European joint doctoral programme

EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project
March 2017 - February 2021
Funded by the European Union

Krishnamani Jayaraman
Bridging the valley of death in biomedical sciences. Progressive adaptations to innovation law and policy

EIPIN Innovation Society
Coordinated by Maastricht University, Faculty of Law,
Bouillonstraat 3, 6211 LH Maastricht, The Netherlands
P.O. Box 616, 6200 MD Maastricht, The Netherlands
E: eipin-is-h2020@maastrichtuniversity.nl

www.eipin-innovationsociety.org

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No 721733
EIPIN Innovation Society
(March 2017 - January 2021)

European IP Institutes Network
Cooperation among IP Institutions and students in Europe since 1999.

EIPIN Innovation Society
• Multidisciplinary and holistic research programme on role of IP in the innovative lifecycle
• Co-supervision of doctoral research leading to joint doctorate degrees from two EIPIN partners
• Tailor-made training programme prepares a new type of IP researcher who is able to ascertain and articulate the complexities of the IP system.

IP as a complex adaptive system
• IP developed from a mere legal title into a complex adaptive system
• IP functions as a
  - Business tool for value creation
  - Vehicle for investment
  - Relationship between right holders, users and society
• Ambition: to enhance Europe’s capacity to foster innovation-based sustainable economic growth globally
• Research objective: to provide reliable conclusions on how to deal with the adaptive complexities of innovation cycles that secure economic benefits and uphold justice in the innovation society.

Research results
• 15 PhD theses, published as monographs
• International peer-reviewed articles
• Presentations at international conferences
• Bi-yearly conferences on the four areas of research
• Training activities on methodology, research and transferrable skills
• Presentations and publications on establishment and management of joint doctoral degree structures

Partner organisations

Bridging the valley of death in biomedical sciences.
Progressive adaptations to innovation law and policy

Krishnamani Jayaraman
Project: ESR1

Research Question
1. How should institutional mechanisms be optimally adapted and implemented to foster stakeholder coopetition in health technology innovation systems to avoid the valley of death and to promote the culture of active innovation as it applies to the realms of smart specialisation, social innovation and Quintuple helix innovation model?

2. How should private ordering be adapted and implemented to foster stakeholder coopetition in health technology innovation systems to avoid the valley of death and to promote the culture of active innovation as it applies to the realms of smart specialisation, social innovation and Quintuple helix innovation model?

3. How should softer relational legal principles interact, coordinate and augment the role of private ordering in enabling stakeholder coopetition in health technology innovation systems to avoid the valley of death and to promote the culture of active innovation as it applies to the realms of smart specialisation, social innovation and Quintuple helix innovation model?

Methodology
Part of the thesis will use two theoretical frameworks. The stakeholder theory of corporations and the Actor-Network theory (ANT) for socio-technical processes. It is also possible that within the context of these theoretical frameworks, concepts from other theories may be used. As a methodical approach, the researcher will involve qualitative reflective thinking methodology with specific actants participating in the immediate context of the research themes.

Societal impact
The social impact of this PhD thesis lies in the fact that this work is centred on the themes of smart specialization and social innovation that have garnered considerable impetus at the global level. In addressing such a complex theme that couples technological progress, economic development and social transformation, the current reductionist economic value view of the “Valley of Death” in healthcare innovation does not suffice. Rather, a larger interpretation of the valley dynamics in terms of integrated science, technology and socio-legislative policy considerations need to be adopted. The thesis may be expected to address vital aspects of such integration for healthcare technologies.
European joint doctoral programme

EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project
March 2017 - February 2021
Funded by the European Union

Girish Nagraj
Push or Pull information to or from the market. Does One Size Fits All?

EIPIN Innovation Society
Coordinated by Maastricht University, Faculty of Law, Bouillonstraat 3, 6211 LH Maastricht, The Netherlands
P.O. Box 616, 6200 MD Maastricht, The Netherlands
E: eipin-is-h2020@maastrichtuniversity.nl

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No 721733
EIPIN Innovation Society
(March 2017 - January 2021)

European IP Institutes Network
Cooperation among IP Institutions and students in Europe since 1999.

EIPIN Innovation Society
• Multidisciplinary and holistic research programme on role of IP in the innovative lifecycle
• Co-supervision of doctoral research leading to joint doctorate degrees from two EIPIN partners
• Tailor-made training programme prepares a new type of IP researcher who is able to ascertain and articulate the complexities of the IP system.

IP as a complex adaptive system
• IP developed from a mere legal title into a complex adaptive system
• IP functions as a
  - Business tool for value creation
  - Vehicle for investment
  - Relationship between right holders, users and society
• Ambition: to enhance Europe’s capacity to foster innovation-based sustainable economic growth globally.
• Research objective: to provide reliable conclusions on how to deal with the adaptive complexities of innovation cycles that secure economic benefits and uphold justice in the innovation society.

Partner organisations

Push or Pull information to or from the market.
Does One Size Fits All?

Girish Nagraj
Project: ESR2

Research Question
1. Whether there exists a direct correlation between patenting and innovation in the technological sector of 5G as compared with AI Pharmaceutical industry?

2. Whether patent theory is tuned to with theory of technological development vis-a-vis 5G and AI pharmaceutical industry?

3. Whether patent examination is tuned to address 4th industrial revolution in pharmaceutical and communication technologies?

Methodology
Complex Adaptive System methodology will be employed, which is, an interdisciplinary approach consisting interactions between legal, technological and economic systems. Quantitative or qualitative empirical research will be conducted as needed. A survey questionnaire will be drafted based on the agent interactions and limiting to the nodal points of interaction between innovation and patents. Existing literature and datasets will be used to ascertain the certain predictors which may fall outside the scope of firm level innovation.

Societal impact
The research aims to address the concerns of anti-commons due to excessive patenting as suggested by Hellen & Eisenberg. The research aims to provide policy recommendations to suggest that innovation is a complex process and a single one size fits all patent system dis-incentivizes innovation in the era of fourth industrial revolution. The study of ICT and pharmaceutical sectors and analysis of legal, economic and technological theories within this sector would enable to address diverse concerns of technological producers, civil society, SMEs and technology implementers.

