal grounds to improve its CL law and improve access to medicine within its territory and elsewhere in emergencies. This supports SDG 3 and the Right to Health in regard to HR compliance.

In conclusion, the EU has CL benefiting access to medicine to a limited extent, and many implications can be made to improve the system, such as providing legal grounds to harmonize EU MS.

It should be noted that the subject matter presented is in the development process. Following the COVID-19 Pandemic, the EU has implemented measures to enhance its efficiency. As a result, the present investigation of diverse resources and arguments has not taken into account recent endeavors to an extent, such as the EC's suggested regulation on 27 April 2023.

A potential avenue for future research could involve a comprehensive analysis of contemporary advancements while considering feedback from relevant constituents. An investigation into the degree of inconsistency between the recent legal and policy implications on CL and IPRs, and

HR would be of significant worth. This inquiry could be approached from the viewpoints of various stakeholders, including patent attorneys, pharmaceutical companies, HRs activists, and other pertinent actors. This approach would facilitate the expansion of the current thesis by conducting a more in-depth exploration of the topic once the subject matter has left the stage of development.

# Appendix A

## Doha Declaration Legal Stance

It is crucial to note that the Doha Declaration's legal standing has been debated. Some scholars argue it is not a legally binding document but rather a political statement that clarifies the interpretation of the TRIPS Agreement concerning public health.[206] However, others argue the contrary and believe the declaration to serve as a legally binding document.[207] Regardless of this debate, the declaration provides clarification and adds a fruitful context to the recognition of the TRIPS Agreement, especially when trying to understand TRIPS flexibilities such as CL. It has legal significance as it forms part of the WTO Agreements and has been incorporated into the WTO's legal framework. This enables and provides WTO MS, which includes the EU and its MS, with a legal basis to take measures to protect public health and access to medicines, particularly in the context of public health crises.[208]

[206] Charnovitz, S., The legal status of the Doha Declarations, *Journal of International Economic Law, 5*, 2002, p.207.
[207] Gathii, J., The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties, *Harvard Journal of Law and Technology, 15*, 2002, p.291.
[208] Charnovitz, S., The legal status of the Doha Declarations, *Journal of International Economic Law, 5*, 2002, p.207.

# Appendix B

## Human Rights Law on the Subject Matter

The ICESCR is one of the most essential and legally binding.[209] This convention is developed in the context of a nonbinding yet quite crucial document in upholding HR: the Universal Declaration of Human Rights (UDHR). On that note, Article 25 of the UDHR includes medical care, among other points, highlighting the cruciality of the right to health.[210]

Additionally, Article 12.1 of the ICESCR explicitly states that everyone is entitled to the best possible state of physical and mental wellness, and the states parties[211] to this convention acknowledge this privilege.[212] Specifically, Article 12.2 (C) of the convention states all required measures for the avoidance, treatment, and management of outbreaks, endemics, occupational, and other illnesses shall be implemented by state parties to ensure the complete fulfillment of this right.[213]

The UNHCR has clarified the notions of Article 12 of the ICESCR that the entitlements consist of the right to a healthcare system that offers an equal chance for all individuals to achieve the best possible degree of health, which includes access to vital medication. Respectively, it is ensured that accessibility of health care and health products, which include medication, and services are crucial, and its state parties should take into account non-discrimination, physical accessibility, economic accessibility, and information accessibility.[214] The commission has further clarified that the right to treatment, which takes into account access to medicine, encompasses the establishment of an immediate medical care infrastructure in the event of

[209] Backman, G., Hunt, P., Khosla, R., Jaramillo-Strouss, C., Fikre, B.M., Rumble, C., Pevalin, D., Páez, D.A., Pineda, M.A., Frisancho, A., and Tarco, D., Health systems and the right to health: an assessment of 194 countries, *The Lancet, 372*(9655), 2008, p.2047.
[210] United Nations General Assembly, *The Universal Declaration of Human Rights* (hereinafter UDHR), 1948, art.25.
[211] State-party: A sovereign nation that has ratified, accepted, approved, or acceded to a particular convention or treaty.
[212] ICESCR, op. cit., art. 12.1.
[213] ibid., art. 12.2(C).
[214] United Nations Committee on Economic, Social and Cultural Rights, *General Comment No. 14: The Right to the Highest Attainable Standard of Health*, 2000, art.12.

