Non-Voluntary use of health technologies:
The good and the bad of the 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

Current EU system for CLs

European Commission had identified the following problems:

Lack of coherence between national compulsory licences in the EU

Burdensome and lengthy administrative procedures

Lack of a Single Market for products subject to compulsory licensing

Limited territorial effect of these licences

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.

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

The EU 's purely national compulsory licensing systems and their resulting divergences would conflict with the increasing European integration of patent law."

- European Commission, April 2023

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52023PC0224

Objectives of the Regulation

To enable the EU to rely on compulsory licensing in the context of the EU crisis instruments.

To introduce an efficient compulsory licensing scheme, with appropriate features, to allow a swift and appropriate response to crises, with a functioning Internal Market, guaranteeing the supply and the free movement of crisis-relevant products* subject to compulsory licencing in the internal market.

**'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.*

Key features of the proposal for a EU-wide CL mechanism

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

Includes provision for access to trade secrets/undisclosed information

Scope:

- Patents, published patent applications
- Utility models
- Supplementary protection certificates (patent extensions on pharmaceuticals)

Key features of the proposal for a EU-wide CL mechanism, cont

CL for manufacture and sale for export across the member states of the EU

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.

Royalty rate of 4%

Patient holder has ‘right to be heard’

Data and Market exclusivity waiver

Data and market exclusivity may seriously hamper effective use of a CL.

EU follows herein Chile, Colombia and Malaysia

Proposed revisions of the EU's pharmaceutical legislation include a suspension of data and market exclusivities for the duration of a compulsory licence granted by a relevant authority in the Union to address a public health emergency. (Art 80.4 of proposed Directive*)

*https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192

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.)

EP strengthened provisions on access to trade secrets/know-how

(Amendment 17, Recital 32(b)):

"*This Regulation should guarantee that the Commission has the authority to oblige rights-holders to provide all necessary information to facilitate the rapid and efficient production of critical crisis-related products, such as pharmaceuticals and other health-related items. This information should encompass details about know-how, particularly when it is essential for the effective implementation of compulsory licensing. While patent licensing alone might suffice to enable other manufacturers to quickly produce simple pharmaceuticals, in case of more intricate pharmaceutical products, such as vaccines during a pandemic, it is often insufficient. Where it is essential for the implementation of the compulsory licence, an alternative producer will also require access to know-how.*"

European Parliament amendments that weakened the proposal

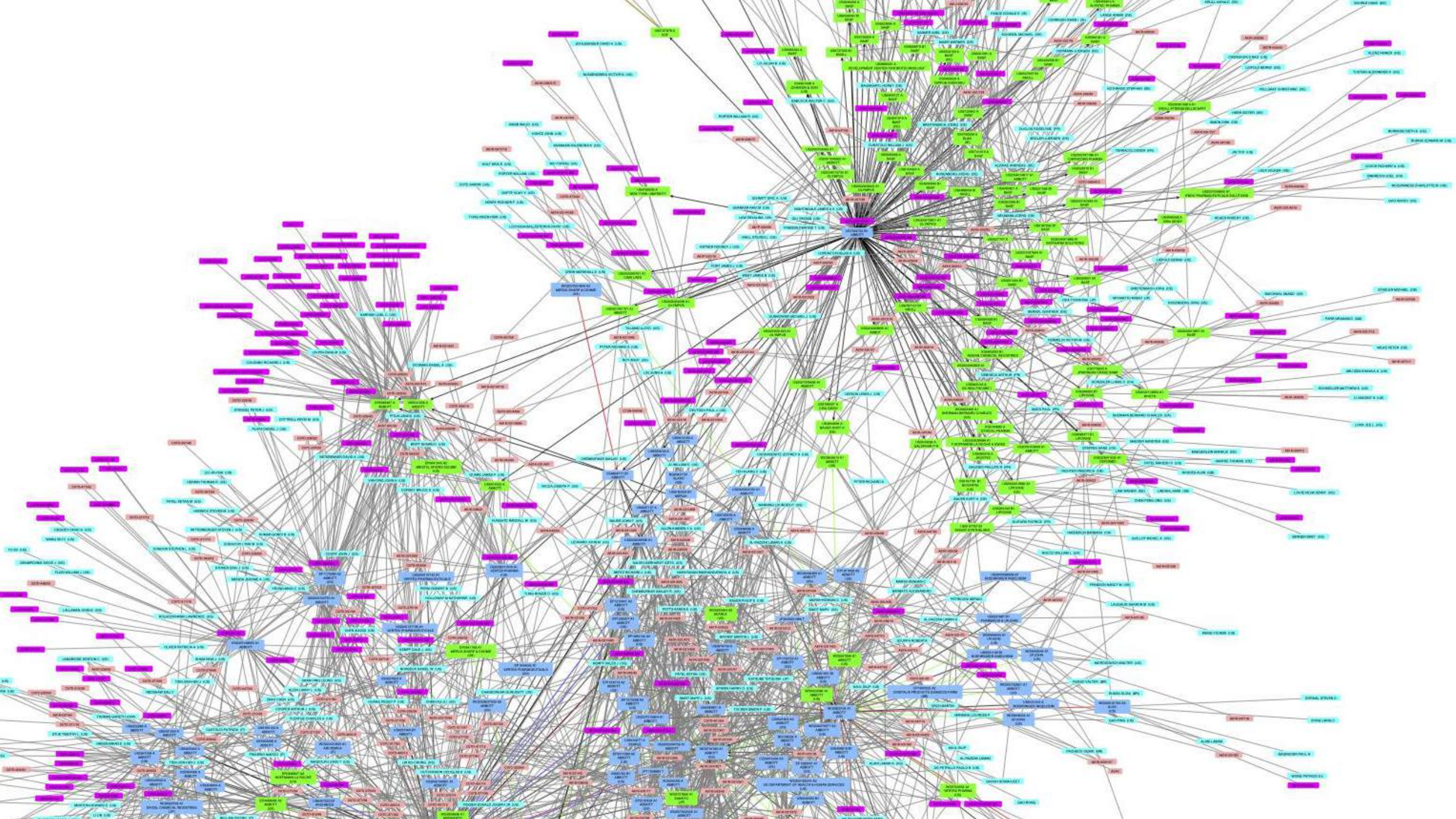
Characterisation of CL as last resort, VL is preferred and more effective etc.

Introduced more complex procedures – incl. additional consultations

Requirement to identify all rights, rights-holders and potential licensees *before* a CL can be issued*

Removed the 4% royalty

*Commission: "*a complete identification of all intellectual property rights and of their rights-holders may seriously undermine the efficient use of the Union compulsory licence to swiftly tackle the crisis or the emergency.*"



Conclusion

The Good

- EU-wide CL mechanism fills a void
- Strong provisions for access to trade secrets/knowhow
- DE and ME exclusivity waivers in pharma legislation

The Bad

- EU-wide CL only for crisis situations despite the fact that the Commission acknowledges that "*purely national compulsory licensing systems and their resulting divergences would conflict with the increasing European integration of patent law.*"
- Export outside of the EU of products produced under a CL is not allowed– not even the non-predominant part
- Complexities introduced by EP

Note: Process for adoption of CL Regulation is still ongoing.

Resources

On the 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
- https://medicineslawandpolicy.org/2024/03/something-is-going-terribly-wrong-with-the-eu-compulsory-licensing-regulation/

Thank you!

ML&P Covid-19 resources

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

TRIPS Flexibilities Database

http://tripsflexibilities.medicineslawandpolicy.org