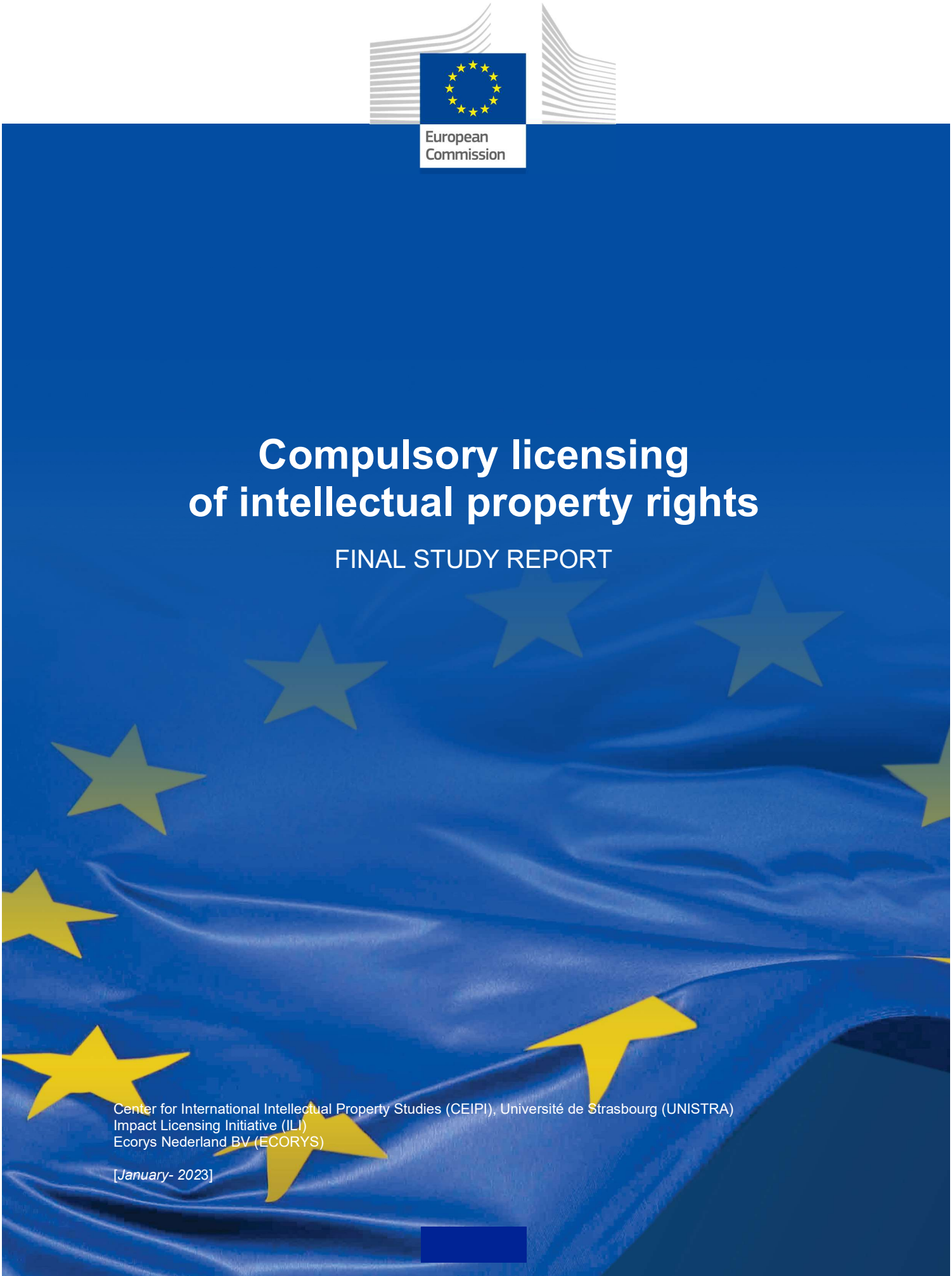

Compulsory licensing of intellectual property rights

FINAL STUDY REPORT

Center for International Intellectual Property Studies (CEIPI), Université de Strasbourg (UNISTRA)
Impact Licensing Initiative (ILI)
Ecorys Nederland BV (ECORYS)

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Abbreviations

AIPPI	International Association for the Protection of Intellectual Property
CEIPI	Center for International Intellectual Property Studies
CJEU	Court of Justice of the European Union
CL	Compulsory licence / Compulsory licensing
COVID-19	Coronavirus
CPI	French Intellectual Property Code
CPVO	Community Plant Variety Office
DG COMP	Directorate-General for Competition of the European Commission
EC	European Commission
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EPO	European Patent Office
EU	European Union
GMP	Good Manufacturing Practices
HERA	Health Emergency Preparedness and Response Authority
HIPO	Hungarian Intellectual Property Office
ILI	Impact Licensing Initiative
IP	Intellectual Property
IPR	Intellectual Property Rights
JPA	Joint Procurement Agreement
LESI	Licensing Executives Society International
MA	Marketing authorisation
MPP	Medicines Patent Pool
MS	Member State
NGO	Non-governmental Organization
OECD	Organisation for Economic Co-operation and Development
PA	Patent Act
PCT	Patent Cooperation Treaty
RDP	Regulatory Data Protection
R&D	Research and development
SPC	Supplementary Protection Certificate
SPTO	Spanish Patent and Trademark Office
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
TSD	Trade Secrets Directive
UN	United Nations

US/USA	United States of America
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Scope of the Study

The study's main objective is to assist the European Commission in defining potential problems as regards compulsory licensing ("CL") in the European Union ("EU") as well as to identify and assess a number of policy options to improve coherence and effectiveness of the compulsory licensing system as applied in the EU. The main focus of the study is on public emergencies, with particular attention to health-related crises. There may be other urgent needs for licensing technologies in order to produce products for other types of emergencies such as natural disasters (e.g., floods and means for purifying water) or nuclear disasters (protective equipment), or essential food shortages (protected plant varieties), among other types of crises. The Study's problem definition, and the development of possible policy options, has been completed with this expansive scope of potential crises in mind, yet in agreement and consultation with the European Commission. Thus, the scope of crises examined in the context of the CL system is considered to a broad extent where possible, with the underlying qualification that a CL should not be issued more frequently than currently possible under a 'last-resort' approach. In other words, CL as a legal tool should be sparingly applied as a solution in the case of failure in reaching voluntary agreements concerning one or more critical technologies.

The COVID-19 pandemic response has demonstrated how access to vital products and services can – even in a developed region such as the European Union – become compromised through a lack of distributed production capacity and logistical challenges. The pandemic also triggered debates regarding the need for more effective legal mechanisms to ensure better access to critical technologies in crises, health-related or otherwise, should reaching voluntary arrangements become an impractical option or fail.

In the same discussion, other possible responses have included forfeiture of intellectual property rights ("IPRs") and their waiver.[1] Crisis situations with an element of time sensitivity require by their very nature a rapid and robust response. Yet, such "severe" responses may come up against established legal rules, especially rights of due process and other procedural safeguards, sacrificed in pursuit of expedience.

These particular concerns in mind, present research examines the legal framework for CLs as a last-resort tool for crisis situations when voluntary arrangements fail. The CL mechanism shall be constantly ready to be triggered in an appropriate crisis situation and therefore allow for an orderly response in the EU, but should be adopted in exceptional circumstances particularly because of the equtability concerns such a measure poses on patent holders.

Another complication relevant to resolving crisis situations in the EU is that CL legislation is considered a largely "national" matter, with CL practices enshrined in the national patent, procedural and institutional laws of EU Member States (MS). These domestic legislations regulate access to IPR's predominantly – or exclusively – for the respective national domestic market. The only EU legislation that provides for CLs are:

- Regulation 2100/94 regarding compulsory licensing of community plant variety rights in the EU[2] .
- Regulation 816/2006 aimed at regulating the export of medicinal products to third countries without a manufacturing capacity, and

[1] 'TRIPS Council Hears Initial Reactions to Quad's Outcome Document on IP COVID-19 Response', accessed 16 June 2022, https://www.wto.org/english/news_e/news22_e/trip_06may22_e.htm. 'TRIPS Council Hears Initial Reactions to Quad's Outcome Document on IP COVID-19 Response', accessed 16 June 2022, https://www.wto.org/english/news_e/news22_e/trip_06may22_e.htm. Historic versions of the Paris Convention and certain national patent laws (e.g. in France and Belgium) provided for forfeiture or revocation of a patent if compulsory licences were insufficient to prevent abuses or if an invention was not practiced during the first two years after its grant.

[2] Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights ("CPV Regulation")

- EU competition law remedies obliging parties to licence, specifically under Art. 102 TFEU and Regulation 1/2003.[3]

As will be further examined in this Study, differences in national practices implementing these EU instruments – from the national legal provisions themselves, to the triggering event of a CL's availability, to the definitions of "crisis" and "national emergency", to the institutional actors competent to evaluate and grant a request for a CL, can create challenges when addressing cross-border crises that require a wide-scale multinational MS response.

Study approach

Under the terms and conditions set forth by the Commission, the research team carried out the Study under the following approach:

- **Apolitical:** The topic of CL of IPRs has attracted considerable media and policy attention in the recent years in large part due to the COVID-19 pandemic. The politization of the topic generated numerous polemic and controversial statements and calls for reform. The research team undertakes a technical and non-ideological analytical approach given the sensitivity of this topic. This understanding is to be reflected in the formulation of research problems, as well as the proposed policy options.
- **Maintaining a "last-resort" approach to CL:** While focusing on various issues of coherence and effectiveness of CL in the EU through procedural and substantive measures, the research team is to uphold a "last-resort" approach to CL. Recognizing that any changes in CL mechanisms could ultimately be interpreted "lowering" or "raising the bar" for evaluating and granting a request for a CL, the research team considers that the Study is not centered on making CL necessisarily more accessible and frequent than it currently is. CL mechanisms should be available only when voluntary cooperation mechanisms, including "impact licensing", fail.
- **Focus on "emergencies" and "critical" technologies:** National legislation provides for CL mechanisms under various conditions and for various situations. The research team understands that the focus of the study is on the CL procedures applicable in public emergencies, with focus placed on health-related crises and covering, to a lesser extent, other potential crises (e.g., energy-related or environmental crises), and/or concerning one or more critical technologies.
- **Focus on CL practices during "crises":** Although CLs could be granted on a variety of grounds, the present study focuses on the situations of crisis, including health crises but also other crises (e.g., energy-related or food crises).
- **Considering EU-scale approaches to CL:** Analysis of national CL mechanisms of MS or their comparison is not the focus of the study, which instead approaches the functioning of the plurality and possible interaction of national CL mechanisms and the EU Regulations with provisions on CL from the scale of EU overall. The EU level will be the analytical level for identifying problems and proposing solutions.

[3] Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty.

- **Empirical basis:** recognising the scarcity of publicly available quantitative and qualitative information relevant for the quantification of some problems related to CL (their impact on supply chains and costs/benefits analysis of policy options), the research team allocated considerable importance and research resources to the fact-finding task through stakeholder consultations, interviews and workshops with IP practitioners and professional organisations, organised under "Chatham House Rules". Questionnaires were also issued to national experts aimed at collecting new and/or confirming established information by preceding studies[4]. This empirical approach provided us with unique and fresh insights into CL practices, and resulted in the formulation of possible solutions for an EU-wide context that are not merely theoretical but build upon real-life practice.

Notion of Compulsory Licence

The term "compulsory licence" (CL) is found in national patent laws but not in TRIPS, where article 31 refers to "use [of IPR's] without authorization of the right holder". There is also mention in the same article of "other use without authorisation of the right holder" that includes uses by governments for their own purposes.

In this study, a compulsory license (CL) refers to a variety of situations ranging from a formalised authorisation by a state authority granted to an applicant to use the IP of a third party to an order of a state authority, obliging the applicant and that third party to agree. Situations start from an assumption that no authorisation could be obtained between the third party and IP owner.

There are many different possible grounds for the grant of a CL. They range from situations of anti-competitive behaviour, non-use of patents, the existence of a dependant and blocking patent, to various situations of crisis, described by terms of "emergency", "urgency" or by broader encompassing terms such as "public interest". In a situation of crisis, various types of CLs could be granted, provided that the underlying conditions are satisfied. A fair remuneration for the IPR holder is also a condition for the grant of a CL, under articles 31 and 31bis of TRIPS.

CLs are only one tool in an array of tools that prevent an IPR holder from misusing or overleveraging his exclusive rights in times of exceptional need. These tools range from the mere waiver of rights at one side of the spectrum to voluntary arrangements that ensure active full and actively supported access to all relevant technology, including transfer of know-how. The first (waiver) only exempts a party or a government from liability for IPR infringement while the latter (tech transfer agreement) effectively ensures access to and use of the protected technology. In between these two extreme sides of the spectrum, there

[4] 'The Compulsory Licensing E-Guide: A Legal Roadmap of over 20 Jurisdictions' (CMS, 2021), https://cms.law/en/media/expert-guides/files-for-expert-guides/cms-compulsory-licensing-global-expert-guide-feb-2021; 'Compulsory Licensing in Europe: A Country-by-Country Overview' (European Patent Office, 2018), https://www.epo.org/learning/materials/compulsory-licensing-in-europe.html; Kyung-Bok Son and Tae-Jin Lee, 'Compulsory Licensing of Pharmaceuticals Reconsidered: Current Situation and Implications for Access to Medicines', Global Public Health 13, no. 10 (3 October 2018): pp. 1430–40, https://doi.org/10.1080/17441692.2017.1407811; WIPO, 'Draft Reference Document on Compulsory Licensing' (1 July 2019), https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_a.pdf; WHO, WIPO, and WTO, eds., Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade, 2nd edition (Geneva, Switzerland, 2020).

are tools such as forfeiture[5], unilateral patent pledges, licenses of right[6] and impact licensing.[7]

Although voluntary arrangements are at the other side of the spectrum, they play an important role in triggering and/or threatening with the grant of CLs. Refusal and/or failure of voluntary negotiations is in TRIPS a precondition for grant of a CL, except in cases of crisis or emergency situations. Even if a CL permitting the use of IPR's is granted, the negotiation of detailed contractual modalities and of remuneration, in particular, could be left to the parties concerned to agree upon.

For example, in the following MS it is for the parties to agree on the remuneration for CL: Bulgaria, Croatia, Czech Republic, France, Italy, Netherlands and Slovakia. If the negotiations on fees fail, the remuneration has to be set by a court.

The stakeholder consultations that were conducted for this study permitted the establishing/confirmation of the important role of voluntary arrangements in the effective implementation of CLs, in particular with regard to the manufacturing of complex products, where production facilities are scarce and access to know-how and its transfer to the beneficiary of the CL is indispensable.

Relationship between CL and competition law

As this study focuses on CL in times of crisis, its main emphasis is put on the grant of CL on legal grounds specifically designed for that purpose, thus excluding compulsory licensing on the grounds of competition law, or for the exploitation of dependent patents.

The term CL is in the literature not only used to designate decisions made on the basis of national patent law, but also decisions issued on the basis of national or EU competition law ordering access to IPRs after finding a violation of competition law. [8]

For instance, the CJEU decision of 29 April 2004 in the matter IMS Health vs. NBC is reported by certain litterature as a "compulsory licensing" decision.[9] Interviews with foreign legal scholars also learned that decisions by US courts denying an injunction on equitable grounds (but granting instead e.g. a reasonable royalty) are often reported as "compulsory licenses". This approach is critisized in the litterature for creating the wrong impression that to refuse an injunction, a court should examine if the conditions for granting a CL under article 31 TRIPS are met. That is not the case because a CL is part of the "Rights" of an IP owner under the TRIPS Agreement, whilst the conditions for granting (or refusing) an injunction are listed in article 44 in the chapter "Remedies" of the TRIPS Agreement, and state different conditions. [10]

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[5] See e.g. article 5 of the Paris Convention and some older versions of national patent laws in France and in Belgium.

[6] See e.g. article 8(1) of Regulation 1257/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, allowing the proprietor of a European patent with unitary effect to file a statement with the EPO to the effect that the proprietor is prepared to allow any person to use the invention as a licensee in return for appropriate compensation.

[7] These tools are represented in a scheme reproduced as Annex V to this study.

[8] WHO, WIPO, and WTO, eds., *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, 2nd edition (Geneva, Switzerland, 2020), p. 241; James Packard Love, 'Recent Examples of the Use of Compulsory Licenses on Patents' (KEI Research Note 2, 8 March 2007), pp. 8, 10 and 11 http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf.

[9] Ibid., p. 8

[10] See the contribution from the Dutch patent judge Peter Blok, "About TRIPS and Trolls" in Liber Amicorum Constant Van Nispen (IE-procesrecht Constant in beweging 2022)(referencing C.A. Cotropia, 'Compulsory Licensing Unter TRIPS and the Supreme Court of the United States' Decision in eBay v. Merck Exchange', in: T. Takenaka (red.), Patent Law and Theory: A Handbook of Contemporary Research, Cheltenham/ Northampton: Edward Elgar 2008, pp. 557-583).

It might seem attractive at first to rely on competition law to seek access to an IP right in case of crisis. However, the legal standard for granting an order to license an IP right on the basis of competition law ("abuse of dominance" in the sense of article 102 TFEU and respective national provisions) is different and higher than for a CL under patent law.[11]

A refusal to licence can be considered as abusive under article 102 TFEU under the so-called "exceptional circumstances" test that requires four cumulative conditions to be met: (1) the access to the product or service protected by the IP is indispensable in order to compete on the market; (2) the refusal prevents the emergence of a new product or service; (3) the refusal is unjustified; and finally (4) the refusal is likely to exclude all competition on the secondary market.[12] For such a legal approach, it does not matter what type of right is abused: it can be a trade secret, an intellectual property right, or any other type of right that confers exclusivity.

These high thresholds, together with the usually long duration of competition inquiries (4 to 5 years in average), make it in reality quite rare that this path is effectively used.

It is also possible to obtain an interim measure on the basis of competition law by virtue of Article 8(1) of EU Regulation 1/2003.[13] But such cases are also extremely rare. The only urgent competition case recently reported relates to a complaint filed initially by the Dutch hospitals against Roche in March 2020 (the early days of the COVID-19 crisis) for withholding its secret recipe on a "*lysis buffer*" which was a product at that time essential for performing corona-tests on patients. There was an acute shortage for this product due to the extremely high demand during the first months of the COVID-19 crisis and the fact that its composition was kept secret by Roche whilst not protected by any patent that would have divulged its composition. The complaint was picked up by the EU competition authorities because of its EU-wide impact and reportedly settled in a few weeks after the complaint was made. [14] Our research and interviews revealed that this was an exceptional case that was driven by the unprecedented circumstances of the COVID-19 pandemic. The matter was settled so quickly that no time was available to initiate formal proceedings and to start a formal investigation.

Another recent decision ordering a CL to an IP owner was issued by the Brussels Enterprise Court on 26 July 2022. The legal basis for this decision was not the abuse of a dominant position, a cause of action under competition law, but the "abuse of economic dependency" sanctioned by article IV.2/1 of the Belgian Code of Economic Law. The legal threshold to show economic dependency is lower than for a dominant position, and the court does not need to determine a relevant product or service market. The Brussels court held that Tunstall Holdings, as owner of European patent EP 2.160.038 covering a telecommunication system necessary to run cloud platforms offering services for televigilance, abused the economic dependency of Tele Secours by refusing to grant it a license, and ordered Tunstall to grant to Victrix and Tele Secours such a license on a non-exclusive basis and on the same royalty terms as for its existing licensees on the Belgian market.[15]

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[11] See Volvo v. Veng (C-238/87), Magill (C241/91 P and C-242/91 P), IMS Health (C-418/01) and Microsoft v Commission (T 201/04)).

[12] Summary of the IMS Health decision of the CJEU of 29 April 2004 by UNCTAD's IP unit, https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020-12/IMS%20Health%20v%20NDC%20CJEU%202004.pdf

[13] "In cases of urgency due to the risk of serious and irreparable damage to competition, the Commission, acting on its own initiative may by decision, on the basis of a prima facie finding of infringement, order interim measures." https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32003R0001

[14] Eelke van Ark and Jan-Hein Strop, 'Roche Releases Recipe after European Commission Considers Intervention Due to Lack of Coronavirus Tests', Follow the Money, 27 March 2020, https://www.ftm.eu/articles/roche-releases-recipe-after-public-pressure-while-european-commission-considers-intervention-due-to-coronavirus-test.

[15] Tunstall vs. Victrix & Tele Secours, Brussels Enterprise Court, 26 July 2022, A/21/01929. An appeal was lodged against this decision. See summary in Annex IV.

Notion of "Crisis"

The present research focuses on **crises with a strong connection to IPRs**, in the sense that access to IPRs could be used as a means to remedy the situation at hand. IPRs protect multiple qualities of products and processes resulting from research and innovation. They do not guarantee the availability of these goods and services and their production in sufficient quantities, but only constitute a means to attract investments for sufficient production and profit optimisation via the promise of exclusivity conferred by these rights.

A crisis situation can challenge this at two different levels. Firstly, it can make production or distribution impossible within the existing facilities and networks (e.g. destruction by war, floods, or other climate disaster) or make them inaccessible (e.g. lockdown during a health crisis). Secondly, a crisis is a driver for innovation because it typically calls for state-of-the-art solutions whereby existing technologies are improved, re-purposed or simply substituted by innovative alternatives.[16]

Because of the impact of a crisis on a country's economy and on the well-being of its citizens, public authorities must have certain legal means to intervene when access to innovative or to already existing products is hindered, either by physical barriers or by legal barriers such as intellectual property rights. This explains why all national patent legislations contain provisions about CLs.

Article 31(b) TRIPS refers to the "case of a national emergency or other circumstances of extreme urgency". These situations would fall within the notion of "**crisis**" for the purposes of the present study. The qualification of a situation as a crisis would further require circumstances of certain gravity for the public. Crisis is understood here as a **public interest** issue, leaving aside a crisis whose impact is limited to a specific organisation or a limited number of individuals. As will be seen later, that does not mean that there can be no crisis if only a small group of patients is affected.[17] "Crisis" is also understood as a temporary situation (e.g. contrary to longer-tem aspects of a climate crisis, which is gradually evolving) and excluding structural problems such as high costs for procurement of medicines, which the consulted stakeholders agreed was unrelated to the notion of "crisis".

A state of a "**national emergency**" is typically a case of a formally declared crisis. It could be said that a cross-border crisis is formally recognised in the EU when more than one MS and/or an EU/intergovernmental organisation declares states of national and international emergency. Such declarations also formally delimit the beginning and the end of emergency situations, delimiting also the application in time of special legal measures (e.g., imitation of rights and freedoms, including property rights). A formal declaration of crisis could inform the choice of a legal measure that could be used to remedy the crisis. The more intrusive the measure, the higher case-specific due process scrutiny it would have to pass. Official recognition of an emergency situation is commonly one of the constitutional safeguards for the protection of fundamental rights.[18]

Some "**circumstances of extreme urgency**" or other crisis situations for various reasons are not declared as national or international emergencies. Public authorities are commonly empowered, and sometimes even compelled, to take measures at any stage of a crisis. A

[16] Isabelle Denervaud, Mercedes Johnson, Etienne Soumoy, Henri Tcheng, "Les Crises, un Terreau d'Innovation" (2009), L'Expansion Management Review 2009/3 (N° 134), pp. 108 - 119, https://www.cairn.info/revue-l-expansion-management-review-2009-3-page-108.htm.

[17] See the "Raltegravir" CL decision of the German Federal Court, commented on below.

[18] The general principles for ensuring fundamental rights compliance of declarations of crisis include that measures are based in law, and are balanced, necessary, temporary, and proportional. See European Agency for Fundamental Rights (2021), "The coronavirus pandemic and fundamental rights: A year in review" 10 June 2021. https://fra.europa.eu/en/publication/2021/coronavirus-pandemic-focus.

legal instrument less prejudicial to the right of property than CL, e.g., impact licensing[19], could be triggered in the absence of a formally-declared crisis.

Regulation No 816/2006, which is intended for grant of CLs for export, refers to the notion of "**public health problems**". It does not define this relatively general notion in detail, but requires that the mechanism should be used to address public health problems and not as an instrument to pursue industrial or commercial policy objectives.[20]

Article 2(21) of the EU/Euroatom Regulation 2018/1046 defines "crisis" as:

> (a) a situation of immediate or imminent danger threatening to escalate into an armed conflict or to destabilise a country or its neighbourhood
>
> (b) a situation caused by natural disasters, man-made crisis such as wars and other conflicts or extraordinary circumstances having comparable effects related, inter alia, to climate change, environmental degradation, privation of access to energy and natural resources or extreme poverty.[21]

Serious Cross-border Threats to Health (SCBTH) has been the subject of a recent Regulation.[22] In Chapter V of the Regulation, titled "Public Health Emergency at Union Level", "**public health crisis**" is defined, along with institutional and procedural measures for declaring such a crisis.[23] Along similar lines, the Council Regulation on the emergency framework regarding medical countermeasures[24] defines the "public health emergency" by referring to the Regulation on SCBTH[25]. As evidenced by these cross-references, ostensibly **the same definition of crisis and emergency will be used**, to avoid future legal uncertainty and complexity.

In July 2022, the Commission's Health Emergency Preparedness and Response Authority (HERA) further presented a list of top-3 health threats corresponding to its 2022 Work Plan[26] and several pieces of upcoming legislation corresponding to EU's "European Health Union" initiative started in 2020[27]. These **serious cross-border health threats** include the following:

1. Pathogens with high pandemic potential: this includes looking into specific viral families of concern, taking herein also into account the zoonotic nature of most high consequence emerging infectious diseases. This category includes mainly respiratory RNA viral families.
2. Chemical, biological, radiological and nuclear threats: these can originate from accidental or deliberate release, taking into account global geopolitical tensions, as well as incidents caused by rogue actors. CBRN substances have been identified based on their likelihood to occur and their potential impact on human health.

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[19] See, e.g., European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Report on the feasibility and analysis of "Impact Licensing Initiative" (ILI) for technology access during a health crisis, Publications Office, 2020, https://data.europa.eu/doi/10.2873/552686

[20] Article 5(b) and Recital 6 of the Regulation No 816/2006.

[21] Regulation 2018/1046 on the financial rules applicable to the general budget of the Union, 966/2012, PE/13/2018/REV/1, OJ L 193, 30 July 2018, pp. 1–222.

[22] Regulation 2022/2371 on serious cross-border threats to health, OJ L 314, 6 December 2022, pp. 26–63.

[23] Ibid.

[24] European Council, "Council Regulation on the emergency framework regarding medical countermeasures - Political agreement", 2021/0294(NLE), Brussels, 17 December 2021. https://data.consilium.europa.eu/doc/document/ST-15132-2021-INIT/en/pdf.

[25] Ibid., Art. 2 Definitions.

[26] HERA Work Plan 2022, https://health.ec.europa.eu/system/files/2022-02/hera_work-plan_2022_en_0.pdf.

[27] European Commission, "Communication: Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats," 11 Nov 2020, COM(2020) 724 final.

3. Threats resulting from antimicrobial resistance, which pose one of the greatest risks to human health, with antibacterial resistance alone causing an annual estimate of over 1.2 million deaths globally.[28]

Article 17(1) of the UPOV Convention[29] states that "[e]xcept where expressly provided in this Convention, no Contracting Party may restrict the free exercise of a breeder's right for reasons other than of **public interest**." The EU and its MS are parties to the UPOV Convention. The only EU provisions regarding compulsory licensing with effect in the European Union relate to plant variety rights and patents[30] and the unified competence of the Community Plant Variety Office (CPVO) to grant a compulsory licence (referred as "compulsory exploitation right") on grounds of public interest with regard to Community plant variety rights[31]. The CPVO enjoys exclusive competence, and MS may not grant CLs in respect of the Community right.[32] Before making its decision regarding a CL, the CPVO should consult its Administrative Council composed of one representative of each MS and one representative of the European Commission.[33] The CL can last only one year and a renewal must be asked for.

The Community Plant Variety Regulation does not define the notion of "**public interest**", but its complementary Implementation Regulation on procedures of the Community Plant Variety Office (CVPO) provide some additional guidance. One recital to the CPV Regulation only states that the notion of public interest (in the context of providing a CL) "may include the need to supply the market with material offering specified features, or to maintain the incentive for continued breeding of improved varieties".[34] The Regulation adopted to implement the Plant Variety Regulation specifies certain cases as examples of public interest.[35] Article 41(2) of the Implementation Regulation indicates that the following grounds may in particular constitute a public interest:

> "*the protection of life or health of humans, animals or plants;*
>
> *the need to supply the market with material offering specific features*
>
> *the need to maintain the incentive for continued breeding of improved varieties*"[36].

[28] European Commission, "Press Release: Health Union: HERA delivers list of top-3 health threats to prepare against." 12 July 2022. https://ec.europa.eu/commission/presscorner/detail/en/IP_22_4474.
[29] International Convention for the Protection of New Varieties of Plants of December 2, 1961, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991.
[30] Article 12 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, 30.7.1998, p. 13–21 (Biotechnology Directive).
[31] Article 29(1) CPV Regulation and Article 12(4) of the Biotechnology Directive. For a comment, see Gert Würtenberger et al., *European Community Plant Variety Protection* (Oxford: Oxford University Press, 2006), 159–62.
[32] Article 29(7) CPV Regulation ("Compulsory exploitation rights may not be granted by Member States in respect of a Community plant variety right").
[33] Article 37(1) CPV Regulation.
[34] Recital, CPV Regulation.
[35] Article 29(6) Commission Regulation establishing implementing rules as regards proceedings before the Community Plant Variety Office ("Implementation Regulation"), (EC) 874/2009, 17 Sept 2009.
[36] Ibid. See also the comments by G. Van Overwalle in her working paper "Improving International Intellectual Property". Festschrift in honour of Professor Rochelle Dreyfuss, 2023.

Case: CPVO Reasoning in Decision NCL001 - Evaluating an Application for CL on public health grounds

The CPVO Decision NCL001[37] applied for the first time the CL provisions in the Community Plant Variety Regulation ("Basic Regulation") and provided some important clarifications of the notion "public interest" and its appreciation by the Office. It is interesting to observe that the CPVO in this interpretative decision referred to the German Federal Court of Justice's judgment of 11 July 2017 in case with docket no. X ZB 2/17, "Raltegravir"[38] According to the case law of that Federal Court of Justice, public interest exists if a medicine to treat serious illnesses has specific therapeutic characteristics that comparable medicines do not have, or not to the same extent. Furthermore, public interest can exist if the use of such a medicine leads to a reduction of side effects that would have been suffered when prescribing/using different medicines.

However, public interest cannot exist if there is a similar treatment possible with a different medicine. The Federal Court of Justice stated that there was a public interest in the continued availability of a medicine for HIV, even though only a small group of patients would have been affected (second requirement). The court determined that there was a considerable risk of serious side effects, interaction or therapy failure for the patients if they had to change the medicine. This would have been the case had the patentee been successful with its infringement suits and the applicant would have had to stop selling Raltegravir. In that case, all patients undergoing treatment with Raltegravir would have had to change the treatment to different medicines with a considerable risk of side effects. The German Federal Court of Justice therefore confirmed that the public interest condition was met.

On the basis of this reasoning from the German "Raltegravir" patent CL case, the CPVO held *inter alia* that an applicant cannot merely rely on the concept of "healthy lifestyle" to substantiate a ground for public interest to be granted a compulsory licence to use a protected plant variety right. Nor did the assertion that the protected plant variety adapted well in different environments and resisted better to a climate crisis convince the Office that there was public interest, since this did not mean that other blackcurrants are not available in the juice market that have such characteristics.

The general principle of proportionality guiding and delimiting actions of public authorities infers that the more intrusive is the regulatory measure with regard to the rightholders' rights and legitimate interests, the closer the rights concerned ought to relate to the crisis. Such relation could be described in the causal proximity of the exercise of IP rights to the cause and/or solution of a crisis.

It is possible that in times of crisis, EU-based producers will not be the one manufacturing the necessary product and/or not able to produce it in the necessary quantity. A situation of shortage could be caused, for example, by decisions of geo-political actors. Such decisions that could dramatically impact supplies of essential products are, for example, export bans and wars.

Export bans: Some countries have undertaken the use of export bans in order to control flow of domestic products and goods, but such mechanisms can carry long-term consequences to a country's credibility as a trade partner. For example, during the COVID-19 pandemic, India's decision to ban vaccine exports has had a severe impact by the shortage of supplies on 91 nations dependent on Serum Institute of India's (SII) products, including the AstraZeneca vaccine (Covishield) and then forthcoming Novavax. As a lasting

[37] Decision of 28 March 2018 in Pixley Berries vs. Lucozade Ribena Suntory denying a request for CL in respect of the plant variety "Ben Starav" of the species Ribes Nigrum L.
[38] CPVO Decision NCL001, 28.03.2018, paras. 31 and 67.

result of the pandemic, an expert monitoring mechanism was established at the EU level in order to ensure greater levels of transparency over EU exports, and ensure that reliable data on EU exports is duly collected from the national customs of each MS.[39]

War: In 2022, during the Russian invasion of Ukraine, the Russian navy blocked the exportation of agricultural products from Ukraine through the Black Sea, creating a shortage of sunflower and wheat products, among others.[40] If there is a war in Taiwan, there could be an acute shortage of supplies in the field of electronics.[41]

[39] EU Commission (2021), "EU replaces COVID-19 vaccines export authorisation mechanism with new monitoring tool" Press Release, 26 November 2021.
[40] Robbie Gramer, Lu Christina, and Mary Yang, 'Russia's Black Sea Blockade Will Turbocharge the Global Food Crisis', *Foreign Policy* (blog), 24 May 2022, https://foreignpolicy.com/2022/05/24/russia-ukraine-blockade-food-crisis-black-sea/. Robbie Gramer, Lu Christina, and Mary Yang, 'Russia's Black Sea Blockade Will Turbocharge the Global Food Crisis', *Foreign Policy* (blog), 24 May 2022, https://foreignpolicy.com/2022/05/24/russia-ukraine-blockade-food-crisis-black-sea/.
[41] Ibid.

Methodology

As referenced above, the aims of this study include 1) **defining potential problems** as regards CL practices in the EU; and 2) **assessing the current state** of CL practices in the EU, with specifc attention to CL activities centered on crises; and 3) **identifying and assessing a number of policy options** to improve the coherence and effectiveness in he application, grant and enforcement of a CL in times of crisis.

To achieve these aims, within the context of this study, a five-part methodology was used[42] to gather relevant information, data points, and practical knowledge of the functioning of CL systems, both overall and in regards to systems of CL in EU MS. These distinctive parts of the study methodology are described below, with reference to the nature of the information gathered in each part.

1. Desk research

Desk research consisted of a review of relevant literature, beginning with academic and scholarly resources (journal articles, textbooks). These findings were tested and verified through reference to sources reflecting practical experiences with the use and implementation of CL systems, including sources from the pharmaceutical industry (white papers; commentaries; etc.), and sources deriving from governmental agencies and authorities (policy publications; guidelines). Legal reference materials, such as laws, cases, and where available contracts referencing CL practices, were further considered and integrated into the analysis.

Collectively, the research team undertook a thorough, systematic review of publicly available materials to identify and analyse the legal framework underlying CL practices, as well as the relevant case-law on CLs in the EU and its Member States, enriched where possible by reference to selected third countries. The diversity of language skills of the team members allowed for this research to be conducted in English, French, German, which enabled access to further documentation that had not been translated from its original language.

Results of the desk research stage contributed in large part to the qualitative content analysis. Namely, desk research allowed the team to draft parts of the questionnaire but also to identify certain exoerts to be interviewed.

2. Questionnaires

To gain both factual and practical information on different legal systems implementing CL practices in EU MS, national experts were identified[43] for each EU MS and contacted to complete a questionnaire focused on national experiences with CL.[44]

The questionnaire was created after a large part of the initial desk research stage, where certain “opaque” aspects of the CL application and granting process required further inquiry. This was especially useful to bridge linguistic gaps in information gathering given the multiplicity of national languages present in the EU (all survey responses were rendered in English). In this regard in particular, the present study provides insights using some of the most comprehensive national MS data points currently available.

[42] Note that the methodology applicable to the assessment of costs and benefits of policy options is separate and distinct from the methodology of the legal analysis described here. See
[43] See Annex III: National Experts.
[44] See Annex II. Questionnaire to National Experts.

The topics of the questionnaire generally covered the following:

- Conditions for grant of compulsory licences.
- Key features of compulsory licences: scope (notably in terms of IP rights and other regulatory regimes covered).
- Duration of CL application and granting process.
- Details of national decision-making processes, including appeals procedures.
- Timeline(s) of the decision-making process(es), with a focus on national emergencies/urgency.
- Recent COVID-19-related changes to national law and/or CL practices, if any.
- Factual cases of CL (including applications for CLs, and "non-cases" covering applications and decisions of refusal to grant CLs).

National experts were provided with 3 weeks for executing the task. Project coordinators managed the interactions with the national experts, including their queries and clarification request to the experts, if there were any.

From the data gathered through the questionnaires, it was possible to conduct a broader cross-border analysis of national CL practices, including comparisons on granting authorities, timeframes for granting CLs, and what impacts (if any), at the national level, did crisis situations have on CL application and granting procedures.

3. Interviews

For gathering data, generating ideas and testing research hypotheses, a series of semi-structured interviews of national experts, academics, policy representatives and industry experts were conducted.[45]

More specifically, the interviews focused on gathering "non-published" data (e.g., with regard to "non-cases", or cases that were initiated to some extent but never resulted in the grant of a CL). Since CL is a sensitive topic, it was initially understood that some stakeholders would only be willing to grant interviews under certain limited disclosure conditions. In anticipation of these concerns, the research team designed an approach to mitigate disclosure of sensitive data collected. Any results of the interview stages included in the Study have been pre-cleared by interviewees prior to publication, and references to specific stakeholder groups have been made where possible.

Interviews further served to establish a small "network" of known, "go-to" national experts and specialists willing to openly cooperate to assess, and possibly improve, CL practices in the EU.

Interviewees were selected on the basis of their knowledge, experiences and the type of the organisation they represent (industry, government, academia). The research team further took into account the following factors, in order to collect a rich data set:

[45] Overall description of the individuals interviewed (organised by industry, sector, etc.) to be included as an annex (conditional on interviewees being listed for inclusion)

- Geographic representation according to organisations' location (Member States / third countries).
- Representatives of both originators (i.e., patent holders) and generic pharma companies.
- Representatives of companies whose IP was subject to compulsory licensing and companies that benefited from compulsory licensing.
- Representatives of a range of organisations (public/private; for-profit/non-for-profit).

In total, the research team carried out 26 interviews. On average, the duration of most interviews was one hour, with some discussions running longer. For the sake of reliability and verifiability of the data gathered, a minimum of two interviewers from Study's research team were present during each interview. During each interview, one research team member was focused on transcription, and one expert member of the team was selected to lead each interview. The "expert" relied on his/her expertise to adjust the standardised interview questions as appropriate.

Occassionally, when appropriate, arrangements were made to follow-up on the responses provided in the interview for the purposes of clarifying or developing the information and data elicited through the interview. One form of such follow-up included a correspondence of written queries, at times requesting specific documents and/or information that the interviewee agreed to provide after the interview. Generally, when reference had been made to a specific case or expert opinion, the interviewees later redirected the team to a competent expert that was able to provide further details relating to the question, hence why the number of interviews was much higher than initially anticipated. Furthermore, certain experts were interviewed more than once, whether on different aspects of the CL mechanism or for further clarifications after other interviews on the same topic.

4. Case studies

Where available, real data on cases regarding CL systems, as implemented throughout the world, have been identified[46] and used in the body of the Study to help illustrate some concepts and/or provide a practical perspective on the effectiveness (or ineffectiveness) of various CL systems. Such cases are highlighted in the text through case boxes, which provide a brief factual description of the law/case relevant to CL practices and key analytical points which are revealed through the case example. A large proportion of cases were provided to the research team by national experts during the course of the questionnaire and interview stages of data-gathering, while some "well-known" cases were gleaned from the desk research.In all cases, clarifications on the obtained cases were obtained from the interviewees, which allowed the team to clarify the information available for some "well-known" cases, and in some instances, obtain further details that were not publicly available, granting the team detailed insight on the course of the cases.

