

# Bridging the 'Valley of Death' in Biomedical Sciences

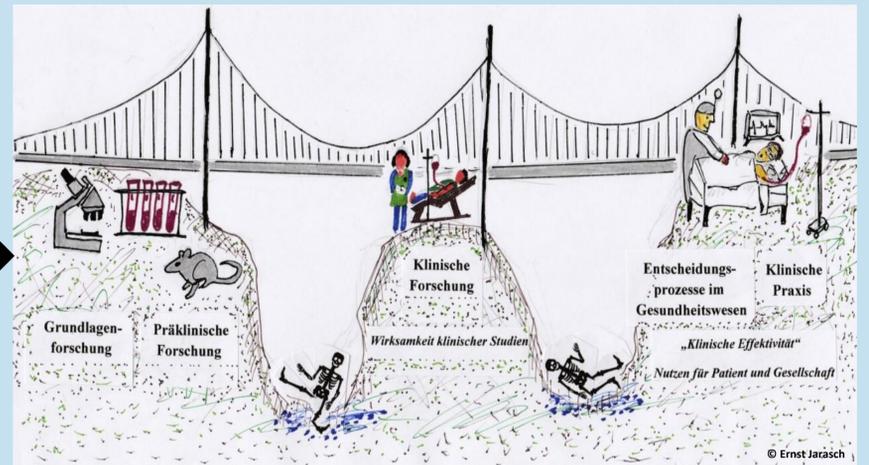
## Progressive Adaptations to Innovation Law & Policy



Technical Disclosure



Stakeholder Engagement



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### 1. Objectives

- To understand that EU Horizon 2020 social innovation (SI) theme capitalizes on **societal stakeholder diversity**.
- To address SI failures ('Valley of Death' or VOD) primarily as **disruptions in stakeholder engagement (SE)**. SE refers to mutual interactive responsiveness among societal stakeholders towards responsible research and innovation (EC 2013).

### 2. Hypothesis/Research Question

- VOD may be bridged by governing **pro-innovative stakeholder engagement** in socio-technical systems.
- Within the work package theme of "IP as a complex adaptive system", specific research question reads, "Does **technical character** of a background patent impact pro-innovative stakeholder engagement in biomedical SI platforms?"

### 3. Methodology

- Theory:** Adapted Stakeholder Theory of Corporation
- Type:** Qualitative Case Study (Snapshot, Discipline-configurative, Theory testing and Plausibility probe)
- Method:** In-depth semi-structured interviews
- Case:** Chemelot Institute for Science & technology (InSciTe) biomedical social innovation model
- Analytical Theme:** Stakeholder Engagement

### 4. Main Results

- Patent technical character** promotes pro-innovative stakeholder engagement in biomedical SI systems
- Specifically, **competence, credibility and self-referential characteristics** of background patent in a biomedical SI platform seem to enable stakeholder collective behaviour in terms of understandings, ties, identity and trust. Such collective behaviour is defined as **stakeholder social capital**.

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## Diversity of Innovation: Does One (Patent Framework) Size Fit All?



### 1. Research Objectives

#### Does One Size Fit All

To study the adaptive plasticity of *patent legal framework* to address ICT and pharmaceutical industries concerns.

#### Patent System in 21<sup>st</sup> century ?

1. Over Patenting and Examination Standards : Considering Socio-Economic Test Criteria.
2. Effect of Anti-Commons in ICT( 5G technologies)

### 2. Research Questions

- Whether patent legal framework is technology neutral ? (Pharmaceutical vs ICT)
- Whether patent system has adapted with the evolution of innovation models ?
- Whether introduction of socio-economic examination criteria's improve quality and bridge the valley of death of patents ?
- Whether anti-commons is an emergent property of the present patent legal framework ? (5G)

### 3. Methodology

- Doctrinal & comparative analysis : to study the evolution of the patent legal framework vis a vi the evolution of innovation models.
- Secondary Empirical Data : Use of secondary empirical innovation data from Community Innovation Survey, Patenting Patterns in industries.
- Complex Adaptive System Analysis will be followed to analyze empirical data.

