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Declaration of interest

- No fee attending/speaking at the meeting
- We work for governments, non-for profit organisations, international organisations
- Our work is funded by charitable foundations/donors
- No financing from industry
- Our work is freely available on the website

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Use of Art 31 during Covid-19 pandemic

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The TRIPS Flexibilities Database

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Show or hide column(s) Country | Date | WTO Classification | Type of Flexibility | Products | Patent filed/granted | Originators | Licensees | Diseases | Royalty rate | Executed | Reason if not executed

Showing 10 result(s)

↑ Country	Date	WTO Classification	Type of Flexibility	Product	Disease	Executed
filter		filter	filter	filter	filter (1)	filter
Chile	Jan 2022	HIC	Art 31	Nirmatrelvir/ritonavir	Covid-19	Pending
Colombia	Mar 2022	DC	Art 31	Nirmatrelvir/ritonavir	Covid-19	Pending
Dominican Republic	Dec 2021	DC	Art 31	Nirmatrelvir/ritonavir	Covid-19	Pending
Hungary	Mar 2020	HIC	Art 31	Remdesivir	Covid-19	Yes
Indonesia	Nov 2021	DC	Art 31	Remdesivir	Covid-19	Yes
Indonesia	Nov 2021	DC	Art 31	Favipiravir	Covid-19	Yes
Israel	Mar 2020	HIC	Art 31	LPV/r	Covid-19	Yes
Peru	Mar 2022	DC	Art 31	Nirmatrelvir/ritonavir	Covid-19	Pending
Russia	Feb 2021	HIC	Art 31	Remdesivir	Covid-19	Yes
United States of America	Aug 2020	HIC	Art 31	Covid-19 vaccine (mRNA based)	Covid-19	Yes

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Germany - Infectious Diseases Prevention and Control Act (amended March 2020)

Federal Ministry of Health was given powers during the epidemic:

- to take measures by statutory instrument, without the consent of the Federal Council, to ensure the supply of medicinal products including narcotics, the active ingredients, starting materials and excipients for these, medical devices, laboratory diagnostics, aids, as well as items of personal protective equipment and products for disinfection and in particular
- to order under s. 13(1) of the Patent Act that an invention relating to one of the products mentioned in No. 4 […] shall be used in the interest of public welfare or in the interest of the security of the Federal Republic of Germany; the Federal Ministry of Health may instruct a subordinate authority to make such an order
- This included use of a patent in order to be able to produce vital active ingredients or medicines.

https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/S/Entwurf_Gesetz_zum_Schutz_der_Bevoelkerung_bei_einer_epidemischen_Lage_von_nationaler_Tragweite.pdf

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Section 13(1) of the German Patent Act

The patent shall have no effect in a case where the Federal Government orders that the invention is to be used in the ***interest of public welfare****. Further, it shall not extend to a use of the invention which is ordered* ***in the interest of the security*** *of the Federal Republic of Germany by the competent highest federal authority or by a subordinate authority acting on its instructions.*

European Commission’s proposal for EU-wide compulsory Licensing regulation

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European Commission – EU wide compulsory licensing

Background

- November 2021 European Parliament called on the Commission to analyse the possibility of CL at EU level
- April 2023 the Commission presented the proposal for a Regulation on compulsory licensing for crisis management.
- March and June 2024 vote in European Parliament

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Current EU system for CL

European Commission had identified the following problems:

- lack of coherence between national compulsory licences in the EU
- limited territorial effect of these licences
- burdensome and lengthy administrative procedures
- lack of a Single Market for products subject to compulsory licensing
- compulsory licensing rules in the EU (with the exception of Spanish law) do not provide for the transfer of trade secrets, test data, or know-how that may be required to be able to produce the product.

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Context

“The COVID-19 crisis highlighted that an appropriate balance between patent rights and other rights and interests is a staple of the patent system. “

Harmonisation of IP protection in the EU “purely national compulsory licensing systems and their resulting divergences would conflict with the increasing European integration of patent law.”

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Compulsory Licensing of patents in crisis situation - Subject matter

"This Regulation has the objective to ensure that in crises the Union has access to crisis- relevant products. To this end, this Regulation lays down rules on the procedure and conditions for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of **crisis-relevant products** to the Member States in the context of a Union crisis or emergency mechanism."

'Crisis-relevant products' means products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union.

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Key features of EU-wide CL mechanism

- Single application made at the European Commission for CL
  - Valid in the entire European Union

Scope
  - Patents, published patent applications
  - Utility models
  - Supplementary protection certificates (patent extensions on pharmaceuticals)
- CL for manufacture and sale for export across the member states of the EU
- Royalty rate is set at 4%
- Includes provision for access to trade secrets/undisclosed information
- Solely for the supply of EU market (export incl. of non-predominant part is prohibited)
  - Export under national CLs under Regulation (EC) No 816/2006 – TRIPS 31bis remains possible
- Patent holder has 'right to be heard'

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Data and Market exclusivity waiver

- Monopolies granted through the regulatory sytem
  - Up to 12 years
- Data and market exclusivity may seriously hamper effective use of a CL
- Revisions of the EU's pharmaceutical legislation include a waiver of such exclusivities the case of a compulsory licence to address a public health emergency.

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Compulsory licensing of trade secrets / undisclosed information

- The Commission proposal recognises the importance of access to know-how and trade secrets for more complex technologies (e.g. biologics, vaccines)
- Commission:
  - May require additional information from the patent holder to fulfill the purpose of the compulsory licence (for example, its manufacturing process is not disclosed in the patents and patent applications, and is instead protected by trade secrets)
  - May impose financial sanctions on the rights-holder in case of failure to provide such information (Recital 34, Articles 15 and 16.)

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A proposal for inclusion in WHO Pandemic Accord

Where the Director-General of the World Health Organization has determined that: (i) a pandemic outbreak, or the threat of a pandemic outbreak, represents a public health emergency of international concern (PHEIC); (ii) the urgent manufacture by qualified third parties of a pharmaceutical product is necessary to respond to the pandemic outbreak, or the threat of the pandemic outbreak; and (iii) the manufacture is prevented or hindered through lack of access to undisclosed information as defined in Art. 39.2 TRIPS possessed by one or more entities located in one or more Parties, that or those Parties shall compel that or those entities to share the undisclosed information with the third parties.

For details see: https://medicineslawandpolicy.org/wp-content/uploads/2023/09/Revised-MLP-Proposal-for-knowhow-trade-secret-sharing_final.pdf

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Thank You!

Resources

EC CL proposal

https://single-market-economy.ec.europa.eu/publications/com2023224-proposal-regulation-compulsory-licensing-crisis-management_en

https://medicineslawandpolicy.org/2023/08/the-european-commissions-compulsory-licensing-proposals-are-sensible-but-do-not-go-far-enough/

https://medicineslawandpolicy.org/2023/11/the-new-eu-compulsory-licensing-regime-needs-to-allow-the-export-of-medicines/

https://medicineslawandpolicy.org/wp-content/uploads/2023/09/Revised-MLP-Proposal-for-knowhow-trade-secret-sharing_final.pdf

ML&P Covid-19 resources

https://medicineslawandpolicy.org/covid-19/

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