5. Workshops

Finally, to gain a more dynamic understanding of pressing issues relevant to CL practices, two workshops were arranged during the course of the Study to bring together legal experts, academics, industry players and policymakers to express their views in real-time.

The purposes of the workshop were articulated as follows:

[46] For an exhaustive list of cases identified in the EU, see Annex IV. Cases of compulsory licensing in the EU

1. To gather input on the **possible problems regarding the overall design and functioning of the compulsory license systems in the EU**, as well as regarding the main drivers (or causes) of such problems;
2. To discuss the **possible policy options**, and any external factors that may be at play;
3. To jointly reflect on **legislative or other solutions** to effectively address the problems.

Selected participants were given a brief informational sheet regarding the purpose and nature of the current study, as well as pre-defined and specific discussion questions to contemplate prior to the workshop. These questions (also taking the form of pre-defined hypothetical scenarios), were controversial in nature and meant to elicit countervailing opinions on pressing and persistent issues surrounding the use of CL procedures in times of crisis. The research team members acted as moderators during the session, prompting the participants with the set questions while also trying to receive more information on some aspects discussed during interviews or read in some national questionnaire responses.

Workshop 1 took place on 28-29 April 2022, in Brussels, Belgium.

Workshop 2 took place on 9-10 June 2022, in Brussels, Belgium.

There were a total of 24 participants who attended the workshops, representing the pharmaceutical sector, patent attorneys from multiple MS, and policy officials (in the capacity of discussion facilitators), among other representatives from a variety of industries. The identities of participants rmains confidential under “Chattam House Rule”. Chattam House Rule is a condition of anonymity imposed during discussions in order to promote openness in discussing public policy and current affairs. These conditions allowed participants to discuss their opinions seperately from the views of their employers, and their corporate affiliation was not disclosed during the workshops.

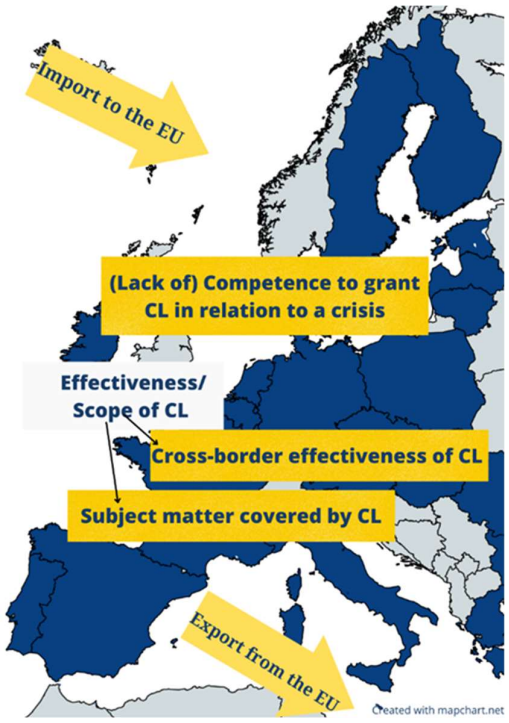
In exceptional circumstances, some participants were invited to join the workshop proceedings via videoconference. The same Chatham House Rules also applied to those participants.

Categorisation of Stakeholders[47]:

Overall, the majority of stakeholders contacted for the questionnaires and interviews were representatives from national legal offices (“Consultancy”). Representatives from Research and Academia were also contacted, followed by Businesses (Industry) and then EU bodies/institutions. Where feasible, stakeholder groups and ther responses are identified specifically below. Otherwise, references to responses made by stakeholders (in general) should be understood as the same response/overall consensus from all categorisations of stakeholders aforementioned.

[47] In accordance with the categorisations established in the Better Regulations Guidelines and Toolbox, 2021.

I. Identified Problems with CL in the EU in Times of Crisis



Description of the picture: A map of the European Union detailing the identified problems with compulsory licenses in Europe.

1. Problem definition: Obtaining CLs for manufacturing or import

Given the purposes and potential economic benefits of utilising the CL system, it is generally known that the CL mechanism as a legal tool has been rarely used, whether in the EU context or globally. The reasoning for this phenomenon has been underexplored, and was therefore an avenue for research in the current study.

By presenting our findings in the form of several likely “problem definitions”, the following chapters describe the competences and mechanisms that MS have in place to compel the use of IPRs in their countries with the purpose of fulfilling a national need, with a focus on situations of crisis. This type of action requires not only rights to manufacture protected products and to apply protected processes, but also the right to effectively put these products on the national market and offer them for sale in that market.

In this Part 1, aspects of obtaining CLs for manufacturing or import are identified in view of discerning potential issues with the CL procedure as implemented by EU MS. The sections that follow identify key problem areas, and the analysis of these problems and their impact on the utility of the CL is constructed through a combination of legal research, stakeholder interviews, and other publicly-available data.

1.1. Inconsistent competences to grant CLs in times of crisis

The international IPR framework offers relatively broad discretion for establishing legislation on granting CLs in case of crises. Article 31 of the TRIPS "Other Use Without Authorization of the Right Holder", provides WTO Members with a general normative framework for the adoption of legislation on CLs of patents for predominant supply of their respective domestic markets. WTO Members enjoy considerable discretion for defining the grounds for granting CLs in case of a crisis. Article 31(b) TRIPS refers to a possibility to provide for CLs in case of "a national emergency or other circumstances of extreme urgence". Article 31 TRIPS explicitly refers to other possible grounds for CL (e.g., to remedy anti-competitive practices and to enable use of a dependent patent), but the present inquiry focuses on the CL directly aimed at tackling a crisis. Article 31 TRIPS develops more in detail and complements Article 5 of the Paris Convention, which is applicable to both patents and utility models. The EU Member States are parties to the Paris Convention and the TRIPS agreement. The EU, as a Member of the WTO, is also party to the TRIPS.

1.1.1. Lack of uniformity of competences with regards to granting CLs in times of crisis

The analysis has demonstrated that Member States' legislation on compulsory licensing in crisis is of different scope, offering respective competent authorities different competences as to the situations in which CLs could be granted.

Most of the Member States have a general (i.e., not limited to certain sectors) competence to grant CLs for dealing with a crisis in whatever field: Austria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Lithuania, Luxembourg, Netherlands and Poland. Such legislations rely on the open clauses of "public interest" or "important public interest". Three Member States, Belgium, Hungary and Italy, have competences limited to the field of health, and Ireland does not seem to have an explicit crisis-focused competence.

Without an explicitly spelt-out competence, public authorities cannot grant CLs in areas other than those defined by law. In a hypothetical scenario of a cross-border crisis in the EU in a domain other than health, some Member States cannot grant CLs.

Laws of some Member States provide for different levels of detail in the definitions of sector-specific crises, as illustrated in the table below.

Table 1. Key national provisions defining competence to grant CLs in crisis:

Member State	Ground for granting CL in crisis	Law
Austria	"public interest", could be also in case of a "national emergency" or "other circumstances of utmost urgency"	Sec. 36 para. (5) Austrian PA
Belgium	"public health" "a) a medicine, a medical device, a medical device or product for diagnosis, a derived or combinable therapeutic product; b) the process or product necessary for the fabrication of one or more products indicated under a); and c) a	Art. XI.38 Code of Economic Law

	diagnostic method applied outside the human or animal body”	
Bulgaria	“public interest”	Art. 32(2) Bulgarian PA
Croatia	“in situations of extreme urgency on a national level, in particular for national security, public interest protection in the field of health, food supply, environmental protection and improvement”	Art. 104(5) Croatian PA
Cyprus	“national defence or public safety”	Sec. 55 Cypriot PA
Czech Republic	“in there exists a threat to an important public interest”	Sec. 20 Act on Inventions and Rationalisation Proposals
Denmark	“important public interests”	Section 47 Danish PA
Estonia	“national defence, environmental protection, public health and other significant national interests of the Republic of Estonia require the use of the invention, including the need to use the invention in connection with a natural disaster or other emergency”	Sec. 47(1) Estonian PA
	“in the event of an epidemic” and in an emergency situation” (referring to the meaning set in the Communicable Disease Prevention and Control Act and in the Emergency Situation Act)	Sec. 47^{1}(1) Estonian PA
Finland	“significant public interest”	Sec. 47 Finnish PA
France	“interests of public health” “(a) a medicinal product, a medical device, an in vitro diagnostic medical device or an ancillary therapeutic product (b) a process for obtaining them, a product necessary for obtaining them or a process for manufacturing such a product c) an ex vivo diagnostic method.” “The patents for these products, processes or diagnostic methods may only be subject to the ex officio license system in the interest of public health when these products, or products derived from these processes, or these methods are made available to the public in insufficient quantity or quality or at abnormally high prices, or when the patent is exploited under conditions that are contrary to the interest of public health”	Art. L613-16 CPI
	“if the absence of working or the inadequacy in quality or quantity of	Art. L613-18 CPI

	the working undertaken is seriously prejudicial to economic development and the public interest	
	"for the needs of national defence"	Art. L613-19 CPI
	In addition, the law n° 2020-290 of March 23, 2020 of emergency to face the epidemic of COVID-19 introduced a new article L.3131-15 in the public health code. This article allows the Prime Minister, when a state of health emergency is declared, and for the sole purpose of guaranteeing public health : - to order the requisition of all goods and services necessary for the fight against the health disaster as well as of any person necessary for the functioning of these services or the use of these goods; - to take any measure allowing the provision of appropriate medicines to patients for the eradication of the health disaster.	
Germany	"public interest"	Sec. 24(1) German PA
	"epidemic situation of national importance is determined by the German Bundestag"	EpidemieSchG and Sec. 13 German PA
Greece	"Imperative reason of public interest". There are public interest reasons when: a. the products or production methods protected by the patent are made available to the public in insufficient quantity, quality, or at abnormally high prices compared to the prices of similar products in similar markets, b. the exploitation of the patent in question is necessary for reasons of public health, c. the exploitation of the patent is necessary to comply with a standard which is in the public interest, d. the lack of exploitation of the patent is detrimental to the economic and technological development of the country.	Art. 13 Greek PA

Hungary	"In the interest of meeting domestic demand stemming from a public health crisis" referred to in Subsection (2) of Section 228 of Act CLIV of 1997 on Health Care. Covering patented medicinal products, active substances or investigational medicinal products as well as medical devices or for patented procedures, equipment or devices required for the production of healthcare products.	Art. 33/B (1) Hungarian PA
Ireland	a demand in the State for the subject matter of the patent is not being met or is not being met on reasonable terms or that the establishment or development of commercial or industrial activities in the State is unfairly prejudiced	
Italy	"national health emergency" for "medicines and medical devices deemed essential for dealing with the health emergency" (requires the declaration of a state of emergency)	Art. 70-bis Italian Industrial Property Code
Lithuania	"public needs, national security and public health protection"	
Luxembourg	"public interest"	Art. 63 Loi du 20 juillet 1992 portant modification du régime des brevets d'invention
Netherlands	"public interest"	Art. 57(1) Dutch PA
Poland	"to prevent or eliminate the state of national emergency, in particular in the field of defence, public order, the protection of human life and health, as well as the protection of the natural environment"	Art. 82(1) Intellectual Property Law Act
	"to prevent or remove a threat to important state interests, in particular public safety and order"	Art. 69(1.2) Intellectual Property Law Act
Romania	"a) in national emergency cases; b) in other cases of extreme emergency; c) in cases of public use for non-commercial purposes."	Art. 43(4) Romanian PA
Spain	"public interest", meaning: (a) the initiation, increase or generalisation of the exploitation of the invention, or the improvement of the conditions under which such exploitation takes place, are of major importance for public health or national defence.	Art. 95(2) Spanish PA

	(b) The non-exploitation or the inadequacy in quality or quantity of the exploitation carried out is seriously detrimental to the economic or technological development of the country. c) The needs of national supply.	
Slovakia	"in there exists a threat to an important public interest"	Sec. 27 Slovak PA

To examine a few examples in detail, the French law defines the situation of the "interests of public health":

> *"(a) a medicinal product, a medical device, an in vitro diagnostic medical device or an ancillary therapeutic product*
>
> *(b) a process for obtaining them, a product necessary for obtaining them or a process for manufacturing such a product*
>
> *c) an ex vivo diagnostic method*.
>
> *The patents for these products, processes or diagnostic methods may only be subject to the ex officio license system in the interest of public health when these products, or products derived from these processes, or these methods are made available to the public in insufficient quantity or quality or at abnormally high prices, or when the patent is exploited under conditions that are contrary to the interest of public health*" (Art. L613-16 Intellectual Property Code).

This approach adopted by France provides for more precision in the definition of triggering situations. At the same time, it runs a risk of not referring to an unforeseen situation. For example, in 2004, France modified its CL legislation to cover health diagnostic technologies, which were previously not explicitly mentioned.[48]

With regard to "national emergencies" and "epidemics", as such, situations commonly involve limitations of fundamental rights and freedoms, their announcement commonly follows an established procedure and their application is limited to situations defined with a level of precision in specialised normative acts. On some occasions, CL provisions cross-refer to the terms defined in such acts. For example, CL provisions in Estonia refer to the Communicable Disease Prevention and Control Act and in the Emergency Situation Act.[49]

In Romania, the Government Emergency Ordinance No. 1/1999 defines the emergency state as:

> "…a set of exceptional measures of a political, economic and public order nature applicable on the entire territory of the country or in some administrative-territorial units that are established in the following situations:
>
> a) the existence of current or imminent serious dangers regarding national security or the functioning of constitutional democracy;

[48] Love, 'Recent Examples of the Use of Compulsory Licenses on Patents', 9–10.

[49] Pursuant to Section 47(1) of the Estonian Patents Act, a patented invention may be used by the Government of the Republic of Estonia or a third person authorised by the Government of the Republic of Estonia without the permission of the proprietor of the patent in the event of an epidemic within the meaning of the Communicable Diseases Prevention and Control Act and in an emergency situation within the meaning of the Emergency Situation Act. National Report for Estonia, p. 3.

b) the imminence of the occurrence or production of calamities that make it necessary to prevent, limit or eliminate, as the case may be, the disasters' consequences."

In Germany, as a part of the governmental reaction to the COVID-19, the law for the protection of the population in an epidemic situation of national scope ("EpidemieSchG"[50]) came into force on March 27, 2020, the day it was passed. The EpidemieSchG supplements the Act on the Prevention and Control of Infectious Diseases in Humans (IfSG[51]) with a regulation that authorises the Ministry of Health to issue so-called *Benutzungsanordnungen,* governmental use orders, for certain patents in accordance with Section 13 German PA when the German Bundestag determines an epidemic situation of national importance. However, the change in the IfSG ties in with an existing (and often overlooked) regulation in Section 13 PatG on governmental use orders. According to the legal materials (draft of EpidemieSchG, BT-Drs. 19/18111), the change serves to "ensure the supply of products in the event of a crisis". In this case "the effect of a patent can be limited, e.g. according to Section 13 German PA, in order to be able to produce vital active substances or pharmaceuticals".

In June 2020, also in reponse to the COVID-19, Hungary created new Articles 33/B and 33C[1] of its PA providing for CL in case of a health crisis. According to Subsection (2) of Section 228 of Act CLIV of 1997 on Health Care to which refers the new provision of the PA, allows the Government to declare a state of public health crisis in the following cases:

A) when there is a public health emergency of international concern in line with the International Health Regulations (2005) of the WHO

B) when there are other – generally unexpected – events that endanger or harm the health, body or life of civilians or the operations of healthcare providers in such a way that there becomes an imbalance between the need for and capacity of healthcare services and that there is a need for the cooperation of healthcare providers.

C) when there is any circumstance that prevents seriously and directly the healthcare provider from providing healthcare services to civilians in its respective area, provided that it would be a disproportionate burden for another healthcare provider to replace the beforementioned.

Limitation to problems that are "national" in scope

Since a patent right is a purely national right and since the authority who grants a patent can therefore only grant a CL for its own country, some provisions for granting CLs in case of crisis explicitly refer to the situations qualified as "national" or "state". Such qualifications define and limit the analytical inquiry of the competence national authorities as to CLs purpose and effect. Such qualification of the triggering event (e.g., "national emergency" or "national defence") constitutes a limitation of the purpose of CLs to the resolution of domestic issue only. Since a national patent authority has no say about the import or use of the patented product in another country, it is unsurprising that there are no CLs triggered by a "foreign" crisis or that tries to resolve a non-domestic issue.

Varying institutions with competences to grant CLs

As demonstrated in the national questionnaires and as confirmed by the stakeholders across all categories, various types of authorities are empowered to issue a CL for different purposes.[52]

[50] Das Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite (EpidemieSchG).
[51] Infektionsschutzgesetz (IfSG).
[52] [*All MS represented except Latvia and Portugal]

Table 2: MS Institutions Competent to Grant CLs[53]

	Ministry/ Gov't	Patent Office/ IPO	Court	Agency	Competition Authority	Other	# of Auth. Competent to Grant CL
Austria		X			X		2
Belgium*	X					X[54]	2
Bulgaria	X	X					2
Croatia			X				1
Cyprus	X	X					2
Denmark			X				1
Estonia	X		X				2
Finland			X				1
France	X		X				2
Germany	X		X				2
Greece*	X	X					2
Hungary		X	X				2
Ireland		X					1
Italy*	X	X		X	X		4
Lithuania*	X		X				2
Luxembourg*	X		X				2
Malta	X						1
Netherlands	X		X				2
Poland		X					1
Romania			X				1
Slovakia			X				1

[53] Results exclude Latvia and Portugal.
[54] Minister + Committee on CL **OR** Minister + Advisory Committee (on Bioethics): "The Advisory Committee on Bio-ethics is an intergovernmental committee established by the national and regional governments to inform the public and the authorities about bio-ethical topics. The Committee is composed of lawyers, geneticists, ethicists, philosophers and physicians from different organizations and representing a broad scale of ideological and philosophical beliefs."

	Ministry/ Gov'mt	Patent Office/ IPO	Court	Agency	Competition Authority	Other	# of Auth. Competent to Grant CL
Slovenia			X				1
Spain	X	X					2
Sweden			X				1
TOTAL	**13**	**9**	**14**	**1**	**2**	**1**	**40**

**= In times of crisis, the usual authority for applying for/granting CLs is different. From Questionnaire Responses, MS responses on question 18.*

In the majority of EU MS, a court or other judicial body (administrative court or specialised court) is chiefly entrusted with the task of evaluating an application for and granting a CL. National ministries or the governments themselves are also often granted the ability to issue a CL, but in these cases another institution is usually also deemed competent to grant a CL alongside the authority of the ministry or governmental actor: of the 13 MS that appointed a national ministry or government actor to issue CLs, each of these MS appointed another authority competent to issue a CL except Malta (only the ministry), seemingly in the interest of granting and enforcing a CL on different grounds. In the few cases where only one authority was competent to issue a CL, that authority was usually a court (Croatia, Denmark, Finland, Romania, Slovakia, Slovenia, Sweden) (exceptions: Ireland (only IPO); Malta (only Ministry); and Poland (only IPO)). Another interesting finding was that, in only 5 of the studied MS, it was reported that the usual authority for granting a CL would change under the circumstances of a crisis (Belgium[55], Greece[56], Italy[57], Lithuania[58], Luxembourg[59]).

According to the responses gathered from national experts and stakeholders/experts invited during the workshops, there are some perceived benefits and limitations to allocating the authority to grant a CL to one institutional actor over another.

For example, it was reported by all categories of stakeholders during interviews and workshops that, although allocating the power to evaluate and grant a CL to a competition

[55] According to Belgian legislation, the provisions on granting a CL for reasons of failure to work and dependency are *not applicable* to the CL regime for public health (Art. XI.38 §12 CEL). Under non-crisis circumstances, a Minister is appointed the role of granting a CL, based on the recommendation of an Advisory Committee. The King (read the Minister responsible for Industrial Property) is competent to grant the CL in times of crisis/public health emergency. National Questionnaire Responses, Belgium.

[56] The Minister of Finance and Development and/or any other competent Ministers following an opinion of the Hellenic Property Organisation (OBI) for granting a CL under normal conditions, competent authority for granting a CL in case of national emergency is solely the OBI. (This was following a revision to the law in 2019 where previously the law on non-contractual licenses provided that the competent court could grant a license without the patent proprietor's consent. Currently, the competency lies with the Hellenic Property Organisation (OBI).) National Questionnaire Responses, Greece.

[57] Italian PTO (UIBM) for granting a CL under normal conditions, competent authority for granting a CL in case of a national health emergency is Italian Minister of Health in agreement with the Italian Minister of Economic Development. National Questionnaire Responses, Italy.

[58] According to Lithuanian legislation, "…the competent authority for granting a compulsory licence differs depending on which grounds such licence is granted. A compulsory licence may be granted by the Government of the Republic of Lithuania (for public interests and in case of anti-competitive exploitation), the Vilnius Regional Court (for plant varieties), or the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania (for exportation of pharmaceutical products)." National Questionnaire Responses, Lithuania.

[59] In Luxembourg, "…for the "common" compulsory licence, the compulsory licence for exportation must be filed with the Tribunal d'arrondissement, contrary to the ex officio licence applying in the case of a crisis, which is granted at the sole initiative of the government." National Questionnaire Responses, Luxembourg.

authority may seem to ensure more expedient review and a more favourable decision (based on economic decisionmaking), competition-based procedures for obtaining a CL may still require a high threshold for demonstrating a patent holder's anti-competitive behaviour on the marketplace. Likewise, though the stakeholder impressions during the workshops (particularly, the impressions of national experts (i.e., patent attorneys)) revealed that courts seemed like "slower" decisionmakers comparatively, in practical terms the possibility for "expedited" procedures available through courts (i.e., removing the requirement for proving that voluntary negotiations have taken place when applying for a CL in a time of "public health emergency") have been well-observed in several jurisdictions. Additionally, based on the experiences of stakeholders in Germany, some cases involving a request for a CL exhibited a willingness for judges to engage in economic analyses in their decision making.[60] This perhaps indicates that the choice of authority for assessing and granting a CL *per se* may not ultimately reflect the effectiveness of such an authority to issue a CL, given that there are certain flexibilities in the granting authorities' competences (i.e., a court that integrates expedited procedures and assesses the economic impacts of granting a CL may be as effective as a competition authority in terms of speed and quality of its decisionmanking).

As a corrolary point, it was observed that in times of crisis (national emergency or for reasons of public health), across the majority of MS, executives situated at the highest level of government, i.e., Ministers, were the competent authority to issue the CL. This is understandable, given that the use of executive power in safeguarding public welfare is a widely recognised principle of governance throughout EU MS.

Finally, when stakeholders were asked during the workshops about the "ideal" type of institution to make decisions on the application and grant of a CL in a time of crisis, stakeholders and experts did not come to a general consensus. For instance, our finding that there were "more" CL cases (published or unpublished) in jurisdictions where authority lies with the courts could not necessarily lead to the conclusion that the judiciary is the best institution to deal with CL requests in times of crisis.Drawing from our analysis of the data collected, collectively we could not observe a direct relationship between the grant/non-grant of CLs, nor the effectiveness/non-effectiveness of a CL procedure, depending solely on the type of authority competent to make such decisions

1.1.2. Lack of competence with regard to EU IPRs and exclusivity

Member States cannot deal in their CLs with types of rights and subject-matter that are exclusively regulated by EU law. The only exception is the Unitary Patent for which the participating Member States keep their competence to issue a CL on their respective territories.[61]

But in the case with a union right such as the Community Plant Variety Rights, only the CPVO may grant a compulsory licence either to a category of persons satisfying specific requirements, or to anyone in one or more Member States or throughout the EU (Article 29(2) of the Plant Variety Regulation). The CL request can be made by a Member State, by the European Commission or by an organisation set up at the EU level and registered by the Commission . According to Art. 29(3) of the Plant Variety Regulation, the CPVO shall, when granting the compulsory exploitation right, stipulate the type of acts covered and specify the reasonable conditions pertaining thereto, which may include a possible time limitation, the payment of an appropriate royalty as equitable remuneration to the holder, and may impose certain obligations on the holder, the fulfilment of which are necessary to

[60] Reference was made to the complex and economic analysis made by German courts in FRAND-discussions
[61] See Recital 10 of the Unitary Patent Regulation 1257/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection: "*Compulsory licences for European patents with unitary effect should be governed by the laws of the participating Member States as regards their respective territories*".

make use of the compulsory exploitation right. The decision of the CPVO regarding a CL request can be appealed to the CPVO's Board of Appeal[62] and later, or directly, to the CJEU[63]. The appeal shall not have suspensory effect.[64]

MS also lack the competence to grant CLs with regard to other types of EU-regulated exclusivity, such as Regulatory Data Protection awarded through the centralised marketing authorisation at EU level (see further below).

Although trade secrets are not considered an IPR in the EU, they are quite relevant for CLs. Since 2016, their scope is determined by the Trade Secrets Directive (TSD). The TSD not only contains a detailed definition of a "trade secret" that MS cannot deviate from, but lists also certain fundamental rights (freedom of expression, whistleblowing, mobility of employees) that cannot be impeded by relying on national trade secret law. The question then arises wether the TSD would pre-empt legislative initiatives of MS to organize access to trade secrets via a CL mechanism.

For the purpose of this study, it is important to observe that article 1.2 sub b of the TSD states explicitly that MS preserve their competence to "*require trade secret holders to disclose, for reasons of public interest, information, including trade secrets, to the public or to administrative or judicial authorities for the performance of the duties of those authorities*." This "duty" of the authorities refers e.g. to their right of inspection of manufacturing processes to ensure their safety and efficacy and the products made therewith. But it does not comprise the right to give the public or specific third parties access to any trade secrets.

The conditions for the "lawful acquisition of a trade secret" are not governed exclusively by the TSD either, since article 3.2 of the TSD provides that the "*acquisition, use or disclosure of a trade secret shall be considered lawful to the extent that such acquisition, use or disclosure is required or allowed by Union or national law*.

Since the TSD does not contain any language about CLs, it could be argued that MS have retained a certain competence to organize CLs for trade secrets, certainly when the public interest and public authorities are involved. This study will demonstrate where this is currently the case in which MS.

1.2. Scope and Effect of National CLs

1.2.1. Subject matter covered by CLs

1.2.1.1. Types of products and processes

We examined if and to what extent the type of products and processes (e.g., their complexity and field of technology) impact the effectiveness of CLs.

We illustrate the various degrees of effectiveness of CLs based on four different technologies:

1. A product covered by a single IPR that only requires a "naked licence" for its manufacture and that needs no further regulatory approval, know-how or instructions for use;
2. A product covered by a single IPR whose manufacturing requires certain know-how and/or Good Manufacturing Practices (GMP) and a regulatory approval;

[62] Article 67(3) of the Plant Variety Regulation.
[63] Ibid., Article 74(1).
[64] Ibid., Article 67(3).

3. A medicinal product covered by several patents, patent applications and trade secrets resulting from a collaboration and cross licensing arrangement between various industry actors, that is subject to a marketing authorisation (MA) and that is therefore also protected by data exclusivity and that requires specialized staff for its use;

4. A complex product such as meant in category no. 3 that is in addition developed to cope with a crisis and therefore developed in such a short time spam that their IP protection is impossible to detect from the outside since the patent applications have not even been published yet (such as e.g. the COVID-19 vaccines[65]). For such complex and new products, the regulatory file is the only publicly available source that can serve as basis to define the product that one wishes a CL for.

In the **first category** belong "simple IP" products such as e.g. sunglasses, valves for a respiratory device, spare parts whose design can be reverse engineered easily and replicated with 3D printers, masks, jodium pills, or water purification pills.[66] They constitute good examples of what a CL might be useful for.

In the **second category** belong e.g. medical devices Class I or Class II such as a respiratory device, a syringe or a diagnostic testing device, or the "Decathlon" mask that was re-purposed for use as a respiratory mask by COVID-19 patients);[67]

Industry stakeholders informed us that there are medicinal products based on so-called "small molecules" whose manufacturing requires know-how that is readily available to those who have some experience in the field, and that would therefore belong to the second category.

The grant of a marketing authorization is a matter controlled sometimes by national authorities and sometimes by EU-authorities. Not only is it a separate procedure that cannot be bypassed via a CL based on national law, but in addition the holder of the marketing authorization is frequently not the same as the holder of the IPR.

The manufacture and distribution of "complex products" in the **third category** requires not only "naked licenses" but also (and most of all) access to secret know-how for which there exists no CL regime, such as biological products (vaccines). Licensing such know-how is only done to parties in whom the licensor can have trust, because the know-how can afterwards be used in other domains as well. In addition, the IP and the know-how are often owned by several parties who each own and have protected different layers within the same technology.[68] This fact makes it quite complex to determine who owns what. A network analysis highlights the complex intellectual property landscape behind mRNA-based COVID-19 vaccines.[69]

The **fourth category** is for products that are developed during and because of the crisis in such a short time span (such as e.g. the COVID-19 vaccines) that the applicable IP and their owners are impossible to detect via public sources since the patent applications are

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[65] World Intellectual Property Organization, ed., *COVID-19-Related Vaccines and Therapeutics: Preliminary Insights on Related Patenting Activity during the Pandemic*, Patent Landscape Reports (Geneva, Switzerland: WIPO, 2022), https://doi.org/10.34667/tind.45030. World Intellectual Property Organization, ed., *COVID-19-Related Vaccines and Therapeutics: Preliminary Insights on Related Patenting Activity during the Pandemic*, Patent Landscape Reports (Geneva, Switzerland: WIPO, 2022), https://doi.org/10.34667/tind.45030.

[66] Vandermeulen, B., Moyersoen, J., Mellaerts, R. (2020), "Report on the feasibility and analysis of "Impact Licensing Initiative" (ILI) for technology access during a health crisis" European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Publications Office, p. 11, https://data.europa.eu/doi/10.2873/552686

[67] Ibid., p. 15

[68] Ibid., p. 18 describing the complex IP situation of an Intensive Care Unit (ICU)

[69] Mario Gaviria and Burcu Kilic, 'A Network Analysis of COVID-19 MRNA Vaccine Patents', *Nature Biotechnology* 39, no. 5 (May 2021): 546–48, https://doi.org/10.1038/s41587-021-00912-9. Mario Gaviria and Burcu Kilic, 'A Network Analysis of COVID-19 MRNA Vaccine Patents', *Nature Biotechnology* 39, no. 5 (May 2021): 546–48, https://doi.org/10.1038/s41587-021-00912-9.

not even published yet. For such complex products, the regulatory file is the only source that can serve as basis to seek a CL.

1.2.1.2. Number of IPRs covered by a CL

The effectiveness of CLs could depend on the number of IPRs a CL could cover, and/or whether it is necessary to undertake the same procedure for several CLs covering a single patent each, for example.

In the majority of the Member States, laws providing for compulsory licensing in case of crisis refers to CL for "patent" in singular form. Some national experts consider that the literal interpretation of the law and the absence of cases to the contrary suggests that a CL could be granted only per single patent, e.g., in Austria, Bulgaria, Denmark, France and Luxembourg. At the same time, in a number of Member States where IP legislation also refers to "patent" in singular, national experts consider that the law does not prohibit that a CL covers more than one patent, e.g., in Estonia, Finland, Greece, Lithuania, Luxembourg, Poland, Romania and Spain. In Italy, Article 70-bis of the Industrial Property Code talks about the granting of compulsory licences for relevant "patents". In the vast majority of CL cases in the Member States, CLs and applications for CLs related to a single IPR, patent or utility model per CL (see Annex IV), with exception to the Netherlands and Sweden.

Case: CL application covering multiple patents

Arguably the first time that Dutch legislation provided for the possibility to grant a compulsory license in case of a crisis was when the Netherlands Patents Act 1910 came into force. The CL was granted for multiple patents in the public interest under the Dutch Patents Act 1910. Article 34 of the Netherlands Patents Act 1910 provided for the possibility to grant a CL "in the public interest".

In the case of the Appeals Division Netherlands Patent Council (*Beroepsafdeling van de Octrooiraadi)* 4 August 1949,[70] the patents in question related to diazotype or were relevant to the application of diazotype.[71] The petitioner requested an application for a compulsory license for multiple patents related to this printing technique. On 24 February 1948, the Receiving Division Netherlands Patent Council (*Aanvraagafdeling van de Octrooiraad*) granted a compulsory license for only one patent and refused to grant a compulsory license for the other patents. At the appeals stage, the Appeals Division Netherlands Patent Council granted a compulsory license for all the patents as requested, considering that under the economic situation at the time, it was in the public interest that a leading Dutch industry operating in the field covered by the patents in question should be enabled to develop its business further through domestic work.[72]

A more recent case in Hungary demonstrated that 3 CLs were granted at once for 3 patents, i.e., one CL per patent, providing an example of multiple CLs granted at the same time for the same licensee.

In November 2020, based on the recently enacted compulsory licensing provision on the ground of public health crisis the Hungarian Intellectual Property Office granted 3 CLs for patents relating to the active ingredient remdesivir and pharmaceutical preparations containing it. The holder of all 3 patents is Gilead Sciences and the applicant was Richter Gedeon. The respective second instance court docket numbers are the following for the 3

[70] Bijblad BIE 1949, no. 10, p. 111-120.
[71] Diazotype is a printmaking technique initially developed as an alternative to the blueprint and used for the manufacturing of light-printing paper (lichtdrukpapier).
[72] Bijblad BIE 1949, no. 10, p. 119.

cases: Metropolitan Appeal Court Pkf. 25.538/2021/6, Pkf. 25.537/2021/6. And Pkf. 25.536/2021/6.

The research did not permit to establish a CL case dealing with several different types of IPRs at once (e.g., patent + design rights).

Taking the examples above, in the interest of procedural economy and taking into account the multitude of IPRs that could cover some complex products (see Section 3.1.1), the effectiveness of CLs in times of crisis could possibly be enhanced if it is clarified that a single CL (i.e., a CL covering a "product" as a whole) could cover several IPRs and several types thereof.

A similar procedural economy can be found in Regulation 816/2006 where a CL is scoped on the basis of a product, so that it can encompass several patents, including an SPC. [73]

1.2.2. Types of IPRs, related rights and related subject matter required for a CL in case of crisis

Patents

National, European and Unitary Patents

All national laws of the Member States explicitly provide for a possibility to grant CLs in crisis situations. All the consulted stakeholders and national experts unanimously confirm that CL provisions apply not only to purely national patents but also to patents stemming from a European patent granted by the EPO.

This affirmation was also confirmed by CL cases.

[73] See Art. 6 of Regulation 816/2006 ("The application … shall set out the following: … (b) the non-proprietary name of the pharmaceutical product or products which the applicant intends to manufacture and sell for export under the compulsory licence; …". And its Recital 14 refers to "the patent(s) and/or supplementary protection certificate(s) in respect of which a compulsory licence is sought".).

Other CL cases of national and European patents

The following examples indicate cases related to CL originating primarily from Spain. These examples show that CL applications and proceedings may occur but not ultimately result in the grant of a CL.

- Spanish patent with publication number ES2068068, Procedimiento y máquina para la mecanización de portalámparas (Process and machine for the machining of lampholders), with application date on 12 February 1992. The patent owner was Juan José Ovejero del Hoyo.

  The application for a compulsory license was filed by an unknown party in 2003 and rejected in 2004. The reasons are undisclosed.

- European patent with publication number EP1059283, validated in Spain with number ES2198244, Process for preparing neuraminidase inhibitor ro-64-0796, with priority date on 21 February 2000. The patent owner was F. Hoffmann-La Roche AG.

  The application for a compulsory license was filed in 2009 by Farmhispania, S.A., and rejected in 2010. The application was based on public interest reasons for the purpose of ensuring the supply to the national market, in the context of the pandemic declared by the WHO in connection with the 2009 swine flu pandemic, caused by the H1N1 influenza virus.

  The Spanish Patent and Trademark Office (SPTO) refused the application because the applicant failed to comply with formal requirements.

- European patent with publication number EP0759917, validated in Spain with number ES2118674, Novel selective inhibitors of viral or bacterial neuraminidases, with priority date on 29 December 1995. The patent owner was Gilead Sciences, Inc.

  The situation was identical to the one referred to above, in respect with EP1059283. The applicant of the compulsory license was the same company and the reason for rejection was also the failure to comply with formal requirements. The application was filed in 2009 and refused in 2010.

As already observed above, a Unitary Patent is subject to the respective CL legislations in the participating Member States despite the fact that is a single title that offers protection in all participating MS and that can only be granted or revoked as a whole and not per Member State. The reason for this peculiar situation is that CL's are so rare and were considered so irrelevant at the time of drafting the Unitary Patent Regulation that it would have been a waste of time and energy to try finding a common ground about CLs at Union level. [74]

The effectiveness of a CL covering a patent could further depend to some extent on the manner in which the disclosure obligation of patent applicants is implemented. For example, Article 83 of the European Patent Convention (EPC) requires that "The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.". The reproducibility and speed thereof of the patented invention could depend on the implementation of the disclosure requirement.

[74] For comments and criticism against this peculiar provision in the Unitary Patent Regulation, see Petersen, Clement Salung and Riis, Thomas and Schovsbo, Jens, "The Unified Patent Court (UPC), Compulsory Licensing and Competition Law" (August 29, 2014) Nordiskt Immaterieelt Rättskydd (NIR), Available at SSRN: https://ssrn.com/abstract=2489006

Supplementary Protection Certificates (SPCs)

An SPC is a temporary extension of a patent, limited in scope by the content of the marketing authorisation for the medicinal product covered by that patent.[75] Compulsory licensing provisions of most national laws do not explicitly refer to SPCs. Responses of the national experts demonstrate that this fact gives rise to an uncertainty, ambiguities and differences in interpretation of similarly worded provisions.

While it was reported that SPCs are covered by CL legislation in some MS, e.g., in Croatia, Czech Republic, Estonia, Greece, Hungary, Lithuania, Romania and Slovakia, it was reported that in several other MS CLs cannot cover SPCs on the basis of literal interpretation (because SPCs are not explicitly mentioned in the CL provisions). In the absence of cases, explicit mention in the law (e.g., Section 70 d of the Finnish PA and Art. 100(5) of the Spanish PA) or in authoritative official documents of interpretative value (e.g., Memorandum (MvT) for the legislative bill of 19 April 2021, amending the Netherlands Patents Act 1995, p. 2, clarifying the application of CLs to SPCs and paediatric extensions of SPCs). Also Regulation 816/2006 refers to SPCs in its article 1 (scope) and 2 (definition of right holder).

Cases: Compulsory licences covering SPCs

On 26 March 2007, the **Italian** Competition and Market Authority accept and made mandatory a commitment presented by the Merck & CO companies. Inc. and Merck Sharp & Dohme (Italy) to close the investigation started in February 2005, for abuse of a dominant position. The Merck group had to grant free licences to make possible, also in Italy, the production and sale of the active ingredient Finasteride and related generic drugs, two years in advance of the expiry (2009) of the SPC. This was decided by the Antitrust Authority which, in the meeting of 21 March 2007, accepted and made the commitment presented by the multinational company mandatory, thus closing, without sanction, the proceeding initiated for abuse of a dominant position.

On the 21th June 2005, the Italian Competition and Market Authority approved the application of a precautionary measure against the company Merck & CO. Inc. of the Merck pharmaceutical group. Merck was the owner in Italy of an SPC which gave it the exclusive right to market a drug (Tienam) based on the active ingredient imipenem cilastatin. It is an antibiotic, intended for the treatment of particularly serious infections, mainly contracted in hospitals. The proceeding against the Merck group was initiated on 23 February 2005, following the refusal by that company to grant a licence for the production in Italy of imipenem cilastatin intended to be exported for the production of generic drugs in Member States not covered by patents.

In these cases, the CLs were obtained on competition law grounds, as the Competition and Market Authority found a violation of competition rules. Article 70-bis of the Italian Industrial Property Code (CPI), providing for a possibility of compulsory licensing in case of a “national health emergency” refers explicitly only to patents. According to the experts’ input received, it is a matter of legal interpretation whether the said legal provision covers also SPCs.

During an interview, one of experts also reported of a CL case in **Norway** regarding the fisheries sector. A company applied for a CL covering SPC on a vaccine for the treatment of salmon. The CL was awarded.

Published patent applications

[75] Hilty, R.M., *Study on the Legal Aspects of Supplementary Protection Certificates in the EU: Final Report*. Reto Hilty, ed., (Max Planck Institute for Innovation and Competition, 2018).

