



Voluntary (VL) and Compulsory (CL) Licensing

An Introductory Fact Sheet and Literature Review

Outline and purpose of the document: This brief introduction to voluntary and compulsory licensing is part of the IMPACT3T IP 'Crisis Scenario' tool-kit. It is designed to explain and illustrate the main issues in these two forms of licensing, with a particular emphasis on recent (2020 +) use for medical technologies. It concludes by offering an overview of some relevant literature, allowing the reader to identify relevant sources more detailed documents on specific topics.

Target readership: This document is aimed at policy makers who are new to the issues of CL and VL and those involved in technology transfer who want to get a balanced over-view of the topic.

Level: This document assumes that the reader has some familiarity with Intellectual Property Rights (IPR) and in particular patent regulations and voluntary technology licensing, as well as an awareness of associated international trade regulations e.g. TRIPS (Trade-Related Aspects of Intellectual Property Rights).

Approach: The document is laid out as a series of frequently Asked Questions (FAQs) with each answer being linked to more detailed publications that can be found in the Bibliography.



1. What is Voluntary Licensing (VL) of rights?

VL of rights allows a rights holder to transfer all or some of the associated rights to a third party of their choosing under terms and conditions set by the rights owner/ licensor. It is a well established way for a patent holder to engage in technology transfer and commercialisation of technology.

2. What is Compulsory Licensing (CL) of patents?

CL of patents allows a government to authorise the use of a patent, or similar 'rights', by a third party, without the consent of the patent right holder, subject to conditions aimed at preserving the interests of the patent holder. The terms and conditions are set by the government. It is a legally established but less used way to make rights more widely available in certain critical circumstances e.g. in times of a 'national emergency' or 'crisis'.

3. What is the relevant international legal framework?

The associated international legal obligations are laid out in the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights).

The first type of compulsory licensing scheme is for the domestic market, (Article 31 TRIPS), which applies to all types of products.

The second scheme is compulsory licensing for export, (Article 31*bis* TRIPS), which only applies to pharmaceutical products.

The EU implemented this second disposition through the adoption of Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health issues.

*For an introduction to the compulsory licensing regimes in different EU countries the reader is directed to the publication "**Compulsory licensing in Europe**", EPO 2018.*

4. Did COVID-19 change legislation and guidelines relating to CL?

The COVID-19 pandemic led many international organisations including the World Health Organisation (WHO), the World Trade Organisation (WTO), the United Nations (UN), the World Intellectual Property Organisation (WIPO), the EU and national government to revisit their guidelines on compulsory licensing and to engage in consultation exercises. Although this led to intense debate it does not seem to have led to significant change.

For more information on the envisaged impact of changed legislation and results of the consultation process see:

Compulsory licensing of patents for crisis management EPRS 2024

EC Impact Assessment Report on the Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 EC 2023

On the European Commission's proposal to create a new EU-wide compulsory licensing regime Gurgula 2023.

5. In what circumstances can CL legally be invoked under TRIPS?

Although TRIPS makes provisions for CLs and provides some examples of relevant grounds that might justify a CL, e.g. a 'national emergency' or 'extreme urgency' or 'anti-competitive practices', it leaves it open to each country to determine and justify the grounds upon which a compulsory license can be granted.

6. Does a lack of clarity on defining circumstances lead to difficulties in application?



While the flexibility in defining a ‘national emergency’ or ‘extreme urgency’ may be helpful in some circumstances, it can lead to legal ambiguity. It has arguably been one of the reasons why CL legislating was not more strongly used during the COVID pandemic. See more under **12. ‘Why is CL not used more frequently?’** below.

7. What are the associated conditions of a CL?

A TRIPS compulsory license can be issued under a number of conditions, including:

- Voluntary license attempt: The applicant must have first tried to negotiate a voluntary license with the patent holder. However, there are some exceptions to this requirement, such as in cases of national emergencies, extreme urgency, public non-commercial use, or anti-competitive practices.
- Scope and duration: The license must be limited to the purpose for which it was granted.
- Remuneration: The patent owner must be paid adequate compensation.
- Legal review: The license must be subject to legal review.
- Non-exclusive: The license cannot be given exclusively to the licensee.
- Domestic use: The license should be granted primarily to supply the domestic market.

