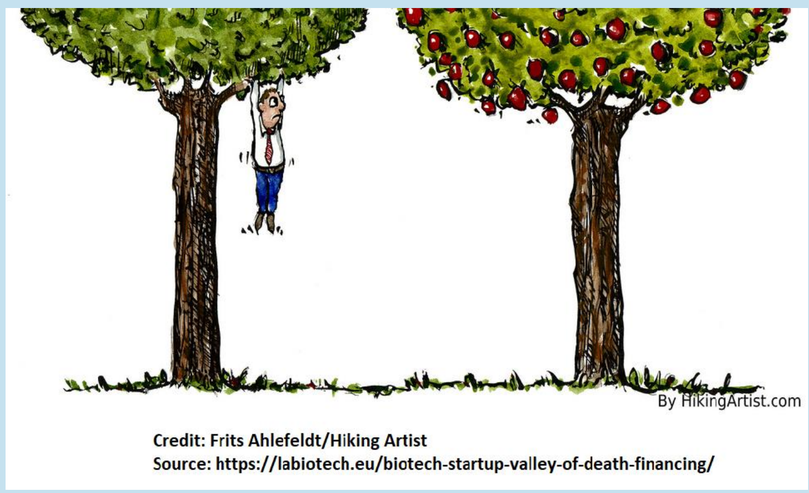
# Bridging the Valley of Death in Biomedical sciences

## Re-defining science-society contracts through progressive adaptations of innovation law and policy




Credit: Frits Ahlefeldt/Hiking Artist
Source: https://labiotech.eu/biotech-startup-valley-of-death-financing/

## 1. Hypotheses

- Operational models for 'knowledge-based healthcare economy' need to incorporate two inter-related paradigms of technology life cycles namely, 'knowledge transfer' and 'engagement'.
- Together these paradigms encapsulate the complexities of science-society interactions and define innovation as 'socially robust knowledge'.

## 2. Research Problems

- Deficits in specific knowledge about 'technology transfer' and 'engagement' along technology life cycles impede innovation.
- 'Science within social contours' is often overlooked in technology development, leading to failures of translational health research.

## 3. Research Questions

- How does 'socially robust knowledge' promote capital perspectives of the translational health technology cycles and how can impediments therein be ameliorated?

Focus areas

1. Intellectual capabilities (IC) transactions as social constructs in private-public partnerships
2. Patient centric/patient provided innovation models
3. IC related market imperfections

## 4. Theory and Methodology

- Theory: Actor Network Theory (ANT) for socio-technical processes
- Methods: Reflexive research (questionnaires, interviews, case studies, participation study); Socio-legal (interdisciplinary) & doctrinal research

Reflexive research will optimally map favorable indices for translational health by scrutinizing actor intent, action & subjectivity in health innovation networks.

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

courtesy:http://cartoonstock.com

## 1. Research Problem/Research hypothesis

- Stagnated and static patent system supporting dynamic innovation cycles.
- Public funding research has not evolved with change in the paradigm i.e. innovation—->invention(invention follows innovation).
- Societal/Economic incentives must be factored during patent prosecution.
- Sector specific measures needed to boost innovation in a individual sectors.

## 2. Research Questions

- Whether patent system address the dynamics of different innovation cycles?
- Whether public funded model for public applied research has evolved with changing 21st century dynamics?
- Whether patent prosecution system is able to address the the changing innovation paradigm?
- Whether patent system can address future needs of digital economy?

## 3. (Theory and) Methodology

- Comparative Analysis: Innovation Cycle in Heavy industries with that of industries in New economy.
- Empirical Study and comparative analysis: Public funded applied research with Pvt. Funded Social Research.
- Normative analysis: Designing the patent system to address individual sectoral characteristics.
- Contextual Analysis: Case studies: [AI in Pharma and ICT industry (IOT)]

## 4. Objectives

- To study evolution of the Innovation cycle.
- To identify scenarios where the patent system induces inefficiencies in the innovation cycle.
- To propose measures to better work the patent prosecution system.
- To ascertain whether the proposal can be applied to any field or the concrete answer depends on the field involved.
- Hypothetical application of the proposed measures to future pharmaceuticals and ICT industries.