Research results
• 15 PhD theses, published as monographs
• International peer-reviewed articles
• Presentations at international conferences
• Bi-yearly conferences on the four areas of research
• Training activities on methodology, research and transferrable skills
• Presentations and publications on establishment and management of joint doctoral degree structures
European joint doctoral programme

EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project
March 2017 - February 2021
Funded by the European Union

Niccolò Galli
Patent Aggregation in Patent and Competition Law
EIPIN Innovation Society
(March 2017 - January 2021)
European IP Institutes Network
Cooperation among IP Institutions and students in Europe since 1999.

EIPIN Innovation Society
• Multidisciplinary and holistic research programme on role of IP in the innovative lifecycle
• Co-supervision of doctoral research leading to joint doctorate degrees from two EIPIN partners
• Tailor-made training programme prepares a new type of IP researcher who is able to ascertain and articulate the complexities of the IP system.

IP as a complex adaptive system
• IP developed from a mere legal title into a complex adaptive system
• IP functions as a
  - Business tool for value creation
  - Vehicle for investment
  - Relationship between right holders, users and society
• Ambition: to enhance Europe’s capacity to foster innovation-based sustainable economic growth globally
• Research objective: to provide reliable conclusions on how to deal with the adaptive complexities of innovation cycles that secure economic benefits and uphold justice in the innovation society.

Research results
• 15 PhD theses, published as monographs
• International peer-reviewed articles
• Presentations at international conferences
• Bi-yearly conferences on the four areas of research
• Training activities on methodology, research and transferrable skills
• Presentations and publications on establishment and management of joint doctoral degree structures

Patent Aggregation in Patent and Competition Law

Niccolò Galli
Project: ESR3

Research Question
Does patent aggregation harm innovation and does therefore competition law provide a remedy to respond to the problem?

Methodology
To disentangle the complexity of patent aggregation, and the descending multifaceted types of research questions, the enquiry follows a mixed-methodology. Indeed, besides traditional black-letter analysis, it employs both quantitative and qualitative empirical legal methods.

Societal impact
This research analyses patent aggregation, a recent phenomenon generally associated with the use of patent portfolios for non-manufacturing purposes. Specifically, it investigates the link between patent aggregation and innovation in the electrical-engineering sector. Posing as hypothesis that patent aggregation might in certain circumstances stifle innovation, for example exacerbating patent hold-up scenarios, the study assesses the compatibility of the phenomenon of interest with European competition law. As a result, the research provides, first, recommendations for policymakers to ensure that patent aggregation and innovation are positively related. Second, legal certainty and lower transaction costs for market-players, clarifying how their patent aggregation practices are regulated under competition law. Indirectly, society experiences more innovation, since lower transaction costs and pro-active recommendations enable more investment in research and development.
Geographical indications: a spurring or hampering device for innovation in agribusiness

Maurizio Crupi

EIPIN Innovation Society
Coordinated by Maastricht University, Faculty of Law, Bouillonstraat 3, 6211 LH Maastricht, The Netherlands
P.O. Box 616, 6200 MD Maastricht, The Netherlands
E: eipin-is-h2020@maastrichtuniversity.nl
EIPIN Innovation Society
(March 2017 - January 2021)
European IP Institutes Network
Cooperation among IP institutions and students in Europe since 1999.

EIPIN Innovation Society
• Multidisciplinary and holistic research programme on role of IP in the innovative lifecycle
• Co-supervision of doctoral research leading to joint doctorate degrees from two EIPIN partners
• Tailor-made training programme prepares a new type of IP researcher who is able to ascertain and articulate the complexities of the IP system.

IP as a complex adaptive system
• IP developed from a mere legal title into a complex adaptive system
• IP functions as a - Business tool for value creation - Vehicle for investment - Relationship between right holders, users and society
• Ambition: to enhance Europe’s capacity to foster innovation-based sustainable economic growth globally.
• Research objective: to provide reliable conclusions on how to deal with the adaptive complexities of innovation cycles that secure economic benefits and uphold justice in the innovation society.

Research results
• 15 PhD theses, published as monographs
• International peer-reviewed articles
• Presentations at international conferences
• Bi- yearly conferences on the four areas of research
• Training activities on methodology, research and transferrable skills
• Presentations and publications on establishment and management of joint doctoral degree structures

PDOS And PGIS: A Pragmatic Approach To The Link To Origin

Research Question
The thesis consists of four chapters built around the notion of link to origin for EU and non-EU products. Every chapter attempts to provide an answer to the following main research question: “Are the differences between PDOs and PGIs reflected in the EU Register?”, the analysis is complemented by the following sub-questions:
1. Are the different legal requirements for the registration of PDOs and PGIs able to reflect their link to origin?
2. What is the difference between PDOs and PGIs concerning the amendment of product specifications?
3. What is the role of PDOs and PGIs in the negotiations of bilateral agreement and in the registration of foreign GIs in the EU?

Methodology
The first chapter explores the nature of the link to origin and the role of natural, human, and reputational factors through a qualitative content analysis of the single documents for EU agricultural products and foodstuffs listed in the EU Register. The results of the empirical analysis are complemented by interviews to producer groups that explore why applicants have opted for a given quality scheme.

The second chapter deals with the relationship among GIs, culture, and innovation. The aim is to prove how traditional products changed during their history, advocating in favour of a dynamic notion of tradition as opposed to a static one. The role of the EU quality schemes is studied through an empirical analysis of the amendments for processed meat products concerning, in particular, the geographical area, raw materials and the method of production.

The third chapter considers the role of PDOs and PGIs in the registration of GIs from third countries. Emphasis is put on the creation of GI lists and on the product-by-product approach that results in the exclusion of some GIs from the negotiations. The chapter explores the reason for the limited number of foreign GIs entered in the EU Register by way of a direct application, made by the applicant or through the competent authority of the third country.

Societal impact
After having explored the link to origin and its change, the fourth chapter provides policy recommendations on how to keep a clear difference between PDOs and PGIs. In particular, recommendations are built on three main objectives: a need for simpler and clearer information on the link to origin, addressing the problem of the blurred difference between PDOs and PGIs; the preservation of a strong link to origin potentially hampered by the amendment of the single documents (alias innovation); and the promotion of international trade.
European joint doctoral programme
EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project
March 2017 - February 2021
Funded by the European Union

Jared Onsando
Agribusiness: The Future of Plant Breeding in the Light of the Developments in Patent and Plant Breeders Rights
EIPIN Innovation Society
(March 2017 - January 2021)

European IP Institutes Network
Cooperation among IP Institutions and students in Europe since 1999.

