The European Commission´s initiative for centralised compulsory licences – An adequate approach with (global) potential?

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Abstract

The Covid-19 crises had major impacts all over the world in many different areas. It also triggered legal reforms worldwide. One of these projects is an initiative of the European Commission which seeks to introduce a system of EU-wide centralised compulsory licences for patents. The overall aim here is to make the EU fit to tackle upcoming crisis situations where patents could play a crucial role, mirroring the situation in the Covid-19 crisis. The general concept of the initiative is to take away the problems which the current fragmented system of national compulsory licences creates by consolidating the process on the EU level.

The paper will analyse the approach the European Commission put forward with respect to an efficiency benchmark. It arrives at the conclusion that the proposal is overall to be welcomed, while some adjustments should be made during the ongoing legislative process. It will also be argued that the very sensible approach to centralise compulsory licences in the EU could be used in more than just crisis situations. The paper suggests widening the scope to other circumstances to make the most out of the excellent idea.

The thesis will also propose to scale the approach of the European Commission up to the global level. It puts forward the concept of introducing a centralised process for the granting of compulsory licences at the World Trade Organisation (WTO). In doing so, the paper will also lay out some of the characteristics of the proposed system. It suggests that it should not be narrowed to crisis situations and that the decisions should be taken by a body whose structure could be based on that of the Appellate Body of the WTO.

Keywords: Compulsory licences; patents; centralisation; European Commission; World Trade Organisation

This dissertation is dedicated to my girlfriend, Luzia, who made not only the year in Malta to the best time of my life. This work is also dedicated to my parents, Ursula and Heinrich, for their constant support, love, and guidance which made me the person I am today.

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Table of Abbreviations

AI	Artificial Intelligence
CJEU	Court of Justice of the European Union
CL	Compulsory Licence
EC	European Commission
ECHR	European Convention for the Protection of Human Rights and Fundamental Freedoms
EMA	European Medicines Agency
EPC	European Patent Convention
EPO	European Patent Office
EST	Environmental Sound Technologies
EU	European Union
IP	Intellectual Property
MPI	Max Plank Institute
NGO	Non-Government Organisation
R&D	Research and Development
Rec.	Recital
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UPCA	Unified Patent Court
WTO	World Trade Organisation
WWI	World War I

A. Introduction

I. Background

Intellectual property law and especially patent law is a dazzling topic which gets hotly debated all over the world. This is not only because of its enormous economic importance but also due to fundamental questions it raises: How can fairness between developed and developing countries be achieved? How can the world make sure that all human beings have access to live saving medicines and technology? How can inventions which help to tackle the issues of climate change be made available all over the globe? How can it be ensured that the world is ready to deal with major crises? To sum it up: 'It is not an exaggeration to state that intellectual property rights are a matter of life or death.'[1]

To solve these questions, many see the instrument of compulsory licensing as a helpful tool because they break the exclusivity a patent holder enjoys regarding the protected invention. This exclusivity, which is enshrined in global treaties like the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Paris Convention for the Protection of Industrial Property, grants the right holder the possibility to exclude everyone from using his or her invention. Hence, it is possible that very crucial technologies cannot be used in the most critical situations. Here, compulsory licences come into play. They are commonly defined in the following way: 'A compulsory licence is an authorisation granted by a government to a party other than the patent holder to use a patented invention without the consent of the patent holder.'[2] They are, like patent protection itself, known to the just mentioned international treaties, but they have to be issued by every country separately. That can create huge or even insurmountable obstacles regarding their granting. The newest development in this area is the proposal of the European Commission (EC) for a centralisation of the issuing of

[1] Christopher May and Susan K. Sell, *Intellectual Property Rights: A Critical History* (Lynne Rienner 2006) 1.
[2] Commission, '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' SWD(2023) 121 final, 4. That definition is also recognized in literature, see e.g. Gianna Julian-Arnold, 'International Compulsory Licensing: The Rationales and the Reality' (1993) 33 IDEA 349, 349; Anja Eikermann, 'Art 31: Other use Without the Authorization of the Right Holder' in Stoll, Busche and Arend (ed), *WTO—Trade-Related Aspects of Intellectual Property Rights* (Brill 2009).

compulsory licences on the EU level.[3] Although the proposal is only applicable in crisis situations, it marks – as will be shown – a major step in the development of the institute of compulsory licences. This is where this dissertation comes in.

II. Aim, relevance, and limits of the dissertation

This paper wants to dive into the concept of the centralisation of compulsory licences. In doing so, it has three main goals. First, it should be assessed whether the EU proposal is fit for its purpose, which is dealing with crises situations. It is also a concern of this work to highlight possible potential for improvement which might help in the ongoing legislative process. Second, it should be demonstrated that centralised compulsory licences are a valuable instrument to deal with some of the major issues of the current international patent system. Third, the dissertation will propose the idea to create a system of centralised compulsory on a global level and will lay out some cornerstones of such a system.

The relevance of this paper can be derived from the enormous problems the current international patent law system creates. It is for instance often argued that it favours the developed countries while not taking the most vulnerable people into account.[4] This debated popped up again during the Covid-19 crises where access to vaccines and medicines was at times only given in the developed world.[5] Compulsory licences, which are supposed to help with these issues, are at the same time rarely used. This dissertation argues that this is at least partially because there is no centralised granting procedure. To research this institute is therefore from utmost importance to deal with major problems of humanity.

But it is also essential to describe the limits of the dissertation what might even help to initiate further research. In that regard, it can be mentioned that the feasibility of creating the proposed international centralised compulsory licencing system must be

[3] 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' COM(2023) 224 final.
[4] See regarding this debate e.g. Evelyn Su, 'The Winners and the Losers: the Agreement on Trade-Related Aspects of Intellectual Property Rights and Its Effects on Developing Countries' (2000) 23 Hous. J. Int'l L. 1; Ruth L. Gana, 'Prospects for Developing Countries Under the TRIPs Agreement' (1996) 29 Vanderbilt Journal of Transnational Law 735.
[5] See e.g. Editorial, 'A patent waiver on COVID vaccines is right and fair' (2021) 593 Nature 478.

assessed from the perspective of political science and is therefore in principle out of the scope of this paper, but always kept in mind. Due to the word limitation, it is also not possible to lay out all the necessary components of the proposed international system. The research has to be limited to major points. What is also left out is the related topic of regulatory exclusivities for medicines which deals at its core with the use of research data in the approval process for pharmaceuticals.[6]

III. Literature review

The EU proposal got accompanied by several publications which deal with its overall approach and also its specific characteristics. The first contribution to mention here is a paper by researchers from the Max Plank Institute (MPI) who welcome the proposal but recommend widening its scope of application to other situations than just crisis's and suggest other more specific adjustments.[7] *Ellen ´t Hoen* is also concerned with the proposal and is in general in favour of it. But she also suggests a broader application and presents ideas for adaptations.[8] Another academic which deals with the developments on the EU level is *Olga Gurgula*. She for instance puts forward adjustments regarding the inclusion of trade secrets, the involvement of the patent holders in the granting process, and the export of medicines to third countries.[9] A major study regarding compulsory licences on the EU level was carried out by *Bruno Vandermeulen* and his co-authors for

[6] An analysis can be found by Laura Valtere, 'The interface between patents and regulatory exclusivities and the view on the new EU proposals concerning patent compulsory licensing and regulatory exclusivities' (2023) University of Luxembourg Research Paper No. 2023-015 <https://ssrn.com/abstract=4591220> accessed 19 August 2024.

[7] Matthias Lamping et al., 'Revisiting the Framework for Compulsory Licensing of Patents in the European Union' (2023) Max Planck Institute for Innovation & Competition Research Paper No. 23-07 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4381959> accessed 19 August 2024.

[8] Ellen ´t Hoen, 'The European Commission's proposal for an EU wide compulsory licensing mechanism' (*Medicines Law and Policy*, 27 April 2023) <https://medicineslawandpolicy.org/2023/04/the-european-commissions-proposal-for-an-eu-wide-compulsory-licensing-mechanism/> accessed 19 August 2024; Ellen ´t Hoen, 'The European Commission's compulsory licensing proposals are sensible but do not go far enough' (*Medicines Law and Policy*, 9 August 2023) <https://medicineslawandpolicy.org/2023/08/the-european-commissions-compulsory-licensing-proposals-are-sensible-but-do-not-go-far-enough/> accessed 19 August 2024; Ellen ´t Hoen 'Something is going terribly wrong with the EU Compulsory Licensing Regulation' (*Medicines Law and Policy,* 12 March 2024) <https://medicineslawandpolicy.org/2024/03/something-is-going-terribly-wrong-with-the-eu-compulsory-licensing-regulation/> accessed 19 August 2024.

[9] Olga Gurgula*,* 'On the European Commission´s proposal to create a new EU-wide compulsory licensing regime' (2023) <https://ssrn.com/abstract=4552851> accessed 19 August 2024; Olga Gurgula, 'The new EU compulsory licensing regime needs to allow the export of medicines' (*Medicines Law and Policy*, 27 November 2023) <https://medicineslawandpolicy.org/2023/11/the-new-eu-compulsory-licensing-regime-needs-to-allow-the-export-of-medicines/> accessed 19 August 2024.

the DG GROW.[10] It concluded that they are the best policy option to have as a method of last resort in the backhand when it comes to tackling the problem of using patented inventions in a crisis situation.

The mentioned publications build an excellent starting point for the present research. They shed light on many characteristics of the proposal and uncover some of its weaknesses. This dissertation will build on these findings and develop them further by putting forward new arguments and by taking a different viewpoint on the discussed issues.

Regarding the second major block of this thesis – the transfer of the proposal to the global level –, less research is available. There have been calls to harmonise the complete patent law system on a global level even further,[11] but they don´t deal with compulsory licences specifically. Regarding this institute, some reforms of the relevant article in the TRIPS Agreement have been proposed.[12] However, they don´t have a centralisation in mind. Instead, they deal with other procedural aspects. Although the idea to set up an international system to coordinate the granting of compulsory licences in cross-border situations got already mentioned briefly by *Deli Yang*[13], it was – as far as can be seen – not further elaborated. To create a completely centralised system for compulsory licences on the global level got – as far as apparent – not proposed till today. Hence, this paper is likely to be novel in that regard.

IV. Methodology

In answering the research questions, the thesis utilizes a legal policy approach. The research goals cannot be achieved by exclusively focusing on the interpretation of the relevant legal text ("black letter approach"). This does not mean that this fundamental method is not applied in this thesis, but it is not at its centre. It merely helps to

[10] Bruno Vandermeulen et al. 'Compulsory Licensing of Intellectual Property Rights' (2023) Study commissioned by DG GROW <https://data.europa.eu/doi/10.2873/514> accessed 19 August 2024.
[11] E.g. Ben McEniery, 'The Time is Nigh: A Proposal for an International Patent System' (2016), 16 Chi. - Kent J. Intell. Prop. 167; Randy Cambpell, 'Global Patent Law Harmonization: Benefits and Implementation' (2023) 13 Ind. Int'l & Comp. L. Rev. 605.
[12] Ezinne Mirian Igbokwe and Andrea Tosato, 'Access to Medicines and Pharmaceutical Patents: Fulfilling the Promise of TRIPS Article 31Bis' (2023) 91 Fordham Law Review 1791, 1843 ff.
[13] Deli Yang, 'Compulsory Licensing: For Better or For Worse, the Done Deal Lies in the Balance' (2012) 17 Journal of Intellectual Property Rights 76, 81.

understand the current and proposed rules in some situations and therefore assists the legal policy analysis. In this assessment, it is important to define the relevant benchmark against which the proposal should be tested. Here, the chosen benchmark is the question whether the proposal achieves its goals efficiently.

When it comes to the proposed international centralised compulsory licensing system, it is important to show off the current problems in international patent law. Subsequently, it can be elaborated on how these issues can be solved.

V. Structure of the dissertation

The paper is divided in four sections. In the first section, the historic development of international patent law and especially of compulsory licences, which led to the current EU proposal, will be outlined. The second section will describe the system and the main characteristics of the EU proposal as far as that is necessary for the following analysis. After that, in third section the EU proposal will be assessed based on the already mentioned benchmark. Lastly, in the fourth section a global centralised compulsory licencing scheme, which is based on the ideas of the EU proposal, will be laid out.

B. Section 1: A look in the rear-view mirror: how we arrived at the current status

No legislative proposal is created in vacuum. There are almost always laws in place which regulate the area of a "law to be" or at least affect its supposed area of application. That is also true for the proposal of the Commission which is at the heart of this paper. To acquire a deep understanding of a new law, it is always helpful to look at the related statutes and discussions that came before it. But in the case at hand, it is especially important for this dissertation as it will argue that the adoption of the proposal would be the next logical step in the overall historic development of international patent law regarding compulsory licencing. It will moreover suggest in section four the further level of this "natural" development.