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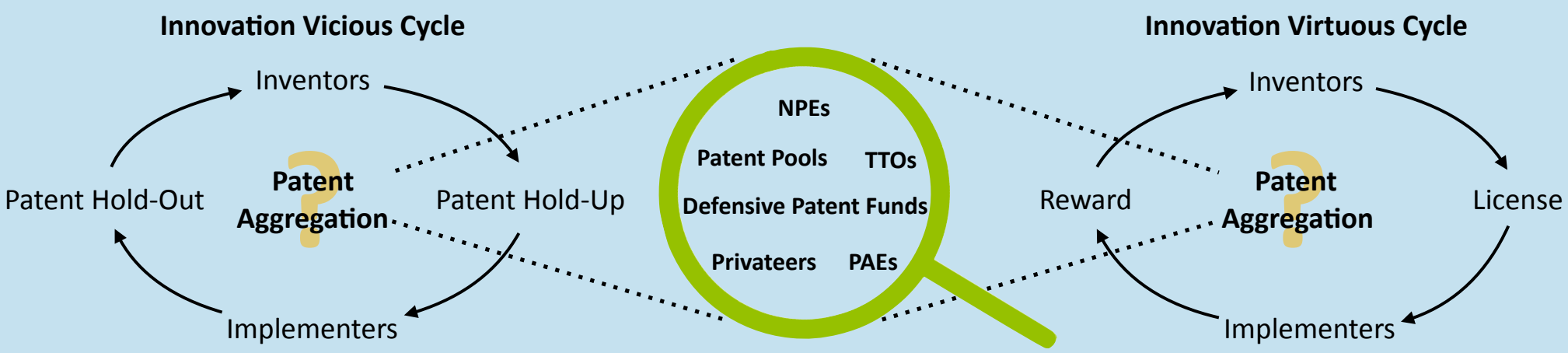
# Patent Aggregation in Patent and Competition Law




## 1. Research Problem

- Patent aggregation pursues yet to identify purposes, both defensive and offensive *vis à vis* other market players.
- Because of its distance from traditional patent exercises, it is uncertain to what extent patent aggregation happens in Europe.
- Patent aggregation activities, resulting either in competitive or anti-competitive conducts, have no definite impact on innovation.

## 2. Research Questions

- To what extent and how is patent aggregation occurring in Europe?
- Which are the entities involved in such activity?
- What impact does patent aggregation have on innovation?
- Can competition law address potentially harmful patent aggregation?

## 3. Methodology

- Mixed research methodology:
  - Quantitative empirical research to clarify the occurrence of the phenomenon in Europe and to classify the operators active in the field.
  - Black letter and law & economics analyses to assess patent aggregation practices under European competition law.

## 4. Objectives

- Find empirical evidence of patent aggregation in Europe and provide a taxonomy of the different actors active in the field.
- Assess the impact of patent aggregation on innovation and develop pro-active policies on the promotion of desirable patent aggregation.
- Investigate the scope for competition law intervention against harmful patent aggregation, *de iure condito* and *de iure condendo*.

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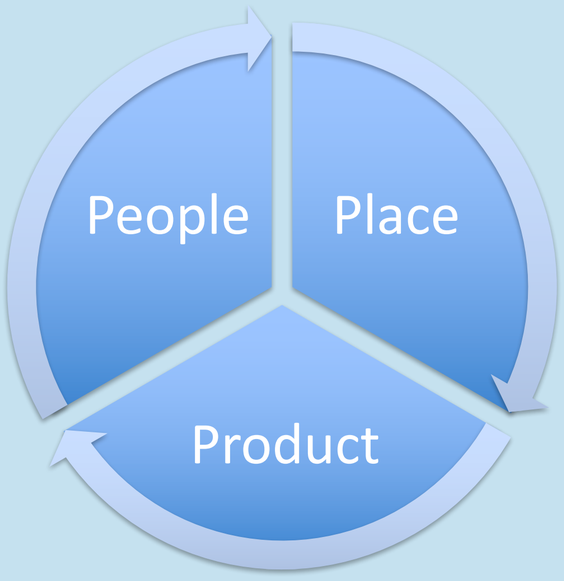
# How to Innovate within Tradition? Geographical Indications for Handicrafts




## 1. Research hypothesis

- TRIPS and Lisbon Agreement do not differentiate between agri and non-agri products, but there is no unitary protection for handicrafts in the EU (except trademark law).
- The EU needs a system that promotes quality and innovation in agribusiness, allowing a successful trade policy with third countries.

## 2. Research questions

- How to define innovation for traditional products?
- Is the current EU-GI system able to protect traditional knowledge, meet market expectations and promote innovation in agribusiness?
- Is there a need for a unitary EU-GI system on non-agricultural products? If so, how should be designed taking into account the trade relationship with third countries?

## 3. Methodology

- Normative analysis: study of the current legislative framework, review of literature and comparison with other systems (focus on registration and amendment issues).
- Empirical analysis: sectorial study on the amendment of product specifications for agri and non-agri GIs, (focus on members of OriGIn), questionnaire to non EU stakeholders on the protection of handicrafts in the EU.