EIPIN Innovation Society
• Multidisciplinary and holistic research programme on role of IP in the innovative lifecycle
• Co-supervision of doctoral research leading to joint doctorate degrees from two EIPIN partners
• Tailor-made training programme prepares a new type of IP researcher who is able to ascertain and articulate the complexities of the IP system.

IP as a complex adaptive system
• IP developed from a mere legal title into a complex adaptive system
• IP functions as a
  - Business tool for value creation
  - Vehicle for investment
  - Relationship between right holders, users and society
• Ambition: to enhance Europe’s capacity to foster innovation-based sustainable economic growth globally
• Research objective: to provide reliable conclusions on how to deal with the adaptive complexities of innovation cycles that secure economic benefits and uphold justice in the innovation society.

Research questions
1. What is the market landscape and who are the main intellectual property holders?
2. Do the IPRs in the European Union provide equitable protection of the interests of all the stakeholders in the plant breeding sector?
3. Do the current IPRs regimes in the plant breeding sector foster sustainable innovations?

Methodology
Semi-structured interviews, which allow for flexibility new ideas to be brought up during the interview.
Secondary data sources from ESA database.
Data will be analysed with the help of qualitative and quantitative data analysis software.

Societal impact
The study will provide insights on how to make IPRs regimes more robust by providing an integrated IPR regimes that will spur sustainable innovation in the European Agricultural sector hence significantly contributing to the to the positive and diverse needs of all stake holders.

Research results
• 15 PhD theses, published as monographs
• International peer-reviewed articles
• Presentations at international conferences
• Bi-yearly conferences on the four areas of research
• Training activities on methodology, research and transferrable skills
• Presentations and publications on establishment and management of joint doctoral degree structures

Partner organisations

Agribusiness: The Future of Plant Breeding in the Light of the Developments in Patent and Plant Breeders Rights

Jared Onsando
Project: ESR5

Research Question
Intellectual Property Rights (IPRs) on plants as they pertain to agriculture has been among the most controversial issues in the long history of intellectual property protection. Traditions dating before the second half of the 19th century excluded plants from national and international IPR regimes. IPRs in plant varieties and other life forms and processes generally evoke opposition from diverse groups for socio-economic, ethical and environmental reasons. This has led some to argue that IPRs on plants have provided perverse incentives for erosion of genetic diversity. According to this view, seed companies have a tendency to concentrate their research and development (R&D) on commonly used high value crops and develop varieties that are widely adaptable leading to spread of monoculture.

With this in mind, this research aims to answer the following questions:
1. What is the market landscape and who are the main intellectual property holders?
2. Do the IPRs in the European Union provide equitable protection of the interests of all the stakeholders in the plant breeding sector?
3. Do the current IPRs regimes in the plant breeding sector foster sustainable innovations?
European joint doctoral programme
EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project
March 2017 - February 2021
Funded by the European Union

Francesca Mazzi
PATENTABILITY OF AI GENERATED INVENTIONS: A CASE STUDY ON PHARMA
EIPIN Innovation Society
(March 2017 - January 2021)

European IP Institutes Network
Cooperation among IP Institutions and students in Europe since 1999.

EIPIN Innovation Society
• Multidisciplinary and holistic research programme on role of IP in the innovative lifecycle
• Co-supervision of doctoral research leading to joint doctorate degrees from two EIPIN partners
• Tailor-made training programme prepares a new type of IP researcher who is able to ascertain and articulate the complexities of the IP system.

IP as a complex adaptive system
• IP developed from a mere legal title into a complex adaptive system
• IP functions as a - Business tool for value creation - Vehicle for investment - Relationship between right holders, users and society
• Ambition: to enhance Europe’s capacity to foster innovation-based sustainable economic growth globally.
• Research objective: to provide reliable conclusions on how to deal with the adaptive complexities of innovation cycles that secure economic benefits and uphold justice in the innovation society.

Patentability of AI Generated Inventions: a Case Study on Pharma
Francesca Mazzi
Project: ESR6

Research Question
Artificial Intelligence and, in general, 4th industrial revolution technologies are bringing radical changes to everyday life. Such technologies allow the automation of not only physical tasks but also intellectual tasks, previously performable by human beings only. The ongoing diffusion of smart processes involves, amongst others, inventive activities. Indeed, AI already has, and will increasingly have, a determinant role in those activities that can lead to inventions. Can and should inventions generated by AI be patented?

The patent system has proven to be adaptable to technological advancement in the past. Nonetheless, the revolutionary scope of interconnected technologies, the rapidity of their constant development and the peculiarities of their functioning, such as the “black box” AI, are likely to challenge practically and theoretically fundamentals of patent law. Therefore, the present research seeks to investigate the potential patentability challenges caused by the engagement of AI and 4th industrial revolution technologies for the production of potentially patentable outcomes (“AI generated inventions”). Given the technological neutrality of the patent system, the pharmaceutical industry is analysed as case study due to the significance of the sector, the ever-growing role in inventive activities therein and the peculiar market competition in relation to R&D investments.

The thesis investigates whether the advent of AI generated inventions challenges the justifications of the patent system. Moreover, the research evaluates to what extent AI generated inventions can and should obtain patent protection in light of specific formal and substantial patentability requirements, such as inventorship, inventive step and sufficiency of disclosure.

Methodology
The research is based on traditional black letter methodology, via analysis of statutory provisions and line of cases, through arguments by analogy, analysis of wording and legal history as a means of understanding, criticizing and assessing the state of the law. Additionally, the researcher engaged in comparative analysis of different jurisdictions and qualitative empirical research.

Indeed, the secondments at Hovione and EFPIA allowed the researcher to conduct semi-structured interviews with relevant stakeholders, from heads of IP departments to inventors. The results of such interviews contribute to the robustness of the findings of the thesis.