The CL legislation of many Member States does not explicitly refer to the possibility for a CL to cover published patent applications. There are different views among the national experts consulted on how to interpret the absence of reference to published patent applications.

In the Netherlands, a CL for a Dutch national patent can only be granted once the patent has issued and a CL for the Dutch equivalent patent based on a European patent can only be granted once the opposition period of nine months has expired or opposition proceedings are completed. [76] The Dutch national report cites a decision from the patent court in The Hague denying a CL for a European patent application on the ground that the final scope of the application was uncertain and could only be determined after the grant of the patent. [77] This view represents one side of the spectrum and is not shared elsewhere.

In some Member States national experts consider that requests for a CL can cover published patent applications, e.g., in Croatia, Greece, Romania and Spain even though the law is unclear.

In other member states the situation is clear but in the opposite direction where the CL provisions explicitly refer to patent applications. This is the case for France (Art. L613-19 French Intellectual Property Code (CPI), Ireland (Section 76(1) Irish PA) and Malta (Art. 40 Maltese Patent and Designs Act).

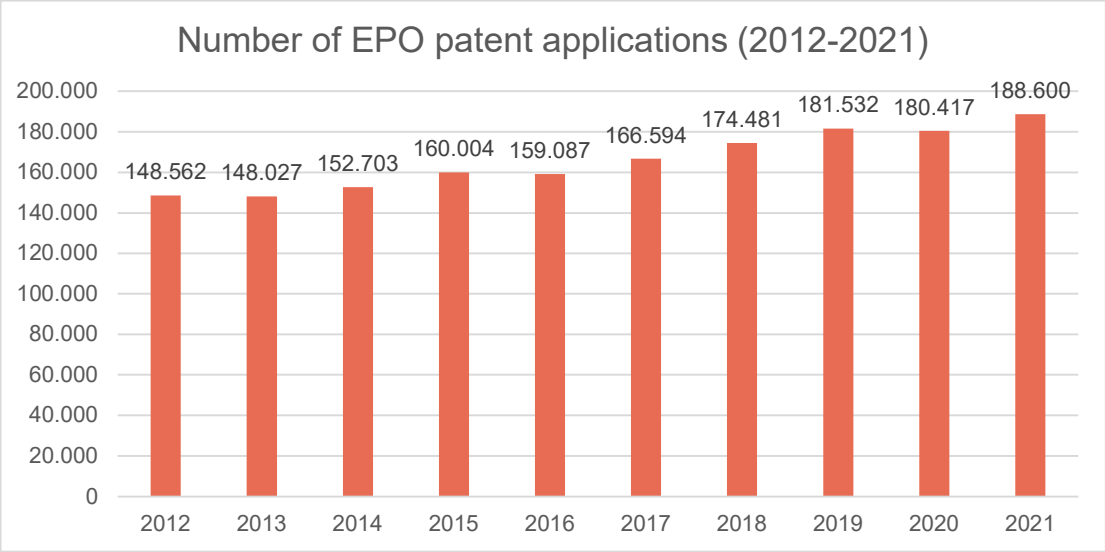
In Finland, according to Section 48 Finnish PA, it is possible for a third party to obtain a CL for the exploitation of an invention where the third party at the time of public disclosure of the patent application documents was exploiting the invention for which the patent has been applied, on the condition that the application leads to the grant of a patent and that there are special reasons for granting the CL and that the third party was not aware or could not have been aware of the patent application. The CL can also extend to a time period preceding the grant of the patent.

A published European patent application gives an applicant so-called “provisional rights” via a “reasonable compensation” as provided for in article 67 of the European Patent Convention and further implemented in national law. For example, under Art. 95 of the Croatian Patent Act, by publication of the patent application, the patent applicant shall acquire provisional rights on the basis of which compensation for damages may be claimed from any third party which has exploited the invention within the period from the publication date and the date of patent registration.

It can be argued that the scope of a European patent application that has undergone full examination and that has received a Notice to Grant is sufficiently specific in scope and could therefore be made subject to a CL (that should then automatically extend to the resulting patent).

[76] This appears from the official Text and Commentary (“Tekst & Commentaar”) on Article 57 of the Dutch Patent Act (version 1995).
[77] President of the District Court The Hague (preliminary proceedings), 26 August 2003 (Cordis/Medinol)

For European patent applications that have not yet received a Notice to Grant, it should be considered that on average, the procedure for delivering patents by the EPO is between 3 and 5 years[78] and that the number of patent applications is continuously growing. For example, in 2021, the EPO [79] alone received a record 188 600 applications[80] (4.5% growth in comparison to 2020) whereas in 2012, the number of EPO applications was "only" 148 562.[81]



Almost 55% of the total number of European applications are represented by the top ten technical fields[82]:[83]

Ranking	Technology field	2012	2013	% change 2013 vs. 2012	2014	change 2014 vs. 2013	2015	change 2015 vs. 2014	2016	change 2016 vs. 2015	2017	change 2017 vs. 2016	2018	change 2018 vs. 2017	2019	change 2019 vs. 2018	2020	change 2020 vs. 2019	2021	change 2021 vs. 2020
1	Digital communication	9809	9398	-4,2%	10427	10,9%	11051	6,0%	10967	-0,8%	11853	8,1%	11853	0,0%	13978	17,9%	14077	0,7%	15400	9,4%
2	Medical technology	10502	10782	2,7%	11234	4,2%	12531	11,5%	12382	-1,2%	13134	6,1%	13707	4,4%	13935	6,1%	15193	9,0%	15321	0,8%
3	Computer technology	8540	9158	7,2%	9787	6,9%	10359	5,8%	10772	4,0%	11348	5,3%	11589	2,1%	12859	13,3%	13370	4,0%	14671	9,7%
4	Electrical machinery, appara	9746	10138	4,0%	10387	2,5%	9794	-5,7%	9900	1,1%	10239	3,4%	10668	4,2%	11297	10,3%	11409	1,0%	12054	5,7%
5	Transport	7002	7443	6,3%	7926	6,5%	8108	2,3%	8559	5,6%	8536	-0,3%	9039	5,9%	9540	11,8%	8933	-5,7%	9399	4,5%
6	Measurement	6633	6779	2,2%	7156	5,6%	7739	8,1%	7460	-3,6%	7999	7,2%	8711	8,9%	9048	13,1%	8606	-4,9%	9167	6,5%
7	Pharmaceuticals	6309	5568	-11,7%	5369	-3,6%	6055	12,8%	5849	-3,4%	6534	11,7%	7371	12,8%	7797	19,3%	8446	8,3%	9026	6,9%
8	Biotechnology	5539	5269	-4,9%	5754	9,2%	5724	-0,5%	5477	-4,3%	6013	9,8%	6689	11,2%	6814	13,3%	7141	4,8%	7611	6,6%
9	Other special machines	4348	4489	3,2%	4732	5,4%	5152	8,9%	5543	7,6%	5750	3,7%	6344	10,3%	6419	11,6%	6216	-3,2%	6450	3,8%
10	Organic fine chemistry	6588	6215	-5,7%	6283	1,1%	6447	2,6%	6195	-3,9%	6464	4,3%	6199	-4,1%	5993	-7,3%	6029	0,6%	5923	-1,8%

Several of these fields were concerned by compulsory licensing in the past, notably medical and pharmaceutical technologies (see Annex IV).

[78] Elisabeth Berthet, Matthieu Dhenne, and Lionel Vial, *COVID-19 : Comment mettre en oeuvre la licence d'office*, 2020, 19, https://halshs.archives-ouvertes.fr/halshs-02970543.
[79] 38 Member States of the European Patent Organisation includes the 27 EU Member States.
[80] European patent applications include direct European applications (Direct) and international (PCT) applications that entered the European phase during the reporting period (PCT regional).
[81] 'Patent Index 2021: European Patent Applications', EPO, accessed 3 July 2022, https://www.epo.org/about-us/annual-reports-statistics/statistics/2021/statistics/patent-applications.html.
[82] The definition of the fields is based on 'IPC Concordance Table', WIPO, n.d., https://www.wipo.int/ipstats/en/statistics/patents/xls/ipc_technology.xlsx.
[83] 'Patent Index 2021: European Patent Applications'.

The latest EPO report provides for the following statistical information on the length of the patent grant procedure:[84]

Patent grant stages	2020 (in months)	2021 (in months)
Searches[85]	4.3	4.8
European examination[86]	23.7	23.0
Opposition procedures[87]	15.4	19.3

As observed previously, situations of crisis typically create a demand for state-of-the-art technology that was recently developed and whose patent protection is therefore still in an early phase. For example, according the WIPO Patent Landscape Report on COVID-19-related vaccines and therapeutics, "since the beginning of 2020 when COVID-19 began to spread quickly around the world, 5,293 patent applications related to COVID-19 have been published across 49 patent offices, including diagnostics, treatments, vaccines and any other references to either the SARS-CoV-2 virus or the COVID-19 infection."[88]

Significant time would be gained and duplication of CL proceedings would be avoided if patent applications were included as basis for a CL request, provided their scope of protection is sufficiently clear and predictable for the purpose of the CL request. For the same reasons, when divisionals are pending on the basis of the same priority patent, it might be more effective to catch an entire patent family via a single CL request.

In the same line of thought, national laws that provide for an "embargo" during which a CL cannot be requested - either by requiring a minimum-term for non-use, or a term after the date of grant or application of a patent - do not make the CL system very efficient, and even impossible during a crisis. [89] It is therefore recommended that these "embargos" are removed.

[84] 'Patent Index 2021: Quality Indicators', EPO, accessed 3 July 2022, https://www.epo.org/about-us/annual-reports-statistics/statistics/2021/statistics/quality-indicators.html.
[85] Mean value for standard searches (i.e. excluding non-unity, clarification request or incomplete search).
[86] Mean value calculated from valid examination request to dispatch of examiner's intention to grant for standard examination (i.e. excluding two or more late payment of fees, two or more requests for extension of time limit, or re-scheduling of oral proceedings).
[87] Mean value calculated from expiry of opposition filing period to date of opposition decision for standard opposition cases (i.e. excluding cases with more than one opponent, participation of a legal member or re-scheduling of oral proceedings).
[88] World Intellectual Property Organization (WIPO), 'COVID-19-Related Vaccines and Therapeutics', 12, accessed 10 March 2022, https://doi.org/10.34667/tind.45030.
[89] See for instance Austria (four years after application date or three years after grant date ; the Netherlands (three years of lack of use before a CL can be requested ; Italy (four years after application and three years after grant)

Plant variety rights

The study permitted to identify three CL cases regarding plant variety rights in the EU: one in the Netherlands, on in the UK (pre-Brexit) and one by the CPVO (see Annex IV). The CPVO case dealt with a CL application for Community plant variety rights on public interest grounds.

It was reported that laws of at least some MS provide for CLs for plant variety rights, e.g., Bulgaria, Czech Republic, Estonia, Netherlands and Slovakia.[90] Further research engagement with a different set of stakeholders and experts with specialised knowledge on this type of IPRs would be necessary to more accurately map the application of CLs to plant variety rights in EU Member States.

Utility Models

It was reported that in a few MS CLs could cover also utility models. Although utility model protection is not available in all MS,[91] further research would be necessary to more accurately map the application of CLs to utility models in EU Member States.

In several reported cases, it was necessary to cover utility models by CLs.

Cases: Compulsory licensing of utility models

- Spanish utility model with publication number ES1044115, Improved valve for liquids applicable in water troughs and the like, with application date on 9 August 1999. The utility model owner was Rotecna, S.A.

  The application for a compulsory license was filed in 2004 by José Lozano Izquierdo, and rejected also in 2004. The application was based on lack of exploitation by the patent owner within three years from the publication date of the utility model grant. The SPTO refused the application due to a number of reasons. An appeal was filed before the SPTO first and subsequently before the Courts, but both appeals were refused.

- Spanish utility model with publication number ES1030720, Set of launchable and assemblable game pieces, with application date on 12 April 1995. The utility model owner was Pepsico, Inc.

  The only information available is that the application for a compulsory license was filed in the year 2001.

- Spanish utility model with publication number ES1036139, Improved scaffolding displacement device, with application date on 30 December 1996. The utility model owner was Railsa Valencia, S.L.

  The only information available is that the application for a compulsory license was filed in the year 2004.

[90] National reports on the CL in the Czech Republic and Slovakia also refer to animal breeds.

[91] Alfred Radauer et al., *Study on the Economic Impact of the Utility Model Legislation in Selected Member States: Final Report* (Publications Office of the European Union, 2015), https://data.europa.eu/doi/10.2873/07203. Alfred Radauer et al., *Study on the Economic Impact of the Utility Model Legislation in Selected Member States: Final Report* (Publications Office of the European Union, 2015), https://data.europa.eu/doi/10.2873/07203.

In jurisdictions where utility models have a similar scope of protection as patent rights, such as the United States, so-called "3DP IP pledges" pledges have been reported to allow 3D printing of respirators and masks during the COVID-19 crisis. [92]

Copyright and design rights

Designs do not have an impact on the effectiveness of CLs, because designs protect only aesthetic elements, leaving technical functions unprotected. Design protection does not prevent use of the same technical functions in objects with different aesthetic elements. A work around is easily made and therefore design rights are not rights for which CLs are commonly provided. It was reported that a CL could cover designs only in Poland. Despite the foregoing, we refer to the interesting "Decathlon" case from the COVID-19 period in Italy identified during our research, where an agreement was reached with the IP owner to re-purpose this mask for hospital use.[93]

It was observed by several stakeholders and experts consulted that **copyright** does not present a significant obstacle and need for a CL, because copyright only protects a particular expression of more abstract ideas and creations, and never that idea or creation as such in an unlimited variety of expressions.[94] The same reasoning applies to software. These creations of the mind can be re-written so as to achieve more or less the same technical effect without infringing the original copyright.

Overall, the research did not permit to establish a problem with regard to the non-application of CLs to copyright and design rights.

[92] Ballardini et al. 3D Printing, Intellectual Property Rights and Medical Emergencies: In Search of New Flexibilities, IIC (2022) 53:1149–1173, https://link.springer.com/article/10.1007/s40319-022-01235-1

[93] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Report on the feasibility and analysis of "Impact Licensing Initiative" (ILI) for technology access during a health crisis, Publications Office, 2020, page 17, https://data.europa.eu/doi/10.2873/552686

[94] On some issues reported in literature, see Sean Flynn, Erica Nkrumah, and Luca Schirru, 'Non-Patent Intellectual Property Barriers to COVID-19 Vaccines, Treatment and Containment', no. 71 (n.d.): 21. On some issues reported in literature, see Sean Flynn, Erica Nkrumah, and Luca Schirru, 'Non-Patent Intellectual Property Barriers to COVID-19 Vaccines, Treatment and Containment', no. 71 (n.d.): 21.

Regulatory data protection (RDP)

For this study, we call "regulatory data protection" the rules that temporarily prevent an applicant for a marketing authorisation to rely on the scientific data that another applicant filed previously for the same product (medicinal, food, chemical or plant variety) having substantially the same composition and formulation. The rationale for such "data protection" is to reward the first applicant for his efforts to invest in expensive trials to prove the safety and efficacy of his product. For medicinal products, the duration of this protection is in Europe basically ten (10) years starting at the date of grant of the marketing authorisation and is organized via Article 14(11) of Regulation (EC) No 726/2004 and Articles 10(1) and 10(5) of Directive 2001/83/EC.

The RDP rules are based on EU-legislation and cannot be supplemented or changed by national legislation. This was confirmed by the Advisory Division of the Dutch Council of State in an opinion of 8 July 2021 on a draft legislative bill no. 35.809 introduced on 19 April 2021 by two members of the Dutch House of Representatives (Ellemeet and Ploumen). The proposal called for setting aside RDP in case a CL would be granted for medicinal products. The Council of State advised not to debate the proposed bill *inter alia* because it was in conflict with the European regulation and directives on RDP that did not provide room for such national initiatives. [95]

Our interviews and Workshops with the relevant stakeholders confirm that RDP should not constitute an additional barrier for making a CL effective when it relates to a medicinal product.

At the outset, firstly, we should note that CL may not be an effective or sustainable way to improve access to medicines or achieve other public health objectives. However, where a CL on a patent is legitimately granted, that is, following due process and duly justified, we acknowledge that RDP should not constitute an obstacle to the implementation of such a licence.[96]

Whilst all stakeholders therefore agree on this principle, they do not agree if and how the existing RDP rules should be set aside. We debated with the shareholders two specific European RDP rules:

First, it was submitted that article 5.2 of Directive 2001/83 already gives Member States the authority to issue emergency authorisations for unapproved medicines and that this should suffice to cope with the problem in case of a crisis. However, it was observed that this rule does not solve the problem for products that are already authorized and covered by an MA. It is precisely to allow that already approved products can be produced on a larger scale via a CL that the RDP rules constitute a barrier for the grant of a second market approval for the identical product.

The second submission was that article 10.c of the same Directive 2001/83 entitles owners the right to give their informed consent to allow making reference to their existing data files and that they would be willing to do so, but that the implementing rules (the "Notice to Applicants") imposed on them also the obligation to give access to their "Drug Master File" (DMF) which was not the intended goal of article 10.c and which would force them to disclose valuable trade secrets. It was observed that if an owner had already caused a CL to be ordered because of his unwillingness to grant a voluntary licence, he is unlikely to cooperate with lifting the RDP rules. There was agreement that access to the DMF was not required for a CL beneficiary since he must constitute this file himself.

Regulation 2006/816 contains in article 18.2 a very simple language to lift the RDP rules:

[95] The proposed legislative bill 35 809 of 19 April 2021 and the opinion of the Advisory Division of the Council of State can be found at https://www.raadvanstate.nl/adviezen/@125169/w18-21-0118-iv/
[96] Feedback collected from stakeholder representing the pharmaceuticals industry.

> *If a request for any of the above procedures concerns a product which is a generic of a reference medicinal product which is or has been authorised under Article 6 of Directive 2001/83/EC, the protection periods set out in Article 14(11) of Regulation (EC) No 726/2004 and in Articles 10(1) and 10(5) of Directive 2001/83/EC shall not apply.*

That is so worded because there may still be rules applicable in the country of importation.

The authors Ellen F. M. 't Hoen, Pascale Boulet, and Brook K. Baker propose the following wording for changing the Regulation :

> *'The protection periods set out in article 14 (11) of Regulation 726/2004 shall not apply in cases where it is necessary to allow access to and the use of pharmaceutical test data to register a generic of a reference medicinal product, which is or has been authorised under article 6 of Directive 2001/83/EC, for reasons of public interest including public health, in case of compulsory licensing of patents, including for public non-commercial use, and in situations of national emergency or extreme urgency'.*

Our research, interviews and meetings with stakeholders did not identify reasons why such proposals would not be efficient to solve the detected problem, even if the specific wording may leave room for discussion. Lifting the RDP rules should not give a blanket license to a CL licensee to make potentially unsafe products because the licensee would still be obliged to make and file e.g. a DMF and submit other evidence that its manufacturing procedures are compliant with GMP-rules.

Cases: Romania: RDP Rules as a Barrier to CL

The Romanian "sofosbuvir" case illustrates how EU data exclusivity is one of the major obstacles to the effective use of compulsory licensing. In 2016, the Romanian government contemplated issuing a compulsory licence for the hepatitis C medicine sofosbuvir, which was only available from the originator company at a price of around 50.000 euro for a 12-week treatment. As reported by Ellen F. M. 't Hoen, et. al., "[s]ince the registration of a generic version of sofosbuvir is not possible before the expiry of the data exclusivity in 2022, Romania, like any other EU Member State, could not give effect to a compulsory licence. Further, the EU market exclusivity for sofosbuvir expires at the earliest in 2024."[97]

Outside the EU, there is national legislation preventing data exclusivity to be an obstacle for the efficient use of a CL in the field of medicinal products :

[97] Ellen F. M. 't Hoen, Pascale Boulet, and Brook K. Baker, 'Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation', *Journal of Pharmaceutical Policy and Practice* 10 (28 June 2017): 4, https://doi.org/10.1186/s40545-017-0107-9. Ellen F. M. 't Hoen, Pascale Boulet, and Brook K. Baker, 'Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation', *Journal of Pharmaceutical Policy and Practice* 10 (28 June 2017): 4, https://doi.org/10.1186/s40545-017-0107-9.

Article 5 "Non-Application of Data Exclusivity" of the Malaysian Directive on Data Exclusivity providing that:

> *"Nothing in the Data Exclusivity shall:*
>
> *(i) apply to situations where compulsory licenses have been issued or the implementation of any other measures consistent with the need to protect public health and ensure access for all; or*
>
> *(ii) prevent the Government from taking any necessary action to protect public health, national security, non-commercial public use, national emergency, public health crisis or other extremely urgent circumstances declared by the Government."*[98]

In Chile, Article 91 of Law 19.996, as amended in 2012 [35], provides that test data exclusivity shall not be applied as follows:

> *(a) Where, for reasons of public health, national security, public non-commercial use, national emergency or other circumstances of extreme urgency declared by the competent authority, it is justified to terminate the protection referred in Article 89 (e.g. on test data exclusivity).*
>
> *(b) The pharmaceutical or agrochemical product is the subject of a compulsory license in conformity with the provisions of this law.*[99]

As already observed, the EU national member states do not have authority to make such similar carve outs via their national laws: this is the exclusive competence of the EU.

RDP in voluntary licensing arrangements: The example of MPP licences

The importance of RDP for manufacturing and marketing of medical products becomes clear from all voluntary licences concluded within the framework of the Medicines Patent Pool (MPP) because they all provide for data exclusivity waivers[100]. For example:

Clause 5.7 of the licence between ViiV Healthcare and MPP on paediatric abacavir (ABC) concluded on 13 February 2013 provides that:

> "ViiV shall provide any Sublicensee with NCE Exclusivity or other regulatory exclusivity waivers to the extent required by the applicable regulatory authorities in order to manufacture or sell Product in the Territory in accordance with the terms of the Sublicence. ViiV shall further provide to any Sublicensee such consents which it has the legal capacity to give as are necessary to enable such Sublicensee to perform its obligations under Clauses 3.2 and 3.3 of the Sublicence."[101]

[98] Directive No. 2, 2011 "Arahan Bagi Melaksanakan Data Eksklusiviti Di Malaysia", issued by the Director of Pharmaceutical Services under Regulation 29, Control of Drugs and Cosmetics Regulation 1984), https://www.npra.gov.my/images/reg-info/DataEx/Directive_on_DE.pdf

[99] Chile Ministerio de Economía. Decreto con Fuerza de Ley 3: Fija texto refundido, coordinado y sistematizado de la ley de propiedad industrial. Biblioteca del Congreso Nacional de Chile. 2012.

[100] 't Hoen, Boulet, and Baker, 'Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union', 4. 't Hoen, Boulet, and Baker, 'Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union', 4.

[101] MPP, ABACAVIR – PAEDIATRICS (ABC): https://medicinespatentpool.org/licence-post/abacavir-paediatrics-abc

Clause 4.1(a) of the licence signed between Bristol-Myers Squibb (BMS) and MPP on HIV medicine, atazanavir (ATV) concluded on 11 December 2013 provides that:

> "BMS will further provide the Sublicensees with NCE or other regulatory exclusivity waivers, as applicable, to the extent required by the Regulatory Authorities for national registration in the Territory of the Licensed Products."[102]

RDP and CLs for exports

A RDP waiver is also present in the Regulation (EC) No 816/2006 on CL of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. Article 18 provides waivers to RDP rules necessary to obtain scientific opinion of the EMA[103] or under any similar procedures under national law, such as scientific opinions or export certificates intended exclusively for markets outside the EU. Such an "export" waiver" does not require the same broad scope as a "domestic" waiver where all RDP obstacles for the grant of an MA need to be removed.[104]

Quantification:

The opinions and inputs of the consulted stakeholders diverge on this issue, and there is a difficulty of quantifying the problem.

An EU "Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe"[105] finds that for 39% of the 558 medicinal products available in the EU in the year 2018, data exclusivity or market protection is the last measure of protection to expire, giving these products an average of 4.8 years of additional protection.

Although there is agreement amongst stakeholders that RDP should not be an obstacle to the effective implementation of a CL, such obstacle still exists and can only be removed at EU-level.

Know how / trade secrets

The European Trade Secret Directive (TSD) does not contain any provisions regarding CLs. It was already observed here above that MS may have some room to regulate access to trade secrets via a CL in their national laws, at least when the public interest and public authorities are involved. [106] This is a sensitive issue because the secret nature and value of a trade secret can be destroyed by a forced divulgation to third party. Such divulgation can according to stakeholders only be prevented by restrictive clauses whose scope would exceed that of classical secrecy obligations (such as non-compete clauses and non-sollicitation undertakings) and that would require individual or block exemption under competition law.

As already stated in section 1.2.1.1 in this study, many complex products require the use of trade secrets during their production. The transfer, teaching and protection of such trade

[102] This license agreement is available on the MPP website at https://medicinespatentpool.org/licence-post/atazanavir-atv.
[103] Article 58 of the Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1–33.
[104] See also below "Potential Regulatory Bottlenecks for RDP" in Ch. 2.1
[105] Directorate-General for Internal Market, Industry, Entrepreneurship and SME's, 2018, page 12.
[106] See above at 1.1.2

secrets is given only to trusted third parties, and owners of trade secrets are typically reluctant to share them with unknown licensees.

The problem for most complex products is that a CL on a patent cannot on its own ensure that the product can be made,[107] and that most legislations are silent about to deal with the communication of trade secrets that are necessary for their production.

The national reports show how trade secrets are dealt with in CL legislation in certain member states:

- Spain: article 100.4 of the Spanish Patent Act (version of 2015) imposes on a patentee on obligation to act in good faith during the exercise of the CL and also a transfer of know-how to the CL beneficiary. [108] Our Spanish national expert reported that no litterature or other sources exist in Spain explaining how this transfer could be organized.
- Austria: Section 36.5 of the Austrian PatentGesets (PatG) provides that the Austrian Patent Office may order know-how transfer and training if warranted by certain circumstances.
- Bulgaria: In article 9 of the Trade secret law there it is provided that "The acquisition, use or disclosure of a trade secret shall not be considered unlawful in the following cases…for the protection of an interest recognized by the law of the European Union or by the Bulgarian legislation"
- Italy: since trade secrets are considered an IP right in Italy, art. 132 of the Italian Industrial Property Code allows a CL for trade secrets.
- Lithuania : The laws of the Republic of Lithuania may establish obligation to trade secret holder to disclose information constituting trade secret for reasons of public interest to court, government, or public administration institution and (or) body..
- Netherlands: The Directive on the Protection of Trade Secrets[109] and the Netherlands Trade Secrets Act do not contain any provisions on forced access to know-how. However, the Directive and the Act leave open the possibility of such a statutory forced access regulation.[110]

Stakeholders expressed during interviews and our meetings a certain willingness to share trade secrets with unknown third parties on the condition that the licensing agreements contained a few restrictive clauses that would allow them to enforce their rights after the crisis. Such clauses were designated by stakeholders as necessary to "clean up the mess" and should be block-exempted. They could consist of, for instance:

- On-site inspections
- Prohibitions for the licensee to file patents or to reverse engineer the products

[107] See e.g. Pors, W., Dwanglicenties zijn geen wondermiddel, Het Financieele Dagblad, 24 July 2020, page 25 and the opinion of the Belgian Council of Intellectual Property of 31 May 2021 (DOC 55 1967/1) page 8, https://economie.fgov.be/sites/default/files/Files/Intellectual-property/Avis%20Conseils%20Propri%C3%A9t%C3%A9%20intellectuelle/avis-CPI-31052021-vaccins.pdf

[108] The full article reads (translated from Spanish) : "*The relationship between the patent holder and the licensee in connection with the grant of a compulsory licence shall be based on good faith. For the patent proprietor, the application of this principle shall include the obligation to make available to the licensee the know-how in his possession which is necessary for the proper commercial exploitation of the invention. In the event of infringement of this principle, declared by a court ruling, by the patent holder, the licensee may request the Spanish Patent and Trademark Office to reduce the licence fee fixed for the licence, in proportion to the importance of the unfulfilled obligation for the exploitation of the invention. If, under the same conditions, the licensee's actions are declared to be contrary to contractual good faith, the licensor may request the aforementioned Office to terminate the compulsory licence*."

[109] Directive (EU) 2016/943 on the Protection of Trade Secrets, OJ L 157, 15 June 2016, pp. 1–18.

[110] Article 1(2)(b) of the Trade Secrets Directive and Article 3(2) of the Dutch Trade Secrets Act.

- Non-compete and non-sollicitation clauses
- Liquidated damages in case of violations of the above.

It was observed that for medicinal products, many trade secrets of the originator are contained in the "Drug Master File" that must be submitted to the health authorities to obtain a regulatory approval. [111] That file is sealed because highly confidential and proprietary to the holder of the marketing authorisation. Only in very exceptional circumstances, the relevant health authority could decide to unseal that file in case its holder is unwilling to co-operate with a CL and refuses to give access to its trade secrets. As already observed, the TSD allows the MS to regulate such access in the public interest and to allow the public authorities to perform their function, but is silent as to whether access to third parties may be organized as well under national law.

Scoping a CL on the basis of IPRs or on the basis of a product

In case of a crisis, particularly for a recently developed product, difficulties can arise to scope a CL because the IP rights that cover the product for which a CL is sought are unclear, unpublished and/or may have multiple owners.

There are two examples of Community legislation where the scope of a request for a CL is defined in terms of the product instead of the IP rights that cover the product. This is the case for:

1. Regulation 2006/816 on the export of medicines whose article 6.3 states that "*The application [for a CL] 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*";
2. Regulation 874/2009 with implementing rules for proceedings before the CPVO provides in its article 37.b that the applicant must identify in his request for CL "*the variety denomination and the plant species of the variety or varieties concerned*"

For both Regulations, there is a specific reason why the IP right that protects the product does not need to be identified. For Regulation 2006/813 there cannot exist a parallel plant breeder's right at national level so the Community Plant Breeder right can be directly determined on the basis of the variety denomination. And for Regulation 2006/813 it is the country of importation (outside the EU) where the IP right is most relevant to stop the product.

A "product scoped" CL is thus already known and has interesting features that are useful to cope with a crisis.

The scope of this study does not allow to explore in detail how a "product scoped" CL could be organized under each national IPR law or EU-law : we can only observe that there exist already two pieces of Community legislation with a "product-scoped" CL and that there are at least five reasons why it may be more efficient than an "IPR-scoped" CL in case of a crisis.

First, "a product-scoped CL" would enhance the precision and the scope of the CL once granted. Second, it is best used for "regulated" products that require a regulatory file and a regulatory approval before being put on the market so that the product can be defined on the basis of that regulatory file rather than on the basis of vaguely worded IPRs. Third, the grant of such CLs can be entrusted to the competent regulatory authories who are familiar with the technology and the products and who enjoy more trust from the stakeholders than

[111] Identified as "Module 3" in the "Notice to Applicants- Volume 2A "Procedures for marketing authorisation", July 2019"

less-specialized courts or administrations. Fourth, such procedure would by the same occasion allow to determine whether any data exclusivity rules need to be declared inapplicable (cfr. previous chapter). A fifth and very important advantage is that a CL could be issued even before any patent application protecting the product has been published, and this is particularly important in times of a crisis.

On the other hand, this method does not address the critical question of which IP rights are involved, and which IP owners have standing to claim a reasonable compensation for the CL. Such CL solution could therefore only be adopted on a temporary basis, but that would suffice to address a crisis. A public authority would in such a crisis examine and grant a CL for a product on an urgent and temporary basis, leaving it to right owners to come up for their right of compensation in a later stage. To prevent that IP owners would try to frustrate such a "product-based" CL by asserting their IP rights before a national court, a stay of national or UPC-proceedings would be needed for the duration of the crisis.

1.2.3. Cross-border effect of CL

The COVID-19 pandemic is an unprecedented public health crisis in contemporary history. The pandemic had a global impact. Different countries were affected differently and adopted different measures for remedying the situation. With regard to the grant of CLs in this worldwide crisis, only two WTO Members (out of 164), including one EU Member Sate, granted CLs for COVID-19-related patents (Hungary and Russia) under Art. 31 TRIPS.[112]31 TRIPS.[113] COVID-19 is not the first nor the last cross-border crisis facing the EU.[114]

CL decisions issued by DG COMP on competition law grounds which are made on the basis of Art. 102 TFEU, and CLs granted by the CPVO regarding CL of Community plant variety rights on grounds of public interest are not limited to a particular MS and have an EU-wide scope.[115] CL decisions of a national competent authority are necessarily limited to the territory of the authorities' MS because the IPRs are purely national. This was confirmed for instance by the CJEU in its case 19/84 of 9 July 1985, Pharmon vs. Hoechst, para. 21, where it reminded that: "in accordance with the principle of the **territoriality** of the acts of the public authorities of a Member State, a compulsory licence cannot confer on its holder rights in the territories of the other Member States."

Scenarios from Workshop 2:

a) A crisis causes an urgent need for a patented product in MS A that can be met by an unlicensed company who has production capacity in MS B. Where should the request for CL be filed?

b) A CL is needed in MS A for the production of an active ingredient needed for a medicinal product in that MS A. Company Z has production capacity for the active ingredient in MS A but its formulation and packaging facilities are located in the neighbouring MS B. Where should the request for CL be filed? What about exhaustion?

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[112] 'COVID-19: Measures Regarding Trade-Related Intellectual Property Rights', WTO, 20 April 2022, https://www.wto.org/english/tratop_e/COVID-19_e/trade_related_ip_measure_e.htm.
[113] Ibid.
[114] Jonathan Smith, 'Q&A: Future Pandemics Are Inevitable, but We Can Reduce the Risk | Research and Innovation', European Commission, 16 December 2021, https://ec.europa.eu/research-and-innovation/en/horizon-magazine/qa-future-pandemics-are-inevitable-we-can-reduce-risk.
[115] Art. 29(5a)(II) of the Plant Variety Regulation states in relation to CLs granted in the situations of dependant patents under Art. 12(2) of the Biotechnology Directive: "The territorial scope of the licence or cross-licence referred to in this paragraph shall be limited to the part or parts of the Community covered by the patent.". The provisions on CL on public interest grounds do not contain such territorial limitation. See also to that end the requirements to applications for CL sent by Art. 37 of the Commission Regulation (EC) No 874/2009 of 17 September 2009 establishing implementing rules for the application of Council Regulation (EC) No 2100/94 as regards proceedings before the Community Plant Variety Office (recast).

During the Workshop, the stakeholders were engaged with a first scenario:

"A crisis causes an urgent need for a patented product in MS A that can be met by an unlicensed company who has production capacity in MS B. Where should the request for CL be filed?"

This scenario illustrates how the current CL rules are ineffective in an EU-context, because:

a) National CL provisions allow the MS to grant a CL *predominantly* for domestic use. MS B could in this scenario not grant a CL exclusively for export to MS A. This is linked to the territorial nature of a patent, and is reflected in the conditions set forth by Article 31 TRIPS. It could only be possible to direct a non-predominant part of the products supplied to MS B's domestic market. Such situation could be helpful to some degree where MS B is one of the largest Member States and MS A is one of the smallest. However, if there is no similar crisis in MS B, there would be no reason for granting a CL predominantly for its territory.

b) Even if a CL was granted in MS B for such manufacture and putting on the market in MS B, the import of that product in MS A could be stopped by the rightholders who could still exercise their rights in MS A because that MS A is not covered by the CL and because there is no exhaustion despite the product has been put on the market in MS B).

c) These problems become exponentially more complex and more difficult to solve when the product for which there is an urgent need in MS A requires the sourcing of components whose processing and assembly is done in still another (over even more) MS. As we observed already, this is more often the case than not for complex products. [116]

These problems may not even disappear if the "crisis" affects both MS A and B, or all MS where the product's components need to be sourced from, because in such case CLs would be needed in each MS that explicitly provide for export / import in the other MS. It is questionable whether MS can organize this via their national CL law as long as the doctrine of Pharmon vs. Hoechst continues to apply.

Even in case of such a "cross-border crisis", MS B would need to grant a CL for supplying its domestic market and provide for export of a non-predominant part to another MS, and MS A would need to grant a CL permitting import of the products concerned from MS B. Unsurprisingly, our research did not detect cases where such a complex scenario was attempted, let alone succeeded. If the domestic market of MS B is relatively small in comparison to the needs of MS A, the cross-border supply would be of very limited help.

Case: CLs for exportation from one MS to another MS

On 21 June 2005, the Italian Competition and Market Authority approved the application of a precautionary measure against the company Merck & Co. Inc. of the Merck pharmaceutical group. Merck was the owner in Italy of an SPC which gave it the exclusive right to market a drug (Tienam) based on the active ingredient imipenem cilastatin. It is an antibiotic, intended for the treatment of particularly serious infections, mainly contracted in hospitals. The proceeding against the Merck group was initiated on 23 February 2005, following the refusal by that company to grant a licence for the production in Italy of imipenem cilastatin intended to be exported for the production of generic drugs in Member States not covered by patents.

[116] We learned during our interviews that the production of many products (not only medicinal but also in the sector of electronics, chemicals and automotive) is nowadays spread over several MS ("multi-state production").

No industrial property rights on this product were claimed by Merck in other EU Member States.

In the present case, it was found necessary to obtain a CL in Italy for exportation to other EU Member States. This objective was achieved by relying on national competition law grounds, because article 31(f) TRIPS requires that CLs are "authorized predominantly for the supply of the domestic market of the [WTO] Member". That same article makes it is only possible to grant CLs by the WTO Members for predominant non-domestic use "to remedy a practice determined after judicial or administrative process to be anti-competitive" (Art. 31(k) TRIPS). This case demonstrates the limitation of a national CL granted on crisis-related grounds in one Member State to be used for remedying crisis in other Member State. The CL was only effective because the product was not covered by IPRs in the MS of destination, so it was possible to ship the product there. But if there had been IPRs in the MS of destination, this CL would not have been effective.

Other obstacles for effectively addressing a cross-border crisis

Under the current CL regime, based on national law and domestic considerations, a MS cannot take into account the impact of a CL granted in its jurisdicion on the situation in other MS. Nor can it make EU-wide arrangements when issuing a CL that would aim at tackling a cross-border crisis.

It is clear that one of the most important obstacles preventing an EU-wide approach for addressing a crisis via a CL is the lack of exhaustion of national patent rights on a product made under a CL. This is caused by the 1985 ruling of the CJEU in the case Pharmon vs. Hoechst [117] according to which products manufactured under a CL do not enjoy EU-wide exhaustion because the patent owner has presumably not given his consent for the first putting on the market of his product.

Therefore, if a product that is important for solving an EU-wide crises can be manufactured in MS A under a CL, that CL would not allow the supply in other MS. Multiple CL's would need to be requested for in all the MS, each with their own conditions and risks for contradiction.

Theoretically, the grant of a CL in one MS for domestic or predominantly domestic purposes should not prevent the ability of the right holder / manufacturer to supply that product to other MS under conditions that he can freely negotiate and determine. But stakeholders pointed out that they have organized themselves to increase production and supply in certain MS for supply to another MS in case of a crisis, and that these voluntary initiatives could be frustrated by (threats for) national CL's because the available manufacturing capacity would in such case be re-oriented on predominant domestic use. A poorly structured CL mechanism could, according to them, limit cross-border supply within the EU. It was submitted that voluntary arrangements would constitute the better alternative to ensure EU-wide supply. No specific cases or examples were however provided to substantiate this position.