8. Who is a CL issued to?

The use of the invention for which a compulsory licence has been granted should only be **authorised to a qualified person** able to make, use, market, sell or import the crisis-relevant product, in accordance with licensee obligations provided for in Article 10 (Articles 5(1)(c) and (d) and 10(1)(a) and (b)).

9. Why is use restricted? Why are the rights not simply made available to anyone who wants them?

The technology licensed under a compulsory license is highly specialised e.g. vaccines and medical devices. It must be manufactured and tested to a specific quality standard and used by people with appropriate training and qualifications. Allowing any organisation or individual to make use of the technology could be very dangerous and could even result in loss of human life. See also **16. Why do many voluntary, non-exclusive licenses place limits on who can legally use them?**

10. How often is CL used?

Compulsory licensing is rarely used. Notable pandemic examples include Israel (a generic version of AbbVie Inc’s patent-protected drug Kaletra), Hungary and Russia (Gilead’s patent protected Remdesivir), Bolivia (Johnson & Johnson’s patented vaccine Ad26.COVS.2) and India (Eli Lilly’s Baricitinib).

Outside of the pandemic it has been more used as a threat to reduce pricing e.g. the UK case of Vertex Pharmaceuticals Kaftrio for cystic fibrosis¹. See more below under **‘Is VL used alongside CL?’**

*For an over-view of compulsory licensing cases dating back to 2002 the reader is directed to **Scope of Compulsory License and Government use of Patented Medicines in the context of the Covid-19 Pandemic** Southcentre.int 2021.*

*For more details on individual cases consult: **Compulsory Licensing of Patents During Pandemics** Sapna Kumar 2022 and **Compulsory Licences during the Covid-19 Pandemic: A European and International Perspective** Bonadio and Contardi 2022.*

¹ See for example <https://www.bbc.co.uk/news/health-67712269> and <https://www.bbc.co.uk/news/health-50144742>



For a number of different multi-country access scenarios see Compulsory licenses, the TRIPS Waiver, and access to COVID-19 medical technologies MSF 2021.

11. Why is CL not used more frequently?

Significant issues remain relating to the ambiguity of legal terms in TRIPS such as 'crisis' and 'complementary measures', the open-ended composition and workings of the proposed advisory body, the trigger for a compulsory licensing procedure, and the circumstances under which a rights-holder would be notified that a compulsory license was being issued.

Political/ economic pressure from power global pharmaceutical companies is also seen to be a factor in limiting CL use. See below **13. Why are CLs contentious?**

12. Why are CLs contentious?

A CL effectively removes the assured and well established monopoly rights normally associated with the IP system. This may benefit end users but a CL is unlikely to fully compensate the rights holder even if they are offered 'adequate compensation'.

There is a need to balance an IP monopoly, without which medicine and drug companies would not invest in new treatments, with the need for more accessible and affordable access for all people. The Medicines Patent Pool (MPP) has noted that while patents work well in HIC (High Income Countries) they do not work well for LMIC (Lower and Middle Income Countries) and compulsory licensing can be a necessity when other approaches to ensuring equitable access have failed.

In addition, the issues around CL are often not well understood by both policy makers and civil society who can take a very different view to the companies who are investing in innovation.

13. What are some of the main challenges to successful use of CL?

The inclusion of know-how/ trade secrets in compulsory licensing has been one of the main debating points for CL in recent years². A number of compulsory licences issued at the beginning of the COVID-19 pandemic were in relation to small-molecule medicines such as Remdesivir and Lopinavir/Ritonavir. These are regarded as more easy to replicate based on the patent specification than vaccines where substantial know-how is required. It is suggested that a CL for a vaccine patent alone would be unlikely to ensure successful production.

For more information on the role of know-how in compulsory licenses consult Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer Olga Gurgula and John Hull, 2021.

14. How can voluntary, non-exclusive licensing provide an alternative to CL?

Voluntary non-exclusive licensing allows non-rights holders to access technology under conditions set out by the rights owner rather than the government. In times of critical need it may allow a technology to be made rapidly available royalty free, but only to licensees that can meet specific conditions (see below).