Societal impact
The pharmaceutical industry is a key sector not only as one of the most relevant players in today’s economy but most of all because of its crucial role in developing medicines. After the Covid-19 pandemic it became even more evident that global health challenges are of primary importance for societies worldwide. Artificial intelligence will play a decisive role in this development. The research presents regulators with tools on how AI could best be addressed through patent law, in order to foster innovation in the pharmaceutical industry and at the same time maximize the societal benefits.

Research results
• 15 PhD theses, published as monographs
• International peer-reviewed articles
• Presentations at international conferences
• Bi- yearly conferences on the four areas of research
• Training activities on methodology, research and transferrable skills
• Presentations and publications on establishment and management of joint doctoral degree structures
European joint doctoral programme

EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project
March 2017 - February 2021
Funded by the European Union

Vicente Zafrilla
Declaration of Standard-essential Patents (SEPs) - Strategic use of IP policies of standard-setting organisations by patent holders

EIPIN Innovation Society
Coordinated by Maastricht University, Faculty of Law,
Bouillonstraat 3, 6211 LH Maastricht, The Netherlands
P.O. Box 616, 6200 MD Maastricht, The Netherlands
E: eipin-is-h2020@maastrichtuniversity.nl
EIPIN Innovation Society
(March 2017 - January 2021)
European IP Institutes Network
Cooperation among IP Institutions and students in Europe since 1999.

EIPIN Innovation Society
• Multidisciplinary and holistic research programme on role of IP in the innovative lifecycle
• Co-supervision of doctoral research leading to joint doctorate degrees from two EIPIN partners
• Tailor-made training programme prepares a new type of IP researcher who is able to ascertain and articulate the complexities of the IP system.

IP as a complex adaptive system
• IP developed from a mere legal title into a complex adaptive system
• IP functions as a
  - Business tool for value creation
  - Vehicle for investment
  - Relationship between right holders, users and society
• Ambition: to enhance Europe’s capacity to foster innovation-based sustainable economic growth globally
• Research objective: to provide reliable conclusions on how to deal with the adaptive complexities of innovation cycles that secure economic benefits and uphold justice in the innovation society.

Partner organisations

Research results
• 15 PhD theses, published as monographs
• International peer-reviewed articles
• Presentations at international conferences
• Bi-yearly conferences on the four areas of research
• Training activities on methodology, research and transferrable skills
• Presentations and publications on establishment and management of joint doctoral degree structures

Declaration of Standard-essential Patents (SEPs) - Strategic use of IP policies of standard-setting organisations by patent holders

Vicente Zafrilla
Project: ESR7

Research Question
The competitive and technological dynamics in the standardization environment shape the way Standard Essential Patents are declared, leading to a scenario where not all the essential patents are declared (underdeclaration) and not all declared patents are essential (overdeclaration). Both deviations have the potential of affecting the evolution of competition and innovation in the ICT sector by reducing interstandards competition, extracting unduly royalties through patent ambush or conditioning technological decisions, among others. On the other hand, Internet of the Things (IoT) technological and market dynamics might alter existing assumptions on the interaction of standards with competition and innovation. The following research questions ensue:
1. What are over and underdeclaration from a legal point of view?
2. What are the causes for over and underdeclaration? What incentivizes or discourages them?
3. How over and underdeclaration affect innovation and competition?
4. Which measures are suitable to prevent over and underdeclaration and/or their negative effects?
5. Might IoT change the answers to the prior questions?

Methodology
• Descriptive study of key concepts from a legal and economic perspective
• Empirical assessment of causes for over and underdeclaration based on semi-structured interviews
• Normative analysis of over and underdeclaration from Competition Law perspective
• Evaluative analysis of existing measures to fight over and underdeclaration

Societal impact
Over and underdeclaration entail a number of negative effects for society. Particularly, them might imply that licensees pay for patents that they do not actually need, leading to lower degrees of efficiency or, conversely, over pay for patents that should have been licensed in FRAND terms. Additionally, both over and under declaration might negatively impact on innovation, by reducing the incentives to create competing standards and by hampering disruptive innovation. By proposing measures towards reducing over and underdeclaration and its negative effects, we aim to contribute to reduce such cost inefficiencies and to remove obstacles for innovation, which will benefit society as a whole. The goal is to achieve more legal certainty for SDOs, SEP holders and implementers, based on an assessment of competition concerns’ full picture, and addressed in consequence. A clearer framework will help to reduce transaction costs and discourage free riding to achieve higher levels of efficiency and welfare.
European joint doctoral programme

EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project
March 2017 - February 2021
Funded by the European Union

Naina Khanna
Balancing the Quality of Patents with Effective Enforcement of Invalidity Claims in the Pharmaceutical Industry in Europe

EIPIN Innovation Society
Coordinated by Maastricht University, Faculty of Law,
Bouillonstraat 3, 6211 LH Maastricht, The Netherlands
P.O. Box 616, 6200 MD Maastricht, The Netherlands
E: eipin-is-h2020@maastrichtuniversity.nl
EIPIN Innovation Society

(March 2017 - January 2021)

European IP Institutes Network
Cooperation among IP Institutions and students in Europe since 1999.

EIPIN Innovation Society

- Multidisciplinary and holistic research programme on role of IP in the innovative lifecycle
- Co-supervision of doctoral research leading to joint doctorate degrees from two EIPIN partners
- Tailor-made training programme prepares a new type of IP researcher who is able to ascertain and articulate the complexities of the IP system.

IP as a complex adaptive system

- IP developed from a mere legal title into a complex adaptive system
- IP functions as a
  - Business tool for value creation
  - Vehicle for investment
  - Relationship between right holders, users and society
- Ambition: to enhance Europe’s capacity to foster innovation-based sustainable economic growth globally
- Research objective: to provide reliable conclusions on how to deal with the adaptive complexities of innovation cycles that secure economic benefits and uphold justice in the innovation society.

Partner organisations

- efpiA
- Hovione
- Kennisland
- CPVO
- ICTSD
- ASTP PROTON
- EUIPO
- ETSI
- orIn
- Maastricht University
- University of Strasbourg
- University of Augsburg
- University of Alicante
- Queen Mary University of London
- Ericsson
- ESA
- CISAC
- GEMA

Balancing the Quality of Patents with Effective Enforcement of Invalidity Claims in the Pharmaceutical Industry in Europe

Naina Khanna

Project: ESR8

Research Question

1. What are the factors influencing the quality of patents in the pharmaceutical sector in Europe?
2. Whether or not existing legal arrangement (including patent grant process and enforcement mechanisms) incentivizes the creation of optimal quality patents in the pharmaceutical sector in Europe?
3. Is it possible to balance the quality of patents with effective enforcement of invalidity claims in the pharmaceutical industry in Europe (specifically with the upcoming Unified Patent Court)? If yes, how?