### 4. Preliminary Results

- The Patent framework has adapted to address sectoral concerns, however it does not appreciate the *needs principle as in access to medicines* (Pharmaceutical industry)
- ICT and Pharmaceutical industries: The patent framework aides rise to Patent Oligarchs.(High Gini -- Coefficient).
- Anti-commons effects simulated in an agent based environment.

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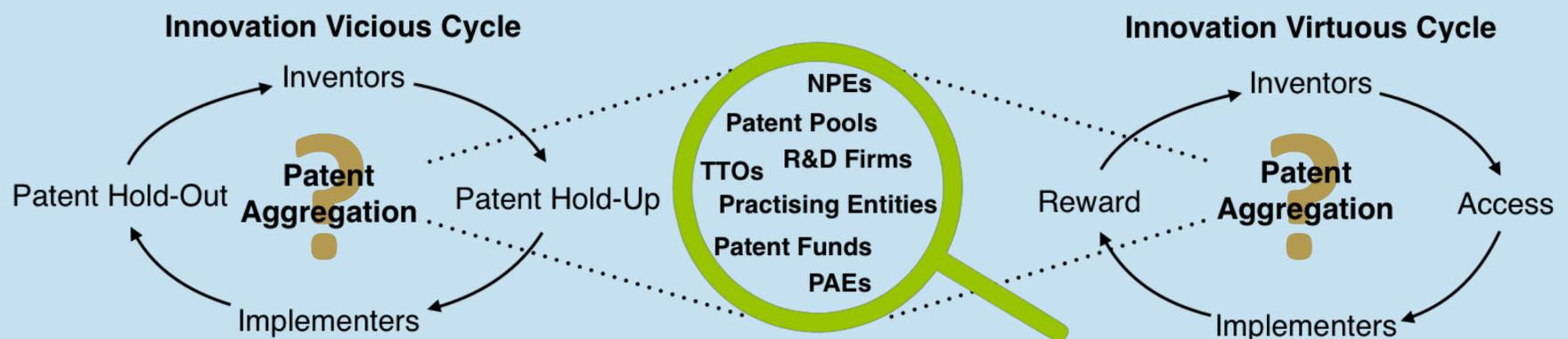
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# Patent Aggregation in Patent and Competition Law

## Patent Aggregation: Retardant or Catalyst of Innovation?



## 1. Background

- In electrical engineering industries, patent aggregation has both **defensive** and **offensive** aims vis-à-vis other market players.
- Insofar as it differs from more traditional patent uses, the extent to which patent aggregation happens in Europe still needs to be ascertained.
- Patent aggregation activities result in either **competitive or anti-competitive conducts** without a clear and certain **impact** on both disruptive and incremental **innovation**.

## 2. Objectives

- **Redefine** patent aggregation and **classify** the underlying economic activities.
- **Find European evidence** of the classified activities.
- **Assess the effect** of different patent aggregation activities on innovation.
- Investigate the scope for **competition law intervention** against harmful patent aggregation instances.
- Develop pro-active policies to **promote desirable patent aggregation** activities.

## 3. Methodology

Mixed research methodology:

- **Black-letter research** to classify the activities falling within the patent aggregation phenomenon.
- **Empirical legal research** to clarify the occurrence of patent aggregation in Europe.
- **Law and economics analysis** to assess patent aggregation practices under European competition law.

## 4. Main Results

- Patent aggregation is redefined as the **accrual** of patents under common ownership or control and their **subsequent non-manufacturing use**.
- New conduct-based bi-dimensional patent aggregation taxonomy comprising the viable means to both **amass patents** and **exploit them beyond production**.
- Non-Practising Entities and Practising Entities pursue different patent aggregation activities in Europe.
- **Competition law can remedy case-by-case to anti-innovative patent aggregation** instances, e.g. both Art. 102 TFEU and Reg. 139/2004 can address patent purchases that stifle innovation.