Examples of EU-wide approaches during the COVID-19 crisis

The COVID-19 crisis stimulated EU unity in developing joint and coordinated crisis responses. EU-scale voluntary arrangements, such as Joint Procurement Agreements

[117] Pharmon vs. Hoechst, 9 July 1985 (case 19/84) https://eur-lex.europa.eu/legal-content/GA/ALL/?uri=CELEX:61984CJ0019

(JPAs)[118] and Advanced Purchase Agreements (APAs) [119], were aimed at accelerating development of COVID-19-related medical products and ensuring their EU-wide availability. Drawing lessons from the pandemic management, a number of the EU initiatives area aimed at tackling future crisis. The Health Emergency Preparedness and Response Authority (HERA) was launched as a new European Commission Directorate-General on 16 September 2021 with the mission to prevent, detect, and rapidly respond to health emergencies.[120] When a health emergency hits, HERA would ensure the development, production and distribution of medicines, vaccines and other medical countermeasures. The ongoing work on the Single Market Emergency Instrument (SMEI) development aims to put in place a flexible and transparent mechanism to respond quickly to emergencies and crises that threaten the functioning of the single market. The initiative will ensure the coordination, solidarity and coherence of the EU crisis response and protect the single market's functioning, ensuring: continued free movement of goods, services & people, smooth-running supply chains and availability and access to goods & services.[121]

[118] 'Signing Ceremonies for Joint Procurement Agreement', European Commission, accessed 3 July 2022, https://health.ec.europa.eu/health-security-and-infectious-diseases/preparedness-and-response/signing-ceremonies-joint-procurement-agreement_en.
[119] Pascale Boulet, 'ADVANCED PURCHASE AGREEMENTS FOR COVID-19 VACCINES', n.d., 58.
[120] 'Health Emergency Preparedness and Response Authority', Text, European Commission, accessed 3 July 2022, https://ec.europa.eu/info/departments/health-emergency-preparedness-and-response-authority_en.
[121] 'Single Market – New EU Instrument to Guarantee Functioning of Single Market during Emergencies', European Commission, accessed 3 July 2022, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13181-Single-market-new-EU-instrument-to-guarantee-functioning-of-single-market-during-emergencies_en.

Case: Hungary: Potential Conflicts between JPAs and National CL Systems

In 2020, Hungary and other Member States had access to Veklury (remdesivir)[122] via the EC's Joint Procurement Agreement (JPA) with the patent holder. The signature of this joint procurement framework contract followed the EC's contract with Gilead to secure 33,380 treatment courses of Veklury that had been distributed across the EU and the UK since August 2020. This contract had been financed from the EC's Emergency Support Instrument (ESI), worth a total of EUR 70 million.[123]

The Hungarian government granted nevertheless a CL for remdesivir, allegedly without contacting the patentee to inform of the intention to grant the CL or to inform the EU that the supply does not meet the national needs. The HIPO granted three CLs for local manufacture of Gilead's drug remdesivir,[124] a COVID-19 treatment conditionally approved by the EMA, citing newly promulgated emergency Law Decrees 283/2020 and 478/2020.[125] The HIPO fixed the term of the license in 6 months and set a 0,8% license fee based on the net revenue of the product, for each of the patents, i.e. 2,4% in total. This was based on 4% license fee found by the Office as general in the field and 60% overlap ration (i.e. the revenue is attributed to the use of the patents in a ration of 60%). The Office relied on the declaration of the National Institute of Pharmacy regarding the capacity and capability of Richter Gedeon to fulfil domestic needs for the product. It was reported that the "Hungarian drugmaker Richter has manufactured enough doses of COVID-19 drug Remdesivir to treat 3,000 patients, [according to] spokeswoman Zsuzsa Beke".[126] This result could indicate the potential of conflicting agreements, as the CL in this case was granted by the Hungarian government despite the presence of the JPA negotiated at the EU level with the patent holder.

1.2.3.1. Exhaustion and CLs

Since IPRs are mostly national rights, the CJEU developed its theory of EU-wide exhaustion in its Deutsche Grammophon vs. Metro SB and Centrafarm vs. Sterling Drug cases to allow the free flow of products between member states.

In order for exhaustion to apply, it is required that the owner of the IPR has given his consent for the first putting on the market of the product protected by his IPR. Such exhaustion only applies to products and to products that are directly obtained via a patented process, and not to patented processes.

As already mentioned, the CJEU ruled in 1985 that products manufactured under a CL do not enjoy such EU-wide exhaustion because the patent owner has presumably not given his consent for the first putting on the market.[127]

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[122] EMA, 'Veklury - Remdesivir', Text, European Medicines Agency, 23 June 2020, https://www.ema.europa.eu/en/medicines/human/EPAR/veklury.

[123] 'Coronavirus: Commission Signs a Joint Procurement Contract with Gilead for the Supply of Remdesivir', Text, European Commission, 8 October 2020, https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1845.

[124] 'WTO | Intellectual Property Measures - COVID-19'. 'WTO | Intellectual Property Measures - COVID-19'.

[125] In support of the case description, to cite the submissions of BIO, PhRMA and the US Chamber of Commerce with information about the case. See the references here : https://www.keionline.org/35558 https://www.keionline.org/35558

[126] Gergely Szakacs, 'Hungary's Richter Has Manufactured Remdesivir for 3,000 COVID-19 Patients', *Reuters*, 7 October 2020, sec. Healthcare & Pharma, https://www.reuters.com/article/us-health-coronavirus-remdesivir-richter-idUSKBN26S283. Gergely Szakacs, 'Hungary's Richter Has Manufactured Remdesivir for 3,000 COVID-19 Patients', *Reuters*, 7 October 2020, sec. Healthcare & Pharma, https://www.reuters.com/article/us-health-coronavirus-remdesivir-richter-idUSKBN26S283.

[127] Pharmon vs. Hoechst, 9 July 1985 (case 19/84) https://eur-lex.europa.eu/legal-content/GA/ALL/?uri=CELEX:61984CJ0019

Less than ten years later, the EU adopted TRIPS via Council Decision 94/800/EC and integrated the TRIPS agreement into Community law. The TRIPS concepts of "predominant market" and "domestic market" hereby became Union terms.

Under EU law, it could be argued that the European Union is a domestic market in its own right for national CL purposes and no longer the individual Member States. [128] This would allow to consider that either the CJEU-ruling in Pharmon vs. Hoechst has been extended to the entire EU, or that this ruling is no longer applicable.

We inquired during our interviews if the exhaustion rule could apply to products that were made under the threat of fines by the EU Commission on the basis of violation of competition law. Our contacts learned that clauses between a patent owner and a "competition law CL" licensee and that aim to prevent export or parallel import of products made under such a CL might be considered as permissible under EU competition law if they are temporary and would allow to better address a local crisis. [129]

Many national CL laws (*cf. Table 1*) force the patent owner to give his consent by ordering him to agree on a license and on the financial terms thereof.

It is currently not possible under EU-law to remove the problem that CLs are based on national rights, unless the EU would take the radical decision to abolish national CLs and replace them with a singe Community-wide CL. However, it is possible to remove at least the problem of exhaustion by considering that EU-wide exhaustion should apply to products manufactured under a national CL because the EU is since its adoption of TRIPS in 1994 a domestic market. If EU-wide exhaustion is taken as a starting point, exceptions to such exhaustion can still be made on a case-by-case basis via contractual arrangements once a CL is granted. For instance, prohibitions against parallel import or re-exportation could be contractually agreed upon, subject to continued scrutiny by the competion authoririties. This is to be preferred over the reverse situation that does not incentivise IPR owners to enter into voluntary contractual arrangements because the lack of exhaustion gives them a stronger legal position.

The facts and answers received in reaction to the hypothetical scenarios developed for this study show that the lack of exhaustion is an important barrier for CLs to work effectively in an EU-wide context. Putting a CL and a voluntary arrangrement on the same footing as far as exhaustion is concerned will encourage patent owners to conclude more voluntary arrangements, because a CL will not offer them a better position.

[128] The Dutch Patent Act already provides that the entire European Union and European Economic Area are the relevant territories for considering the grant of compulsory licenses for non-use/lack of exploitation of an IP right. See the answers on our Question no. 7 for the Netherlands, page 6.
[129] Anonymised source.

2. Problem definition: CL for export/import from/to the EU

2.1. CL for export outside the EU

TRIPS, the Doha Declaration and Regulation (EC) No 816/2006

The EU is a founder and Member of the WTO since its creation on 1 January 1995. Following Council Decision 94/800/EC on the conclusion on behalf of the EU of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994), the TRIPS agreement's provisions were integrated into Community law.

In light of interpretation questions regarding Art. 31's paragraphs (f) and (h), the WTO Ministerial Conference of 2001 adopted the Doha Declaration on the TRIPS Agreement and Public Health on November 14, 2001[130].

The Declaration provides the mandate to negociate on a wide range of topics in WTO councils and committees, such as agriculture, regional trade agreements and intellectual property. The Declaration also sought to negociate issues concerning the implementation of some WTO Agreements such as GATT and TRIPS, the latter being of interest for this report.

Regarding TRIPS, the Doha Declaration aimed to bridge any gaps between public health policy issues and intellectual property[131], and its sixth paragraph highlighted the issue of effectiveness of CLs for WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector. Following the eventual adoption of a Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health on August 30, 2003, The WTO General Council adopted a Decision on the "Amendment of the TRIPS Agreement" on December 6, 2005[132].

The 2005 protocol entered into force after two-thirds of the WTO members accepted it in January 2017 and subsequently became known as Article 31bis. Article 31bis of the TRIPS Agreement provides that a WTO Member may grant a CL to the extent necessary for the production of one or several pharmaceutical products and its export to an eligible importing Member[133] the Annex to that article clarifying its intended use for cases of public health emergencies[134].

However, many WTO Members had accepted the provision by the first deadline for acceptance (which was 1 December 2007), which included the EU. As such, the European Parliament and The Council of the EU had issued Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

[130] World Trade Organization, Declaration on the TRIPS Agreement and Public Health of 14 November, 2001, WTO Doc. WT/MIN(01)/EC/2, 41 ILM 755 (2002) [hereinafter TRIPS Declaration]
[131] See Ellen 't Hoen, TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha, 3 CHI. J. INT'L L. 27, 28 (2002)
[132] General Council, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, WTO Doc. WT/L/540 and Corr. 1 (Sept. 1, 2003); TRIPS Agreement—Article 31bis (Practice), WTO ANALYTICAL INDEX, https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf
[133] Art. 31bis of the TRIP Agreement, Section 1.
[134] Annex to the TRIPS Agreement, Art. 31bis, Section 1, sub-section a.

"TRIPS-plus" measures in Regulation (EC) No 816/2006

It should be noted that the TRIPS agreement only provides for a minimum standard of IP protection[135] . Any measures taken by WTO members that go beyond the standards imposed by the TRIPS provisions are known as "TRIPS-plus" measures[136]. Regarding Art. 31bis, the "TRIPS-plus" measures relating to it are any measures that would create an additional burden on the importing country that has been granted a CL for export to respond to a public health issue. In that sense, the most commonly referred to "TRIPS-plus" measure is data exclusivity and protected information (that are provided for in TRIPS Art. 39 (3)), which could imply the abstention of the manufacturer in the exporting country from sharing the clinical trials' data with the importing country[137]. As such, this abstention would hinder the approval of the drug before its marketing in the importing country if that approval were not previously done. This hindering factor would be exacerbated in case of a national crisis, even more so in a country that lacks the resources to respond to regulatory requests in a short period of time[138].

As for the European Union's transposition of Art. 31bis TRIPS, Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems entered into force on 29 June 2006[139]. The Regulation's aim was to address public health problems and improve access to medicines, while avoiding distortion of competition in the EU market and preventing re-importation of products into the single market[140].

Articles 1 to 3 of the Regulation (EC) No 816/2006 provide its scope, definitions of terminology and mechanism of designating a competent authority. Articles 19 and 20 provide for the review and entry into force of the Regulations. These five articles do not contain any noteworthy modifications, substitutions or additions in comparison with TRIPS.

As for Articles 4 to 12 and 16 to 17 of the Regulation No 816/2006, these provisions provide for the conditions related to the identification of the importing country, the procedure of application for a CL and the conditions of grant, with all necessary notifications to be made. *Mutatis mutandis* – and with respect to the specificities of the EU's competence and that of its Member States regarding IPR – these provisions incorporate those provided for in Articles 31 and 31bis of TRIPS and all related annexes and appendices. Thus, no "TRIPS-plus" measures were identified in these articles.

Article 13 provides for the prohibition of importation, in accordance with the waiver of importation signed by the EU at the WTO's Doha Ministerial Conference[141]. Regarding Articles 14 and 15, they provide for the actions by customs authorities to ensure the effectiveness of Article 13's importation ban and are out of the scope of this study.

Lastly, article 18 envisages the safety and efficacy of medicinal products. The article provides that the applicant for a CL on a medicinal product may take advantage of different procedures under EU law and national law alike.

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[135] J.H. Reichman, "Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement", The International Lawyer, Vol. 29, No. 2 (Summer 1995), pp. 345-388; Overview: The TRIPS Agreement, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm , art 1.1

[136] P. Roffe, "TRIPS and its Aftermath: an Overview of Normative Developments" in C. Geiger, "The Intellectual Property System in a Time of Change : European and International Perspectives", 2016, LexisNexis -CEIPI Collection, p.266

[137] See "Data exclusivity and other "TRIPS-plus" measures", WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR SOUTH-EAST ASIA (2017), https://apps.who.int/iris/handle/10665/272979 ; C. Correa, "The Preamble, General Provisions and Basic Principles" in C. Geiger, "Trade-related International IP Law: The TRIPS Agreement, assessment and perspectives", 2017, Lexis-Nexis – CEIPI Collection, p.43

[138] Ibid *supra* WHO Regional Office for South-East Asia

[139] Official Journal of the EU, Volume 49, 9 June 2006, ISSN 1725-2555

[140] Regulation (EC° No 816/2006, preamble, paragraphs (4) and (5)

[141] See below: Problem definition - CL for import to the EU

Potential regulatory bottlenecks

Article 18 of Regulation (EC) No 816/2006 refers to the scientific opinion procedure provided for under Article 58 of Regulation (EC) No 726/2004 for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

Article 58 of Regulation (EC) No 726/2004 provides that the European Medicines Agency, in collaboration with the WHO, can give a scientific opinion to evaluate the quality, safety and efficacy data of medicinal products intended exclusively for markets outside the EU. The Committee for Medicinal Products for Human Use (refered to as CHMP), which draws up the aforementioned opinion, also verifies the third country importer's ability to manufacture the medicinal product concerned and/or carry out the necessary control tests[142]. The procedure shall be finalised within 210 days after receipt of a valid application[143]. Art 18 of Regulation (EC) No 816/2006 also provides for similar procedures by national authorities as well as export certificates. However, if these procedures concern a generic of a medicinal product that has already obtained an AMA, test data exclusivity is waived[144].

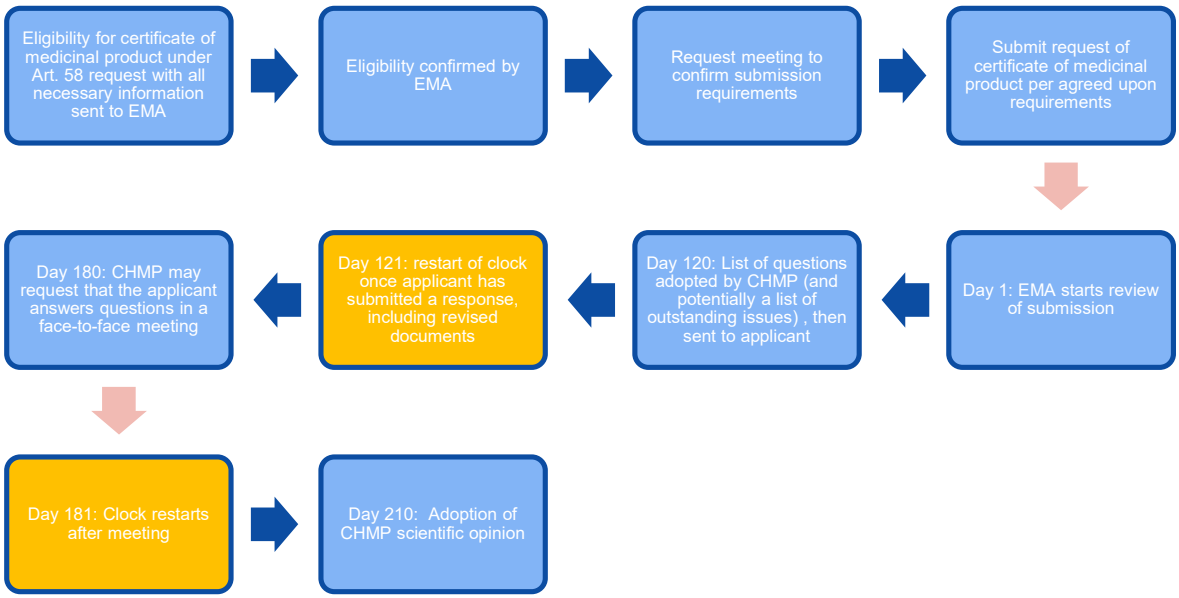
Data exclusivity essentially prevents regulatory authorities from relying on data submitted by originator companies in order to register a generic product, consequently compelling generic producers to repeating clinical and pre-clinical trials, while also raising ethical questions regarding the withholding of effective medicine from the control group, rendering the repetition of clinical trials *de facto* impossible[145].

From the perspective of public health and enhancing access to medicines within the compulsory licensing mechanism, data exclusivity could prevent the registration—and hence the actual sale and use—of generics produced under a compulsory license[146]

Although it may be considered that Art 18 provides for TRIPS-plus measures at first glance, it is worth noting that the timeframe of 210 days is for the centralized procedure and is only compulsory for certain types of medicine[147] and can be accelerated to be limited to 150 days upon request of the applicant[148], and that the EMA can issue certificates of medicinal products to support the work of health authorities in countries outside the EU within 10 working days (standard procedure), reduced to two working days for the urgent procedure.

[142] Art.8 (1) Regulation (EC) No 726/2004
[143] Art. 8 (3) and Art. 6(3) Regulation (EC) No 726/2004
[144] Art. 18 (2) Regulation (EC) No 816/2006
[145] K. Timmermans, "Monopolizing Clinical Trial Data: Implications and Trends", PLoS Med. 2007 Feb;4(2):e2. doi: 10.1371/journal.pmed.0040002. PMID: 17298163; PMCID: PMC1796904.
[146] C.Correa, "Protecting test data for pharmaceutical and agrochemical products under free trade agreements", in Roffe P, Tansey G, Vivas-Eugui D, "Negotiating health – Intellectual Property and Access to Medicine" , EarthScan/International Centre for Trade and Sustainable Development, 2006: https://books.google.fr/books?id=1cwycSEoHsUC&printsec=frontcover&hl=fr&source=gbs_ge_summary_r&cad=0#v=onepage&q&f=false
[147] EMA Website, "About Us", Authorisation of medicine: https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines
[148] Article 14(9) of Regulation (EC) No 726/2004

Figure 1: Process for request and grant of a certificate of medicinal product under Article 58 of Regulation (EC) No 726/2004



Color code : Yellow boxes indicate the restart of the clock after the time limit of 210 days had been stopped. Blue boxes indicate the normal course of the CHMP opinion process.

Furthermore, Art. 18 (2) clearly provides for waivers of data exclusivity, as do certain EU trade agreements which allow MS to provide exceptions for reasons of public interest and for situations of national emergency or extreme urgency[149]. The provisions of Art.18 therefore can facilitate export as all EMA certificates also confirm the good manufacturing practice (GMP) compliance status of the manufacturing site, which is essential in most importing countries. Given the flexibilities provided for under Art. 18 and their relative expedience, the Article's provisions cannot be considered as a "TRIPS-plus" measures as its mechanisms do not create an additional burden on the importing country as defined above. Nevertheless, the involvement of a regulatory authority (EMA) can be considered as a bottleneck due to the different competences of the regulatory authority and the authority granting the CL.

[149] See for instance: Article 231(4) of the EU-Peru Agreement

However, it should be noted that there is no case applying the mechanism provided for under Regulation No 816/2006, despite the ability of several EU Member States to do so. Since the decision of 30 August 2003 on the implementation of paragraph 6 of the Doha declaration on the TRIPS Agreement and public health, only one fully executed case of CL for export exists to date. Our consultation with stakeholders did not reveal any specific comments or explanations for this situation. It can only be observed that the mechanism organized in the Regulation is based on the assumption that the current national CL procedures are effective, which has been shown not to be the case. The Regulation therefore tries to organize a hypotetical situation that is unlikely to take place. Due to the lack of empirical data, sub-section 2.1.1 will focus on a comparative legal analysis of CL for export under Art. 31bis TRIPS, while sub-section 2.1.2 will tackle the issue of export of non-predominant part of products manufactured under a CL for the domestic market.

2.1.1. CL for export under Art. 31bis TRIPS

The EU is the top exporter of pharmaceuticals worldwide, with eight EU MS counted in the top 10 exportering countries of pharmaceutical products[150], and with all EU MS having pharmaceutical production capacities and being exporters of pharmaceutical products[151]. Nevertheless, there have been no successful cases of granting a CL for export under 31bis among EU MS.

As explicitly mentioned in Section 5 of Art. 31bis, the text should be interpreted under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health[152].

Therefore, the EU has the competence to use the system provided for in Art. 31bis to export pharmaceutical products in situations of emergency as provided for in paragraph 1. B) of the Annex to Art. 31bis: "*a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use*". These emergency cases may include global crises that pose a risk for the EU as a whole, for example, where global crises could not be extinguished without it being tackled in third countries.

During the unprecedented COVID-19 global pandemic, international trade was negatively affected, except for the trade of goods related to preventive/restrictive measures used in direct response to COVID-19 (such as personal protective equipement, diagnostic testing equipement, and oxygen therapy equipement). More importantly, the need to vaccinate populations grew exponentially, and European pharmaceutical companies were pioneers in the development of safe and effective vaccines in reponse to the COVID-19 pandemic, with over 40 subcontractors of these companies having production plants across EU Member States[153].

However, only one WTO Member State made notifications to benefit from CL under Article 31bis TRIPS in specific response to COVID-19, Bolivia[154] (see Annex I).

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[150] GlobalEDGE global insights, filtered by industry, section on Trade Statistics: https://globaledge.msu.edu/industries/pharmaceuticals/tradestats

[151] Ibid.

[152] WTO, DOHA WTO MINISTERIAL 2001, 20 November 2001, "Declaration on the TRIPS agreement and public health", WT/MIN(01)/DEC/2: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[153] S. Valentino, "COVID-19 vaccines: here's who is producing them in Europe, and where", March 2021, The European Data Journalism Network: https://www.europeandatajournalism.eu/eng/News/Data-news/COVID-19-vaccines-here-s-who-is-producing-them-in-Europe-and-where

[154] See WTO, "Bolivia outlines vaccine import needs in use of WTO flexibilities to tackle pandemic" https://www.wto.org/english/news_e/news21_e/dgno_10may21_e.htm.

Comparative Perspectives of Legislation for CLs for Export from Selected Countries

As aforementioned, due to a lack of empirical data regarding successful applications of CL procedures for export, this sub-section develops a legal comparison between the implementation of Paragraph 6 of the Doha Declaration on TRIPS into EU legislation (EU Regulation (EC) No 816/2006) and its related implementations in selected third countries. The three selected countries were Canada, the UK, Switzerland and India. These countries were selected based on several factors, including their relative socio-economic characteristics and similarities to some extent with EU Member States (e.g., with respect to manufacturing capacity of generics). All selected countries have had experiences with compulsory licensing (including attempts thereof), and have sufficient manufacturing capacity to be considered as possible exporters under the mechanism of Art. 31bis TRIPS.

Canada

Canada announced its intention to implement the 30 August 2003 WTO General Council temporary decision in September of the same year, allowing for the exportation of a drug under a CL and waiving the requirement of a predominantly domestic production.

The bill transposing this decision into Canadian national law in 2004 became known as "Canada's Access to Medicine Regime (CAMR)".[155] The objective of CAMR is to enable manufacturers of pharmaceuticals in Canada to apply for a CL from the Commissioner of Patents to "provide[] a way for the world's developing and least-developed countries to import high-quality drugs and medical devices at a lower cost to treat the diseases that bring suffering to their citizens."[156]

Case: Canada – Rwanda CL under Art. 31 bis TRIPS

The only fully executed case of compulsory licensing for export under Article 31 bis of the TRIPS agreement is the case of importation of HIV drug TriAvir from Canada to Rwanda.

The purpose of CAMR is to use compulsory licensing to give access to less developed eligible importing countries to a low-cost version of high-quality patented Canadian medicines and medical devices.

For a country to be considered eligible for importing a drug pursuant to CAMR, it must have little to no manufacturing capacity, notwithstanding the potential importing country's membership of the WTO, which conditions the exoneration for least-developed members of the WTO from the general notification provided for under paragraph 6 of the Doha Declaration (*the eligible countries have been identified in Schedules 2 to 4 of the Canadian Patent Act*). The threshold of requirements for importation for an eligible country of a Canadian drug under CAMR has been kept to a minimum: identify a drug or medical device listed on Schedule 1 of Canada's Patent Act, notify the WTO or the government of Canada of a need for a product and find a suitable Canadian pharmaceutical company from which to import the needed product.

Schedule 1 of Canada's Patent Act consists of a list of pre-approved patented pharmaceutical products that are eligible for export under the Canadian Access to Medicines Regime[157]. This list can be extended to any "patented product that may be used to address

[155] *Patent Act (Canada),* R.S.C. 1985, P-4.
[156] Government of Canada, "Canada's Access to Medicines Regime": https://www.canada.ca/en/health-canada/services/canada-access-medicines-regime.html
[157] Canada's Patent Act - Schedule 1 - Definition "pharmaceutical product" in section 21.02 and paragraph 21.03(1)(a): https://www.laws-lois.justice.gc.ca/eng/acts/P-4/page-17.html#h-413972

public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics"[158] . Upon successful amendment of Schedule 1, the applicant may submit their drug submissions for Health Canada review, for both the Domestic Submission and the Division 7 Submission (related to labelling and marking of the product).

The timelines for the procedure extend from 180 days (for an Abbreviated New Drug Submission) to 345 days for a New Drug Submission, with a priority submission's timeline being reduced to a total of 205 days159. As for the Division 7 Submission, the timeline is a combined 75 days for both screening and review.

The CAMR also gives Non-Governmental Organisations the opportunity to play a role in the Regime. When an NGO has the permission of the government of an eligible importing country, it may enter into a sales agreement with a Canadian manufacturer for the purchase of pharmaceutical products on the country's behalf.

In such a case, the importing country is still required to make the appropriate notification to the World Trade Organization (WTO) or the Government of Canada of its intention to import a drug or medical device under the Regime.

Humanitarian group "Médecins Sans Frontières" (Doctors without Borders) had identified five urgently needed drugs for its field projects, one of them being a treatment for HIV/ AIDS, and identified Rwanda as a potential importing country in need of access to HIV medicine[160].

A Canadian privately held generic manufacturer called Apotex agreed to produce a fixed-dose combination of the three prevalent antiretrovirals that were a part of the WHO's guidelines for first-line treatment of HIV, a first of its kind treatment that would have significant impact on ease of access to treatment for patients.

However, fixed-dose combination drugs were not provided for under Schedule 1 of Canada's Patent Act, so a request for addition had to be made during the process of obtaining a CL for export to Rwanda.

The chronology of the process of exporting Apo-TriAvir went as follows[161]:

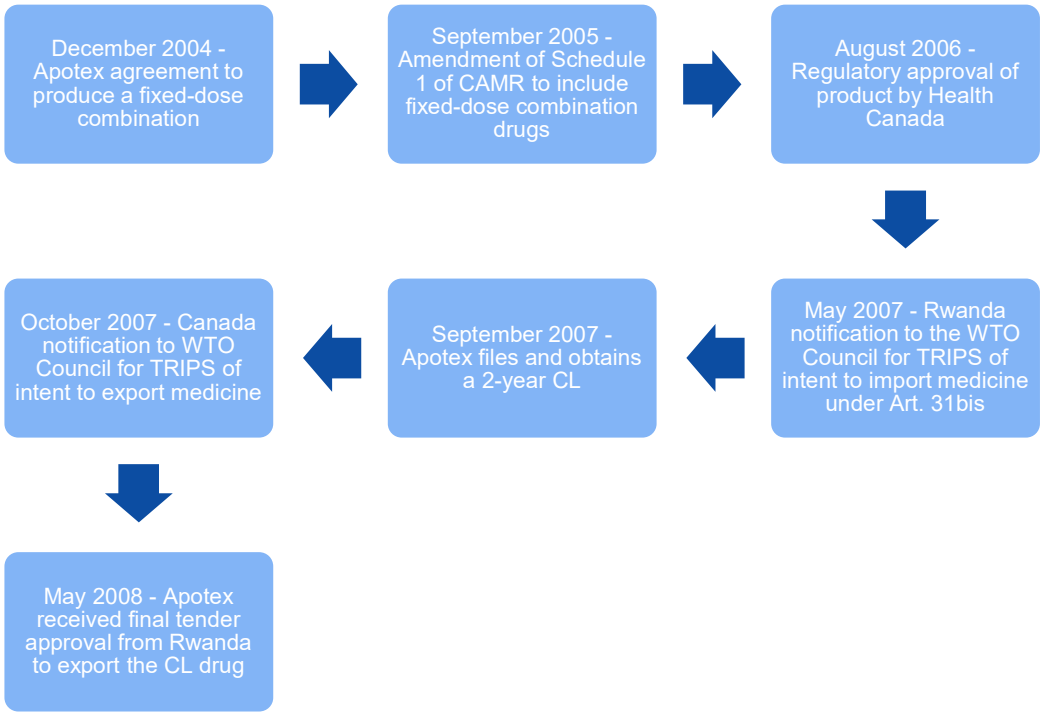
[158] Canada's Patent Act - Section 21.03 – Amending schedules: https://www.laws-lois.justice.gc.ca/eng/acts/P-4/page-3.html#h-412365

159 Canada's Access to Medicines Regime: Application Process for drugs for Export to Developing and Least Developed Countries, *Health Canada (6 December 2006),* available at: https://www.canada.ca/en/health-canada/services/canada-access-medicines-regime/documentation/health-canada-guidance-documents/application-process-drugs-export-developing-least-developed-countries.html#a231

[160] Médecins Sans Frontières, "Neither expedious, nor a solution: The WTO August 30th decision is unworkable", Issue Brief, 29 August 2006 : https://msfaccess.org/neither-expeditious-nor-solution-wto-august-30th-decision-unworkable

[161] Rwanda's notification to the WTO Council for TRIPS, 19 July 2007, https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=67527&CurrentCatalogueIdIndex=0&FullTextSearch=

- Canada's notification to the WTO Council of grant of a CL for export under the 30 August 2003 decision, 4 October 2007: https://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm



Lace process image demonstrating the steps of the Canada-Rwanda case based on publicly available information

The first shipment of the Apotex drug was sent to Rwanda in September 2008[162].

However, according to the statement of an interviewed stakeholder that was implicated in the process, by the time the first shipment of Apo-TriAvir arrived to Rwanda, a generic product made by a Chinese manufacturer was already on the market.

Although the export of Apo-TriAvir is the first and only fully executed case of CL under Art. 31 bis, all parties involved in the procedure criticized the CAMR and deemed it "unworkable"[163]. In their review of the CAMR submitted to the Government of Canada, Médecins Sans Frontières criticized the process provided for in the CAMR as being onerous and unnecessarily hindered by Health Canada's approval for eligibility under the regime[164]. A key criticized element is the timeframe in the Rwandan case expanding over four and a half years before the first shipment was ever made. Upon completion of the application, the manufacturing company in Canada declared that they would not go through the CAMR process again unless it were simplified165

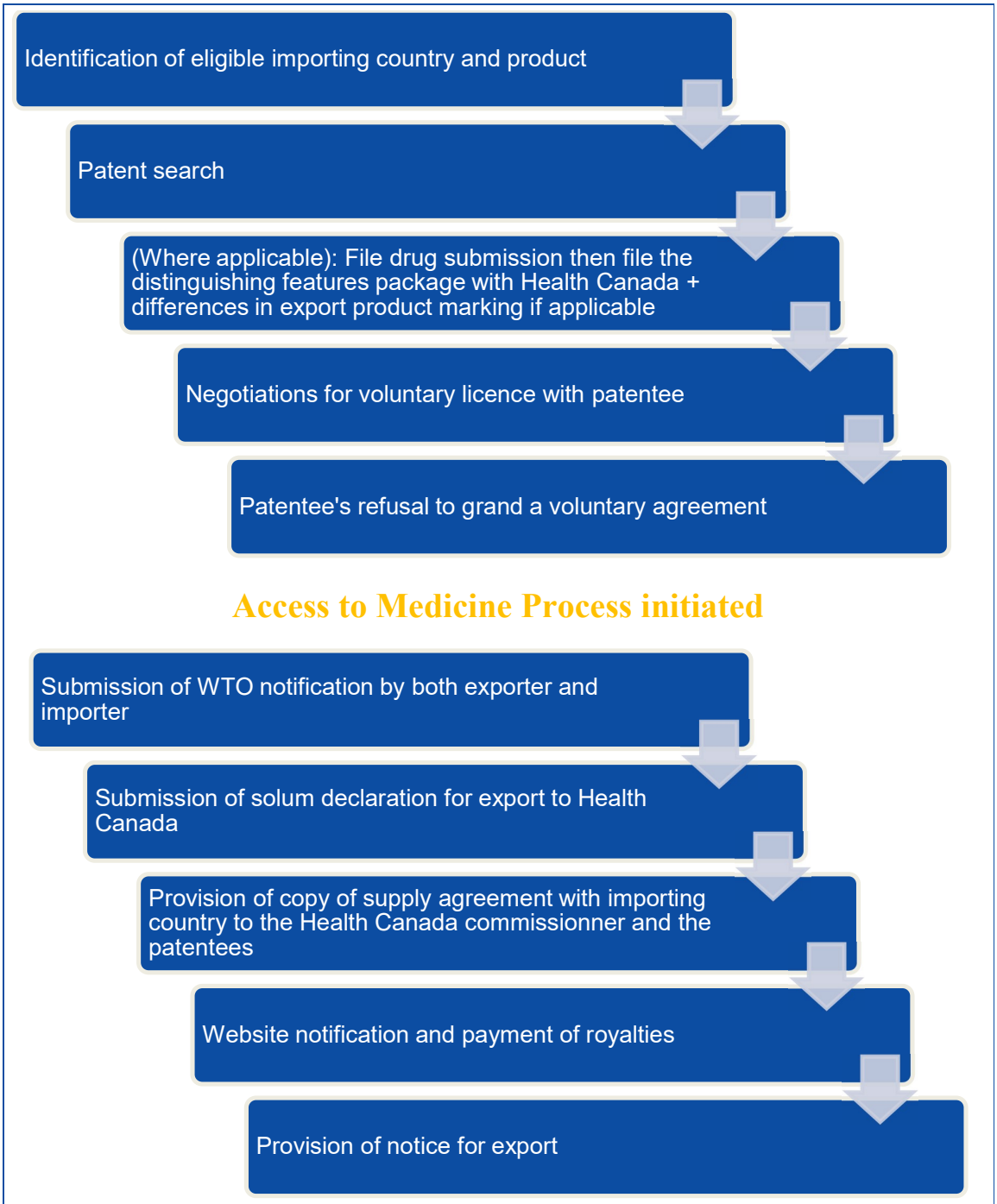
The delay could be explained by the implication of Health Canada and the Canadian Intellectual Property Office as evidenced by the process map below:

[162] K. Lybecker and E. Fowler, "Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules", Journal of Law, Medicine & Ethics, Vol. 37, Issue 2, Summer 2009, pp. 222-239

[163] Apotex Corp. Press Release after receiving final tender approval from Rwanda for Vital HIV drugs, 7 May 2008, https://www.biospace.com/article/releases/apotex-corp-receives-final-tender-approval-from-rwanda-for-vital-aids-drug-/

[164] Médecins Sans Frontières, idem supra p. 130.

165 T. Talaga, "Hope for cheap HIV drugs dims", *Toronto Star*, 19 September 2009, available at: https://www.thestar.com/life/health_wellness/2009/09/19/hope_for_cheap_hiv_drugs_dims.html.



The CAMR has been amended several times since the Médecins Sans Frontières initiative, but it appears it has not been used since the Rwandan case, as demonstrated by Health Canada's[166] most recent reports as well as the WHO, WIPO and WTO 2020 study on "Promoting Access to Medical Technologies and Innovation"[167].

[166] Health Canada evaluation reports: https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/evaluation.html

[167] "Promoting Access to Medical Technologies and Innovation - Second Edition - Intersections between public health, intellectual property and trade", 29 July 2020: https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm

Although Canada faced significant controversy in what is referred to as the “pre-Doha” period, to date it is the only TRIPS MS to date to have successfully issued a CL for export. Five attempts to apply for a compulsory license under CAMR have been recorded since its entry into force, with only three having succesfully amended Schedule 1 of the Canadian Patent Act168. The amendement takes a substantial time investement (ranging from 7 to 15 months since the initiation date), with only the Apotex CL being granted for export. Apotex’s former CEO even testified to the difficulties encountered with the CAMR process, stating that it was ”impossible to navigate”169, proving the procedure’s lack of accessibility and timeliness.

In recent years, in response to the COVID-19 pandemic, Canada enacted the COVID-19 Emergency Response Act as a law on 25 March 2020, allowing the Canadian government to produce, sell, and use a patented invention. This act goes both “above and around” compulsory licensing. Under the new law, the production license can be issued without first negotiating with the rights holder or having local manufacturing ability, but the patentee must be compensated. The law is to be revoked when the crisis is over.[170]

United Kingdom (UK)

The UK is home to one of the top five pharmaceutical companies worldwide and exports more than 40% of the pharmaceuticals produced on its territory[171]. As the UK was an EU Member State until 1 February 2020 (date of Brexit), it is useful to study its CL for export mechanism compared to that of the EU.

As of 1 January 2021, the EU and UK systems became fully separate with automatic reciprocal arrangements falling away. Following the Agreement on the withdrawal of the United Kingdom and Northern Ireland from the European Union[172], the UK and the EU signed a Trade and Cooperation Agreement[173], which dedicates its second chapter to the standards concerning intellectual property rights.

Section 4 of the aforementioned chapter, regarding patents, reaffirms that both the UK and the EU recognise the importance of the Doha Declaration and their willingness to implement Article 31bis of TRIPS[174]. The lack of provisions relating to the substantive law is due to the fact that the EPO is not an EU agency, and Brexit does not consequently affect the applicability of the European Patent Convention nor its applicability in the UK.

Subsequently, the UK consequently continues to apply the same rules to CL for export as those set forth in Regulation No 816/2006, and Section 48A of the UK Patents Act of 1977 has been amended in accordance. Given that the EU has not added any specific measures in its Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the

[168] A. Schouten, ”Canadian Experience with Compulsory Licensing under the Canadian Access to Medicines Regime”, KEI Briefing Note 2021:2, 31 March 2021, available at: https://www.keionline.org/bn-2021-2

[169] Canada, Standing Committee on Industry, Science and Technology [INDU], ”Canada’s Access to Medicine Regime”, 39th Legislature, 1st Session (18 April-14 May 2007), available at: https://www.ourcommons.ca/Document/Viewer/en/39-1/INDU/meeting-55/evidence

[170] Urias, E. and Ramani, S. V., (2020), “Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence” 3 J. Int’l Bus. Pol., 367–84 (citing Houldsworth, 2020).

[171] Entreprise Ireland (Irish Government’s trade and innovation agency), “The UK pharmaceutical sector”, March 2020 Report, available online: https://globalambition.ie/wp-content/uploads/2020/03/Enterprise-Ireland-Report-UK-Pharmaceutical-Manufacturing-Sector-Overview.pdf

[172] Agreement 2019/C384 I/01, published in the Official Journal of the European Union, C 384 I, Volume 62, 12 November 2019, p. 1

[173] Decision (EU) 2021/86 of the European Union, 29 April 2021, published in the Official Journal of the European Union, L 149/2, 30 April 2021, p. 2

[174] Ibid, supra, Art. 250

manufacture of pharmaceutical products for export to countries with public health problems[175] that could be considered "TRIPS-plus" measures, by deduction, the UK has no "TRIPS plus" measures in its legislation.

It is worth noting that, given the absence of change of the patent protection system in the UK, all patents registered with the EPO are applicable in the UK, and it is therefore possible to apply for a compulsory license in the UK on the basis of a European Patent.

Switzerland

As a WTO Member with a significant manufacture capacity for chemical products (notably pharmaceuticals, biotechnology and macromolecular chemistry and polymers)[176], Switzerland has been on the forefront of discussions regarding market dominance during the COVID-19 pandemic[177], as the issue had been raised almost 20 years earlier during the HIV crisis, when prices of pharmaceutical products manufactured in Switzerland were so high that lesser developed countries in need of said products could not afford them and were excluded from that market.