mishaps, diseases, or other health risks, as well as the supply of aid in emergency circumstances.[215]

Moreover, Article 27 of the UDHR states that everyone has a right to the defense of the economic and moral interests arising from any creative, literary, or scientific work that they have contributed to. Key concepts include the quest for information and the need to adapt creatively to an ever-evolving environment. Following, the article requires creating a setting in which individuals can participate in intellectual inquiry and may question, research, and contribute notions, which may include the development of new pharmaceuticals.[216]

This has also been introduced under Article 15.1 (c) of the ICESCR, which shines the light on the right to participate in cultural life and enjoy the advantages of scientific advancement and its applications must be considered alongside IPRs.[217] Article 15.2 of ICESCR furthermore mandates states to take measures to preserve, advance, and disseminate scientific knowledge and cultural traditions. IP regimes should help achieve these objectives if they are to be compatible with an HRs-based guideline.[218]

[215] ibid., art.12.
[216] UDHR, op. cit., art.27.
[217] ICESCR, op. cit., art.15.1.
[218] ibid., art.15.2.

# Bibliography

## Official Publications

European Commission, *Compulsory licensing of intellectual property rights: final study report*, 2023.

European Commission, *Proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006*, 2023.

European Union, *Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matter within its competence of the agreements reached in the Uruguay Round multilateral negotiations*, 1994.

United Nations General Assembly, *The Universal Declaration of Human Rights*, 1948.

United Nations, *The 2030 Agenda and the Sustainable Development Goals*, 2015.

World Trade Organization, *Ministerial Declaration of 14 November 2001; Doha Declaration*, 2001.

World Trade Organization, *Ministerial Decision of 6 December 20200; on the TRIPS Agreement*, 2022.

## Cases

European Court of Justice, *Case 15-74 Centrafarm v. Sterling Drug*, 1974.

European Court of Justice, *Case C-414/11 Daiichi Sankyo and Sanofi-Aventis Deutschland*, 2013.

European Court of Justice, *Case 78-70 Deutsche Grammophon v. Metro S*B, 1971.

European Court of Justice, *Case 19/84 Pharmon v. Hoechst*, 1985.

European Court of Justice, *Case 26/62 Van Gend & Loos*, 1963.

## Literature

Abbas, M.Z., COVID-19 and the Issue of Affordable Access to Innovative Health Technologies: An Analysis of Compulsory Licensing of Patents as a Policy Option, *In Law and Economics of the Coronavirus Crisis*, 2022.

Abdalla, S.M., Chua, A., De Foo, C., Haldane, V., Jung, A.S., Perez, T., Shrestha, P., Singh, S., Tan, M., Verma, M., and Wu, S., Health systems resilience in managing the COVID-19 pandemic: lessons from 28 countries, *Nature Medicine, 27*(6), 2021.

Ansell, C., Boin, A., and Keller, A., Managing transboundary crises: Identifying the building blocks of an effective response system, *Journal of Contingencies and Crisis Management, 18*(4), 2010.

Backman, G., Hunt, P., Khosla, R., Jaramillo-Strouss, C., Fikre, B.M., Rumble, C., Pevalin, D., Páez, D.A., Pineda, M.A., Frisancho, A., and Tarco, D., Health systems and the right to health: an assessment of 194 countries, *The Lancet, 372*(9655), 2008.

Bagley, M.A., The morality of compulsory licensing as an access to medicines tool, *Minnesota Law Review, 102*, 2017.

Batista, P.H.D., Correa, J.I., Hilty, R., Kim, D., Lamping, M., Slowinski, P.R., and Steinhart, M., Revisiting the Framework for Compulsory Licensing of Patents in the European Union, *Max Planck Institute for Innovation & Competition Research Paper*, 2023.

Bayleyegn, T.M., Schnall, A.H., Ballou, S.G., Zane, D.F., Burrer, S.L., Noe, R.S., and Wolkin, A.F., Use of community assessments for public health emergency response to rapidly assess public health issues, *Prehospital and Disaster Medicine, 30*(4), 2015.