### References

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# Innovating within Tradition: Geographical Indications for Agricultural Products and Handicrafts



## 1. Hypothesis

- The EU needs to promote quality and innovation in agribusiness, together with a successful trade policy.
- GIs have to provide clear information to consumers on the link to origin of the products.
- International treaties do not differentiate among products but there is no unitary GI protection for handicrafts in the EU.

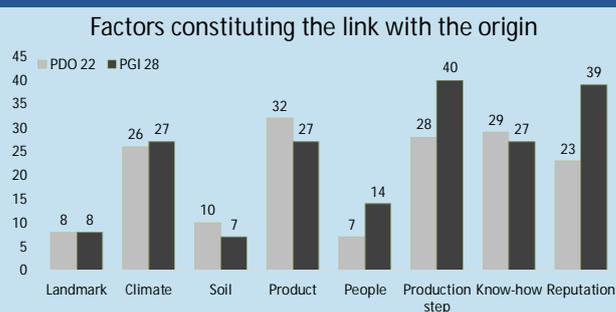
## 2. Objectives

- Analysis of the link to origin in the current EU GI system.
- Verify the flexibilities of the EU GI system on product and process innovation for traditional products.
- Pros and cons of trademark protection as opposed to *sui generis* GIs, impact on innovation and trade.
- Alternatives for the protection of non-agricultural products in the EU.

## 3. Methodology

- Doctrinal and comparative analysis: study of the EU GI legislative framework and comparison with US and Canada (focus on registration and amendment).
- Empirical analysis: qualitative content analysis on GI applications and their amendment + interviews to EU producers (focus on members of oriGIn).

## 4. Main Results



## References

- Tomer Broude, Taking Trade and Culture Seriously: Geographical Indications and Cultural Protection in WTO Law, (2005) 26 U. Pa. J. Int'l Econ. L. 638.
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## The Future of Plant Breeding and the Dynamic Landscape in Patent and Plant Breeders' Protection



### 1. Hypothesis

- The EU needs a balanced IPR regimes that are sensitive to the needs of all stakeholder groups in the plant breeding sector.
- Lack of harmonised IPR regimes sensitive to exploitation of farmers' rights, breeders' exemptions and biodiversity conservation has contributed to conflicting interests by stakeholder groups in the plant breeding sector.

### 2. Research Questions

- What are the market landscapes and who are the main intellectual property holders?
- Do the IPRS in EU provide equitable protection of the interests of all the stakeholders in the plant breeding sector?
- Do the current IPRs regimes in the plant breeding sector foster sustainable innovations?

### 3. Methodology

- Comparative analysis: Analyse EU IPRs in plant breeding with those in other jurisdictions (USA and India)
- Qualitative analysis: surveys and or interviews for plant breeding entities and regulators
- Quantitative analysis of data from ESA, EPO and CPVO databases (partner organisation).

### 4. Main Results

- IPR plays a significant role in cereal seed technology from food security perspective through the green revolution.
- IPR promotes development of new plant varieties and agricultural biotechnology innovations in the private sector.
- IPR provides incentives for domestic agriculture through foreign companies investments.
- IPR play a role in **economic concentration**.

#### References

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# Patentability of 4<sup>th</sup> industrial revolution generated inventions: a case study on pharma

## 1. Hypothesis

The Fourth Industrial Revolution is promising to significantly impact on inventive dynamics. Technologies such as Artificial Intelligence are increasingly involved in the production of patentable outcomes.

Such involvement may challenge fundamentals of patent law theoretically and practically. Certain aspects of the patent system, such as entitlement and inventive step, might require reconsideration.

The examination provided under the present project explores the extent to which our present patent regime is equipped to meet the challenges presented by inventions developed with 4<sup>th</sup> industrial revolution technologies involvement.

## 2. Objectives



To address the compatibility of the current patent regime with 4<sup>th</sup> industrial revolution generated inventions.