The Swiss Federal Patent Act provides for CL in its Art. 40, with Art. 40(d) providing that "*Any person may bring an action before the court to be granted a non-exclusive licence for the manufacture of patent-protected pharmaceutical products and for their export to a country that has insufficient or no production capacity of its own in the pharmaceutical sector and which requires these products to combat public health problems(…)*"

As for the procedure, in accordance with Art. 40e(6) Swiss Patents Act and Art. 26(1)(a) Swiss Federal Act on the Federal Patent Court (known as the "Patent Court Act"), the Swiss Federal Patent Court has the competence to grant a compulsory licence. Should the compulsory licence be granted in the framework of Art. 40(d) Swiss Patent Act (i.e. for export), the President of the Federal Patent Court acting as a single judge (rather than with a panel of judges such as in compulsory licence cases for the internal market) is competent to grant this compulsory licence[178]. The procedure begins with the applicant filing an action with the Federal Patent Court and the parties exchange briefs. As the rules of summary proceedings apply to cases pertaining to the grant of compulsory licences undert Art. 40(d), the President of the Federal Patent Court has to issue a decision within one month from the filing of the action, and the rules pertaining to standard compulsory license proceedings do not apply due to lack of time to order a (double) exchange of briefs and for all hearings. The President of the Federal Patent Court summons the parties to an oral hearing following the filing of the action and issues the decision immediately afterwards.

The terms of the compulsory licence, such as its scope, duration and remuneration, which must be adequate, are determined by the Federal Patent Court based on its discretion.

[175] Regulation (EC) No 816/2006 of The European Parliament and Of The Council, 17 May 2006, compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, Art. 10

[176] EPO Annual Reports, Statistics and Trends: https://www.epo.org/about-us/annual-reports-statistics/statistics.html

[177] Jessica Davis Plüss, "Fight over rights to Covid-19 drugs puts Switzerland in a tough spot", May 29, 2020, SWI swissinfo.ch : https://www.swissinfo.ch/eng/patent-protection_the-fight-over-the-rights-to-covid-19-drugs-puts-switzerland-in-a-tough-spot/45781430

[178] Article 23(1)(e) of Swiss Patent Court Act

Despite the absence of TRIPS-plus measures in the Swiss Patent Act and Switzerland's ability to manufacture and export pharmaceutical products[179], no cases of compulsory licences under Art 40(d) of the Swiss Patents Act were recorded since its entry into force.

Indian legislation

India is the largest provider of generics globally in contrast to the countries above, and this status created some challenges regarding its legislative history of TRIPS implementation.

Prior to TRIPS, patent protection for pharmaceutical products and/or processes was forbidden in roughly 40 countries, including India.[180] In these countries, low-price copies of medicines developed by research-based pharmaceutical companies could be exported to international markets without the permission of the patent holders. However, one of the main requirements of TRIPS is that all member nations have ''to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability''. The agreement also sets 20 years as the minimum period of patent protection in all World Trade Organisation (WTO) member nations and prohibits discrimination between domestic and imported products. Thus, as all WTO signatory countries are required to grant patent protection of pharmaceutical products and processes, TRIPS effectively removed the possibility for generic manufacturers to reverse-engineer pharmaceutical process in order to produce and sell medicines at lower prices.

Prior to India's accession to the WTO, pharmaceutical companies lacked concrete patent protection there. The 1970 Indian Patent Act allowed in its fifth section for the patenting of pharmaceutical process patents, yet the patent for the product itself was not allowed. This lack of protection led to a complaint by the USA in 1996[181] for inconsistency between the filing system based on "administrative practice" for patent applications for pharmaceutical and agricultural chemical products and TRIPS Art. 70.8 and 70.9[182]. This led to India introduce TRIPS-compliant national laws in 2005.

However, the new Indian Patent Act (though it deleted section 5) brought on some TRIPS flexibilities, notably regarding the CL system with Chapter XVI on working of patents, CL and their revocation.

Section 92 (A) of this Chapter provides that a CL may be granted for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems. The Article adds that this grant is subject to a grant of a CL "by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India".

Nevertheless, after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence

[179] See for instance "The United States and Switzerland were the largest trade partners for COVID-19 related products", EUROSTAT statistics of EU trade in COVID-19 related products: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=EU_trade_in_COVID-19_related_products#The_United_States_and_Switzerland_were_the_largest_trade_partners_for_COVID-19_related_products

[180] Boulet, P., Perriens, J., Renaud-Thiéry, F., & Velasquez, G. (2000). "Pharmaceuticals and the WTO TRIPS Agreement: Questions and Answers" UNAIDS/WHO, Available at: https://medex.com.bd/downloads/KthHLY8Dav8b5p4ftTMLk4MZB9qcGvoDaLCG4jIyyxZ1gqs3q5/pharmaceuticals-and-trips-agreement.pdf.

[181] WTO Dispute Settlement Body (DSB), Panel established pursuant to the request of the United States (WT/DS50/4), in accordance with Article 6 of the DSU (WT/DSB/M/26), all documents found here: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(%40Symbol%3d+wt%2fds50%2f*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true

[182] Idem.

on patent on the grounds of non-satisfaction of the reasonable requirements of the public with respect to the patented invention[183]. The "reasonable requirements of the public" are interpreted as unsatisfied if, due to the refusal of the patentee to grant a licence or licences on reasonable terms, a market for export of the patented article manufactured in India is not being supplied or developed[184].

As such, the licensee may export the patented product despite the CL being granted under the general conditions of granting a CL[185] (rather than it being granted under Section 92 (A)). The patented product may also be exported in case the licence is granted to remedy a practice determined to be anti-competitive after judicial or administrative process[186].

Therefore, the Indian legislation provides for the minimum requirements set forth under Art. 31bis TRIPS but takes many liberties regarding the general conditions of grant of CLs.

Overall Observations

From the cases of legislative implementations of TRIPS described above, a few key observations can be made.

First, as demonstrated by the procedural challenges encountered by the pharmaceutical company in *Apotex,* Canada's system has produced the first example of a successful use of the 31bis procedure for obtaining a CL for exportation of a drug, yet not without its difficulties. As remarked by the CEO of the pharma company using the Canadian procedure (CAMR), the regulatory burden was "onerous" and made it difficult to understand how to comply. In particular, the step which required proof of voluntary negotiations with each (medical company) in order to apply for the procedure caused unforeseen delays and created a greater administrative burden than necessary. This much is acknowledged by the revision to the law made during the time of the COVID-19 pandemic, which eliminated this step among other streamlining measures.

Second, as demonstrated by the Swiss and UK examples, manufacture capacity and innovativeness of a national market are not the most determining factors for compulsory licenses for export of pharmaeutical products, as neither country has had a case of compulsory license grant, despite hosting 3 of the top 5 pharmaceutical companies worldwide on their territories.

As for India, despite its dominance in the generics market and its leniency in applying adequate patent protection, which puts it in a diametrically opposed position to Switzerland and the UK, it also has never granted a compulsory license for export of pharmaceutical products since the introduction of TRIPS-compliant laws on its territory in 2005.

Thus, the comparative legal analysis leads the discussion on CL for export towards a question on the need for further clarifying, and potentially simplifying, the procedure provided for in Art. 31bis TRIPS in national legislation.

2.1.2. Export of non-predominant part under CL for domestic market

Art. 31bis TRIPS is not the only possibility for exporting products under CL to WTO Members. Art. 31(f) TRIPS provides that any CL granted under this provision of the TRIPS Agreement shall be "predominantly for the supply of the domestic market" of the WTO Member granting the CL. It is therefore possible to export a non-predominant part of the products produced under CLs granted for the predominant supply for the domestic market.

[183] Indian Patent Act, Section 84, sub-section 1, clause a.
[184] Indian Patent Act, Section 84, sub-section 7, clause 4, sub-clause (iii).
[185] Ibid., Section 90, sub-section 1, clause (vii).
[186] Ibid., Section 90, sub-section 1, clause (ix).

Differently from Art. 31bis and the Regulation No 816/2006 transposing it in the EU (see section above), Art. 31 TRIPS does not limit CLs to any field of technology or crisis. Of course, should the product covered by the CL be patented in the WTO Member of exportation, a CL must be issued in that Member as well.[187]

As the EU authorities, other than DG COMP and the CPVO, currently do not have the competence to grant cross-border CLs for the supply of the territories of all or several EU Member States, and since there is no EU-wide exhaustion for national CLs, the non-predominant part for export outside the EU could only be defined in relation to a domestic market for which a national CL is granted.

2.2. CL for import to the EU

The COVID-19 pandemic illustrated how access to certain important products and services can, also in a developed region such as the European Union, be compromised by lack of local production capacity and logistical problems.

Scenario: An EU-wide or worldwide crisis emerges, and there is no (or non-sufficient) manufacturing capacity in the EU. Creation and/or scaling up of the manufacturing will take time. For example, out of 5 producers of the COVID-19 vaccines (BioNTech & Pfizer, Moderna, AstraZeneca, Janssen Pharmaceutica NV and Novavax) that received conditional marketing authorisations of the EMA, following positive assessment of their safety and efficacy, only one is located in the EU.[188] Given the experience of export bans of critical medical products and components thereto (see above, Notion of “crisis”), the situation when there is no manufacturing of an essential medical product in the EU is not impossible.

Problem: As discussed above, Art. 31 TRIPS permits grant of CLs predominantly for domestic use. Under this provision, only a non-predominant part, however it is defined, of the quantity of products made for a domestic market of a third-party WTO Member could be imported to the EU. Art. 31bis TRIPS was specifically created for remedying a situation of lack of manufacturing capacities for pharmaceutical products. However, the EU and its Member States unilaterally committed not to rely on their rights under Art. 31bis TRIPS. Following the deadlock during the WTO Ministerial Conference in Doha in November 2001, WTO MS agreed on the amendment that has become Art. 31bis TRIPS by creating a “waiver” of importation rights for the MS that specifically declare it. In the 30 August 2003 decision, the EU has waived its right to import any products manufactured under a CL[189] .

The problem could be formulated as a problem of lacking competence to trigger the mechanism of the CL for import from third countries in case of crisis. While the EU has a robust pharmaceutical industry, a possible crisis could reveal a lack of the capacity or its loss. Given this waiver, EU and its Member States lack the competence to import pharmaceutical products under Art. 31bis in case of an unforeseen health crisis.

[187] See to that end Art. 10(7) of Regulation No 816/2006.
[188] European Commission, ‘Safe COVID-19 Vaccines for Europeans’, Text, accessed 16 June 2022, https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans_en.
[189] WTO press release, 30 August 2003, Decision removes final patent obstacle to cheap drug imports, Press Release. https://www.wto.org/english/news_e/pres03_e/pr350_e.htm

II. Policy Options

The policy options contemplated by this report are ordered from least to most invasive, ranging from maintaining the status quo to significantly overhauling elements of the current institutional and regulatory order.

Section I deals with policy options that are specific to the EU's domestic market (MS specific to EU-wide solutions). Section II deals with options relevant to the export from and import to the EU of products requiring one or more IP (mainly patent) rights.[190]

3. Improving EU Domestic Use and Import

3.1. Status Quo

Maintaining the status quo might seem less costly and less burdensome for stakeholders in the short term, but could result in long-term costs for the EU and its population if a crisis arises that confronts Member States with unexpected challenges and a sudden high demand for certain products.

The existing CL procedures are already complex enough and one might argue that there is no need to add an additional layer of complexity by creating another CL granted at EU-level. The options described here below try to avoid adding complexity, by either simplifying and harmonizing the existing rules, or by introducing an additional level of EU decision making only for temporary measures in case of a declared crisis.

Industry stakeholders are familiar with preserving the status quo and for them the option of doing nothing would be the easiest.

However, our study demonstrates that the current CL system is inefficient because of its individual complexities and because of its national limitations. Most CL laws date from a time when innovative products were considered to be protected by one patent only and where each country has its own production capacity. That does no longer match with today's reality where most complex products are covered by multiple IP rights and are manufactured and assembled in various steps taking place across several Member States (and even outside the EU). And in some MS a CL can only be applied for after an "embargo" period of several years. Whereas it is precisely in crisis situations that an urgent need arises for new and complex products. So doing nothing may not be the preferred policy option.

3.2. Member State coordination

According to the stakeholder responses, as demonstrated in Section 1.1.1 above with respect to the variety of institutions with competences to grant CLs, multiple different authorities can be empowered to issue a compulsory license for different purposes.

In most cases, a national court is entrusted with the ability to grant a CL, whereas the competence to grant a CL in times of national emergencies or "public health" reasons is often entrusted to a ministry or government[191]. In other cases, only IP offices are entrusted to grant a CL once the requesting party has provided sufficient information.

[190] For the purposes of this Report, these options/proposals are presented here in a simplified and preliminary form.
[191] Ibid.

This variety of MS approaches to allocating authority to evaluate and grant a CL frustrates the possibility of communication between authorities across borders, and ultimately creates barriers against engaging in holistic and uniform crisis responses across the EU. Since national-level actors can be quite diverse both in terms of their institutional mandates and authority to regulate in the sphere of patent law, it can generate costs for parties seeking a CL covering multiple MS territories or obtaining a CL for producing a product for the EU market as a whole.

While maintaining the principle of subsidiarity and respect towards national-level decisionmaking, perhaps there is still some useful manoevring room in terms of aligning MS practices. For example, issues such as the need for a CL, the scope of a CL (in terms of the technology concerned and the duration of the CL), the financial conditions surrounding the grant of a CL, etc., can perhaps be dealt with through the use of soft law measures such as guidelines or best practices which are negotiated at the EU level.

On the potential coordination issues that may result from the variety of MS authorities granting CLs for a crisis covering multiple or all EU MS, one solution which builds upon the existing infrastructures present in MS would be to formalise a regulatory network of institutions. This formalised network of regulators would prioritise transparent and open exchanges of information in order to properly weigh the benefits and limitations of granting a CL across multiple MS jurisdictions.

To illustrate this concept, one regulatory network worth mentioning is the European Competition Network (ECN). According to its establishing Regulation, the network functions by virtue of "*a system of parallel competencies in which the Commission and the Member States' competition authorities…can apply Article 81 and Article 82 of the EC Treaty*."[192] An additional benefit of this approach is that subsidiarity and proportionality principles may be more easily satisfied. Networks have been recognized within the EU regulatory sphere as a "natural by-product of subsidiarity," which in turn fuels, "…a considerable expansion of bilateral and multilateral cooperation and coordination among national regulatory bodies, leading to the emergence of more or less formalised network structures."[193] The approach advocated here reinforces this concept.

Another existing, relevant infrastructure for coordinated regulatory action takes the form of European Medicines Agency (EMA), which is responsible for the scientific evaluation of centralised marketing authorisation applications (MA).[194] Similarly, the HERA maintains in its 2022 Work Plan that, "a network will be set up of national or regional agencies in EU Member States responsible for carrying out tasks related to the availability and accessibility of relevant medical countermeasures in case of a health emergency."[195] In the interest of improving and building upon current EU level arrangements, such cooperative network infrastructures can likely be expanded to encompass a broader range of national authorities in order to cover a greater range of potential crises.

Perhaps one of the largest hurdles to overcome in suggesting a network of national regulators is that some of the actors may be completely competent to carry out the functions described above, while others may lack the finances, authority, or requisite expertise to carry out the same. It further bears reiteration that, in the long term, it is uncertain how

[192] European Council, 'Council Regulation No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty' (2002); See also Part. 1.2 ("Scope and Effect of National CLs").

[193] Littoz-Monnet (2013), "European Cultural Networks, Social Communication and the Construction Process of the European Community" in McMahon, R (ed.). Post-Identity? Culture and European Integration, London: Routledge.

[194] EMA, "How the Committees Work" https://www.ema.europa.eu/en/committees/how-committees-work ("Composition of committees and working parties :EMA's committees, working parties and related groups are composed of European experts made available by national competent authorities of the EU and EEA Member States.")

[195] HERA Work Plan 2022, p. 3. https://health.ec.europa.eu/system/files/2022-02/hera_work-plan_2022_en_0.pdf.

effective national governments can continue to be at regulating conduct occurring across MS borders, especially in terms of responding to a pandemic-level crisis. In this regard, even establishing a more formalised network of exchange between national level authorities competent to grant CLs may fail to be sufficient given existing jurisdictional rules which limit the roles of MS authorities to regulating chiefly within their national borders.

3.3. Member State coordination & harmonisation

In addition to formalising a network of MS regulators which can be brought together and mobilised in times of crisis, harmonising national legislation and practices can offer clear advantages since it contributes to a better functioning CL system in a European market without introducing additional layers of complexity.

One element that seems necessary to be harmonized is the condition under which national authorities can step in to deal with a "crisis". If these conditions and situations are not the same across all Member States, a crisis that affects several Member States could not be adequately addressed. Nor a crisis that would affect one MS but than can be solved via production facilities in another MS. As reported above, many MS have provisions in case of a health crisis, or a public emergency, but it is unclear if that applies to all types of crisis that the EU could face in the future. For instance, our research learns that it is unclear if national authorities can address a food crisis or the consequences of a natural disaster when it comes to granting CLs. Therefore, a harmonisation is needed around the definition of a "crisis" (or any other appropriate generic term) and the technology sectors that are concerned by such crisis.

Other subject matters that our study shows could be harmonized (in times of crisis or in general) are :

1. Nature of IPRs:
    a. Patents should comprise also the SPCs based thereon (this is more a need for clarification than a need for change or harmonisation of national law)
    b. Patent applications should be part of a request for a CL if they are close to being granted or sufficiently clear in scope in view of the requested CL
    c. Multiple patents should be part of a single CL procedure as long as they have the same owner (or group of owners) and patent families (divisionals) should be part of a single CL request
    d. The scope of a CL can rather be conceptualised as covering a "product," which can broaden the scope of relevant and necessary rights [196]
2. To provide a "carve-out" for the applicable data exclusivity rules (RDP) for medicinal products, plants and approved chemicals
3. To remove national provisions providing for an "embargo" during which no request for a CL can be filed
4. Re-affirm EU-wide exhaustion as the starting point for products made under any CL, whether in times of crisis or not, taking the view that the EU is in itself a "predominant market" and a "domestic market", and that the 1985 CJEU decision in Pharmon vs. Hoechst is legal history. This principle would not prejudice the possibility to conclude voluntary arrangement that provide for derogations from this principle (no parallel imports or passive sales) on a temporary and case-specific basis (individual exemption by national or EU competition authorities) or on a more predictable and

[196] See the five advantages of such approach described elsewhere in this study ("Scoping a CL on the basis of IPRs or on the basis of a product", supra), including empowering regulatory agencies with the authority to grant CLs for products that are not yet covered by a published or granted patent application.

organized basis (block exemption) that will remain subject to scrutiny by the competition authorities

5. Mutual recognition of CLs and of declaration of a "crisis" in another member state to allow e.g. more efficient movement of CL-made products across the Member States, and to avoid duplication of procedures to obtain marketing approvals

Harmonisation measures of this nature, when combined with heightened levels of coordination between MS regulators, can likely solve many of the problems considered in the first part of this study.

3.4. EU-level compulsory licence

Responding to crises which encompass two or more EU MS typically requires a level of coordination and institutional competence that may not be readily available at the national level. With respect to granting a CL in response to a crisis for the same product in two or more MS, issues of cross-border information gathering, poor communication between MS and industry parties, and other unforeseen administrative hurdles may impede the swift realisation of a solution.

Legislative measures achieved at the EU level, taking the form of directives or regulations, are typically considered an effective means for achieving harmonised regulatory practices among EU MS. In many different sectors, and in IP sectors specifically, the centralisation of certain regulatory tasks to the EU level have provided a unique avenue for harmonizing enforcement practices across MS.

According to stakeholders from industry and national experts in particular, during interviews and workshops, a strong preference was expressed for allocating responsibilities for administering CLs to "specialised" or expert authorities: authorities which hold the requisite knowledge of a product and relevant expertise in order to properly evaluate applications for CLs and make key assessments regarding the necessary scope of a CL. Some complex determinations, including those relevant to obtaining a market authorisation for a product (e.g., considering whether the CL should extend to a patent application, and under which circumstances), are especially crucial given the exigent circumstances of the crisis at hand.

It is also reasonably foreseeable that new products created as a response to the crisis, especially complex products involving more than one patent, would require a regulator to consider granting a CL over applications for multiple innovative patents at once that are at varying levels of being examined and are not yet published or granted. In such cases, a balancing of private and public interests – especially interests relevant to health and safety – would seem to require a regulator with competences that extend far past its ability to engage in mere economic assessments of the impact of a CL granted during times of crisis.

Another missing element for responding adequately to crises on an EU scale is the lack of a fixed authority to declare an EU-wide crisis.[197] Developing appropriate crisis responses "horizontally" in the EU will require clearly defining the parameters of a crisis in order to reduce the many negative externalities that may result from a rapid response, especially concerning the issuance of a CL at the EU level.

[197] Developing the specific criteria for determining the threshold of a "crisis" in the EU is outside the scope of this Report.

As emphasised, crises which affect most or all EU MS, i.e., crises which reach the magnitude of a pandemic, require by their very nature a unified and highly-coordinated response at the EU level. This has been frequently acknowledged and emphasised through the numerous European Health Union initiatives launched since 2020, which have all been founded on this very recognition.[198] Yet as described in the Proposal for a Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures, an important additional consideration to be made is that individual MS responses may actually impede the efficiency and successfulness of a more uniform crisis response:

> "Actions by individual Member States could neither address the challenges resulting from such an emergency [COVID-19] nor are they able to provide a sufficient response on their own. **Unilateral action through Member State initiatives aiming to ensure the sufficient and timely availability and supply of crisis-relevant medical countermeasures runs the risk of increasing internal competition and suboptimal Union level response**. Such unilateral action can ultimately result in significant economic consequences and affect the health of Union citizens."[199]

Taking these considerations into account, in our view there are clear benefits to centralising aspects of crisis response at the EU level as opposed to relying on purely national solutions. Decision making at the EU level can first provide for a stronger sense of legal certainty for stakeholders operating in the "single market." In principle, determinations by EU principal institutions (Parliament, the Council, the Commission, and the CJEU) regarding the grant or denial of a CL spanning multiple MS can deliver clearer and more binding instruction to MS when issues span across MS borders.

Designating an authority or combination of authorities at the EU level (3.4.1) to declare a crisis, i.e. by establishing baseline criteria or "trigger points" for reaching the threshold of a "crisis" in the EU,[200] can be a preliminary step in defining one of the many potential functions for such an authority/combination of authorities. These arrangements are contemplated in further detail below.

Furthermore, as discussed in 3.4.2.2, since CLs are mostly based on national IPRs, a CL recommended at the EU level should be sufficiently tailored to address the specific conditions of the crisis at hand. Such a CL would therefore be only provisional in nature, clearly limited in temporal and territorial scope of its application.

[198] European Commission, "Communication: Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats," 11 Nov 2020, COM(2020) 724 final.
[199] European Commission, "Proposal on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level" 16 Sept 2021, COM/2021 577 final, p. 4 (emphasis added).
[200] The declaration of a "crisis" at the EU level may also correspond with the recommendations of international organisations such as the WHO.

3.4.1. Crisis Response at the Institutional Level

At the EU level several specialized bodies already exist which are tailored to specific sectors and have specialised expertise:

- The European Health Emergency preparedness and Response Authority (**HERA**), was created to work with other EU and national health agencies, industry and international partners to improve the EU's readiness for health emergencies, and further participates in the global effort to ensure availability and access to medical countermeasures, e.g., by facilitating vaccine donations to non-EU countries[201];
- For plant and breeder's rights, the Community Plant Variety Office (**CPVO**)[202] for which there already exists detailed legislation and procedure regarding CLs[203];
- For dangerous chemicals, the European Chemical Agency (**ECHA**)[204];
- For biological medicinal products, the European Medicines Agency (**EMA**)[205];
- For food products, there is the European Food Safety Authority (**EFSA**)[206].

Each of these specialised authorities/agencies exhibit differing levels of competencies and can recommend different types of responsive measures in times of crisis, particularly with respect to granting a CL. Similarly, at the national level, a variety of authorities ranging from administrative (i.e., patent offices) to courts to Ministries to competition authorities[207] can be empowered to evaluate an application for and grant a CL depending on specific circumstances. The overall choice of authorities in the CL decisionmaking process is highly dependent on provisions in international (i.e., TRIPS) and national legislative acts, the nature of the issue at hand, and the predefined competences of the authority at hand. Therefore, in considering a new EU procedure for evaluating and recommending a CL, the same institutional dilemma should be resolved when deciding the appropriate authority (or group of authorities) and procedures for evaluating and issuing a CL at the EU level. This becomes even more crucial when designating decisionmaking powers and setting up an efficient procedure in response to crises ocurring across multiple MS or EU-wide.

As a starting point, our interviews and discussions with stakeholders revealed a preference for the allocation of powers for evaluating an application for/granting a CL to specialized agencies and administrative bodies over institutions whose decisionmaking can be influenced by political concerns. In this regard, we suggest two options: setting up a regulatory consortium at the EU level involving a combination of specialised authorities with varying areas of expertise; or establishing a new, separate and independent authority at EU level for assessing and issuing a CL which can be applied by multiple or all EU MS in times of crisis.

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[201] European Commission, Press Release: European Health Emergency preparedness and Response Authority (HERA): Getting ready for future health emergencies. 16 September 2021. https://ec.europa.eu/commission/presscorner/detail/en/ip_21_4672

[202] Council Regulation No 2100/94 on Community plant variety rights, OJ L 227, 27 July 1994.

[203] Commission Regulation establishing implementing rules as regards proceedings before the Community Plant Variety Office, (EC) 874/2009, 17 Sept 2009.

[204] Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, OJ L 136, 29 May 2007.

[205] Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency, OJ L 136, 30 April 2004.

[206] Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1 February 2002.

[207] See, supra, Section 1.1.1.

3.4.1.1. EU-level Regulatory Consortium

Crises may involve multiple sectors at once, and may require the response from more than one of the specialised agencies listed above. At the international level, "regulatory consortiums," or coalitions of regulatory authorities, have been utilised in order to to promote greater regulatory collaborations and decisionmaking which is in alignment with different types of regulatory requirements.[208] The goal of a regulatory consortium is typically to build upon existing, sector-specific knowledge and expertise of institutions and create an avenue for the exchange of such knowledge at the regulatory level when dealing with cross-sectorial issues. Such "intensive and extensive inter-agency networking" appears in many forms, particularly when the conduct to be regulated lies at the intersection of critical economic, social, cultural and political interests.[209]

In this respect, creating an ad-hoc EU committee, regulatory consortium or similar – which may include representatives from a combination of principal EU institutions (e.g., the Commission, representatives of DGs), relevant EU agencies and national level authorities – may become necessary in order to reach more holistic evaluations over appropriate crisis responses in the EU.[210]

Such a committee, or "regulatory consortium" may be however limited in terms of what actions they can compel on actors relevant to the crisis. At the EU level, the competencies to issue a CL based on an IPR, for example, do not rest with agency authorities currently, nor with the EU's executive institutions. Therefore, any conclusions reached by an EU-situated committee regarding defining a crisis, as well as delivering recommendations on an appropriate response to such a crisis, would also require the designation of a complementary authority with the executive power to direct MS to grant a CL.

In the EU there are already substantial institutional and regulatory infrastructures in place to build upon when considering the introduction of an EU level regulatory consortium for CL. In the EU Commission, several DGs and internal bodies are equipped with the capabilities of carrying out the assessments necessary for issuing and anticipating the effects of the grant of a CL across multiple MS.

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[208] See, e.g., European Medicines Agency, "Partners and Networks: the International Coalition of Medicines Regulatory Authorities (ICMRA)" https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-coalitions-initiatives/international-coalition-medicines-regulatory-authorities-icmra.
("ICMRA is a voluntary, executive-level entity of worldwide medicines regulatory authorities set up to provide strategic coordination, advocacy and leadership. ICMRA acts as a forum to support international cooperation among medicines regulatory authorities. The coalition aims to:

- identify ways to better use existing initiatives and resources;
- develop strategies to address current and emerging challenges in global human medicine regulation, such as the growing complexity of globalised supply chains;
- provide direction for common activities and areas of work.")

[209] See, Schlesinger, Philip. (2021). The neo-regulation of internet platforms in the UK. Zenodo. https://doi.org/10.5281/zenodo.5708186

[210] For details on a proposed administrative procedure and relevant bodies for issuing a CL at the EU level, see, supra, *3.4.2.3.*

One of these key actors situated within the Commission which could also be involved in the evaluation process of a CL issued at the EU level could be HERA. HERA is an organisation arranged within the European Commission, comprised of 3 separate interrelated groups (Coordination Committee, HERA Board, HERA Advisory Forum) with its Head ranked as a Director-General.[211] In its role, the HERA, in close cooperation with EU MS, is responsible for the following tasks:

> (a) assessment of health threats and intelligence gathering relevant to medical countermeasures;
>
> (b)promoting advanced research and development of medical countermeasures and related technologies;
>
> (c) addressing market challenges and boosting the Union's open strategic autonomy in medical countermeasures production;
>
> (d) swift procurement and distribution of medical countermeasures;
>
> (e) increasing stockpiling capacity of medical countermeasures;
>
> (f) strengthening knowledge and skills in preparedness and response related to medical countermeasures.[212]

In recent times, HERA has been critical in facilitating the completion of Joint Procurement Framework Contracts to supply EU MS with COVID-19 vaccines[213], in large part due to its unique positioning at the EU level uniting members of industry, MS, and other relevant stakeholders in negotiating collective solutions.[214]

Other relevant DGs situated in the Commission which are equipped to aid in the assessment of the impact of a grant of a CL include DG COMP, DG GROW, and DG Santé.

Finally, other existing EU agencies would play a significant role in contributing resources, institutional and industry connections, and specialised expertise into the evaluation and enforcement of a CL measure issued at the EU level.[215] In terms of resolving public health related crises especially, the cooperation of the EMA and the ECDC are needed in order to provide a comprehensive crisis response given their established expertise.

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[211] Art. 4, European Commission, "Commission Decision of 16 Sept 2021 establishing the Health Emergency Preparedness and Response Authority" COM(2021) 6712 final.
[212] Ibid, Art. 2(2).
[213] European Commission, "Press Release: Health Union: Commission signs Joint Procurement contract with HIPRA for COVID-19 vaccines," 2 August 2022. https://ec.europa.eu/commission/presscorner/detail/en/IP_22_4782.
[214] Art. 2, Commission Decision of 16 Sept 2021 establishing the HERA.
[215] See, e.g., European Commission, "Factsheet: A European Health Union: Tackling health crises together: The role of EU agencies," 13 November 2021.

3.4.1.2. A New EU Authority for declaring a crisis

In the EU, there is a need for cross-sectoral determinations of what is a crisis. As discussed, this decision-making role can take the form of increased cooperative measures between MS authorities and among EU institutional actors. Taking these essentially centralising measures a step further, we may further conceive of a single authority situated at the EU level that can make assessments to determine the full range of solutions possible in times of multi-territorial and EU wide crises. This "new" authority, potentially taking the form of an agency, would be empowered to make decisions on 1) the necessary thresholds for declaring a state of crisis in the EU; and 2) the scope and enforcement of measures used to respond to the crisis, including but not limited to, issuing a CL at the EU level. Such an independent agency can carry out a similar mandate as existing agencies operating at times of crisis, but can avoid the issues that arise during times of crises involving multiple sectors at once (e.g., health, food, natural disaster).

This specialised agency, with a sector-neutral mandate, could create Recommendations for addressing the crisis, and options can also include creating appropriate incentives for encouraging stakeholders to engage in the use of voluntary agreements. It is worth mentioning here again that, to avoid the problems of "democratic deficit" that may arise with empowering an authority to make choices which can result in the calcification of its own power, we can contemplate an authority which is limited to delivering unbiased, non-binding Recommendations, and which requires a competent executive authority (i.e., the Commission) to make the final decision to issue a CL under the circumstances of the ongoing crisis.

3.4.2. Availability of a CL issued at the EU level

There are several potential benefits for creating the option of issuing a CL at the EU level in times of crisis. First, it can help to mitigate the negative impact of relying on purely national CLs in times of crises covering multiple MS territories. In terms of scope, a CL issued at the EU level could potentially cover several or all EU MS, eliminating the requirement for obtaining multiple CLs per jurisdiction in times of a crisis spanning outside one MS jurisdiction. Put differently, making available a CL at the EU level does not necessarily imply that the CL will only cover an EU-wide territory. There could be the possibility of introducing a temporary EU measure that complements the functioning of national CLs, especially in times of crisis, in order to ensure that the most efficient and expedient route to the production of goods is utilised. In this regard, it may become necessary to provide for the stay of national (or UPC) infringement proceedings, or to lift temporary injunctions or seizures, in order not to frustrate the effectiveness of a CL issued at the EU level.[216] And, of course, the scope of a such a temporary CL issued at the EU level should also be accompanied with reasonable and equitable guarantees for financial compensation and due process for the right holders at the level recommended by national CL procedures once the temporary EU issued CL term has expired.

3.4.2.1. Legal Basis

Taking current EU legal instruments into consideration, the possibility of granting a temporary CL covering two or more MS at the EU level can be accomplished in a variety of ways. To be precise, the legal bases for intervention described below should be further understood as grounds to suggest an EU Regulation on the use of CLs in times of crisis.

[216] The Commission has authority to do so in, for example, the Regulation on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, (EU) No 1215/2012, OJ L 351, 20 December 2012.

One clear Treaty basis for an intervention of this manner can be found in Article 122(1) TFEU, which provides for "…*the Council, on a proposal from the Commission…[to] decide upon the measures appropriate… if severe difficulties arise in the supply of certain products*".[217]

Furthermore, according to Article 31(f) TRIPS, compulsory licences "*shall be authorized predominantly for the supply of the domestic market of the [WTO] Member authorizing such use*". This treaty provision is not prejudicial to the possibility for a WTO Member - such as the EU - to grant CLs for a part of its domestic territory. It is possible to envisage a mechanism where an EU-level decision would designate two or more Member States as the parts of the EU domestic market concerned by the CL. Another option is that an EU institution (e.g. the Commission or the Council) would adopt a Decision instructing certain Member States to grant a CL. This option seems to best complement existing national legislation and respects the principles of subsidiarity which delimit the scope of exercises of EU level authority on MS.[218]

For the scope of a CL to cover the territory of two or more MS, it would further be appropriate to consider the relevant circumstances in the Member States concerned. For example, a situation may arise where a MS is given an unfair advantage by allowing a product manufactured under a CL granted to it to be delivered in a MS outside the scope of the CL territories (i.e., outside of the territories deemed "in crisis"), where a parallel patent exists.[219] It therefore seems imperative that a proper multi-territorial analysis regarding the current situation of MS is conducted in advance order to accurately anticipate the potential impact of the grant of a multi-territorial CL.

Finally, since the correction of anti-competitive practices (Art. 31(k) TRIPS) under Art. 101 and 102 TFEU already provides a competence for granting a CL at the EU level, there may be consideration towards extending the power of the European Commission to grant a CL in cases of crisis. However, such a use of authority may be considered unbalanced in view of the principles of subsidiarity and proportionality, and may not be easily justified given the recognition of the CL measure as a measure of "last resort."

3.4.2.2. Scope and Enforcement of a CL issued at the EU level

It is emphasised that the grant of a temporary CL at EU level should be an exceptional measure and can therefore only be made available in times of crisis. Therefore, the terms of the CL must be sufficiently narrowly tailored to meet the challenges posed by the crisis.

[217] "Without prejudice to any other procedures provided for in the Treaties, the Council, on a proposal from the Commission, may decide, in a spirit of solidarity between Member States, upon the ***measures appropriate*** to the economic situation, in particular if severe difficulties arise in the ***supply of certain products***…" Emphasis added.

[218] To be more specific, this would be considered an area of non-exclusive competence of MS, given that there would be a cross-border dimension underlying the measure proposed. A similar legal justification is made in the context of the Proposal for a Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, COM(2021) 577 final, p. 4.

[219] CJEU case 19/84, 9 July 1985, Pharmon vs. Hoechst, para. 19: "the objectives of a compulsory licence and a licence freely granted are different. Whilst a licence freely granted is a means of exploitation which goes to the specific subject-matter of the patent right as defined by the Court, a compulsory licence, on the other hand, is essentially intended to meet the special needs of a Member State. Accordingly, it would be unfair, and even dangerous, to accord that Member State a further advantage by allowing a product manufactured under the compulsory licences granted by it to be delivered directly in Member States where a parallel patent exists." (emphasis added). This issue could potentially be pre-empted through the application of TRIPS safeguards.

First, the temporal scope of a CL granted at the EU level should be strictly limited to periods of crisis, where circumstances require robust responsive measures. Yet, this period of time cannot solely relate to the duration of the crisis itself, but must take into account equitability on behalf of the patent holder. Crises that are environmental in nature or related to food shortages, for example, might be rather classified as prolonged crises due to underlying systemic issues. Such issues cannot be adequately dealt with through the grant of compulsory licenses, regardless of the subject matter or territories that might be covered.

Creating a suitable timeframe for a CL that is responsive to a crisis but is not unduly prejudicial to the patent holder requires a careful balancing of public and private interests. While some legal certainty can be attained by creating a fixed upper time limit for the grant of a CL at the EU level, e.g., by limiting its exercise to a period of no longer than one year,[220] or installing a "review clause" after a certain defined period of time has elapsed, in the context of a crisis (especially one in the health sector) fixing such an upper limit may seem arbitrary in light of the situation and the complexities of the products at stake. Therefore, the temporal limitations of a CL granted at the EU level in times of crisis should take into account a combination of factors relevant to the resolution of the crisis, as well as principles of fairness and equitability on the side of the patent holder.

Second, the territorial scope of a CL granted at the EU level should be narrowly-defined in order to correspond to the territorial scope of the crisis[221]. When the crisis is cross-border in nature, this can create complexities in applying the CL across jurisdictions.

One possible approach to resolving any potential cross-border issues in the recogntion of a CL may include create an obligation for MS to recognize a CL issued at the EU level covering multiple or all MS, or alternatively, to encourage MS to adopt domestic legislation which can give rise to mutual recognition of CLs in times of crisis. Indeed, this approach may expose the need for MS to complement the grant of a CL at the EU level by ensuring its enforceability at the national level. With respect to such complementarity, MS may further require new rules for ensuring the import and export of products manufactured through the use of a CL granted at the EU level, which could extend to new monitoring obligations, gathering import/export data on behalf of national customs authorities, and other similar coordination and oversight mechanisms to create a more transparent environment for the circulation of such products.

Relatedly, as far as the potential legal basis for issuing a CL covering multiple or all EU MS, if the legal concept of a "domestic market" according to Art. 30 TRIPS is interpreted as the "EU market",[222] a CL can potentially be issued at the EU level covering part or all of such a market.

The enforceability of a CL issued at the EU level is also in part dependent on changing the concept of exhaustion, as elaborated on in greater detail in Policy Options: Section 5.

[220] This is the maximum term for a CL under Art. 29(4) of Council Regulation on Community plant variety rights (EC) No 873/2004, 29 April 2004.
[221] This evaluation of geographical scope of the CL should include MS (not necessarily in crisis) which are critical for the relevant manufacturing chain.
[222] This interpretation may also be available given the fact that the "European Union" is considered a signatory (and therefore Member State) of TRIPS. (Article 30 – Exceptions to Rights Conferred -- Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

3.4.2.3 Administrative Procedure for Issuing a CL at the EU Level

In this part, we have started outlining the contours of a CL procedure available at the EU level in times of crisis. As a matter of policy, making available a unified "European" response mechanism during crisis situations can both reinforce and build upon the foundation of cooperation and goodwill that characterises Europe as a union of MS. Furthermore, the numerous costs of evaluating the impact of the issuance of CL, coordinating, and communicating among multiple MS authorities and industry actors, can be minimised through a single, centralised EU procedure once two or more MS are concerned with using the measure.

To aid in the conceptualisation of the process of issuing a CL at the EU level, five basic steps have been identified:

Step 0: Triggering Event for the Availability of the CL procedure at the EU level

As a preliminary matter, the basic principle of the availability of a CL procedure at the EU level is that it is a measure "of last resort," after reasonable efforts to obtain a license at the national level have failed.