Methodology

I envisage that I will be following an empirical approach for evaluating the legal arrangement (i.e. the patent system for my concern). ‘Legal normative analysis’ approach will be followed, ‘what the patent system is’ and ‘what it ought to be’ (for the Pharmaceutical sector in Europe).

The aim is to identify the most critical aspects of the system and as well as the expectation of the major European Innovative Pharmaceutical companies from prospective reforms. Having done an analysis of the literature on patent quality to develop a theoretical framework for the subsequent thesis, broad factors influencing patent quality (these will be the focus of my subsequent study) will be analysed step-by-step. The subsequent study will then follow a methodology that will be a combination of desktop research and the observations that I will deduce from the time I spend interning at Hovione (either based on the field-note method or case-study method) and EFPIA (including the interviews/survey I will conduct). Also, I may point out that I expect that I will conduct a qualitative analysis of the data collected through interviews. Depending on the number of experts that will agree to be interviewed, I may also use the software- ATLAS.ti for a smooth qualitative analysis and coding of the data. In the next part of the thesis I will dwell on the second important aspect of the legal arrangement (i.e. the patent courts). This will entail a review of the literature. I will do a desk-research analysis aided by the views (collected after interviews) of the major innovative pharmaceutical companies regarding the expected effect of the upcoming Unified Patent Court.

Societal impact

Scholars have mutually agreed that there exists the problem of deteriorating patent quality in most of the prominent jurisdictions and Europe is no exception to this case. Low quality cannot be ignored especially for a business operating in patent-dense markets, and pharmaceutical business is one of those. This may not reflect real innovation taking place in the sector. Further, pharmaceutical inventions have a great role in public policy and public health; therefore, any decisions about patents or such monopolies should come more cautiously and accurately.

Research results

- 15 PhD theses, published as monographs
- International peer-reviewed articles
- Presentations at international conferences
- Bi-annually conferences on the four areas of research
- Training activities on methodology, research and transferrable skills
- Presentations and publications on establishment and management of joint doctoral degree structures

Research Question 1

1. What are the factors influencing the quality of patents in the pharmaceutical sector in Europe?
2. Whether or not existing legal arrangement (including patent grant process and enforcement mechanisms) incentivizes the creation of optimal quality patents in the pharmaceutical sector in Europe?
3. Is it possible to balance the quality of patents with effective enforcement of invalidity claims in the pharmaceutical industry in Europe (specifically with the upcoming Unified Patent Court)? If yes, how?

Methodology

I envisage that I will be following an empirical approach for evaluating the legal arrangement (i.e. the patent system for my concern). ‘Legal normative analysis’ approach will be followed, ‘what the patent system is’ and ‘what it ought to be’ (for the Pharmaceutical sector in Europe).

The aim is to identify the most critical aspects of the system and as well as the expectation of the major European Innovative Pharmaceutical companies from prospective reforms. Having done an analysis of the literature on patent quality to develop a theoretical framework for the subsequent thesis, broad factors influencing patent quality (these will be the focus of my subsequent study) will be analysed step-by-step. The subsequent study will then follow a methodology that will be a combination of desktop research and the observations that I will deduce from the time I spend interning at Hovione (either based on the field-note method or case-study method) and EFPIA (including the interviews/survey I will conduct). Also, I may point out that I expect that I will conduct a qualitative analysis of the data collected through interviews. Depending on the number of experts that will agree to be interviewed, I may also use the software- ATLAS.ti for a smooth qualitative analysis and coding of the data. In the next part of the thesis I will dwell on the second important aspect of the legal arrangement (i.e. the patent courts). This will entail a review of the literature. I will do a desk-research analysis aided by the views (collected after interviews) of the major innovative pharmaceutical companies regarding the expected effect of the upcoming Unified Patent Court.

Societal impact

Scholars have mutually agreed that there exists the problem of deteriorating patent quality in most of the prominent jurisdictions and Europe is no exception to this case. Low quality cannot be ignored especially for a business operating in patent-dense markets, and pharmaceutical business is one of those. This may not reflect real innovation taking place in the sector. Further, pharmaceutical inventions have a great role in public policy and public health; therefore, any decisions about patents or such monopolies should come more cautiously and accurately.
European joint doctoral programme

EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project March 2017 - February 2021
Funded by the European Union

Clara Ducimetiere
The Protection and Enforcement of Intellectual Property in EU Investment Agreements

EIPIN Innovation Society
Coordinated by Maastricht University, Faculty of Law,
Bouillonstraat 3, 6211 LH Maastricht, The Netherlands
P.O. Box 616, 6200 MD Maastricht, The Netherlands
E: eipin-is-h2020@maastrichtuniversity.nl
The Protection and Enforcement of Intellectual Property in EU Investment Agreements

Clara Ducimetiere
Project: ESR9

Research Question

Intellectual property is invariably included under the definition of investment in international investment agreements, including in recent agreements signed by the European Union. Intellectual property right holders thus have access to investor-state dispute settlement and to investment protection standards, and are able to challenge States’ measures affecting their intellectual property investments. This research aims at identifying the legal and policy consequences of protecting intellectual property under investment agreements, especially for the European Union. In other words, what is the impact of the interaction between both fields for the regulation of IP in the EU and for the adjudication of intellectual property disputes?

Methodology

Interpretivism is the meta-theory of research that is mainly applied; any conclusion as to the legal and regulatory consequences for protecting intellectual property as an investment will depend on the stakeholder’s perspective.

Empirical research is conducted on a qualitative basis, by gathering relevant EU legislation, policy documents, arbitral awards, and domestic courts’ decisions touching upon the interaction between investment and intellectual property laws, as well as doctrinal analysis.

Quantitative analysis is carried out based on existing data sets such as the Investment Policy Hub from UNCTAD, to identify statistical evidence and trends in arbitral awards and policy making as to the protection of intellectual property as an investment.