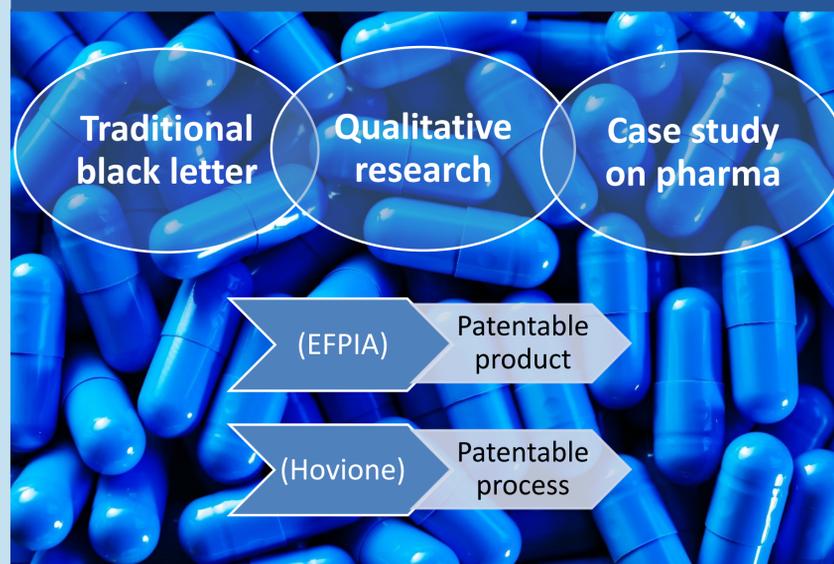


To evaluate the pharmaceutical sector as a case study, in relation to the aforementioned examination.



To provide conclusions and recommendations based on the above mentioned examination and analysis.

## 3. Methodology



## 4. Main Results

1) To establish which facets (if any) of patent law may require reconsideration in light of inventions developed with 4<sup>th</sup> industrial revolution technologies involvement.

2) To provide policy recommendations tailored for the pharmaceutical sector.

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# Over and Underdisclosure of Standard-Essential Patents: an EU regulatory approach to their effects on innovation and competition



## 1. Background

- External and internal factors condition holders' behaviors in SEP disclosure, leading to overdisclosure (OD) and/or underdisclosure (UD)
- OD and UD may negatively impact innovation and competition, while Internet of the Things (IoT) technological and market dynamics might alter existing assumptions on such impact

## 2. Objectives

- Understanding why SEP holders deviate from their duty to disclose
- Analysing the origin and scope of the duty to disclose and its legal consequences.
- Studying how IoT might affect competitive dynamics, with a special focus on the legal dimension
- Proposing a set of preventive measures and remedies to fight against harmful deviations from the duty to disclose

## 3. Methodology

- Descriptive study of key concepts from a legal and economic perspective
- Empirical assessment of causes for OD/UD based on semi-structured interviews
- Normative analysis of OD/UD from a competition law perspective
- Evaluation of existing measures to fight OD/UD

## 4. Main results

- OD/UD are either caused by strategic behaviours or by the mere evolution of the standard/patent scope
- A duty to declare may arise from competition law but its scope is conditioned by SDOs IPR Policies and business practices
- IoT impacts competition within and among standards
- Measures addressing potential UD should only be taken if their benefits outweigh the risk of producing more OD and vice versa

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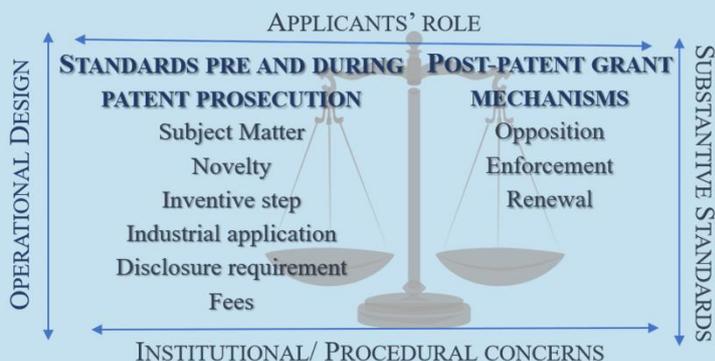
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# PATENT QUALITY IN THE EUROPEAN PHARMACEUTICAL INDUSTRY