To trigger the availability of the CL procedure at the EU level, two interrelated prerequisites must be fulfilled. First, **two or more MS** must be involved in the request order to trigger the availability of the EU procedure, in alignment with principles of subsidiarity[223]. Second, two or more MS must be declared "in crisis" by the designated EU authority (e.g., EU Commission[224]).

Given that the resolution of a cross-border crisis may benefit from centralised decision making and enforcement at the EU level as opposed to the national level, such minimum thresholds for triggering the availability of the EU procedure are sufficient for mitigating a crisis in which the solution relies on the rapid supply of a particular product across multiple MS. Furthermore, making available a single application procedure for the grant of a CL at the EU level covering the same product across multiple MS would seem to reduce the administrative and regulatory costs of undergoing multiple national-level assessments through differing national authorities.

Furthermore, in order to resolve a crisis in full alignment with existing TRIPS principles, MS intending to utilise the EU procedure may also be required to show that they have attempted to enter into a voluntary agreement (i.e., contractual license) before triggering the availability of the EU procedure.[225] In the case of an unprecedented crisis, should the legislator choose to include a further option for the EU Commission or MS governments to trigger the availability of the CL procedure at the EU level, providing evidence of an unsuccessful attempt to obtain a contractual license may be waived.[226]

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[223] Art. 5, TEU.

[224] Recital 35, Regulation 2022/2371 on serious cross-border threats to health, OJ L 314, 6 December 2022 ("To that end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level"). See also, Recital 36 regarding liaising with the WHO on the declaration of a public health emergency.

[225] 18 Art. 31(b), TRIPS ("Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government ... [only] if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.")

[226] This corresponds to the approach available in Art. 37(4) of the Commission Regulation on Proceedings before the Community Plant Variety Office: "The application for a compulsory licence shall be accompanied by

Step 1: MS Application and Preliminary Information Gathering

Once the availability of the EU CL procedure has been triggered, the Member State(s) in question may begin the application process.

Depending on the selected institutional arrangement in place[227], affected MS will disclose their previous failed attempts at reaching a voluntary agreement with the evaluating body or group of authorities in order to prove the need for a CL. Disclosure of this information can be made alongside other basic information on the parties, the serious nature of the crisis at hand, and the exceptional scope/cross-border element of the issue which would merit the CL solution. The parties which are identified at this stage will be continuously involved with the procedure for the CL assessment and grant, and should ideally have the right to enter into a voluntary agreement at any stage of this process should the agreement align with the needs of the MS concerned. However, individual or partially realised agreements between MS and the patent holder may prove a worse solution should the crisis require a unified and broader solution, and this is a danger inherent in initiating a procedure for a CL covering multiple MS territories.

Information on the relevant market for the product in question should also be gathered, disclosed and verified independently of the parties. This information would be used not only for determining the legitimacy of the request, but would also be used during the assessment stage for anticipating the effects of a CL granted at the EU level which applies across different EU markets. As mentioned above, a multi-territorial analysis regarding the current situation of MS should be conducted in advance order to accurately anticipate the potential impact of the grant of a multi-territorial CL.

Step 2: Assessment Stage

While several aspects of the assessment of a CL issued at the EU level have been summarised above, there will be a significant number of factors to balance in order to properly assess the need vs. the impact of the grant of a CL as a response to the crisis. This balancing of factors would necessarily be fact-specific, and potentially require novel assessments of the potential impact of issuing the CL in response to the unique circumstances of the crisis at hand. To complete this task, the authorities situated at the EU level which are deemed competent to make this assessment[228] should be allowed to consider a flexible, rather than fixed, list of criteria for completing the assessment of the grant or rejection of the CL in light of the crisis.

Nevertheless, some determinations can be made as a matter of course. As far as determining the scope of a CL issued at the EU level, the temporal limitations of the CL should ideally take into account a combination of factors relevant to the resolution of the crisis at hand, as well as principles of fairness and equitability on the side of the patent holder. The other approach could be to establish a fixed term (e.g., one year)[229], subject to

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documents evidencing that the applicant has applied unsuccessfully to obtain a contractual licence from the holder of the plant variety right. **Should the Commission or a Member State be the applicant for a compulsory licence pursuant to Article 29(2) of the basic Regulation, the Office may waive this condition in the case of force majeure**." (emphasis added).

[227] Sections 3.4.1.1, 3.1.4.2, supra.

[228] In this regard, the role of HERA may be of importance, as its level of specialisation and expertise (with such expertise already demonstrated with regards to its key role in negotiating JPAs at the EU level) can serve as a useful tool for facilitating the evaluation of requests for a CL made at the EU level.

[229] The CPV Regulation indicates a period for the CL lasting no longer than one year from the date of grant, subject to cancellation or amendment on request of the parties after one year. Art. 29(4) of Council Regulation on Community plant variety rights (EC) No 873/2004, 29 April 2004. ("On the expiry of each one-year period after the grant of the compulsory exploitation right and within the aforementioned possible time limitation, any

cancellation or renewal by the parties depending on the evolution of the crisis. At any rate, the term of a CL issued at the EU level should not be permanent, as this would contravene the purpose of the CL as a measure designed to solve a specific crisis. The geographical limitations of a CL issued at the EU level can also be clearly defined by the number of MS in crisis, but there is also a necessary assessment that should be made identifying the MS relevant for the channel of manufacturing and production of the product. Without this consideration, the CL may fail to remove all required obstacles for ensuring the provision of the required product in multiple MS in the most efficient manner.

A preliminary list of questions for the EU assessing authorities to consider would include, but not be limited to, the following:

- Does the current request for the CL in this instance comport with the principle of its use as a measure of "last resort"?
- Does the negative impact on patent holder unduly outweigh the public interest if a CL spanning multiple MS territories is granted in this instance?
- What other positive and negative externalities across MS markets can be anticipated at this stage? Have the parties produced enough evidence to support this determination?

Other elements of the EU assessing authority would include the following:

- Identifying "trusted licensees", customers, and all steps of manufacturing to safeguard the flow of sensitive, proprietary information;
- Establishing a timeframe which is suitable to respond to the crisis (potentially subject to cancellation or renewal after a period of time has elapsed);
- Setting license terms of remuneration based on a "fair market" evaluation of the license;
- Assessing the need for supplementary contractual provisions required (3.4.2.4.1).

To the extent possible, this assessment stage, particularly the authority/authorities' evaluation of the relevant factors described above, should be carried out as transparently as possible not only in the interest of the MS implementing the CL, but also in the interest of the public-at-large.

Finally, in defining appropriate procedures in the application for and evaluation of the CL issued at the EU level, some useful inspiration can be drawn from the procedures already laid out in the Regulation on Community Plant Varieties ("CPV Regulation") and the accompanying Commission Regulation on Proceedings before the Community Plant Variety Office ("Proceedings Regulation").[230]

Step 3: EU Recommendation and MS Implementation of CL

Once authorities competent to make the assessment for the grant (or rejection) of a CL issued at the EU level makes a decision, it would be the responsibility of EU executive actors, i.e., the European Commission or, alternatively, one of its DGs, to adopt a Decision directing the MS in question to issue the CL within its national territory. It is then the

of the parties to proceedings may request that the decision on the grant of the compulsory exploitation right be cancelled or amended. The sole grounds for such a request shall be that the circumstances determining the decision taken have in the meantime undergone change.")

[230] For further comment on the CPV Regulation and CPVO procedure, see van Overwalle, Geertrui (2023), "Food Security, Food Crisis and Boundaries to Intellectual Property," in: Improving International Intellectual Property. Festschrift in honour of Professor Rochelle Dreyfuss (forthcoming).

responsibility of the affected MS to recognise and implement this decision, with full respect to its national laws on CL.

Step 4: Monitoring and Enforcement

As it is currently the case with CLs granted based on competition law by the DG COMP and on the basis of public interest by the CPVO, any EU-level decisions should have the option of being appealed to the CJEU. The same would be applied regarding the decisions reached by EU level authorities regarding the grant or rejection of an application for a CL issued at the EU level.

After the grant of a CL at the EU level, since the CL will encompass a broader geographical scope and a wider range of stakeholders than a "typical" CL issued at the national level, certain measures related to monitoring the cross-border manufacturing and supply processes, import and export of the products between affected MS, and measuring the sufficiency of the response may be better accomplished at the EU level. To this extent, legislators might consider the addition of transparency-oriented measures which compel parties to produce information regarding aspects of the effectuation of the CL to an appropriate actor situated at the EU level (e.g., HERA). Centralising information gathering regarding the effects of the CL on the EU market for the product may also be necessary information with respect to conforming to relevant competition law. Furthermore, collaboration between national law enforcement and EU level authorities may be necessary in order to effectively to prevent the emergence of parallel markets/grey markets during a crisis.

Regarding potential infringement proceedings linked to the grant of a CL issued at the EU level, currently no legal system of enforcement is available at the EU level.[231] Instead, procedures will largely be governed by national law. In accordance with the existing rules governing cross-border jurisdiction over civil and commercial disputes as established in the Brussels Recast Regulation, at the national level a competent court can be determined, and where national courts maintain jurisdiction, the rules of procedure of the MS governing the type of action relating to the corresponding national property rights shall apply.[232]

For determining a reasonable duration for this administrative process as a whole, factors such as the complexity of the product to be manufactured as a result of the grant of the CL, the nature of the crisis at stake, and the number of MS involved, will have particular relevance.[233] The duration of similar existing administrative procedures taking place at the EU level, e.g., the grant of CL at the EU level under the CPV Regulation, the CPVO's review procedures, may provide a useful preliminary benchmark.[234]

3.4.2.3. Managing Externalities of a CL issued at the EU level

3.4.2.3.1 Complementary contractual provisions

[231] This may, however, potentially come under the purview of the Unitary Patent Court (UPC), should the CL in question relate to a patent which has been granted with unitary effect.
[232] Regulation 1215/2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recast) ("Brussels Recast Regulation") OJ L 351, 20 Dec 2012, p. 1–32.
[233] Additional potential factors relevant for this evaluation are described, below.
[234] One known procedure for the rejection of an application for a grant of a CL by the CPVO is documented in CPVO Decision NCL001 (CPVO Decision) [2018] (unpublished). For detailed analysis of the case, see Geertrui Van Overwalle & Amandine Léonard (2022), 'The Public Interest in Compulsory Licensing: Examining the Complementarity Between IP and Competition Law', in A Critical Mind in the Triangle of Internal Market Law, Intellectual Property and Competition Law – Liber Discipulorum for Hanns Ullrich, Christine Godt and Matthias Lamping (eds.), Springer: Berlin (forthcoming).

Stakeholders explained that patent holders which are subjected to a CL run risks that may not adequately be dealt with by the enforcement of patent and CL-relevant laws alone.

When a CL is issued in a time of crisis, there is need to structure around the CL some complementary contractual control mechanisms which can help to reduce the negative consequences of the CL once the crisis is over and the CL comes to an end.

For example, during the crisis and the period of the CL, the exchange of relevant know-how and trade secrets can be better controlled by only granting the CL to identified, capable manufacturers. This can also help to ensure that the know-how is not used or abused afterwards. To achieve this, patent holders and administrative authorities can prioritise the pre-approval of “trusted licensees”, identification and control of customers, and other strict monitoring steps to safeguard the flow of sensitive, proprietary information.

Safeguards are also needed after the crisis, which may include measures which prevent the emergence of a grey market for unsold surplus of products that were produced and stockpiled during the crisis period. This can have a negative effect on the original patent holder and his ability to obtain revenues from the production and sale of their product when resuming their normal production channels. Non-compete and non-sollicitation clauses may be also be needed for a limited period after the CL in order to restore the patent holder to his original position before the grant of the CL.

To achieve these goals, a complementary set of restrictive contractual clauses accompanying the issuance of the CL could be used for such scenarios, ranging from prohibitions of passive sales to prevent parallel imports, an order to destroy stocks after the crisis, vertical pricing arrangements, on-site inspections, etc.

Finally, additional remedies such as making available expedited judicial review and injunctive relief can further help to mitigate the externalities of granting a CL at the EU level. Stakeholders maintained that, in the interest of equity, the opportunity for obtaining injunctive relief for infringing use of a patent as a result of a CL should be made as simple and inexpensive as possible for patent holders.

3.4.2.3.2. Setting guidelines and principles for application of CL

As a consequence of the complexities of modern products, responses need to consider legal recourses available not just as a matter of IP protection, but also as a matter of good faith, best practices, and fairness.

Establishing principles of good faith, best practices and fairness can be accomplished at the EU level (in terms of issuing a CL at the EU level) by assigning a regulatory body (e.g. the European Commission) with the authority to issue such guidelines for the implementation and use of a CL issued at the EU level in times of crisis.

3.5. EU wide exhaustion

A product made with the consent of the holder of an EU-wide IP right (such a Plant Variety Right) or of a national IP right (such as a patent) enjoys automatically EU-wide exhaustion. A product made with the consent from the holder of a Unitary Patent also enjoys the right of exhaustion in the Participating Member States. [235]

That is not so for products made under a CL because the CJEU ruled in 1985 that a right holder does not give his consent in case of a CL.

As indicated before, it can be argued that the exception to this EU-wide exhaustion decided by the 1985 CJEU ruling of Pharmon vs. Hoechst is no longer applicable since the EU adopted TRIPS in 1994. This makes no longer the individual MS but the EU itself a "predominant market" and "domestic market". A CL would then (again) provide for exhaustion in the entire EU.

Confirming EU-wide exhaustion as a default rule and imposing the free circulation of products made under a CL is the most logical and most effective remedy to resolve many of the problems described in this study. It eliminates not only the need for seeking multiple CLs in multiple MS for the same product, or multiple CLs for the supply of their components, but also gives a greater reach to CL measures. Hence, it gives also greater leverage to authorities that consider to seek or grant a CL. The threat for a CL with EU-wide exhaustion will encourage IPR holders to enter into a voluntary licensing agreement that contains provisions to limit the benefit of the CL to the predominant market where the crisis is effectively taking place, and to prevent that these benefits spill over to other markets where there is no crisis and where the right owner would see his IP rights unnecessarily compromised. For instance, the right owner could agree with a licensee – regardless of whether he is under a CL or acting on a voluntary basis on certain temporary restrictive clauses to prevent parallel import, passive sales, and even allow vertical pricing only in the relevant domestic market where the crisis takes place. Such restrictive clauses could be exempted on an individual basis or be block exempted if certain thresholds are respected.

In case the crisis only affects a few member states and a CL is only needed in these few member states, the possible negative consequence of an EU-wide exhaustion for the right holder could likewise be avoided or alleviated via contractual agreements between the right holder and the licensee (regardless of whether he is benefitting from a CL or not). Such provisions could be scrutinized by competition authorities or be block exempted if certain conditions are met. This solution is to be preferred over the existing situation where a right holder is in the more confortable position to negotiate his license and does not feel sufficient pressure when confronted with the risk for a CL.

If the IPR owner receives a fair remuneration under the CL that equals the remuneration received under free market conditions with exhaustion, there should be no drawbacks to the introduction of such EU-wide exhaustion.

4. EU Import and Export from/to third countries

As aforementioned in the problem definition of CL for export, EU Regulation (EC) No 816/2006 does not include any "TRIPS plus" measures, meaning it does not add any provisions or limitations to Art. 31bis TRIPS and its Annex and Appendix.

[235] Article 6 of the Unitary Patent Regulation 1257/2012 of 17 December 2012. At the time of this study, there are 17 Participating Member States : Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia, Sweden. For an update see https://www.epo.org/applying/european/unitary/unitary-patent.html

Therefore, no provisions can be subtracted from Regulation No 816/2006. However, the existing Regulation may be clarified to promote the recourse to the CL for export mechanism provide for in Art. 31bis TRIPS and Regulation No 816/2006.

Art. 3 of the Regulation explicitly defines the competent authority as the authority competent to grant a CL under national patent law. As evidenced in the problem definition, competent authorities for assessing and granting a CL differ from one MS to another. With the lack of an EU-level guidance for potential importing countries to know to which authority to address, potential importers may not consider looking for a European licensor.

Moreover, section 2 of Art. 10 of Regulation No 816/2006 provides that, when determining the quantity of product manufactured under the CL to meet the needs of the importing country, the licensee shall take into account the amount of products manufactured under other CL granted elsewhere. In practice, the verification procedure may be lengthy, and further complicated if other CLs are granted in another member state while the manufacture is ongoing. Hence why, as mentioned in policy options for Domestic Use and Import above, even minimum level of coordination between EU MS could solve these issues and facilitate the implementation of the existing mechanism for CL for export.

III. Impact of Policy Options

5. Costs and benefits of the policy options

This section provides the economic analysis of each policy option, outlining the costs and benefits (cost-savings) that might arise from their implementation. Each of the policy options involves different legal, administrative, and other steps to establish a CL, with corresponding diverging cost levels.

As policy options in such analysis are usually hypothetical, the policy historical data on the actual costs of the options is scarce, as the policy options scarce either hypothetical proposals or very rarely used by EU MS. The analysis can only be prospective, based on costs anticipated through qualitative economic reasoning or advanced modelling techniques. In light of limited data availability which restricts the possible application of modelling techniques, a qualitative approach appears to be the most appropriate methodological choice.

The analysis is based mainly on qualitative information gathered through publicly available sources, stakeholders' questionnaire responses, and feedback from stakeholder interviews and workshops. Consequently, the economic assessment in this part has been primarily designed to help conceptualize the policy options by providing an economic perspective as a complement to the legal analysis conducted in the report.

Costs and benefits or cost-savings considered for assessing the effectiveness of each policy option follow the recommendations to the Commission provided in the revised Better Regulation Toolbox 2021[236]. For sake of clarity and in order to provide an appropriate conceptual framework to our study, we have taken the liberty of modifying/creating some definitions.

A first important distinction to be made is between generic costs and benefits of a CL and costs and benefits of a CL procedure resulting from a specific policy option. Generic costs and benefits of a CL are defined as costs and benefits which do not vary across policy options. These costs and benefits are at the hearth of the economic justification of a CL[237] and can be sketched as a trade-off between:

- Generic benefits consist of an improvement of market static efficiency through a decrease of the price of the corresponding product and an increase of the competition level. These benefits might refer to the concepts of "improved welfare" and improved market efficiency" from the Better Regulation Toolbox 2021.
- Generic costs consist of a deterioration of market dynamic efficiency through a potential decrease of firms' incentive to innovate. These costs might refer to the concept of "negative effects on market functioning" from the Better Regulation Toolbox 2021.

The theoretical and empirical arguments from the economic literature behind these generic costs and benefits elaborated are detailed in Annex V.

[236] https://ec.europa.eu/info/sites/default/files/br_toolbox-nov_2021_en_0.pdf
[237] In the rare cases where a generic cost or benefit varies because of a chosen policy option, we specify and include it in the policy option evaluation below.

By contrast to the generic costs and benefits of a CL, there are costs and benefits which vary according to policy options and that allow an assessment of the effectiveness of each of them. Costs and benefits (conceptualized as costs-saving in what follow) are based on an *ad hoc* typology of costs inspired by the revised Better Regulation Toolbox 2021. The typology is provided in Table 3.

Table 3

Typology of costs relevant to the study

	Administrative costs	Adjustment costs	Enforcement costs	Transaction costs	Crisis costs
Public authorities	x	x	x		
CL applicant	x		x	x	
CL licensor			x	x	
Citizen/Public					x

Costs and costs-savings are borne either by the relevant public authorities which are in charge of implementing the option procedure; the public which is affected by the crisis; the licensor of the CL; or the licensee of the CL. Costs are defined as follows:

- **CL administrative costs**: costs in implementing the granting procedures of the option such as costs of gathering, collecting, and processing information and resources needed to effectively build and monitor the procedure. These costs are borne mostly by the licensees applying to the CL granting procedure and the relevant public authorities monitoring the granting procedure. High administrative costs may deter the licensee to apply for the CL procedure, undermining the relevance of the option to face a crisis.
- **CL adjustement costs**: costs paid *ex ante* by public authorities, which are all the investments and expenses ("fixed costs") that public authorities will have incurred in regular times, i.e. before any crisis occurs, and which are, however, required for implementing the option (such as recruiting new public servants, paying for commissioned expertise etc.). We provide an estimation of such costs displayed in text boxes for each policy option.
- **CL enforcement costs**: *ex post* costs resulting from enforcing the terms of the CL, including, e.g. ensuring that the terms and conditions of the license are met/payment of the license is made, monitoring costs, inspection costs of third parties, beneficiaries of the license, and costs of having a dispute in court/litigation costs. Note that these costs can be borne by multiple stakeholders, including the patent owner, licensee, courts and/or public authorities depending on the nature of national CL laws and the underlying agreement. Enforcement costs linked to contractual arrangements and obligations are, in the case of a CL, mostly borne by the applicant/licensee.

- **CL transaction costs**: costs borne by licensees and licensors arising from the transaction. Transaction costs would encompass any informational costs incurred by the applicant (costs of preparing an initial license "bid", assessing willingness to pay of the licensor, negotiations, contract drafting, etc.). In the context of a CL, as the transaction is forced and partly handled by public authorities, some of these costs can also refer to the notion of hassles costs from the “Better Regulation” Toolbox. For a licensee, high transaction costs have a similar effect as high administrative costs or enforcement costs in deterring from applying for the CL procedure, which ultimately could undermine the relevance of the solution to face the crisis while high transaction costs can deter a licensor to further invest in R&D in the future, which ultimately could hinder the production of innovations on the market.
- **Crisis costs**: these costs are the only ones which are not explicitly mentioned by the Commission guidelines as they have been conceptualised for the context of this report which is first concerned with emergency issues. Crisis costs are defined as the costs undergone by the public during the duration of the granting procedures of the solution. Depending on the crisis at stake, these costs could also include social and environemental costs. A rough proxy for understanding these costs in a pandemic context such as COVID-19 crisis would be, e.g., the loss in GDP of restrictive measures (lockdown etc.) to contain the pandemic or the cost of the number of deaths caused by the absence of vaccines over the granting period of the licence. Put differently, these costs measure the “responsiveness” or “readiness” of the option to the crisis. The faster the granting of a CL is, the lower these costs will be, and the more responsive the option can be considered.

Following the Better Regulation Toolbox 2021[238], we assess each policy option against a benchmark, which is referred to as the baseline (scenario). The baseline reflects what would happen under a ‘no-policy-change’ scenario without new policy intervention, and assuming realistic implementation of CL existing legislations. In this report, the baseline is then the current status quo of the existing national-based CL procedures as detailed in the following section Policy Option 0. The four remaining policy options (Member State Coordination, Member State Harmonisation, EU-level CL and Exhaustion) are referred to as Policy Option 1, 2, 3 and 4 and are compared against the baseline outcome in terms of costs and benefits.

Baseline scenario

The baseline scenario is the current status quo of the existing national-based CL procedures to which we apply a “hypothetical crisis” . The main dimensions of the status quo are detailed in the legal analysis and are recapped below. The “hypothetical crisis” that is part of the baseline is described after the recap of the status quo.

Status quo recap:

Competences to grant CL

Most of the Member States have a general (i.e., not limited to certain sectors) competence to grant CLs for dealing with a crisis in whatever field: Austria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Lithuania, Luxembourg, Netherlands and Poland. Such legislations rely on the open clauses of “public interest” or “important public interest”. Three Member States, Belgium, Hungary and Italy, have

[238] European Commission, “Better Regulations Toolbox” November 2021.

competences limited to the field of health, and Ireland does not seem to have an explicit crisis-focused competence.

In the majority of EU MS, a court or other judicial body (administrative court or specialised court) is chiefly entrusted with the task of evaluating an application for and granting a CL. National ministries or the governments themselves are also often granted the ability to issue a CL, but in these cases another institution is usually also deemed competent to grant a CL: of the 13 MS that appointed a national ministry or government actor to issue CLs, each of these MS appointed another authority competent to issue a CL except Malta (only the ministry). In the few cases where only one authority was competent to issue a CL, that authority was usually a court (Croatia, Denmark, Finland, Romania, Slovakia, Slovenia, Sweden)(exceptions: Ireland (only IPO); Malta (only Ministry); and Poland (only IPO). In only 5 of the studied MS, it was reported that the usual authority for granting a CL would change under the circumstances of a crisis (Belgium, Greece, Italy, Lithuania, Luxembourg).

Scope of national CLs

Under the current CL regime, based on national law and domestic considerations, a MS cannot take into account the impact of a CL granted in its jurisdicion on the situation in other MS. Nor can it make EU-wide arrangements when issuing a CL that would aim at tackling a cross-border crisis. Patent law is still recognised and enforced on a national basis, and therefore any decisions regarding the grant or rejection of an application of a CL are necessarily confined to national-level considerations and the impact of a CL on a national market.

Furthermore, in the majority of the Member States, laws providing for CL in case of crisis refers to CL for “patent” in singular form. Some national experts consider that the literal interpretation of the law and the absence of cases to the contrary suggests that a CL could be granted only per single patent, e.g., in Austria, Bulgaria, Denmark, France and Luxembourg. At the same time, in a number of Member States where IP legislation also refers to “patent” in singular, national experts consider that the law does not prohibit that a CL covers more than one patent, e.g., in Estonia, Finland, Greece, Lithuania, Luxembourg, Poland, Romania and Spain.

A hypothetical crisis

There is a crisis occurring in ten MS. The crisis has caused a lack of an important product in the markets of all ten MS.

The product is produced by company D along a manufacturing chain located across four Member States, including two where the crisis is not present. The product is protected by several patents, trade secrets and data exclusivity protection. The product is complex and requires multiple manufacturing processes (i.e., multiple manufacturers). Patents are registered in each Member State by company D.

Among MS in crisis, only one company from one Member State has all manufacturing capacities for the product required to resolve the crisis (company A). However, company A has not obtained the relevant license of several underlying patents, trade secrets and data exclusivity protections from company D.

Two other Member States in crisis have only partial manufacturing capacities for the product required to resolve the crisis through company B and C. However, B and C have not obtained the relevant license of several underlying patents, trade secrets and data exclusivity protections from the company D.

In each of the ten Member States, in cases of "national emergency", voluntary negotiations are no longer required before applying for a CL. This crisis qualifies as a "national emergency" according to laws in all ten MS.

Policy option 0: Maintaining the status quo

Policy option 0 is unable to provide Member States with a systematic response to a situation of crisis such as the one described in the baseline scenario, resulting in a suboptimal collective result. In the status quo, not every Member State can solve the crisis in their domestic market because seven of them are not able to manufacture the product in the relevant Member State from which the CL is issued. Moreover, even for Member States which have the relevant manufacturing capacities, the implementation of a national-based solution would be costly and fraught with many uncertainties so that its relevance may be compromised as detailed below.

In the Member State in which company A operates, many costs are to be paid before it is able to produce the relevant product to deal with the crisis. Firstly, company A has to apply to four national CL procedures in the four Member States where company D is manufacturing the product for each underlying patent. Significant administrative and transaction costs will be incurred from the application process as a result of the diversity of the laws and regulations in force in each country. In addition, company A must also face significant uncertainties related to the application outcomes, as there are two Member States which are not in crisis and therefore might not be inclined to recognise the crisis situation in other Member States.

Assuming that all relevant CLs are granted, two other obstacles must be considered which incur other transaction costs. First, obtaining licenses may not be enough for applicants to operate since the product is also protected by trade secrets and data protections which are not included in the scope of most national CL procedures. Although remedies exist and have been recognised by many stakeholders interviewed for the study, such remedies could create further transaction and administrative costs, delaying the production and therefore the effectiveness of the solution to minimize crisis costs. In particular, the licensor would seek to protect itself from the negative externalities that could arise from the transfer of sensitive data, know-how or trade secrets through various contractual controls and provisions that could be long and costly to negotiate and implement by parties.

Secondly, in addition to CLs allowing the production in the relevant MS, applicant company A must also obtain a license to lawfully import the quantities produced in the MS in crisis. This second license in turn creates its own administrative and transaction costs that are added to the previous ones. It would not only increase the delays and therefore the crisis costs endured by the MS in crisis, but also the cost of fees and subsequently, the price of the imported products through the double pricing imposed by the licensor on the applicant (i.e. license fee to be able to produce, plus license fee to be able to import).

Regarding companies B and C, the costs to be paid are even higher as they do not have, by assumption, the full relevant manufacturing capacities. As a result, they have to incur further transaction costs and effort to lawfully obtain the relevant protected inputs from company D or from one of its suppliers in order to solve the crisis in their respective domestic markets. These additional costs would then generate further costs for implementing the CL solution in these countries. Ultimately, if one of these multiple procedures fails, related administrative and transactional costs borne by applicants and administrations would be invested at a loss, adding up to significant crisis costs.

Finally, the seven remaining MS in crisis in the scenario could not find any satisfying solution from this status quo option. They do not have the required manufacturing capacities and consequently undergo the highest level of crisis costs.

It is worth noting that in such a situation, crisis costs are not only increasing in the latter group of MS but also in other MS, including those not impacted by the crisis, in the form of negative externalities. Because EU economies are largely interrelated, any local aggravation of the crisis in some Member States directly impacts other national economies. Moreover, considering the crisis as evolutive, negative externalities may also eventually consist of the aggravation or the expansion of the crisis itself. For instance, in the event of a pandemic, the emergence of a new variant of the underlying pathogen could make it more contagious or make the product under CL less effective, requiring new emergency solutions.

Policy option 1: Member State Coordination

Policy option 1 consists of building upon the existing national-based CL procedures by formalizing a regulatory network of institutions. For a detailed description of this policy option, see Part III Section 3.2.

Benefits of the option

Policy option 1 builds upon the existing national CL granting procedure in each MS by formalising a regulatory network of institutions, within which information can be openly exchanged in order to properly weigh the pros and cons of granting a CL across multiple MS jurisdictions/EU wide. While the actual CL granting decisions would remain at a national level, such coordination should improve coherence, resulting in various costs-savings compared to the baseline situation with option 0.

The main advantage of this option relative to the policy option 0 is to decrease the administrative costs borne by CL applicants as coordination would allow the candidate licensee to face a less complex legal and administrative situation. For example, if an applicant submits a request for a CL in the four relevant Member States, instead of applying separately in each MS, coordinated efforts between relevant national regulators would enable a single application for a CL to be submitted and assessed by the relevant Member States.

However, since each MS retains its authority for national-level decision making, a successful (or unsuccessful) application for a CL in one MS may have no impact on the result of the application in another MS. In other words, in the absence of any further harmonisation of national laws, the only costs that seem to be mitigated through the application of policy option 1 would be administrative and/or transactional in nature. Furthermore, it is unclear if such a process would be more expedient than policy option 0, as the same periods of assessment would necessarily have to occur in each MS.

A final advantage of this option compared to policy option 0 is the increasing coordination among MSs regarding the conditions and threshold required to declare the crisis at stake as “national emergency” or “public health emergency”. In a similar fashion to what has been explained, such coordination would allow the CL applicant to potentially have a clearer understanding of the procedural conditions under which it can apply for a CL across multiple MS. Ultimately, where a MS mutually recognise the decision-making of the others regarding the declaration of a crisis/grant of a CL (perhaps via expedited review procedure), MS coordination as described in option 1 could avoid crisis costs where, under similar crisis circumstances occurring in several MS, multiple CL applications lead to unsystematic national responses (as exemplified by the policy option 0 analysis). Likewise, MSs which are not impacted by the crisis but have company D that is manufacturing part of its product could recognise more easily the situation of crisis of the other MS. This facilitates the gathering of relevant information which is a prerequisite of granting a CL.

Costs of the option

It is important to note that the relative benefits of policy option 1 over policy option 0 are conditional on the quality of the coordination carried out by the MSs ahead of the emergence of a crisis. Such efforts incur high administrative costs borne by public authorities. In addition to fixed costs associated with current MS authorities’ functioning (personnel necessary, wage costs, translation costs, secretariat, IT, etc.), additional costs of information sharing on a larger scale may consist of increasing funding for the relevant national bodies and improving or introducing new inter-MS networking mechanisms to better collect and exchange relevant information and practices across all the EU MS. To some extent, these costs can be conceptualised as a kind of “investment” in that they are mainly paid before the crisis occurs to save costs during the crisis (e.g., administrative costs borne by the licensee, as elaborated above). The net benefit of such a coordination network of national regulators would then depend, among other things, on the magnitude of the *ex-ante* administrative costs engaged by public authorities to ensure alignment. In order to minimize these costs and maximize the quality of the coordination, the report suggests relying on the successful experiences of existing structures such as the ECN or EMA.

However, several limiting factors might mitigate the overall net benefit of policy option 1: either by increasing the adjustment costs borne by public authorities or undermining the quality of the coordination that would result from it. First, one of the largest hurdles to overcome in suggesting a network of national regulators is that some of the actors may be completely competent to carry out the functions described above, while others may lack the finances, authority, or required expertise to carry out those same functions. As the legal analysis had demonstrated, there are a variety of MS approaches to allocating authority to evaluate and grant a CL. More specifically, the benefits of coordination could be very limited for MS assigning to courts the evaluation and the granting of a CL. Unlike ministries or administrations, courts do not have by design the capabilities to collect and process information required to conduct cross-border coordination. This diversity of national-level actors, both in terms of their institutional mandates and authority to regulate in the sphere of patent law, can then generate further administrative costs for seeking a CL covering multiple MS territories or obtaining a CL for manufacturing a product for the EU market as a whole.

Moreover, it is uncertain to what extent national-based coordination mechanisms alone can decrease administrative costs without further harmonisation in national laws. For example, coordination is of no help in aligning MS views about a legal definition for a scope of CL that would include other types of protections in addition to patents, except supposing a harmonisation which goes beyond the policy option 1 (and detailed in the policy option 2) as it requires a change in national laws. The same is true for other key legal definitions, such as the ones defining the conditions for which a crisis is declared as a "national emergency" or "public health emergency". If coordination is inadequate to align MS practices, the expected benefits in the form of crisis cost savings could vanish, reducing the net benefit of investing *ex-ante* in such coordination.

It should also be kept in mind that although policy option 1 may reduce administrative costs borne by applicants, these costs are likely to remain relatively high. Coordination does not in itself resolve the duplication of these costs due to the number of MS involved in the crisis, the number of underlying patents covered by CL procedure and the further contractual arrangements required for company B and company C to produce, as exemplified in the option 0 section. Similarly, enforcement costs mentioned in the analysis of policy option 0 and their possible duplication would not be substantially reduced by this option. Likewise, policy option 1 does not solve the fact that the scope of the CL may be still too limited in practice as the CL legislation in many MS's does not cover data exclusivity protection, leading to the same level of delay and crisis costs of ones exemplified in the baseline scenario with option 0.

Finally, policy option 1 does not provide any further solution compared to policy option 0 for the seven remaining MS. These undergo the highest level of crisis costs, which in turn causes related negative externalities that could impact other MS that are not in crisis, as exemplified in the policy option 0 section.

Exemplary quantification of administrative and coordination costs borne by public authorities for implementing Policy option 1 in regular times

Under Policy option 1, coordination will be established through setting up a network of national regulatory authorities (NRAs). Data on actual procedures of granting compulsory licenses are scarce, hindering accurate assessments of costs involved in dealing with a crisis situation. Nonetheless, we can develop a rough estimate of the costs borne by EU and national public authorities to design, implement and maintain the measures proposed under policy option 1, using wage statistics and informed estimates of full-time equivalents (fte) required. Importantly, this text box provides a quantitative estimate of the administrative and coordination costs in maintaining Member State coordination in non-crisis times.[239]

We apply a ten-year time horizon to map costs over a longer period of time, as different levels of costs are involved with establishing and maintaining the network of NRAs. Establishment of the network might be a relatively intense activity, but costs related to it are made only in the initial phase, while costs

[239] Useful indications of rough costs for establishing a network and maintaining coordination between national regulatory authorities within the EU comes from the *European Commission (2021). Annex to the Commission Implementing Decision on the financing of the Programme for the Union's action in the field of health ('EU4Health Programme') and the adoption of the work programme for 2021 (C(2021) 4793 final), Brussels, 24 June 2021*.

Under this programme, various measures involve similar activities, such as the preparation and establishment of a network of Comprehensive Cancer Centres (DP/C-g-10.1.2/3); coordination on pharmaceutical good manufacturing and good distribution practices (HS-g-18.2.1); a coordinated safety assessment (HS-g-18.3.1); support to the support the ERN eUROGEN Coordinating Centre (HS-g-22.2.1); developing health data semantic interoperability and build national capacity on health terminologies (DI-g-25.5.1); and recurrent horizontal and communication activities (OT-P-26.1). The budget allocated for such activities range from € 500,000 to several million €'s.

related to maintaining and coordinating communication between Member States are recurring, long-term costs.

In developing the estimate, we use a bandwidth consisting of a lower band (assuming limited effort) and a higher band (assuming substantial involvement). Both bands of the estimate are based on two parameters:

1. Average wage per national civil servant (for NRAs) and per EU policy officer

The average wage of national civil servants is established through the Eurostat database[240] on average remuneration of national civil servants in central public administration. The EU average wage is € 2,328.30 per month, which translates into an annual average of € 27,939.56 per fte.

We use the median salary of policy officers at the European Commission (€ 8,408.50[241]) as an estimate of the salary costs per fte for EU policy officers. This gives an annual average of € 100,902.00.

2. Overall fte involvement per NRA and for the European Commission

We estimate the phase of establishing the network to last for roughly a year. During this period, coordination is needed between a representative of each EU Member State to develop the structure and internal processes of the network. On average, such involvement could take 0.2 to 0.5 fte (or 1 to 2.5 days a week) per Member State in the establishment phase – these provide the lower and upper band. In addition, we foresee that EU-level policy officers will be involved to monitor and coordinate the process. This would require roughly 1 to 2 fte of EU policy officers.

Once the network has been established, the main involvement of Member States and the Commission will be to maintain the network and have frequent meetings (e.g. monthly or quraterly) to exchanges views, practices and considerations. On average, we expect this could cost 0.1 to 0.25 fte per EU Member State and 1 to 1.5 fte of EU policy officers over the remaining nine years of the reference period.

Based on these two parameters, we can make a **rough estimate of costs involved in both scenarios**.

In the scenario with limited involvement, total costs for the establishment phase (year 1) would be around € 250,000. For year 2 to 10, the total costs would be approximmately € 175,000 per annum – a total of nearly € 1.6 million. The estimated costs over the total reference period would be over € 1.8 million.

In the scenario with substantial involvement, total costs in year 1 would be around € 580,000. For year 2 to 10, the total costs would be approximmately € 340,000 per annum – a total of over € 3 million. The estimated costs over the total reference period would be roughly € 3.6 million.

Policy option 2: Member State Coordination & Harmonisation

Policy option 2 consists in harmonizing national legislation and practices, aligning the definitions and conditions for granting a CL in all EU MS, in addition to enhancing MS coordination. This option also addresses the system underlying CL decisions, e.g. by including in the CL application procedures of several patents if relevant, *sui generis* rights (SPC) and other types of IPR (data exclusivity). For a detailed description of this policy option, see Part III Section 3.3.

Benefits of the option

The first range of benefits from this policy option are similar to those identified in the policy option 1. However, because policy option 2 would imply a change in MS national laws

[240] Eurostat (2022). Average remuneration of national civil servants in central public administration (PRC_REM_AVG).

[241] The salary scale of the European Commission has 16 grades. We took the median salary from this scale (grade 8, step 5 – grade 9, step 1). Source: https://www.ecdc.europa.eu/sites/default/files/documents/Information-on-salaries-2022.pdf.

towards a unified and consistent set of definitions and conditions for granting a CL, administrative and enforcement costs should decrease more significantly. Most of the legal uncertainty and readability issues borne by the licensee, particularly costly in case of multiple CLs, should thus be resolved via this policy option.

Another relative benefit from policy option 2 compared to the two previous options is the improvements that would be brought to the CL system itself as part of the harmonisation process. Such improvements would allow to reduce significant administrative costs in situations where the product targeted by the CL is said to be complex, thanks to the possibility of gathering several patents in a single granting application. Because part of the improvements would consist of providing a new legal framework for other protections (e.g., data exclusivity, trade secret etc.), it could also decrease transaction costs compared to the policy option 0 in offering clearer legal conditions for the applicant during the negotiation and the implementation of the solution with the right-holder.