Societal impact

Access to investment protection to protect intellectual property assets is a highly controversial tool in the legal toolbox of investors. While it could be fostering innovation in countries that have signed such agreements by increasing investments in R&D and intellectual property intensive industries, it also impacts the regulatory freedom of States and therefore their capacity to regulate in the public interest. Investor-state dispute settlement also involves high costs for both the investor and the State, and therefore the society.

High profile cases involving tobacco and pharmaceutical companies have shed light on the societal impact of the interaction between IP and investment protection, in particular on public health. While there is little doubt that such cases could arise in the European Union, the specificities of the European legal framework could offer some safeguards to the States, the investors, and the society in general, to achieve a balanced system.
European joint doctoral programme

EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project
March 2017 - February 2021
Funded by the European Union

Anastasiia Kyrylenko
Enforcement of intellectual property rights and trade
**EIPIN Innovation Society**

(March 2017 - January 2021)

**European IP Institutes Network**
Cooperation among IP Institutions and students in Europe since 1999.

**EIPIN Innovation Society**
- Multidisciplinary and holistic research programme on role of IP in the innovative lifecycle
- Co-supervision of doctoral research leading to joint doctorate degrees from two EIPIN partners
- Tailor-made training programme prepares a new type of IP researcher who is able to ascertain and articulate the complexities of the IP system.

**IP as a complex adaptive system**
- IP developed from a mere legal title into a complex adaptive system
- IP functions as a
  - Business tool for value creation
  - Vehicle for investment
  - Relationship between right holders, users and society
- Ambition: to enhance Europe’s capacity to foster innovation-based sustainable economic growth globally.
- Research objective: to provide reliable conclusions on how to deal with the adaptive complexities of innovation cycles that secure economic benefits and uphold justice in the innovation society.

**Enforcement of intellectual property rights and trade**

**Anastasiia Kyrylenko**

**Project: ESR10**

**Research Question**
What are the European Union’s external trade and/or neighborhood objectives and guiding principles in the field of IPR Enforcement? To what extent such objectives and corresponding actions were modified with the European Commission’s IPR Enforcement in Third Countries Strategies from 2004 and 2014?

Are these changes reflected in the IPR Enforcement chapters of free trade agreements, negotiated by the European Union (case study: Georgia, Moldova and Ukraine)? To what extent did the IPR Enforcement system exported by the EU through free trade agreements signed with these countries correspond to their internal legal systems? Shall discrepancies be detected, in which way can the EU External actions be reshaped to take into account such discrepancies?

**Methodology**
Doctrinal research through literature review; comparative and diachronic legal analysis, qualitative research through semi-structured interviews with stakeholders from third countries.

**Societal impact**
This research aims at corroborating, based on three case studies, the critics voiced towards the European Union’s approach to introduce strong IPR Enforcement standards in third countries, without allegedly adopting a tailor-made approach or considering broader societal interests. Using the free trade agreements, negotiated correspondingly with Georgia, Moldova and Ukraine, the researcher will undertake an analysis of the countries’ legal systems after the entry into force of these agreements.

Unlike the existing researches based exclusively on the content of the agreements themselves, such analysis will also take into consideration the internal legal order of the countries in question, which would allow to draw conclusions on the resulting system of checks and balances and its fitness for beneficiary countries. The results of research might be used for countries, which enter into trade negotiations with the European Union, as well as for a further generation of the European Union’s IPR Enforcement Strategy.
European joint doctoral programme

EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project
March 2017 - February 2021
Funded by the European Union

Letizia Tomada
The Unitary Patent Court

EIPIN Innovation Society
Coordinated by Maastricht University, Faculty of Law,
Bouillonstraat 3,  6211 LH Maastricht, The Netherlands
P.O. Box 616, 6200 MD Maastricht, The Netherlands
E: eipin-is-h2020@maastrichtuniversity.nl
EIPIN Innovation Society (March 2017 - January 2021)

European IP Institutes Network
Cooperation among IP Institutions and students in Europe since 1999.

EIPIN Innovation Society
• Multidisciplinary and holistic research programme on role of IP in the innovative lifecycle
• Co-supervision of doctoral research leading to joint doctorate degrees from two EIPIN partners
• Tailor-made training programme prepares a new type of IP researcher who is able to ascertain and articulate the complexities of the IP system.

IP as a complex adaptive system
• IP developed from a mere legal title into a complex adaptive system
• IP functions as a
  - Business tool for value creation
  - Vehicle for investment
  - Relationship between right holders, users and society
• Ambition: to enhance Europe’s capacity to foster innovation-based sustainable economic growth globally
• Research objective: to provide reliable conclusions on how to deal with the adaptive complexities of innovation cycles that secure economic benefits and uphold justice in the innovation society.

Research results
• 15 PhD theses, published as monographs
• International peer-reviewed articles
• Presentations at international conferences
• Bi-yearly conferences on the four areas of research
• Training activities on methodology, research and transferrable skills
• Presentations and publications on establishment and management of joint doctoral degree structures

Partner organisations

The Unitary Patent Court
Letizia Tomada
Project: ESR11

Research Question
The thesis answers the following main research question: “To what extent does the establishment of a Unified Patent Court have an influence on the innovation of start-ups?”.

The analysis is divided in the following sub-questions:
1. What is the interplay between start-ups, innovation and the patent system?
2. What are the implications of the establishment of the UPC for start-ups in the role of plaintiffs and defendants? Does the establishment of the UPC strike an appropriate balance of the interests involved?
3. What are the systematic implications of the UPC asymmetries on the population of start-ups? Which could be an alternative and more balanced system?

Methodology
The thesis is divided in three main parts. Part I looks at the interplay between start-ups, innovation and the patent system. The analysis takes into account empirical economic studies on the uses of the patent system by start-ups and also explores the extent at which start-ups have been taken into account during the negotiations for the establishment of the Unified Patent Court.

Part 2 analyses specific issues which can have important implications for start-ups and in this light compares the current system with the envisaged future system of unified patent litigation. The main issues relate to the proximity to the venue of litigation, to the territorial scope of Court’s decisions with specific attention to the implications of the grant of injunctions and provisional measures and the use of bifurcation. The thesis foresees proposals for each specific issue.