## 1. Objective

•To study the factors that may influence the quality of pharmaceutical patents in Europe and understand its relationship with innovation. This, in turn, requires an evaluation of the legal arrangement namely the patent prosecution process and post-patent grant mechanisms.

## 2. Research Questions

- What are the factors influencing the quality of patents in the European pharmaceutical sector?
- Whether or not existing legal arrangement (patent grant process and post grant mechanisms) affects the European pharmaceutical patent quality?

## 3. Methodology

CONTEXTUAL/ LITERATURE ANALYSIS	→ concept of patent quality and innovation and its implications for pharmaceutical industry. → existing European legal arrangement (including patent grant process and enforcement mechanisms) for pharmaceutical sector.
QUALITATIVE ANALYSIS	→ case study at Hovione. → (semi-structured open ended)interviews with the stakeholders (EFPIA members, Patent Office etc.).
LEGAL NORMATIVE ANALYSIS	→ 'what the patent system is' and 'what is ought to be'. → ex ante analyses of the UPC for pharma sector.

## 4. Preliminary Field Results

Case-study at Hovione (interviews and observation)

- ✓ *Internal workflow from idea submission to patent prosecution*
- ✓ *Perception about 'quality patent' ✓ Innovation/IP department*
- The high costs of litigation have encouraged the company to adopt a rigorous patent drafting/reviewing process.
- The provision to be able to file a provisional application (with the possibility of amendments for upto one year after filing) is often used to secure priority and impact the quality of patent writing.
- Internal award/incentive system encourages inventors to invest efforts in a patent application.
- Legal/IP training for inventors who draft patent application has a positive impact on their search and drafting skills.
- A difference exists in the treatment of a product and a process patent as product patents are easy to enforce.

### References

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# The Protection and Enforcement of IP in Investment Agreements with the EU

## 1. RESEARCH QUESTIONS

- What are the legal and policy implications of protecting IP under investment agreements in the EU?
- Is IP 'only' an investment? Which standards of protection and dispute settlement system are available under IIAs for IP and what are their consequences?
- What future for IP adjudication in the EU in light of the upcoming investment court system and multilateral investment court?

## 2. RESEARCH OBJECTIVES

IDENTIFY

- Relevant agreements and case-law.
- Historical and political developments.

ASSESS

- Suitability of investment protection and dispute settlement for IP.

CONCEPTUALIZE

- Balanced legislative framework, fostering sustainable investments in IP and innovation in the EU.

## 3. METHODOLOGY

COMPARATIVE  
ANALYSIS

QUANTITATIVE  
EMPIRICAL  
RESEARCH

QUALITATIVE  
EMPIRICAL  
RESEARCH

## 4. MAIN RESULTS



### CHAPTERS

- IP and FDI in the EU
- IP in IIAs and lessons for the EU

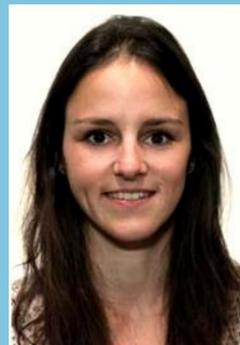


### SECONDMENT

- International dimension of the topic
- Representation in International Organizations and networking

## References

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# Enforcement of IPR and Global Trade



## 1. Background

- EC's 'Strategy for the Enforcement of Intellectual Property Rights in Third Countries' in 2004 and 2014.
- Starting point of the research: an academic discussion, underway in the European Union, concerning the export of IPR enforcement *acquis* norms to third countries, which might be or not be ready for such norms.