Bennett, A.A., McLachlan, A.J., and Sakeena, M.H.F., Enhancing pharmacists' role in developing countries to overcome the challenge of antimicrobial resistance: a narrative review, *Antimicrobial Resistance & Infection Control, 7*(1), 2018.

Birdsall, N., Rodrik, D., and Subramanian, A., How to help poor countries, *Foreign Affairs*, 2005.

Bole, A., Soft law in international law-making, *International Law, 5,* 2014.

Boyer, C.A., and Lutfey, K.E., Examining critical health policy issues within and beyond the clinical encounter: patient-provider relationships and help-seeking behaviors, *Journal of Health and Social Behavior, 51*, 2010.

Boly, V., Morel, L., and Camargo, M., Evaluating innovative processes in French firms: Methodological proposition for firm innovation capacity evaluation, *Research Policy, 43*(3), 2014.

Cavaleri, M., Sweeney, F., Gonzalez-Quevedo, R., and Carr, M., Shaping EU medicines regulation in the post-COVID-19 era, *The Lancet Regional Health-Europe, 9*, 2021.

Casola, A., Kelly, E., Smith, K., Kelly, S. and de la Cruz, M.S., Impact of the COVID-19 Pandemic on Medical Students' Perceptions of Health Care for Vulnerable Populations, *Family Medicine*, 2023.

Charnovitz, S., The legal status of the Doha Declarations, *Journal of International Economic Law, 5*, 2002.

Correa, J.I., Hilty, R., Kim, D., Lamping, M., Batista, P.H.D., Slowinski, P.R., and Steinhart, M., Revisiting the Framework for Compulsory Licensing of Patents in the European Union, *Max Planck Institute for Innovation & Competition Research Paper*, 2023.

Cygan, A., Regional governance, subsidiarity, and accountability within the EU's multi-level polity, *European Public Law, 19*(1), 2013.

Davies, K., Van Munster, M., and Düsterhöft, I., *Understanding European Union Law*, 2022.

De Campos-Rudinsky, T.C., Intellectual property and essential medicines in the COVID-19 pandemic, *International Affairs, 97*(2), 2021.

De Foo, C., Abdalla, S.M., Chua, A., Haldane, V., Jung, A.S., Perez, T., Shrestha, P., Singh, S., Tan, M., Verma, M., and Wu, S., Health systems resilience in managing the COVID-19 pandemic: lessons from 28 countries, *Nature Medicine, 27*(6), 2021.

Duina, F., Explaining legal implementation in the European Union, *International Journal of the Sociology of Law, 25*(2), 1997.

Easterbrook, F.H., Intellectual property is still property, *Harvard Journal of Law and Public Policy, 13*, 1990.

Estella de Noriega, A., The EU principle of subsidiarity and its critique, *Oxford University Press*, 2002.

Fabbrini, F., The principle of subsidiarity, *Oxford Principles of EU Law*, 2016.

Fatma, A., Bharti, N., and Kumar, M., Access to Medicines and Medical Equipment during COVID-19: Searching Compatibility between the WTO and the WHO, *India Quarterly, 78*(1), 2022.

Gathii, J., The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties, *Harvard Journal of Law and Technology, 15*, 2002.

Gold, E.R., What the COVID-19 pandemic revealed about intellectual property, *Nature Biotechnology, 40*(10), 2022.

Gori, A., Villa, S., Lombardi, A., Mangioni, D., Bozzi, G., Bandera, A., and Raviglione, M.C., The COVID-19 pandemic preparedness... or lack thereof: from China to Italy, *Global Health & Medicine, 2*(2), 2020.

Grafström, R.C., Bekker, C., Dekkers, S., Groenewold, M., Hadzhiyski, Y., Herbeck-Engel, P., Hoehener, K., Karagiozakis, V., Kelly, S., and Soeteman, L.G., Safe innovation approach: Towards an agile system for dealing with innovations, *Materials Today Communications, 20*, 2019.

Gurgula, O., Compulsory licensing vs. the IP waiver: what is the best way to end the COVID-19 pandemic?, *Policy Brief, 104*, 2021.