## 4. Objectives

- Verify the impact of the European GI system on product and process innovation.
- Analysis of the pros and cons of trademark protection as opposed to *sui generis* GIs when it comes to non-agri products.
- Design a system aimed at protecting and promoting quality handicrafts and an efficient trade policy.

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# Agribusiness-The Future of Plant Breeding and the Dynamic Landscape in Patent and Plant Breedrs' Protection

**Introduction**

As the world population continues to grow, commensurate growth in agricultural productivity has become a critical necessity, especially when challenges such as scarcity of arable land, biotic and abiotic stress are considered. Various interventions are required to overcome these challenges including but not limited to varietal improvement through breeding and legal or policy frameworks which support the interventions. Breeding as one of the interventions requires significant technical resources as well as capital outlays. In breeding the copying of the end product by competitors has been a reality facing the industry and as such a form of enforceable protection regime for breeders is necessary. The protection of the plant varieties has faced considerable opposition over the years. Despite the opposition, significant progress has been made in the area of establishment of intellectual property rights (IPRs) regimes in plant breeding and biotechnology. However, the adequacy of protection of breeders' rights under this regime remains questionable particularly when pitted against protection of biotechnological innovations. There is a gap as to how these two regimes can work in concert with the aim of advancing innovation in the plant breeding sector while being able to protect the rights of all the players in the sector without the danger of losing their existing said rights to competitors. As such the study seeks to bridge this gap by interrogating avenues through which these regimes can be integrated from a technical, policy or legal framework perspective in order to spur innovation in the sector.

## 1. Research Problem/Research hypothesis

- **Problem**: Lack of plant variety protection regimes that are sensitive to biodiversity conservation and exploitation, farmers' rights and ethical issues has brought about conflict among different players in the European Union agricultural industry.
- **Hypothesis**: 'An integrated system sensitive to local and international conditions will spur innovation in the European Union plant breeders sector.'

## 2. Research Questions

- What is the market concentration in different players and the role of intellectual property in this?
  - Who are the main intellectual property holders in plant breeding?
- What are the socio-economic or environmental consequences of the developments in the markets for the diversity of the players in the industry within the European community and other regional markets?
- What are the possible consequences for the use of genetic diversity in food and nutritional security as well as in the production of green energy (Bio-economy)?
- What are the possible positive and negative effects, which parties in the breeding sector do they affect, and how can the negative effects be prevented?
  - How can we fill gaps where there no measures to counter the negative effects?
  - Which different legal systems in the world play a role in this?

## 3. Methodology

- The theoretical framework will take a desk top approach.
- Quantitative analysis of the data provided by the partner organizations.
- Qualitative analysis will be done e.g. surveys and or interviews of the players in the partner organizations.
- Further, since study predominantly seeks to answer the question how an integrated system can lead to increased innovation in the sector, the anticipated methods employed for data collection may include comparative case studies.

## 4. Objectives

- Present a review of the trends in different plant breeding sectors and there products (propagating materials and plant biotechnology.
- Establish whether the standards set under domestic laws or the European Union Legislation and other applicable regulations or international policy frameworks are able to safeguard the different interests of all players in the agricultural plant breeding sector.
- Propose or develop a framework of integrative solutions where there are shortcomings.

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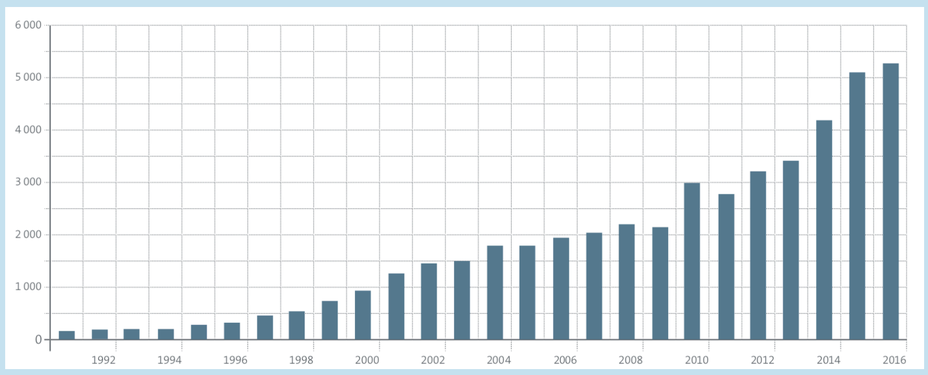
# The implications of the 4th Industrial Revolution on patent law: a case study on pharma




4IR patent applications at the EPO 1991-2016
Source: European Patent Office

## 1. Research problems

- The 4th industrial revolution is changing the invention process, that is progressively independent of human intervention due to increasing automation. Therefore, it poses a challenge to the current patent system.
- The cost of advanced technologies and limited access to vital data may result in concentration of patent ownership in a small number of entities. This may generate anti-competitive effects.