## 2. Objectives

- Understanding the EU's trade and neighborhood objectives and guiding principles for IPR Enforcement, their evolution.
- Corroborating or refuting, based on three case studies (Georgia, Moldova, Ukraine), the critics voiced towards the EU's approach to introduce strong IPR Enforcement standards in third countries, without allegedly adopting a tailor-made approach or considering broader societal interests.
- Shall the critics be confirmed, suggesting possible improvements.

## 3. Methodology

- doctrinal research, literature review;
- comparative and diachronic legal analysis;
- qualitative research through semi-structured interviews with stakeholders from third countries (Georgia, Moldova, Ukraine).

## 4. Preliminary Results

- Varied level of enforcement commitments and legal approximation techniques: EU's tailor-made approach?
- Different implementation methods in Georgia, Moldova and Ukraine.
- First national case law suggests potential problems with application of transplanted *acquis*.

### References

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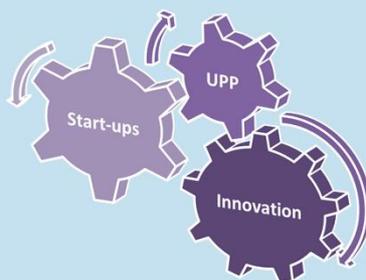
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# The Influence of the Unitary Patent and Unified Patent Court on Innovation of High-tech Start-Ups



## 1. Background

- In today's economy start-ups play an important role in innovation.
- Any reform of the patent system should take into account the needs of the different market actors.
- The impact of the implementation of the Unitary Patent and establishment of the Unified Patent Court on innovation of start-ups remains an open question.

## 2. Objectives

- Identify the incentives to innovate and the needs of start-ups and assess how start-ups relate to the patent system.
- Establish whether the legal framework of unitary patent protection adequately addresses the needs of start-ups.
- Propose amendments to the provisions which are relevant to safeguard the interests of start-ups.
- Propose an alternative design for a system of unitary patent protection that is more responsive to the needs of start-ups.

## 3. Methodology

- Descriptive assessment of the start-ups' environment.
- Empirical assessment of the perceptions of relevant stakeholders through qualitative interviews.
- Comparative analysis between the legal framework of the current system and of the unitary system of patent protection and enforcement.

## 4. Main Results

- Obtaining a Unitary Patent may increase the opportunity for a start-up to receive financing.
- The additional layer of unitary patent protection creates more complexity and uncertainty for the users.
- The Unified Patent Court system increases the risk for start-ups as defendants to be sued in a foreign forum in comparison to the current system of national courts.

### References

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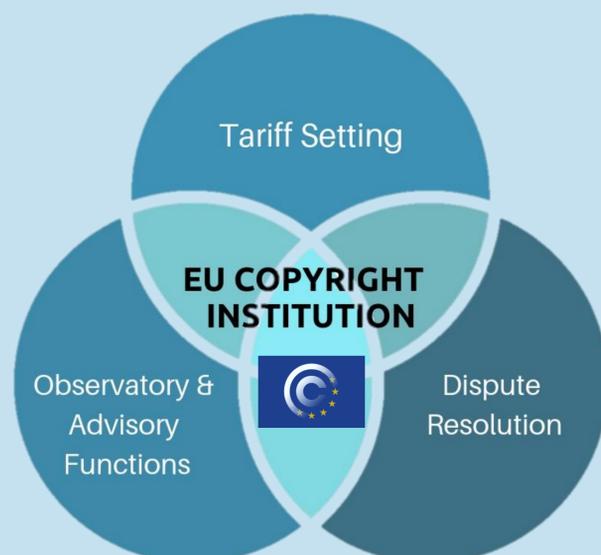
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# Copyright Reform in the EU: An Institutional Approach