15. Why do many voluntary, non-exclusive licences place limits on who can legally use them?

Voluntary non-exclusive licensing ensures that 'blue-prints' for technology are not simply distributed without restrictions that ensure that they are manufactured and used in compliance with regulations and that the technology provider is protected from any liabilities arising from their use. This is clearly important for medical drugs and devices including respirators. It can also offer some safeguards for

² See for example Gurgula, Olga and Hull, John, Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer (June 23, 2021). Queen Mary Law Research Paper No. 363/2021, Journal of Intellectual Property Law & Practice, Volume 18, Issue 6, June 2023, Pages 418–431, Why is Available at SSRN: <https://ssrn.com/abstract=3872796>



companies who are also sharing trade-secrets in the form of specialised know-how as terms of use and remedies for misuse can be controlled through the license.

16. How has voluntary, non-exclusive licensing been supported?

Support for voluntary, non-exclusive licensing has taken a number of forms including establishing technology pools, developing pledges and issuing guidelines on licensing conditions. Direct supporting tools have included rapid online non-exclusive licensing e.g. as used for the UCL and Mercedes Ventura breathing aid³.

17. Are there any negative effects of VL?

Voluntary licenses have been seen by organisations such as MSF (Medecins Sans Frontieres) to impact the ability of health authorities around the world to procure and provide essential medicines. These include lack of transparency, varying terms through multiple licenses, overly broad scope of patents, geographic limitations, differential treatment of age groups, formulations and medical indications, differential treatment of health care systems, complexities of tiered royalties, restrictions on the source and production of API (active pharmaceutical ingredients), anti-diversion requirements, restrictions on research and clinical studies and grant-back terms.

For more information see Voluntary Licensing and Access to Medicines Task Force on Voluntary Licensing and Access to Medicines 2023.

18. Is VL used alongside CL?

CL has been found to be a useful ‘lever’ (or threat) to push some companies to issue voluntary licenses (anthrax: Bayer’s ciprofloxacin antibiotic and avian flu: Roche’s Tamiflu) or to help reduce pricing of drugs (see the UK case of Vertex Pharmaceuticals Kaftrio for cystic fibrosis). During the COVID pandemic it was found that the threat of a CL was sufficient to trigger a VL from a company e.g. Eli Lilly’s *Baricitinib* in India and AbbVie Pharmaceuticals Inc’s *Kaletra* in Israel.

For more information on the way that the threat of a CL can help to trigger a VL see Compulsory Licences during the Covid-19 Pandemic: A European and International Perspective Bonadio and Contardi 2022 and Compulsory Licensing of Patents During Pandemics Kumar 2022.

19. What else is needed alongside voluntary licensing to ensure patient access to all medicines?

Voluntary licensing alone is not sufficient to ensure patient access to all medicines – healthcare system capability to diagnose patients and deliver treatments are critical, together with other key capabilities along the regulatory and supply chains, including raw materials sourcing, cold chains, tariffs, and export restrictions. Finally, political commitment and government funding to invest in health are key to enabling access to medicines.

For more information see Voluntary Licensing and Access to Medicines Task Force on Voluntary Licensing and Access to Medicines 2023.

³ See <https://www.ucl.ac.uk/healthcare-engineering/ucl-ventura-breathing-aids-covid-19-patients>



Summary of some existing resources

Much has been written in recent years about Compulsory Licensing. The brief summary below is intended to offer further points for more in-depth consultation on the topic. It is by no means comprehensive. Original copies of the 11 document can be found in the crisis CL resource section.

1. Compulsory licensing in Europe

“Compulsory licensing in Europe”, published by the EPO in 2018, provides a country-by-country overview of compulsory licensing regimes across the 38 EPC contracting states including possible grounds for grant, procedural framework and jurisprudence. It also indicates examples of how the legislative framework has been applied in the past (‘statistics and jurisprudence’).

It is important to note the date of this publication as it pre-dates the COVID pandemic of 2020 when a number of EU MS took action. Statistics and jurisprudence may therefore now be out of date.