I. The debate on compulsory licences: A centuries old discussion

Patents were mainly "invented" to promote innovation, economic growth and in general inventions which are useful to society.[14] The idea behind this can be summarised as follows: The patent system fosters innovation 'by giving the innovator an exclusive legal right to the economic exploitation of his innovation for a period of time; the reaping of profits serves both to reward the innovator for his investment and to induce others to strive to innovate in the future.'[15] So much for the social benefits of patent protection. But intellectual property rights like patents have a downside: They create a pseudo[16] monopoly for the patent holder, which can cause a variety of problems.[17] From difficulties in the field of competition law over a possible slowdown of innovation towards the withholding of extremely societal relevant products. To compensate for this

[14] See e.g. Edwin C. Hettinger, 'Justifying Intellectual Property' (1989) 18 Philosophy & Public Affairs 31, 47 ff.; Julian-Arnold (n 2) 357; Susy Frankel and Jessica C. Lai, 'Recognised and Appropriate Grounds for Compulsory Licences: Reclaiming Patent Law's Social Contract' in Reto M. Hilty and Kung-Chung Liu (eds), *Compulsory Licensing Practical Experiences and Ways Forward* (Springer 2015) who also lay an emphasis on the publication of the patent. Nevertheless, this theory is sometimes criticized, see e.g. Adam D. Moore, 'Intellectual property, innovation, and social progress: the case against incentive based arguments' (2003) 26 Hamline Law Rev 602.

[15] OECD Competition Committee, 'Competition policy and intellectual property rights' (1989) 10 <https://www.oecd-ilibrary.org/docserver/49d5957f-en.pdf?expires=1721211409&id=id&accname=guest&checksum=D502B2C7D739DA620F91DF6FC70ABFB1> accessed 19 August 2024.

[16] Pseudo because they in theory do not prevent others from offering products, Frankel and Lai (n 14).

[17] See e.g. Colleen Chien, 'Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?' (2003) 18 Berkeley Tech LJ 853, 858; Muhammad Zaheer Abbas and Shamreeza Riaz, 'Evolution of the concept of compulsory licensing: A critical analysis of key developments before and after TRIPS' (2013) 4 Academic Research International 482, 483 f.

tension, one instrument is the institute of compulsory licences. It works as a safeguard to the system by taking the use of the patent outside the will of its holder.[18]

Compulsory licences have a rich history dating back to the inception of formalised patent systems. They were addressed in the world's first patent framework in Venice in the fifteenth century, where the state had the right to obtain one.[19] Compulsory licences are also dealt with in the English Statute of Monopolies from 1623.[20] Here they were related to the non-use of a patent.[21] This idea of a working obligation spread to different countries afterwards.[22] In the nineteenth century – when intellectual property became ever more important – compulsory licences were known to almost all national IP-rules (except the US), which formed a diverse patchwork.[23] European countries especially popularised compulsory licensing under the anti-patent movements in the 1850s.[24] As a result of this development, the UK for example adopted a compulsory licencing system under the Patent Act of 1883 for cases in which the patent was not being worked in the UK, the reasonable requirements of the public with respect for the invention were not supplied, or any person was prevented from working or using an invention.[25]

The famous Paris Convention[26] (also from 1883) accepted a 'working obligation' for patents, despite opposition from the US and other countries (see Art. 5 of the Paris Convention).[27] But it did not mention any form of compulsory licensing.[28] It was the

[18] Abbas and Riaz (n 17) 482. With respect to the access to pharmaceuticals see e.g. Beatrice Stirner and Harry Thangarja, 'Learning from practice: compulsory licensing cases and access to medicine' (2013) 2 Pharmaceutical Patent Analyst 195, 195.
[19] May and Sell (n 1) 58.
[20] Abbas and Riaz (n 17) 484.
[21] Van Anh Le, *Compulsory Patent Licensing and Access to Medicines: A Silver Bullet Approach to Public Health?* (Palgrave Macmillan 2022) 52.
[22] ibid.
[23] ibid; May and Sell (n 1) 111.
[24] Yang (n 13) 77.
[25] David J Brennan, 'The First Compulsory Licensing of Patents and Copyright' (2017) 17 Legal History 1, 12 f.
[26] Paris Convention for the Protection of Industrial Property of March 20, 1883 <https://www.wipo.int/wipolex/en/text/287780> accessed 19 August 2014 (in French).
[27] South Centre, 'IPRs and the Use of Compulsory Licenses: Options for Developing Countries' (1999) T.R.A.D.E. Working Papers 5, 3 <https://www.iatp.org/sites/default/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf> accessed 19 August 2024.
[28] Michael Halewood, 'Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law' (1997) 35 Osgoode Hall L J 243, 266.

Hague Conference of 1925 which adopted – after a long debate[29] – a compulsory licensing system as the main means to ensure the exploitation of a patent (see Art. 5 of the reformed Paris Convention[30]).[31] They could now be used as a remedy for non-working, and as a remedy for other 'abuses' of the exclusive right.[32]

After WW II also the anchoring of compulsory licencing in national legislation increased further. In the 1990s, about one hundred countries recognised such licenses.[33] But the adoption of more compulsory licencing systems around the world was not the only development in that field. The grounds for issuing them also broadened. If they were originally related to the lack of working, they have been extended to other areas of application, for instance public interest, government use, and competition.[34]

The last big cornerstone was the TRIPS Agreement from 1994, which harmonised compulsory licences for every World Trade Organisation (WTO) member to a certain extent.[35] The agreement created a minimum standard of patent protection for this group of countries (see Art. 1 of TRIPS). These minimum requirements had to be implemented by each country into its national law. In the relevant Art. 31 of TRIPS, compulsory licences are not explicitly named, however, they are regulated there. These rules are sometimes – although the grounds for a licence are not restricted[36] – described as so strict that this strategy of governments can practically no longer be used.[37] They can be seen as a step to play down the role of compulsory licences.[38] That is especially because of the high procedural requirements.[39] For the further analysis, it is important

[29] Le (n 21) 52 f.
[30] To be found under <https://www.wipo.int/wipolex/en/text/287779> accessed 19 August 2024 (in French).
[31] South Centre (n 27) 3; Yang (n 13) 77; Brennan (n 25) 3.
[32] Halewood (n 28) 268.
[33] Le (n 21) 54; South Centre (n 27) 3.
[34] Le (n 21) 54; South Centre (n 27) 3.
[35] Regarding the critique see E.
[36] Jerome H. Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) 37 JL Med & Ethics 247, 248.
[37] May and Sell (n 1) 171.
[38] But some still argue that TRIPS leaves too much room for the countries to issue compulsory licences, e.g. Jamie Feldman, 'Compulsory Licenses: The Dangers Behind the Current Practice' (2009) 8 Journal of International Business and Law 137.
[39] See under E.I.1.

to note that the issuing of compulsory licences has to be done by each country for its own territory and that no centralised process exists.

In the field of EU law, only one legal instrument exists which concerns specifically compulsory licenses. In 2006 the EU introduced Regulation 2006/816[40] which deals with the export of medicines to developing countries. But until now, this mechanism was not used once.

To sum it up, it can be stated that the concept of compulsory licencing always existed in the field of patent law and is known to (probably) all countries with a patent law system. But the attitude towards the legal institute changed significantly in the course of history. At some times it was relatively strict and bound to the lack of working the invention, while over time, the field of application broadened. Today, the boundaries of the TRIPS Agreement are procedurally relatively strict. And a further direction of development can be observed: The institution of compulsory licenses has been, through international treaties, become increasingly harmonised. But that only concerns the prerequisite for the granting of a compulsory license and not the issuing process.

II. Political and factual context and legislative process of the Commission's proposal

The Commission found the described state of affairs when it began to reflect on its current proposal. However, the trigger for these reform considerations was not the overall idea to develop and harmonise international patent law. Rather, it was a global crisis: The Covid-19 pandemic, which began in 2020, accelerated the idea to look into the EU system for compulsory licences.[41] It became clear that pharmaceuticals (esp. vaccines) were crucial to fight Covid-19. But it was also obvious that these products would contain intellectual property and especially patents. Therefore, it was realised that the exclusivity rights this would give to the pharmaceutical companies could create

[40] 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, OJ L 157, 9.6.2006, p. 1.
[41] See Commission, 'Making the most out of the EU´s innovative potential: An intellectual property action plan to support the EU´s recovery and resilience' COM(2020) 760 final, 11 f.; Commission (n 3) 1.

problems in supplying the world with these extremely important medicaments.[42] Hence, worldwide many voices called for compulsory licences for these patents or even a complete waiver. Regarding the waiver, the most famous advocates were the initiative of South Africa and India on the WTO level in 2020[43] and scientist of the famous scientific journal "Nature" which called for a waiver in an editorial in 2021.[44] The EU, however, did not follow the waiver approach, but proposed a solution under which the requirements for a compulsory licence under TRIPS should have been reduced.[45] However, this legal instrument does not seem to have been very effective. When it comes to compulsory licences regarding patents for pharmaceuticals that are used in the context of Covid-19 (not just vaccines), only ten initiatives have been started worldwide.[46] Nevertheless, at least the debate on compulsory licences came back to the table.

Against this backdrop, it can be said that the Commission with its proposal 'seized the momentum created by the pandemic as an opportunity to reclaim responsibility for the functioning of the European patent system.'[47]

The start of the legislative process can be seen in the Commission's intellectual property action plan of November 2020 which deals, among other things, with compulsory licenses.[48] In this communication, they were already seen as a tool to tackle crises situations.[49] It was especially recognised that the 'EU's IP system remains too fragmented'.[50] In the following, the European Parliament issued a resolution in November 2021 which asked the Commission 'to analyse and explore possible options

[42] See e.g. Editorial (n 5) 478; Mrityunjay Kumar and Nalin Bharti, 'Why patent waiver for Covid-19 vaccines and pharmaceuticals?' (2023) 26 J World Intellect Prop. 195, 196; Olga Gurgula and Wen Hwa Lee, 'COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?' (2021) 17 The Journal of Generic Medicines 61, 62.
[43] Communication from India and South Africa, 'Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19' (2 October 2020) IP/C/W/669. A revised proposal was submitted on 21 May 2021. See WTO, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19. Revised Decision Text' (25 May 2021) IP/C/W/669/Rev.1.
[44] Editorial (n 5) 478.
[45] EU, 'Urgent Trade Policy Responses to the Covid-19 Crisis – Communication from the European Union to the WTO General Council' (4 June 2021) WT/GC/231.
[46] See the database: <http://tripsflexibilities.medicineslawandpolicy.org> accessed 19 August 2024.
[47] Lamping et al. (n 7) para 1.
[48] Commission (n 41).
[49] ibid 11 f.
[50] ibid 2.

for ensuring effectiveness and better coordination of compulsory licensing in the EU'.[51] The Council's conclusions from June 2021 also pointed in that direction.[52] So, it can be said that even before a formal proposal was worked on, there was a general understanding of the Commission, Parliament and Council. This might be promising regarding the chances of the proposal becoming actual law.

The Commission launched its formal initiative in January 2022 when the problems of the Covid-19 crisis were still present.[53] The goal was to create a compulsory licencing regime which would be an efficient instrument for combating crisis's.[54] An academic study on behalf of the Commission then took a closer look on the different instruments which might be used to achieve the Commission´s goal.[55] It concluded that centralised compulsory licencing would be the favourable policy option and argued against other approaches (e.g. maintaining the status quo, soft law measures and member state coordination & harmonisation of compulsory licences).[56] The Commission´s impact assessment also dealt with these other approaches and ruled them out in favour of a centralised compulsory licencing regime:[57]

Unbinding recommendations, as a form of soft law measure, were seen as to have only a limited harmonising effect because of their unbinding nature.[58] In addition, it was argued that only one deviation by a member state could already strongly harm the supply of crisis relevant products in the EU.[59] Another disadvantage would be that in each involved member state a compulsory licence would still be needed.[60]

[51] European Parliament, 'Resolution of 11 November 2021 on an intellectual property action plan to support the EU´s recovery and resilience' 2021/2007(INI).
[52] Council, 'Conclusions on intellectual property policy' (18 June 2021) 9932/21.
[53] The relevant material can be found under <https://eur-lex.europa.eu/legal-content/EN/PIN/?uri=CELEX:52023PC0224> accessed 19 August 2024.
[54] Commission, 'Enhancing the coherence and effectiveness of compulsory licensing of patents in the EU, especially in crisis situations, including for export purposes to third countries' Document Ares(2022)2413270, 3.
[55] Vandermeulen et al. (n 10).
[56] Vandermeulen et al. (n 10) 104 ff.
[57] Commission (n 2) 27 ff.
[58] Commission (n 2) 34.
[59] Commission (n 2) 34.
[60] Commission (n 2) 34.