Part 3 explores the potential consequences of the establishment of a Unified Patent Court from a systematic perspective, such as the potential increase of patent-trolls activities and envisages the implementation of an alternative system which can better respond to start-ups’ needs.

Societal impact
The results of the study envisage changes which streamline patent litigation in Europe, in light of the interests and needs of start-ups. The proposed changes would help start-ups to defend themselves and enforce their patent rights. Prioritizing their needs is important, as it encourages the implementation of inventions that respond to the needs of society.
European joint doctoral programme

EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project
March 2017 - February 2021
Funded by the European Union

Natasha Mangal
An Institutional Approach to EU Copyright Reform
EIPIN Innovation Society
(March 2017 - January 2021)

European IP Institutes Network
Cooperation among IP Institutions and students in Europe since 1999.

EIPIN Innovation Society
• Multidisciplinary and holistic research programme on role of IP in the innovative lifecycle
• Co-supervision of doctoral research leading to joint doctorate degrees from two EIPIN partners
• Tailor-made training programme prepares a new type of IP researcher who is able to ascertain and articulate the complexities of the IP system.

IP as a complex adaptive system
• IP developed from a mere legal title into a complex adaptive system
• IP functions as a - Business tool for value creation - Vehicle for investment - Relationship between right holders, users and society
• Ambition: to enhance Europe’s capacity to foster innovation-based sustainable economic growth globally
• Research objective: to provide reliable conclusions on how to deal with the adaptive complexities of innovation cycles that secure economic benefits and uphold justice in the innovation society.

Partner organisations

Research results
• 15 PhD theses, published as monographs
• International peer-reviewed articles
• Presentations at international conferences
• Bi-yearly conferences on the four areas of research
• Training activities on methodology, research and transferrable skills
• Presentations and publications on establishment and management of joint doctoral degree structures

Research Question
What can be learned from the practices of administrative bodies (copyright boards, tribunals, offices) in EU and non-EU jurisdictions?
- What are the forms and functions of these authoritative norm-setting entities?
- How do these characteristics help to effectuate changes in copyright?
- How might institutional structures aid in channeling stakeholder input, academic discourse, and economic evidence into more comprehensive legislation?
- How can copyright policymaking in the EU be optimized for the digital era through reconceptualizing its own institutional approach?

Methodology
The methodology will primarily consist of case studies of EU and non-EU copyright institutions to inform the structuring of the proposed institutional framework. Traditional doctrinal research will be used to answer the questions posed above, with empirical legal research supplementing evidentiary gaps. In terms of the empirical legal research for consideration, stakeholder interviews and economic data (e.g., information related to the calculation of royalties/levies) will be of particular interest to this project.

Societal impact
From music streaming to social media, society encounters copyrighted content daily. With the rise of technology, consumers and creators have readily embraced new ways of enjoying and sharing creative content. Yet in the EU, persistent practices such as geo-blocking have created artificial barriers to the cross-border exchange of content. These limitations have amounted to great administrative, financial and cultural costs to every stakeholder involved in the EU market for creative content.

Action at the EU-level seems promising to reconcile longstanding differences in national systems regulating copyright, yet this option remains under explored. This project will give policymakers a comparative view of select copyright administrative institutions, and will provide a practical assessment of these institutions to explore the feasibility of an EU-level regulatory body in promoting a more vibrant and well-functioning market for creative content.

An Institutional Approach to EU Copyright Reform

Natasha Mangal
Project: ESR12
European joint doctoral programme
EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project
March 2017 - February 2021
Funded by the European Union

Gerben Hartman
European decision-making institutions

EIPIN Innovation Society
Coordinated by Maastricht University, Faculty of Law,
Bouillonstraat 3, 6211 LH Maastricht, The Netherlands
P.O. Box 616, 6200 MD Maastricht, The Netherlands
E: eipin-is-h2020@maastrichtuniversity.nl

www.eipin-innovationsociety.org
EIPIN Innovation Society
(March 2017 - January 2021)

European IP Institutes Network
Cooperation among IP Institutions and students in Europe since 1999.

EIPIN Innovation Society
• Multidisciplinary and holistic research programme on role of IP in the innovative lifecycle
• Co-supervision of doctoral research leading to joint doctorate degrees from two EIPIN partners
• Tailor-made training programme prepares a new type of IP researcher who is able to ascertain and articulate the complexities of the IP system.

IP as a complex adaptive system
• IP developed from a mere legal title into a complex adaptive system
• IP functions as a - Business tool for value creation - Vehicle for investment - Relationship between right holders, users and society
• Ambition: to enhance Europe’s capacity to foster innovation-based sustainable economic growth globally.
• Research objective: to provide reliable conclusions on how to deal with the adaptive complexities of innovation cycles that secure economic benefits and uphold justice in the innovation society.

Research results
• 15 PhD theses, published as monographs
• International peer-reviewed articles
• Presentations at international conferences
• Bi-yearly conferences on the four areas of research
• Training activities on methodology, research and transferrable skills
• Presentations and publications on establishment and management of joint doctoral degree structures

Partner organisations

European decision-making institutions

Research Question
The main research questions are: How should the normative hierarchies of the relevant legal orders in the UPC framework be determined? How could supranational courts such as UPC ensure full effect (primacy, uniformity, effectiveness) of EU law in collaboration with the CJEU? How should this cooperative relationship be constructed to make it work? And could sufficient safeguards of EU law be achieved by UPC participation of EU Member States and (future) third countries?

Methodology
The research methodology comprises in-depth studies of primary and secondary law (incl. case law), legislative history and commentaries. In this assessment the areas of EU law that are relevant to patent enforcement in the UPC framework will be mapped out in order to identify potential conflicts and to work out hierarchies. This analysis will not only be made in light of EU law and (supra)national laws, but also in comparison to accepted practice of other international agreements between EU Member States and/or third countries that allow for creation of tribunals or courts (e.g. European Court of Human Rights, European Free Trade Area Court, Benelux Court of Justice or Investor-State Dispute Settlement courts/tribunals) which may or may not operate without adverse effect on the autonomy of the EU legal order as safeguarded by the CJEU. Further parallels will be drawn in comparison to other European decision-making institutions such as - the Boards of Appeal of - EUIPO and EPO.