## 1. Background

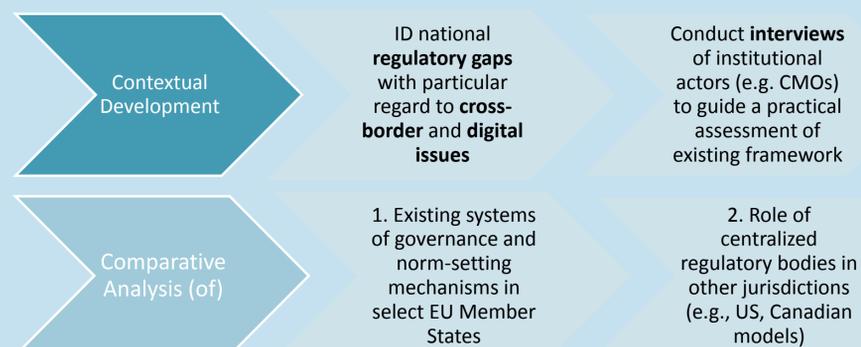
- Copyright law in the EU should be **adaptive and flexible** to keep pace with technology, while ensuring **legal certainty** in cross-border commerce
- Some jurisdictions have created **special administrative bodies** with competencies to **set norms** and facilitate the regulation of the copyright system (e.g., tariff-setting, reporting, dispute resolution mechanisms)

## 2. Objectives

**What can be learned from the practices of copyright administrative bodies (boards, tribunals, offices) in EU and non-EU jurisdictions?**

- What are the **forms and functions** of these authoritative norm-setting entities?
- How might institutional structures aid in **channeling stakeholder input, academic discourse, and economic evidence** into more comprehensive legislation?
- How can an institution **avoid excessive judicialization** of copyright disputes by providing a **mediation platform**?

## 3. Methodology



## 4. Main Results

- EU-level intervention can potentially facilitate the administration of private copying levies by providing a single point of collection and distribution for cross-border manufacturers and importers
- Monitoring technological advancements at the EU-level may anticipate potential copyright issues faster, and can provide early guidance for Member States
- Adding competencies to existing EU-level institutions (e.g. EUIPO) may eliminate subsidiarity and proportionality concerns

## References

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# National or supranational courts as European decision-making institutions for cross-border IP dispute settlement

## 1. Research Problem & Question

- European cross border IP enforcement faces challenges of jurisdiction and the autonomy of the EU legal order;
- How can courts or tribunals with cross border jurisdiction in IP disputes between individuals from EU member states or third countries be established without detriment to the autonomy of the EU legal order?

## 2. Objectives

- Identify boundaries of EU legal order autonomy and compatibility requirements for establishing new European courts or tribunals such as a Unified Patent Court or Multilateral Investment Court;
- Design systemic amendments to solve any identified compatibility issues

## 3. Methodology

- Doctrinal comparative law analysis of relevant primary and secondary laws (including normative hierarchies);
- Analyzing cross-border jurisdiction and enforcement issues and solutions of present EU legal system and proposed EU legislative reforms such as a Unified Patent Court or a Multilateral Investment Court

## 4. Preliminary Results

- Book chapter "*Cross-border questions on IP evidentiary seizure in view of the Enforcement Directive, Brussels Ibis Regulation and national law*", SDU Compendium seizure and execution law (NL, October 2018)
- Working paper '*Safeguarding EU legal order autonomy and establishing new European courts or tribunals such as a Unified Patent Court or Multilateral Investment Court*' (article forthcoming)



Some references:

- Hoyng, Does Brexit mean the end of the UPC?;
- Gordon and Pascoe, The effect of 'Brexit' on the Unitary Patent Regulation and the Unified Patent Court Agreement;
- Ubertazzi, Brexit and the EU Patent I&II – What shall we do?
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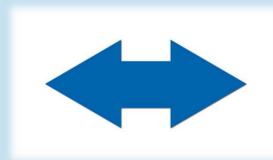
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# IP and Judicial Design in the EU



<https://www.actu-environnement.com/ae/news/concours-innovation-transition-ecologique-pme-strat-up-31665.php4>



<https://schoolsonline.britishcouncil.org/about-schools-online/about-programmes/commonwealth-class/values/rule-of-law>

## 1. Research Questions

- What are the specificities of the EU law that have an impact on the functioning of IP judiciary?
- What is the effect of specialised or general courts/judges on the efficiency and effectiveness of IP proceedings and decisions?
- How does the case examination and decision-making take place in the courts of EU MSs/at the supranational level?
- How should the deficiencies be addressed if there are any?