A harmonisation of national laws on compulsory licensing for crisis management (i.e. a directive) was also seen as insufficient. The reason being that the decisions if a crisis exist and if a compulsory licence should be issued would be with the member states. Therefore, a uniform application in the EU would not be guaranteed and the problem of fragmentation would not be fully solved.[61] And, as with unbinding recommendations, multiple compulsory licence would have to be issued in different member states.[62]

The approach pursued is to create a centralised compulsory licencing system on the EU level through a regulation. The idea of the Commission here is to make the system of compulsory licences in the EU more efficient so that in a crisis situation the Union can act swiftly.[63] The road towards the goal is seen in centralising the procedure to grant compulsory licences on the EU level so that in an EU-wide crisis there is no fragmentation between the member states.[64] However, the Commission recognised that a compulsory licence can just be a 'last-resort tool'.[65] The reason to focus on patents for the compulsory licences scheme is made clear by the Commission. It assumes that patents are the 'most powerful' type of IP and therefore the most important issue.[66]

After a public consultation,[67] the Commission adopted its proposal in April 2023. In September 2023 the Economic and Social Committee gave its opinion.[68] In March 2024 the proposal went – with some changes – through the first reading of the Parliament and is now in the so-called Trilogue proceeding involving Commission, Parliament, and Council.[69]

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[61] Commission (n 2) 36.
[62] Commission (n 2) 36.
[63] See Commission (n 54); Commission (n 3) 1.
[64] Commission (n 54).
[65] Commission (n 54) 1; see also already Commission (n 41) 12.
[66] Commission (n 54)1.
[67] Commission (n 54).
[68] Economic and Social Committee, 'Opinion on a proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) No 816/2006' (COM(2023) 224 final — 2023/0129 (COD))' C/2023/865.
[69] European Parliament, 'Legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))' P9_TA(2024)0143.

III. The proposal of the Commission in the context of developing international patent law

It must be said that the approach of the Commission to centralise the granting of compulsory licences is truly innovative. It is – so far as can be seen – the first attempt to set up such a system beyond national borders. This idea can be seen as the next level in the development of international patent law regarding compulsory licences. The Paris Convention and TRIPS set internationally harmonised rules for granting and scope of compulsory licences. The Commission's approach takes the international cooperation in that field to a new stage in centralising the process. Not every country would issue compulsory licences on its own for its own territory. Rather, the granted compulsory licence of a common institution would be recognised by several different countries. That is a new layer in patent law when it comes to compulsory licences. It is the next logical step on the ladder and would be the natural development in the general move towards more harmonisation in the field of compulsory licences. That such a "natural" harmonisation movement exists was shown for patent law in general in literature before.[70] The Commission's approach fits in well here. If this idea may be sensible beyond EU-boarders and in wider circumstsances than just crisis's will be explored in the coming sections of this dissertation.

[70] See McEniery (n 11) 172 f.

C. Section 2: The structure and main content of the proposal on the EU level

The fundamental idea of the proposal got precisely summarised by the Commission. It states that '[t]he proposal creates a compulsory licencing system centralised at EU level. In crises a compulsory licence covering the whole EU can be granted by filing a single application and using a single procedure under unitary procedural rules and conditions.'[71] So, at the heart of the proposal is a 'Union compulsory licence'.[72]

Such a Union compulsory licence can be granted especially for patents, but also for selected other kinds of intellectual property: utility models and supplementary protection certificates (see Art. 2 (1) of the proposal). A quite important amendment of the Parliament in that regard was to insert a new Art. 13a, which would widen the scope of the licences to trade secrets and know-how, when the licensee would need such information to make use of the compulsory licence for the patent.[73]

The scope of the proposal is tailored to crisis situations and crisis relevant products (see Art. 4 of the proposal). This is the main reason why the Commission expects the recourse to compulsory licensing based on the proposed mechanism to be low.[74] A compulsory licence can only be granted if an emergency or crisis mode is declared (Art. 4 of the proposal).[75]

The only institution who can issue such a licence is the Commission (see Art. 4 of the proposal). That is justified by the argument that uniform conditions in the EU should be ensured.[76] The Commission must, before taking a decision, get an unbinding opinion from an advisory body, which is staffed with experts (see Art. 6, 7 (1, 2) of the proposal). That process is comparable to the process of certification of pharmaceuticals, where the European Medicines Agency (EMA) issues an opinion and the Commission takes the decision afterwards based on the recommendation.[77] The involvement of the advisory

[71] Commission (n 3) 8.
[72] See Rec. 6 of the EC's proposal.
[73] European Parliament (n 69) amendment 66.
[74] Commission (n 3) 9.
[75] See also Rec. 8 of the EC's proposal.
[76] See Rec. 38 of the EC's proposal.
[77] See regarding that procedure the website of EMA <https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines> accessed 19 August 2024.

body has the goal to guarantee 'a comprehensive, thorough, and concrete assessment of the situation, taking into consideration the individual merits of each situation.'[78] The significant inclusion of specialised experts in the field was also demanded by different stakeholders[79] and is a reasonable concept in the highly complex field of patent law. What is interesting on a sidenote about the decision-making powers is that the academic study for the Commission suggested a 'regulatory consortium at the EU level involving a combination of specialized authorities with varying areas of expertise; or establishing a new, separate and independent authority at EU level for assessing and issuing a CL' as the decision maker.[80] So it seems like it proposed to give the Commission a bit less power in that regard in comparison to the proposal. But it looks like the Commission does not want to give any power out of its hands.

Before a decision is rendered, the patent holder has the right to give his or her statement on the topic (see Art. 7 (3) of the proposal). In the first reading, the Parliament amended the timeframe for this consultation towards the time before the advisory body announces its decision.[81] It also proposed a 4-weeks deadline for prior negotiations between the patent holder and the potential licensee for a voluntary agreement.[82]

To protect the interest of the patent holder, a clear determination of the scope, duration and territorial coverage of the licence must be made.[83] The details can be found in Art. 5 of the proposal. Worth mentioning is that it should be prohibited to export products manufactured under a Union compulsory licence.[84] An exception should be implemented concerning countries with public health problems.[85]

The licensee must pay an 'adequate' renumeration to the patent holder (Art. 5 (1) (d) of the proposal).[86] That is an essential point because Art. 31 (h) of TRIPS demands for this. The benchmark for 'adequate' is, not purely an arm's length one. Rec. 27 of the proposal

[78] Rec. 18 of the EC's proposal.
[79] See Vandermeulen et al. (n 10) 73.
[80] Vandermeulen et al. (n 10) 75 ff.
[81] European Parliament (n 69) amendment 47.
[82] European Parliament (n 69) amendment 26.
[83] See Rec. 16 of the EC's proposal.
[84] Rec. 29 of the EC's proposal.
[85] Rec. 37 of the EC's proposal.
[86] Rec. 27 of the EC's proposal.

lists the deciding factors: 'The amount of the remuneration should be determined considering the economic value of the exploitation authorised under the licence to the licensee and to the Member States concerned by the crisis, any public support received by the rights-holder to develop the invention, the degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the Union compulsory licence […]. In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence.' This is reflected in Art. 9 of the proposal. It must be said that this point seems to be quite controversial, as the Parliament in its first reading dropped the 4 % cap, for example.[87]

[87] European Parliament (n 69) amendment 55

D. Section 3: Is the EU proposal up to its task?

The proposal marks a strong systemic change in European patent law. So far, so good. But a change can be for good or for worse. So, when considering if the approach can work as a blueprint on the global level, as a first step it must be analysed if the proposal can achieve its goals in an efficient way and, therefore, can be a positive part for the (EU-)system as a hole. As a separate question, it could also be asked if the approach of the proposal could be used to achieve even more than the goals set by the Commission. To answer these two questions, is the aim of this section.

I. Will the proposal achieve its goals in an efficient way?

The most obvious and intuitive benchmark for assessing a proposal are the goals which were set for it. So, that is what will be done in this part of the dissertation. Another possible upstream analysis would be to take a closer look on the goals itself and analyse if they are justified. But this assessment can be skipped here, as the overall aims of the proposal should be generally accepted.[88] The goals articulated by the Commission can be namely summarised as follows: Swift and appropriate reaction to crisis situations in the EU.[89] Or in the original words of the Commission: 'Our general objective is to enable the EU to respond to crisis situations in a timely manner using the full potential of the Single Market and ensure that in time of crisis, critical products and components can be made available across EU countries and supplied without delays to EU citizens and firms or non-EU countries.'[90] In another place the Commission also articulated which interest must be taken into account. It posed as the central question, 'how we can preserve the balance and incentives for innovation while ensuring swift access to critical products and technologies in crises, even in the absence of voluntary agreements.'[91] It can be read from these statements that the aim is to create a centralised compulsory licence mechanism which on the one hand ensures that especially patents cannot hinder a quick EU response in times of an emergency and on the other hand does not interfere too much with the central objectives of patent law (i.e. foster innovation). Hence, the goal

[88] But maybe the laudable goals are too narrow. For an assessment regarding that question see D.II.
[89] Commission (n 3) 2.
[90] Commission (n 2) 22. In the same vein Commission (n 3) 2.
[91] Commission (n 3) 1.

is to create an efficient system for compulsory licenses in times of crises. When laying out this benchmark, it is important to keep in mind what is meant by 'efficiency'. *Posner* defines this concept in the following way: 'Efficiency means exploiting economic resources in such a way that value – human satisfaction […] – is maximized.'[92] Therefore, the costs and the benefits to achieve the goal are to be analysed. The goal must be achieved without unnecessary costs.[93] In the present case, the cost which have to be kept in mind are especially the costs for the IP holders. As discussed earlier, when they suffer majorly this might take away incentives for innovation which would hurt society in the end. Efficiency must be distinguished from 'effectiveness'. This term is wider than efficiency and means 'the ability to be successful and produce the intended results.'[94] Here, the costs are not important.

Before starting the actual analysis, it seems useful to highlight one point: In the public consultation, a large majority of participants (82%) said there was a need to resort to a compulsory licence in a crisis.[95] That is of course not a proof for anything, but as a first indicator one can keep in mind this overall very positive response.

1) General advantages of compulsory licences

As a starting point, it should be assessed whether compulsory licences in general are a suitable and efficient instrument to achieve the goals of the proposal. In that regard, they are seen by the Commission to have two functions: An incentive role and an enabling role.[96]

By 'incentive role' it is meant that just the possibility of the granting of a compulsory licence influences prior negotiations between the patent holder and a possible licensee. It can create a (psychological) threat for the patent holder, who knows that the licence might get issued either way.[97] That might increase the willingness to enter into a

[92] Richard A. Posner, *Economic Analysis of Law 10* (2d ed Little Brown and Company 1977) 10; quoted after Stephen E. Margolis, 'Two Definition of Efficiency in law and Economics' (1987) 16 J Legal Stud 471, 471.
[93] cf <https://dictionary.cambridge.org/dictionary/english/efficiency> accessed 19 August 2014.
[94] <https://dictionary.cambridge.org/dictionary/english/effectiveness> accessed 19 August 2024.
[95] Commission (n 2) 8.
[96] Commission (n 3) 1; Commission (n 2) 7 f.
[97] Commission (n 2) 7 f.

voluntary agreement. This argument – which was also articulated in literature[98] – is well understandable. That is because the eventuality that a compulsory licence gets issued has an impact on the negotiating powers of the involved parties. Without this institute, the patent holder could take the standpoint of an absolute refusal of a licencing agreement, for example. That tactic would essentially get taken away. And also, when it comes to the licencing fees, a compulsory licence "in the background" can have an impact. In that case, the parties know that when no agreement is reached, the decision about the high of the renumeration might get taken by an authority. That can keep away the patent holder from demanding exaggerated fees.[99] These points together may have an impact on another important factor in a crisis situation: time. The negotiation of licencing agreements can take several months or even years.[100] A compulsory licence at the horizon (or just a stone's throw away) may accelerate this process. The phenomenon of the influence of a compulsory licencing regime on licencing bargaining's has been vividly described in literature as 'negotiating in the shadow of the law'.[101]

Compulsory licenses are also attributed an 'enabling role' as they assign a licence to a manufacturer who would otherwise not be able to produce the crisis relevant product which includes the patent.[102] That function is straight forward and easy to grasp. It is considered by the Commission as a backup when voluntary agreements fail.[103]

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[98] E.g. Gorik Ooms and Johanna Hanefeld, 'Threat of compulsory licences could increase access to essential medicines' (2019) BMJ 2019, 3 and Chien (n 17) 856 footnote 7 with several references to several examples.

[99] See e.g. Reed Beall and Randall Kuhn, 'Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis' (2012) 9 PLoS Med 1 who documented 24 instances between 1995 and 2011 where compulsory licensing was employed as a bargaining tool in negotiations between governments and pharmaceutical patent holders. In half of these cases, compulsory licenses were granted, and in the majority the tactic led to concessions such as price reductions from the patent holders or the voluntary issuance of licenses. In the same vein see, Shyama V. Ramani and Eduardo Urias, 'Access to critical medicines: When are compulsory licenses effective in price negotiations?' (2015) 135 Social Science & Medicine 75, 76 with further references.

[100] See the information by EPO under <https://www.epo.org/en/learning/learning-resources-profile/business-and-ip-managers/inventors-handbook/dealing-companies/negotiating-licensing-agreement#:~:text=Most%20licensing%20negotiations%20take%20a,you%20want%20from%20the%20negotiations> accessed 19 August 2024 and Rec. 1 of the EC's proposal.