## 2. Research Questions

- Is the 4th industrial revolution compatible with the current patent regime in pharma?
- What are the crucial aspects of the patent system that are challenged and why?
- Are anti-competitive consequences likely to result from the analysed scenario?
- What steps could be taken to address those challenges?

## 3. Methodology

## 4. Objectives

- To identify and analyse the aspects of the patent system which are challenged by the use of the latest technologies for the production of potentially patentable outcomes.
- To evaluate the potential effect of the patentability of such outcomes on competition.
- To provide recommendations, with a specific focus on the pharma sector.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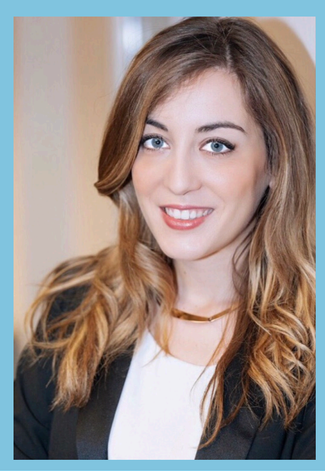


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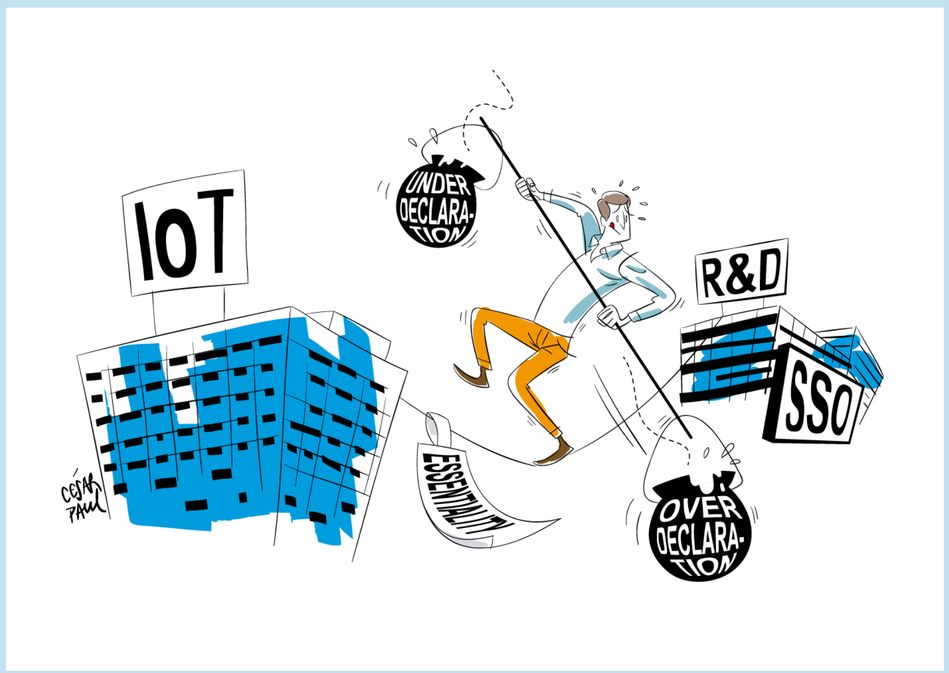
# Impact of SEP declaration on innovation and competition




## 1. Research Problem

- External and internal factors condition SEP declaration → Overdeclaration (OD) / Underdeclaration (UD)
- OD and UD may negatively impact innovation and competition
- IoT technological and market dynamics might alter existing assumptions on the interaction of standards with competition and innovation

## 2. Research Questions

- What are the internal and external causes for OD/UD? What incentivizes or discourages them?
- How OD/UD affect innovation and competition?
- Which measures are suitable to prevent OD/UD and/or their negative effects?
- How will IoT impact in the answers to the prior questions?