More importantly, CL harmonisation improvements would result in a greater effectiveness of the granted CL to face complex crisis, and thereby decrease crisis costs. In particular, as already mentioned above, the effectiveness of a CL proceeding from policy options 0 and 1 can be seriously undermined when complex products, either protected by several patents or by other protections (data exclusivity etc.) are involved. The fact that harmonisation would include the possibility to have a single CL application for both several patents and other types of related protections would lead to faster procedures and implementation of the solution. Ultimately, this faster and tailored granting process would allow the public to access products more quickly, saving them from crisis costs.

Costs of the option

Costs associated with the policy option 2 partly overlap with those identified in policy option 1. For example, the savings in administrative costs incurred during a crisis are conditional on the "investments" in adjustment costs relative to the coordination and the harmonisation process performed by the regulatory network. Policy option 2 could, however, require further adjustment costs for enabling relevant national authorities to manage the new competences and mechanisms given by the harmonisation framework, such as the ones implied by the extension of CL scope on data exclusivity or SPC etc.

It is worth noting that policy option 2 does not solve the duplication of the different kinds of costs stemming from the multi-territorial nature of the crisis compared to the status quo. Put differently, though the magnitude of the costs is much lower in this option compared to policy option 0, they are still to be multiplied by as many MSs affected by the crisis and for which national CL procedures are initiated.

Finally, policy option 2 does not provide any further solution compared to policy option 0 for the remaining seven MS. These undergo the highest level of crisis costs, which in turn causes related negative externalities that could impact other MS that are not in crisis, as exemplified in the policy option 0 section.

Exemplary quantification of administrative and coordination costs borne by public authorities for implementing Policy option 2 in regular times

Policy option 2 incorporates the efforts of policy option 1 related to establishing a network of NRAs. In addition, it involves the harmonisation of national legislation and practices, aligning the definitions and conditions for granting a CL in all EU MS. We will again develop a rough estimate of the costs borne by EU and national public authorities to design, implement and maintain the measures proposed under policy option 2.

We rely on the same base principles and parameters as in policy option 1, in terms of applying a similar bandwidth, wage statistics, time horizon and focusing on costs involved with non-crisis times. New assumptions will be made about the full-time equivalents (fte) required by NRAs and EU institutions.

Overall fte involvement per NRA and for the European Commission

As in policy option 1, we assume different levels of involvement in the initial phase (involving the establishment of the network and the harmonisation of the national legislation and practices) and the remainder of the time horizon (maintaining and coordinating the network of NRAs).

We estimate the initial phase to take more time than in policy option 1, as it involves negotiations around harmonisation of national legislation as well as setting up the network. Academic literature finds that a one-shot negotiation process – from tabling of a proposal to publication of the final act – takes 21 to 23.5 months in non-emergency cases.[242] Hence, we expect the initial phase to last for roughly two years in policy option 2. During this period, intense collaboration and negotiation is required between representatives of each EU Member State to develop the structure and internal processes of the network. On average, we expect this process to require non-stop involvement of 3 to 6 fte per Member State. In addition, we foresee that EU-level policy officers will be involved to monitor and manage the process. This would require roughly 3 to 5 fte of EU policy officers.

Once the network has been established, involvement of Member States and the Commission will reduce and focus primarily on maintaining the network, similar to policy option 1. In line with policy option 1, we expect this could cost 0.1 to 0.25 fte per EU Member State and 1 to 1.5 fte of EU policy officers over the remaining eight years of the reference period.

Based on these capacity estimates, we can make a **rough estimate of costs involved in both scenarios**.

In the scenario with limited involvement, total costs for the initial phase (year 1 and 2) would be around € 5.1 million. For year 3 to 10, the total costs would be approximmately € 175,000 per annum – a total of nearly € 1.4 million. The estimated costs over the total reference period would be over € 6.5 million.

In the scenario with substantial involvement, total costs in year 1 and 2 would be around € 10 million. For year 3 to 10, the total costs would be approximmately € 340,000 per annum – a total of over € 2.7 million. The estimated costs over the total reference period would be roughly € 12.8 million.

Policy option 3: EU-level compulsory licence

Policy option 3 consists of creating the option of issuing a CL at the EU level in times of crisis. For a detailed description of this policy option, see Part III Section 3.4.

Benefits of the option

The most obvious advantage of this option is the significant savings of multiple cost categories. Particularly, the costs borne by the licensee candidate for the CL, as it eliminates the requirement for applying for and obtaining multiple CLs per jurisdiction in times of a crisis spanning beyond one MS jurisdiction. Due to a unique and centralised procedure at the European level, the total delay of the CL granting procedure would also be greatly reduced, allowing a faster implementation of the solution, and thus substantially reduced crisis costs.

Importantly, because the EU CL outcome would be applied in all the EU countries in crisis, policy option 3 does provide a viable solution to MS countries which do not have relevant manufacturing capacities. This would lead to a significant decrease in crisis costs that were impossible to contain in policy option 0.

Similar to policy option 2, the coherence and the speed of this policy option would increase in bringing to the EU-CL system the possibility of gathering several patents and data

[242] Reh, C., Héritier, A., Bressanelli, E., & Koop, C. (2013). The Informal Politics of Legislation: Explaining Secluded Decision Making in the European Union. *Comparative Political Studies*, *46*(9), 1112–1142. https://doi.org/10.1177/0010414011426415

exclusivity protections in a single granting application, allowing to reduce further administrative costs and crisis costs in making its implementation faster.

Decision making at the EU level can provide a stronger sense of legal certainty for the right-holder in having a larger range of possibilities to select "trusted licensees" compared to policy option 0 in which applicant selection is constrained by the geographical scope of the CL. As explained in the legal part, the exchange of relevant know-how and trade secrets in order to produce the product could be better controlled by only granting the licence to "trusted licensees", suggested by the licensor, in order to control the flow of underlying sensitive, proprietary information, and subsequently mitigate transaction and enforcement costs. More generally, trust is unanimously recognised as an effective way to reduce transaction costs, allowing to reduce the costs and time spent on negotiating and monitoring contracts. Offering additional remedies such as making available expedited judicial review and injunctive relief can further help to mitigate the externalities of granting a CL at the EU level.

EU-CL option can also result in higher economic efficiency compared to policy option 0. Indeed, in the status quo option, the production route for the applicant is, by law, confined to MS from which national CLs have been granted. Companies could find further legal solutions to bypass these limitations, but this would cause additional administrative and transaction costs and delays. By contrast, within the framework of the EU-CL option, the applicant would no longer be limited geographically and could, therefore, select the most efficient route at its disposal to the production of goods throughout the single market without incurring additional costs. This would allow the applicant to not only save significant administrative costs compared to policy option 0 (related to multiple importation licences procedures etc., for example) but to produce also at lower costs and then at a lower price, reducing crisis costs even more.

A similar beneficial effect on production costs and prices might be expected through greater economies of scale as the EU-CL procedure would select a single applicant for producing all the required quantities to solve the crisis in the MS in crisis by contrast to the outcome in policy option 0 in which several companies (A, B, and C) produce separate quantities for domestic markets in which they operate.

Another consideration for policy option 3 is the associated generic costs and benefits of CL detail in Annex V. The simultaneous existence of CL at EU-level and at national-level means that positive and negative externalities at the European level could be internalised more easily. The EU institution could integrate some these externalities in their decision process. At least three elements from Part 1 could be included:

1. The level of competition at the EU-level and not only at the country-level will be better analysed by European institutions rather than national ones. CL is effective against the excessive market power of a firm and stimulates innovation path, especially when the ex-ante level of competition is low.[243] But the *ex-ante* level of competition at the national level could be low at the national level and not at the EU-level, which reduces the effectiveness of a CL at EU-level. If there is no EU-level institution in this decision, the use of CL triggers some negative externalities related to the market power.
2. The patent owner forced with a CL could still segment the international market and European institutions could internalize the global firm strategy. With a CL, firms lose control over their optimal pricing strategy, but they could compensate for the losses by setting higher prices in other countries. The price strategy is still determined by the consumer's willingness to pay, and a European institution could determinate in which countries the firm will compensate the losses. This "beggar-thy-neighbour"

[243] Seifert, J. (2015). Welfare effects of compulsory licensing. *Journal of Regulatory Economics*, *48*(3), 317-350.

policy at the national level could trigger prices in other European countries or in other non-European countries, whereas a European institution internalize this risk.

3. Because the CL also support local production and corresponding national employment/industry, European institutions could internalize the potential “beggar-thy-neighbour" policy from European countries using CL. Because it could reallocate the industries within European countries, European institutions will include these mechanisms in their decision, and it will be in line with their common industrial policy.

Finally, as already suggested in the legal part, another advantage of this solution is that it would provide stronger incentive to the right-holder to be engaged in voluntary licence negotiations with potential applicants compared to the policy option 0. Indeed, as policy option 3 consists of making the CL procedure more cost-efficient and easier to implement when facing a cross-border crisis compared to policy option 0, the threat of a CL being actually granted is higher, encouraging further the right-holder to find a more profitable solution through a voluntary license agreement.

Costs of the option

The benefits of policy option 3, mentioned above are highly conditional on the quality of the interplay between on the one hand, the national level of CL granting procedures, and, on the other hand, the CL EU-level. Depending on the quality of this interplay, the administrative and crisis costs of policy option 3 could vary. Indeed, the higher the criteria for meeting thresholds required to trigger an EU-CL, the more MS and applicants would rely on national CL solutions (when such solutions are available), despite their relative ineffectiveness in addressing the crisis. However, the magnitude of this issue should be significantly mitigated by the fact that the criteria proposed in the legal part of the report are low so that it is possible to easily trigger the examination of the EU-CL solution to resolve the crisis.

Regardless of this CL trigger conditions issue, costs of policy option 3 consist mainly of adjustments costs borne by public authorities for both elaborating the EU-level CL directive or regulation and running the related EU body. These latter costs might be lower in the case of a regulatory consortium relying on existing regulatory authorities compared to the creation of an *ad hoc* EU entity. Adjustment costs could also occur at the national level as the directive or regulation would require, to some extent, to change the national law and administration practices. For example, it may become necessary to provide for the stay of national (or UPC) infringement proceedings (or to lift temporary injunctions or seizures) in order not to affect the effectiveness of a CL issued at the EU level.[244] However, as conceptualised in policy option 2, these adjustment costs can be seen as “investments” committed before the emergence of a crisis in order to limit administrative costs during the crisis (especially those paid by the applicant) or, in this case, benefit from an EU-level CL solution to face complex crises and then spare ultimately dramatic crisis costs that may result from relying on policy option 0.

For the same reasons as those explained in policy option 2, policy option 3 could also generate high transaction costs between licensees and the licensor and high enforcement costs in enlarging the CL scope. In particular, the licensor would tend to protect himself from the negative externalities that could arise from the transfer of sensitive data, know-how or trade secrets through various contractual controls and provisions that could be time-consuming and costly to both negotiate and implement. If such externalities are later found to exist once the licence expires, then *ex post* transaction costs, typically incurring in the form of litigation costs, may also arise in addition to adjustment costs.

[244] The Commission has authority to do so in, for example, the Regulation on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, (EU) No 1215/2012, OJ L 351, 20 December 2012.

Finally, specific administrative costs resulting from the multi-territorial nature of EU-level CL may also arise during the EU-level CL approval procedure that could impact the length of the procedure and generate further difficulties. In particular, for the scope of a CL to cover the territory of two or more MS, relevant EU authorities would have to consider the relevant circumstances in the MS concerned. For example, a situation may arise where a MS is given an unfair advantage by allowing a product manufactured under a CL granted to it to be delivered in MS where a parallel patent exists.[245] It seems, therefore, imperative that a proper multi-territorial analysis regarding the current situation of MS is conducted by the relevant EU body in advance, in order to accurately anticipate the potential impact of the grant of a multi-territorial CL.

Example of quantification of administrative and coordination costs borne by public authorities for implementing Policy option 3 in regular times

Policy option 3 consists of creating an EU-level entity for issuing a CL in times of crisis. This requires personnel investment from relevant public authorities to elaborate the EU-level CL directive or regulation and run the related EU body. We will again develop a rough estimate of the costs borne by EU and national public authorities to design, implement and maintain the measures proposed under policy option 3.

We rely on the same base principles and parameters as in policy option 1, in terms of applying similar wage statistics, time horizon and focusing on costs involved with non-crisis times. New assumptions will be made about the full-time equivalents (fte) required by NRAs and EU institutions. The bandwidth will again use a lower and an upper band, where the lower band represent the option of a Regulatory consortium while the upper band signifies the option of an ad hoc EU entity.

Overall fte involvement per NRA and for the European Commission

As in the previous options, we assume different levels of involvement in the initial phase and the remainder of the time horizon.

At the national level, we assume a similar involvement in negotiations and preparations from national civil servants authorities as under policy option 2 in the initial two-year phase (3 to 6 fte per Member State). From the third year onwards, we assume the costs of maintaining frequent interaction with the new EU body will mimic the fte involvement in policy options 1 and 2 as well (0.1 to 0.25 fte per Member State).

We expect that a larger effort is required predominantly at the EU-level for establishing EU-level CL rules and a related EU body. In total, we expect that these two steps take 12 fte in the initial two-year phase in the case of the Regulatory consortium, and up to 24 fte in case of an ad hoc EU entity. In the remainder of the reference period, we assume a total of 12 fte are involved with coordination and management of the Regulatory consortium, while 30 fte are assumed to be necessary to run the EU entity.

Based on these capacity estimates, we can make a **rough estimate of costs involved in both scenarios**.

In the scenario with a Regulatory consortium, total costs for the initial phase (year 1 and 2) would be around € 6.5 million. For year 3 to 10, the total costs would be nearly € 1.3 million per annum – a total of nearly € 10.3 million. The estimated costs over the total reference period would be over € 17.2 million.

In the scenario with a EU-level entity, total costs in year 1 and 2 would be around € 13.9 million. For year 3 to 10, the total costs would be approximmately € 3.2 million per annum – a total of over € 25.7 million. The estimated costs over the total reference period would be roughly € 39.6 million.

[245] CJEU case 19/84, 9 July 1985, Pharmon vs. Hoechst, para. 19: "the objectives of a compulsory licence and a licence freely granted are different. Whilst a licence freely granted is a means of exploitation, which goes to the specific subject-matter of the patent right as defined by the Court, a compulsory licence, on the other hand, is essentially intended to meet the special needs of a Member State. Accordingly, it would be unfair, and even dangerous, to accord that Member State a further advantage by allowing a product manufactured under the compulsory licences granted by it to be delivered directly in Member States where a parallel patent exists." (emphasis added).

5.2.4. Policy option 4: Exhaustion

Policy option 4 consists of confirming EU-wide exhaustion as a default rule and imposing the free circulation of products made under a CL. For a detailed description of this policy option, see Part III Section 3.4.

Benefits of the option

Similar to policy option 3, the first range of benefits of this option consists in the savings of many administrative and transaction costs borne by the applicant in significantly simplifying the overall process for obtaining a CL. With the EU-wide exhaustion, applicant is no longer obliged to request multiple CLs in the relevant MS to be able to produce and eventually import the product in the MS in crisis. Only one CL procedure issued in one MS is required for the applicant to be authorized to produce and then sell the product in the whole European market.

Administrative costs borne by public authorities should also significantly decrease compared to policy option 0 as such costs would be only borne by the national public authorities involved in the unique CL procedure. The same reasoning hold with enforcement costs, which would significantly decrease compared to the policy option 0 as there would be only one CL to monitor and enforce for the whole EU market.

It is worth noting that, as EU-wide exhaustion imposes the free circulation of the product made under CL in the EU market, benefits would not be confined to MS in crisis but in those where the crisis is not present. Such benefits would first consist of a decrease of the price of the product under CL through parallel imports within EU. The economic literature has indeed collected evidence showing that parallel imports result in a decrease of the price of the product as producers may face higher competition through parallel import products.[246] Thus, in addition to providing a solution for all MS in crisis from the baseline scenario, including those which do not have any manufacturing capacities, exhaustion increases the static efficiency of the CL product market at an EU scale.

Likewise, policy option 4 would lead to significant economies of scale as the procedure would select a single applicant which would produce all the required quantities to solve the crisis in the impacted MS, resulting in a more cost-efficient situation compared to policy option 0.

Similarly, a final advantage of this solution compared to policy option 3 is that it would provide stronger incentive to the right-holder to be engaged into voluntary licence with potential applicants compared to policy option 0. This is because within the framework of a voluntary license the right-holder can contractually negotiate clauses limiting, among other things, the geographical scope of the license to MS in crisis so that the company could still benefit from a monopoly rent in the MS not affected by the crisis. Thus, the right-holder has

[246] See e.g. Ganslandt and Maskus (2004), which provided the first statistical analysis on parallel imports based on Sweden dataset. They found that the prices of original producers decreased by competition from parallel imports with a reduction of their pricing power by 12 to 18 %. Based on data from six markets in the EU, Kanavos and al. (2004) found that direct savings from parallel import were around 45 million € in 2002. However, they also found that the profit margins of parallel import companies ranged from 46 to 60%, suggesting that the magnitude of reduction of costs for patients is highly mitigated by the pricing strategy of importers. More recent studies as the one Duso et al. (2014) find that parallel import for patented anti-diabetic drugs in Germany reduces the price by 11%. Méndez (2018), based on a Danish dataset for statins, find a moderate price effect by 3% but a reduction of total welfare by 18% of the yearly market revenue due, in particular, to a smaller variety of drugs available to the consumer. Using 2003–2007 data from Sweden Granlund and Köksal-Ayhan (2015) investigate whether EU enlargement in 2004 increased competition from parallel imports. They find that drugs facing competition from parallel imports are found to have on average 19–22% lower prices than they would have had if they had never faced such competition. Because of some methodological limitation, Granlund (2022) has conducted a new study finding that parallel imports were on average 9% cheaper than locally sourced drugs, which yielded a direct saving of 24 million € per year.

every interest in engaging in such voluntary negotiations rather than waiting for a MS in crisis to grant a CL, which would then lead to the exhaustion of rights and thus the dilution of its monopoly rent on the entire EU market.

Costs of the option

Costs associated with the policy option 4 compared to policy option 0 are first related to adjustment costs borne by national MS authorities as the exhaustion directive or regulation would require changing the national law. However, most of the adjustment costs are to be found at the EU level, vis à vis competition authorities which would be in charge of examining the provisions negotiated between the right holder and the applicant within the framework of voluntary licence conducted by the right holder in order to avoid the implementation of a CL with exhaustion. In particular, EU competition authorities would have to scrutinise to what extent these provisions do not exclude the agreement from the MS in which the crisis is occurring.

Example of quantification of administrative and coordination costs borne by public authorities for implementing Policy option 4 in regular times

Policy option 4 consists of confirming EU-wide exhaustion as a default rule, which requires a policy process at EU-level without involvement from national NRAs to change the EU-level rules of exhaustion. We will again develop a rough estimate of the costs borne by EU and national public authorities to design, implement and maintain the measures proposed under policy option 4.

We rely on the same base principles and parameters as in policy option 1 and 2, in terms of applying a similar bandwidth, wage statistics, time horizon and focusing on costs involved with non-crisis times. New assumptions will be made about full-time equivalents (fte) required by NRAs and EU institutions.

Overall fte involvement per NRA and for the European Commission

Once again, we assume different levels of involvement in the initial phase (involving the implementation of rules on exhaustion at the EU-level) and the remainder of the time horizon.

We estimate the initial phase to last for three years. Like policy option 2, the first two years will be used for policy negotiations, while the third year will be used for the implementation of the exhaustion rules. The period will require intense involvement from EU policy officers, as well as some involvement from the Member States in monitoring how the situation will impact national rules and providing possible support or inputs to the Commission. On average, we expect this process to require involvement of 1 to 2 fte per Member State. In addition, we foresee that EU-level policy officers will be involved intensively in the preparation and throughout the process. This would require roughly 5 to 10 fte of EU policy officers in the initial phase.

Once the new rules are in place, we assume that involvement of national civil servants will be completed (0 fte per Member State). Given the formalisation of the EU's competences and authority regarding the new rules, we assume EU-level policy officers will remain involved to monitor, evaluate and (if necessary) intervene to ensure its seamless functioning. We expect this would involve 2 to 4 fte of EU policy officers over the remaining years of the reference period.

Based on these capacity estimates, we can make a **rough estimate of costs involved in both scenarios**.

In the scenario with limited involvement, total costs for the initial phase (year 1 to 3) would be around € 3.8 million. For year 4 to 10, the total costs would be approximmately € 200,000 per annum – a total of roughly € 1.4 million. The estimated costs over the total reference period would be € 5.2 million.

In the scenario with substantial involvement, total costs in year 1 to 3 would be around € 7.6 million. For year 4 to 10, the total costs would be approximmately € 400,000 per annum – a total of over € 2.8 million. The estimated costs over the total reference period would be roughly € 10.4 million.

6. How do the options compare?

In this section, we provide a general discussion of all the different policy options resulting from the economic analysis conducted above.

The analysis reveals that the status quo *policy option 0* is the least preferred option. Indeed, although this option may be workable in "simple" crisis situations, involving for example two or a few MS, it remains the costliest due to the diversity/heterogeneity of MS CL legislations and their relative inability to cover certain types of protections (data exclusivity etc.). Thus, while some administrative and transaction costs might be saved *ex ante* as the option does not require any change in the MS law or practices, enforcement, transaction, and administrative costs are expected to increase dramatically when the crisis scenario includes an ever-increasing number of MS, as exemplified in the baseline scenario. Such cost levels could jeopardize the implementation of coordinated and effective solutions among MS to minimize crisis costs, especially since these efforts would have to be carried out in an emergency. More importantly, this policy option does not offer any viable solution to MS which do not have the manufacturing capacities to produce the product, as exemplified in the baseline scenario with the seven remaining MS.

By contrast, *policy options 1 and 2* consist of investing in administrative efforts from public authorities before the emergence of a crisis in order to increase MS coordination and responsiveness capabilities and then decrease administrative costs (especially those paid by the applicants) when a crisis arises.

As explained above, *policy option 2* could however require more adjustment costs to enable relevant national authorities to manage the new competences and mechanisms given by the harmonisation framework, such as the ones implied by the extension of CL scope on data exclusivity or SPC etc. However, the net benefit of such further "investments" appears to be clearer in this option compared to policy option 1 as they would result in a CL system adapted to more crisis scenarios in enhancing and aligning the national CL systems themselves (i.e., possibility for the licensee candidate of grouping several patents and/or other protections in a single procedure etc.), which would result in a more consistent and faster speed of implementation of the solution. Then, policy option 2 outperforms policy option 1 in all the cost dimensions. In particular, policy option 2, through combining coordination and harmonisation mechanisms, would be able to go further in saving administrative, transaction and enforcement costs in a context of multiple national CL granting procedures, which ultimately translates into reductions of crisis costs.

However, policy option 2 remains sub-optimal given the fact that, ostensibly, decision-making still has to take place on a MS-by-MS basis; harmonisation, even to a significant extent, does not mean eliminating binding EU legal principles such as subsidiarity. As it remains at the exclusive initiative of the MS, option 2 could indeed lead to unsystematic or inconsistent MS responses to a crisis as an increasing number of MSs are involved, despite the harmonisation efforts made before the crisis. This is evidenced in the scenario by the fact that policy option 2 is unable to offer any satisfactory solution for solving the crisis in the seven remaining MS which do not have any manufacturing capacities in the relevant MS.

The analysis shows that the two most relevant options to face the crisis described in the baseline scenario are policy option 4 and policy option 3. Indeed, policy option 3 outperforms policy option 2, and *a fortiori* policy option 1 and 0, in providing a tailored EU-CL licence that would be applied to all MS considered as in a state of crisis. This would result to very significant crisis cost savings compared to the policy option 1 and 2 in which the remaining seven MS undergo the maximum level of crisis costs. Likewise, policy option 4 would also result in lower crisis costs compared to option 1 and 2 in allowing every MS to have a wider access to the product and then solve the crisis through parallel import.

It is worth noting that administrative costs borne by public authorities could also be lower in policy option 3 compared to policy options 1 and 2 thanks to its more centralised nature. Indeed, while policy option 3 is certainly more costly in terms of adjustment costs paid *ex ante* as it would require creating an EU-CL system from scratch, it is nevertheless less costly to implement when a crisis occurred compared to policy option 2 for which each MS must constantly invest in communication and information efforts in order to implement their national-based solutions. Option 3 creates indeed a different avenue to apply for a CL, from the "top down" - the only "harmonisation" would be the fact that all EU MS agree to recognise and apply the decisions made at the EU level, regarding both the declaration of a crisis and the necessity to grant a CL. Thus, at the assessment and enforcement stages of the CL timeline, an EU option would seem to eliminate the need to MS to coordinate crisis/CL grant decision making (i.e., informational exchanges) individually among many different MS authorities. Moreover, as explained above, the adjustment costs of policy option 3 could be contained by engaging existing European authorities.

Considering policy option 3 and 4 as the most appropriate ones, we will now compare their relative costs and benefits. Because policy option 4 does not rely on creating a new CL system, the adjustment cost would be lower by the ones paid for in policy option 3. Moreover, if an EU-wide exhaustion CL is eventually granted, economies of scale from the applicant could even be higher compared to policy option 3 as the applicant would be allowed to provide the whole EU market with the CL good instead of being constrained to produce quantities only for MS in crisis.

For that reason, policy option 4 offers the most threatening solution for right-holders compared to all the other alternatives, including policy option 3, as the CL outcome would impact the whole EU market through parallel imports. In this perspective, EU-wide exhaustion appears as a two-edged solution: on one hand, the incentive of the right-holder to find a voluntary agreement is even higher compared to policy option 3 because of the higher magnitude of its shortfall through the EU-wide exhaustion, on the other hand, it is precisely because such solution could generate a significant higher level of shortfall compared to policy option 3 than it could compromise further dynamic efficiency as detailed in the Part 1 of the report.

This issue is made even more complicated by the fact that the solution remains ultimately in the hands of MS while its effects are EU wide. Then, it could be that one or several MS decide to a grant “unilaterally” an EU-wide exhaustion CL – because, for instance, the voluntary agreement between the right-holder and the applicant under discussion does not provide for the inclusion of these MS in the license scope – whereas this solution prove to be disproportionated to fix their own domestic situations. If such behaviours occur, it could further deter the right-holder to invest in R&D in the future compared to other options as its monopoly rent would be dissipated not only in the domestic markets of MS in crisis but also in the whole EU market. Put differently, the fact that the decision to grant an EU-wide exhaustion CL is a pure national-based decision while having direct consequences for the EU market as a whole can lead to a suboptimal situation in which a CL is granted even though it appears to be over-dimensioned to solve all or part of the crisis.

It is also worth considering an opposite situation, in which, for example, the crisis is only present in MS that do not have any manufacturing capacities in the relevant MS to solve the crisis. In such a scenario, the three MS in crisis incur the same crisis costs as the ones of the remaining seven MS from baseline scenario for policy options 0, 1 and 2, because they do not have the legal means to trigger the CL, diminishing the right-holder incentive to find a voluntary license agreement.

The fact that Policy Option 4 is triggered and deployed only at the national level also further constrains the right-holder and potential applicants in their production/partner choice compared to policy option 3. On the one hand, the right-holder has less latitude in choosing the applicant, who must necessarily be located in the country in which the CL is issued. Conversely, the applicant is constrained in its choice of production route as it would be

restricted to select only facilities present in the country in which the CL is issued, as in policy options 0, 1 and 2.

Finally, because policy option 4 remains at the national level, this option cannot internalise the positive and negative externalities as explained in the policy option 3 (and detailed in the Part I) in which the decision process is centralised at the EU level.

In conclusion, the above theoretical comparison of the policy options reveals that policy options 3 and 4 seem to provide the most optimal approaches for policy action. The assessment shows that policy option 4 is the less costly to implement, especially in terms of adjustment costs, though it might create coordination issues because of its national-based nature, making policy options 4 a more resilient solution.

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Annex I: CLs for export during COVID-19

Current Antigua and Barbuda's demand:

On May 12 2021, Antigua and Barbuda notified the WTO's TRIPS Council of their general intent to use the compulsory license system provided under Art. 31 bis TRIPS (WTO Notification IP/N/8/ATG/1, 17/05/2021)[247]. The nation had been significantly impacted by the pandemic, and although it had received 40,800 doses of COVID-19 vaccines through the COVAX Facility in April 2021, it still could not vaccinate enough of its population. As of the time of writing of this report, Antigua and Barbuda has not yet submitted its specific notification for the use of the Paragraph 6 system, in which it must indicate its lack of manufacturing capacity (or insufficiency of that capacity to meet the national needs), as well as the identified patent with the authorization (or intention to authorize) of the exporting Member to issue a compulsory license[248]. In this specific notification, the importing member (Antigua and Barbuda) must also notify the names and expected quantities of the pharmaceutical product needed to the TRIPS Council[249]. This specific notification is essential under the mechanism provided for under Art. 31bis TRIPS.

It can be assumed that, given the publicly accessible data, Antigua and Barbuda has no manufacturing capacity[250]. No presumption can be made as to the identity of the importing country, as it is not publicly known whether Antigua and Barbuda had entered into negotiations with any pharmaceutical company or any potential exporting member in general.

Bolivia's demand:

Bolivia notified the TRIPS Council of its need to import pharmaceutical products under the special compulsory license system set out in Article 31 bis of the TRIPS Agreement, and the Annex and Appendix to it (WTO notification IP/N/8/BOL/1; 17/02/2021)[251].

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[247] WTO Notification IP/N/8/ATG/1: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Language=ENGLISH&SourcePage=FE_B_009&Context=Script&DataSource=Cat&Query=(((%40Symbol%3d%22IP*%22+OR+%22JOB*%22+OR+%22WT%2fL%2f*%22)+AND+(%40Title%3damend*+AND+%40Title%3d%22trips+agreement%22)+NOT+(%40Title%3dchina+OR+acceptances+OR+%22regulations+under+article+63.2%22))+OR+(%40Symbol%3d%22WT%2fLET%2f1236*%22))+&DisplayContext=popup&languageUIChanged=true

[248] WTO, Guide to notifications, Model notifications for the use of the Paragraph 6 system, Model 2: Importing Member's Specific Notification: https://www.wto.org/english/tratop_e/trips_e/art31bis_modelnotifs2_e.htm

[249] L.G. Abinader, "Antigua and Barbuda notified the WTO of their intent to import products using compulsory licenses", Knowledge Ecology International Blog, June 2021: https://www.keionline.org/36241

[250] Ibid, supra, p. 115

[251] WTO Notification IP/N/9/BOL/1 : https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Language=ENGLISH&SourcePage=FE_B_009&Context=Script&DataSource=Cat&Query=(((%40Symbol%3d%22IP*%22+OR+%22JOB*%22+OR+%22WT%2fL%2f*%22)+AND+(%40Title%3damend*+AND+%40Title%3d%22trips+agreement%22)+NOT+(%40Title%3dchina+OR+acceptances+OR+%22regulations+under+article+63.2%22))+OR+(%40Symbol%3d%22WT%2fLET%2f1236*%22))+&DisplayContext=popup&languageUIChanged=true

At the time of the notification, Bolivia had only vaccinated roughly 5% of its population. In a May 2021 press conference held in La Paz[252], the Bolivian Minister of Foreign Affairs announced that his government reached a deal with Canadian company Biolyse Pharma that would allow Bolivia to import a low-cost generic version of Janssen Biotech Inc. /Johnson & Johnson's COVID-19 vaccine. More specifically, Ad26.COV2.S, a replication-incompetent adenovirus type 26 (AD16) vectored vaccine encoding a stabilized variant of the S protein of SARS-Cov-2, with the State of Bolivia reserving the right to import other vaccines.

Bolivia estimated a need for 15 million doses of COVID-19 vaccines and reported having no manufacturing capacity, hence the recourse to CL for export (WTO notification IP/N/9/BOL/1; 10/05/2021; Notified to the TRIPS Council in WTO document IP/N/9/BOL/1).

This CL, should it come to fruition, would have to follow the same procedure set forth under the CAMR that was used in the only fully executed case under Art. 31 bis TRIPS, the Canada – Rwanda case.

[252] L.G. Abinader, "Bolivia seeks to import COVID-19 vaccines from Biolyse, if Canada grants them a compulsory license", Knowledge Ecology International Blog, May 2021: https://www.keionline.org/36119

Annex II: Questionnaire to national experts

Objectives:

The study's main objective is to assist the European Commission in identifying, defining and quantifying potential problems affecting the effectiveness of compulsory licensing mechanisms in the EU in times of national, EU-wide and global crises as well as to develop and assess a number of policy options to improve the coherence and effectiveness in the field. The focus of the study is on public emergencies, with particular attention to health-related crises and covering to some extent also other crises.

This questionnaire contributes to the identification and quantification of the differences between the national legal mechanisms for the granting of compulsory licensing. This document contains questions on the requirements for granting compulsory licences, their scope, procedures and practices. Some questions also inquire about the relation, if any, between the goals and the relief available through compulsory licensing on one hand and through competition law on the other hand. Responses will feed into the EU-level analysis on the effectiveness, costs and benefits of the current legal framework in light of future health-related cross-border, European or global, public emergency or other circumstances of extreme urgency.

While answering this questionnaire, please bear in mind that it covers governmental use and similar mechanisms, not only compulsory licence in the narrow sense. Where possible, please, support your answers with references to the relevant legislative acts, court cases and decisions of administrative authorities. Please, feel free to indicate any further information that you consider to be useful for the research team for this study.

These publications on compulsory licensing may be of service while answering the questionnaire:

- "The Compulsory Licensing E-Guide: A Legal Roadmap of over 20 Jurisdictions" (CMS, 2021): https://cms.law/en/int/expert-guides/cms-expert-guide-to-compulsory-licensing;
- "Compilation of Various Legal Provisions on Compulsory Licenses and Government Use" (WIPO, 21 May 2019) :

  https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-appendix1.pdf
- "Compulsory Licensing in Europe: A Country-by-Country Overview" (EPO, 2018): https://www.epo.org/learning/materials/compulsory-licensing-in-europe.html
- "Special compulsory licences for export of medicines: key features of WTO Members' implementing legislation" (Roger Kampf, WTO, 2015): https://www.wto.org/english/res_e/reser_e/ersd201507_e.pdf
- WTO, COVID-19: Measures regarding trade-related intellectual property rights: https://www.wto.org/english/tratop_e/COVID-19_e/trade_related_ip_measure_e.htm

I. Scope of Application

Please address the procedural aspects of your answers in the second chapter of this questionnaire

1. Can you briefly describe the conditions for applying for a compulsory licence in your jurisdiction in case of a “crisis” and how “crisis” (or a similar term) is defined? Is it only related to health or to other types of a crisis?

2. From a historical point of view, when was the first time that your national legislation provided for the possibility to grant a compulsory licence in case of a crisis? Please provide a reference to the law.

Has this concept of “crisis” been amended since? If yes, When?

3. Are compulsory licences available in all areas of technology in case of a crisis, or for certain areas only?

4. Have any legislative or other regulatory changes regarding compulsory licensing been made in your jurisdiction since the beginning of the COVID-19 pandemic? If yes, please, describe them. If not, have such changes been or are being discussed? If yes, please, describe them.

5. Are there other measures available in your jurisdiction (e.g., based on regulatory law or competition law) that allow gaining access to IP rights in case of an emergency?

6. Which of the following could be applied for to obtain a compulsory licence:
   - National patent (including those stemming from a European patent)
   - National patent application
   - Supplementary protection certificate (SPC)
   - Regulatory pharmaceutical protections (data protection and market exclusivity, e.g., as in Art. 18(2) of the Regulation 816/2006)
   - Other types of intellectual property (copyrights, trade secrets) or regulatory exclusivity?

Please, indicate any information you consider useful in this respect (e.g., possible uncertainty, reasons).

7. If one of the criteria for granting a compulsory licence is the lack of exploitation of the IP right, what territory is relevant? The domestic market only? Or the entire European Union (see CJEU case C-30-90, 18 February 1992, EC vs. United Kingdom, re compulsory licences)

8. Do you consider that a domestic market definition prevents compulsory licencing at the EU level (production/supply to many MS)?

9. What is the duration of a compulsory licence and/or how it is defined (e.g., number of months, years, or duration of the public emergency that was the cause for granting the licence)?

10. Can the term of a compulsory licence be subject to certain conditions (e.g., until a certain amount of vaccines has been produced, the end of the state of emergency)? Or is a new intervention needed to put an end to the compulsory licence?

11. Can a compulsory licence be made conditional on showing the capacity to produce a safe and effective product?

12. What are the criteria for determining the fee paid to the IP owner? It is the same competent authority who grants the compulsory licence and determines the fee? If not, who is the separate authority (e.g., a court)?

13. Is there a possibility to review the terms and conditions of the granted compulsory licence (e.g., to review the fees when the circumstances change)? If yes, under what conditions?

14. Can a compulsory licence cover more than one single patent? And if more than one IP owner is involved, how is the split in the fee for each patent owner determined?

15. Does the law in your jurisdiction say anything about the exhaustion of the rights in products made under a compulsory licence? Can the patentee oppose the import of products in your jurisdiction if they were manufactured in another EU jurisdiction under a compulsory licence? (see CJEU case 19/84, 9 July 1985, Pharmon vs. Hoechst, exhaustion of rights and compulsory licensing)

16. Is there any literature or case law in your jurisdiction suggesting that the rule laid down by the CJEU in the Pharmon vs. Hoechst case should also apply to products made under a license granted by a patentee who was sanctioned - or threatened to be sanctioned - on the basis of competition law? If not, what is your view on this question?

II. Procedural Aspects

1. Who is the competent authority for granting a compulsory licence? Is it granted by the judiciary (a court) or by a government authority (minister or government agency)? If there is more than one authority, please, indicate how the competencies of the two authorities differ?

2. Is the competent authority for granting compulsory licences for exportation (under the Regulation 816/2006) the same as the one competent for granting a compulsory licence in the case of a crisis or public emergency? If not, please indicate which is the competent authority for granting compulsory licences for exportation.

3. Is there a separate procedure for obtaining a compulsory licence in case of emergency or crisis, e.g., by way of preliminary injunction? If yes, is it handled by the same or by a different competent authority?

4. Is there a mandatory step of voluntary negotiations between the right holder and the petitioner that must take place before a compulsory licence can be applied for? If yes, please describe whether this is the same in case of a public emergency, or whether the deadlines are shorter.

5. Is there a maximum duration for deliberations regarding an admissible application for a compulsory licence? If yes, how long is it?

6. Is it possible to appeal the decision to grant or not to grant a compulsory licence?

7. What are the limitation periods for an appeal?

8. Who are the competent authorities for the appeal? Please, indicate if there are different authorities competent for different appeal procedures (judicial or administrative).

9. Is there a maximum duration for deciding on an appeal? If yes, how long is it?

10. Do the limitation periods/maximum durations for processing the application, the appeal and the deliberations change in case of an emergency?

III. Practice

1. Please take into account that the following questions also refer to the practices regarding compulsory licences for exportation (under the Regulation 816/2006).

2. How many compulsory licences have been granted in your jurisdiction? Please list them briefly, indicating the reasons/domains for which they were granted. You can include cases that granted access to IP rights on the basis of regulatory law or competition law.

3. Has an application for a compulsory licence been refused in your jurisdiction? Please, provide any information you consider helpful for this inquiry.

4. Has any application for a compulsory licence been withdrawn by the applicant in your jurisdiction? Please, provide any information you consider helpful for this inquiry.

5. Is there an application for a compulsory licence currently pending in your jurisdiction? Please, provide any information you consider helpful for this inquiry.

6. Has there been a situation when an organisation expressed an intention to apply for a compulsory licence but eventually there was no case (e.g., the parties concluded a voluntary licence). Please, provide any information you consider helpful for this inquiry.

7. What is, in your view, the relation between compulsory licensing and competition law? Can access to patents be obtained via either mechanism, or are the conditions too different? What is your view on the interaction between these two sets of legislation?