[101] Lamping et al. (n 7) para 4.

[102] Commission (n 2) 7 f.

[103] Commission (n 2) 7 f.

But compulsory licences are not only seen as positive. It is often argued that they carry severe disadvantages with them.[104] As such, it is frequently stated that they impair the idea behind the patent system to incentivise innovation by weakening the rights of the patent holder.[105] That standpoint also got recognised by the Commission and taken into account.[106] The theoretical idea behind this seems to be quite convincing, as it seems to be logical that less investment in patents will be made, when the patent holder has to fear that his or her intellectual property right might get weakened. But the empirical evidence for a negative impact of compulsory licences on innovation is – at least – not clear. Empirical studies are scarce but, for example, an analysis from Germany showed a 30% increase in invention of German firms after their products were involuntarily licenced after WW I, when the US made 4,706 German-owned US patents available for compulsory licensing and 1,246 compulsory licences were issued.[107] When it comes to the US, *Chien* in 2003 examined six case studies of compulsory licensing, which took place in the 1980s and 1990s, and found that five of six patent holders did not reduce patenting after the compulsory licensing took place.[108]

So, to sum it up it can be said that while there is a (small) risk of harming innovation, which is a cost to be avoided from an efficiency standpoint, compulsory licencing in general is a useful tool to promote the fast supply with crisis relevant products, which contain patented inventions. They do that on a first level by influencing "free" negotiations, and on a second level by enabling manufacturers to produce the products against the will of the patent holder.

2) Solving the problem of fragmentation

After the general observation that compulsory licences can help to take efficient action in a crisis situation, it has to be analysed if these licences have to be centralised at an EU

[104] See e.g. Richard P. Rozek, 'The Effects of Compulsory Licensing on Innovation and Access to Health Care' (2000) 3 J World Intell Prop 889.
[105] See e.g. Julian-Arnold (n 2) 357 f.; Richard A. Epsteint and F. Scott Kieff, 'Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents' (2011) 78 The University of Chicago Law Review 71, 80. The OECD puts it that way: 'The excessive use of compulsory licensing, for example, could lead to increased secrecy and lower investment in R & D.', OECD (n 15) 12.
[106] See Commission (n 3) 1.
[107] Joerg Baten, Nicola Bianchi and Petra Moser, 'Compulsory licensing and innovation – Historical evidence from German patents after WWI' (2017) 126 Journal of Development Economics 231.
[108] Chien (n 17) 853.

level. That is not only relevant from an efficiency point of view, but also from a legal standpoint. The background here is that in Art. 5 (3) TEU enshrined is the principle of subsidiarity. This means that, in areas which do not fall within the exclusive competence of the EU (like compulsory licencing[109]), the EU can only act if an issue cannot be sufficiently solved by the member states and can only or better be addressed at EU level.

The Commission defines the current state of affairs regarding compulsory licences in the EU in the following way: The 'EU compulsory licences rules are characterised by inadequate territorial architecture, uncoordinated national procedures and decision-making, which is especially problematic in view of cross-border value chains increasingly predominant in the EU.'[110] The analysis concludes that 'today's rulebook on compulsory licensing can lead to a situation when access to certain goods in crisis is not secured on time, which may generate broad negative socio-economic consequences.'[111]

This analysis is to be agreed with. The current system of purely national compulsory licences is inefficient in an international or EU crisis. A crisis relevant product which got produced in one member state under a compulsory licence can, under the current rules, only be supplied in another member state if there exists a compulsory licence in that particular country.[112] The underlying reason for this is a judgement of the CJEU which states that the principle of exhaustion does not apply to products produced under a compulsory licence.[113] Therefore, the patent holder has to agree to further distribution in another member state. But it is not only the selling side which is impacted. It's also the production side which is problematic: For every member state in which the production takes place a separate compulsory licence would have to be acquired as they only have a national territorial reach.

That patchwork means mainly two things:[114]

[109] See Commission (n 3) 4.
[110] Commission (n 2) 11.
[111] Commission (n 2) 19.
[112] Commission (n 3) 2.
[113] CJEU, Case C-19/84 *Pharmon v Hoechst* [1985] ECR 2281 para 20.
[114] For a detailed overview of the different problems with a compulsory licencing patchwork see Commission (n 2) 11 ff.

First, it can take a lot of time to get all the required compulsory licences,[115] and it would also be uncertain if they all would be granted in the end. This is since several decisions by different decision makers in the member states must be taken,[116] and on top of that the thresholds for a compulsory licence can differ from country to country.[117] Hence, there exists a huge level of complexity and uncertainty what stands contrary to efficient measurements. The result can even be a state where compulsory licences are issued in some member states and not in others, what would disturb the internal market and therefore the efficiency of crisis response.[118]

Second, the described problems of the current system can lead to a situation in which manufacturers might be deterred from trying to get the necessary compulsory licences. There is a high risk that, based on an economic calculation, it just would not be sensible for a company to take the risk of going down that path. That would be the worst outcome because in that case there would definitely be not enough supply of the crisis's relevant product if the patent holder has not enough capacities and refuses to enter into licencing agreements. Hence, in these situations the current system is not only inefficient but also ineffective.

These issues can be solved with the centralised system proposed by the Commission. In that way, there would be only one institution which has to render a decision, only one process would have to be completed and the grounds on which a compulsory licence could be issued are always the same. It has, therefore, the advantage of being faster than the current purely national system.[119] There would further be a higher degree of legal certainty because only one decision would have to be taken. The Commission also rightly put forward that a centralised procedure would reduce legal and enforcement cost for

[115] See Vandermeulen et al. (n 10) 98.
[116] Who has the authority to issue a compulsory licence is also very different in the Member States, see Vandermeulen et al. (n 10) 30 f.
[117] See Rec. 4 of the EC's proposal. An overview of the (sometimes very) different grounds for crises related compulsory licence in EU member states can be found in the already mention study for the Commission, Vandermeulen et al. (n 10) 24 ff.
[118] See Rec. 5 of the EC's proposal and Lamping et al. (n 7) para 2.
[119] See Vandermeulen et al. (n 10) 98.

the patent holders, potential licensees, and the member states, as there would be only one procedure on EU level.[120]This is to be welcomed from an efficiency standpoint.

Therefore, the centralisation is a good approach to achieve the goals of the Commission in an efficient way.[121]

3) Compulsory licences for a patent or a product?

After the founding elements of the proposal have been discussed, it is also important to have a closer look at – on the first sight – more minor issues. These more technical details can in practise make the difference between a good law, which serves its purpose, and a bad one which cannot or only with a lot of trouble be applied in real life. As it is often said: "The devil is in the details". Thus, it is very worth, and necessary, to elaborate also on the smaller things.

The start will make the question if a compulsory licence should be granted for a patent or a product. The difference here is that if a compulsory licence would be issued for a product, it would contain all patents which are used in the product.[122] At first sight, this approach seems to be very unusual in the field of patent law, and it had – at least until now – not a very high profile. But such an idea is not totally unknown, also to EU law. Art. 6 (3)(b) of Regulation 2006/816 on the export of medicines states that '[t]he application [for a compulsory licence] shall set out [....] the non-proprietary name of the pharmaceutical product or products which the applicant intends to manufacture and sell for export under the compulsory licence.' Hence, in that case, the compulsory licence might actually be requested for the whole product and not for a specific patent.[123] The compulsory licence itself, however, would just contain the patent (see

[120] Commission (n 3) 7.
[121] For the same view e.g. Pallavi Arora, 'Compulsory Licensing for Crisis Management: Revisiting the EU's Approach' (*OpinioJuris*, 29 June 2023) <http://opiniojuris.org/2023/06/29/compulsory-licensing-for-crisis-management-revisiting-the-eus-approach/> accessed 19 August 2024.
[122] See regarding that idea e.g. Vandermeulen et al. (n 10) 49.
[123] However, according to Rec. 14 member states may require naming the patents. That rule was the result of a compromise between Parliament and Council, Jakob Cornides, 'European Union Adopts Regulation on Compulsory Licensing of Pharmaceutical Products for Export' (2007) 10 The Journal of World Intellectual Property (2007) 70, 73 f.

Rec. 14 of the regulation). The idea of a product compulsory licence was also discussed in the study for the Commission, where the scholars did not take sides.[124]

This procedure has important advantages. It would allow to scope the compulsory licence in a more precise way, as it would allow targeting a specific end-product which is needed in the crisis situation.[125] The approach could also enhance the overall pace because there would be only one procedure even when more than one patent is involved. It would be an opportunity to bundle the process even further. If the compulsory licence would be issued for a product, that would also tackle the problem of swiftness from another angle: It would allow to grant the licence even when it would be hard or even impossible to figure out which patents are used in a product and who the holders of these patents are. That can especially be a problem for very complex products which contain a lot of knowledge. Also, the licensee would not have to fear to infringe an "unknown" patent when manufacturing and distributing the crisis relevant product.

To protect the rights of the patent holders, it would surely be necessary to carry out that analysis afterwards and make sure that they get their fair compensation. In doing so, the authorities might for example ask publicly for patent holders to make their claim.[126] But it would be possible to do that when the storm of the crises has calmed down and, therefore, the time would be less pressing.

So, after all it seems reasonable from a cost-benefit standpoint to include the possibility to grant a compulsory licence also for a product.[127] The most practical way would be to include both opportunities in the Regulation. In that case, it could be decided on a case-by-case basis if the situation is so clear that it would be enough to grant a compulsory licence for a patent or the patents or if the authorities should go for the whole product. It would also be a possible approach to differentiate between different types of products in the first place. For example, "regulated" products, which must be officially approved

[124] Vandermeulen et al. (n 10) 49 f.
[125] See Vandermeulen et al. (n 10) 49.
[126] Vandermeulen et al. (n 10) 50.
[127] The only scholars who deal with the issue in some detail besides the Study for the Commission do not articulate an own standpoint, Lamping et al. (n 7) para 38 ff.

before distribution (e.g. medicines),[128] are good candidates for a "product compulsory licence" as they are clearly defined in the regulatory file.[129]

However, in the Commission's proposal this issue is (on the first sight) answered clearly in the (conservative) sense that a compulsory licence cannot be granted for a product. According to Art. 2 (1) a compulsory licence can only be granted for patents, utility models and supplementary protection certificates. But it was also put forward that under the Commission's proposal if not all IP can be identified, a compulsory licence can still be issued.[130] That relates to Art. 8 (2)(a) of the proposal where it states that the 'Union compulsory licence shall specify the following: (a) the patent, […] for which the licence is granted or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence.' So, when it comes to the proposal of the Commission, a compulsory licence which focuses on a product would be possible.[131]

The Parliament, though, seems to oppose such an approach. That becomes clear when one reads the amended Rec. 23 of the proposal. It stipulates that the 'procedure should first involve the identification of the intellectual property rights concerned, the rights-holders concerned.'[132] In the amended Rec. 25 it is further put forward that '[w]here the rights-holder or not all the rights-holders could be identified in a reasonable period of time, the Commission should not grant the Union compulsory licence.'[133] It also deleted the second half sentence in Art. 8(2)(a).[134]

These amendments got harshly criticised in literature.[135] This is to be agreed with because the procedure to identify every patent and its holder could take precious time

[128] But when it comes to medicines, it has to be noted that they normally contain just one (most often known) patent and therefore, the compulsory licence for the product would not be that helpful, see Cornides (n 123) 73.
[129] For that idea see Vandermeulen et al. (n 10) 49.
[130] Hoen (n 8 2024).
[131] This was welcomed by Aisling McMahon, 'EU's compulsory licensing proposals, patents and crisis preparedness – Some steps in the right direction but more to do for future pandemic preparedness' (*Journal of Medical Ethics*, 4 May 2023) <https://blogs.bmj.com/medical-ethics/2023/05/04/eus-compulsory-licensing-proposals-patents-and-crisis-preparedness-some-steps-in-the-right-direction-but-more-to-do-for-future-pandemic-preparedness/> accessed 19 August 2024.
[132] European Parliament (n 69) amendment 12.
[133] European Parliament (n 69) amendment 14.
[134] European Parliament (n 69) amendment 51.
[135] Hoen (n 8 2024).

in a pressing crisis. The rights of the patent holder can be taken care of afterwards. That would be the more efficient approach.

4) Deceleration because of the right to be heard and the requirement of prior negotiations?

Another field of discussion again revolves around the swiftness of the response in crisis situations. While there is consensus that this is one of the most important parts of the proposal,[136] some argue that the rights of participation of the patent holders might impair this objective.[137] The debate focuses on two main areas. The right of the patent holder to give his or her opinion before the compulsory licence can be granted, and the requirement of failing prior negotiations.