## 3. Methodology

- Bibliographical research of legal and economic literature
- Empirical research based on different stakeholders participating in ETSI standardization processes
- Analysis of  EU legal framework

## 4. Objetives

- Understanding the logic that motivates certain players to over/ underdeclare their SEPs
- Explore the role of existing legal regimes to fight OD/UD, differenciating between supervening essentiality (or lack of) and opportunistic behaviors
- Suggest legal and institutional measures to fight harmful OD/UD and/or mitigate their negative effects, with a view to the upcoming IoT scenario

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# BALANCING THE QUALITY OF PATENTS WITH EFFECTIVE ENFORCEMENT OF INVALIDITY CLAIMS IN THE PHARMACEUTICAL INDUSTRY IN EUROPE.

**CONCERNS** → **FOCUS AREAS** → **EXPECTED RESULT**

- Patent Quality
- Effective Enforcement
- Market Access of Generics
- Innovation

- Maintain Balance
- Refine Substantive Law
- Amend Procedural Law
- Consider Revisions to Upcoming Unified Patent Court (Judicial)

## CENTRAL ARGUMENT

The study aims to understand the relationship (if any) between innovation and patent quality in the pharmaceutical sector. This, in turn, requires an analysis of the sufficiency of the existing patent system to balance the concerns of (i) patent quality and the linked effective enforcement of invalidity claims in the pharmaceutical industry in Europe on one hand, while (ii) allowing broader and quicker market access to generics on the other.

## METHODOLOGY

| | |
|---|---|
| CONTEXTUAL ANALYSIS/LITERATURE REVIEW | → Patent Quality in the Pharmaceutical Sector in Europe<br>→ Concept of Innovation for Pharmaceutical Patents<br>→ Present European Patent Instruments (Legal, Procedural and Judicial) for Pharmaceutical Sector |
| INTERVIEWS/ QUESTIONNAIRE/CASE STUDY | →Interviewing or distributing Questionnaire among EFPIA members<br>→Taking up a Case Study at Hovione |
| LEGAL AND NORMATIVE ANALYSIS | → 'what the patent system is' and 'what it ought to be |

## RESEARCH QUESTIONS

1. To what extent does the quality of patents reflect the level of pharmaceutical innovation in Europe?
2. Whether or not existing legal instruments (including procedural and substantive elements of applicable laws) are appropriate to balance the above described concerns?
3. Do the present patent systems (including the upcoming Unified Patent Court) need to be revised/reformed to better address the above concerns?

## OBJECTIVE(S)

To suggest reforms (present patent system and the upcoming system of the Unitary Patent Court for the enforcement of invalidity claims) so that for pharmaceutical industry a patent system should generate optimal quality patents that must reflect the level of innovation, while still providing sufficient market access of generics.

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# Intellectual Property as a Protected Investment

# A Double-edged Sword for the EU?

## 1. Research Problem

- Investor-state dispute settlement: highly controversial from legal and regulatory perspectives – need for deeper analysis with regards to intellectual property rights.
- European Union: recent agreements such as CETA raise concerns in the civil society and amongst policy makers – lack of expertise on EU specific issues.

## 2. Research Questions

- What are the implications of the introduction of intellectual property in international investment agreements for EU stakeholders?
- What are the possible mechanisms to safeguard fundamental rights and ethics while fostering investments in innovation?

## 3. Methodology

**BACKGROUND**
- Identify relevant agreements and case-law to evaluate the impact of the different policy choices.
- Focus on EU framework and projects.

**LEGAL ANALYSIS**
- Assess the compliance of current practices with EU law and public policy.
- Analyze the interactions between the different bodies of law and their effects on innovation.

**EMPIRICAL RESEARCH**
- Use data from companies and governmental bodies to formulate different policy options.

## 4. Objectives

- Assess the legal and regulatory effects of protecting IP as an investment.
- Make policy recommendation to ensure a balance of the different interests involved at the negotiation and implementation stage.
- Draft guidelines for future IIA negotiations and EU reforms based on research findings.

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# Enforcement of IPR and Global Trade

## 1. Research hypothesis

- The EU External Policy in the field of IPR is failing because the actions undertaken have not shown enough results to achieve the Policy's objectives.

## 2. Research Questions

- What are the European Union's trade and/or neighborhood objectives in the field of IPR?
- Do the actions foreseen under the EC *Strategy for the protection and enforcement of IPR in third countries* allow to achieve these objectives?
- How could the EU policy in the field be reshaped?

## 3. (Theory and) Methodology

- Bottom-up (EU approach towards Cariforum countries and towards the Eastern Neighborhood as case studies)
- Desk research and interviews with stakeholders in third countries and in the EC
- Comparative analysis of legal transplants from FTAs
- Official reports: US 301 Special Report, Global Innovation Index, etc.