The research structure starts from historical developments of a unified European patent judiciary to consolidate European patent law and reduce fragmentation of patent markets. In view of brief historic lessons, it will further focus on working out the potential conflicts and normative hierarchies of the multiple legal orders involved as well as specific constructions of CJEU Opinion 1/09 on conceivable ways to create a unified patent court considering the identified issues and needs for sufficient safeguards of EU law. Then, comparisons with other international treaties creating courts for dispute resolution between EU member states and/or third countries are made. When this research comes to its conclusions, it seeks to derive practical guidelines for a working cooperative relationship between the CJEU and other (supra)national courts such as the UPC.

Societal impact
This research may not only benefit patent-dependent innovation industries, but the working model it aims to derive may also be transposed to other industries that may benefit from guidelines for a working relationship between the CJEU and other relevant (supra)national courts.

Gerben Hartman
Project: ESR13
European joint doctoral programme
EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project
March 2017 - February 2021
Funded by the European Union

Tamar Khuchua
Innovation and Justice: Constructing Just and Efficient Court Systems

EIPIN Innovation Society
Coordinated by Maastricht University, Faculty of Law,
Bouillonstraat 3, 6211 LH Maastricht, The Netherlands
P.O. Box 616, 6200 MD Maastricht, The Netherlands
E: eipin-is-h2020@maastrichtuniversity.nl

www.eipin-innovationsociety.org
**EIPIN Innovation Society**
(March 2017 - January 2021)

**European IP Institutes Network**
Cooperation among IP Institutions and students in Europe since 1999.

**EIPIN Innovation Society**
- Multidisciplinary and holistic research programme on role of IP in the innovative lifecycle
- Co-supervision of doctoral research leading to joint doctorate degrees from two EIPIN partners
- Tailor-made training programme prepares a new type of IP researcher who is able to ascertain and articulate the complexities of the IP system.

**IP as a complex adaptive system**
- IP developed from a mere legal title into a complex adaptive system
- IP functions as a - Business tool for value creation - Vehicle for investment - Relationship between right holders, users and society
- Ambition: to enhance Europe’s capacity to foster innovation-based sustainable economic growth globally
- Research objective: to provide reliable conclusions on how to deal with the adaptive complexities of innovation cycles that secure economic benefits and uphold justice in the innovation society.

---

**Research Question**
The thesis 'The Future of the European Patent Judicial Design in the Light of the Harmonising Role of the CJEU’ deals with the issue of designing an optimal European patent judiciary in the light of the European harmonisation agenda. For this purpose, the upcoming Unified Patent Court (UPC) is analysed in order to ascertain to which degree the specialisation of courts in IP can be regarded as an instrument to foster judicial harmonisation and what sort of institutional changes should be implemented. Going beyond the current reform package, it is provided that the cooperation mechanisms amongst the national and European judges as well as the courts should be implemented in any case, with or without the UPC, in order to meet the EU harmonisation goals and guarantee a higher degree of legal certainty.

**Methodology**
The research employs the traditional legal dogmatic method which entails: 1. Collecting and analysing the relevant literature. 2. Collecting information regarding the existing law, models and procedures of selected courts. 2. Collecting and analysing the case law in order to assess the decisions of national courts (France, Germany and the UK) as well as the Court of Justice of the European Union. The research includes an empirical portion as the interviews have been conducted with IP experts and a survey targeting European patent practitioners.

**Societal impact**
Since the present research is seeking to explore patent litigation models within the EU, business participants will undeniably be beneficiaries of this research. For large and medium-sized corporations for which the patent protection is crucial to their commercial success, the analytical work and the policy recommendations provided in this research will be of great assistance as they are extensively targeted by the courts’ system together with its efficiencies as well as its shortcomings.

Dispute settlement in patent matters has an important impact on whether and how innovation takes place. Therefore, the research highlighting the importance of an efficient patent judiciary in the European Union that will guarantee legal certainty is essential for all stakeholders, such as inventors, third parties and the wider public. Flawless adjudicating system in general benefits the society as a whole since the effective judicial protection is one of the fundamental principles enshrined in many countries’ constitutions and also on an international and EU level.
European joint doctoral programme
EIPIN Innovation Society

Horizon 2020, Marie Skłodowska-Curie project
March 2017 - February 2021
Funded by the European Union

Lucius Klobučník
Collecting Management Organisations and Institutional Users

EIPIN Innovation Society
Coordinated by Maastricht University, Faculty of Law,
Bouillonstraat 3, 6211 LH Maastricht, The Netherlands
P.O. Box 616, 6200 MD Maastricht, The Netherlands
E: eipin-is-h2020@maastrichtuniversity.nl
Research Question

1. Can the EU legislator solve or reduce problems of fragmentation of rights, right holders and repertoires faced by on-demand online music streaming services by further structural regulation of licensing entities or by finding alternative solutions to EU-wide licensing of online rights in musical works? Can this measure lead to easier entry into the EU digital music market for on-demand online music streaming services?

2. Where can examples of facilitating rights clearance for on-demand online music streaming services be found (offline broadcasting rights clearance system in the EU, cross-border licensing solutions for neighbouring rights or the US systems of mechanical rights licensing)?

3. If safe harbour rules are reformed in the EU, how should the relationship between licensing entities and Internet platform be defined with regard to music streaming? What kind of licenses will Internet platforms need and should they be treated differently from on-demand music streaming services?

Methodology

The following methodology is employed in order to answer the research questions:

- Doctrinal research
- Comparative analysis (regulation of CMOs in the US and EU, role of competition law regulation in other areas of IP)
- Empirical research methods: interviews with open questions for CMOs' legal departments and CISAC - CMO umbrella organisation; interviews with on-demand music streaming services and Internet platforms (user generated content platforms)
- Law & economics (market delineation, transaction costs - quantitative methods for measuring transaction costs, copyright <-> competition relationship)

Societal impact

This project aims to answer a question as to how can fragmentation of rights, right holders and repertoires be reduced in order to provide a fertile soil for diverse, innovative and profitable music streaming services providing wider choice of music services to European consumers. This is done by way of legislative and policy suggestions amending the current licensing system and CMO regulation connected therewith.