When it comes to the first, the relevant rule of the proposal is Art. 7 (3). This provision grants the patent holder a right to be heard. Its design has undergone some change in the legislative process: While the Commissions original proposal states that the Commission has to grant the opportunity to give the opinion, it reads after the amendment in the first reading of the Parliament[138] that '[b]efore issuing the opinion, the advisory body shall give the rights-holder and the licensee an opportunity to comment within a reasonable timeframe.' So, it was moved one step forward, and a time-element entered the text.

Some voices in literature seem to be sceptical about the (original) provision as it might give the patent holder a chance to delay the issuing of the compulsory licence.[139] It is undoubtedly true that the involvement of the patent holder may slow down the process, as he or she will always need some time to prepare the statement. A malignant patent holder could even use delaying tactics. Still, it should be held that the involvement of the patent holder is worth it. First, the opinion of the patent holder might give valuable information regarding the decision to issue a compulsory licence and also regarding the

[136] See Commission (n 3) 2.
[137] E.g. Gurgula (n 9) 7.
[138] European Parliament (n 69) amendment 47.
[139] See Gurgula (n 9) 7.

renumeration.[140] Second, the right to be heard is a fundamental right in any circumstance where a person is subject to a – from his or her perspective – disadvantageous decision of the state.[141] Thus, it is legally essential that the patent holder can give his or her opinion. That is also recognised in the proposal as the 'right to be heard' is expressively named and 'guaranteed' in Rec. 21.

Nevertheless, it is necessary to put safeguards in place to avoid an abuse. Here, the amendment of the Parliament seems to be a good compromise. It leaves the patent holder the opportunity to comment, but gives the advisory body the chance to set a specific timeframe as well. That seems to be a balanced, fair and efficient approach which also brings enough flexibility to adjust to a crisis. If, for example, the issues are extremely urgent and every hour is important, the advisory body might consider a response time of a few or even one day as 'reasonable'. Therefore, this change will hopefully stay during the coming negotiations.

A quite similar problem is linked to the necessity of prior negotiations between the patent holder and the potential licensees about a voluntary licencing agreement. As background, it is important to remember that Art. 31 (b) of TRIPS demands this process in "normal" situations, but according to the same article that requirement can be waived in 'case of a national emergency or other circumstances of extreme urgency.' So, especially in the here relevant crisis situations, a waiver might be possible when it comes to international law. With a view towards the Commission's proposal, it got shown in literature that the Commission is not quite clear if it wants to make use of that clause, especially because it considers compulsory licences as a means of 'last resort'.[142] In the same vain, a study for the Commission spoke of compulsory licences as a tool that should only be used 'in the case of failure in reaching voluntary agreements.'[143] The problem with these prior negotiations is that they can take a long time, and might even create a

[140] '[T]o enable the competent authority effectively to take into account all relevant information' is recognized by the CJEU as one aim of the right to be heard, Case C-166/13 *Mukarubega* (ECJ, 5 November 2014) para 47.
[141] See CJEU (n 140) para 43 with reference to Article 41(2) of the Charter.
[142] See Lamping et al. (n 7) para 14 ff.; BEUC, 'Comments on the Commission's proposal for a regulation on compulsory licensing for crisis management' 3.
[143] Vandermeulen et al. (n 10) 9.

substantial opportunity for the patent holders to delay the granting of a compulsory licence.

Against this backdrop, it would be feasible to insert a clause which clearly states that prior negotiations might be waived by the Commission in case of an extreme urgency, when this process could create a lot of harm regarding the reaction to a crisis. Additionally, it might be wise to set a specific timeframe for the negotiations.[144]

The last idea got picked up but the Parliament which proposed an amendment to Art. 1 that includes a four-week period for the negotiations.[145] That is a step in the right direction, but an inflexible timeframe seems to be not the most efficient approach for crisis situations. A general characteristic of a crisis is that a fast response is feasible, but how fast the move must be can differ from situation to situation. Therefore, it would be advantageous to set in place a more flexible mechanism. A role model here could be the amendment of the Parliament regarding the right to be heard. The timeframe could be left to the discretion of the advisory body.

5) Consideration of know-how and trade secrets

Another important point in the debate is the treatment of know-how and trade secrets which are related to a patent that could be used under a compulsory licence. It got recognised in literature and by the Commission that sometimes it would be not possible to make use of a patent when corresponding (secret) knowledge is not transferred.[146] That comes, at first sight, as a bit of a surprise because in the patent documentation the invention has to be presented in a way that it can be carried out by a 'person skilled in the art'.[147] But the interaction between different ideas and concepts as well as the sometimes huge complexity, nevertheless, makes the disclosure of more knowledge in

[144] This got for example suggested by Gurgula (n 9) 7.
[145] European Parliament (n 69) amendment 26.
[146] E.g. Commission (n 2) 13; Aisling McMahon, 'Patents, Access to Health and COVID-19 - The Role of Compulsory and Government-Use Licensing in Ireland' (2021) 72 N Ir Legal Q 117, 126 f.; Sara Eve Crager, 'Improving Global Access to New Vaccines: Intellectual Property, technology Transfer and Regulatory pathways' (2014) 104 Am Jo Pub Health e87, 414, 415 and 417; Gurgula (n 9) 11.
[147] E.g. Art. 83 of the EPC

many cases necessary.[148] Therefore, this can be an essential part of a compulsory licencing structure.

In the original proposal of the Commission, this issue got somewhat neglected. It just dealt with it in Art. 14 (2). Here it reads that '[w]here necessary, the Commission shall decide upon reasoned request by the rights-holder or the licensee or on its own initiative on additional measures complementing the Union compulsory licence to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between the rights-holder and the licensee.' In Rec. 32 it is mentioned that the Commission can especially request further information to work the compulsory licence. These provisions were seen in literature as too vague.[149] This assessment can be agreed with. It is supported by the fact that in the Commission's impact assessment, it is mentioned in a footnote that '[t]he patent owner(s) would have to collaborate in good faith. An obligation to disclose trade secrets would not be provided.'[150] Hence, there would be quite a bit of uncertainty how this would play out in practice (giving (unknown) information without disclosing trade secrets seems to be not an easy task). But there is definitely a chance that an unwilling patent holder tries to use this state to his or her advantage.

This analysis was obviously shared by the Parliament.[151] *Adrián Lázara* – the rapporteur of the responsible Legal Affairs committee – even mentioned during the first reading in the Parliaments' session that the access to technical knowledge was one of the most important points during the negotiations in the legal affairs committee.[152] The Parliament put forward a new Art. 13a which deals with these issues. Additionally to the competence under the original proposal, it gives the Commission the power to demand the disclosure of trade secrets and know-how (see. Art. 13a (2)).[153] This is very interesting as in intellectual property law a compulsory licence for these types of IP is

[148] See Lamping et al. (n 7) para 42.
[149] Gurgula (n 9) 12; see also Lamping et al. (n 7) para 42 f.
[150] Commission (n 2) 32 footnote 123.
[151] See European Parliament, 'Compulsory licensing of patents in crisis situations' 2023/0129(COD) - 13/03/2024 - Text adopted by Parliament, 1st reading/single reading.
[152] To be found under <https://www.europarl.europa.eu/doceo/document/CRE-9-2024-03-12-ITM-021_EN.html> accessed 19 August 2024.
[153] European Parliament (n 69) amendment 66.

not very common (but also not unknown).[154] *Lázara* seems to share this view as he recognised during the debate that this approach is ambitious.[155]

The problem with know-how and trade secrets is their general low level of protection in practise. Essentially, when they are "out there" they are often unprotected and free to use for everybody. That could produce costs which should be avoided from an efficiency standpoint. There might be laws which prohibit to take advantage of them, like rules on unfair competition or specific trade secret legislation. In the EU, that is the case as this area is covered by the so-called Trade Secrets Directive (Directive (EU) 2016/943). But these rules are generally hard to enforce, and to prove misconduct can be an impossible challenge.[156] That is why they are normally just given to very well trusted partners.[157] Against this backdrop, it is often even more threatening for the "holder" of this kind of information to be forced to transfer it to a third party than patents, for example.

So, how should this conflict be solved in an efficient way? When it comes to the opinion of the stakeholders during the public consultation, there seems to be quite a clear answer. Only a third was in favour of including know-how and trade secrets in the law.[158] But it has to be said that this view was mainly shared by the business side, while NGOs and academia seemed to be more open about it.[159] An answer can be found when the different (legal) interest are put in perspective. The IP of the holder of the information is protected by Art. 17 of the EU Charter[160] and (probably) Art. 1 of Protocol No. 1 of the ECHR[161] which gives his or her position a lot of strength. On the other side of the dare lays the interest in responding to an EU-wide crisis situation which impacts millions of

[154] An overview of different EU-countries can be found by Vandermeulen et al. (n 10) 48.
[155] To be found under <https://www.europarl.europa.eu/doceo/document/CRE-9-2024-03-12-ITM-021_EN.html> accessed 19 August 2024.
[156] See e.g. Gill Grassie, 'Trade secrets: the new EU enforcement regime' (2014) 9 Journal of Intellectual Property Law & Practice 677, 682 who stresses the fact that obtaining of evidence can be very challenging or even not possible.
[157] See Vandermeulen et al. (n 10) 47 f.
[158] Commission (n 2) 25.
[159] Commission (n 2) 25.
[160] Marco Bronckers and Natalie McNelis, 'Is the EU Obliged to Improve the Protection of Trade Secrets? An Inquiry into TRIPS, the European Convention on Human Rights and the EU Charter of Fundamental Rights' (2012) 34 European Intellectual Property Review, 673, 681 f.
[161] The ECHR has – as far as can be seen – not decided specifically on trade secrets. But it has stated e.g. in *Anheuser-Busch v Portugal,* App no 73049/01 (ECtHR, 11 January 2007) para 72 that the article 'is applicable to intellectual property as such.' See also Bronckers and McNelis (n 160) 680 f.

people and could be hindered by the omission to transfer the knowledge. Against this backdrop, it seems quite clear that a forced transfer of knowledge and trade secrets should be possible.[162] But the holder of the information should receive a very considerable level of protection. Hence, it would be necessary to put specific safeguards in place. Other than an obvious non discloser rule for the receiver, these could for example include (high) fines or damages and the possibility of giving specific instructions regarding the organisation of the receiver. These ideas got taken up by the amendment of the Parliament in Art. 13a (3). Therefore, this amendment is to be welcomed.

II. Further goals an EU-wide centralised compulsory licence system might achieve

As we have seen, the Commission made it clear that the proposed centralising of compulsory licences should only be an instrument to tackle a crisis situation. In that sense, the scope got consequently narrowed to circumstances in which such a crisis got declared. That is reasonable and straight forward. But one could ask the question of why such a huge change in the system of compulsory licences – which can, as discussed, bring many benefits with it – should only be applicable to (hopefully) no or once in lifetime situations. Thus, it does not come as a surprise that some scholars suggest that the proposed system of unified compulsory licences should not only be used to deal with (current) crisis situations.[163]

But before discussing the different possible approaches, it should be elaborated on the idea that it would be unnecessary to widen the scope in the first place.[164] This thought is based on the argument that when there is the need to act on an EU level, there will probably always be a crisis.[165] Although this trail of thought might seem convincing at first sight, it won't sustain a closer analysis. A crisis always carries an element of emergency and a shortage of time.[166] But there might be issues that are not extremely urgent, while at the same time in need of an EU-wide approach. The climate "crises" might serve as an example here. It is certain that an EU (or even global) wide action is

[162] For the same view see e.g. Lamping et al. (n 7) para 43.
[163] McMahon (n 131); Arora (n 121); Lamping et al. (n 7) para 5 ff.; Hoen (n 8 August 2023).
[164] Gurgula (n 9) 13.
[165] Gurgula (n 9) 13.
[166] See Lamping et al. (n 7) para 8.

necessary to tackle that issue. But it is still hard to say that this would be an emergency in the sense of the proposal. That is also because a crisis is generally seen as a temporary situation that does not carry on for an extremely extended (possibly infinite) period of time.[167]

So, how could such a widening of the scope look like? There are basically three main trails of thought. The first one would be to detach the compulsory licence from crises and create a framework which could apply in completely different situations (e.g. the well-known non-use of the patent, competition law considerations or public needs in general).[168] The second – less ambitious – idea would be to stay true to the crisis approach, but to make sure that the system can also be triggered before a crisis occurs to prevent or mitigate it in the first place.[169] And the third proposed amendment would be a geographical adjustment. It was put forward to include third countries and their crises in the scope.[170] As the second approach would be the smallest change, the following analysis will start with that option.

1) Compulsory licences to prevent or mitigate a crisis

The first option would be to authorise the Commission to grant compulsory licences not only in a declared crisis but also in advance to such a situation to enable a better preparation or to keep the crisis from happening.[171] The idea behind it is that being prepared for a problem in the first place or avoiding it completely is most often more efficient than starting to react in stress after the difficulties occurred.