## 4. Objectives

- To assess the impact of the *Strategy for the protection and enforcement of IPR in third countries* against the European Union's objectives.
- Where relevant, to suggest possible improvements both to the general EU External Policy in the field and to IPR chapters in potential free trade agreements, signed by the EU.

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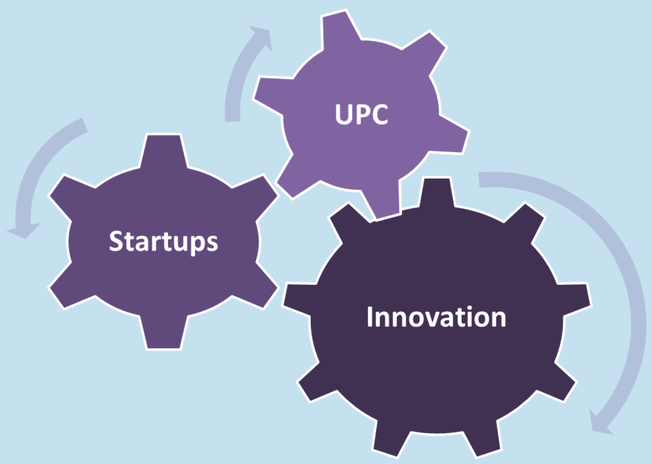
# The impact of the UPC on the incentives to innovate of start-ups




## 1. Research Problem

- How should the legal framework within which the UPC will operate be reformed, in order to ensure that its implementation will increase the incentives to innovate of start-ups?

## 2. Research Questions

- Why start-ups do (or do not) patent and what is their patent litigation activity?
- Which issues of the UPC legal framework can be critical for start-ups?
- What will be the impact of the new patent litigation system on incentives for plaintiffs and defendants to innovate?
- Is the current system an appropriate point of comparison to assess this impact?

## 3. Methodology

- Empirical analysis of available economic studies in relation to the patent application behavior of start-ups in EU;
- Empirical analysis of data gathered from literature review and databases (*i.e.* Darts-IP) related to patent litigation of start-ups in EU;
- Qualitative interviews with relevant stakeholders.

## 4. Objectives

- Advice public policy makers to improve the capacity of start-ups to make better use of the UPC system;
- Provide guidance to Institutions on interpretation of the relevant provisions and on legal reforms that could be implemented;
- Address improvements to the current national systems if the UPC does not come into force.

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- Callens, Pieter, and Granata, Sam, *The Unitary Patent and the Unified Patent Court* (Wolters Kluwer, 2017)

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# Copyright Policy in the EU:

# Regulating at the Speed of Technology

https://www.csee-etuce.org/ig

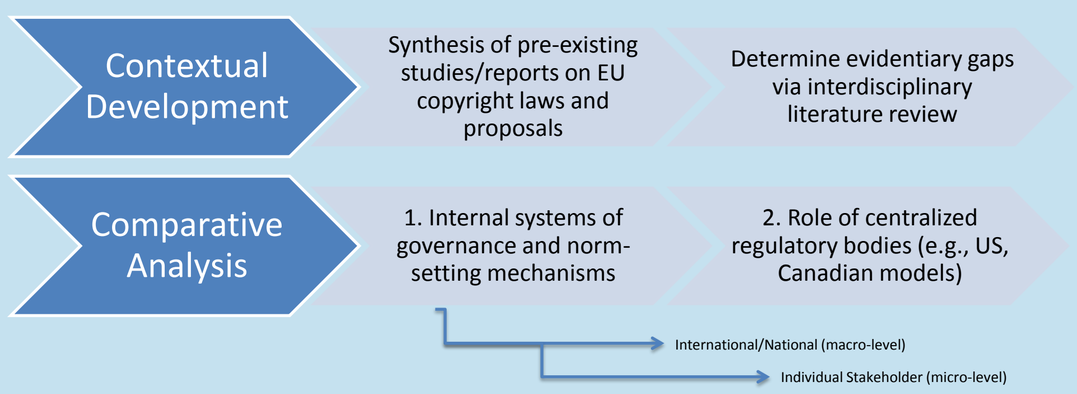
## 1. Research Problem

- Challenge of copyright in the EU: **unifying a disjointed system of rights** across all Member States.
- EU-level reform provides **legal certainty**, but may be **impractical** considering the **lengthy legislative process**.
- Copyright should be **adaptive and flexible** to keep pace with technology, while ensuring **legal certainty** in cross-border commerce.

## 2. Research Questions

- What alternatives to legislation exist in changing/updating copyright law in the EU?
- What may be the role of a centralized regulatory body in contributing to the advancement of copyright law in the EU?