Haldane, V., De Foo, C., Abdalla, S.M., Jung, A.S., Tan, M., Wu, S., Chua, A., Verma, M., Shrestha, P., Singh, S., and Perez, T., Health systems resilience in managing the COVID-19 pandemic: lessons from 28 countries, *Nature Medicine, 27*(6), 2021.

Henry, C., and Stiglitz, J.E., Intellectual property, dissemination of innovation and sustainable development, *Global Policy, 1*(3), 2010.

Hoen, E., TRIPS, pharmaceutical patents, and access to essential medicines: a long way from Seattle to Doha, *Chicago Journal of International Law, 3*, 2002.

Holman, C.M., Minssen, T. and Solovy, E.M., Patentability standards for follow-on pharmaceutical innovation, *Biotechnology Law Report, 37*(3), 2018.

Hu, W., Compulsory licensing and access to future Covcines, *Centre for European Policy Studies*, 2020.

Jaluzot, B., The Legal Framework Of Intellectual Property Rights In Comparative Law: Japan–France, Dynamics Of Regional Innovation, *The Policy Challenges In Europe And Japan, 10*, 2011.

Klabbers, J., The undesirability of soft law, *Nordic Journal of International Law, 67*, 1998.

Kiesling, K., The European Patent with Unitary Effect-a Unitary Patent Protection for a Unitary Market?, *UCL Journal of Law and Jurisprudence, 2*, 2013.

Kumar, A., Kumar, S., and Nanda, A., A review about regulatory status and recent patents of pharmaceutical co-crystals, *Advanced Pharmaceutical Bulletin, 8*(3), 2018.

Kumar, S., Compulsory licensing of patents during pandemics, *Connecticut Law Review, 54*, 2022.

Lamping, M., Batista, P.H.D., Correa, J.I., Hilty, R., Kim, D., Slowinski, P.R., and Steinhart, M., Revisiting the Framework for Compulsory Licensing of Patents in the European Union, *Max Planck Institute for Innovation & Competition Research Paper,* 2023.

Lee, S.K., Mahl, S.K., Green, J.J., and Lexchin, J., Multinational Pharmaceutical Companies Shortchange Canada in Research and Development Investments: Is It Time to Pursue Other Options?, *Healthcare Policy, 18*(3), 2023.

Lieblich, E., How to Do Research in International Law? A Basic Guide for Beginners, *A Basic Guide for Beginners*, 62. 2020.

Liu, C., Beyond Compulsory Licensing: Pfizer Shares its COVID-19 Medicines with the Patent Pool, *New York University Journal of Legislation & Public Policy, 25*(1), 2023.

Liu, C., Zhou, Q., Li, Y., Garner, L.V., Watkins, S.P., Carter, L.J., Smoot, J., Gregg, A.C., Daniels, A.D., Jervey, S., and Albaiu, D., *Research, and development on therapeutic agents and vaccines for COVID-19 and related human coronavirus diseases,* 2020.

Liu, J., Compulsory Licensing and Anti-Evergreening: interpreting the TRIPS flexibilities in sections 84 and 3 (d) of the Indian Patents Act, *Harvard International Law Journal, 56*, 2015.

Marques, J.R., Biotechnological Patents, Compulsory Licensing, and SARS-COV-2 in a Pandemic and Epidemic Context, *Blue Planet Law*, 2023.

Maume, P., Compulsory licensing in Germany, *In Compulsory Licensing: Practical Experiences and Ways Forward*, 2014.

Oser, A., The COVID-19 Pandemic: Stress Test for Intellectual Property and Pharmaceutical Laws, *GRUR International, 70*(9), 2021.

Paquin, S., and Plouffe-Malette, K., *The WTO and the Covid-19 "vaccine apartheid": Big pharma and the minefield of patents, Politics and Governance*, *11*(1), 2023.

Perehudoff, K., Hoen, E.T. and Boulet, P., Overriding drug and medical technology patents for pandemic recovery: a legitimate move for high-income countries, too, *BMJ Global Health, 6*(4), 2021.

Reichman, J.H., Comment: compulsory licensing of patented pharmaceutical inventions: evaluating the options, *Journal of Law, Medicine & Ethics*, *37*(2), 2009.