Available online at: <https://www.epo.org/en/learning/learning-resources-profile/judges-lawyers-and-prosecutors/compulsory-licensing-europe>

2. Scope of Compulsory License and Government use of Patented Medicines in the context of the Covid-19 Pandemic

Published by the South Centre intergovernmental think tank (see <https://www.southcentre.int>), as part of the Health Intellectual Property and Biodeiversity programme, this short report provides brief tabulated, chronological information of instances of compulsory licenses, largely made under the WTO TRIPS Agreement. While some are linked to the COVID pandemic, e.g. Remdesivir in Russia and Hungary, other predate this with the earliest use listed being in 2002 for ARV (Antiretroviral) drugs to treat HIV in Zimbabwe. Information was last updated on 2 March 2021

Available online at: <https://www.southcentre.int/wp-content/uploads/2021/03/Compulsory-licenses-table-Covid-19-2-March.pdf>

3. Compulsory Licences during the Covid-19 Pandemic: A European and International Perspective

Authors: Enrico Bonadio (Reader in IP Law - City, University of London) & Magali Contardi Research Fellow at Sant’Anna School of Advanced Studies of Pisa, Italy, and Phd Candidate at the University of Alicante, Spain).

This article, first posted on November 21, 2022, looks at the context for compulsory licensing, created by the 2020 COVID pandemic; the international legal framework for compulsory licensing and in particular the TRIPS agreement; Covid related licenses filed and/or granted in various countries including i.e. Israel (a generic version of AbbVie Inc’s patent-protected drug Kaletra), Hungary and Russia (Gilead’s patent protected Remdesivir), Bolivia (Johnson & Johnson s’ patented vaccine Ad26.COVS) and India (Eli Lilly’s Baricitinib). The paper examines how Covid triggered amendments to national law including in Germany, (Law on the Prevention and Control of Infectious Diseases in Humans, March 2020), France (Law on the Prevention and Control of Infectious Diseases in Humans, Article L.3131-15, March 2020), Hungary, (Government Decree No. 212/2020); and Italy (Government Decree No. 212/2020 amending the Italian Intellectual Property Code (IPC)). The article also reviews changes outside the EU including in Canada and Latin America (Chile and Ecuador).

The article concludes that while the issuance of compulsory licences during the Covid emergency has been encouraged, including by changing legislative regimes, such flexibility may be insufficient to transfer the underlying technology, especially when it comes to vaccines. Recently developed know-how in vaccines, e.g. mRNA, plays a critical role and is difficult to acquire and much know-how is not disclosed in a patent; forcing disclosure of the information would be very hard under law. However, the articulate also concludes that keeping the option open for a compulsory license has been shown



to trigger a voluntary one (Eli Lilly's *Baricitinib* in India and AbbVie Pharmaceuticals Inc's Kaletra in Israel).

Available online at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4282886

4. Compulsory licenses, the TRIPS Waiver, and access to COVID-19 medical technologies

This article is part of an access campaign, published by Medicine Sans Frontiers (MSF) and dated May 2021 includes an annex which examines three different multi-country access scenarios in the COVID-19 pandemic using compulsory licenses and the TRIPS waiver. It also contains a very comprehensive bibliography related to the topic.

The article lays out their position that monopoly rights, granted to pharmaceutical corporations impede the timely and sufficient accessibility of life-saving medicines, vaccines, diagnostics and other health technologies. MSF state that the barriers if has identified undermine healthcare providers ability to respond to health challenges including HIV/AIDS, drug-resistant tuberculosis, hepatitis C and COVID-19.

The article focuses on how a TRIPS waiver could supplement existing compulsory licensing laws. It lays out the grounds for granting a compulsory license with examples of how they have been used in the past and their positive impact on availability (Malaysia 2017 sofosbuvir for hepatitis treatment). The article summarises how national law has been updated in eight countries for COVID -19 including (EU) Germany (Act on the Protection of the Population in the Event of an Epidemic Situation of National Significance) and Hungary (an emergency measure that allowed the government to issue compulsory licenses to address domestic needs for COVID-19 related medical products) and for specific COVID medicines (Hungary and Russia for remdesivir and Israel for lopinavir/ritonavir).