## 3. Theory & Methodology




## 4. Objectives

- Draft recommendations for updating/revising copyright policy in the EU, including ideas for implementation
- Ascertain role of a potential pan-European regulatory body for copyright (e.g. tariff-setting; dispute resolution)
- Anticipate and reconcile conflicts with EU competition law and international agreements

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- What Constitutes Evidence for Copyright Policy? Digital Proceedings of ESRC Symposium, 2013. Eds. M. Kretschmer, R. Towse. Available at: http://www.create.ac.uk/publications/what-constitutes-evidence-for-copyright-policy-digital-proceedings-of-esrc-symposium/.

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- Images: https://www.csee-etuce.org/images/Pictures/EU/digitalSingleMarket.jpg


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

## 1. Research Problem

- Efficient IP enforcement impeded by lack of jurisdiction to decide on validity of foreign patents and lack of uniform procedural rules;
- Inititiaves for harmonisation of European patent enforcement have not yet come into existence

## 2. Research Questions

- How could national or supranational IP courts such as UPC achieve efficient IP enforcement in harmonised collaboration with CJEU, ECHR or EPO?
- What can be learned from collaborations between national courts, CJEU or ECHR and other European decision-makers (eg. EU IPO) in the fields of trademark, design and copyright?

## 3. Methodology

- Doctrinal comparative law analysis of relevant primary and secondary law;
- Analyzing cross-border IP enforcement issues and solutions of present system under Brussels Convention vis-à-vis UP/UPC legislative reform

## 4. Objectives

- Identify promotors and inhibitors for procedural economy, enforcement, recognition and due account of cross-border decisions;
- Provide practical guidelines to allow national or supranational courts achieve efficient IP enforcement and harmonization on a European level

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;
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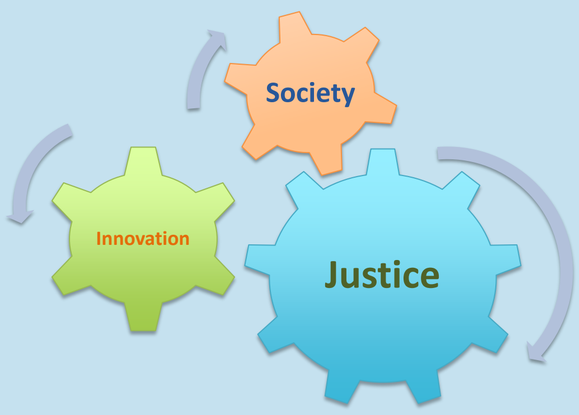
# What Court System is the Best for IP and Innovation?



http://www.nianseng.com.my/index.php?ws=pages&pages_id=9176

## 1. Research Problem

- **Complex technological issues** making the task of judges more difficult;
- **Lack of empirical analysis** regarding the effects of the courts' architecture and the judges' background on the field of IP and innovation;
- **No specific requirements identified** based on which the appropriate court model should be established.

## 2. Research Questions

- How do specialised and general courts function and what are the advantages and disadvantages of both types of courts in terms of the IP dispute handlings?
  - Is it necessary to specialise the courts or is it about the special expertise of judges?
  - What exactly is required from judges?
- What elements can be identified for a just and efficient court system which will support creativity and innovation?

## 3. Methodology

Comparative analysis

**Traditional legal dogmatic method:**
-Collect existing data regarding courts' models;
-Collect relevant case law;
-Find the link between court models and their decisions;
-Identify the purpose of existing policy choices.

**Empirical Analysis:**
-Assess to what extent the existing models are suited for innovation-driven market;
-Assess how law works in practice in the eyes of practitioners (interviews and /or meetings).

## 4. Objectives

- Identify what the effects of specific characteristics of proceedings are on the efficiency of IP adjudication in terms of time, costs and quality of decisions;
- Illustrate overall picture regarding litigants' incentives to file lawsuits and ability to pursue innovative activity;
- Provide relevant recommendations for policy-makers.

### References


- Jacques De Werra, 'Specialised IP Courts: Issues and Challenges' [2016] Specialised Intellectual Property Courts: Issues and Challenges , Global Perspectives for the Intellectual Property System, Issue Number 2, CEIPI-ICTSD, 15.
- Michael Goodman, 'What's so Special About Patent Law?' [2016] 26 Fordham Intell, Prop. Media & Ent. L. J. 797.
- Matthew B. Weiss, 'Options for Federal Circuit Reform Derived from German Legal Structure and Practice' [2015] 16 Column. Sci & Tech. L. Rev. 358.

