Bridging the ‘Valley of Death’ in Biomedical Sciences
Progressive Adaptations to Innovation Law & Policy

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.

References


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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 21st century?

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 need’s principle as in access to medicines (Pharmaceutical industry)
• ICT and Pharmaceutical industries: The patent framework aids rise to Patent Oligarchs (High Gini – Coefficient).

• Anti-commons effects simulated in an agent based environment.

References

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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
- EPO Economic and Scientific Advisory Board, Patent aggregation and its impact on competition and innovation policy (Workshop Report, 2014);

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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.

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

- 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.

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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.

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).

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?

References


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Patentability of 4th 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 4th industrial revolution technologies involvement.

2. Objectives
To address the compatibility of the current patent regime with 4th 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
Traditional black letter
Qualitative research
Case study on pharma

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

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

4. Main Results

References
- Ana Ramalho, Patentability of AI-Generated Inventions: Is a Reform of the Patent System Needed? (February 15, 2018)
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

References

- Pohlmann T and Blind K, Landscaping study on Standard Essential Patents (European Commission- DG GROW, 2016)
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.

References
- Lakdawalla DN, 'Economics of the Pharmaceutical Industry' (2018) 56 Journal of Economic Literature 397

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 up to 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**
- Lakdawalla DN, 'Economics of the Pharmaceutical Industry' (2018) 56 Journal of Economic Literature 397

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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
   - Relevant agreements and case-law.
   - Historical and political developments.
   - Suitability of investment protection and dispute settlement for IP.
   - 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
- Website: https://investmentpolicyhub.unctad.org/

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Enforcement of IPR and Global Trade

1. Background

- 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

- Van der Loo G, The EU-Ukraine Association Agreement And Deep And Comprehensive Free Trade Area (Brill Nijhoff 2016)

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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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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 judiciarization of copyright disputes by providing a mediation platform?

3. Methodology

ID national regulatory gaps with particular regard to cross-border and digital issues.

Conduct interviews of institutional actors (e.g., CMOs) to guide a practical assessment of existing framework.

1. Existing systems of governance and norm-setting mechanisms in select EU Member States.

2. Role of centralized regulatory bodies in other jurisdictions (e.g., US, Canadian models).

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

- 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?;
- Ubertazzi, Brexit and the EU Patent I&II – What shall we do?
- Rosas, The EU and international dispute settlement

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IP and Judicial Design in the EU

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.

References
• 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).

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Innovative Models for Multi-territorial Licensing of Musical Works for Online Use: An Answer to Rights’ Fragmentation 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
- Hvid, 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

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