## 2. Objectives

- **Analyse** the EU legal framework concerning IP judicial and quasi-judicial structure at national and supranational level;
- **Evaluate** the efficiency of current judicial design in the light of promoting innovation;
- **Provide recommendations** with regards to improvements of the current system and/or proposing new judicial mechanism(s).

## 3. Methodology

- **Legal analysis:** Studying the EU legislation and institutions concerning the procedural aspects of lifecycle of IP rights;
- **Empirical analysis:** Qualitative research via interviews with different stakeholders involved in the process of examination and the enforcement of IP rights.

## 4. Preliminary Results

- IPR enforcement is divergent across the Member States of the EU;
- There is a link between the specialisation of courts/judges and the efficiency and effectiveness of the decisions;
- Countries have established more patent specific tribunals compared to other IP rights.

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- J. de Werra, 'Specialised Intellectual Property Courts - Issues and Challenges', CEIPI/ICTSD Publications Series, Issue 2 (2016).
- M. Favale, M. Kretschmer and P. C. Torremans, 'Is there a EU Copyright Jurisprudence? An empirical analysis of the workings of the European Court of Justice', *Modern Law Review*, Vol. 79, Issue 1 (2016).
- Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, A balanced IP enforcement system responding to today's societal challenges, COM (2017).
- ICC Report on Specialised IP Jurisdictions Worldwide, ICC (2016).



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# Innovative Models for Multi-territorial Licensing of Musical Works for Online Use: An Answer to Rights' Fragmentation Problem?

## Problem?



### • Objectives

- Mapping the **particularities of new players and products** in the multi-territorial (MT) EEA-wide market for licensing of musical works for online use
- Determining **how do incumbent CMOs respond** to challenges connected to MT online licensing
- Analysing **measures employed by the CRM Directive** regulating licensing entities and MT online licensing market

### • Research questions

- Does the CRM Directive **contribute to new forms of rights' fragmentation** in the MT online licensing market? How can **further fragmentation be prevented** by legislative or contractual measures?
- What **regulatory response** should be given to activities of various players involved in MT online licensing?
- Which **problems arise in connection to licensing** of on-demand music streaming services and multi-sided platforms?

### • Methodology

- *Qualitative empirical data analysis*: semi-structured interviews with licensing entities and users of musical works (most notably digital service providers – DSPs)
- *Comparative analysis*: European and US approach to licensing of online rights in musical works
- *Doctrinal research*: EU legislative framework, national legislation, case law, legal commentaries

### • Main results

- To provide a clear analysis on forms of rights' fragmentation in the MT market for licensing of musical works for online use – its reasons and **possible ways to reduce fragmentation**
- To show whether the **current licensing framework favours** certain users e. g. multi-sided platforms as opposed to streaming services or whether it benefits only certain licensing entities

#### References:

- Hilty, Li; *Remuneration of Copyright Owners – Regulatory Challenges of New Business Models*, (Springer Verlag), 2017
- Hviid, Schroff, Street; *Regulating Collective Management Organisations by Competition : An Incomplete Answer to Licensing Problem*, JIPITEC, 2016
- Kling; *Gebietsübergreifende Vergabe von Online Rechten an Musikwerken: Probleme einer Effizienten Lizenzierungspraxis unter Geltung der VGG*, Walter de Gruyter, 2017
- European Commission Merger Procedure Regulation (EC) 139/2004, Case M.6800-PRsFM/ STIM/ GEMA/ JV, Merger Procedure Regulation, C(2015) 4061 final
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