The article makes the case in considerable detail that compulsory licenses under TRIPS have shortcomings that need at times to be overcome by temporary waivers and that compulsory licenses have also been inappropriately politicized and countries discourage from their usage for fear of trade retaliation. The case for temporary waivers to TRIPS is strongly linked in this article to a waiver proposal made in October 2020 by South Africa and India where negotiations on the text were ongoing in May 2021. The article forms part of the MSF access campaign.

Available online at: <https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies>

Or directly at: https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf



5. Compulsory Licensing of Patents During Pandemics

This US focused paper critically examines the different approaches taken in the USA and other countries and legislative regions, including the EU, to address drug shortages through compulsory licensing. It focuses in particular on the situation seen during the Covid 19 pandemic.

The paper compares and discusses the differences between some EU member states (including France, Germany and Hungary), Canada, and other governments that passed pandemic-specific laws that provided their health ministers with greater authority to issue compulsory licenses as well as countries such as Israel, Hungary and Russia who issued pandemic-related drug specific compulsory licenses, with the USA where the situation was perceived to have been much less supportive in ensuring that drugs produced with funding from Operation Warp Speed would be made available to the public in sufficient quantity. The US focus was on securing domestic supply rather than supporting the needs of other countries. The issue of preventing future domestic drug shortages is also highlighted as not having been sufficiently considered.

TRIPS related legislation is discussed in some detail including evolution over time with regard to compulsory licenses and waivers designed to benefit health care in LMIC. This is compared to the legal situation in other countries including the United State and the EU. The US approach to compulsory licensing for safeguarding public health is introduced and its development over time discussed in some detail. Use of compulsory orders and voluntary licenses is discussed with regard to drugs needed to address the threats of anthrax (Bayer's ciprofloxacin antibiotic) and avian flu (Roche's Tamiflu). The contrasting attitudes of the US government to unauthorised use of defence-related patent rights (frequent) and compulsory licensing of patents for drugs (rare) is highlighted.

The paper critically examines issues such as the benefits, ethical and moral implications for LMIC of compulsory licensing as well as its possible effect on innovation in general.

The core of this paper focuses on the U.S. approach to developing and obtaining Covid-19 drugs and in particular the U.S. Remdesivir Shortage of 2020. The paper notes that the US government experienced domestic shortages, the patent holder Gilead Sciences did not make available voluntary licenses to boost supply and unlike other countries, including India and Russia, the US Government did not issue compulsory licenses to generics companies who proved themselves able to reverse engineer the drug rapidly.

The paper suggests that the EU position on compulsory licensing shifted to a more positive stance partly in response to President Trump's 2020 attempts to buy EU developed and manufactured drugs exclusively for the USA (CureVac in Germany and BARDA in France). The paper notes that in November 2020, the European Commission formally embraced compulsory licensing in its Intellectual Property Action Plan. Although the Commission recognized that compulsory licenses are "to be used as a means of last resort and a safety net," it highlighted the broad flexibility that TRIPS provides. The EC also called on member states to pass "fast-track procedures for issuing compulsory licenses in emergency situations" and encouraged member states to coordinate with each other regarding the duration of any licenses and the remuneration to be paid. The Commission said that it would consider "the possibility of creating an emergency co-ordination mechanism, to be triggered at short notice when Member States consider issuing a compulsory license." The EU also committed to facilitating low-income countries' use of compulsory licensing during the COVID-19 pandemic.

Author: Sapna Kumar

Published in the Connecticut Law Review

Full citation: Kumar, Sapna, "Compulsory Licensing of Patents During Pandemics" (2022). Connecticut Law Review. Vol. 54. No. 1.

Available online at https://opencommons.uconn.edu/law_review/514

6. Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer

Olga Gurgula and John Hull, *Journal of Intellectual Property Law & Practice* (2021)

This journal publication looks at the complexities of licensing the trade secrets that are commonly needed to be able to work patent protected vaccine manufacturing process and how this can impact on a compulsory license of rights or IP waivers. It argues that compulsory licensing of trade secrets is also needed alongside patent licensing to ensure increased access to vaccines under a non voluntary license.