While this approach seems to be very reasonable at first sight, it carries one important drawback with it: It is impossible to name all and at the same time only the patents which will matter in a future crisis. It could probably be argued for any major and even some minor inventions that they might help to prevent or tackle a future crisis. That is, first, because of the wide variety of different reasons for crises (e.g. wars, pandemics, riots, natural disasters, and food shortages). Second, many patents have a multitude of

[167] Vandermeulen et al. (n 10) 14.
[168] See e.g. the thought of Hoen (n 8 April 2023); Hoen (n 8 August 2023); McMahon (n 131).
[169] See Lamping et al. (n 7) para 11.
[170] See Gurgula (n 9 November 2023).
[171] For this approach see Lamping et al. (n 7) para 11.

different use cases. Hence, this approach would create a lot of legal uncertainty for stakeholders and would give too much discretion to the executive decision makers. This could ultimately harm the trust in the European patent system. Therefore, this option does not seem to be a favourable way to extend the scope of the Commission's proposal.

2) Helping with crises in third countries

Although the proposal aims to help in crisis situation in the EU, some argue that the geographical field of application, especially when it comes to exports, should be widened.[172] The Commission's proposal is quite clear in that field. According to Rec. 28 '[i]t is imperative that products manufactured under a Union compulsory licence reach only the internal market.' This requirement is enshrined in Art. 11. The provision states that the export of the products manufactured to third countries is prohibited. Some hold the opinion that this restriction is too harsh, for example when one looks towards Ukraine – which will probably not become an EU member for several years – where a devastating war is still ongoing.[173] It is put forward that the prohibition of exports might hinder the supply of essential medicines to the country.[174] It is also argued that the strong pharmaceutical industry in Ukraine would not be able to support the EU in a crisis which considers itself.[175]

Although this proposed amendment is politically and morally highly understandable, it should still not be inserted in the final regulation. This has legal systematic reasons. The proposal is aimed towards the EU, and it would create strong political and legal uncertainties if the scope is widened towards third countries. The EU cannot save the whole world, and to create such an option could set the Commission under pressure to use its power to issue compulsory licences for crises everywhere. This approach would overstrain the powers of the EU because it could lead to the idea that the EU must

[172] See for example the letter of 70 civil society organizations and academics to the Parliament <https://msf-access-campaign.prezly.com/letter-civil-society-calls-on-european-parliament-to-support-global-access-to-medical-tools-by-removing-export-prohibition-in-union-compulsory-license#attachment-eff6bb76-f5be-4a0b-acbd-d4ebf6fc9bf2> accessed 19 August 2024 and Gurgula (n 9 November 2023).
[173] E.g. Gurgula (n 9 November 2023).
[174] Gurgula (n 9 November 2023). The Regulation (EC) No 816/2006 is – comprehensible – seen by the author as not sufficient in that regard.
[175] Gurgula (n 9 November 2023).

intervene in every crisis on the globe. But it should be emphasised that a patent system which is able to tackle regional and global problems all over the world is desirable. A set of ideas to create such tools will be laid down in section four.

3) Detachment from crises – Revolutionising the EU system for compulsory licences by harmonising it

The EU sometimes thinks big (e.g. the "Green Deal"[176]). But regarding the centralised compulsory licencing proposal, it decided to go with the smallest possible scope. Although it would have also been possible to not just target crisis situations but to truly harmonise the compulsory licencing system in Europe by creating a Union compulsory licence which can be applied in all sorts of situations.[177] This would have been a huge step in completing a coherent European patent system.

Right now, neither the European Patent Convention (EPC)[178] nor the Agreement on a Unified Patent Court (UPCA)[179] – while creating a relatively harmonised system – contain rules regarding compulsory licences. They are the "blind spot". Creating a comprehensive set of rules for compulsory licences would bring the system closer to completeness.

This approach would most certainly create a huge debate in which circumstance such a licence could be granted. But a good starting point here would be to look at the different grounds which are codified in the national laws.[180] Although they differ quite a lot, it is possible to figure out main commonalities (e.g. non-use, public interest, public health issues). To create a balance between legal certainty and flexibility, it would also be possible to have a general clause (e.g. "public interest") which is accompanied by more specific examples.[181]. The debate on this topic might even be healthy as it could lead towards a common way of thinking.[182]

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[176] Commission, 'The European Green Deal' COM(2019) 640 final.
[177] McMahon (n 131) for example suggest 'public interest' as a ground to issue a Union compulsory license.
[178] Convention on the Grant of European Patents (European Patent Convention), OJ EPO 2001, Special edition No. 4.
[179] Agreement on a Unified Patent Court, OJ C 175, 20.6.2013, p. 1.
[180] See for an overview EPO, 'Compulsory licensing in Europe – A country-by-country overview' (2018) <https://link.epo.org/elearning/compulsory_licensing_in_europe_en.pdf> accessed 19 August 2024.
[181] See for that approach Lamping et al. (n 7) para 13.
[182] See Lamping et al. (n 7) para 12.

When it comes to the advantages of such an approach, one can name almost all the points which were discussed with a view towards the "crisis only" approach. Especially, the problem of fragmentation which creates inefficiencies is as relevant to crisis situations as to non-crisis situations. The possibility for centralised compulsory licences on other grounds than crises would, therefore, also help to develop the Internal Market. It would also take away to a certain extent the debate around the question when a crisis exists. Because this is always a political decision, this would be a way to more legal certainty.

A contra-argument to expect would be that compulsory licences could lead to less investment in R&D.[183] But here it can be answered that the aim would not be to issue more compulsory licences in general. The goal would be to make the system more efficient for all stakeholders.

From a political point of view, it seems logical that the proposal only includes crisis situations because it is part of the Unions package to make the EU fit for such events.[184] But from a higher perspective, there are many convincing pro-arguments to explore a much wider approach. A good summary which can be followed comes from a MPI research group: 'It is true that the shortcomings of the existing framework are particularly obvious in the event of a crisis, where a prompt and coordinated response can be crucial. However, limiting the scope of the reform to crisis situations could be seen as a missed opportunity for the EU to participate in the debate on the framework conditions of innovation policy in the Internal Market.'[185]

III. Conclusion of section 3

The Commission's proposal has the aim to enable the EU to react swifter and more forcefully to crisis situations. An analysis of the proposal shows that this goal would be achieved in an efficient way. The Commission rightfully followed the idea that compulsory licences can help in a crisis and came up with a system that especially solves

[183] This is recognized for example by the OECD (n 15) 12.
[184] See Gurgula (n 9) 13.
[185] Lamping et al. (n 7) para 6. In the same vein Valtere (n 6) 12.

the current main problem: fragmentation. This is done in general also efficiently. Therefore, the proposal is to be welcomed.

When it comes to the details, the proposal is also up to the tasks, especially if one considers the proposed amendments of the Parliament. It found a fair balance between the procedural rights of the patent holder and the public interest in a swift reaction. An idea for a further development here would be to create a more flexible approach regarding the set time for prior negotiations. When it comes to the issue how to deal with situations in which the patents and its holders are not easily identifiable, the amendments of the Parliament should not be kept. Further to be highlighted as a positive feature is the inclusion of know-how and trade secrets. Hopefully, this practically very important amendment of the Parliament survives the Trilogue.

Despite all these positive words, the proposal is still to be considered as a missed opportunity. The “big thing” – a general system for union wide compulsory licencing – was not even tried to achieve. On the one hand this is very understandable from a political point of view, but on the other hand, it is a bit of a disappointment that such a good general idea is only to unfold itself in such a narrow space.

E. Section 4: Scaling it up to the global level – Own proposal for reform

Patent law cannot be seen as a solely national or European matter. Over the course of the last decades, an elaborated and quite complex system of different multinational conventions and frameworks evolved which deals with this subject. In times of globalisation, that is a necessity because patents are national in scope. This problem must be overcome or reduced when companies are wanted to operate cross-border. One of the most important rules in that regard is the already mentioned TRIPS Agreement. This legal framework must be accepted by every country which wants to join the WTO. That is the main reasons why TRIPS has today 164 members.[186] As it is a binding international treaty which even can be enforced through the judiciary system of the WTO, all members states must obey its rules. When it comes to compulsory licences, Art. 31 of TRIPS sets out a set of requirements which have to be fulfilled so that a compulsory licence can be granted.[187] The overall legal system here is that the countries transpose Art. 31 of TRIPS into their national law. The compulsory licence can then be granted by every state for its territory under its national laws. So, there is – like in the EU till today – no centralised process on the WTO level which may lead to a compulsory licence for all or several countries.

After going through the previous chapter of this paper, that status may arise questions. When one argues that the centralisation of compulsory licences is sensible at a European level and should even be substantially broadened regarding the material scope, the question occurs why one should not also think bigger in the territorial sphere. In that sense, it was already suggested in literature that the EU proposal could serve as an example for national legislation.[188] But it might also be useful to look at the other direction and ask if it could be a role model on the global level to update the TRIPS Agreement. Even though that might seem very ambitious because the reformation of rules on the TRIPS level is extremely challenging due to the high number of participating countries, it is not unimaginable. The EU has been a global trend setter in other fields of

[186] See the WIPO statistic <https://www.wipo.int/wipolex/en/treaties/parties/231> accessed 19 August 2024.
[187] An overview of the different prerequisites can be found by Manisha A. Desai, 'Compulsory licensing: Procedural requirements under the TRIPS agreement' (2016) 18 Pharmaceuticals Policy and Law 31.
[188] Gurgula (n 9) 2.

law (e.g. privacy,[189] "tech" regulation,[190] and (maybe) AI[191]). Why should it not have an impact in the field of compulsory licences for patents? Therefore, it seems sensible to investigate the idea to create a centralised process for the granting of compulsory licences on a global level. That is the purpose of this chapter. First, it will examine what the current problems of the TRIPS system are and will show in that way why an amendment is necessary. Subsequently, it will be explored if the considered compulsory licencing approach is the best way to go forward. After that, the paper will look into selected necessary adjustments of the EU proposal to refine it for the TRIPS/WTO level.

I. Current problems of the global TRIPS system

The TRIPS system was highly controversial since its introduction in 1994.[192] The most debated issue was the treatment of developing countries. Some said, because TRIPS is a junktim to join the WTO, these states were – regarding IP protection – forced to take a bad deal.[193] The dispute also revolved to a substantial part around the issue of compulsory licences.[194] The main and "traditional" field of the TRIPS debate is the question of medicine supply in poorer countries.[195] But in the last few years another area of discussion arose: The dealing with so-called "green patents".

1) Access to medicines in the global south

The focus of the debate has long been on health-related issues. The "accusation" was that because of the strict TRIPS system with its strong patent protection, poorer countries would not be able to afford basic medication.[196] The background here is that they could not import cheaper generics and are not able to produce the drugs

[189] Mark Scott and Laurens Cerulus, 'Europe's new data protection rules export privacy standards worldwide' *Politico* (Brussels, 31 November 2018) <https://www.politico.eu/article/europe-data-protection-privacy-standards-gdpr-general-protection-data-regulation/> accessed 19 August 2024.
[190] Madhumita Murgia, 'Europe a global trendsetter on tech regulation' *Financial Times* (London, 29 October 2019 <https://www.ft.com/content/e7b22230-fa32-11e9-a354-36acbbb0d9b6> accessed 19 August 2024.
[191] Adam Satriano, 'E.U. Agrees on Landmark Artificial Intelligence Rules' *New York Times* (New York, 8 December 2023) <https://www.nytimes.com/2023/12/08/technology/eu-ai-act-regulation.html> accessed 19 August 2024.
[192] See for example Wenwei Guan, 'IPRs, Public Health, and International Trade: An International Law Perspective on the TRIPS Amendment' (2016) 29 Leiden Journal of International Law 411, 412; Igbokwe and Tosato (n 12) 1817 each with further references.
[193] E.g. Gana (n 4) 739 f.; see also Reichman (n 36) 247: 'take it or leave it decision'.
[194] Reichman (n 36) 247 f.; Le (n 21) 55.
[195] See Guan (n 192) 412 f. with 9 references regarding the topic in footnote 7.
[196] E.g. Gurgula and Lee (n 42) 62 ff.

themselves. That argument is pretty straight forward and convincing. With an almost global patent protection, the pharmaceutical companies in the developed nations, which invent the drugs, have a strong bargaining position which they can use in price negotiations, for example. They are the only ones who can produce or sell the medicines.[197] The countries in the global south do not have the money to pay these high prices. And then they have a hard time to do something about it because of the strict compulsory licensing rules.

These claims got heard from the international community what led to the so-called Art. 31bis-agreement in 2001.[198] It is also known as the Doha-Declaration. The agreement in general aimed to bridge any gaps between public health policy issues and intellectual property[199], and in its sixth paragraph it acknowledged the issue of compulsory licences in countries with insufficient or no manufacturing capacities in the pharmaceutical sector.