Ruse-Khan, H.G., The international law relation between TRIPS and subsequent TRIPS-plus free trade agreements: towards safeguarding TRIPS flexibilities, *Journal of Intellectual Property Law, 18*, 2010.

Rutschman, A., Ministerial Decision on the Trips Agreement (WTO), *International Legal Materials, 62*(2), 2023.

Sagan, A., Erin, W., Dheepa, R., Marina, K. and Scott, L.G., Health system resilience during the pandemic: It's mostly about governance, *Euro health, 27*(1), 2021.

Sakeena, M.H.F., Bennett, A.A., and McLachlan, A.J., Enhancing pharmacists' role in developing countries to overcome the challenge of antimicrobial resistance: a narrative review, *Antimicrobial Resistance & Infection Control, 7*(1), 2018.

Singh, K.K., Patent and Pandemic: Exploring Duties, Obligations, and Responsibilities, *In Relevance of Duties in the Contemporary World: With Special Emphasis on Gandhian Though*t, 2023.

Soeteman, L.G., Apostolova, M.D., Bekker, C., Dekkers, S., Grafström, R.C., Groenewold, M., Hadzhiyski, Y., Herbeck-Engel, P., Hoehener, K., Karagiozakis, V., and Kelly, S., Safe innovation approach: Towards an agile system for dealing with innovations, *Materials Today Communications, 20*, 2019.

Stavropoulou, C., and Valletti, T., Compulsory licensing and access to drugs, *The European Journal of Health Economics, 16*, 2015.

Tariq, M.U., Future Health Care and Medical Entrepreneurship in the Age of Pandemic, *In Medical Entrepreneurship: Trends and Prospects in the Digital Age*, 2023.

Sun, Y., Liu, T., Ye, T., and Shi, P., Coordination and cooperation are essential: a call for a global network to enhance integrated human health risk resilience based on China's COVID-19 Pandemic coping practice, *International Journal of Disaster Risk Science, 12*, 2021.

Tenni, B., Moir, H.V., Townsend, B., Kilic, B., Farrell, A.M., Keegel, T., and Gleeson, D., What is the impact of intellectual property rules on access to medicines? A Systematic Review, *Globalization and Health, 18*(1), 2022.

Vawda, Y.A., Compulsory Licenses, and Government Use: Challenges and Opportunities, *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law*, 2022.

Villa, S., Lombardi, A., Mangioni, D., Bozzi, G., Bandera, A., Gori, A. and Raviglione, M.C., The COVID-19 pandemic preparedness... or lack thereof: from China to Italy, *Global Health & Medicine, 2*(2), 2020.

Xiao, Y., Norris, C.B., Lenzen, M., Norris, G., and Murray, J., How social footprints of nations can assist in achieving the sustainable development goals, *Ecological Economics, 135*, 2017.

Zaheer, M., Pros and cons of compulsory licensing: An analysis of arguments, *International Journal of Social Science and Humanity, 3*(3), 2013.

## Online Sources

European Commission, Better Regulation: why and how, *European Commission Webpage*, retrieved from: https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation_en#objectives-of-the-better-regulation-agenda, last access 29 April 2023.

European Commission, Crisis-proofing the Single Market: equipping Europe with a robust toolbox to preserve free movement and availability of relevant goods and services, *European Commission Webpage*, 2022, retrieved from: https://ec.europa.eu/commission/presscorner/detail/en/ip_22_5443, last access 1 May 2023.

European Commission, European Chips Act, *European Commission Webpage, 2022,* retrieved from:https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/european-chips-act_en, last access 1 May 2023.

European Commission, Health Emergency Preparedness and Response Authority, *European Commission Webpage*, 2022, retrieved from:

https://commission.europa.eu/about-european-commission/departments-and-executive-agencies/health-emergency-preparedness-and-response-authority_en, last access 1 May 2023.

European Commission, Internal Market, Industry, Entrepreneurship, and SMEs, *European Commission Webpage*, 2023, retrieved from: https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/unitary-patent-system_en#:~:text=The%20unitary%20patent%20is%20a,a%20single%2C%20specialised%20patent%20jurisdiction, last access 1 May 2023.

European Commission, Questions and Answers on Compulsory Licensing, *European Commission Webpage*, 2023, retrieved from: https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_2456, last access 1 May 2023.