The paper offers quite a detailed introduction of the vaccine manufacturing process and trade-secrets and know-how and trade secrets play a role. It argues that 'show-how' is often critical for being able to work the process. It examines the relative risks for a pharmaceutical company of releasing patent rights and trade secrets and concludes that releasing know-how will always carry much higher commercial risks and that these need to be addressed in licensing agreement.

The paper introduced different types of technology licenses and an example of a compulsory patent and know-how license, (*Mallinckrodt Ard Inc. (Questcor Pharmaceuticals*⁴)). It concludes by outlining the licensing clauses that would need particular attention if know-how and show-how were to form a part of future compulsory licenses to support access to healthcare, particular for vaccines.

Full citation: Gurgula, Olga and Hull, John, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer* (June 23, 2021). Queen Mary Law Research Paper No. 363/2021, *Journal of Intellectual Property Law & Practice*, Volume 18, Issue 6, June 2023, Pages 418–431, Available at SSRN: <https://ssrn.com/abstract=3872796>

Available online at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3872796

7. Pros and Cons of Compulsory Licensing: An Analysis of Arguments

This 2013 paper pre-dates the COVID-19 pandemic. It provides a quite basic review of some of the arguments for and against compulsory licensing. Care needs to be exercised when reading this paper as the author does not demonstrate a real world understanding of many of the issues inherent in pharmaceutical research, IPR and licensing. There is at times a high degree of naivety in the discussion and a lack of understanding of the underlying issues. The starting point is that patents are a 'necessary evil' and that 'pharmaceutical patent protection, works well only in high income countries with citizens having purchasing power to buy expensive patented pharmaceuticals'. This trivialises the complexity of both IP rights and licensing including voluntary and compulsory licenses.

For a more informed, knowledgeable and up-to-date review that also addresses 'pros and cons' see Olga Gurgula 'On the European Commission's proposal to create a new EU-wide compulsory licensing regime' below.

Full citation: Muhammad Zaheer Abbas, *International Journal of Social Science and Humanity*, Vol. 3, No. 3, May 2013

⁴ See *FTC v Mallinckrodt Ard Inc*, 'Stipulated Order for Permanent Injunction and Equitable Monetary Relief', Case Number: 1:17-Cv-120 EGS (20 January 2017, US District Court for the District of Columbia)

https://www.ftc.gov/system/files/documents/cases/stipulated_order_for_permanent_injunction_mallinckrodt.pdf



8. Compulsory licensing of patents for crisis management On the European Commission's proposal to create a new EU-wide compulsory licensing regime

This 12 page 2024 briefing paper was produced by the European Parliamentary Research Service for the European Parliament. A first version was published in February 2024 and then updated when the European Parliament voted to signal its first-reading position.

Full citation: EPRS | European Parliamentary Research Service Authors: Hendrik Mildebrath with Hugo Carmona Bas Members' Research Service PE 757.634 – March 2024.

This 2024 article discusses the European Commission's proposal to implement a new EU-wide compulsory licensing regime and its key elements. It includes a summary of the feedback on the consultation process. It was prepared in the run-up to the Committee vote.

The briefing notes introduces the current status quo with regard to compulsory licensing in the EU under the TRIPS agreement Article 31bis, through EU Regulation (EC) No 816/2006. It notes that this regulation has never been evaluated. The proposed EU regulation on compulsory licensing would amend Articles 18a and 18b of Regulation (EC) No 816/2006 by laying down rules on granting a Union compulsory licence for the purposes of exporting medical products to third countries with public health problems (Article 23 and Recital 37). This compulsory licence would provide a Union-level solution to avoid rights-holders having to apply for various compulsory licences under national schemes in cases where manufacturing and sales are spread across different Member States.

The paper outlines the existing situation and rationale for envisaged intervention and specific objectives for change. The proposal was not the preferred policy option but reflects the option that most efficiently achieves these objectives.