That agreement recognised a major flaw of the compulsory licensing regime under Art. 31 of TRIPS: The compulsory licences could only be granted for the jurisdiction which issued them. Export compulsory licences were forbidden, and a compulsory licence had to be 'predominantly for the supply of the domestic market' of the WTO member granting the licence (Art. 31 (f) of TRIPS). Because most developing countries – who often need the medicines the most – do not have the knowledge or capacities to produce the drugs themselves, the system was ineffective and was often unusable for countries in the global south.[200] It was no option for these countries to issue a compulsory licence simply because nobody could make use of them. Under Art. 31bis, export compulsory licences were made possible under certain conditions. The idea here was to enable a system where a country with enough production capacities can produce

[197] It must be mentioned that a couple of experts argue that the strong patent protection helps developing countries in the end and that a weakening (e.g. through compulsory licensing) would have no or even a negative effect, see e.g. Desai (n 187) 32.
[198] WTO, 'Declaration on the TRIPS Agreement and Public Health of 14 November 2001' WT/MIN(01)/DEC/2.
[199] See Ellen 't Hoen, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha' (2002) 3 CHI. J. INT'L L. 27, 28.
[200] See Le (n 21) 61; Reichman (n 36) 248.

the drugs under a compulsory licence and export it to the country in need.[201] So, on the first sight the matter seems settled. The EU, for example, reacted to the Doha-Declaration with the aforementioned Regulation on compulsory licences for the export to third countries.

But if one watches closer, the success of the Art. 31bis-agreement is more than doubtful. Evidence shows that until now only 1 compulsory licence under Art. 31bis got granted.[202] The aforementioned EU-Regulation was not invoked once. The "normal" Art. 31 mechanism was used only 108 times from 2000-2019 regarding pharmaceutical products, predominantly for HIV medicines.[203] All in all, the Art. 31 and the Art. 31bis TRIPS flexibility got rarely used in practise.[204]

This is a clear indication that the system is still ineffective. The Covid-19 pandemic also showed how unreliable it is. Instead of granting compulsory licences, many developing nations put their efforts into the issuing of a complete waiver for Covid-19 vaccination patents.[205] Only one country (Bolivia) made a notification to profit from Art. 31bis of TRIPS with respect to Covid-19.[206] Though, this was not successful because no country was willing to arrange the export of Covid-19 vaccines to the country.[207]

So, where lay the problems? The literature indicates that the main obstacles regarding the Art. 31bis-system are the complex processes that have to be fulfilled by a country or

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[201] Jhanvi Tripathi, 'The TRIPS Agreement and Public Health: Understanding the Reform Agenda' (2023) ORF Issue Brief No. 509, 5 f. <https://www.orfonline.org/research/the-trips-agreement-and-public-health> accessed 19 August 2024.

[202] Weinian Hu, 'Future-proofing pandemics: Analysing the EU's proposal to clarify and simplify the compulsory licensing procedure' (2022) CEPS Policy Insights, No 2022-04, 2.

[203] Milorad Stamenovic and Sanja Jelisavac Trosic, 'Cross-sectional Analysis of the Countries and Corresponding TRIPS Flexibilities for Pharmaceuticals' (94th International Scientific Conference on Economic and Social Development -"The Dark Side of Management and Governance: power, ideology, tensions, and destructive traits" (XI. OFEL), Dubrovnik, March-April 2023) <https://www.researchgate.net/publication/369949473_CROSS-SECTIONAL_ANALYSIS_OF_THE_COUNTRIES_AND_CORRESPONDING_TRIPS_FLEXIBILITIES_FOR_PHARMACEUTICALS> accessed 19 August 2024.

[204] Gurgula and Lee (n 42) 65; Eikermann (n 2) 557. When they were used the compulsory licences got for diseases like HIV, Hepatitis C and cancer, Gurgula (n 9) 3.

[205] See the Communication from India and South Africa (n 43).

[206] See WTO, 'Bolivia outlines vaccine import needs in use of WTO flexibilities to tackle pandemic' (2021) <https://www.wto.org/english/news_e/news21_e/dgno_10may21_e.htm> accessed 19 August 2024.

[207] Duncan Matthews, 'The Covid-19 Pandemic: Lessons for the European Patent System' (2022) Queen Mary Law Research Paper No. 377/2022, 7, <https://ssrn.com/abstract=4022509> accessed 19 August 2024.

company to be allowed to grant or get a compulsory license.[208] The process just takes too much time or is too burdensome for poorer counties which lack expertise in the field.[209] Another suggested reason is that developing countries and potential producers might fear long-lasting, costly and uncertain legal battles over the granted compulsory licences.[210] Furthermore, for the pharmaceutical companies, who could produce the medicines, it is often not economically attractive to produce generics for a single or even a few small and poor countries.[211] Political pressure might also play a role in the decision not to grant a compulsory licence under TRIPS.[212]

2) Use of "green patents" to fight climate change

Another focal point of the current debates are the so-called green patents or patents on environmental sound technologies. This term refers to patents that can help to fight environmental issues and especially climate change.[213] There exists a heated discussion in literature and politics[214] if a softening of IP protection in this field should be aimed at so that a wider range of stakeholders can profit from them. Some argue that for the greater good that may be desirable.[215] The Commission might seem to lean in that direction. In its compulsory licencing proposal it states that '[w]ith regard to the environmental impact, the initiative's positive impacts could be decisive in increasing access to products and technologies that can tackle environmental crises.'[216] Others hold that such a path will lead to less research and development and will ultimately do harm to the good aims.[217] But overall it seems to be consent that the green technology that gets patented can help to fight climate change and that it should be available to as many stakeholders as possible. This can for example be seen in statements of the Commission

[208] See Tripathi (n 201) 6; Vandermeulen et al. (n 10) 68 with respect to a Canadian case.
[209] See Guan (n 192) 438 with further references; Igbokwe and Tosato (n 12) 1832 ff.
[210] Igbokwe and Tosato (n 12) 1836 f.
[211] See e.g. Igbokwe and Tosato (n 12) 1834 ff.
[212] See e.g. Arora (n 121); Ooms and Hanefeld (n 98) 3; Igbokwe and Tosato (n 12) 1824 ff.
[213] Keith Maskus, 'Differentiated Intellectual Property Regimes for Environmental and Climate Technologies' (2010) OECD Environment Working Papers, No. 17, para 4 f.
[214] See regarding the debate between the US and developing countries Maskus (n 213) para 1.
[215] See e.g. Khorsed Zaman, 'The TRIPS Patent Protection Provisions and Their Effects on Transferring Climate Change Technologies to LDCs and Poor Developing Countries: A Critical Appraisal' (2013) 3 Asian Journal of International Law 137.
[216] Commission (n 3) 8.
[217] See Maskus (n 213) para 3, 70 ff., 94; Eric L. Lane, 'Cancun Climate Change, and Intellectual Property Rights: No News Is Good News for Green Patents' (2011) 2 Eur J Risk Reg 61, 62 ff.

when it makes a connection between a 'green' economy and 'tools to facilitate access to critical IP protected technologies in times of crisis'.[218]

This is not the place to dive deep into the discussion. Rather, it is argued that if one decides to see compulsory licences as part of the solution, the current system is not appropriate to tackle this issue. It would render this option essentially useless. The problem lays in the fragmentation of the system. Insofar, it can be referred to the explanations regarding the Commission's proposal (e.g. the necessity of multiple licences and legal uncertainty).[219] On the global level, these problems can multiply because there are more states involved. This would make the system so slow and burdensome that it practically cannot be used. When it comes to countries in the global south, there additionally arises the problem that they can't produce the environmentally friendly products themselves, mirroring the issue known from the field of medicines.[220] Also, the political disputes between countries will most likely be a lot more intense when one state wants to grant a compulsory licence for a foreigner's patent. The background here is that on the global level the countries are not as close to each other as in the EU and the approaches to intellectual property vary a lot more. Against this backdrop, it was argued in literature that compulsory licences will in the current state of affairs probably never be used to make the use of green patents possible.[221]

II. The new idea: Centralised compulsory licences as a solution

If one recognises the described problems with the current system, he or she should look for a solution. The presented issues are too important to be ignored. Here, the centralised compulsory licences come into play. This thesis argues that setting up a centralised compulsory licence system on the global (WTO/TRIPS) level could be the way to tackle these matters efficiently. It could also provide the final step towards a balanced international patent system which protects the interests of developed and developing countries. The cornerstone of such a system – which is borrowed from the EU proposal – would be that compulsory licences cannot only get issued by a single country for its

[218] Commission (n 41) 11.
[219] See D.I.
[220] Zaman (n 215) 156 f.
[221] Kuei-Jung Ni, 'Legal Aspects (Barriers) of Granting Compulsory Licenses for Clean Technologies in Light of WTO/TRIPS Rules: Promise or Mirage?' (2015) 14 World Trade Review 701, 719.

own boarders,[222] but by a central institution and for the territory of every WTO member or a selected group of WTO members.

1) Efficient and fair procedure

As we have seen, one of the main problems of the current compulsory licensing system lays in its complex and lengthy procedures. That is especially true in cases where compulsory licenses would be needed in many countries.[223]

Therefore, a very important point – as with the EU proposal – is that a system of centralised compulsory licences would be swifter and faster in comparison to a framework where every country must act for itself. It would take a lot less administrative effort to issue one compulsory licence for several jurisdictions because there would be just one single process. That would also help to solve some of the current problems with the Art. 31bis approach. The smaller or poorer countries could profit from a compulsory licence for pharmaceuticals without taking an active role in the process when one applicant gets the permit.

Because of the process pooling, the way towards a decision would also be fairer. The smaller or poorer countries with less resources would not face the financially well-equipped patent holders on their own. In that way, the centralisation would take away possible restraints these countries might have because they fear a long, costly, and often uncertain legal battle which possibly even goes before the WTO panels.

A centralisation of compulsory licences on the global level would also address difficulties at the political level. When every state must act separately, it is often easy for the bigger and more powerful countries to use political pressure in order to stifle these approaches. If, for instances, a smaller country in Latin America wants to grant a compulsory licence for a patent which is used in an environmentally friendly product and the patent holder has its seat in the US, the latter country would have a strong incentive and a lot of political tools to put this project to an end. But if the process would be centralised at the

[222] Or in the case of Art. 31bis for singularly exports.
[223] Carlos M. Correa, 'Expanding the production of COVID-19 vaccines to reach developing countries' (2021) South Centre Policy Brief No. 92, 3 <https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf> accessed 19 August 2024 regarding covid vaccines.

WTO level and the compulsory licence would be granted for all states in Latin America, the political force of the participants would be more even.

2) Making compulsory licences more attractive for manufacturers

Another problem of the current country-by-country approach is rooted in missing incentives for stakeholders to take part of such a procedure. Especially, the companies which could produce the products where the patent is used in, often decide that it would be not economically feasible to produce under a national compulsory licence. The background here are the missing economies of scale. This problem even got recognised in the Art. 31bis agreement.[224]

In that field, a centralisation would help in getting more drive to go for compulsory licences. The markets would be much bigger if the licence would be granted not only for a single country. Hence, it would become economically more attractive for private companies to work with such a licence. There are just more opportunities to make profit if one can serve the whole African continent for example instead of one small country. The companies could also produce in every country which falls under the licences what makes the manufacturing more flexible.

In that sense, it was already argued in literature that economies of scale could be achieved under the current rules.[225] It was put forward that under Art. 31bis (3) countries could notify the TRIPS Council on their intent to import pharmaceuticals. They could pool their demand to jointly become a bigger market.[226] That position is to be agreed with. But it has two major disadvantages in comparison to real centralisation: The scope includes only medicines, and the countries must be parties of a regional trade agreement.[227] Hence, this economic problem can only partially be solved under the current framework.

[224] See Art. 31bis (3).
[225] Igbokwe and Tosato (n 12) 1840 f.
[226] ibid.
[227] That was recognised see ibid

3) Protecting the interests of patent holders

A centralised process for compulsory licences might even be in some respects favourable for the patent holders. The first reason for this is legal certainty. This also from an economical point of view hardly overestimated matter gets promoted when the companies do not face a patchwork of compulsory licences, issued by different jurisdictions. The affairs are a lot clearer when the patent holders just have to deal with one major case at the WTO. This also saves resources on the company's side and helps to prevent unpleasant surprises that may occur when countries take action themselves.

Nevertheless, from the perspective of the patent holders it could seem unattractive if the unpopular compulsory licences can get issued for a greater region. This can be read from the industry statements during the public consultation on the EU proposal. They showed a strong opposition even regarding the limited local and material scope of the proposal.[228] The Commission itself analysed that 'a majority of companies and business associations consider that the impact would be negative.'[229] But one must keep in mind that the burden for the patent holders is weakened by the high requirements that have to be fulfilled and by the renumeration they get for the compulsory licence. This helps to justify the impairment of their intellectual property right.

4) Conclusion

All in all, the centralisation of compulsory licences on the global level has similar advantages as it has on the EU level. It would bring this instrument back to the table so it can be used to tackle major world issues like the access to medicines, climate change, and, more broadly, the relationship between the global south and the global north. It would be doing so by taking away the hurdles which are created by the fragmentation of the current compulsory licencing system.