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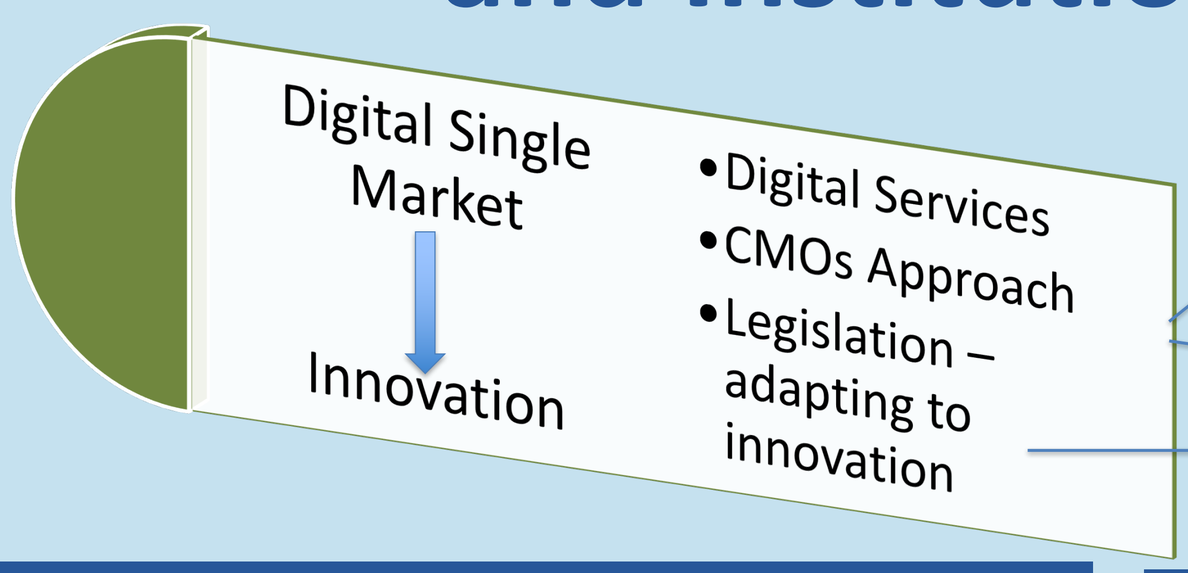
# Collective Management Organisations and Institutional Users




## 1. Research Problem/Research hypothesis

- Despite the adoption of the Directive 2014/26/EU, there is a need for a more uniform regulation of CMOs, especially with regard to tariff-setting systems in cross-border use.
- It remains unclear whether CMO joint ventures should be treated as CMOs or Independent Management Entities (IMEs). Moreover, CMOs have different status in EU MS.
- Small CMOs will in the long term disappear between IMEs and supranational CMOs -> detriment to cultural diversity

## 2. Research Questions

- Is there a need for a closer regulation for CMOs, CMO joint ventures and IMEs on the EU and national level (especially with regard to tariff-setting systems and enforcement for unauthorized use of copyright protected works) ?
- Will the Directive 2014/26/EU have the effect of creating oligopolies and thereby cause small CMOs to crumble and niche repertoires be unrepresented?

## 3. Methodology

| Comparative Analysis | Doctrinal Research | Empirical Data Analysis |
|---|---|---|
| • Small & Medium CMOs<br>• Big CMOs, CMO Joint Ventures<br>• National legislation | • Legal Commentaries<br>• Books | • CMOs and other management entities<br>• Regulators (national ministires of culture etc) |

## 4. Objectives

- To provide a clear analysis on the impact of the Directive 2014/26/EU on different kinds of CMOs in the EU (big and small) to see if it leads to “race to the bottom” regarding tariffs and emergence of oligopolies of major CMOs.
- To explore how will cultural diversity be affected in case niche repertoires will be underrepresented?
- To answer whether there is a need for closer regulation of CMOs, CMO joint ventures and IMEs.

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- Daniel J. Gervais, *(Re)Structuring Copyright A Comprehensive Path to International Copyright Reform* (Elgar Monographs in Intellectual Property Law 2017)
- Emanuela Arezzo: Competition and Intellectual Property Protection in the Market for the Provision of Multi-Territorial Licensing of Online Rights in Musical Works – Lights and Shadows of the New European Directive 2014/26/EU, (2015)
- Romana Matanovac Vučković, ‘Implementation of Directive 2014/26/EU on Collective Management and Multi-Territorial Licensing of Musical Rights in Regulating the Tariff – Setting Systems in Central and Eastern Europe’ (2016) IIC Max Planck Institute for Innovation and Competition
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