Annex III: National Experts (Questionnaires) and Interviewees

Member State	National expert
Austria	*Ms. Gaia Merhej, CEIPI, University of Strasbourg* *Mr. Manuel Wegrostek (peer review)*
Belgium	*Prof. Geertrui Van Overwalle, KU Leuven* *Mr. Thierry Debled (peer review)*
Bulgaria	*Mr. Stoyan Sirakov, Interius*
Croatia	*Ms. Albina Dlačić, Dlačić Law Offices*
Cyprus	*Ms Maria Kyriacou*
Czech Republic	*Jiří Malý, Vojtěch Chloupek, Martin Taimr, Bird & Bird, and Kateřina Hartvichová, HARBER IP s.r.o.*
Denmark	*Ms Lotte Vinggaard Andreasen*
Estonia	*Ms. Sirje Kahu, Patendibüroo Ustervall*
Finland	*Mr. Rainer Hilli, Roschier Attorneys Ltd.*
France	*Ms. Caroline Le Goffic, Lille University, and Mr. Yann Basire, CEIPI, University of Strasbourg* *Mr. Pierrick Rousseau (peer review)*
Germany	*Ms. Gaia Merhej, CEIPI, University of Strasbourg* *Mr. Joachim Von Oppen (peer review)*
Greece	*Mr Athanasios Tsimikalis, Tsimikalis Kalonarou Law Firm*
Hungary	*Eszter Szakács, Danubia*

Ireland	*Mr. Anthony O'Dwyer, Queen's University Belfast* *Mr. Richard Gillespie (Inventorship and peer review)*
Italy	*Ms. Gaia Merhej, CEIPI, University of Strasbourg* *Ms. Agata Sobol (peer review)*
Latvia	*Ms Maija Tipaine, COBALT*
Lithuania	*Ms. Justina Nikė, Attorney at Law* *Ms. Jurga Petniūnaitė, European patent attorney* *Ms. Otilija Klimaitienė, European patent attorney, AAA Law*
Luxembourg	*Olivier Reisch, Partner* *David Alexandre, Counsel* *Camille Malécot, Associate* *Alejandro Gonzalez Vega, Associate* *Amin Bouazza, Associate* *Benoîte Chanfray, Intern* *Samia Dehmeche, Intern, DLA Piper*
Malta	*Mr. Luigi A. Sansone, Salomone Sansone*
Netherlands	*Mr. Bert Oosting, Hogan Lovells*
Poland	*Ms. Anna Ławrynowicz-Drewek, CEIPI, University of Strasbourg* *Ms. Justyna Rasiewicz, ROA (peer review)*
Portugal	*Mr. Luis Ferreira, PATENTREE*
Romania	*Ms Oana Boncea and Ms Adina Badarau, Rominvent SA*
Slovakia	*Mr Jiří Malý, Mr Vojtěch Chloupek, Mr Martin Taimr, Bird & Bird, and Ms Kateřina Hartvichová, HARBER IP s.r.o.*

Slovenia	*Mr Urban Vrtačnik, Odvetniška pisarna Vrtačnik*
Spain	*Mr Rodrigo Manzanares Sanz, Ms Estefany Betances Soriano, Legal Department, Ms Laura Montoya Terán, Head of the Legal Department, ABG*
Sweden	*Ms Siri Alvsing, Senior Associate and Mr Björn Rundblom Andersson, Partner, Westerberg & Partners Advokatbyrå AB*
USA	*Ms Natasha Mangal, CEIPI, University of Strasbourg*

Interviewees (Anonymised)

Person	Position
A member of a multinational company specialized in the health sector	Director of IP
A member a multinational pharmaceutical company	Manager of IP litigation
A member of a European academic institution	Professor of IP law
A patent-solicitor with CL experience	Partner at a law firm
A member of a multinational telecommunications company	Director of IPR Policy
Two members of a European representative organization for the generics industry's Board of Administrators	Consultant in Health Management The second member is former Managing Director of the Association

Person	Position
A member of a pharmaceutical and cosmetics company	Former IP Director
Two members of a nano electronics and digital technologies company	IP director and IP manager
A member a multinational pharmaceutical company	Senior Patent Attorney
A member a multinational pharmaceutical company	General Counsel (ex- IP Litigation Counsel)
A member of a European generics manufacturing and trading company	Head of IP
All members of a European representative organization for the pharmaceutical industry	N/A
An expert in medicines policy and intellectual property law	Consultant
A member of a multinational generics company	Industry Affairs Manager
A member of an intergovernmental policy research and analysis institution	Professor of IP Law
A member of a non-European academic institution	Professor of IP Law
A patent attorney specialized in the fields of biotechnology and pharmaceuticals	European Patent Attorney and Partner

Person	Position
Two members of a medical and humanitarian NGO	Policy advisors
Two members of an organization of national and regional associations for licensing executives	Patent Attorneys
A member of a law firm specialized in patents	European Patent Attorney
A representative of a multinational active in food and crops	Head of IP
An independent legal practitioner in the field of intellectual property litigation and regulation of medicinal products	Attorney at law
A patent attorney specialized in regulatory affairs	Doctor of IP Law and European Patent Attorney

Annex IV: Cases of compulsory licensing in the EU

The cases should reflect the change of the EU (Brexit, Croatia was the last to join, etc.)

The table could refer to cases as well as to what we refer as "non-cases" for the purpose of the study.

Sources:

1. "The Compulsory Licensing E-Guide: A Legal Roadmap of over 20 Jurisdictions" (CMS, 2021): https://cms.law/en/int/expert-guides/cms-expert-guide-to-compulsory-licensing;
2. "Compilation of Various Legal Provisions on Compulsory Licences and Government Use" (WIPO, 21 May 2019):

   https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-appendix1.pdf
3. "Compulsory Licensing in Europe: A Country-by-Country Overview" (EPO, 2018): https://www.epo.org/learning/materials/compulsory-licensing-in-europe.html
4. KEI: https://www.keionline.org/cl
5. The TRIPS Flexibilities Database: http://tripsflexibilities.medicineslawandpolicy.org/
6. Interviews

The number of CLs granted seems to indicate that the system is not misused.

The three cases that were recognised even by the industry as being "good" cases:

- German HIV case
- Chiron case: change in the method of royalty calculation; Red Cross was involved.
- Myriad case regarding BRCA breast cancer gene diagnostics (some relevant information[253])

Could be relevant for the quantification:

1. Number of MS in which CL in cases of crises were granted
2. Domains in which CLs were granted
3. Number of CLs granted in case of crises per MS

[253] Aaron S. Kesselheim et al., 'Gene Patenting—The Supreme Court Finally Speaks', *The New England Journal of Medicine* 369, no. 9 (29 August 2013): 869–75, https://doi.org/10.1056/NEJMhle1308199; E. Richard Gold and Julia Carbone, 'Myriad Genetics: In the Eye of the Policy Storm', *Genetics in Medicine* 12 (1 April 2010): S39–70, https://doi.org/10.1097/GIM.0b013e3181d72661.

COVID is a worldwide crisis. COVID-related CLs in the world:

1. Hungary: HIPO CL for Gilead's remdesivir
2. Israel: CL granted for lopinavir/ritonavir (Kaletra) produced by AbbVie
3. Russia: CL granted by the government for the Eurasian patents (EA025252, EA025311, EA029712, EA020659, EA032239 and EA028742) Gilead for remdesivir

Compulsory licenses ordered on the basis of "economic dependency"

Brussels Enterprise Court, 26 July 2022, A/21/01929, Tunstall vs. Victrix & Tele-Secours (under appeal)

US:

Gore Tex compulsory licence: https://www.scotusblog.com/wp-content/uploads/2015/08/W.L.-Gore-Petition.pdf

Table 4 : Identified case law on compulsory licences

Member State	Year	Domain / product	Outcome	Further information	The parties	Source
EU	2018	Protected plant variety of blackcurrant / "Ben Starav"	Not issued	Application made on "public interest" grounds	Defendant: Lucozade Ribena Suntory Limited Claimant: Pixley Berries (Juice) Limited	CPVO Decision NCL001, 28.03.2018
Germany	1995	Medicine / Interferon gamma (rheumatoid arthritis)	Issued and cancelled in review procedure	The public interest did not call for the grant of a CL. Court found, inter alia, alternative treatments were available.	Confidential	WHO/WIPO/WTO (2020), p. 240
	2016	Medicine / raltegravir (HIV/AIDS)	Issued	Preliminary CL granted to a pharmaceutical company involved in an injunction procedure with another pharmaceutical company.248 The patent was eventually invalidated (see Box 4.22).	Applicant: Shionogi Defendant: Merck Sharp & Dohme	WHO/WIPO/WTO (2020), p. 240
	2018	Medicine / alirocumab (cholesterol-lowering treatment)	Not Issued	The public interest did not call for the grant of a CL. Court found, inter alia, alternative treatments were available.	Confidential	WHO/WIPO/WTO (2020), p. 240
Italy	2005	Medicine / imipenem-cilastatin (antibiotic)	Issued	CL granted as remedy to anti-competitive behaviour.	Defendant (Rightholder): Merk & Co.	WHO/WIPO/WTO (2020), p. 240

		SPC			C: Competition and Market Authority	
	2007	Medicine / finasteride (prosthetic hyperplasia) SPC	Issued	CL granted as remedy to anti-competitive behaviour and to allow parallel export to neighbouring markets with expired patent protection.	Defendant (Rightholder): Merk & Co. C: Competition and Market Authority	WHO/WIPO/WTO (2020), p. 240
Netherlands	1986	Protected plant variety of tulips	Not Issued	CL to plant variety rights	Defendant: Schoorl C: Pennings	Case nr. BIE 1987.18, Chairman of the District Court of Haarlem; Pennings vs Schoorl, 16.07.1986
Spain	2015	Medicine / Sofosbuvir (hepatitis C)	Not Issued	The Supreme Court ruled that granting of compulsory licences in cases of public interest is at the discretion of the government, and not an obligation imposed by the law		WHO/WIPO/WTO (2020), p. 240
UK (pre-Brexit)	2015	Medicine / T-DM1 (breast cancer)	Not Issued	CL requested by patient group following plans to remove T-DM1 from list of cancer treatments paid for by UK Government (Kmietowicz, 2015a). Price discount negotiated.	Rightholder: Roche Request made to: UK Government Request made by: The coalition for affordable T-DM1	WHO/WIPO/WTO (2020), p. 241
	2019	Medicine / lumacaftor-ivacaftor (cystic fibrosis)	Not Issued	A Crown Use licence was requested by a patient group.261 The UK Government considered issuing a Crown Use licence (a type of government-use licence) after a pricing deal had not been reached with the originator following three years of negotiations (McConaghie, 2019). A few months after the government announced that it was considering a Crown Use licence, a confidential pricing deal was agreed (Parsons, 2019).	Request made for: NHS England Rightholder: Vertex Request made by: Just Treatment	WHO/WIPO/WTO (2020), p. 241
	2001	Protected plant variety of potato	Not Issued	Dutch seed breeder Meijer owns the UK plant breeders' rights in 'Lady Rosetta', a potato variety popularly used in crisp manufacture, with MBM	Defendant: Meijer BV & MBM Produce Limited C: Sacker Potatoes Ltd	UK Controller of Plant Variety Rights, UK Plant Variety Rights Office and Seeds Division of DEFRA; Sacker Potatoes Ltd

				acting as its exclusive agent in the UK. Sacker applied unsuccessfully for compulsory exploitation rights in the protected variety, arguing that Meijer's refusal to issue a licence was unreasonable, and that the rights' holder was failing to satisfy demand in the UK market.		vs C Meijer BV & MBM Produce Limited, 31.10.2001
Belgium	2022	EP2160038B2 method for Tone Signalling	Appeal pending	With respect to Télé-Secours, the Court considered that Tunstall's behaviour was abusive because the patented system became necessary to Télé-Secours' activities over the years. This system was the safest way to connect the hardware sold by Tunstall to the Télé-Secours call center. If Télé-Secours could not use the patented system with third parties' software, it would be forced to stay with Tunstall. The Court therefore considered that Tunstall's refusal to license was an abuse of the economic dependency of Télé-Secours. With respect to Victrix the Court also considered that Tunstall's refusal to license was abusive. This license was necessary for Victrix to compete on the Belgian market and the refusal was discriminatory because Tunstall already licensed its technology to other major actors of the telecare market. The Brussels court ordered Tunstall to grant a non-exclusive license to Télé-Secours and to Victrix for the remaining duration of the patent and for the Belgian territory. The the license fee should be equal to the average price paid by the other licensees taking into consideration the	Claimant: Tunstall (UK) Defendants : Victris SL (Spain) & Téle-Secourts (Belgium)	

				remaining duration of the patent. The parties have three months to conclude a license agreement. It also ordered Tunstall to furnish all information needed to use the protocols it developed based on its patented telecommunication system.		

Annex V. Economic Assessment of the Impact of Granting a CL

The economic impacts of granting a CL have been subject of study in numerous academic publications.[254] Prior research focused on developing theories and finding empirical evidence of positive and negative effects of CL. The effects could be positive for both customers and firms or could suggest a bridge between theirs interests. Some papers focus on one specific additional cost or benefit, while others provide determinants of the optimal use of CL.

Optimal use of CL could be assessed in multiple ways:

1. Current aggregate welfare of the associated agents, with the quantity and price for current customers and the corresponding profit for firms
2. A first distinction between the welfare of customers and the welfare of firms
3. A second distinction with a disaggregated view across customers and across firms[255]
4. A dynamic view of welfare with the dynamics of innovation. The entry-exit processes of firms are linked to innovation and to firm's market shares. Both research and market concentration are likely impacted by CL.

In this section, the static economic effects of granting a CL will be briefly outlined, which corresponds to the three first measures of welfare, and focusing particularly on works from the pharmaceutical industry. The focus will then turn towards evidence found of any dynamic effects of CL, the fourth measure of welfare below, especially the determinants of the optimal use (ex-ante level of competition, the elasticity of the demand).

A static economic approach: CL leading to a positive net surplus

In essence, the debate around the economic effects of granting CL revolves around a clash of two perspectives. One is focused more on the business point of view, where producers' interests are prioritised. This producers' perspective advocates strong patent protection to allow producers to earn back their investments and stimulate research and development of new drugs. The other perspective focuses on broader society, and supports exemptions or restrictions on the patent rights to allow all of those in need to have access to and benefit from the invention.[256]

From a purely economic perspective, the CL involves a shift from a voluntary transaction, taking place because two parties expect to gain from the exchange to an involuntary transaction where one party (the patent owner) is forced to partake in a transaction at terms s/he would initially not be willing to accept. The involuntary aspect of the transaction leads to doubts as to whether a CL leads to increased allocative efficiency.[257] However, this involuntary transaction could be an efficient exchange if negative externalities that could result from the issuance of a CL are sufficiently mitigated (e.g., CL limited in time, limited in geographical

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[254] Moser, P., & Voena, A. (2012). Compulsory licensing: Evidence from the trading with the enemy act. *American Economic Review*, *102*(1), 396-427. Seifert, J. (2015). Welfare effects of compulsory licensing. *Journal of Regulatory Economics*, *48*(3), 317-350.

[255] For example, some firms could benefit from the market with high mark-up, while other firms are forced to exit or to sell the product at a market price without a positive mark-up. The same holds for customers. The surplus of customers could indeed be generated for some customers, while other customers are unable to pay the price and do not enjoy a surplus.

[256] Bailey, T.C. (2001), 'Innovation and Access: The Role of Compulsory Licensing in the Development and Distribution of HIV/AIDS Drugs' U. Ill. J.L. Tech. & Pol'y 193, 194.

[257] Lee, R.S. (1982), An Economic Analysis of Compulsory Licensing in Copyright Law, *Western New England Law Review*, 5(5), Issue 2. Source: https://digitalcommons.law.wne.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1447&context=lawreview;an

scope, patentee paid the fair market value for the license). It also depends on the reasons of the refused voluntary transaction and the cost-benefit analysis conducted by the patent owner, who could not anticipate the private and social cost of his strategic use of property rights.

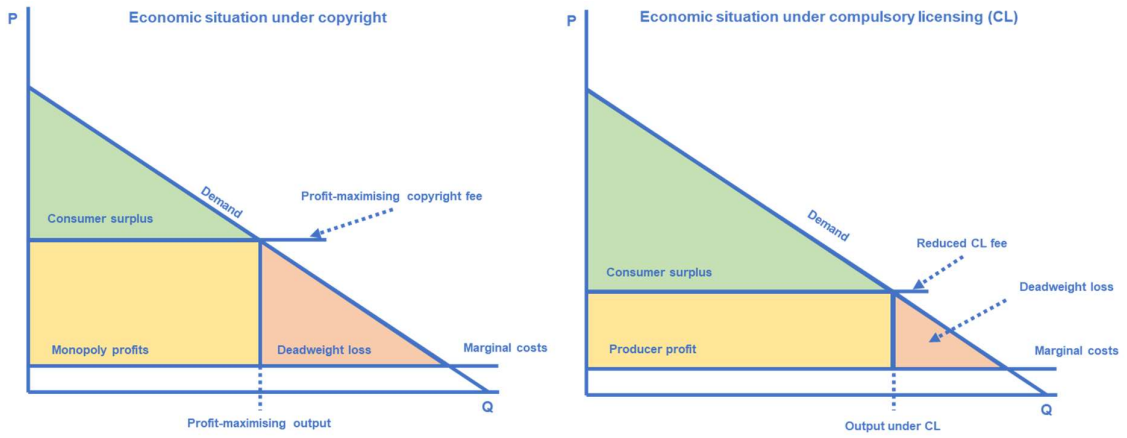
This first approach does not address the incentives of innovation, nor all the potential negative effects of issuing a CL. Even if there is the potential for long-term costs resulting from the issuing of a CL, knowledge of the short-term benefits is also important for engaging in comprehensive policy design.

Here are highlighted some important effects of the grant of a CL to consider for the analysis:

First effect: a drop in the monopoly power, including a decreasing price of the corresponding product.

The CL would allow a larger group of manufacturers to make use of the invention in their production processes, spurring production of the invention as well as new innovations built upon them. In the case of medicines, this could lead to a higher production output of a drug.

For first economic intuitions, Fisher (2013) applicates the case of copyright and analyses the potential costs and benefits of a compulsory licensing system. We assume here that patents and copyrights follow the same basic economic mechanisms. As shown in the figure below, the increased quantity lowers the price for consumers.



Source: Ecorys visual based on: Fisher, W. (2013), 'The Economics of Compulsory Licenses', Harvard Presentation from January 25, 2013, at: https://cyber.harvard.edu/people/tfisher/IP/Cls.pdf

The previous equilibrium represents a monopolistic situation, while the new situation reflects a competitive equilibrium with imperfect competition. The market power is not concentrated on one firm anymore. Graphically, the producer profit in the left-hand figure goes to the monopolist, while the producer profit in the right-hand figure is shared between multiple producers. The reduced price associated with the consumer access to the product increases consumer surplus, thereby reducing the deadweight loss in this market.

The CL induces a **decrease in social costs** of the monopolistic scheme, as the latter is contingent on the price-elasticity of demand.[258] The social cost of a monopoly is quite high in the case of inelastic demand; when demand is relatively inelastic, the monopoly will choose a high price, or in the worst case engage in extortive practices. The shift of market equilibrium caused by a CL has the potential to push new firms into the market, which reduces the market price. But the drop in prices is not an automatic answer, the variation depends on the price-elasticity of demand, and then are different across markets. To do so, the gap between monopolist price and price with CL is negatively associated with the price-elasticity of demand. These mechanisms are empirically confirmed by the literature. The presence of new sellers leads to a decrease in the market prices. This relationship exists for various industries, especially for the pharmaceutical industry. This is clear for all new sellers, namely brand entry and generic entry sellers.[259]

More specifically on the effects of CL, two cases in Brazil and Thailand related to the AIDS program show a large drop in drug prices, between 70% and 85% resulting from CL practices.[260] This detailed analysis confirms the previous empirical papers on several countries in the developing world: the CL led to tens of percentage points of price reduction of medicines on the market, up to cases where total price reduction was 98%.[261] This significantly improved access to medicines for consumers.

Second effect: the CL could create a variety effect and additional drop in prices through substitution effects.

The CL introduces new firms into the market as generic firms, but it is not only a pro-competitive effect. Their presence does affect monopolistic power if consumers are willing to pay the same price for branded or generic products. In other words, the effect of CL depends not only on the price-elasticity of demand but also on the cross-elasticity of demand. When a CL appears, the patent owner strategically adapts its price.

1. If many consumers are willing to pay a premium for the pedigree and brand reputation of its product, the patent owner may raise its price, which creates two markets. If the brand and generic products are not complete substitutes for customers, the segmentation of markets could be interpreted as a variety effect, which substantially improves consumer surplus. It may compensate for the negative effect of the rise in price for branded products.

By contrast, if the branded and generic products are perceived as close substitutes, the patent owner is forced to decrease their price.

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[258] Lerner, A. P. (1934). The concept of monopoly and the measurement of monopoly power. *The review of economic studies*, *1*(3), 157-175.

[259] Wiggins, S. N., & Maness, R. (2004). Price competition in pharmaceuticals: the case of anti-infectives. *Economic Inquiry*, *42*(2), 247-263.

[260] Guennif, S. (2017). Evaluating the usefulness of compulsory licensing in developing countries: a comparative study of Thai and Brazilian experiences regarding access to AIDS treatments. *Developing world bioethics*, *17*(2), 90-99.

[261] Khor, M. (2010), 'Patents, compulsory licenses, and access to medicines: some recent experiences', World Health Organization Regional Office for South-East Asia. Intellectual property and access to medicines: papers and perspectives. New Delhi: WHO. Paper 8. Available on: http://infojustice.org/download/gcongress/global_architecture_and_the_development_agenda/gopakumar%20article%202.pdf#page=96

Using detailed product-month-level data on a specific segment in the Indian pharmaceutical market, Chaudhuri et al. (2006) demonstrate the mechanisms described above. The introduction of a patent triggers a consumer welfare loss because of the reduction in varieties available in the corresponding market. The withdrawal of domestic products is key here, and then suggests a role for compulsory licensing by increasing domestic market supply. Additionally, CL could help to add variety to the market, while other policy tools such as price regulation is not effective. The latter only affect the price-quantity dimension but does not affect the number of varieties in the market.

Some customers could say that brand products could be better than generic products, especially for marketing and behavioural issues. In this hypothetical case, the interpretation of variety loss could be wrong. Still, this does not mean that overall welfare effects are negative. From a global welfare perspective, it can be argued that it is still beneficial to supply a relatively lower quality drug to a larger share of the population under CL.

The CL also affects other substitute markets if consumers consider alternative close markets. If the substitutes of the product are sold in an imperfect market, then the decrease in price in the market with the CL will lead to a corresponding downward price adjustment in the related market. Other firms for substitute products would then reoptimize their price-quantity strategy. Though this can generate consumer surplus, the magnitude of this gain crucially depends on (1) the cross-elasticity of the demand within the first market, (2) the cross-elasticity of the demand between the two markets, and (3) the degree of competition in the two markets. If the secondary market is highly competitive, then the downward price adjustment will be intensive. The previous quoted paper from Chaudhuri et al. (2006) estimates a range of cross-product-group and cross-molecule substitution effects. With a high degree of substitutability, they find non-negligible welfare loss to the patent owner through substitution effects. The quantitative results and the corresponding scenarios are for this specific pharmaceutical segment in India. In the same way, the difference between Indian firms and foreign subsidiaries cannot be easily compared to the European case, but this research suggests a key role for substitution effects. Then the CL could also reduce the price for customers in substitute markets.

The CL could finally affect international markets. A further concern for business around the granting of CLs is that the TRIPS agreement does not offer a solution for parallel imports of products manufactured under a CL. The price of products under the involuntary CL are lower than in situation where the manufacturer voluntarily sets the price for use of his patent. This will incentivise other producers to import the product from a country where it is marketed at lower prices, and profit from the price margin. The patent holder will be forced to reduce its prices to maintain competitive. As such, the threat of parallel imports following the granting of CLs constitutes a further hesitation for businesses in investment in innovation.

No solution has been found by regulators to counter the potential adverse impact of parallel imports on innovation, while it could benefit both manufacturers and society. Reichman suggested that, provided parallel imports are prevented, the patent holder could implement price-discrimination in marketing their products based on countries' GDP per capita. This way the manufacturer could sell large volumes at lower profit margins in poorer countries, compensated by higher profit margins in wealthier countries.

Third effect: the CL appears as a way to protect competition and does not create market failure.

All these previous mechanisms highlight that CL creates some welfare gains for customers and reduces the static welfare for monopolistic firms. But a monopoly is generally associated with excessive profit and deadweight losses for society. Then the CL reduces the robustness of the marketplace of the patentee but does not *a priori* generate failures.[262] The patent owner forced with a CL could still segment the international market. With a CL, firms lose control over their optimal pricing strategy, but they could compensate for the losses by setting higher prices in other countries. The price strategy is still determined by the consumer's willingness to pay, and it is likely that this compensation strategy will be made in other advanced economies rather than low-income countries. It is assumed here that the European market is not the principal market of the patentee. Without this assumption, the risk of failure cannot be fully excluded.

The CL also supports local production and corresponding employment and national industrial invention.[263] In fact, countries may even deliberately pursue CL as a means to develop internal pharmaceutical capacities in their territory – and ensure access to medicine. Countries have the autonomy to grant CL within their territory, and develop the needed drugs at affordable prices. The industries needed for the local development would also generate thousands of jobs in the region.[264]

Finally, the effect of CL on the total welfare is also contingent on the ex-ante degree of competition.[265] As previously said, the welfare gains for consumers from CL increase with higher levels of previous monopolistic power from a patent. The CL reduces the patent owner's dominant position. But the level of competition is also key for the welfare costs for firms. The loss for the patent owner from CL is quite high when the industry is sufficiently competitive due to an increased rivalry effect. By incorporating both effects, the CL generates a positive net total surplus (consumers and firms) when there is low competitive intensity in the market.

Fourth effect: the CL is not a free lunch and the patent holder should receive adequate remuneration.

The adequate remuneration of the patent holder for a CL has been a debate for a long time. Since 2003, WTO member countries may allow CL of patents in pharmaceutical products under some conditions. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides some guidelines for the associated royalty to the patent holder when issuing a CL for export. Various countries have refined their policies:

- The 2006 EU CL Regulation (816/2006) use the figure of 4% of the total contract between the patent owner and the generic firm as the maximum royalty. This maximum level of royalty should be determined taking into account other determinants (humanitarian and non-commercial circumstances).
- Canada's law "Jean Chrétien Pledge to Africa Act" uses the same reference for the maximum royalty, and they provide a sliding scale based on the importing country's UNDP Human Development Index ranking.
- In 1998, the Japanese Patent Office provides a similar range of 0 to 6 percent of the price of the generic product

[262] Guennif, S. (2017). Is compulsory licensing bad for public health? Some critical comments on drug accessibility in developing countries. *Applied health economics and health policy*, *15*(5), 557-565.
[263] Guennif, S. (2017). Evaluating the usefulness of compulsory licensing in developing countries: a comparative study of Thai and Brazilian experiences regarding access to AIDS treatments. *Developing world bioethics*, *17*(2), 90-99.
[264] Abbas, M. Z. (2013), Pros and Cons of Compulsory Licensing: An Analysis of Arguments. International Journal of Social Science and Humanity, Vol. 3, No. 3
[265] Seifert, J. (2015). Welfare effects of compulsory licensing. *Journal of Regulatory Economics*, *48*(3), 317-350.

These guidelines are not sufficient to calculate the adequate remuneration for CL, but they provide a welcome departure. [266] Even in these exceptional circumstances, the patent owner could anticipate a floor price. The literature also includes the level of this royalty rate as a key factor for profitability and R&D investments. A recent paper shows how the level of royalty is a necessary condition to make the patent owner economically better off.[267] They model a dynamic game between the patent owner and other firms and includes various periods. They include the first three years following the patent grant, the second period when the CL can be issued and the third period with the expiration of the patent. They compare the case with CL and without CL. The researchers find that the CL could even improve the profitability of the patent owner if two conditions are met: (i) the high level of royalty, (ii) the high sensitivity of consumers to the price of the patent holder, and the low sensitivity to the price of the generic's product. The high level of royalty reduces the ability of the other firms to provide a low price. Customers cannot be easily captured by these firms.

A dynamic economic approach: the costs of CL for innovation are low. The CL could even trigger innovation under some conditions

To a large extent, the academic debate revolves around the **incentives** created by CLs. Property rights are designed to offer protection to companies that made significant investments in R&D to develop inventions with societal value, often against unknown pay-offs. Property rights allow businesses over a restricted period of time to earn back investments in an invention and possibly generate profits on the innovation, creating an economic incentive for businesses to innovate. As an example, R&D in the Italian pharmaceutical industry multiplied seven times in the decade following the approval of drug patent law in the Member State.[268] As such, CL could modify the potential dynamic benefits of innovations that may result from patents.

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266 Solovy, E. M., & Raju, D. (2021). The UNDP/WHO remuneration guidelines: a proposed formula for inadequate remuneration for compulsory licencing in violation of the TRIPS agreement. *Journal Of Intellectual Property Law and Practice*, *16*(11), 1192-1202.

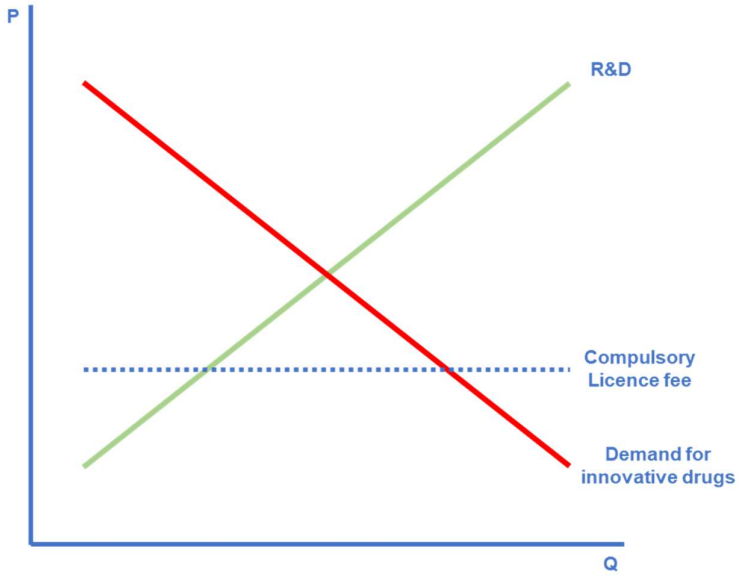
267 Sarmah, A., De Giovanni, D., & De Giovanni, P. (2020). Compulsory licenses in the pharmaceutical industry: Pricing and R&D strategies. *European Journal of Operational Research*, *282*(3), 1053-1069.

268 Abbas, M. Z. (2013), Pros and Cons of Compulsory Licensing: An Analysis of Arguments. International Journal of Social Science and Humanity, Vol. 3, No. 3

The potential threat: the CL could disincentivise innovations. The drop in innovations will be large and the country could be banned from firms' foreign direct investments.

Without proper protection of their innovations, businesses might be less incentivised to develop new products in the first place. Royalty fees received under a CL are substantially below the fees patent holders would receive for the use of patents under a voluntary license.[269]

In this perspective, the potential benefits with CL are thus marginal compared to a situation without CL, and businesses will factor in this diminished possibility to capitalise exclusively on their inventions. As such, the lower fee will attract less investment in innovations through R&D than what is required to meet the demand for medical innovations. Following this reasoning, "an increase in the use of CL would lead to less R&D for the development of drugs that are more likely targets in compulsory license proceedings".[270]



Source: Ecorys visual based on Kleeff, R. van (2021), 'The unintended effect of compulsory licenses' Intellectual Property Expert Group. Available on: https://www.ipeg.com/the-unintended-effect-of-compulsory-licences/ (visited on 19 July 2022).

In addition, the increased access to innovations facilitated through CL potentially has some adverse consequences. CL could first modify the perceptions of a country. A survey of British pharmaceutical executives highlights that they believe that CL harms innovations and, in turn, modifies their international strategy.[271] It could lead pharmaceutical companies to lower direct investment in countries that grant CLs, lower R&D investments, or leave the country altogether.[272]

[269] Abbas, M. Z. (2013), Pros and Cons of Compulsory Licensing: An Analysis of Arguments. International Journal of Social Science and Humanity, Vol. 3, No. 3
[270] Kleeff, R. van (2021), 'The unintended effect of compulsory licenses' Intellectual Property Expert Group. Available on: https://www.ipeg.com/the-unintended-effect-of-compulsory-licences/ (visited on 19 July 2022).
[271] Taylor, C. T., Silberston, Z. A., & Silberston, A. (1973). *The economic impact of the patent system: a study of the British experience* (Vol. 23). CUP Archive.
[272] Reichman, J.H. (2009), Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options. Journal of Law, Medicine & Ethics, Vol. 37, No. 2.

The reality behind this threat: CL is a little cost in the firm's strategy and does not affect the dynamics of innovation.

The theoretical costs of CL should be compared to the associated costs and benefits of the innovation, and a large empirical literature concludes that CL has no effect on the patent dynamics. The costs of CL should be low compared to the other benefits of innovation. There are at least two hypotheses:

One can argue that firms should invest significantly in innovation to stay competitive in their market. Therefore, CL reduces the earnings of the innovation, but this extreme event in terms of probability does not change the expectations.

As an alternative explanation, the domestic market associated with CL could also be a small market compared to the worldwide market. The last argument could be problematic for the use of CL in the European Union, but the use of CL in the US or Canadian market does not affect the patent rate.

The large empirical literature that presents the low costs associated with CL employs multiple methodologies, studies in various industry segments, and covers multiple decades. The literature provides three key messages:

Various studies compare R&D intensities in industries with and without CL and they do not find striking differences. [273] [274]

Some studies even found a positive relationship between the R&D-to-sales ratio and the use of CL. Scherer (1977)[275] analyses 700 firms, including 42 with the use of CL by US authorities. The positive impact of CL is verified for various industries, including the pharmaceutical one.

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[273] Gorecki, P. K., & Henderson, I. (1981). Compulsory patent licensing of drugs in Canada: a comment on the debate. *Canadian Public Policy/Analyse de Politiques*, 559-568.

[274] McFetridge, D. G. (1998). Intellectual property, technology diffusion, and growth in the Canadian Economy. *Competition policy and intellectual property rights in the knowledge based economy*, 65-104.

[275] Scherer, F. M. (1977). *The economic effects of compulsory patent licensing* (No. 2). New York University, Graduate School of Business Administration, Center for the Study of Financial Institutions.

Only predictable CL with a significant impact on a recent discovery could reduce the innovation rate at a slow rate. Chien (2003)[276] successively tests this hypothesis by analysing six cases over 1980-2000 in the US pharmaceutical industry. But the evidence is mixed and largely supports that there is no real impact of CL on innovations.Besides, a comprehensive analysis of the history of economic effects of patents on innovation found that relatively restrictive and broad patents have actually discouraged innovation, as it restricts the possibilities of other companies to rely on previous inventions as an input for their inventions.[277] An example of this effect comes from a study on the case of the American company Bell Labs, which had to release the patents to its disruptive telecommunication technologies in the 1950s to increase competition and innovation.[278] The study found that patents were a barrier to entry for new entrants. Although the CL indeed facilitated further innovation based on Bell's patents, this happened predominantly through downstream application of the formerly patented technology in other industries. In the telecommunications market, innovation did not increase and it turned out that without structural remedies compulsory licensing in this case was ineffective in solving market foreclosure.

This burgeoning literature suggests that CL does not reduce the dynamics of innovation, but we could discuss the three key messages of this literature. There is no direct evidence of a potential effect of CL in an European context. The size or specificities of European Union could potentially trigger adverse effects.

The reality behind this threat: the CL could trigger the rate of innovation

In a normal market situation, a firm can decide to use (or not) voluntary licensing, based on reasons of profit maximization, neglecting motives such as total welfare maximization. CL involves involuntary transfers and could reduce the effectiveness of a patent owner's strategy.[279] CL forces the monopoly to innovate, because the latter cannot refuse to license anymore, and then reduce the monopoly power. CL also provides a higher rate of innovation than voluntary licensing, and then improves consumer surplus.

The threat of competition à la Arrow (1962)[280] indicates a positive role of competition for innovation. When the firm has patents without any real or potential competition, it could anticipate its stream of technological "rents". But the competition reduces the rents and improves the incentives to innovate. Then, CL can favour innovation **by increasing the threat of competition**. This idea developed by Petra Moser and her co-authors is empirically proven in two papers. They use the 1917 US Trading with the Enemy Act (TWEA) as an exogenous shock. This Act allows US firms to violate enemy-owned patents if they are related to the corresponding war.

US invention substantially increases with this Act in the industries if and only if they use CLs. By comparing the dynamic of 130 000 chemical inventions in US, in industries with or without CL, they conclude that CL increased domestic invention by 20 percent.[281] The US firms use foreign inventions and complement this with their own innovation process in order to establish their own technology.

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[276] Chien, C. (2003). Cheap drugs at what price to innovation: does the compulsory licensing of pharmaceuticals hurt innovation. *Berkeley Tech. LJ*, *18*, 853.
[277] Moser, P. (2016), 'Patents and Innovation in Economic History', Annual Review of Economics, vol 8(1), pages 241-258.
[278] Watzinger, M, T A Fackler, M Nagler and M Schnitzer (2017) "How antitrust enforcement can spur innovation: Bell Labs and the 1956 Consent Decree", CEPR, Discussion paper 11793.
[279] Seifert, J. (2015). Welfare effects of compulsory licensing. *Journal of Regulatory Economics*, *48*(3), 317-350.
[280] Arrow, K. (1962). Economic welfare and the allocation of resources for invention. In *The rate and direction of inventive activity: Economic and social factors* (pp. 609-626). Princeton University Press.
[281] Moser, P., & Voena, A. (2012). Compulsory licensing: Evidence from the trading with the enemy act. *American Economic Review*, *102*(1), 396-427.

The authors also create new firm-level data on German patents to analyse the effects of CL on firms whose patents were licensed.[282] They find that " compulsory *licensing can promote invention by encouraging competitors to enter fields with licensing, which increases the threat of competition for incumbent inventors and motivates them to invest more in R&D* ". This effect is particularly true for industries with an ex-ante low level of competition.

Moreover, the argument relative to the lack of property rights and the associated drop in innovation is not just empirically supported, it is heading into the wrong direction. A lower increase or a reduction in the rate of research investments does not necessarily result in a net social cost, because current investment levels are substantial and might be well above the social optimum, caused by the incentives originating from strong patent protection.[283] In fact, weakening patent protection could resolve socially unfavourable levels of spending on R&D, and the current patent protection could be artificially too strong. This paper uses the 1917 US Trading with the Enemy Act as a natural experiment. We could discuss the efficacity of this mechanism for the current context.

Finally, the firms are not equally well-positioned within the process of innovation, and the impact of CL as a way of reducing the incentive to innovate clearly depends on their position. The model of optimal patents with CL from Tandon (1990)[284] investigates an additional positive mechanism from CL: *"Diminishing the incentive to innovate through weakening patent protection may selectively remove trailing competitors. While this may reduce the absolute level of research activity along a particular line of innovation, this reduction may in fact be socially optimal since competitive developmental processes may engender socially wasteful levels of research activity in the race to be the first to innovate and reap the attendant awards."* Put differently, the CL creates additional competition across firms and forces the least productive to exit.

The reality behind this threat: the two conditions for the effectiveness of CL

At least two conditions emerge from this literature for CL to be effective:

CL is likely to be effective against the excessive market power of a firm and stimulates innovation path, especially when the ex-ante level of competition is low.

The benefits of CL depend on the credibility of the government, and especially their ability to commit that CL is an urgency measure. The effectiveness of the 1917 US Trading with the Enemy Act (TWEA) for the CL is likely explained by the exceptional circumstances and the fact that is *"perceived as a one-shot event"* (Moeser et al., 2012; Moeser et al., 2017).

To summarize, CL generates various static and dynamic benefits. It triggers a drop in the monopoly power, creates a variety effect and additional drop in price through substitution effects. With our assumptions, the potential threat for innovation does not really exist: CL is a little cost in the firm's strategy and does not affect the dynamics of innovation. By contrast, CL could trigger the rate of innovation.

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[282] Baten, J., Bianchi, N., & Moser, P. (2017). Compulsory licensing and innovation–Historical evidence from German patents after WWI. *Journal of Development Economics*, *126*, 231-242.
[283] Bailey, T. C. (2001). Innovation and Access: The Role of Compulsory Licensing in the Development and Distribution of HIV/AIDS Drugs. *U. Ill. JL Tech. & Pol'y*, 193.
[284] Tandon, P. (1982). Optimal patents with compulsory licensing. *Journal of Political Economy*, *90*(3), 470-486.

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