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[228] See e.g. Joanne S. Eglovitch, 'Pharma groups slam EU's compulsory licensing proposal' (*Regulatory Focus,* 14 August 2023) < https://www.raps.org/News-and-Articles/News-Articles/2023/8/Pharma-groups-slam-EU's-compulsory-licensing-propo> and Statements by Business Europe, European Federation of Pharmaceutical Industries and Associations (EFPIA); American Chamber of Commerce to the European Union (AmCham EU).

[229] Commission (n 3) 5.

Regarding green patents, a compulsory licensing approach is shared by different voices in literature.[230] But it must be mentioned that the idea to centralise the process also faces opposition in academia. *Guan* for example states that '[a]dministration of compulsory licensing for public health should be left solely within the hands of domestic authorities as it is in the Paris Convention. Domestic policy makers should bear more responsibility and be more active through domestic instead of international framework in promoting public health.'[231] For the given reasons, this view is to be opposed.

III. Necessary adjustment for the global level

After arguing that the EU proposal should in principle be exported to the WTO/TRIPS level, it is necessary to look into required changes that have to be made for such an approach. It is obvious that a mere copy and paste approach would not be sufficient. This is, for instance, due to the existing institutions in both frameworks which differ quite substantially. Furthermore, the structure of the members states of booth agreements differs enormously. The WTO members are much more diverse than EU countries and the political, cultural, and economic connection is significantly lower between WTO members.

Since the room in this dissertation is limited, it will not lay out a complete spelled out proposal for a centralised compulsory licensing system for the global level. Instead, the attention will be brought to the most focal points. These are the (material) scope of the system and the decision-making institution.

1) Scope of the system

When it comes to the scope, the most basic question is if the compulsory licenses should be exclusively available in crisis situations as it is the case with the EU proposal. There are two reasons to disagree:

First and most important, crisis is such a narrow concept that it would not fit well with many of the problems which could be addressed under a centralised compulsory

[230] Zaman (n 215) 157 f.; Alexander Adams, 'Technology Transfer to Combat Climate Change: Opportunities and Obligations Under TRIPS and Kyoto' (2009) 9 Journal of High Technology Law 1, 20.
[231] Guan (n 192) 440.

licensing scheme. The already mentioned “green patents” are a good example here. The climate “crises” and other long environmental developments would, most likely, not qualify as a crisis.[232]

Second, to decide at a global level if a crisis exists could be even harder than in the EU. For some countries, a problem might seem as a minor issue, while other qualify it as a major thread. Not every issue is as clear as the Covid-19 pandemic. This could lead to political tensions and uncertainty for the different stakeholders which would make the system unusable.

Therefore, the grounds on which a compulsory licence can be granted should not be narrowed by a crisis approach. Rather, the deciding institutions should get more leeway in that regard.

A second question which can play a crucial role in practise is the handling of know-how and trade secrets. These should be included in the scope, parallel to the amendment of the Parliament in the EU proposal. The argumentation here is similar. Therefore, reference can be made to it at this point.[233] As an addition, it can be pointed out that when it comes to “green patents” it was put forward in literature that they are often unusable without additional trade secrets.[234]

2) Power to take decisions

Another significant, and potentially most controversial question would concern the decision-maker. Who will be the competent body to take the decision to grant or not to grant a compulsory licence? To create as little disturbance as possible and ensure continuity it would be favourable if an already existing institution of the WTO could be assigned with that task. Therefore, this approach is pursued first.

[232] See D.II.
[233] See D.I.5).
[234] Neel Maitra, ‘Access to Environmentally Sound Technology in the Developing World: A Proposed Alternative to Compulsory Licensing’ (2010) 35 Colum J Envtl L 407, 425; Maskus (n 213) para 76.

The current main organs of the WTO are the Ministerial Conference and the General Council as well as other Councils and Committees and the General Secretariat.[235] Other important organs are the Dispute Settlement Panels and the Appellate Body. But whether one of these institutions seems suitable is questionable:

The Ministerial Conference is not the right organ to take over the decision. It is the highest body of the WTO, responsible for the shape of the institution as well as the most important decisions.[236] The Ministerial Conference should not be burdened with often more small-scale decisions regarding compulsory licences which need deep factual knowledge of the law and the case in question. Also, the Ministerial Conference is a highly political institution which would not fit with the required minimum of independence to take the bureaucratic decision. In the end, there would probably be a political war even within the decision-making organ. That should be avoided.

Prima facie, the General Council seems to be more fitting. This organ is responsible for the day-to-day business of the WTO between meetings of the Ministerial Conference.[237] But to entrust it with the task to decide over compulsory licences also carries significant disadvantages. Because every member country is represented in the General Council, there is again the possibility of a politicisation of the decision. It would also be disproportionate if the representative of every member had to work himself or herself into the facts of the case. That would also carry the risk that the decision would be taken by uniformed persons which would not do justice to the technical matter.

The other Councils and Committees are quite specialised and have tasks which are tailored to them. So, it would in general not be desirable to assign one of them with the decision over compulsory licences. It would not fit their status. The matters might be different for the Council for Trade-Related Aspects of Intellectual Property Rights which

[235] See the publication of the German Federal Ministry for Economic Affairs <https://www.bmwk.de/Redaktion/DE/Artikel/Aussenwirtschaft/wto-mitglieder-struktur.html> accessed 19 August 2024.
[236] See WTO, 'WTO Analytical Index: Guide to WTO Law and Practice' (3rd ed CUP 2012) Art. IV para 62.
[237] See the publication of the German Federal Ministry for Economic Affairs <https://www.bmwk.de/Redaktion/DE/Artikel/Aussenwirtschaft/wto-mitglieder-struktur.html> accessed 19 August 2024

has competences regarding TRIPS (see Art. 68 of TRIPS).[238] However, the problem would be again that every country could participate in the decision (see Art. IV:5, sentence 7 of the WTO Agreement) what does not fit to the task. An issue would also be the consensus procedure in the Council what would allow every country to block a decision.[239]

The next candidate is the General Secretariat which tasks are to prepare and conduct negotiations between the WTO contracting parties, to advise them, to analyse and present the development of world trade and to support activities in dispute settlement procedures.[240] It is sometimes described as an "honest broker" without executive functions.[241] These current responsibilities show that the General Secretariat has an organisational and neutral position without major decision-making powers. That is a major difference in comparison to the European Commission for example. To create the least amount of upheaval, it is therefore argued that the General Secretariat is also not the right body to assign the decision to. It would not fit to the character of the institution which can be described as administrative and focused on management as well as aiding the WTO members.

But there is another body that could serve as a role model. This refers to the Dispute Settlement Panels. These act in a dispute between different countries about WTO law essentially as judges. They are appointed for each case separately and in general in agreement of the parties.[242] Against this background, that procedure would not be practical in the case of granting compulsory licences because there is only one party (the applicant or applicants) who should not be able to choose the decision-makers itself.

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[238] For an overview see Karen Kaiser, 'Art. 68: Council for Trade-Related Aspects of Intellectual Property Rights' in Stoll, Busche and Arend (ed), *WTO—Trade-Related Aspects of Intellectual Property Rights* (Brill 2009).

[239] See ibid.

[240] See the publication of the German Federal Ministry for Economic Affairs <https://www.bmwk.de/Redaktion/DE/Artikel/Aussenwirtschaft/wto-mitglieder-struktur.html> accessed 19 August 2024; Gregory Shaffer, 'The role of the Director-General and Secretariat: Chapter IX of the Sutherland Report' (2005) 4 World Trade Review 429, 429 f.

[241] Alan Wm. Wolff, 'WTO 2025: Constructing an executive branch' (2022) Peterson Institute for International Economics Working Paper Series WP22-8, 10 <https://www.piie.com/sites/default/files/documents/wp22-8.pdf> accessed 19 August 2024.

[242] Jeanne J. Grimmett, 'Dispute Settlement in the World Trade Organization (WTO): An Overview' (2009) 3 f. <https://ecommons.cornell.edu/server/api/core/bitstreams/ea89e8c6-b978-446e-a810-b7d99700c83c/content> accessed 19 August 2024.

So, the last candidate would be the Appellate Body. This is a permanent body which decides over appeals against the rulings of the Dispute Settlement Panels.[243] But choosing the Appellate Body to decide over compulsory licences would have one major flaw. Although it is not called a court and its members are not called judges, it has a judicial function.[244] Hence, it is not suited to take the administrative decision regarding compulsory licences. But its structure could be copied to a certain extent. The Appellate Body has 7 members, and each case is heard be 3 of them.[245] Each of the individuals has a 4-year term and cannot be affiliated with any government[246]. These conditions seem to be fitting since it takes away the politization and ensures that each deciding member is in detail familiar with the law and case at hand.

Following the approach of the Appellate Body would result in the creation of a new organ within the WTO. This is – as mentioned – not necessarily desirable but seems to be the best option there is under the current system. The Appellate Body itself should be competent to decide over appeals by the parties of the proceedings.

IV. Conclusion of section 4

In this section, it was shown that the current international patent law system on the WTO level has some major problems especially when it comes to fighting some of the main struggles of mankind. Hence, a reform of the system seems desirable. It was argued that the introduction of a global centralised compulsory licencing system which takes the EU initiative as a role model can help to cope with these issues. But obviously some adjustments have to be made. In that regard, this chapter looked into the questions if the scope should be widened to make the system applicable to other situations than just crises scenarios and who should be the competent body to take the decisions. These issues are not the only important structural points which must be tailored for the international level. Other – equally important – topics could only not be discussed because of the limitation of this thesis (e.g. how the decision makers at the new body

[243] Grimmett (n 242) 2.
[244] Gregory Shaffer, Manfred Elsig and Sergio Puig, 'The Extensive (but Fragile) Authority of the WTO Appellate Body' (2016) 79 Law & Contemp Probs 237, 246.
[245] Grimmett (n 242) 2.
[246] See the WTO publication under <https://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm> accessed 19 August 2024.

should be appointed, the exact process which must be fulfilled to issue a compulsory licence, and an in-depth analysis on the grounds for granting such a licence).

F. Conclusions and recommendations

Patent law is a living creature. Although reforms on a European and international level often need extensive battles between the different interest groups and the involved countries, time has shown that this field of law changes constantly with the direction being more harmonisation. Compulsory licences are no exception here. In the course of time, a similar approach has emerged worldwide. The current EU initiative to centralise compulsory licences for crisis situations is the newest development in that regard. This thesis has shown that the proposal has the potential to make the patent system in the EU more efficient to tackle these situations and is therefore to be welcomed. It could be demonstrated that compulsory licences are a useful tool to deal with the problems of the current patent system in the first place. That is because they have an incentive role and an enabling role. Furthermore, the proposal would overcome the biggest flaw of the current system: fragmentation. In an internationally linked economy, a compulsory licence for one country is often useless. And to get compulsory licences in all member states is an unsecure, lengthy, and costly process which does not fit the urgency inherent in a crisis. Centralising the process on the EU level would solve this problem. However, some adjustments could be made during the upcoming legislative process. These concern, for instance, the involvement of the patent holder in the granting process, where concrete deadlines could be set to streamline the process. Also, the inclusion of trade secrets in the scope would be preferable because patents can be unusable without the extra knowledge. It is also debatable if a compulsory license could be granted not for a single patent but for a whole product. This could help to make the reaction even faster and could provide additional security for the licensee. But one must be realistic. The change which would help the most and which would be the biggest is out of reach: It is almost certain that the law to be will not go beyond crisis situations to use the potential of centralised compulsory licences in other circumstances. That is something which is left for the future. Here, the fourth chapter of this thesis comes into play. In this section, it was proposed to install a wide centralised compulsory licensing system on the global/WTO level that builds on the main idea of the EU initiative which is the

centralisation of the granting process over several jurisdictions. It was argued that such an approach would help with two of the major issues of current international patent law: The access to medicines and the use of green patents. This is mainly because it makes the process more efficient by tackling the problem of fragmentation. The approach would also create more legal certainty for all stakeholders by taking everything in one hand. It also enables economies of scale by enlarging the potential market. In that way, it would be more interesting for private companies to make use of compulsory licences. An international centralisation could also help to balance out the political powers which are always present in these kinds of decisions. Such a system could be built on the basic principles of the EU proposal, but it would need major adjustments. Two of the most important areas in that regard have been discussed in this paper. These are first the question in which circumstances a compulsory licence could be issued. The advice here would be not to narrow the scope to crisis situations but give the decision makers more leeway. Second, it got investigated which body on the WTO level could be the competent committee. It was shown that none of the existing organs are really fit for the task. Hence, it was proposed to set up a new body at the WTO which takes the Appellate Body as a role model. Further research could dive into other complex issues which revolve around the question of how a centralised compulsory licensing system on the global level could look like (e.g. how the decision makers at the new body should be appointed, the exact process which must be fulfilled to issue a compulsory licence, and an in-depth analysis on the grounds for granting such a licence). It would also be necessary to analyse how and if it would be possible to create the necessary international consensus between the involved states. That would be hard in any case, but a throughout analysis in the field of political science could help to estimate the chances and improve them. It would be worth it.

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