The changes that would come from the proposal are introduced and discussed including Compulsory licensing powers and procedures and supervisory powers and procedures. It summarises stakeholders' views on the change including from The European Consumer Organisation (BEUC), Médecins du Monde, Médecins Sans Frontières, European Federation of Pharmaceutical Industries and Associations (EFPIA), American Chamber of Commerce to the EU (AmCham EU), SME United, and individuals representing patients. It also summarises academic views (see Olga Gurgula below).

Status: On 13 March 2024, Parliament voted its first-reading position ahead of future trilogue negotiations. Parliament insists on empowering the Commission to mandate the disclosure of relevant trade secrets and know-how, and on significantly strengthening the position of rights-holders. In its position of 26 June 2024, the Council recommends a more industry-oriented approach.

Available online at:

[https://www.europarl.europa.eu/RegData/etudes/BRIE/2024/757634/EPRS_BRI\(2024\)757634_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2024/757634/EPRS_BRI(2024)757634_EN.pdf)

9. EC Impact Assessment Report on the Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

Accompanying the document Proposal for a regulation of the European Parliament and the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

Available online at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0121>



10. On the European Commission's proposal to create a new EU-wide compulsory licensing regime

This 2023 paper was produced in part in response to the EC's consultation process for their proposed EU-wide compulsory licensing regime (see above). It is an informed, well argued and insightful paper that covered a number of issues related to compulsory licensing as well as the proposed EC proposal.

It lays out the existing compulsory licensing regime related to TRIPS, its historical use and shortcomings identified during the COVID-19 pandemic. It cites compulsory license use in Hungary and Russia (Remdesivir) and Israel (Lopinavir/ Ritonavir) as well as amendments to national compulsory licensing laws in developed countries (Australia, Canada and Germany). It highlights the failure of the WHO C-TAP technology pool to secure support from most manufacturers with production capacities and links the failure of countries to issue compulsory licenses to political reasons. However, it also acknowledges that compulsory licenses for patents and similar rights are inadequate to address modern vaccine manufacture unless they are accompanied by enforceable access to trade-secrets/ know-how.

The paper focuses on the need to improve the current regime for cross border compulsory licensing. It explains the 'hybrid' proposal from the Commission, including procedure and implications for issues such as remuneration as well as possible shortcomings e.g. potential abused by a pharmaceutical company seeking to stall the process unless specific timeframes are set for negotiations. It lays out in clear detail the key elements of the new regime and its novel and useful elements to improve the effectiveness of compulsory licensing. This includes the critical issue of access to confidential information and know-how.

The paper concludes that the proposal represents an important step forward to addressing emergency situations and demonstrates a clear visible shift from 'pro-industry' to a more 'pro-access' approach.

Author: Olga Gurgula

Full citation: Gurgula, Olga, On the European Commission's Proposal to Create a New EU-wide Compulsory Licensing Regime (August 26, 2023). Forthcoming in the European Intellectual Property Review (EIPR), Available at

SSRN: <https://ssrn.com/abstract=4552851> or <http://dx.doi.org/10.2139/ssrn.4552851>

11. Voluntary Licensing and Access to Medicines.

This report was produced in April 2023 by the Task Force on Voluntary Licensing and Access to Medicines. It sets out 11 key issues with VL for access to medicines, namely lack of transparency, varying terms through multiple licenses, overly broad scope of patents, geographic limitations, differential treatment of age groups, formulations and medical indications, differential treatment of health care systems, complexities of tiered royalties, restrictions on the source and production of API (active pharmaceutical ingredients), anti-diversion requirements, restrictions on research and clinical studies and grant-back terms.

The report looks at opportunities for government action including Regulating voluntary license practices, compulsory licensing and enabling patent oppositions.

It offers a number of useful case studies to illustrate key issues including on medicines (Atazanavir, Delamanid, Lopinavir/ritonavir) and on country responses (Brazil's voluntary licenses under the framework of national industrial policies, India's lack of transparency of licenses, Israel's compulsory license addresses worldwide barriers to HIV medicine, Malaysia successfully addresses voluntary license exclusion).

It ends with a series of actions oriented and detailed recommendations and conclusions.



Available online at: https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf