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Knut Jørgen Egelie

Management of intellectual property in university-industry collaborations

Public access to and control of knowledge

Doctoral thesis

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Management of intellectual property in university-industry collaborations - public access to and control of knowledge

By

Knut J. Egelie

Dissertation submitted to:
Norwegian University of Science and Technology
Faculty of Natural Sciences
Department of Biology

For the degree of Ph.D.

Supervisor: Professor Berit Johansen, NTNU
Co-supervisor: Professor Roger Sørheim, NTNU
Co-supervisor: Professor Ulf Petrusson, University of Gothenburg

Abstract

Biotechnology research is important for social and economic welfare. It covers utilization broadly, many useful technology platforms are being developed. One of them is CRISPR/Cas9. This gene editing technology has been criticized for creating a knowledge monopoly. The access to technologies like CRISPR/Cas9 can be restricted, and access to and utilization of the technology depends on the intellectual property management and contractual terms devised by the owners of the technology. Collaborations in research between universities and industry are essential for academic knowledge to be transferred to the public. Industry benefit from accessing scientific knowledge that they can use to anticipate future research problems in new technological areas. Examples include setting up new businesses, creating products and services, and engaging in existing market transactions. Universities benefit from a close collaboration with the market and the implementers of new technologies.

This thesis examines university intellectual property management. Public funded research collaboration agreements have been analyzed, and a research model and a contribution for an ontology for investigating intellectual property in such agreements have been developed. These investigations are the first, to the best of my knowledge, empirical investigations of intellectual property elements in university-industry collaboration agreements. The research represents results and tools for use by university managers, innovation managers, and policy makers to improve their intellectual property management strategies in collaborations. The thesis investigates the patent landscape of CRISPR/Cas9. This exemplifies the intellectual property management challenges universities face when performing commercialization of research.

This thesis provides new knowledge to universities intellectual property management of research results in collaborations with industry. I have investigated the use of intellectual property management at the university in collaborations with industry. By analysing IP models of university-industry collaborations, I explore how different ways of managing IP have emerged to balance the norms of open science within the framework of university entrepreneurship and commercialization and accessing university research. The thesis' contribution is based on models providing a broad focus on the university missions of teaching, research, and economic and social contribution. I analyse the relationship between these missions in relation to IP management. This has enabled me to suggest solutions to how the university could improve strategies of intellectual property development and management in a fast-growing knowledge economy, and its interaction and integration with society. Prior literature is missing tools for empirically investigating collaborations agreements in university-industry collaborations. There is a need for research studying why and how universities should be concerned about how access to disruptive biotechnological tools are being managed in collaborations with industry. This thesis fills a research gap in universities intellectual property management strategies and models for purposes beyond their classical first, second and third missions.

Keywords: access, openness, intellectual property, research, knowledge, university, biotechnology, contracts, agreements, innovation management, patents.

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This work was carried out at the Department of Biology, NTNU, between March 2015 and January 2019. Professor Berit Johansen has been an amazing supervisor, always positive as well as constructively critical. As an experienced entrepreneur and very familiar with intellectual property management, she has recognized the need for someone investigating the topic of university intellectual property management. Without her support it would have been difficult to realize this project.

Haakon Thue Lie is the other companion that it would have been very hard to manage without during this work. His expertise, knowledge and a great appetite for good IP discussion have made my work through this thesis so much more interesting and stimulating – thank you Haakon!

My gratitude and appreciations also goes to my great colleagues and friends at the University of Gothenburg and the Centre for Intellectual Property - CIP. In particular, Professor Ulf Petrusson and Dr. Bowman Heiden. These amazing people has been a pleasure to collaborate with. I have been very fortunate get to know them and to be able to learn from their wide and long time experience. This thesis would have been much poorer without their contributions.

Professor Gregory Graff contributed significantly to the research in paper no. 1. Greg has been a good and tough discussion partner through out all my work. He also contributed to paper no.4 as a discussant. My good colleague at the NTNU Technology Transfer Office, Dr. Sabina Strand, contributed to the planning of the experiments in paper no.1 and 2 and in the discussions of the complex CRISPR situation. Professor Bjørn K. Myskja provided a great alternative view and insight through paper no.2 on the ethical considerations the intellectual property management in the CRISPR case. For paper no.3 and 4 both Professor Christoph Grimpe, Professor Roger Sørheim as well as Haakon Thue Lie have all made important contributions, and it has been a privilege to be co-authoring with you on these papers. Roger has also been an amazing supervisor with substantial knowledge of innovation management that has been critical for this thesis.

The NORSI-Norwegian Research School in Innovation is the national research school for PhD students has been useful in providing relevant training and support.

All the above mentioned fantastic people have been critical for being able to do this project, but the ones that I could not have done without their support at all is my one and only Hilde – you make it all worthwhile, and my amazing daughters, Oda and Anna – walk your own paths and make your own prints! I am so lucky to be a part of your lives. You have made it so much easier to walk these Ph.D. miles for almost 4 years. Love you forever☺

Knut J. Egelie,
Trondheim, February 2019

Contents

List of publications

This thesis contains material from the following paper publications. The rights have been granted by publishers and co-authors to include the material in this dissertation.

Author's contribution

1. EGELIE, K. J., GRAFF, G. D., STRAND, S. P. & JOHANSEN, B. 2016. The emerging patent landscape of CRISPR-Cas gene editing technology. *Nature Biotechnology,* 34**,** 1025-1031.
2. EGELIE, K. J., STRAND, S. P., JOHANSEN, B., MYSKJA, B. K., 2018. The ethics of access to patented biotech research tools from universities and other research institutions. *Nature Biotechnology,* 36, pages 495–499.
3. EGELIE, K. J.**,** GRIMPE, C., SØRHEIM, R., THUE LIE, H., 2018. Public funding of collaborative research and the access to research. *DRUID18.*
4. EGELIE, K. J., GRIMPE, C., SØRHEIM, R., THUE LIE, H., 2019. Biotechnology research collaborations between universities and industry create knowledge monopolies–an empirical study of access and openness. *Submitted to Nature Biotechnology, April 2019*

'Acquire new knowledge whilst thinking over the old, and you may become a teacher of others. The essence of knowledge is, having it, to apply it; not having it, to confess your ignorance.' [Confucius, 551 BC].

1 Introduction

This introduction intends to guide the reader through the foundation and the epistemological elements for the conduction of this thesis. The introduction also provides a brief overview of the literary landscape of accessing university knowledge, innovation development, and the main theme of the thesis. The main theme is management of access to university knowledge and innovation development through intellectual property. The research questions explored in the thesis is presented in the introduction to provide insight into the motivation of the thesis studies. The research background is presented after the introduction and discussed in relation to the research theme. The thesis then moves onto the detailed motivation for the research, detailed explanation of the various research questions and the relation between this and the research background. The details of the related literature, the relationship between this and the research theme, the deficiencies, and gaps in the literature are explained in more detail in the research background chapter.

The introduction and research background is quite detailed presented. There is a reason for this. Intellectual property, knowledge and research access and the management of these themes are complex and interdisciplinary research subjects. It is also, as a research topic in the context of intellectual property management and entrepreneurship, historically young. Intellectual property research was, before becoming a management element, economic and scientific debate, a philosophic debate. This means that there is a need to explain the transitions of intellectual property management in the development of university knowledge, which now as a topic has become a research discipline of its own.

This thesis aims to shed light on why and how intellectual property management should be explored in the context of accessing research results and in the framework of the university as a fundamental holder of knowledge. The goal has been to uncover improved strategies for university intellectual property management and models and tools that could aid intellectual property management for universities.

The main research question being asked is in the details of the investigations on how university intellectual property management can facilitate improved knowledge access to and openness of biotechnology research results in university-industry research collaborations financed by public funders. The research question is sectioned into four sub-questions with their own research subject. These are presented in four separate studies and papers reproduced in this thesis. The sub-research sections and appurtenant papers are as follows:

1. How is access to disruptive research results such as the biotechnology tool CRISPR-Cas9, managed by universities? (Egelie et al., 2016)

2. What are the ethical challenges presented by university involvement in patenting biotechnology innovations such as the CRISPR/Cas9 genome tool? (Egelie et al., 2018b)
3. How can intellectual property management in public funded collaborative research improve access to research results? (Egelie et al., 2018 and Egelie et al., 2019-unpublished, submitted for review)
4. Are biotechnology research collaborations between universities and industry creating knowledge monopolies? – An empirical study of access and openness (Egelie et al., 2018 & Egelie et al., 2019-unpublished, submitted for review)

I have, based on these research questions, developed and explored intellectual property development and management of specific biotechnology cases and intellectual property management models in university-industry collaborative research projects. I have done so to investigate whether such cases and models improve the understanding of public access to and sharing of research results. The details are presented in thesis paper no.1-4. Paper no.1 and 2 investigates and debates the university property management challenges in university-industry collaborations based on data and details of a recent research discovery in the biotechnology area of a research tool named CRISPR/Cas9. In paper no.3 and 4 I present results from analysing data of how the involvement of the public through both funding and contract management in collaboration agreements between universities and industries, improves the public's access to knowledge and research results.

Prior research has not empirically investigated intellectual property management and contractual regulations in public funded university-industry collaborations projects. It has not been investigated how this might influence the access to research results and the public availability for the knowledge produced. These considerations of prior literature and what is missing in the prior research motivated me to investigate the main research question: how does the management and control of intellectual property from universities influence access to knowledge and innovation development. I was inspired to explore if there is a possibility that university focus on intellectual property management could improve access to the knowledge produced. Biotechnology was in particular chosen because of its importance to the overall socio-economy contribution and the public awareness of the technology. Access to public funded biotechnology collaborative research and universities ability to manage related intellectual property is what this thesis is about.

1.1 University intellectual property management and access to research results

The transfer of knowledge from academic institutions, such as universities, to society, takes a number of forms. The classic form is the dissemination of research results through journals and the education of skilled people, who then provide this knowledge outside the academic learning and study environment (Perkmann & Walsh, 2007; Gibbons, 1994). A

new social contract is now being developed between academia and governments. This contract makes funding available to academia in exchange for more specific participation in the development of the economy. Universities provide society with access to knowledge, to promote economic progress through intellectual property rights (IPRs) (Gibbons, 1994). This is achieved through collaborations with industry parties and other organisations. Industry usually has a closer relationship with the market and with the public need for new products and services. Industry also have to adapt to a world that is constantly changing at an ever accelerating rate. Industry is, rather than pursuing their own research and development, therefore turning to existing knowledge providers to accelerate access to innovations and to save R&D costs. The question of who is entitled to use this knowledge and for what purposes, therefore, becomes a question of control and ownership of what some might argue is a public good (Stiglitz, 1999). The management of university-based intellectual property becomes a central element in the control of and achieving balance in the sharing of societal and economic goods at both the individual, organizational and institutional level. The way we use and manage knowledge through intellectual property is therefore not a systemic or descriptive question. It is much more a normative question through knowledge and science being considered to be a mutual social and economic resource. Or as David Teece explains it: 'Many sectors are animated by new economics, where the payoff to managing knowledge astutely has been dramatically amplified.' (Teece, 1998).

This thesis builds on prior knowledge of how universities are using intellectual property (IP) in making new research available to other parties (Etzkowitz, 1998; Eztkowitz & Leydesdorff, 2000). How IP is strategically used by universities in relation to the degree of public funding of research collaborations has not previously been available in prior research studies (Perkmann et al., 2013; Czarnitzki et al., 2015a).

1.2 Biotechnology research development in university-industry collaborations

Prior literature shows that public organisations like national research councils are often a funding party in collaborative research projects (Salter, 2001). The public funding party may have policy requirements for public access to research results. The degree of funding should then associate with the degree of public access to the results. If there is no clear policy enforcement, the collaborating partners are free to negotiate the terms. These terms often specify the ownership of the results, the rights to use such results and the openness through regulations of the right to publish and the right to keep results confidential. Typical topics are who are entitled to use the research results for what purposes, how and when publication may take place, and how to manage intellectual property (Stevens et al., 2016).

The results from projects that develop new biotechnology results may have value both commercially and for future research. The parties to the university-industry collaboration agreements have different objectives. For some projects, the value may be higher for

society if the research results are controlled by industry. For others, public control by a university may guarantee better societal utilisation. There should then be groups or clusters of projects with similar control mechanisms according to their organisational features (Czarnitzki, 2015; Perkmann, 2011; Thune, 2014).

Industry-controlled biotechnology projects should differ from university-controlled projects in terms of how the parties to the collaboration agree on the control mechanisms (ownership or use rights, publication, and confidentiality). Prior studies discuss how industry may require more secrecy from researchers in collaborations than they or the university see as beneficial for the flow of knowledge in society and the advance of science (Czarnitzki, 2015; Blumenthal, 1996; Lerner & Merges, 1998). Findings from a survey of 4000 U.S. life science faculty indicates that a large project budget is also associated with both more secrecy and more publication restriction (Louis et al., 2001).

Although several prior studies have been concerned about the management of intellectual property in university-industry projects, there is no discussions or empirical analysis to what extent the contract management and intellectual property regulation influence access to further research, dissemination of knowledge or the ability of the public to further innovate. Industry partners in university-industry collaboration projects may wish to restrict publication of the results in the collaboration. Contractual control might be used by industry to maintain control position and to reduce public access to the results. Projects with a high degree of public funding should provide more transparency and less confidentiality. Intellectual property management in technology transfer is critical to facilitate this.

2 Structure of the thesis

2.1 The structure of the chapters

The forthcoming chapters are structured such that the research questions are introduced in detail and explained in chapter 3. The overall question is 'how does the management and control of intellectual property from universities influence access to knowledge and innovation development.' Furthermore, in chapter 3, the research question is explained in a number of sub-chapters by formulating several sub-questions. Chapter 4 outlines the contribution of the thesis to the existing research of how university collaborates with industry and what role intellectual property management plays into this. In chapter 5 I introduce the research background in relation to the research question. The frame of reference and its relation to and motivation of the research is described in chapter 6. The methodology is outlined in chapter 7. Here it is also explained some of the techniques used in the different studies, but explained in relation to the overall work and not so much as to the details in the different papers which makes the basis and foundations of this thesis as this is explained in the different papers itself. The details of the thesis papers and its relation to the overall research topic of the thesis are explained in chapter 8. A short summary of each paper is also presented in this chapter. The thesis ends off by discussing

the results in chapter 9 and then some conclusions of the researched intellectual property management strategies and tools are proposed. It is also suggested what could be done to improve both the tools and the future use of these in chapter 10.

2.2 Research presentation and design

The research of this thesis has been performed in two parts. Each part is connected to the overall research theme, intellectual property management of research results produced by universities. Designing the research in two parts was made in order to be able to investigate how universities manage access to research results from more than just one angle. Part one describes a quantitative case study of a disruptive biotechnology research tool developed at a number of leading universities. The case of the CRISPR/Cas9 technology represents intellectual property management concerns when universities are performing technology transfer of disruptive research tools of potential broad utilization potentials. Technology transfer focus can be short-sighted, and only the near-future commercial potential is prioritized (Eisenberg, 1996; D'este & Perkmann, 2011). The long-term consequences of follow-on research issues and the broad mission of the university is overlooked. The patent landscape of the CRISPR/Cas9 tool and the appurtenant conceptual discussion of the ethics of the distribution and access is described in detail in paper no.1 and 2 reproduced at the end of this thesis.

Part two of the thesis research comprises two scientific publications represented by thesis paper no.3 and 4. These publications are describing a quantitative, empirical study of university-industry collaborations agreements. The research focus and results in these contribute to the development of an intellectual property-based access scoring model and access ontology that provides a basis for analysing some 8000 university-industry agreements in relation to 312 research and collaboration projects funded by the Research Council of Norway (RCN). This exemplifies how access to and openness of research results are managed by universities when developing research results in collaborations with industry. The results of the study of these collaboration agreements provide a model that could be used for adjusting the degree of access and openness correlated with the degree of public funding. The results are suggested also to be used as a guiding tool of intellectual property management in research collaborations.

The two research sub-parts are inter-related to the overall theme of this thesis, university access to research and intellectual property management in collaborative research projects. The sub-parts are presented separately in the methodology chapter but discussed together throughout the thesis. Table 1 displays and explains the thesis structure and the two sub-parts – how the research questions are formulated in relation to the different studies and the four papers that represent the studies.

Research paper	Research question	Frame of reference	Target field/group	Design of research
1. The emerging patent landscape of CRISPR-Cas gene editing technology	How is access to disruptive research results managed by universities?	Sociology of Science Anticommons, Patent thicket	Researchers and scientist University innovation managers	Quantitative analysis and empirical, illustrative case study
2. The ethics of access to patented biotechnology research tools from universities and other research institutions	Are there ethical challenges proposed by university involvement in patenting innovations?	Academic entrepreneurship and Triple Helix	Researchers and scientist	Conceptual case study
3. Public Funding of Collaborative Research and the Openness of Research Results	Is there a correlation between public funding of collaborative research and the access to research results?	Innovation Industry funding and access to research University-industry collaboration Academic engagement	Innovation policy makers	Quantitative analysis and methodology, model developing
4. Biotechnology research collaborations between universities and industry create knowledge monopolies – an empirical study of access and openness	Is there a correlation between open sharing/access and secrecy in university-industry collaborations?	Open innovation, trade secrets, university-industry collaboration, Mode 2, Triple Helix and Third mission	University managers Innovation policy makers	Quantitative analysis and methodology, model developing

Table 1: Thesis research structure outlining each paper in the thesis and the focus of each study in the papers.

The subparts aim to connect together with the overall research question: 'How is access to intellectual property from biotechnology research results managed by universities?' The question is investigated in different ways in the subprojects and related to the different research papers. By asking the same overall question in different ways, the intention is to provide an in-depth understanding of the main research question. I will, throughout this thesis, reflect upon and discuss the research questions and explain their relationship with intellectual property management in universities. The following sub-chapters present and explain the structure of the main text of this dissertation. This relationship between topics for the frame of the research for this thesis is schematically outlined in figure 1.

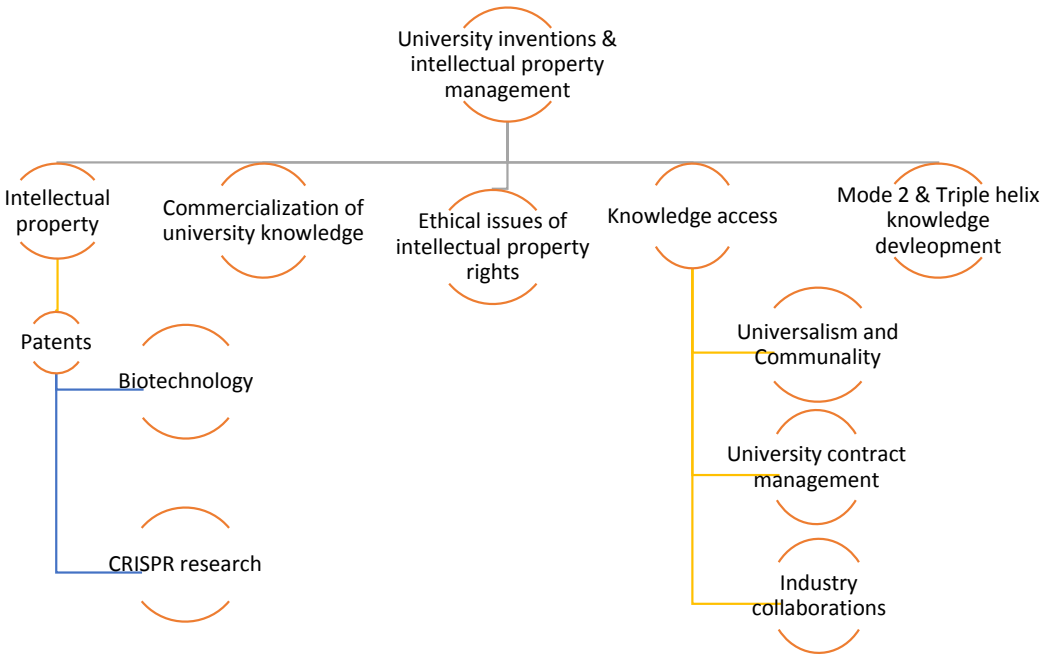

Figure 1: Relationship between topics for the frame of the research

The common linking element is intellectual property management that connects the ways universities are approaching knowledge management in society, both linearly through history and integrated into the development and progress of society and the economy. All research in the thesis rests on an intellectual property management based epistemological logic. In the universe of this thesis, the logic starts with the open sharing philosophy of Robert K. Merton in his thinking and debating of the norms of science (Merton, 1938). The university and management of science have naturally developed since Merton proposed his norms. It has, in particular, been witnessed a dynamic change in how the university and other academic institutions interact, develop and share knowledge through entrepreneurship and inventions. In the Triple Helix model and third mission debate (Etzkowitz & Leydesdorff, 1996), in the considerations of the triple helix in the academic scientist collaborative work (Jacob, 1997; Jacob, 2003), its contribution to new innovation and new knowledge (Gibbons, 1994; Gibbons, 1998), in the university collaborative relationship with industry (Perkmann et.al., 2013; Perkmann & Walsh, 2007) and its implications for the university beyond the classical missions of education, teaching and dissemination (Petrusson and Pamp, 2009; Petrusson, 2003; Petrusson, 2016).

The objective of the study in this thesis is to improve the knowledge and understanding of the role and use of intellectual property in the management of university access to research results. Two different groups of data were selected for this study:

1. Biotechnology patents, the CRISPR/Cas9 technology patents in particular, the regulations for access to platform technologies such as CRISPR and the management of its intellectual property claims.
2. Research Council of Norway (RCN) funded university-industry collaboration agreements and the contractual terms and regulations of access to research results.

The study of these different data groups will be presented in more detail later in this thesis.

As shown by biotechnology as a whole and the gene editing technology of CRISPR more specifically, industry interest in entering partnerships with universities has increased substantially. This increased interest is motivated by a wish to access research results at an early stage, but also to decrease own spending on research and development and minimize technology development risks. The development of a number of potentially high commercial value inventions has also lead to massive growth in the number of biotechnology patent filings (Blumenthal et al., 1996; Hemphill, 2012; Cook-Deegan & Heaney, 2010). A number of these inventions have originated from university environments. However, this patenting focus in biotechnology has led to a debate on public access to and openness of research results from academia utilised in the commercial space and the challenges this represents (Lemley, 2007). The CRISPR biotechnology tool has shown some very specific challenges. The development of the technology exemplifies why it is important that the parties involved in the development manage access to research results in a way that is optimal for societal development and value creation (Sherkow, 2015; Sheridan, 2014).

3 Research motivation

3.1 Universities increasing role in technology transfer

The main research question asked in this thesis questions that when there is a lack of intellectual property management in universities when collaborating with external parties and co-creating research results, could this provide different levels or grades of access to produced knowledge and research? Research and discussions on the greater involvement of universities in the third mission of commercialization and entrepreneurship, has led to debates and the questioning of whether universities and other Public Research Organizations (PROs) are able to manage this expansion and provide efficient management of knowledge for society (Etzkowitz, 2003; Rasmussen, 2006). The education and research roles are well-established missions of public knowledge developers and holders. The new role of producing knowledge as part of a commercial transaction, however, provides universities with new and different challenges. These challenges have been discussed and debated in paper no.2 of this thesis (Egelie et al, 2018). This publication debates the ethical issues of the university as a major holder of intellectual property; the assumption is taken is that this challenge is particularly present

in the management of intellectual property that is based on the research results of biotechnology research platforms due to its social impact and influence.

A more philosophic question was initially developed as to why should universities control knowledge-based research and manage intellectual property. Publicly funded research sometimes leads to new and important discoveries that be can be transformed into commercial successes. One of the issues discussed in this thesis is if the use of exclusive rights as patents is the only way that such public research can turn into economic successes. Another issue discussed is whether the need for good intellectual property management, including through the use of contracts and agreements, is merely for safeguarding the economic success of universities. As an example, of the Norwegian Research Council's total budget for funding collaborative research projects, the industry sector receives about one-sixth (Egelie et al, 2018). In addition, the universities, colleges, and departments cooperate with the private sector. But, how should the rights to innovation be designed to ensure a fair distribution of knowledge? What are the role of intellectual property and the transfer of university innovations to private industry? How can society manage publicly funded research and development for increased value creation in the near and far future? In a broader perspective, this is not about whether the universities must patent or not. What this thesis discusses and tries to exemplify through studies of the research platform CRISPR/Cas9 and the research contracts of the Norwegian Research Council in university-industry collaborations is how the public through universities can provide improved access to publicly funded research. What is discussed is that to ensure such balanced access, the universities are required to handle intellectual properties through solid contract management and regulation, but also through well-established routines and predictable frameworks and models in their collaborative relationships.

The global knowledge economy and new forms of innovation provide the business community with new opportunities. At the same time, it places companies, universities, university colleges, health enterprises, research institutes, and government institutions facing new challenges in dealing with intangible assets and rights. Companies increasingly compete internationally and with knowledge as the premier competition factor. This knowledge is more and more often obtained from external partners, to a larger extent these are public actors. These actors have a broader agenda to launch new products and services into a competitive market. Assignments such as education and research are important to ensure for universities. Good intellectual property management of research assets through among other contracts and agreements with partners is therefore important in order to provide knowledge flow and openness that the whole society benefits from.

3.2 Data sources – CRISPR/Cas9 and research collaboration agreements

I began this thesis work by investigating the existing challengeable case, CRISPR/Cas9 [the acronym and the technology will be explained later], its appurtenant patent landscape

and licensing scheme to gain insight into how university research tool platform stakeholders manage a research tool that is so important to society. I found that the CRISPR/Cas9 technology protected by patents was under a structured commercial use control. Provisions are made within the structure that allows broad dissemination for research or non-profit purposes. CRISPR/Cas9 control positions are used by leading universities to structure the access given to a range of commercial entities and non-profit organisations. The findings show that for similar gene editing technology cases such as the Cohen-Boyer recombinant DNA technology or the Axel co-transformation technology, technology transfer offices designed licensing programs that balanced control and access between the multiple commercial applications and access for research investigative purposes (Colaianni & Cook-Deegan, 2009; Cook-Deegan & Heaney, 2010). It appears that the university licensing offices have not taken such a strong position in licensing scheme design for CRISPR/Cas9, allowing both commercial development and further academic research. Its relation to the overall research topic is to show through a case study how an intellectual property element likes patents is being managed in university-industry relations for a specific technology and research platform.

Indications from prior studies indicate a lack of university-industry collaboration agreement data sources. Thus the first step of the research was to identify such a data source. I was early in the project allowed to access the Research Council of Norway (RCN) agreement database. This database comprises records of collaborative research projects funded by the RCN in the period 2008 to 2017. The RCN is a public funder of university-industry collaboration managed by the Norwegian government. Using their records, a collection of research data of 312 collaboration agreements was built up. The sample is randomly drawn from a total population of 21,838 projects, of which 8,000 were selected. The criterion for selection was that a project had at least one university and one industrial partner. The study was granted access to all the data RCN holds on these projects, including participants, funding amounts and the collaboration agreements partners have entered into with RCN and with each other. This database source has then been the foundation of the second part of the thesis study in relation to investigating how intellectual property management is reflected through university-industry collaboration agreements.

3.3 Research question and motivation in the context of biotechnology

The growth in the number of patents filed in the field of biotechnology has correspondingly increased the need for intellectual property management (Walsh et al., 2007; Walsh et al., 2003; Perkmann & Walsh, 2007). There are many reasons for managing intellectual property in the form of patents. One is the challenge represented by the science involved in biotechnology often coming from inside academia which is often to be transferred to the public by increasing industrial awareness. Also, there is a need for new inventions increasing the popularity of university-based biotechnology in commercial use (Powell and Owen-Smith, 1998). This has led to an increase in the intellectual property licensing activity of academic institutions and industry parties, in

the form of filed patents, increasing the need for a more structured focus on intellectual property management (Cook-Deegan & Heaney, 2010). A number of these patents filings have played fundamental roles in biotechnology innovation development. Examples include Stanford University's Cohen-Boyer patents for recombinant DNA, which were licensed to over 450 companies, the major and most famous licensee of this being the biotechnology locomotive Genentech Inc. These patents had generated more than $250 million in licensing revenue at the point in time that they expired in 1997 (Colaianni & Cook-Deegan, 2009). Literature investigations indicate that the intellectual property management of results from biotechnology research in university-industry collaborations has been well explored (Walsh et al., 2003). Investigations of how well universities manage access to this type of intellectual property shared with others have not been well researched (Egelie et al., 2016). One aspect that is of particular interest is whether universities are capable of combining sharing knowledge through patents and commercial collaborations with the fundamental mission of research and education. A further aspect of interest is whether universities are able to provide society with the information it requires to promote knowledge building, where gateways controlled by an intellectual property mechanism that is only opened by access to patents and collaboration agreements are used.

Universities that provide exclusive opportunities to partners, influence access to follow-on research (Perkmann & Walsh, 2009). This is explored in the first and second paper of this thesis, the two papers examining the influence of the intellectual property management of the CRISPR/Cas9 technology and how this exemplifies downstream the research result challenges of intellectual property management. Thesis paper no.1 explores and analyses the management of the CRISPR/Cas9 intellectual property by the universities involved. The production of knowledge is often regulated in collaboration agreements between parties. How contractual agreements affect knowledge production in projects has been studied by a few researchers. Rasmussen and Gulbrandsen use the framework of agency theory to study the contractual frameworks which gave an improved understanding of the roles of the parties and how funding was decided (Rasmussen and Gulbrandsen, 2012). They did not, however, propose clear management programs for relating and correlating public funding with access to follow-on research. I have therefore explored this in paper no. 3 and 4, to shed some further lights on the contractual terms of access to research results in research collaborations potentially influencing public access to downstream research (Egelie et al, 2018a; Egelie et al, 2019-unpublished, submitted to Nature Biotechnology for review).

A number of studies indicate that access to research tools within biotechnology and life science knowledge production are not being hindered by universities greater involvement in patenting activity as well as even more specific commercial activity (Perkmann, 2013; Walsh, Arora & Cohen, 2003; Walsh, Cohen & Cho, 2007). Murray & Stern, however, suggest that universities involved patenting in the field of biotechnology and life science result in access restrictions to knowledge as they experienced a decrease in the number of citations for a publication when such a publication also have been the basis of a patent application (Murray & Stern, 2007). Few studies have, however, explored this in the

context of the ethical implications (Mowery & Sampat, 2004). This is investigated in thesis paper no.2, which discusses the ethical implications of allowing more commercial involvement and greater engagement of universities in the exploitation of publically developed knowledge and intellectual property (Egelie, 2018b). Whether increased public governmental engagement will increase access to university intellectual property is, to some extent, also explored in paper no.3 and 4, examining the issue that the public funding of research projects influences access to intellectual property elements in research collaboration projects.

Whether intellectual property tools and access ontology models based on university-industry research collaboration agreements can provide improved knowledge management through an improved explanation of ownership rights and public access balance is explored in depth in paper no. 3 and 4. In these studies, I have explored a number of university-industry research contracts partly funded by the public based on a data source provided by the Research Council of Norway (RCN). These studies discuss how access to intellectual property elements was managed at the contractual level in a number of research collaborations. There have been discussions in the literature of the implications to universities of different funding schemes of research collaborations. It is suggested that models are required if how public funding programs affect university-industry collaboration projects is to be understood (Vorley & Nelles, 2008). Thus, a motivation for the need of further exploration is established and challenged.

Each research question has, in this thesis, been discussed and explained in relation to the sub-parts represented by the four mentioned research papers. There is produced a summary of each research paper in chapter 8, and they are available in full as an attachment to the thesis.

4 Contribution to existing research

In discussions and investigations of intellectual property (IP), terminology can often become confusing. Before going into the specific discussion of the research provided herein, I provide a better understanding of the concept and the terms I have used. I also describe what the different definitions and explanations of IP are about and how I relate to these terms throughout the thesis. Then I briefly go through the various concepts, what they mean and how they typically can be used. I then provide an overview of the recent development of IP in the context of the Norwegian innovation system and the transformation of IP in Norway in relation to the university being a major contributor to innovation. The Norwegian context is chosen because it relates to the dataset of collaboration agreements form the Research Council of Norway that have been investigated in this thesis.

4.1 Intellectual property terms and definitions in the context of university inventions

Intellectual property is a function which provides and organizes, and in certain cases grants legal rights of a non-material nature, such as a patent, design, trademark, and copyright and know-how. The term often used of the granted rights is "intellectual property rights" (IPR). IPR's are regulated in several different sets of rules and are largely based on national laws and international conventions. It is important to differentiate between the terms "intangible assets," "intellectual capital" and "intellectual property." The term intangible assets (IA) refers to assets that are not of physical substance and which in an organization are usually the result of the employee's knowledge. Intangible assets are also called intellectual capital (IC) and can be divided into human capital, structural capital and relationship capital. The term IPR includes how to define an invention, which is constructed and regulated legally in the form of a patent. Inventions are material constructions and technologies that find new and useful applications. Inventions include the process from idea to production of something new that has not previously existed, at least not in that combination or adaptation, such as wheels, unbreakable glass or a new drug, while discoveries include the disclosure of what is, but still unknown, for example new lands, laws of nature and a new natural element. An invention (in a patent-law context) is a practical solution to a technical problem. The solution must have a technical nature, technical effect and be reproducible.

4.2 Patents and its instrumental use - exemplified by the Norwegian Patent Act

In the case of a patent, there is a time-limited exclusive right to an invention. This is defined in the Norwegian Patent Act (Norwegian Industrial Property Office, 2017). The exclusive right to an invention means that the patent holder can exploit the invention for commercial purposes, while others are prevented from exploiting the invention without the patent holder's consent. The patent protection is territorial, which means that the exclusive right applies only in the countries or regions where the applicant has been granted a patent (Prime, 2017). In most Patent Acts, certain types of exploitation are exempt from exclusive rights, e.g., for medical or ethical reasons. Private individuals can freely exploit inventions in private use without infringing their exclusive rights. If the invention is used for research or experimental purposes, it is also clear of the exclusive right provision. In order to be granted a patent application, an application must be submitted to a governmental intellectual property office with a patent authority - in Norway for example to the Norwegian Patent Office.

The starting point of the patent law is that the rights of an invention belong to the one who has made the invention. The particular legal protection provided by inventions through patent law is a reward for the inventor's intellectual efforts, and the reward will motivate the inventor to make new inventions. Through the changes in 2003 in the Norwegian Employee Inventions Act, a greater responsibility has been given to

universities and colleges for the commercialization of research results and the implementation of such in the society (Bengtsson, 2017). In 2012, the Norwegian government presented a bill and a parliamentary report, both of which aimed at strengthening the protection of intellectual property rights. Parliamentary report and white paper 28, 2012–2013, "Unique ideas, great values - about intangible values and rights," explains the Norwegian government strategies in this area (Government, 2012-2013).

The patent law is today perceived primarily as a social-economic instrument; a means that stimulates research and development, which in turn leads to economic growth (Salter, 2001). The policy reasoning for implementing the legislation is the idea that the inventors' socially beneficial activities are best stimulated by the inventor having the exclusive right to reap the fruits of what has been produced (Sampat, 2006; Gulbrandsen, 2007). An inventor who knows that he or she can achieve a financially valuable right will also strive to make new inventions. Inventions made by teachers and academic staff at universities and colleges were previously exempt from the law. The exception - the so-called "teacher's exemption" - was justified on the grounds of the researchers' freedom and a free position these persons should have as scientists. The rationale was, among other things, to distinguish between the right to free research and the right to free commercial exploitation of research results, but which has not been entirely achieved (Gulbrandsen, 2005). In Norway, this meant that in practice, researchers at universities and university colleges had a special right to financial returns from their inventions (Fagerberg et al., 2009). With effect from January 2003, the "Teacher Exemption" was abolished in Norway, primarily with a view to increasing the commercial exploitation of inventions that originated in research at universities and university colleges, and strengthening the knowledge transfer between the institutions and business community (Stenvik, 2009).

4.3 The employer-employee relationship and the Norwegian Patent Act

The Norwegian regulation on IPR is based on the Act on the Right to Inventions made by employees (https://lovdata.no/dokument/NL/lov/1970-04-17-21). The Act on Employee Inventions regulates many of the questions that arise in connection with inventions made in working conditions. The Act applies only to patentable inventions, that is, inventions that fulfill the requirements of the Patent Act for obtaining a patent. However, the Act applies regardless of whether the invention is actually patented. Most of the provisions of the Act, but not all, can be waived by an agreement. Under certain conditions, the Employee Inventions Act gives the employer the right to take over the ownership of the invention or a right of use. The employer's opportunities to take over the invention are determined, among other things, on the nature of the tasks the employee has in the company and how strong the connection there is between the invention and the employee's work tasks. Whether the exploitation of the invention falls within the organization's operational area, as well as any agreements the employee has entered into with the employer, also affects the employer's right to take over the invention.

4.4 IPR policies and university IP management related to the Patent Act in Norway

The main tasks of the universities are to conduct research, teaching, and knowledge dissemination for the benefit of society. Universities are a very significant producer of knowledge and new research. As part of their socio-economic responsibility, universities are obliged to help society to make use of the research results that emerge from research. Furthermore, the dissemination task includes various aspects of utilization or disclosure of knowledge, intellectual property, and research results. Through the Norwegian Employee Inventions Act, the legislators have made it clear that the universities must also facilitate commercial exploitation and further innovation of research results. In Norway several of the universities have therefore seen a need for a specific policy for handling intellectual property rights through a specific IPR policy based on a review of what results of the employees' activities are related to rights in order to improve implementation of the revised Act on the right to inventions, and in which cases the university should or should take over these rights. An example of such an IPR policy is NTNU's rights policy on IPR that handles the management of knowledge results based on work performed by employees at NTNU (Gulbrandsen, 2010).

Ideas, inventions, and intellectual property created at or together with the university or with the university's resources should be used so that they benefit the community first and foremost. Ensuring transparency in proper management of intellectual property is thus important for the universities in order to facilitate this At the same time, both the university and the employees can have a self-interest in ensuring the greatest possible earnings based on the employees' results. To the extent that students are involved in research activities, it is also important that the IP policy provides a clear framework for the ownership of the students' research results and facilitates that these are also managed and processed in a good way. However, the university's IP policy must be designed and enforced so that self-interest must deviate from the interests of society when these two conditions are not compatible. The research community has developed norms and values for how scientific results are obtained and disseminated. The university will protect and safeguard the customary and legal access of scientifically appointed persons to decide for themselves whether and in what way a non-literary publication should be published. It is, therefore, part of the university's IP policy to provide positive incentives for the employees both for the commercial exploitation of results where the conditions are suitable for it, for traditional dissemination and for public use of ideas, results, and intellectual property created at the university. Technology Transfer Offices have become important actors for universities in managing intellectual property (Siegel et al., 2007). The tasks of these units, often wholly owned by the universities and other public institutions, are to ensure good management of the rights of inventions made by the employees of those institutions and facilitate utilization of intellectual property based knowledge.

The activities at universities are often characterized by openness to society and widespread collaboration with various partners in the private and public sector. It is also

a question of external parties benefiting from the knowledge of the university employees, partly because external partners contribute or pay for services and activities at the university. Much research activity at the university is critically dependent on external funding. This openness and exchange of expertise is important for both parties, but demands for tidiness in relation to the rights issue. The distribution of rights should be clarified in advance in the form of agreements between the parties. The university's policy on IPR's is based on the above principles and must balance the above needs. Both the legal framework and IP policy in Norway are justified by the fact that the universities take more responsibility for managing knowledge and intellectual property as a socio-economic instrument to stimulate more research and development, which in turn leads to economic growth. The idea behind the rules is that innovation is best stimulated by making knowledge available as much as possible and open through controlled mechanisms such as ensuring intellectual rights among good contract management and predictable legislation. This can be perceived as a contrast to Merton's four norms of openness and free communication but is really a parallel where one does not rule out the other. The critical element for the universities is to implement proper IP management. As shown this is an integration of both policy on innovation and a legal framework. Merton's norms will be discussed in detail in chapter 6.2.

4.5 Contribution to the existing literature

The literature presented further on in this thesis confirms that access to research and appurtenant intellectual property relates primarily to norms and practices of knowledge sharing within the not-for-profit research sector. Actual projects or collaboration contract studies are referred to less frequently.

4.5.1 Access to university knowledge managed by intellectual property

Knowledge monopolies through contractually restricted or limited access are counterproductive and hinder innovation. This is irrespective of whether the research collaboration monopoly is controlled by the industry or academic institutions (Cook-Deegan & Rai, 2017). Knowledge must be shared and used to create value broadly defined. If a number of parties are involved in new research development in formal collaborations, then such collaborations must be contractually regulated to optimized balanced and controlled sharing of intellectual property results. As claimed by Cook-Deegan and A. Rai: 'Broad knowledge monopolies even in the hands of universities can hinder scientific progress' (Rai & Cook-Deegan, 2017). They suggest that those monopolies '…are not only likely to hamper downstream development, they are also likely to encourage upstream duplication.'

The first publication produced during the course of this thesis explores universities' claims to intellectual property in the development of the powerful CRISPR/Cas9 gene editing tool. The paper suggests that sub-optimal intellectual property management by the universities that own and control the research and that originally created the knowledge

monopolies and exclusivity may lead to issues of downstream research access (Egelie et al., 2016). In thesis paper no.2, I discuss the ethical issues associated with the university as the patent owner of disruptive technologies such as the CRISPR/Cas9 platform. I propose that knowledge access might be more efficient where stricter governmental regulations that require more optimal sharing in research collaboration are imposed on such technologies. With this in mind a scoring model for access to research results in university-industry collaboration projects was developed. I used this model to propose four dimensions that express access to and openness of intellectual property which are important when exploring these issues. Two dimensions relate to ownership of rights (ownership and foreground) and two express access (publication and confidentiality).

The question that applies to the first two dimensions is who owns the rights to research results which is public funded when developed. Is it industry or university or somewhere in between? The question that applies to the next two relates to the level of public access, ranging from low to high. These four knowledge access dimensions contractually determine the degree or level of access of each partner in a research collaboration project and their access to the research collaboration project results. These dimensions can be, as will be explained, contractually tuned in research collaborations to achieve a research collaboration that creates a more optimal sharing ground for knowledge.

4.5.2 **Structure of knowledge production activities in universities**

The research parts of this thesis are connected by the recognized expanded role of universities in the contribution to social welfare and knowledge development, the so-called third mission (Etzkowitz et al., 2000). Many argue that this is an additional mission to the fundamentals of teaching and research, but not a new one (Jacob, 1997). I developed this thesis from the Mertonian ethos of open access and the sharing of biotechnological knowledge in the third mission and Mode 2 era. Gibbons et al. describe universities' move from Mode 1 to Mode 2 as corresponding with the production of knowledge becoming more result problem-driven research. Etzkowitz and Leydesdorff take this even further in their Triple Helix Model, discussing how the entrepreneurial universities have emerged as a result of universities becoming multitask organizations. We now see that some universities move beyond the 3rd mission of technology transfer and entrepreneurship, a new phase is observed in which the university is integrated into the global knowledge exchange as earlier proposed in the literature by, e.g. Vorley & Nelles, Scott, Trencher and Petrusson (Scott, 2006; Vorley & Nelles, 2008; Trencher et al., 2013; Petrusson, 2016). I propose this relationship more schematically by introducing four university activity quadrants in figure 2:

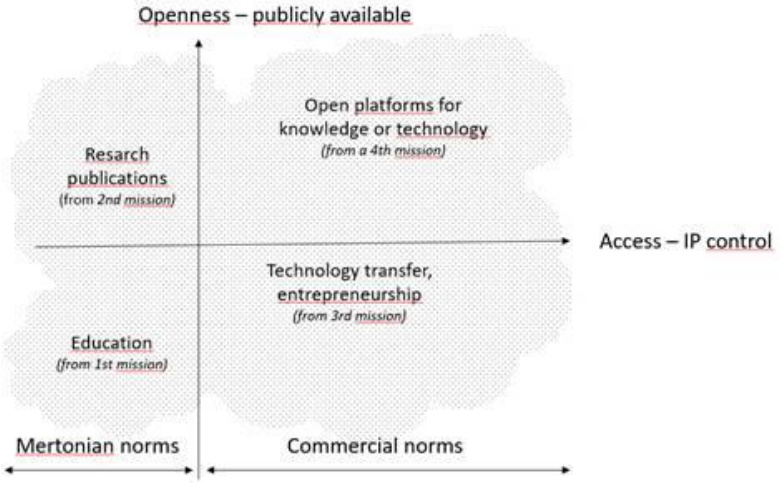

Figure 2: The university four different activity quadrants. The left side represents core educational and research activities without commercial interests, while the right side represents activities with external parties that requires control of access to intellectual property and assets (Egelie et al., 2019).

These four quadrants of university activity missions are connected by the interplay between intellectual property control, management of knowledge and the ability to control the dissemination of knowledge. The quadrant "Open platforms for knowledge or technology" is a state which has not yet been fully developed and in which the actors, universities in particular, are trying to find ways and strategies to optimize their knowledge management activities, including intellectual property management. This is a quadrant that by most universities yet have been under-explored. The need to clarify how universities in this state could operate in regard to intellectual property management is critical for accessing knowledge. The numbering of the missions from one to four may give the impression that these are always separate and distinguishable missions. This is not the case, but the numbering allows us to display these missions as areas spanned out by "openness" in terms of publicly available and "access" in terms of controlled by intellectual property. In figure 2 I have illustrated this conceptual framework. The two right-hand quadrants illustrate the universities' interactions with industry. This half-plane is governed by industrial norms as opposed to academic norms, and intellectual property will be used to control the access to the research results. In collaborative research universities need to balance the openness and access together with the other parties, that may have different objectives from the university.

Intellectual property management within universities and its role in creating and sharing knowledge seem not yet to have been completely explored for the tasks of education and research nor the entrepreneurial and commercialization activities. Earlier periods in the history of knowledge development have, however, been quite well explored. How the more socially and economically integrated university should relate to intellectual

property, therefore, requires further investigation. I thus keep coming back to the question: How could management of intellectual property improve access to research and knowledge developed by public institutions and contribute to further innovation? Biddle tries to answer this question from a Mertonian point of view the solution suggested being to subject science to social sharing mechanisms such as voluntary agreements, research exemptions and the more radical suggestion of the elimination of the patent system (Biddle, 2014). There are no clear positions on how universities should integrate intellectual property management with all its other activities. There are no positions on how this can facilitate control and access to the core activities of education and research while performing the activities of entrepreneurship, commercialization and global supplier of knowledge to society.

5 Research background

5.1 Intellectual property management and the sociology of science

As proposed earlier on in this thesis Robert K. Merton introduced a number of norms for socializing science and knowledge through various studies and papers (Merton, 1938; Merton, 1942; Merton, 1973). Some of these norms are integrated with intellectual property elements, but which in reality can be questioned if they are also managed sufficiently in collaborations where pieces of intellectual property are either co-produced or exchanged. The norm of communalism introduces an intellectual property proposal that suggests complete openness of a scientist's work: 'All scientists should have equal access to scientific goods, and there should be a sense of common ownership to promote collective collaboration, secrecy is the absolute opposite of this norm.' His norms are connected with what has been named the 1st and 2nd mission of universities, education, and research. Somewhat later Henry Etzkowitz and colleagues launched the idea of universities having a third mission of contributing to economic development (Etzkowitz, 2001; Martin & Etzkowitz, 2000). This, together with the first mission of teaching and the second of performing research, had emerged as a way of transferring knowledge to society. Etzkowitz proposed that 'Entrepreneurial scientists and entrepreneurial universities are reshaping the academic landscape by transforming knowledge into intellectual property' (Etzkowitz, 2001). This idea challenged Merton's norm of openness to all science produced. Etzkowitz idea involves the dynamic interaction with parties that require some level of controlled openness and not an autonomous approach to how science is disseminated to society. Both these philosophies of university interaction with society target what has been a major concern in the development of knowledge distribution to the society - that is, how does the scientific community manage intellectual property in a way that is for the common good of both economic and social development? Is it through open access and channels to knowledge or through commercial collaborations and interactions with other stakeholders of intellectual property? Recent research has targeted the management of university intellectual property from a perspective that access must be provided while broadly preserving the classical 1st and

2nd mission activities of education and research and while adapting the university to the generation of the knowledge economy and the commercialization of such knowledge.

Science is regarded as a construction created on the basis of certain research standards (US National Research Council, 1996). Construction of these standards will be institutionally conditioned. Part of the university culture that is based on the idea of science as a construction was presented by Merton as a normative structure for academic behavior (Merton, 1938; Merton, 1973). Science development was, in this, explorative and clearly separated from applications. Science sociology and knowledge creation have, evolved since Merton. Development has become more integrated with user needs, becoming closer to commercial partners who develop applications. The number of research collaborations with commercial partners at US and European universities has, over the past few years, increased. This evidences an academic dynamic of greater external collaboration and leads to important performance and policy implications in terms of management, control and the sharing of knowledge and science as intellectual property (Henderson et al., 1998; Perkmann et al., 2013). The consequences of these activities are immense. It is therefore important to shed light on some of the implications and to propose solutions for overcoming some of the issues involved in the use of knowledge-based intellectual property from public universities and other academic institutions.

5.2 The transforming university

The global economy has, in recent decades, been moving towards the integration of entrepreneurial and innovative activities with academic activities, the role of the university, therefore, becoming more diversified. A 'third-mission,' which entails economic development beyond traditional education and research missions and a need for more strategic attention to intellectual property, has led to a number of public institutions establishing formal structures for entrepreneurial activities, in particular, technology transfer offices (Foss & Gibson, 2015). Universities are today widely perceived as being more than institutions of higher education and research. They are increasingly viewed as being proactive contributors to technological development and economic growth, the transition to a new economy based on knowledge as a raw material, leading to the reorganization of knowledge production. Funds for research will still primarily come from governmental initiatives. Research is also increasingly receiving funding from private industry and other organizations. The state will therefore no longer be the only contributor to the production of new knowledge, contributors becoming a mix of many parties who are in need of absorbing knowledge from universities (Vorley & Nelles, 2008). A challenge that can arise is founded on indications that industry funding of academic research hinders access to public research (Gans & Murray, 2012). Industry-funded collaborations may be imposing access limitations, such as on the publication and the use of research results (Bruneel et al., 2010).

Public and private research institutions regularly conduct research that results in new knowledge. Academics at universities must re-think ways to develop knowledge to ensure they do not repeat themselves. Interdisciplinary research groups that include non-academic actors are one alternative to the traditional university researcher (Foss & Gibson, 2015). Scientific employees adapt through this alternative to a new social structure (Gibbons, 1994). This structure involves both collaborative and contract research that is funded by private parties. Such interdisciplinary research groups are made up of researchers from universities, private research institutes, and industries whose task is to find solutions to specific issues in society. Research groups often work on assignments given by an external client, either the state or a business. This is the opposite of the classical Mode 1 knowledge production. Gibbons defines much basic science as being the 'disciplinary structure of knowledge' and as being autonomy driven research without any institutional management and little co-operation with other knowledge producers and institutions outside the academy (Gibbons, 1998). Mode 2 knowledge production describes university scientists who are more motivated to work in an application-oriented way. This makes it easier for industry to come into contact with academia. Through heterogeneous research groups the daily lives of academics is therefore characterized by heterogeneity. This participation by academics in interdisciplinary research groups is a response and an adaptation to a new knowledge production regime (Jacob et al., 2000). Mode 2 is a working theory method that can be used to investigate the dynamics between university researchers and external partners. Universities have long been a participant in and engaged in cooperation and value creation in society. There is no basis for considering industry collaborations to be a new form of production of knowledge. However, the Mode 2 theory can be used to illustrate how collaboration between researchers and external parties is taking place and how researchers' working lives can be changed by strategic research efforts in order to expand how their research efforts are being utilized.

The Triple Helix framework has been used to describe university collaborations with industry and the state for the development of intellectual property from knowledge (Etzkowitz & Leydesdorff, 2000). The framework builds on the three actors and the intertwining of their axes through cooperation and research policy within a national system of economic development. The Triple Helix model is useful in developing an understanding of how higher level processes within the third mission are performed, in this context meaning research policy decisions. Collaboration between universities, the state, and business, will manifest at a lower level among researchers in the theory of the entrepreneurial university and entrepreneurial academics (Etzkowitz, 2001). Figure 3 explains the Triple Helix framework and its conceptual details. The model is based on the cooperation of three parties: the government exercising legislative control, universities performing education and production of new knowledge and entrepreneurs and

businesses generating economic growth based on new innovations.

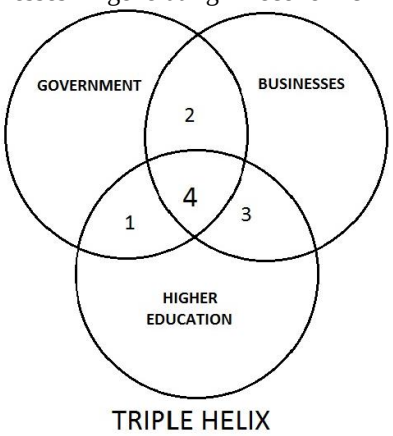

Figure 3: The triple helix model explaining the intertwined relationship between academia-industry-government (Leydesdorff and Etzkowitz, 1996).

A knowledge-based economy develops when government, universities, and businesses cooperate, which in turn requires attention to be given to intellectual property. This is referred to as the second academic revolution, the first revolution being the addition of research to the primary task of universities (Etzkowitz, 2001). The second revolution adds the role of converting knowledge into economic development, which is represented by the entrepreneurial university. This third mission of core activity, however, creates a time-limited knowledge monopoly situation. This is a situation that needs to be governed if the first core missions of teaching and research are still to be able to be performed. The recent dynamics in society within intellectual property production and development also need to be explained, guided by the notion of the mentioned Mode 2 knowledge production phase (Gibbons, 1994). The main proposition of the Mode 2 theory is the emergence of a knowledge production system that is 'socially distributed.' Knowledge production was primarily located in scientific institutions such as universities, government institutes, and industrial research labs, and structured by scientific disciplines. Its new locations, practices, and principles are, however, much more heterogeneous.

Mode 2 knowledge is generated in a context of utilization and is also transdisciplinary, mobilising a range of theoretical perspectives and practical methodologies to solve problems. Knowledge is also produced in a wide range of organizations, resulting in a very heterogeneous practice. All the Mode 2 characteristics referred to suggest that intellectual property management is important if a more controlled sharing of knowledge is to be achieved. The Triple Helix framework and the Mode 2 phase both explain the complex and dynamic changes that a university is exposed to in the transformation from a 1st and 2nd mission university into a 3rd and possibly, as suggested in this thesis, a 4th mission generation university. In this transformation, intellectual property management is essential in providing balanced knowledge distribution and sharing for all parties.

5.3 Universities as multitask organizations

The new agenda that has emerged over the last 30 years in the distribution of knowledge has manifested in the demand for technological and economic development, often through intellectual property as a central tool (Martin & Etzkowitz, 2000). This type of knowledge distribution takes on a number of points from Merton's early description of the social organization of science. It also emphasizes that science is increasingly influenced by political, social and economic interests and that this causes a number of changes in scientific practice. Developing relevant knowledge in today's working life and society is becoming increasingly important. Globalization brings with it a growing need for knowledge sharing, economic innovation in such a society relying as much on innovation as on the management of intellectual property (Etzkowitz & Leydesdorff, 2000). Politicians in the knowledge economy form institutions such as a university to participate in and contribute to both regional and global community development (Slaughter et al., 2004). Such management of research and knowledge implies challenges to the autonomy of academia and the long-term goal of research (Slaughter and Leslie, 1997). The awareness of the power of intellectual property and how it regulates access to and the sharing of knowledge becomes critical.

5.3.1 The 1st and 2nd Mission university and intellectual property

Most historians agree that the formal and legal IPR system began with the introduction of patent legislation and regulation in 1474 in the Italian city of Venice (Hardin, 1968; Cook-Deegan & Heaney, 2010). Universities in Europe and the United States were for many centuries not involved in bringing new inventions to society through patents (Machlup & Penrose, 1950). Industry and academia operated in vastly different spheres. Industry produced goods, tools, and machines while universities mainly provided teaching and carried out small scale research. They were not truly institutional developers of inventions. Innovation and technology improvements were published in the scientific literature and related publications, but not patented because scientists were concerned about bringing their reputation into the light of day and avoiding exclusive protection which would decrease their recognition.

The first university in Europe was founded in Bologna in 1088 (Hermans and Nelissen, 2005). Universities for centuries after this educating the elite in society, its role of manager and disseminator of knowledge remaining unchanged over a long period of time. Science was reserved for teaching and the educational system. The teaching institutions was developed to educate the upper societal class being referred to as the first mission of the universities. Modern science-based research emerged during the scientific revolution of 1550 - 1750 (Henry, 2008). It is not entirely clear how to characterize its idea and normative basis. Much suggests that the establishment of science academies, especially in England, France, and Italy, marks a milestone. This starting point does not undermine the importance of individual contributions from such as Galileo Galilei and Isaac Newton but emphasizes that scientific activities take place in a socially organized and systematic framework. The first pieces of the modern intellectual property legal system started to

develop as the need to structure and regulate scientific contribution and to stimulate further development became necessary. The Humboldtian universities emerged a few centuries after Italian patent legislation was introduced in Venice, but was still an educational institution reserved for the select few. However, it sparked the second task of universities, research, being recognized as a key activity within most universities as the importance of exploring beyond teaching came to be viewed as beneficial (Denning, 1997).

The integration of the university with society has been limited to these core activities. Some universities contributed to questions from and discussions with industry and politicians on how to contribute through these core academic elements. The university placed emphasis on the relationship between education, and the research carried out by scientific staff, the basics of this activity being the idea of academic freedom and the ideal of knowledge existing for the sake of knowledge. Research, therefore, was a second key activity of the university, so forming the two core missions carried out on behalf of society. Patents have in recent times been a new core activity of universities, in addition to the primary teaching and research missions. Patent activity in itself is not a core activity but indirectly as a consequence of engaging in entrepreneurial and commercial collaborations initiated by the university or together with external parties, such as relevant industry partners.

5.3.2 **The entrepreneurial university – it's 3rd mission**

There is no clear basis for talking about a 'new' form of production of knowledge or a new shape of intellectual property (Martin & Etzkowitz, 2000). The new aspect is how it is used and in which relations. The university has long been a participant in societal contribution and in creating economic value to the society. Collaboration and interaction between universities and industry are therefore not new, it has existed for centuries (Jacob et al., 2000; Etzkowitz, 2001). Merton refers to cooperation between European business and universities as early as the 17th century (Merton, 1938).

The university contributes to economic development in society through the development of new knowledge and technology, often through inventions protected by intellectual property rights such as patents. The transfer of technology to society was previously the transferral to industry. The core of the university's new role therefore is it's establishment as an independent player and supplier of intellectual property in a value creation system. Academics who can 'capitalize on knowledge' can change the university and make it a symbol of a more entrepreneurial organization. 'Capitalization of knowledge' indicates the ability of researchers to see the economic utilization potential of academic activities and that the development of academic entrepreneurship is a desired development from a research policy perspective (Jacob, 2003). The principle of research as a public good does not change within an entrepreneurial university. People educated at universities can promote further economic development in society, the knowledge laid down by universities in their students legitimising the university as an educational institution. The knowledge that comes from research is still divided between different groups in society,

the university contributing to economic development through the creation of spin-off companies and patent development. Such a development is part of the university's third mission and is a focus area in research policy. Etzkowitz and Leydesdorff claim that 'The increased salience of knowledge and research to economic development has opened up a third mission: the role of the university in economic development. A 'second academic revolution' seems underway since World War II, but more visibly since the end of the Cold War' (Etzkowitz & Leydesdorff, 2000).

The university brings together companies and industry through its research, the university's role is strengthened, not impaired, through entrepreneurial development. Pieces of intellectual property are created in this and so are intellectual property rights. These rights need to be managed if they are to be controlled and shared by multiple purposes. Access to IPRs is crucial to exploration that can improve societal value creation. This is particularly true when the role of the university develops beyond the three missions and is integrated with all societal activities of knowledge production on a global scale.

5.3.3 **The 4th Mission university – a global knowledge distribution organization**

The way knowledge is controlled and distributed by universities and other academic institutions to the global society through intellectual property management is changing. Knowledge is being increasingly developed in a framework where a number of partners are involved, often on a global scale, entrepreneurship being one framework in which universities share knowledge based on intellectual property control. Utilization of knowledge becomes more critical to all three missions of a university when outreach is global and is integrated into all levels of knowledge building in society. This leads to the development of a possible 4th mission. Scott talks about all policies, economics and educational development issues being driven globally from universities by this 4th mission. Scott claims that as an emerging mission of the university, internationalization, or services to several nations, involves the multiple missions of teaching, research, and public service or nationalization' (Scott, 2006). Trencher et al. explore the university beyond the 3rd mission, how partnerships can facilitate a more sustainable transformation, how they are different from the 3rd mission and from the economic focus and conventional technology transfer practices (Trencher et al., 2013). Universities now have a further (4th) mission with which to engage in co-creating the social, technical and environmental transformations utilised in the pursuit of sustainable development. This needs critical control of all levels of university engagement by intellectual property management. As Petrusson et al. describe; utilization of research needs intellectual property management that is clear and precise, to create a non-fogginess framework for university management and for researchers to work within (Petrusson, 2016). An academic institution can promote utilisation in four ways, or logics, according to Petrusson and as shown in figure 4. For all four logics, a prerequisite is that the knowledge assets can be identified, described and are possible to transfer. Intellectual property rights, such as patents and software copyright, are needed if the academic institution wants to be in control. The four logics in this model are:

i) Publicly available. No IP is needed, aside from publication under Open Access license such as Creative Commons. The academic institution has no control.

ii) Licensing to specific stakeholders. Technology Transfer Offices typically facilitate this. IP licenses are important.

iii) Innovation processes. The academic institution participates in innovation processes, such as Open Innovation. IP is licensed to all participants in the innovation process.

iv) Contractual networks and knowledge platforms. The academic institution takes part in creating portfolios of IP and knowledge, that is available to all through, e.g., standards. Licensing is usually performed in technology consortia.

This 4 logic model is discussed in detail in the book 'Research and utilization,' as an intellectual asset management framework for managing intellectual assets (Petrusson, 2016).

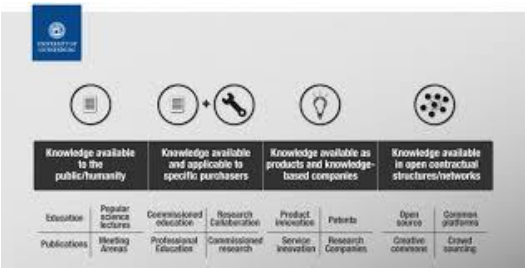

Figure 4: The 4 logics of utilization as a starting point for addressing the challenges of intellectual property management in the university. The model illustrates various states in which a university is developing, utilizing, offering and managing knowledge (Petrusson, 2016).

The 4 logics of utilization as developed by Petrusson et al. and shown in figure 4 is a model for a university's or a public research organization's knowledge management and implementation. The model presents how the university provides different control levels of its knowledge assets. The governance of knowledge must specify how the university is ensuring that the knowledge developed can be taken advantage of by the surrounding community. One optimal way to do this is through intellectual property claims, which are managed and controlled in accordance with the university strategy. How research results can bring the greatest benefit to society is, as already stated, difficult and influenced by a number of factors. This thesis aims to explore this further, the subparts suggesting different mechanisms for improving university knowledge distribution and appurtenant intellectual property management beyond the 3rd mission and into a 4th mission.

5.4 The relevance of research background

It is important to explore mechanisms of management and control of university intellectual property assets in this dynamic landscape of exchanging and utilizing university knowledge. Mechanisms could be patent management through license agreements with industry and spin-off partners or the sharing of research results through research agreements with collaborating partners. This relates to the issues stated by Petrusson of how to claim and manage research results and knowledge in university-industry interactions, with the aim of providing controlled sharing for the benefit of society as a whole.

The research studies performed during this thesis are presented in the publications listed at the end of this cover paper. They explore how universities manage intellectual property in the production of knowledge, in which a number of parties have interests in the knowledge. Management of intellectual property and access to research in university-industry collaborations shape the distribution of knowledge and the collaborating parties' access to the research before, during and after the collaboration. Such collaborations, particularly those involving research results, are often partly or fully funded by public institutions and agencies (Perkmann & Walsh, 2007; Siegel et al., 2003; Gulbrandsen & Smeby, 2005). It, therefore, becomes critical that the public, as a provider of knowledge developed with the intention of being widely shared, also provides mechanisms that allow optimal sharing and balanced access. Much of the literature supports an intellectual property system where patents, trademarks, designs are IPR's necessary for incentivizing innovation development (Teece, 1998). There are however critical voices to the intellectual property institution and patents in particular as to a socio-economic contribution. There are claims that there is "no empirical evidence that they serve to increase innovation and productivity" (Boldrin and Levine, 2013). There have also been critics to the social costs and benefits of intellectual property in terms of all the efforts and resources that are being used to run and administers the intellectual property system (Biagioli, 2018). Still, the amount of evidence that intellectual property and patents in particular contributes to drive innovations forward and create socio-economic benefits are in a plurality (Jaffe et al., 2002). This thesis is not aiming to prove the benefits or the downsides of a defined intellectual property system such as the patent regime as we see it today. The thesis rather aims to discuss that when there are universities engaging in commercial activities and other partnership activities where intellectual properties are created and exchanged the need to managed and control these assets is critical. One of the control mechanisms in collaborative research is to contractually agree to the ownership and user rights to possible research results. This control mechanism is necessarily important to secure a commercial outcome. Rather a contractual structure of intellectual property provides the university and the other partners a mechanism to manage, control and share results according to the partners' motivations and missions for joining collaborations. The core motivation of the university in collaborations might be dissemination and thus concerned about confidentiality and publication clauses.

The sources that universities can obtain funding from might have an impact on the results. Hottenrott and Thorwarth analyzed a number of German universities and found that industry funding has a positive impact on the quality of applied research and a negative impact on the quality and quantity of publications (Hottenrott & Thorwarth, 2011). Czarnitzki et al. claimed that industry funding of research could restrict access to publications from universities (Czarnitzki et al., 2015b). There have been very few studies that have investigated how public funding impacts access to research and measures this empirically by applying customized tools. I had to develop customized tools and models to examine how the public manage intellectual property and how this is impacted by public funding because of the absent of proper tools.

6 Frame of reference

Here I present the theoretical framework for the research and discuss its relevance to my work. The thesis builds on the literature of university-industry collaborations and the management of knowledge sociology and intellectual property. The theory framework in particular relates to university science sociology, the third mission and access to research results created in collaborations with external parties. The background literature explains that management of knowledge through clear intellectual property control is essential in providing society with a better option for accessing and making use of research results. What is, however, unclear is how this should be achieved and how to adapt this to the 21st century's fast-growing knowledge economy. There seems to be a gap in explaining how to manage research results in collaboration projects. More specifically, little research has provided empirical results on how to control or manage knowledge contractually in a way that provides a framework for universities to operate within the third mission and even beyond and that allows parallel public access (Etzkowitz, 2014; Leydesdorff & Etzkowitz, 1998; Steinmo, 2015; Thursby & Thursby, 2003).

6.1 Socializing science and its relation to intellectual property

The ontological framework of the thesis rests on Merton's philosophy of socializing science. The essence of this is free and open science and democratizing access to knowledge (Merton, 1973; Gans et al., 2017). Merton's philosophy is important to any university regardless of mission focus, describing the fundamental norm for academia of being the performance of objective and free research and disseminating this freely according to academic principles of scrutiny. In this thesis, the fundamental critique is Merton's communalism norm which is challenged by universities now being exposed on many fronts in their 3rd and 4th mission activities. This no longer makes it possible to operate exclusively and freely under full openness without any intellectual property management and control.

Several of Merton's norms propose full openness and autonomy for scientists in relation to intellectual property and the dissemination of knowledge. There are universities,

situations, projects, collaborations and similar that do not have the opportunity to operate without structured intellectual property control. This was perhaps functional in the pre and immediate post-war period. The situation has changed dramatically over the last half-century. Etzkowitz has framed this as universities constantly challenging the 'academic landscape by transforming knowledge into intellectual property.' (Etzkowitz, 2001). The concept of The Triple Helix model and the third mission assigned to universities around the mid-80s has, furthermore, been heavily discussed in this respect.

Universities, industries, and others, long before Merton and his norms, mutually engaged in creating common goods. After world war two, this kind of collaboration started to be more structured and systematically performed (Leydesdorff & Etzkowitz, 1998; Etzkowitz & Leydesdorff, 2000). This systematic approach of industries and others of accessing and utilising knowledge from academic institutions emerged in the 1980s. This expanded way of accessing knowledge starting to be investigated and analyzed by academic scholars and managers. The third mission phase and the triple helix model became recognized and established scientifically and operationally as important contributions to the development of social and economic welfare and as a core role of the activities of universities, roles that are in addition to teaching and research.

This thesis therefore fundamentally builds on and challenges the literature and research studies of Robert Merton and his universalism and communalism of scientific knowledge. It equally supports and expands on Etzkowitz, Gibbons, Jacob, Petrusson, and colleagues. This theoretical basis of intellectual property management is present throughout the thesis, forming a reference point in descriptions of how pieces of intellectual property, such as the CRISPR/Cas9 patents, are managed and shared by university communities and the ethical implications of how this is managed (Egelie et al., 2018a; Egelie et al., 2016). It is also present in the studies of the RCN contract management framework (Egelie et al, 2018a and 2019-unpublished, submitted for review).

Etzkowitz and Leysdorff's explanation in the 2000s of the university's third mission and of university licensing and the third mission further supports the frame of reference that I build this thesis on. The conceptual discussions about the Triple Helix project emerged in the mid-1990s. This was a time when universities and industry were strongly urged by policymakers to work more closely together in the commercialization of new knowledge for the benefit of society. Walsh, Arora, and Cohen examine the details in their discussion of intellectual property in academic biomedical research (Walsh et al., 2003). They surveyed academic researchers in biomedical sciences to assess the effects of access to knowledge and material inputs in an intellectual property management framework (Walsh et al., 2003). They found no significant effect on industry funding. Blumenthal et al. surveyed life science companies to find evidence of publication delays and secrecy restrictions upon information from academic research (Blumenthal et al., 1996).

These studies found that researchers working on industry-sponsored projects were more likely to report industry ownership of results, pre-publication review, publication delays, and secrecy. Thursby and Thursby surveyed firms engaged in university licensing and found that 90% of university contracts include clauses on withholding research results (Thursby & Thursby, 2007). The literature, therefore, seems to present good grounds for carrying out investigations into the early stages of university-industry collaborations and the terms agreed by parties prior to knowledge development. A discussion on how intellectual property is managed is therefore needed, on the details of research collaborations and, strategically at a management level, on interaction with external parties for the utilisation of the commercialization potential of university-based knowledge for the benefit of society.

6.2 Merton's norms of science & intellectual property

Merton, in his famous essay 'A Note on Science and Technology in a Democratic Order,' described four overarching norms of a scientific ethos: universalism, communality, disinterestedness, and organized skepticism (Merton, 1942). He relates these norms to the democratizing of science. He argues that these norms, though not codified, represent commonly held values among scientists. They are represented by four main themes:

1) 'Universalism' which is the idea that scientific claims must be held to objective and 'pre-established impersonal criteria.' E.g., peer review is required before publication in the vast majority of academic journals, as a way of securing such objectivity.

2) 'Communality' which is described by Merton as the results and investigations of science belonging to the whole scientific community and scientific progress being very much dependent on an environment in which there are open communication and open sharing.

3) 'Disinterestedness,' which Merton argues, is the performance of science for the sake of science and with no other focus. There are a number of situations, he argues, in which unfocused science is influenced by power interests or self-bias. Merton argues that 'there is competition in the realm of science, a competition that is intensified by the emphasis on priority as a criterion of achievement, and under competitive conditions, there may well be generated incentives for eclipsing rivals by illicit means.'

4) 'Organized skepticism' is described as a need for science to be evaluated thoroughly and objectively by the scientific community itself. This describes why the peer review process of scientific publications is so important and why all science must embed a reproducibility property.

One of the more essential opinions of Merton was that it must be possible to observe and measure scientific activity performed by universities, through dissemination in journals, books, and educational programs. The four norms are essential to any

university operating in the open innovation and science domain. The norms of universalism and communality are perhaps more critical in the space of open society, including industry participants and entrepreneurial activities. Control that allows these two norms to be upheld and still provide knowledge distribution becomes critical in such an open innovation model of knowledge.

The critique of Merton from this thesis point of view is that Merton is leaving out on the essential of the university to be in control of its knowledge in order to provide openness and sharing of the knowledge. Management of intellectual property is essential to the control of this openness and sharing. The entirety of this thesis can be explained within the context of controlling these Mertonian norms of intellectual property from a public perspective. Universities must be able to control access to uphold the normative values of universalism and communality. The management of university inventions and intellectual property are critical in this control. Merton is, in terms of intellectual property, clear. In his explanation of his communality norm, he explicitly argues that all scientists must have access to science-based information on similar terms and in the form of intellectual property. He furthermore argues that there should be, in collaborations, joint ownership of intellectual property because the results are based on joint efforts, both long-term and short-term efforts and belongs to the community of science. The opposite of this norm is secrecy. This must be avoided, as secrecy is the opposite of communalism. The institutions of science, therefore, need to be measured through careful empirical work, to ensure this kind of structured control of empirical work and research is achieved. What seems to be missing are targeted tools for and studies of the distribution of knowledge.

This thesis, by introducing the patent landscaping studies, the CRISPR/Cas9 university-industry licensing analysis, the access models, tools and measurements of the RCN collaboration agreements, adds to the gap in the landscape of university-industry knowledge exchange. This improves the understanding of how intellectual property management is essential to the management of access to publicly funded knowledge.

Intellectual property management at universities, when collaborating with external parties and co-creating research results, is not just a matter of commercialization, but also about research access in itself and to ensure that research is open and further accessible. Merton discussed openness and research freedom, but never considered this in the light of a holistic need to manage access to research when cooperating with all stakeholders in society. Nelson and Mowery and colleagues discuss this where the implementation of legislation and policies have motivated university researchers to contribute more structurally and controlled (Nelson, 2001; Mowery, 2001). To consider the studies of Merton in the context of universities third mission, it must be adapted to the current reality of intellectual property management, knowledge access and regulation of this. An example of this is research platforms such as the CRISPR technology. For fundamental research platform like CRISPR which impacts socio-economically broadly, these platform needs regulations, e.g., contractually, to ensure further access in favor of broad dissemination and research freedom as Merton advocates. The approach assumes IP

management that most people will consider as commercial. But it is not necessarily a commercial management need that is the trigger foremost for the universities. The contractual regulations of the involved IP also must consider aspects of access beyond the commercial. If one is to maintain Merton's values, then one must do so with an IP management focus such as having a clear relationship with intellectual rights and contract law that help the universities to ensure access to research and transparency. If one is to ensure public openness, then one must maintain a contractual structure that requires good and clear contract management to secure research platforms that are of greater importance to society, such as the CRISPR platform. Cook-Deegan and Heaney have in detail shed light on several similar technologies where access through structured licensing programs by the universities involved has facilitated access to both further research and dissemination (Cook-Deegan & Heaney, 2010). This thesis core investigations pinpoints the same issues and brings on the issues of using intellectual property management to not primarily secure commercialization of research from universities, but avoid universities not being able to use research results for follow-on research or to be able to continue dissemination of such (Egelie et al., 2016).

6.3 University entrepreneurship & invention participation in society

Entrepreneurship and commercial activities with external parties, which emerged between the 1960s and 1980s as activities beyond the well-established university missions of teaching and academic research, emerged not as something new but became more systematically established as a so-called Third Mission activity (Etzkowitz, 2004). The three well-defined missions of universities have been widely studied. A fourth mission has, however, emerged that is not yet well known and explored. This fourth mission is tightly related to the third. Entrepreneurial activities co-exist in direct interplay with commercial and industrial activities in the third, the fourth mission taking into consideration the complete integration with all societal and economic activities that a university is able to perform through an expanded responsibility in society.

To understand this relatively new mission and its relation to and need for strong intellectual property management, one first needs to understand how the mission has emerged in relation to other university activities, in relation to the third mission in particular. Universities, as a part of their mission, have always contributed to societal engagement, firstly through education, then in combination with research. These activities were, in the early 1920s, also, directly and indirectly, offered commercially to external parties such as industries, research institutions, and non-governmental organizations. Universities have always made contributions, directly and indirectly, to society in general, not only in academic fields.

There are a number of ways of describing the Third Mission. The first is the 'Triple Helix' model of university-industry-government relations (Leydesdorff & Etzkowitz, 1996). Another defines the Third Mission as: 'all activities concerned with the generation, use, application and exploitation of knowledge and other university

capabilities outside academic environments' (Molas-Gallart et al., 2002). All, however, focus on the specific entrepreneurial activity of the university and the direct commercial outcome. None has focused on presenting the university as a globally integrated institution contributing to multiple sets of parties, including industries and similar. A number of other relationships, however, require a firm and systematic approach to managing intellectual property.

The fourth mission involves universities collaborating with government, industry, and society to advance sustainable development and create sustainable transformation in these industries and communities. The fourth mission is therefore not only about contributing to economic and social development through, for example, technology transfer activities. It is also about how universities collaborate with many different partners, industrial and non-industrial and of a more societal character, to contribute to complete societal development.

Universities' exchange of knowledge and through this interaction with the larger public, is based on many activities. Examples of such activities include research collaborations, contract research, student exchange, sharing of physical resources, and community events. Commercialization is also one of the knowledge exchange activities, although a somewhat different one. A critical aspect of the commercialization of university technology is university knowledge-based intellectual property being utilized to create products and services. The university often provides funds for research, directly or indirectly, through research funds/grants from public sources. Association with a university might also be important when applying for research funding and in commercialization projects. A university often claims ownership of inventions that are a result of publicly funded research. Some industry-university collaborations are, however, based on research agreements in which ownership is not well defined. In these situations, conflict situations can arise where both parties claim ownership of the invention, but for different reasons. Industry has a need to secure control of market positions and competitive advantage. Universities need to claim ownership of their intellectual property to secure control of further access to essential research results.

There is little systematic understanding of organizational practices in the management of university intellectual property. This is despite the potential importance of university-industry funded technology as a source of financial gain and economic growth for universities and firms (Siegel et al., 2004).

Legislation such as the Bayh-Dole Act in the United States has led, since the 1980s, to many universities establishing technology transfer offices to manage and protect their intellectual property (Mowery et al., 2002). This trend has been followed in Norway, the Employment Act which includes legislation of the ownership of intellectual property by academic employees, being changed in 2003. After 2003, employees not only of private organizations but also university employees are obliged to report their patentable inventions to their employer.

Inventions are managed by patents, perhaps the most recognized element of intellectual property. Any intellectual property claim by any party involved in the development of research results and appurtenant innovation, has to take into consideration how this will affect immediate access to the research and long-term access restrictions. A party that claims a research results as their intellectual property and is legally granted this claim is able to restrict access to these research results. All providers of research, whether industry or academic, therefore need to carefully manage their research results in order to consider how this control of their intellectual property claims will affect further research access.

6.3.1 Intellectual Property systems and universities

The legal description of intellectual property focuses upon legal property rights. These rights are enjoyed and can be asserted upon products of the mind. The creation of such rights is the basis of all intellectual property law, patent law for the protection of inventions, copyright law for the protection of literature, music, art, films, sound recordings, and broadcasts and industrial design and trademark law. A detailed discussion of the definitions of the terms and the legal basis of intellectual property have been discussed in chapter 5.1. This chapter will discuss how and why intellectual property and the management of this has become important for universities.

The importance of intellectual property in modern times was first recognized in the Paris Convention for the Protection of Industrial Property of 1883, as administered by the World Intellectual Property Organization (WIPO) (Halbert, 2006). WIPO is one of the 15 specialized agencies of the United Nations. The organization was created in 1967 'to encourage creative activity, to promote the protection of intellectual property throughout the world.' The convention entered into force in 1970 and was amended in 1979 (WIPO, 1979). WIPO now works with national offices in a number of international intellectual systems/arrangements covering the 191 member countries. The IP systems that WIPO administers are the Patent Cooperation Treaty for patents, the Madrid system for trademarks and the Hague system for industrial designs.

Intellectual property is essential in the many activities of an organization like a university, whose main function is the development of knowledge and people with knowledge. It is essential in education to be able to transfer knowledge from people with knowledge to others. In research, it is critical to be able to document results and be able to use this documentation for disseminating and passing this on to society for scrutiny, critical review, use, and inspiration.

Intellectual property is critical in the third mission of commercialization and entrepreneurship for the capture, documentation, and control of the knowledge that is presented and leveraged to collaboration parties (often commercial industries/companies) or used in own entrepreneurial activities. Intellectual property in the 4th mission is critical for the capture and control of every aspect of the activity to, and maybe most importantly, allow this cornerstone of knowledge and intellectual capital to be used to make society prosper and maintain sustainability.

6.3.2 **The Bayh-Dole act and innovation development**

A much-discussed event in the United States was the adoption of the Bayh-Dole Act in 1980. This was, in a strict sense, in addition to the patent act. It is, however, used in practice as a collective term for a set of instruments implemented in the period 1980-87 (Mowery & Sampat, 2004). These instruments determined that universities should be given the right to exploit inventions that arose out of US federally funded research. A uniform public patent policy was also established, standard licensing terms for patents being eventually developed that are included in public funding agreements and which are required to be reported by universities. These rules, which initially only applied to universities and non-profit organizations, have been extended to include for-profit organizations and other 'research and development agencies.'

Regulations have been drawn up in this system that specifies the rights and duties of all participating parties. There are also handbooks for university technology transfer offices, many universities today having set up such offices. The law states that the researcher is obliged to inform the university of an invention, the university then informing the source of funding. The university has two years to decide whether the right to exploitation will be used. If the university does not wish to patent the invention, the right is transferred to the source of funding. There seems to be a universal consensus that the 'Bayh-Dole Act' has contributed to the greater transfer of technology from research environments to industry than before the 1980s (Mowery & Sampat, 2004; Henderson et al., 1998).

In Norway, a Bayh-Dole type of framework was adopted through the removal in 2003 of the 'teacher exemption clause' in the Employee Inventions Act. Gulbrandsen et al. have analyzed, using different empirical sources, the relationship between industry and universities in Norway and the effect of introducing such a framework (Gulbrandsen & Slipersaeter, 2007). This change in the Norwegian legal framework made the university, not researchers, the owner of the rights of commercial exploitation of patentable inventions. Changes were at the same time made to university and university college law that specified that researchers always have the right to publish their results unless otherwise specifically agreed in cooperation and collaboration agreements. The intention of these changes to the legal framework that stipulates how universities engage in the 3rd and 4th mission is that more researchers file patents, become entrepreneurs and follow their results all the way to exploitation. A robust and detailed system for handling intellectual property rights must, however, be in place to achieve this.

Most other European countries have, like Norway, removed 'teacher exemptions' from their “legislations of innovation”. This has given the educational institutions in these countries a more formal responsibility for the utilization of research. Examples include the United Kingdom, Belgium, Denmark, France, Netherlands, and Germany. Sweden is now the only country in Europe where inventors employed at academic institutions still own their inventions. The purpose of the introduction of a Bayh-Dole like framework is more or less the same in all countries: more patents, more entrepreneurs

and more high-tech companies. Public institutions hold many patents as a result of their activities funded by public sources. The motivation for introducing Bayh-Dole in the US and Bayh-Dole like amendments in other countries was the concern that state-funded research was not being utilized optimally when materialized in patents. Few of these were licensed to industry before the legislative changes were introduced. In many research collaborations inventions in the form of patents were directly assigned to industry parties, and many times the academic party was not recognized, and research results were difficult to be reused by the academic party.

The Bayh-Dole and similar frameworks are contradictive where the results are compared with the original motives. The development of patent portfolios today at US universities looks very impressive. Mowery and colleagues in the paper 'The Bayh-Dole Act of 1980 and university-industry technology transfer: a model for other OECD governments?' were skeptical of this development (Mowery & Sampat, 2004). They believe there was a long history of commercialization before the 1980 act came into force and that this legislation has not resulted in a clear change. Mowery et al. claim that patents are not of such great importance in commercialization and that other elements play a significant role, elements such as the patent law itself, the support structure and venture capital, particularly in emerging technologies such as biotechnology and ICT.

It is common to claim in the debate on the usefulness of public engagement in intellectual property development in general and patent protection of research in particular, that there are 'too many' patents or that patents are 'too strong' or both. Or, alternatively, the even more skeptical claim that patents hinder and undermine research and knowledge development. The net result of this is, according to the argument, that the patent system is decreasing the rate of development. The focus on intellectual property and patents in public knowledge organizations slows rather than promotes innovation by entangling the university as a party with a commercial entity in a 'thicket' of licensing negotiations and infringement litigation (Shapiro, 2000; Lemley and Shapiro, 2007). There are argued that there is a danger that patents are causing a situation in which no one is really able to utilize knowledge and innovation, the minefield of intellectual property rights blocking every attempt to expand existing innovations. A theoretical publication that has often been cited in this skepticism is the thesis of the anti-common put forth in 1998 by Michael Heller and Rebecca Eisenberg (Heller & Eisenberg, 1998). They claim that over-patenting of research in the field of biotechnology is hindering the research and development of new innovations. The tragedy of the anti-commons arises when there are multiple gatekeepers, each of whom must grant permission before a resource can be used. Such excessive property rights are likely to lead to the resource being underused and, in the case of patents, the stifling of innovation (Shapiro, 2000). Heller and Eisenberg argue, through the theory, that rights ownership that is divided across numerous parties or a situation in which it is impossible to point to a clear single ownership situation, often leads to inefficient underuse because potential users of the intellectual property cannot gain legal access.

Heller and Eisenberg exemplify the anti-commons theory by biomedical research, an area in which many companies hold different patents that protect similar and overlapping research tools needed to develop new drugs. Heller and Eisenberg discuss the complementary problem in the context of biotechnology patents, drawing an elegant comparison with G. Hardin's classic tragedy of the commons published in 1968 (Hardin, 1968). Hardin's debate refers to the fact that a resource can be overused if it is not protected by property rights. Standard examples include fishing grounds and clean water.

Heller and Eisenberg point out that a very different problem arises with multiple blocking patents. They defined the anti-commons as a situation in which 'multiple owners are each endowed with the right to exclude others from a scarce resource, and no one has an effective privilege of use' (Heller, 1998). Although no empirical evidence was cited, the theory quickly gained traction (Biddle, 2012). A few have, however, expressed skepticism that thickets would persist. Walsh et al. claim that access to patents does not impose any major hurdles upon research within biomedicine (Walsh et al., 2007). Biddle questions the validity of the Walsh et al. study and whether it does in fact not support the anti-common theory. The overall argument of both Biddle and Walsh et al., which I indirectly and anecdotally interpret, is that the theoretical construct of the anti-commons world is too simplistic to describe the world of intellectual property in biotechnology and biomedicine.

This further motivated me to investigate whether this correctly describes the activity of university patenting in biotechnology, through finding theory proving cases or through developing models that can be used to empirically test whether this correlates with access to research results in collaborative projects and, if so, are these patents funded by industry or public parties.

6.3.3 **Patents and intellectual property as a strategic tool for universities**

The most focused piece of intellectual property for universities and public research organizations (PROs) and in which natural science is the main activity, is patents. Patents protect and control technical inventions and are the most visual tangible of any science-based academic institution that utilises knowledge as a source of creating innovative activities in collaborations with industries and other commercial partners. A patent for an invention is granted to the inventor by the government through the various public patent and trademark offices (PTO's). The inventor obtains an exclusive period of making, using or selling the invention. In exchange, the invention is made public to society for learning from the invention and building further on it. A granted patent, like any other form of property or business asset, can be bought, assigned or licensed.

Patents are territorial rights. This means that it is only valid in the country or region where it is filed and prosecuted. It provides an exclusive right for a time-limited period to the assignee (owner) to use and/or sell an invented product or process and grants the

use stipulated in patent protection. Patents are the main form of intellectual property rights for new knowledge and are complemented by copyrights and trademarks.

All major economies in the world use the patent system to support their development of new products, services, and commercial markets. The incentives of the patent system are, however, somewhat two-sided. They both stimulate the development of and access to new knowledge by introducing exclusive mechanisms that could be used by industries to create market positions in the protection of new knowledge. A patent could also, at the same time, impose restrictions on access to knowledge and limit its flow. What is important to note is the balance provided by the patent system between incentives and stimulation for innovations and allowing for and requiring the flow and dissemination of knowledge.

The system has to try to rectify this dualism, some embedded requirements for allowing the free flow of knowledge. The most significant requirement is that all patented inventions must be made public at a certain point in time (maximum 18 months after filing). Furthermore, anyone wanting to use the invention for purely non-commercial purposes is allowed to do so providing this does not lead to any direct or indirect profit making. This is, however, somewhat unclear as follow-on inventions could be dependent on an already protected invention. The exclusivity period lasts for maximum of 20 years (up to 25 years for some pharmaceutical compounds). Patent protection expires after this. It also expires at an earlier stage if different fees are not paid or it is invalidated by other parties than the owner. Many patent owners also abandon their patents before the full term is reached for technological, commercial, financial or strategic reasons. Anyone can then use the invention for commercial purposes. The idea behind this is that the monopoly and exclusivity period should, at a certain point in time, cease so that others can expand on the original invention and build on and advance new solutions to progress innovation and science.

There are other restrictions that limit what can be patented. The European Patent Organization has made it explicitly clear in European patent law that only a specific application of genetic code can be patented, providing the other requirements such as novelty, inventive step and industrial applicability are met. One cannot, therefore, expect to be granted a patent for a generic genetic code. An application for a specific genetic code must be specified, such as a therapy based on the code. The purpose is to allow anyone to screen for new applications to be invented and not use the patent system to hinder new inventive activity (Akers, 1999). The US patent system has different terms for genetic code patenting, allowing much broader protection. Over the last few years, the US patent system has expanded its broadness and now only allows patents for lab-developed genetic codes and only for specific applications (Graff, 2013; Sarnoff, 2010; Jaffe, 2000). The patent system, therefore, introduces, in essence, a paradox between providing incentives and enabling a free flow of knowledge. The goal should be a balance.

Intellectual property rights in the form of patents have, as an appropriability mechanism, been critical in the third mission activity of universities. It has not always been the default

that the university acquires ownership of the patentable inventions employees produce. Bayh-Dole, as mentioned, introduced some limitations and restrictions on ownership of publicly funded research results. A number of other countries, including Norway, have adapted similar legislation that assigns patentable inventions to the university whenever these inventions are a consequence of public funding (Gulbrandsen & Smeby, 2005).

There have, as mentioned earlier, been arguments around patents within biotechnology whether they impose hurdles in accessing vital scientific research from academia. Heller & Eisenberg (Heller & Eisenberg, 1998) and Walsh, Arora & Cohen (Walsh et al., 2003) also introduced the phenomenon of the anti-commons, patent hold-up, and royal stacking ideas. These are theories that propose that obstacles are a consequence of university patenting. Shapiro and Lemley even claim that university patenting is creating a patent thicket that will decrease the ability of universities to perform long-term research (Shapiro, 2000; Lemley & Shapiro, 2006).

The reality proposed by a number of journals is the opposite - that this phenomenon is not often played out in reality. Epstein et al. for example present the opinion that Heller and Eisenberg have overstated the case against patent protection at both the theoretical and empirical levels (Epstein & Kuhlik, 2004). Universities also have demonstrated, through good management of intellectual property, that it is possible to establish a balance between access and control for essential research tools. Cook-Deegan and Heaney discuss and analyze the importance of accessing research tools in life science through good licensing strategies that facilitate broad access (Cook-Deegan & Heaney, 2010).

The maintenance of access to research tools by the scientific community and broader commercial innovation activities, in particular underscore the importance of these university licensing strategies in their discussions. A strategic dilemma that Cook-Deegan calls 'rational forbearance' is the control of and access to disruptive research tools and how access is being provided and managed. How could patent holders actively restrict access for research use, as they are already widely used in academic laboratories? Scientists frequently share equipment they develop themselves or borrow from fellow colleagues without taking into consideration any legal boundaries. This 'practice by scientists may be supported by commitments to 'open science,' but it may also be due to the pragmatic awareness that no company, let alone university, would like to go down in history as having sued every other university for patent infringement' (Egelie et al., 2016).

6.3.3.1 Biotechnology, CRISPR and intellectual property

Another important intellectual property decision other than the Bayh-Dole Act was decided in US Supreme court in 1980. This decision has had huge implications on how intellectual property in the form of a patent in the US can be used, in particular within the life science area. The decision was the U.S. Supreme Court ruling in Diamond v. Chakrabarty that man-made, living organisms could be patented (Robinson and Medlock, 2005). This was a disruptive change for intellectual property within biotechnology with worldwide implications.

The case was as follows: Ananda Chakrabarty, a research scientist at General Electric, applied for a patent for a Pseudomonas bacterium that had been bioengineered to carry multiple plasmids. These plasmids had the ability to influence microbial digestion of complex mixtures of hydrocarbons, potentially offering a biotechnological solution to oil spill clean-up. The US Patent Office rejected Chakrabarty's patent application, arguing that living organisms could not be patented. Chakrabarty appealed the USPTO's decision to the courts, the case ultimately being accepted by the U.S. Supreme Court. The US Supreme Court urged, in the Chakrabarty decision, a broad interpretation of patent eligibility with it's by now famous ruling that 'anything under the sun that is made by man,' including living organisms, can be patented. Since then biotechnology and intellectual property have been essential in the development of a huge biotech industry both in the US, in Europe and in Asia. Knowledge from universities, in particular in the form of intellectual property, being critical to the development of the biotech industry (Owen-Smith & Powell, 2003).

The Diamond v. Chakrabarty ruling has, by far, set out the terms of what is accepted as patentable within the biotech sector over the last 30 years. Around the year of 2010 something began to change. A number of non-governmental organizations (NGOs) and other public interest organizations began to oppose how and what could be monopolized through the patent system to one or just a few parties. After massive political lobbying in the last 6-7 years, major U.S. Supreme Court decisions have investigated the definition of Diamond v. Chakrabarty and what should be allowed as patent-eligible subject matter.

In Mayo Collaborative Serv. v. Prometheus Labs. ('Mayo') from 2012, the U.S. Supreme Court decided that the correlation between drug metabolite levels and the toxicity of a drug is a law of nature that should not be approved for patent protection. Furthermore, in the Association for Molecular Pathology v. Myriad Genetics ('Myriad') case from 2013, the U.S. Supreme Court passed a decision that a naturally occurring DNA segment is a product of nature even when isolated from an organism's genome and should also not be allowed to be patented.

The picture was clear in the US prior to these decisions, the precedence of Diamond v. Chakrabarty determining the boundaries of patent-eligible subject matter. However now, after the US Supreme Court had adopted different views and changed the direction of patent-eligible subject matter, a somewhat uncertain landscape of what genetic material is patentable has been created. How the USPTO and the courts interpret the Mayo, and Myriad decisions will decide whether the uncertainty around patentable subject matter for genetic material continues or whether they will create new guidelines and decisions in the lower courts that will lead to greater predictability.

For example, genetic material patents of pharmaceutical companies may be invalidated. Universities delivering intellectual property to these will also have to relate to this

situation one way or another. Management of intellectual property will not become less important after this and pharmaceutical companies require that universities delivering knowledge are able to control and document control of their IPR. In Europe, development has however been the opposite, allowing cases that would not pass in the US.

In this thesis I have case studied the CRISPR/Cas9 disruptive biotechnology genome editing tool, which represents a major breakthrough in biotechnology that enables scientists to make very specific changes to any species DNA. Economically it is a 'research tool.' Cas9 is the CRISPR enzyme associated with nuclease 9. Referring to such a specific molecular protein in a thesis about intellectual property and access might seem unusual. There is, however, a purpose behind this. The CRISPR/Cas9 construct exemplifies some of the hurdles, changes, and access to knowledge opportunities that exist within the university sector and its third mission activities.

CRISPR/Cas9 is perhaps one of the most promising biotechnology tools of this century. The genomic construct has been developed by a number of researchers from a number of academic institutions. It significantly impacts the way researchers perform genomic manipulation. It is therefore important to investigate how this tool is shared and accessed, both by science and commerce. CRISPR is a molecular tool that can be programmed to target many potential matching DNA sequences in the genome of, ultimately, all species. The purpose is to introduce changes at that site. This has led to an explosion in the number of potential applications of genome editing.

Early developers and inventors of the technology were from a number of academic institutions, the University of California, the Broad Institute of the Massachusetts Institute of Technology (MIT) and Harvard University. All are fighting for the U.S. patent rights to CRISPR technology. In June 2012, J. Doudna of UC and E. Charpentier and colleagues demonstrated in vitro that a system comprising of a Cas9 DNA endonuclease could be programmed using a single chimeric RNA molecule to cleave specific DNA sites (Jinek et al., 2012). A few months later, in January 2013, F. Zhang of the Broad Institute at MIT reported genome editing in mammalian cells using CRISPR/Cas9 (Cong et al., 2013). The research underlying both of these seminal publications was supported and funded by the U.S. National Institutes of Health (Bar-Shalom & Cook-Deegan). Ther results of the research were therefore subject to the terms of the Bayh-Dole Act.

CRISPR science has, from the outset, been closely connected with commercial considerations. UC filed its provisional patent application in May 2012, one month before publication of the research findings (Doudna et al., 2014). Some of UC's initial claims swept very broadly, encompassing any DNA targeting RNA containing a segment that is complementary to the target DNA and a segment that interacts with a 'site-directed modifying polypeptide.' UC subsequently restricted its claims to a type II CRISPR-Cas9 system. UC, however, continues to claim this system in any species as

well as in vitro. The Broad Institute began filing patent applications in December 2012 (Zhang, 2014). Broad paid for an expedited examination, the result being that it began issuing patents in April 2014. The corresponding Broad patent is based on the alteration of eukaryotic cell DNA by using type II CRISPR-Cas9 systems.

UC asked after the Broad patents began to be issued, for a legal proceeding known as an interference. UC argued that because of the subject matter of its application, which had not yet been granted, overlapped that of the Broad patents, that the U.S. Patent and Trademark Office (USPTO) must declare who was the 'first to invent.' In February 2017, the USPTO ruled that the overlap did not exist. USPTO held that the Broad team's success in eukaryotes was not scientifically 'obvious' in the light of UC's demonstration of success in vitro. UC appealed this decision and currently, in November 2018, the case is awaiting a new ruling from the USPTO.

There are a number of other important tools besides CRISPR/Cas9 that have been developed by universities and that to some extent also have had an impact on the development of the biotech industry and its commercial impact in society. The implications of any owner of the intellectual property of such technology holding back or restricting utilization of the technology could be fatal to the further development of the technology. Universities that have been assigned responsibility for the development of these technologies, therefore, face the challenge of taking on the immensely important role of knowledge gatekeeper. How to manage intellectual property in this situation is critical, this thesis providing some models, tools, and clarifications in this landscape.

6.3.4 **Commercialization of university knowledge**

Universities are under pressure to deliver greater research value, industries are facing competition in the search for the next business-sustaining product and governments want their economies to grow. In this landscape, university-industry collaborations in science and technology-based sectors have long been recognized as an important source of economic growth (Cohen et al., 2002). Universities today should receive the majority of the credit for the innovation ecosystem, at least those with a focus on innovation. They are, through generating inventions, patents and licensing agreements and creating new companies, driving the knowledge society forward towards a faster-growing economy, by introducing new products and services much faster than previously.

There are many funding sources for driving this innovation ecosystem. The public contributes through governmental funding research and innovation schemes, through both contract and collaborative research with companies and through consulting. Private industry contributes either by funding contract research, by directly sponsoring research programs or by funding academic positions. Venture capital is funding venture creation. The essential aspect of this is the management and control of intellectual property.

Geuna et al. found that university licensing is not profitable for most universities and so questions the impact of increased institutional ownership of intellectual property rights,

indicating that this might affect other important activities (Geuna and Nesta, 2006). On the other hand, work has been published that clearly indicates a positive effect of university licensing and engagement in intellectual property management for the purposes of commercialization (Colaianni and Cook-Deegan, 2009).

I provide in-depth analysis in this thesis of the terms which partners involved in a project agree to, terms relating to the ownership of research results, the distribution of rights to all commercial uses of intellectual property and provisions regarding the dissemination and publication of project results. I explore how, in general, commercial access to university-based research results is being affected by commercial interests. Access is a term of to what degree parties can utilize research results, commercially, for further research or in education.

6.3.5 Ethical considerations of intellectual property managed access to knowledge

Paper no.3 of this thesis presents a conceptual discussion of major ethical concerns about the university and its third and fourth missions (Egelie et al., 2018b). These considerations relate to the intellectual property control of knowledge and research results. This is an issue which is heavily debated in the literature. Universities that collaborate with industry and perform innovation activities for the benefit of the economy and society have a more evident and critical ethical obligation to ensure access to intellectual property based on knowledge from the universities.

In the discussion of thesis paper no.3 Stanford's concept for licensing, which is known as the 'ethical commercialization' of intellectual property created by the university, is compared with the initial CRISPR licensing schemes. Stanford has been a pioneer within university-industry collaboration and licensing, and their model has been expanded by leading academic institutions such as the Broad Institute and UC Berkeley. The model introduces free-of-charge use of patented inventions in academic research, facilitated through material transfer agreements (MTAs) via the Addgene non-profit clearinghouse (Fitzmaurice, 2017). This is tightly linked to my investigations of the CRISPR invention, a number of these US institutions being involved in its development. It has therefore been useful to investigate whether the licensing model Stanford used for some of their more critical research tool inventions also complies with some of the ethical norms of science.

6.3.6 Access to public research & knowledge

The 'entrepreneurial university' model presented both by Etzkowitz (Etzkowitz, 2003) and Leydesdorff (Etzkowitz and Leydesdorff, 2000) proposes a change in how universities collaborate with third parties and industry in particular. Researchers in universities are, in this model, incentivized to perform innovation activities through patenting collaborations with industry or by collaborating with technology transfer offices in academic entrepreneurship. Such a model could improve the transfer of technology and

knowledge and could also lead to more funding of research through larger sponsored research agreements with industry. There are concerns that the 'entrepreneurial university' model could impact the quality of research at such universities (Czarnitzki et al., 2015b). There is evidence of research results not being published, research results not being used or being withheld from the public because of an engagement with industry parties (Walsh et al., 2003). The third mission of universities means interactions with the outside non-academic world, industry, public authorities, and society. The third mission of universities strongly relates to its first (Norwegian Ministry of Education and Research)second (research) activities. It has, however, its own dimension. It tells something about university capabilities (knowledge capabilities and physical facilities) being integrated into the economy and into society. The third mission is therefore much more than merely commercialization activities. It is essential that universities have access to knowledge for innovation to proceed and knowledge to advance. The serious hindering of this will affect the way universities and academic science is able to deliver knowledge in the future.

6.3.6.1 University contract management

Prior research has frequently shown that the innovation performance of firms benefits from collaboration with universities and research institutions (Howells et al., 2012; Steinmo, 2015). These collaborations may suffer from tensions related to institutional logics, firms often focussing on innovation outcomes. University researchers, on the contrary, primarily driven toward long-term outcomes and their publication reputations in the international arena (Steinmo, 2015; Becher & Trowler, 2001), i.e. toward disclosure and openness of research results. Researchers focus on their autonomy, research freedom and curiosity-driven research. Firms will try to regulate this freedom and drive researchers' actions in the directions of the firms' needs (Al-Tabbaa & Ankrah, 2015; Perkmann et al., 2011).

Czarnitzki et al. conclude that there are no similar studies on contract management that deal with how public funding affects secrecy and access to research (Czarnitzki et al., 2015a). They found that scientists who receive external funding are more likely to be denied access to research. Perkmann et al. claim that 'Records held by universities on industry contracts would represent an ideal source of information but are not readily available because they are often considered commercially sensitive by university administrators, in addition to which such records are likely to underestimate consulting activities. Moreover, they are difficult to standardize across large numbers of universities. Nevertheless, studies using record-based information for single universities or a small number of institutions can offer powerful insights with a high level of granularity' (Perkmann et al., 2013).

The main thesis question is 'How do research based organizations like public universities manage knowledge and access to research results and intellectual property when collaborating with industry?' For access to biotechnology research tools universities play an important role in foreseeing broad access to these technologies as

they are vital in the bringing of new technologies to the public. Studies of contractual terms in collaborations projects between universities and industries and how this influence access to the results are hard to come by. I have thus provided both empirical material and models to overcome this gap of studies of contractual terms. This is presented in paper no. 3 and 4 of this thesis. In these papers, I focus on the managerial aspects of the contractual terms in the agreements and not on the agreement as a legal document. The agreements contain management details on how the parties expect one another to act, who owns and controls the research results, who can access results and the background needed for utilization, and how the parties should resolve any conflicts. The importance of investigating this is related to university engagement in collaborative work and their capabilities in accessing research results during and after collaborations.

6.4 Relevance of literature for research

The thesis theoretical foundation builds on Merton, Etzkowitz and Gibbons theories and models of access to and utilization and development of knowledge. The challenge presented by these models, the Gibbons Mode 2 theory model, the Etzkowitz Triple Helix model and Merton's social science norms, is that they do not provide specific attention to the challenges that arise when universities engage in entrepreneurship and commercial activities through a model that integrates the global needs of the general population in terms of life quality, impact and economic prosperity. All these models focus either on the development of knowledge in the isolated academic setting in which full scientist autonomy is required or on the integration of entrepreneurship with knowledge development to create innovative products and services. None of the models consider a complete integration with society on a global scale where access to knowledge and management of intellectual property becomes critical.

This thesis relates, in particular, to the management and control of intellectual property rights to overcome some of the gaps in the discussed prior art models of knowledge management and entrepreneurship. The issue of more highly focused intellectual property management must be given a more central role in the discussion and in the use of models, as there seem to be vital challenges for researchers-entrepreneurs as they move from purely academic to a more integrated industrial focus, as suggested in my discussion of the 4th Mission university in figure 3 and 13. This is what this thesis is about, how universities can manage intellectual property more broadly to not only pursue the Mode 2 motivations of Gibbons of pursuing commercial value but also to preserve the societal value through the university as a gatekeeper of public knowledge, that also provides control over this knowledge by using the opportunities that lie within intellectual property management.

I have used the biotechnology sector as the research context because this technology area stands at the confluence of multiple technologies and depends substantially on collaborative work between the public and the private sectors. It exemplifies the tension and challenges in the collaborative interface between these parties when knowledge is

created in the third mission agenda and the triple helix interface, government-industry-university. The biotech sector has an enormous public and societal impact. This includes decision making from not only the parties themselves, academia and industry, but also politicians, federal governments, funding agencies, non-governmental organizations, and public interest organizations. Intellectual property management and control of potentially highly valuable assets for the society is an issue of importance that cannot be ignored.

A fairly widely used definition of biotechnology is the OECD's: 'the application of science and technology to living organisms, as well parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods, and services' (OECD, 2005). The definition covers all variants of biotechnology. An even broader scoped definition is 'Life Sciences,' which covers a wider range of biotechnology-related tools, methods, and applications. The technology in both life science and biotechnology is developing quickly. The payback time for investments is, at the same time, longer. It is evident that entities such as universities, through developing knowledge and IP to protect this knowledge, provide long-term control positions and solid management of the intellectual property to play its role in the 4th mission.

7 Methodology and design of research

The methodology applied is designed to fit the various data sources analysed. The main research question 'How is access to knowledge-based research results managed by universities in relation to intellectual property?' is interdisciplinary, technological and scientific in its nature. The research, therefore, required a mixed methodological approach. To be able to explore this question I found it necessary to investigate empirically and statistically different aspects of core technology cases such as CRISPR/Cas9, to exemplify access considerations to research tools. In this interdisciplinary research I also investigated the concept of access to knowledge in terms of being able to develop tools that are responsible for measuring the quality of intellectual property management from a public point of view.

Thus the research of this thesis is structured into a quantitative case based section, which empirically investigates the patent landscape of the CRISPR/Cas9 technology. The other section of the research is based on the construction of a model tool and ontology contribution, to be able to perform empirical, quantitative investigations of contractual terms in university-industry research collaborations. The methodology of the thesis structure design is illustrated in figure 5.

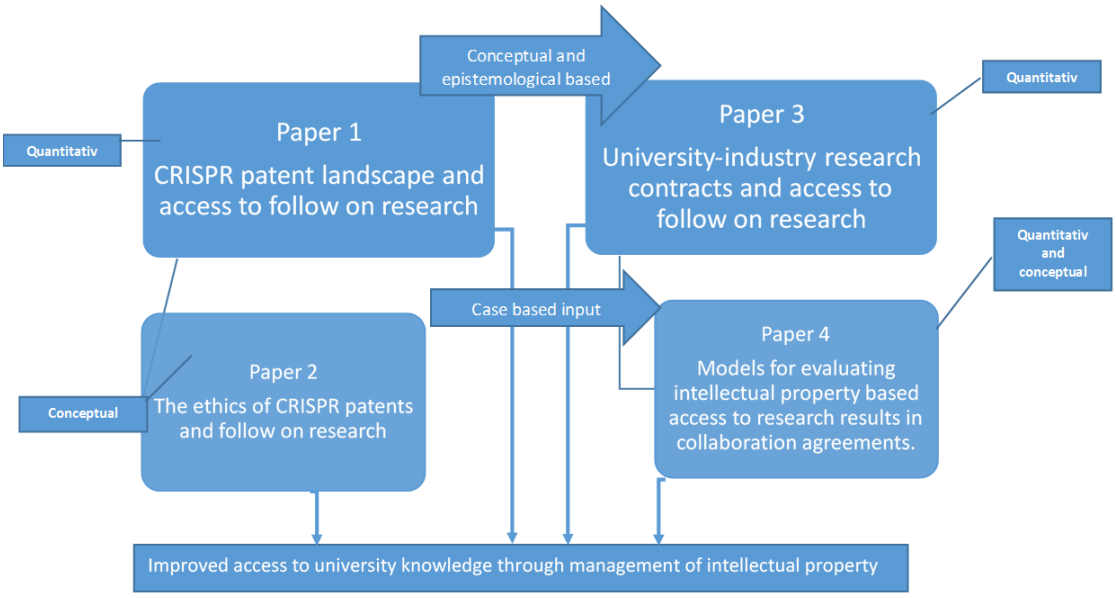

Figure 5: Design and relationship of the publications representing and supporting the investigations of the thesis. The methodology used in each paper is indicated.

The first part of the research is an empirical study of the patent landscape and the license opportunities for the CRISPR/Cas9 case [the case will be detailed further down]. This is performed using a mixed method, an empirical analysis of the patent and license landscape for research tools, CRISPR/Cas9 being used as a case example. This mixed method includes a theoretical, ethical discussion and a model for discussing university access to research tools and management of intellectual property.

I present in the second part, the results of the work I jointly carried out with Ph.D. candidate Haakon Thue Lie at NTNU. The work includes the extensive material collection and appurtenant data analysis of the 312 RCN collaboration agreements. A quantitative methodology was applied to a statistical study, and a tool was developed for the extensive data from the RCN contract database. Both parts comprised both qualitative and quantitative methodologies, case studies and conceptual developments. These contribute to the overall aim of understanding intellectual property mechanisms in the public sharing of knowledge.

The framework of this thesis is that access to science is determined by how a university of the 21st century balances their activities between Merton's theories and norms and the Etzkowitz Third Mission framework of entrepreneurship in which both requires solid intellectual property management. I have throughout the work of this thesis challenged

and expanded on Merton's norms of the assumption of full openness and scrutiny without any intellectual property management and control. I argue that such a view of the world of knowledge exchange is difficult to defend and possibly decreases access to further research in the present knowledge society. Merton based his views on universities operating in a Mode 1 phase with limited external and applied research activities, in a 1st and 2nd mission state where entrepreneurial activities for academic institutions were much less present than of today. The world post-Merton has changed and the Triple Helix state, provided first by Etzkowitz et al., suggests that knowledge exchange and sharing has become much more intertwined and complex. This requires knowledge holders to be more concerned about intellectual property, to ensure that they maintain control of their assets and that they are able to continue to develop knowledge. I have, to investigate this further, used a mix of empirical qualitative and quantitative studies combined with case study methodology and conceptual studies, to deeply analyze how universities manage intellectual property. This approach also allows tools to be provided that can view and analyse how the public, through various parties, develop control mechanisms that allow sharing mechanisms that suggest stakeholders use knowledge in accordance with their motivations.

A scientific method assumes a starting point and a goal. The starting point can be something we do not understand, something we doubt. For example, in this thesis, the question is 'How is access to knowledge-based research results managed by universities in relation to intellectual property'? The goal may be to make good measurements or to find the explanation for something or to test a research question or to investigate some light phenomena in the sky or to test a theory (such as the theory of relativity) as classically stated by Karl Popper (Popper, 2005). A number of scientific methods have been used in this research to achieve the goal to be able to explain the main research question and to discuss the research questions proposed, as its interdisciplinary nature requires. There is not just one but a myriad of scientific methods that would be relevant. Some may be used in a number of sciences, others may be specific to a particular science, for example, medicine, law, history, sociology, psychology, literature. It is therefore difficult to say anything in general about scientific methods. Each subject has its own methodology. A research method defines the ways we collect data to answer a research question. The data collection techniques include how I ask questions as well as how the data I have proposed is being analysed. In prior research, an overall framework for the methodology, which combines the measurement of the degree of access of university-industry collaborations in biotechnology projects and hypothetically-deductive test methods as explained in Poppers theories and in Godfrey-Smith's 'Theory and reality: An introduction to the philosophy of science' (Godfrey-Smith, 2009). This framework deducts one or more tangible consequences of the question or the theory to be tested and then investigates the correctness of these consequences. The outcome of this investigation is then used to say something about how precise the questions or theory is.

The deduction of this thesis first argues for an interpretive perspective based on the empirical results from the investigations of the university-industry collaboration projects. Then the thesis continues with a discussion of the choice of research design, data

collection, and data analysis. The primary goal throughout the work of this thesis has been to explore the universe of utilizing knowledge from the viewpoint of the university and intellectual property management. The research question if management of intellectual property by universities in the distribution of knowledge influences access to research results, is also tested throughout the thesis in various interrelated research studies. I have aimed at understanding how access to intellectual property is managed when collaborating with external parties, in particular by balancing open innovation with intellectual property control through the use of specific IPR's like patents. The way universities interact with external parties and offer to utilize their knowledge, involves societal challenges in how intellectual property claims are offered. Exploring these challenges has required the use of a mixed method in the systematic approach of these investigations. Methodologically, the thesis is based on a combination of quantitative studies and case presentation as outlined in figure 6.

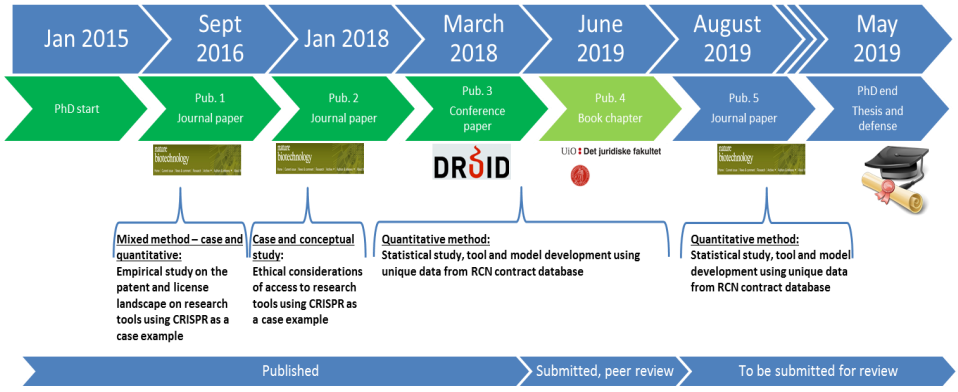

Figure 6: Different research methods used throughout the thesis to allow for in-depth investigations and its time frame.

7.1 The research philosophy of knowledge – explaining the epistemology and ontology of the research methodology

It is useful to explain the epistemology and ontology fundamentals of the thesis, to allow the reasoning of choice of the methodology used throughout and which this thesis is based on, to be explained. Epistemology is from the Greek and is a common name for recognition theory. The name is constructed from the two Greek words epistêmê and logos, which are often translated as knowledge, insight and recognition and the theory of its explanation or teaching. Epistemology is consequently the teaching of knowledge and insight. The basis of the intellectual property investigations and discussions in the thesis is how knowledge is managed and distributed in society. Knowledge theory, which then translates to epistemology, would then be the philosophy of teaching the nature of our knowledge, its assumptions and basis, and the origin, opportunity, scope, and validity of our knowledge. It, therefore, becomes critical to explain why knowledge sharing and distribution is important from many perspectives. The university is a societal holder of

knowledge. This thesis, therefore, recognizes that the investigations of how knowledge can be controlled and governed through intellectual property are useful in the understanding of how society shares knowledge and how society, through universities, can optimize further sharing and distribution of knowledge through using intellectual property as a mechanism of knowledge governance.

Knowledge distribution and the intellectual property governance of knowledge is a complex matter. How the different knowledge holders, such as universities, define their role of being an intellectual property distributor in society is complex. Many parties could be involved when trying to locate and share knowledge-generated intellectual property in research collaborations. Intellectual property is both a normative institution and a descriptive legal function that has been developed to incentivise innovation and the distribution of knowledge. Access to knowledge through intellectual property management has therefore made it necessary to approach the topic of this thesis by explaining the intellectual property concept from a normative and a descriptive approach. The balance between the two is not easy to capture. The case study of the CRISPR/Cas9 patent landscape addresses the interchange between a descriptive case story of how the patent and innovation system works in the US when one party files a patent application and claims monopoly and exclusivity of an innovation and another party attempts to overcome those claims. At the same time while introducing access restrictions to this piece of intellectual property from a normative position. As outlined in the related publication (Egelie et al, 2016), this case study illustrates the importance for the future of intellectual property management in obtaining control of knowledge and what happens with follow on inventions when universities that capture a piece of intellectual property offer exclusive access to and development of it. The epistemology, knowledge, and knowledge per se are therefore of interest in the analysis of some of the mechanisms involved.

Ontology (from the Greek, onto, 'being,' and -logia, 'the teaching of') is the study of what exists and the forms of existence. It is one of the key areas of study in philosophy. It is, however, also related to the fundamentals of science theory. As can be recognized throughout this thesis, the foundation theory rests on the shoulders of Merton on the one side and his thinking and discussions of the socialism of science. Merton worked on a number of fields within the subject of socialism of science, particularly in the field of professional and scientific sociology, and was a key figure in the American sociology of the 20th century. He is known for his distinction between manifest and latent functions, and for his recommendation to social scientists to seek a balance between theory and empery by formulating 'theories of the middle range.' Science sociology deals with how science interacts with society and describes science-intensive norms in all science. University interactions with external parties have developed rapidly and remarkably during the 19th and 20th century. So has the foundation and basis of knowledge and science distribution. Understanding the sociology of science in relation to intellectual property is a fundamental part of this thesis. This, at first sight, might be contradictive. Merton's socialism of science involves open sharing and a constant critical review of the fellow scientific, academic community. Intellectual property, in particular in the form of patents,

involves control and protection mechanisms and postponement of publications so that competing industries can obtain knowledge monopolies. I, however, with the discussions and studies in this thesis, propose that knowledge sharing and access is in fact improved by a robust intellectual property system and appurtenant intellectual property management system. It is critical that control mechanisms such as robust intellectual property management systems are in place so that science can be shared and socialized, in particular for academic institutions such as universities, whose prime function is to develop and share knowledge for society. This includes industries that are trying to obtain market positions by introducing knowledge monopolies.

7.2 Details of the methodology of the CRISPR case studies

The case studies are presented in paper no.1 and 2. The case study is concentrated on the patent landscaping of the CRISPR/Cas9 gene editing technology. It provides a comprehensive overview of patent analysis in the technology domain of the CRISPR/Cas9 patent landscape in the years 2008-2017. Analysis of patent data has long been considered to be an important method of assessing aspects of changes in technology domains.

CRISPR is a biotechnology that is predicted to create disruptive changes within the use of gene editing tools. It was also developed by major universities. This was therefore chosen for established patent landscape studies to monitor how the intellectual property situation for this technology has evolved (Barrangou & Doudna, 2016).

The analysis provides an insight into the overall trends in sub-technologies, key players, major jurisdictions and key inventors in the CRISPR domain. The approach used to identify patents in the CRISPR study combined keywords and classification codes. As Bubela et al. suggest 'The most effective patent landscaping protocols align scope and methodology with the purpose of the target audience and the specific issues to be addressed' (Bubela et al., 2013). A patent dataset was generated to capture all the patent applications published since the earliest priority year of 2004 using Derwent Thomson Innovation. An elaborated taxonomy was built to identify the sub-technologies in the CRISPR domain. A focused analysis of the use of CRISPR technology in areas such as pharmaceutical, health, agriculture, food, energy, and veterinary was also carried out to gain in-depth insights into these areas. The data were classified in these areas based on Derwent manual codes, IPC or CPC classification codes. Another example of how a patent landscape analysis could be carried out is found in Bergman and Graff (Bergman & Graff, 2007). A patent landscape analysis is described in their study for the development of stem cell technology. Their approach was to analyse the patents granted to the Wisconsin Alumni Research Foundation (WARF) on embryonic stem cells, which are said to be one of the strongest intellectual property owners in the stem cell field. Their goal, when performing such an analysis, was to investigate the implications of this for efficient technology transfer and commercial development within the stem cell area, in particular for public institutions.

Assignee standardization was furthermore performed to regularize any assignee name variations. This benefits from the name standardization provided by the Derwent World Patents Index (DWPI) and employs an additional automated and manual review. Assignee name reformatting reduces the heterogeneity of assignee names to a more manageable and more instructive level. Inventors' clean-up was also similarly carried out for recognizing key inventors in this domain.

Based on data availability on Derwent Thomson Innovation, inventor addresses were identified to provide in-depth analysis of the country and city level contribution in CRISPR research. Finally, a statistical analysis was carried out of all the retrieved patent data, to investigate who owns the critical patents, where these patents provide exclusivity and for how long these patents will provide this exclusivity. The results are presented in chapter 7.4.1 and in thesis paper no. 1.

7.3 The methodology of the empirical studies of the collaborative research agreements

The empirical setting of this thesis is two-fold, different methodologies having been used to complete the studies. An ontology for access [to intellectual property] was first developed, the elements of access being undefined, had to be made definable. One way to achieve this was to develop an ontology for access [research results from universities]. Variables in a research collaboration framework that could be used in the statistical analysis can only be described empirically after this has been completed. It was necessary, once the ontology for access had been defined, to establish and define the specific variable to be used. Templates provided by larger public research agencies that provide funding to university-industry research collaboration projects and existing research collaborations were used during the ontology of access as a model framework.

Hannah, D. R. and B. A. Lautsch talk about the 'Counting in Qualitative Research: Why to Conduct it, When to Avoid it, and When to Closet it.' in the Journal of Management Inquiry (Hannah and Lautsch, 2011). In this essay, they discuss the issue of counting and the process of assigning numbers to data that are in non-numerical form. This has been useful in the development of the methodology for investigating the contractual relationships between universities and industries and access to knowledge.

In the investigations on contract management all research programs that the agreements have been extracted from are subject to the RCN contract management program, this including a policy document, general terms and a number of template agreements for collaborative research projects. I performed detailed studies of the results of contract management in RCN projects. I understand the agreements and the contracts as a mechanism to govern public access to research results. Collaboration agreements in public research projects are central mediators in the exchange of data and research results. Such agreements may restrain or facilitate sharing and access to data and research results. In the context of research policy and knowledge management, the aim was to investigate

the role of agreements in publicly funded research projects as a mechanism for establishing robust and sustainable access to research results and knowledge in the context of the responsibility of the public to disseminate knowledge broadly through both education, research, and entrepreneurial activities. Empirical models had to be developed to allow this to be possible.

7.3.1 The methodology of the collaboration agreement investigations

The agreements were scored between April 2017 and April 2018 by contract management experienced principal investigators. The scoring criteria are objective; see Table 2. We used Stata version 15.1 and created descriptive statistics. We then made multinomial probit and ordered probit models. Further details in thesis paper no.3 and 4 as well as in Table 3-5 in the additional statistical tables in Appendix A.

The agreements that have been studied have several different parties that we have grouped according to the motive they have for participating in a research collaboration. A random selection of agreements was financed by the Research Council to assess to what extent the agreements give the public access to the research results. Each deal was read in detail, eight facts recorded and ten variables were cut, all recorded in a spreadsheet. Altogether, this 43234 data point is recorded in 8694 data fields. When a deal was scored, a model was used for the purpose.

Each of the ten variables received a value from one to five. "One" was used for the agreement clause where the industrial partner acquired the ownership rights, "five" were used if the universities obtained the ownership rights. For example, the variable "Ownership" was scored with "one" if the industry acquired the ownership rights, "three" whether it was a co-ownership, and "five" if a university became the owner of the research results. In the variable "Foreground," for example, a score on "one" includes a clause in the agreement that gives full exclusivity to industrial parties, while a score of "five" will mean that the industry under the agreement does not have commercial use rights.

The provisions of the agreements that regulate access to the research results were then evaluated. Subsequently, statistical analyzes of the material were carried out and based on this, various outcomes for access were concluded and correlated with the degree of public funding in the projects.

All the RCN funded projects analyzed have at least one academic partner and one industrial partner. Research institutes are identified separately. The term academic partner was used for universities, university colleges, and other public educational institutions. Industrial partner also encompasses some public bodies that mainly have an operational focus, and some companies set up to do research for profit. RCN is the public sponsoring body for all the projects and the source for all the collaboration agreements.

An initial ontology based on studies of a subset of our research data was developed, together with contract templates. Based on the ontology a scoring model was created.

Then each project was scored, using five main parameters. These scores were used for researching possible correlations.

The dataset created includes:

- The funding amount and share by RCN vs. the funding from the project participants.
- Institutional composition of the consortium (firms, universities, etc.)
- The field of technology or scientific discipline of the project
- Contractual details, such as jurisdiction, bilateral or consortium agreements and clauses on arbitration, warranties, liability, and confidentiality.
- Our scoring of the access restrictions found in the contracts in terms of five parameters

At the beginning of research contract studies, it was assumed that one could find a simple mapping between all the 10 variables and the openness and access control dimensions. The final scoring model ended with a complicated map of possible relations. For example, will user rights to the results depend on ownership to the results and to background rights? Also will requirements to publication and confidentiality limit the use rights? The final scoring model comprised variables that are major parts of the access control of a collaborative research project: The ownership of research results ("Ownership") and the distribution of rights to all commercial use of intellectual property ("Foreground IP"). We regarded the openness to a large extent to be governed by the provisions on the dissemination and publication of project results ("Publication"), and the degree of confidentiality ("Confidentiality"). Table 2 presents the details of the final version of the scoring model:

	Ownership	**Foreground**	**Publication**	**Confidentiality**
Score				
1	Industry owns all IPR and Project results.	Industry has exclusive user rights to all commercial use of IPR and Project results.	All dissemination of project results is strictly controlled. No publications allowed.	All Information is by default confidential if not already public. No specified time limits or other limitations.
2	A specific party owns Project results if based on own background, dominating contribution or own commercial interests. Otherwise jointly owned.	All parties have by default exclusive (within a specified field of use) or non-exclusive, world-wide, royalty free User Rights to any utilization of all the Project Results.	Project results must be published but could be delayed according to participants needs. Not specified publication veto for academics.	All Project results and background information disclosed to the other parties is by default confidential if not already public, limited in time.
3	All Project results are jointly owned. Separate agreements for User rights.	All parties are granted non-exclusive user rights to all Project	Results shall be published, but publication must be sent to the Steering	Project Results and Background information is confidential if marked

		results if needed to be able to utilize their own Project result.	committee which could object and request modifications before publication.	and justified for particular reasons and limited both in content and/or time.
4	Ownership of all Project results is individually owned. Where a number of Parties have carried out work generating Project Results and where the share of the work cannot be ascertained, they have joint ownership.	All parties have royalty-free user rights, but only during the project period to results that are needed to perform utilization of their own Project result, further user rights may be given upon request.	Publications could be delayed due to patent or other justified grounds, but according to Norwegian laws. Must be clearly stated that results must be published within a time frame.	Project partners have to specifically call for confidential information. Must be marked Confidential, time-limited and approved by a Project Board. Parties could refuse.
5	Academic institution owns all IPR and Project results.	Only academic partner has specified user rights of Project results.	No publication restriction. Specified that results must be published	No confidentiality conditions specified

Table 2: The different variables in the access model. From thesis paper no.3 and 4 (Egelie et al., 2018a).

There is a discussion below on the basis for the dataset and how it has been analyzed.

7.3.2 **Research Council of Norway and Selecting the Projects for the Study**

Norway is a wealthy country in Scandinavia, with around five million inhabitants. Norway is not a part of the European Union but participates in the European Research Area. The Research Council of Norway (RCN) annually funds research with one billion EUR per year to around 5000 projects. In 2016, public allocations to research comprised more than one percent of Norway's gross domestic product.

All these research programs are subjected to the RCN contract management program. This management includes a policy document, general terms and several template agreements for collaborative research projects.

The study investigated the results of contract management in RCN funded projects. The agreements are understood as a mechanism to govern public access to research results. From their mission, the universities are proponents of public access, to ensure that education and research benefit from the project results. In such empirical evaluation, there is a need for a starting point is to see if there is a correlation between the grade of public funding and terms which regulate access to research results in university-industry collaboration projects. If the industry party finances the projects to a high degree, then they could argue for industry ownership and a low degree of public access to the results. On the other hand, they could regard a high degree of access as a way of contributing to society, to research and education. Another possibility is that the industrial partners could secure ownership of the results and the public access could be low regarding future

commercial use. In this situation, the universities could still secure the right to use the results in education and future research. In practice, this could be arranged by the industry partners owning essential patents.

Collaboration agreements in public research projects are central mediators in exchange of data and research results. Some opinion that agreements restrain instead of facilitating sharing and accessing data and research results. In the context of research policy and knowledge management, we aim to investigate the role of agreements in publicly funded research projects as a mechanism for establishing robust and sustainable access to research results and knowledge in the context of the responsibility of the public to disseminate knowledge broadly through both education, research, and entrepreneurial activities.

7.3.3 **The structure of projects and agreements in the data set**

The agreements are managed by a project owner that is responsible versus RCN and has a contract between themselves. The RCN does not review or monitor the content of the consortia project agreements (between participants), except for a few large and prestigious projects. The agreements are confidential, as is the identity of the projects we have studied. Our research needed special permission from the Norwegian Ministry of Education and Research. A premise is that the selection of projects and contracts in the study is only known to the principal investigators. Contact with the project participants was not allowed.

Projects across multiple research programs that span over the last decade were selected. There were several practical difficulties in finding and accessing the agreements, due to archival issues. As a result, we removed projects we initially had selected because the agreements were in poor quality or not available from the archive. Also, we discarded a small number of selected projects, as they were not real research collaborations, but other grants. Control variables include contract size, number of partners and field of industry.

In the case of projects involving partners, the project owner must enter into written collaboration agreements with all partners. Collaboration agreements are to be completed at the latest within three months after RCN has sent the contract to the project owner. RCN will not disburse any funds until they receive the collaboration agreements.

Agreements based on contract templates constitute a large body of our data set. Such templates are often initiated by the RCN or the academic institution as well as the industry parties (to a lesser extent than the public institutions) but then subjected to negotiations between project managers and legal staff from the parties involved in the projects.

7.3.4 **Basis for designing collaboration agreements**

The collaboration agreements are to regulate the reciprocal rights and obligations of the project owner and partners in the project. RCN communicates directly with the project

owner alone and is not a party to the collaboration agreements. RCN does not stipulate special requirements for the content of the collaboration agreements, except about certain aspects involving the distribution of rights in the project. It is up to the parties to determine the appropriate format for and content of the collaboration agreement for the individual project. Unless otherwise specified, the project owner may choose to draw up one common collaboration agreement or individual collaboration agreements for projects with multiple partners. The project owner is responsible for ensuring that the collaboration agreements comply with the terms and conditions of the contract. Partners are institutions, companies and other types of enterprise (as well as any designated individuals) that RCN, in its contract with the project owner, has stipulated are under obligation to provide professional or financial resources for the implementation of the project. The partner is responsible vis-à-vis the project owner, and the project owner is responsible vis-à-vis the RCN.

7.3.5 Regulation of rights to project results

The Research Council stipulates specific requirements for the regulation of ownership and rights to project results in a collaboration agreement. These requirements build on the Principles for the Research Council of Norway's Policy on Intellectual Property Rights and are set out in chapter 7.2 and 7.3 of the General Terms and Conditions for R&D Projects. Figure 7 shows the RCN contract management framework.

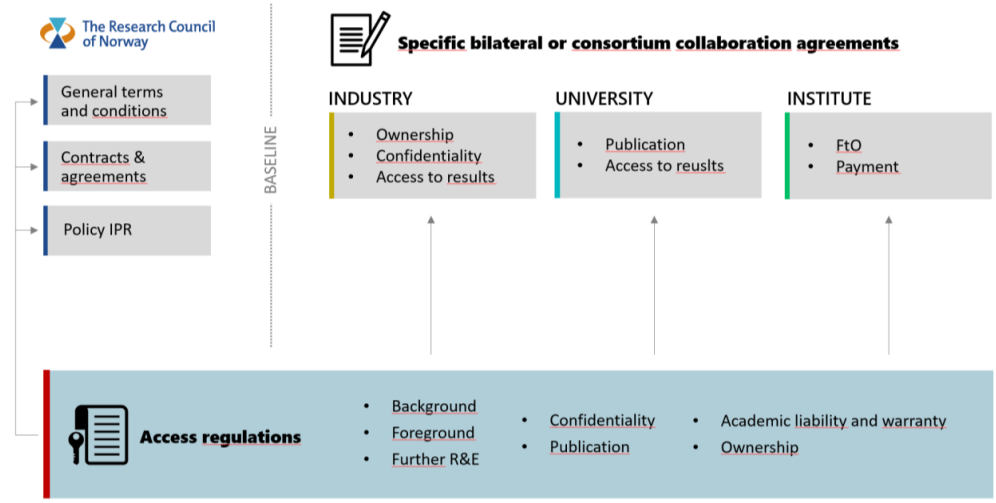

Figure 7: The RCN contract management framework and baseline and the subsequent collaboration research project agreement framework

7.3.6 The agreement framework of the RCN

After a research project has been granted a pledge of funding, contract negotiations will be initiated between the Project Owner and the Research Council. The contract sets out the terms and conditions for the use of the research funding and the parties' rights and obligations about the implementation of the project. Once the application review process has been completed, and the outcome has been published on the Research Council website, the project administrator, and project manager will receive an email notifying them of the formal decision. It is frequently the case that certain aspects of the grant application must be revised and updated before a contract can be signed. The email from the Research Council will list any required revisions. The contract between the Research Council and the recipient of the research funding consists of the following documents at a minimum:

- an **agreement document** that contains the concrete conditions associated with the allocation, such as specification of the project's objectives, management, budget, financing, progress plans, and reporting requirements;
- the **project description** that was submitted by the Project Owner together with the final, often a revised, version of the grant application;
- the **General Terms and Conditions for R&D Projects**, which are the Research Council's standard terms and conditions and are applicable to all R&D projects, unless otherwise specifically agreed in writing.

These documents form the baseline of the model development in figure 8.

Figure 8: The baseline of the RCN contract management framework comprises General Terms and Conditions, the templates for contracts and agreements and the Policy on IPR.

If the provisions of the various contract documents conflict with one another, the agreement document will take precedence over the General Terms and Conditions for R&D Projects and the project description. When it comes to the parties to the contract, they are the Research Council and the Project Owner. A designated project administrator signs the contract on behalf of the Project Owner which is either the institution, company or activity that is responsible for the R&D project. The project administrator is the

individual who is authorized to represent and commit the Project Owner on behalf of the Research Council.

7.4 Strengths and weaknesses

There are some limitations to the thesis investigations. The data in the contract studies are from a Norwegian data source only, the RCN. The results might be different if the data were from a different source of public funding than the RCN or from a different country. Another element that might be a limitation is that the data set may be skewed as some of the agreements were unavailable in the RCN database as where the quality of some of the scanned available documents. The lacking agreements may be due to, e.g., scanners not working from time to time, and affecting the data randomly, or there could be systematic errors.

Another limitation in the investigations of the collaboration projects is that the agreements are in English or Norwegian language, with standard European contract terms. Some are inspired by English or US contract tradition. Almost all are using Norwegian law. There is however used common English terms and expressions for intellectual property regulations for the development of the method and the ontology. The method can thus be adapted to similar future research, also in other countries. The collaboration agreements regulate fall-back positions if the practical cooperation between the R&D partners breaks down. The persons working on the project will hardly consult the agreement whenever knowledge is exchanged within the project. Nor will the agreements reflect every possible situation or problem that can arise. The different scoring results do not reflect the actual access to the results and the background, but the idealised position in case of further negotiations.

The results from the studies of the RCN collaboration agreements concerns the initial negotiations of contractual terms. To complete the early project phase studies one should ideally perform follow up studies of the results of the same RCN collaboration projects and how the results from the projects are used further in research or utilisation. Only then one would able to control early project phase intentional agreeing elements with later on factual happenings.

For the CRISPR patent landscape investigations there might be several limitations. In general patent landscape studies are often subjectively based on one or just a few peoples opinion of a technical area. In addition, these people might have limitations when it comes to legal (intellectual property) knowledge. Literature indicates such limitations, and it has been said that despite the quantitative nature of patent data, there remain significant limitations to its use as an empirical measure. One limitation of patents as a measure of innovation, for example, is that patenting rates differ between countries, firms, and industries, thus engendering inter-firm and inter-sector bias. The use of patent data as a measure of knowledge flows through citation analysis may be unreliable because patent examiners often add citations to earlier patents of which the inventor may have been unaware (Grant et al., 2014).

7.5 Results – data collection and analysis

The overall data collection process can best be described as a process of data acquisition that involved collecting or adding data. There are a number of methods for acquiring data. In this thesis, data has been collected in two ways for the two different projects:

1. CRISPR patent landscaping. In this project, we collected new data from patent databases such as Derwent Thomson Innovation and Questel Orbit.
2. RCN contract studies. In this project, we reused RCN data and made our own collection for a purpose developed ontology and access model.

- **Data processing.** A series of actions or steps performed on data to verify, organize, transform, integrate, and extract data in an appropriate output form for subsequent use. A general rule is that methods of processing must be rigorously documented to ensure the utility and integrity of the data. Each step in both the studies in this thesis are documented and described
- **Data analysis** involves actions and methods performed on data that help describe facts, detect patterns, develop explanations and testing of research questions. This includes data quality assurance, statistical data analysis, modelling, and interpretation of analysis results.

The results based on the actions above were published as research papers. The quality and utility of data acquisition, analysis, evaluation and research in the different sub-projects fundamentally relied on the ability to collect and analyse quantitative and qualitative data.

7.5.1 The CRISPR patent case study

Universities rarely stop projects or commercial developments or avoid them because of access to IP. Many universities instead engage in such activities through exclusively licensing IP rights or taking contractual actions to deal with or avoid problems of access to IP.

I analysed a collection of 1,456 patent publication records comprising 93 patent grants, 1,363 published patent applications relating to CRISPR/Cas9, which collapsed into 604 patent families (all filings worldwide). These were from 2004 and onwards. The overall inventive activity in this area has been steadily increasing, no doubt partly due to the interest CRISPR has generated in the scientific community. Among the leading players, Massachusetts Institute of Technology is the top patenting entity followed by Harvard University and the Chinese Academy of Science. Most of the top players are from academic and government entities. The top entities show a varied filing pattern, a large proportion of their patent filing activity taking place in the United States, Japan, and Europe. The exceptions to this are Chinese entities, their interest mostly being in

protecting their technology locally. Interestingly, a lot of top assignees use the PCT route for gaining geographically widespread protection for their inventions.

Based on the filing location of the inventor, which was identified through the inventor address field of Derwent Thomson Innovation, inventors from USA and China lead followed by South Korea and France. Inventor city address was also identified, but only for the USA and Europe, to gain further in-depth analysis at the city level. The analysis of inventor address concluded that Cambridge followed by Boston and San Francisco are the leading cities for patenting activity.

Different sectors have shown notable applications of CRISPR technology. The dataset was segregated in the two domains to identify key players and filing trend analysis, particularly in pharma and the agriculture sector. The pharma sector shows greater growth than the agriculture area, the regulatory laws in agriculture in different countries perhaps contributing to the low inventive activity. MIT, Broad Institute and University of California are the top universities carrying out research in both Pharma and agriculture. The very prominent agriculture industry company DowDuPont was, as expected, a major player in the agriculture domain. The main result of this patent landscape study is that the core patents for the CRISPR/Cas9 inventions are developed and owned by universities financed by public organisations. A number of these universities licence their patented inventions, either exclusively (some being field of use specific, but not all) or non-exclusively to spin-off companies or established industries.

7.5.2 RCN contract data and intellectual property access

One of the main findings is that there is a significant low, positive correlation between access to research results in the form of intellectual property and the degree of public funding. The positive correlation is as expected, but not as low. Figure 9 shows the expected access variations with the degree of RCN funding.

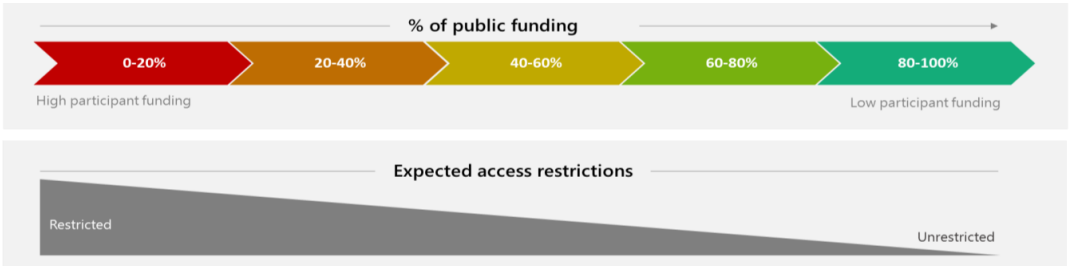

Figure 9: The expected balance between public funding and degree of access to research in university-industry collaborations - from thesis paper no. 3 (Egelie et al., 2018a).

When looking at the collaboration agreements from the Research Council of Norway (RCN) contract database I have investigated data from research collaboration agreements of 312 research projects funded by the RCN. I have used this to study the role of the

public in managing intellectual based research results. I have discussed the role of funding and how public sources influence university-industry research collaborations. The discussion covers how legal terms in collaboration agreements between parties influence access to research results and knowledge. Public funded research may be granted to technologies and new insight that affects human health and well-being. Measuring the impact of public funding research collaboration is therefore of public interest. An assumption of policy makers could be that a high degree of funding implies a high degree of public access to the research. The assumption could also be the opposite, a high funding degree imposing low access, which should also be of concern to the public funder. It could even be that there are differences between different technology sectors, i.e. that biotechnology research projects have greater openness and access than ICT projects. In the framework of this research, it would be useful to know how access is managed at the contractual phase of a research collaboration between universities and industry. This could propose indications on the university's role and capability as a knowledge provider early in a collaboration framework.

8 Summary and the relationship of the research papers

The relationship between the papers and the overall research questions is described in the methodology chapter and figure 13. The papers are summarized in the sub-chapter below. Each paper is then presented in full at the end of the thesis.

8.1 Paper 1: The emerging patent landscape of CRISPR–Cas gene editing technology

The aim of this study was to take a deeper look into how universities that create larger ground breaking research tools manage the intellectual property of this knowledge. The CRISPR/Cas9 research platform is a heavily debated technology developed and patented by leading universities. It was chosen as a case example to explore and explain the challenges facing universities and the public when playing the game of commercial utilization of patents.

Research question: How is access to disruptive research results such as the CRISPR/Cas9 technology managed by universities?

Paper summary:

Academic scientists and industry researchers are increasingly concerned that patents may hinder open science and the early stage development of commercial products and services. The patenting of disruptive enabling technologies influences the freedom and incentives of others to carry out follow-on research and to create commercial applications of those breakthroughs. How and where this freedom is influenced, however, is not straightforward. The clustered, regularly interspaced, short palindromic repeats (CRISPR) and the CRISPR associated protein (Cas9) system is a powerful new

technology platform for genome editing. The identity of patent holders, the technology coverage of the patents that have been filed for different components, and the national and regional distribution of those filings all influence future access to the technology. We explored these factors, analyzed the emerging patent landscape for CRISPR-Cas, and compared it with previous breakthroughs in biotechnology.

Results: We argue in this publication that the use of patents per se should not unduly restrict access to the CRISPR/Cas9 technology. However, use of the technology platform in further research and development will depend upon how the different parties that control key patents determine how the platform is made available.

Further research: Previous successful biotechnology licensing mechanisms may need to be considered and emulated for the CRISPR/Cas9 technology to be fairly, reasonably, and efficiently utilized.

The major issue discussed in this paper was what happens when researchers at other universities make potentially valuable discoveries of their own using the research tool they obtained for non-profit or research use. We proposed for further investigations that there are some questions related to what are academic institutions options for commercializing follow-on technologies and how likely is it that the commercial entities now in control of CRISPR/Cas9 will decide that broad, non-exclusive sublicensing is a viable business model. The paper indicates that without improved focus on intellectual property management access to research results from university based collaborations might be difficult in the future.

8.2 Paper 2: The ethics of access to patented biotechnology research tools from universities and other public institutions

In this paper, we investigated access to intellectual property research results for larger research tools that have a significant influence on further technology and product and service development and examined the challenges this presents. Society not creating optimal access and the ethical challenges this represents is of even greater importance and was discussed and debated

The research question asked: What are the ethical challenges presented by university involvement in patenting innovations?

Summary:

- The paper discusses the ethical obligations of ensuring access to patented biotechnological tools.
- This ethical issue of improving access to biotechnology research tools differs from others pertaining to biotechnology patents, through it being concerned with the

inherent justification of the patent system, namely the promotion of innovation for societal benefit.

- In the study we propose:
  - a self-regulation model in which universities and PROs provide access to research through balanced licensing models
  - a federal regulation model in which access is provided through state regulations
  - that the self-regulation and the federal regulation model should be further explored and developed where universities and research organizations are involved in the patenting and commercialization of technology platforms that have a fundamental social significance.
- The study concludes that strategies regarding the two proposed models of self-regulation and federal-regulation should result in licensing practice guidelines that are consistent with the pursuit of both economic profit and the activation of social value for public institutions performing third mission activities.

We discuss the two models, self-regulation and federal-regulation, for ensuring access to fundamental biotechnology tools without undermining the incentive function of patents. Universities and public research organizations increasingly partner with industry to fulfil their 'third mission' of innovation activities for economic and societal benefit. Public institutions have ethical obligations to ensure access to patented research tools. A number of universities and public research organizations (PROs) have developed tight partnerships with industry, justifying this through their 'third mission'. Patenting research-based innovation is a central strategy in the fulfilment of this mission. Universities and PROs have, however, ethical obligations to ensure access to patented biotechnological research tools. CRISPR is a new and useful technology platform and research tool for genome editing and a promising basis for revolutionizing gene therapy, agricultural biotechnology and drug screening and development. The fundamental patent rights for this tool are held by universities and PROs, and exemplifies a third mission dilemma of balancing commercial profits with further access for research and development. This paper discusses the ethical obligations associated with ensuring access to patented biotechnological tools such as the CRISPR technology platform, in the light of the third mission. This ethical issue differs from others pertaining to biotechnology patents by being concerned with the inherent justification of the patent system, namely the promotion of innovation for societal benefit. The third mission places the combined responsibility for innovation and securing social value creation upon universities and PROs. We discuss two models for ensuring access to fundamental biotechnology tools without undermining the incentive function of patents, the two models being the self-regulation and federal-regulation model.

8.3 Paper 3: Public funding of collaborative research and the access to research results

Prior research has frequently shown that the innovation performance of firms benefits from collaboration with universities and research institutions. (Howells et al., 2012; Steinmo, 2015) These collaborations may, however, suffer from tensions related to institutional logics, firms often focussing on innovation outcomes. University researchers, on the contrary, are primarily driven toward long-term outcomes and their publication reputations in the international arena (Steinmo, 2015; Becher & Trowler, 2001). I.e. toward disclosure and the openness of research results. Researchers will focus on their autonomy, research freedom and curiosity-driven research. Firms will try to regulate this freedom and drive researchers' actions in the direction that meets the firms' needs (Al-Tabbaa & Ankrah, 2015; Perkmann et al., 2011).

Research question: Is there a correlation between public funding of collaborative research and access to research results?

Summary:

This study targets whether the public funding of collaborative research between academia and industry is associated with access to project outcomes and research results. To explore this we investigated the contractual terms of 312 publicly funded research projects in Norway. It is provided an in-depth analysis of the terms which the partners involved in projects agree to. These terms include ownership of research results, the distribution of rights to all commercial use of intellectual property, dissemination and publication of project results, and the degree of confidentiality.

The results indicate, overall, a positive though weak relationship between public funding and the dimensions of access and openness, the association being strongest for the ownership of research results. It is furthermore shown that the institutional composition of the project determines the project's openness and access to a project's research.

The study has implications for public funding bodies and for science, technology and innovation policy.

Previous research indicates that industry funding of academic research is preventing access to public research, particularly publication and dissemination. Industry appears to prefer secrecy rather than disclosure, to increase the appropriability of the returns from the research carried out in collaboration with public science (Gans & Murray, 2012). A key issue is therefore the regulation of access to research results. Firms will impose limitations on the disclosure of research results, will keep the results confidential and try to protect and control the knowledge developed (Bruneel et al., 2010). The contractual terms of university-industry collaboration agreements therefore will frame and limit the exchange of knowledge, and thus the openness of and access to the research results.

Studies of actual contractual terms and how these influence access and the utilization of research results are, however, scarce. There is therefore a dearth of studies on how access to research results is regulated in contracts between universities, public research institutions and industry partners. University-industry collaborative research is, furthermore, often sponsored by public funding bodies. Intuitively, we would expect an increased share of public funding to be associated with a higher degree of public access to the research results. Little empirical evidence, however, exists on this relationship despite its obvious interest and relevance to science, technology and innovation policy. This gap has been recognized in previous research, which has called upon research into real contracts that regulate knowledge access (Perkmann et al., 2013).

This paper builds on the unique data of 312 collaboration agreements from a total population of 21,838 projects, of which 8,000 where selected. The degree of public funding of these projects is between 19% and 100%. Our exploratory study investigates the correlation between the degree of public funding of collaborative research projects, participation in the projects by academia and industry, and the extent to which restrictions are imposed on the openness of research results. We focus on four dimensions of access and openness: the ownership of research results, the distribution of rights to all commercial use of intellectual property, provisions stipulating the dissemination and publication of project results, and the degree of confidentiality.

We furthermore show that the institutional composition of a project determines public access to the project's results. We specifically find access and openness to be driven by the number of industry partners and universities in the projects. These results have implications for public funding bodies and for science, technology and innovation policy.

Additional tables are presented in statistical tables 3-5 in Appendix A.

It is essential that universities give a clear policy mandate to the functions and people set up to manage intellectual property. Management needs to recognize that to succeed requires the realisation that knowledge dissemination, economic development, service to faculty and generation of revenue for the institution requires resources, skills and leadership to be top-down anchored. Any university that does not recognize this will fail in the pursuit of becoming a player in the global market knowledge provider area.

8.4 Paper 4: The balance between publishing and confidentiality - Access to research results in collaborative projects between academia and industry

Summary:

In the last 20 years, universities have contributed to the commercial development of technology, products and services, and to the creation of new companies. Norwegian universities have evolved towards a 'Triple Helix Model' in which the state gives the universities a third mission. One of the research project parties is responsible for the

contract with the RCN, which pays a share of the project budget. Those who have project responsibility enter into agreements, either bilaterally or jointly, with all the other parties in the project. The parties themselves negotiate and control these agreements. The council usually does not review them nor are they a party in these negotiations. This thesis paper no. 4 examines research collaborations within biotechnology and its contractual relations. A number of collaboration agreements between university and industry, which govern ownership and usage rights for a number of biotechnology research projects, were examined. Based on the analysis of 162 publicly funded collaborative research projects contractual provisions were identified that govern access to and openness of research results. A methodology was developed to assess how access to and openness of research results coincides with public funding, industry and project participants. The method can also be used to study a portfolio of contracts, either from an industry party or a research institution. The focus is access and openness in two dimensions represented by figure 1 in the publication:

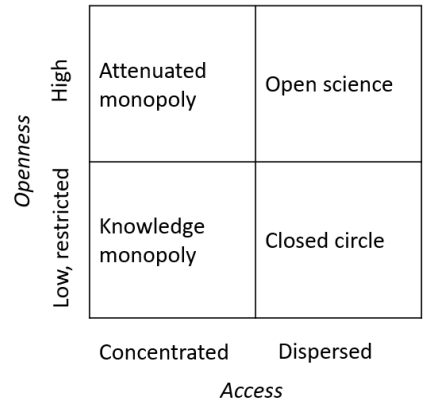

Figure: The knowledge monopoly 2D matrices of access and openness - from thesis paper no. 4 (Egelie et al., 2019-unpublished, submitted for review to Nature Biotechnology).

One dimension is openness represented by low or high restrictions. The dimension of access is represented by concentrated or dispersed. In this study and the appurtenant paper we discuss the variations of the dimensions of access and openness and suggest that the contractual provisions in research projects could imply different knowledge monopolies based on different variants of access and openness. This figure 1 from the thesis paper no.4 shows a simplified account of the dimensions, depending on how they score according to a for-purpose coding scheme regarding their provisions on access and openness.

The research topic discussed was how to identify provisions around access and openness, which attenuate or aggravate knowledge monopolies in biotechnology collaborative research projects. It was also discussed how do these contractual provisions impact the actual variations of the different dimensions of access and openness.

The findings can be summarized as follows: Knowledge monopolies in disruptive biotechnology research are problematic, no matter whether they are controlled by academia or industry, because they likely hamper downstream development and encourage upstream duplication. The results in the paper indicate that publicly funded research does end in knowledge monopolies in a non-trivial number of cases. It was also identified that variants of knowledge monopolies may be equally harmful to follow-on research since they violate the norms of open science in one or the other form.

The paper examines access to research results in collaborative projects between academia and industry and how publishing and business secrets are balanced. There were two central insights. First, the distinction between access and openness provisions that prior literature has often lumped together due to a lack of detailed information. This distinction allows systematic analysis of contractual agreements in collaborative research projects.

Possible collaboration conflicts were discussed. Such as when an industrial partner wants to keep some of the research results secret, while researchers at a university would like to publish or use the results in education. Another difficult area that we discuss is whether allowing private actors the exclusive right to commercialize research results provides the greatest benefit to society. An alternative may be that the university offers licenses to anyone who requests this, on commercially equal terms. This may be reasonable for research projects that are predominantly publically funded, if the public is also ensured access to the results.

Finally confidential, underlying university-industry collaboration agreements where investigated and knowledge monopolies in university-industry collaborative agreements were identified. These agreements provide a picture of how the parties, in free negotiations, agree to share and use new knowledge. It is also agreed whether they will give the public access to all or part of the research results. It is concluded that the model developed allows the study of complicated contractual provisions and their interrelationships in order to clarify issues like these up front and before engaging in collaborative research. This could be used to could increase the quality of any collaboration agreement and more transparent handling of IP vis-à-vis a funding body or society at large.

9 Contributions and implications

9.1 University-industry collaborations

The innovation performance of many industries benefits from collaboration with universities and research institutions (Howells et al., 2012; Steinmo, 2015). Companies will, however, try to regulate freedom and try to drive researchers' actions in the direction of the firms' needs (Perkmann et al., 2011). Industries will also impose limitations on the disclosure of research results, and will try to keep results confidential and protect and control the knowledge developed (Bruneel et al., 2010). There is some theoretical and

empirical evidence that openness enhances the incentives for increasing the level and diversity of upstream research (Gans & Murray, 2012). This does not, however, relate to the contractual terms of access regulations, but to investigations of funding sources, industry funding in particular. Gans and Murray explored whether industry funding restricts access, dissemination in particular. Public funding was not investigated. It has, however, been investigated by others, although not through the empirical investigation of contractual access terms. Czarnitzki et al. explicitly state that: '…we did not find any studies that systematically analyse the contractual terms of scientific … contracts from state sponsors or private foundations' (Czarnitzki et al., 2015b) and Perkmann et al., claimed that: 'Records held by universities on industry contracts would represent an ideal source of information but are not readily available' (Perkmann et al., 2013). In the landscape of university intellectual property management Dahlstrand and Gabrielsson et al. investigated a number of Swedish patents originating from academic environments based on a unique hand-crafted database (Gabrielsson et al., 2014). In their study they developed a categorization framework that identifies three subsets of patents involving university based inventions. The aim of their investigations of these patents was to facilitate technology transfer and intellectual property management of university based research. The contractual regulations of access to these patents and the appurtenant intellectual property was not a part of their study as their focus was to distinguish between technology differences and details of commercialization of these patents.

9.2 University intellectual property management

I have explored the main research question based on these prior literature considerations. I argue that empirical analysis of publically funded university-industry research collaboration agreements could build on and improve prior research. The thesis provides empirical evidence that there are challenges in the management of access to university intellectual property where knowledge is created in collaboration with partners. These challenges are associated with the consequences of exclusive access to intellectual property, such as patents and the contract management of collaborative R&D projects with industries. When exploring these challenges I have tried to understand to what extent could negative effects be mitigated by adjusting the contractual terms for access to and management of intellectual property. Exploring these challenges involves analysing which different identified dimensions of knowledge access such as ownership, user rights, publication, and further research, are differentially impacted by the degree of public funding. This, as previously explained, has been explored from the industry side (Czarnitzki et al., 2015b, Czarnitzki et al., 2015a). Czarnitzki et al. investigated a number German scientists collaborating with different industries and found that increasing industry funding of research can restrict the dissemination of results and materials. A different source of funding is governmental research agencies. Salter et al explored how collaborations between university and industry are on a regularly basis funded by public funding agencies and the rational behind the importance of public funding sources (Salter & Martin, 2001). I claim that an increase in the share of public funding is potentially likely to be associated with a higher degree of public access to the research results,

regulated through contractual agreements. I have, however, discovered no evidence of this in prior literature. Others have also recognized this gap and the need for empirical research into the regulation of knowledge access by collaboration agreements (Perkmann et al., 2013). Thune and Gulbrandsen also looked at this from a perspective which measured prior relationship and found that defining rights and obligations takes time in the initiation phase, where parties are new to each other (Thune & Gulbrandsen, 2014). They also found that this led to 'an unclear role in the collaboration since it joined the partnerships with unspecific goals of 'getting access to frontier knowledge', 'access to relevant networks', 'access to potential new product candidates'. This indicates that knowledge monopolies are influencing, through access restrictions, the further development of research. Another study (Perkmann et al., 2011) clearly states that there is a need, from the industry perspective, for an empirical measurement system that can measure and score collaboration agreements.

This thesis has shown that universities have changed their dynamics from being focused on the 1st and 2nd missions of education and research, to being included in societal and economic development through an interplay with external parties. Universities have become the ultimate knowledge provider responsible for contributing economically, socially and politically in entrepreneurial and commercial activities in the 3rd mission and now also in the 4th mission. Intellectual property management and control becomes an important element of the balance between being able to provide exclusivity for an invention to one or more parties and being able to provide controlled dissemination, openness and other elements of controlled access to research results. This thesis shows that there is a need for a more intellectual property based control of access to knowledge in universities that perform entrepreneurial activities, as proposed by previous research (Rai, 1999); (Perkmann et al., 2013). As Perkmann et al explains: 'This limited evidence suggests, however, that academic researchers with an interest in commercialisation may employ greater levels of secrecy about their research results than their open science oriented colleagues.' Merton's norms and arguments for an absolute open approach to science and access to knowledge provide a need for an expanded, alternative and additional view on science management. Merton's views on open science and intellectual property are based on the university's need to disseminate knowledge for scientific development purposes only and not in the context of a more Mode 2 phase, which Eztkowitz and Gibbons and others later brought into the debate on accessing university based knowledge. Intellectual property is universal in its normative function, regardless of whether the user is a university or industry. It is expected by the holder of intellectual property rights that there are some access restrictions and that openness and general usage is limited. It is furthermore expected that this creates a situation in which some commercial activities or at least the activities of some economic elements are involved. This sometimes conflicts with the general idea of a university, or at least the first and second mission activities of education and research. A university is, to a much larger extent in the 3rd and 4th mission, required to control and manage knowledge through intellectual property, such that it can continue to also meet its first two missions.

9.3 Collaboration agreements and public funding of research

I have explored intellectual property with the aim of understanding how universities can improve their management of intellectual property in their interaction with other parties. Previous research has shown that there is a need to understand how universities, in their relationships with other parties, form research collaborations. This is necessary to capture how parties mutually control and share knowledge and research results and to investigate how intellectual property is accessed throughout society. The main focus of this thesis has therefore been to shed light on university-industry research collaborations through the empirical analysis of research collaboration agreements in which parties negotiated and agreed to the sharing of research results and level of access to intellectual property.

The different phases of sharing and developing knowledge in university-industry collaboration projects funded by RCN is described in figure 10. This is a standard way of setting up projects that involve both a public institution and a private industry. As a number of authors have proposed in the literature, there is a need for both data access, specific research and for models of how public funding impacts the management of and access to research in university-industry collaborations (Perkmann et al., 2013, Czarnitzki et al., 2015b). The intentions of the parties and the project results framework is most easily studied in the agreements and contracts in project development. It is possible to study, based on those results and at a later stage, how and when restrictions are created and their impact on the actual results. I then compare the intentions and motivations with the actual outcome.

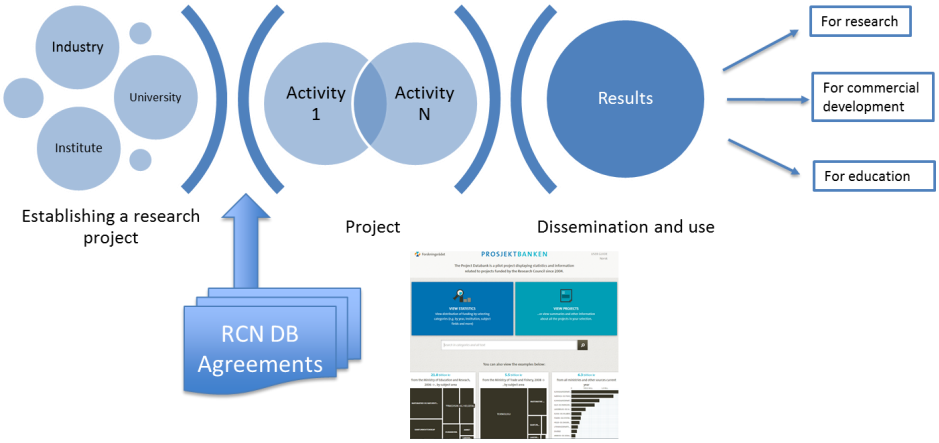

Figure 10: the different phases of project development in a RCN funded collaborative research project.

I investigated empirically, using the unique data material, what was agreed before a project started. Agreements provide the best source for studying the intentions of the parties and the framework of the project results. How and when restrictions are created,

and their impact on the actual results can later be studied, comparing the intentions and motivations with actual outcomes. This not only needs to take into consideration the context in which intellectual property is integrated into university activities, but also the context in which intellectual property is embedded with collective societal and economic activities when developing and utilizing new knowledge.

As presented in this thesis, a new coincident with the increase in university patent filings in biotechnology is the emerging CRISPR biotechnology research tool developed by leading US and European universities (Contreras and Sherkow, 2017). This universal genome editing tool is in the process of being commercialized through university spin-off companies and with larger industry partners. There is an intellectual property dispute between some of the universities who control these patents, which might potentially lead to parts of the CRISPR knowledge not being utilized (Sherkow, 2015). I have thus investigated the patent landscape of CRISPR and through this exemplified how university-industry intellectual property management shapes future access to biotechnology knowledge and research results. This case has allowed the research in this thesis to discuss the ethical implications of intellectual property control and sharing mechanisms by looking at different ways of providing utilization that might have implications for implementation of public funded research in society.

9.3.1 **Control of access to research through contract management**

I have in this research, developed a model and a tool for analyzing access to knowledge through the large RCN dataset of university-industry collaboration agreements. I investigated, using this model and tool, how ownership rights for intellectual property and public access are being agreed in research collaboration agreements ex ante research collaborations between parties. It has been explored whether knowledge monopolies are emerging on the industry or the university side and this has been combined this with an analysis of public access provisions such as publication and confidentiality. It has been observed from the analysis of 8000 collaboration agreements and 312 projects funded by RCN that when universities provide and manage access to knowledge, that the most important aspects in the early stages of a research collaboration with external parties are aspects such as ownership, rights to commercial use, publishing and confidentiality. The parties can, in these collaborations, enter into agreements in which publishing and confidentiality do not interfere. The motivations behind their engaging in an agreement most likely differ. Different European countries have different public funders, all with different funding schemes. This particular study is based on funding from a Norwegian national research agency but still subjected to similar policies and research funding norms throughout Europe.

Most are also subject to their national strategic innovations and economic development programs. These funding schemes have their own collaboration dynamics. Intellectual property rights regulation is, however for all, mostly subject to the same reference point,

the EU research framework and the legal regulation of collaborations through both the earlier Framework programs and now the Horizon 2020 program.

The RCN Project Databank displays statistics and information related to projects funded by the council. This data goes back to 2004. Figure 11, which is also discussed in thesis paper no.3 and 4, explains the RCN contract management framework, Norway's major funder of public research. RCN participates in the interplay and contributes by funding collaboration between universities and industries and with research institutes. The RCN contract management framework, its general terms and conditions, IPR policy and contract templates create a baseline. Collaboration parties create their own set of collaboration agreements that are intentionally based on the RCN baseline.

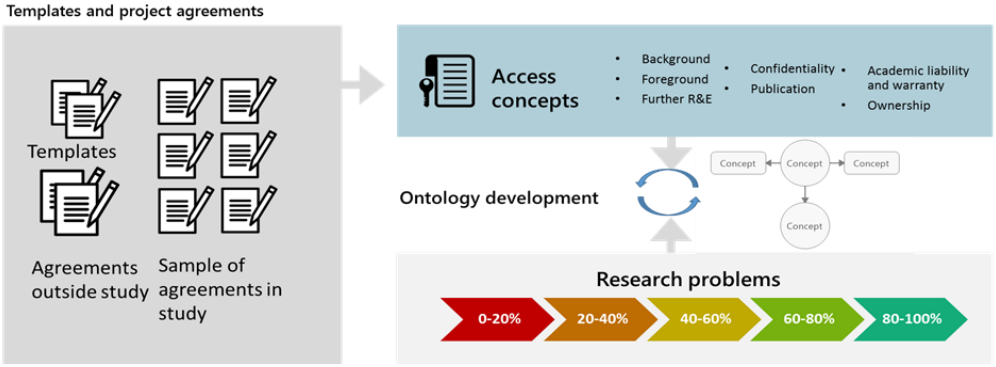

Figure 11: The RCN contract management framework and its relation to the degree of funding.

9.3.1.1 Intellectual property access ontology

An ontology is, in the philosophy of science, a description of what exists within a limited area. Understanding research collaboration agreements required an ontology of access that was developed during this thesis for identifying variables for empirical analysis. The university-industry collaboration agreements that regulate RCN projects were the central element of the empirical investigation of this thesis. There are many contract models, and RCN provides what can be called agreement templates. There are also agreements for European research projects, many agreements working well. These, as a whole, provide a good basis for finding best practices. For inspiration in the development the EU Horizon 2020 contractual model, the EU's sixth and seventh framework program, DESCA agreement templates, Lambert Toolbox and agreements I knew and had worked with in the past have been analysed. In addition, RCN's contract templates have been used as a reference guide. A tree structure was developed based on the mind mapping of different access terms for knowledge control and intellectual property based on inspiration from these contract regimes and templates. Access rights terms in research collaboration agreements are unrelated to terms agreed on confidentiality. The result was the overview shown in figure 12, which is also discussed in thesis paper no. 3 and 4.

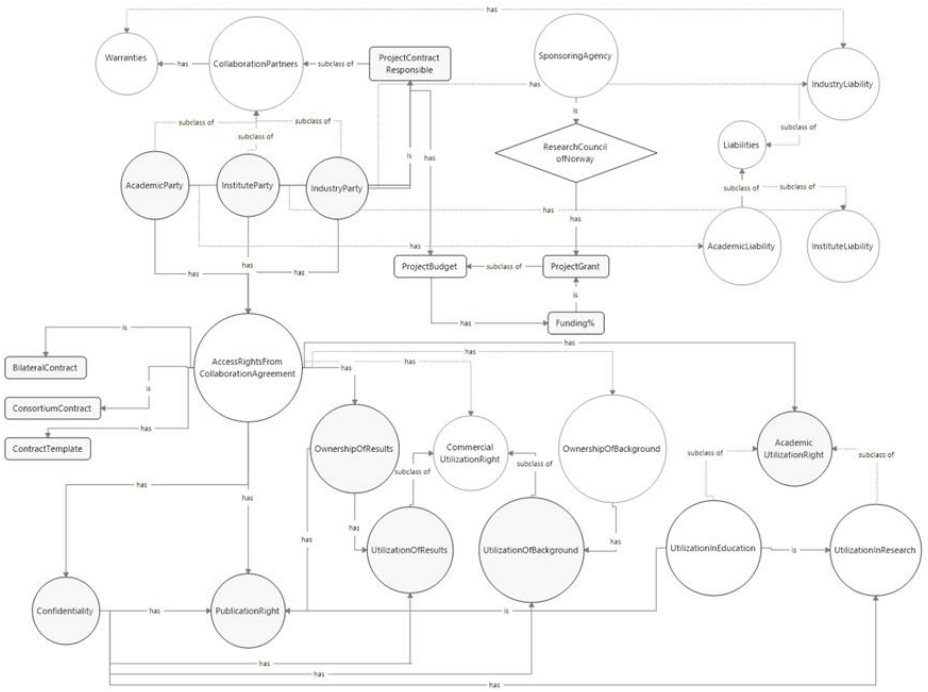

Figure 12: Ontology for access to research results in collaborative projects. Developed together with Haakon Thue Lie, Ph.D. candidate NTNU (Egelie et al, 2018a and 2019-unpublished, submitted for review).

The purpose of the ontology is to contribute to the understanding of the access concept in terms of intellectual property. The ontology is based on common terms and expressions used in research collaboration agreements between university and industry parties. Common clauses, terms, and terminology used in template agreements from public collaboration agreements used within the European research area were investigated.

The ontology was then adapted to the scoring model in previous shown table 2, which is also discussed in more detail in thesis paper no.3 (Egelie et al., 2018a). The scoring model included parameters found in RCN project agreements, parameters that are related to the research question and to the wider concept of 'access.' The four access concepts found in collaboration agreements are all related to openness in their broad definition

The focal point of the table 2 is the concepts of access. I grade each of the parameters in the model with a score from 1 to 5 depending on the descriptions of the ontology terms. A score of 5 represents the highest degree of openness. The university owns the results, which will be publically available. This does not preclude patents being owned by the university. It may preclude universities from using trade secrets as an appropriation mechanism unless the industry partners agree. A score of 3 indicates a balanced situation. All foreground IP is jointly owned. Results will normally be published, but the university

can agree to it being kept secret. A score of 1 indicates that the industry has ownership and can require that all results are kept confidential in perpetuity. The university partners are liable if confidential results are published.

9.3.2 **Intellectual property and access to biotechnology research**

I have investigated how the results from a particular research platform played out in a true commercialization and knowledge transformation process (Egelie et al., 2016). The CRISPR/Cas9 technology has issued a number of patents, and a number of universities have patent applications that relate to this technology. This thesis is comprised of a patent landscape study which highlights the major patent holders and its inventors and some geographical and technical characteristics of the patent landscape where two of the parties are involved in a major patent dispute. The top ten patent holders and the number of patent applications filed by each (percentage of the total) have been determined. MIT is the top patent holder, followed by Harvard College and the Broad Institute. In the analysis, it was revealed that one of the parties in the dispute over the patents, MIT, Broad Institute and Harvard together hold 119 patented inventions. The other party in the patent dispute, University of California, at the time, was holding 14 patented inventions. The list of the top ten patent holders was based on a search of the keywords CRISPR and Cas9 in the patent database from Thomson Innovation. The number of total inventions represents patent families, each family representing one unique invention. The unit is the 'number of inventions.' Patent families are counted in this, each including the set of granted patents and published patent applications for a given invention. The study shows that the patents have been licensed to a number of companies and that numerous patent applications have been filed. Broad Institute and UC Berkeley only issue exclusive licenses in this field of use. An exclusive license agreement was concluded between the Broad Institute and Editas Medicine for 'human therapeutics,' the exclusive license only granting one sublicense. UC Berkeley and the University of Vienna granted an exclusive license in all fields of use to Caribou Biosciences, the licensee granting an exclusive sublicense to Intellia Therapeutics in the field of human therapeutics. E. Charpentier co-owns patents licensed to Caribou Biosciences by UC Berkeley and the University of Vienna and also granted an exclusive license to ERS Genomics in 'all fields of use except human therapeutics' and an exclusive license to CRISPR Therapeutics for human therapeutics. The exclusive licensing has, for all, been granted to a surrogate company formed by the university and one or more of its researchers. This has concentrated control of the use of CRISPR in a for-profit entity. Short and long-term goals are, however, likely to be in conflict with the broad dissemination of the CRISPR-Cas9 gene-editing technology. The licensing landscape for human therapeutics may appear uncomplicated but is complex for many uses of CRISPR within human therapeutics.

None of the CRISPR/Cas9 players are discussing a broad, non-exclusive, commercial licensing program, one that would make the technology platform widely and efficiently available to the many competing commercial applications that are likely to arise at fair and reasonable terms. Figure 13, which was developed for thesis paper no.1, indicates that it seems that for CRISPR/Cas9, the university technology transfer units have given

up the role of securing broad knowledge access, by handing over exclusive rights to venture capital-backed commercial entities (Egelie et al., 2016).

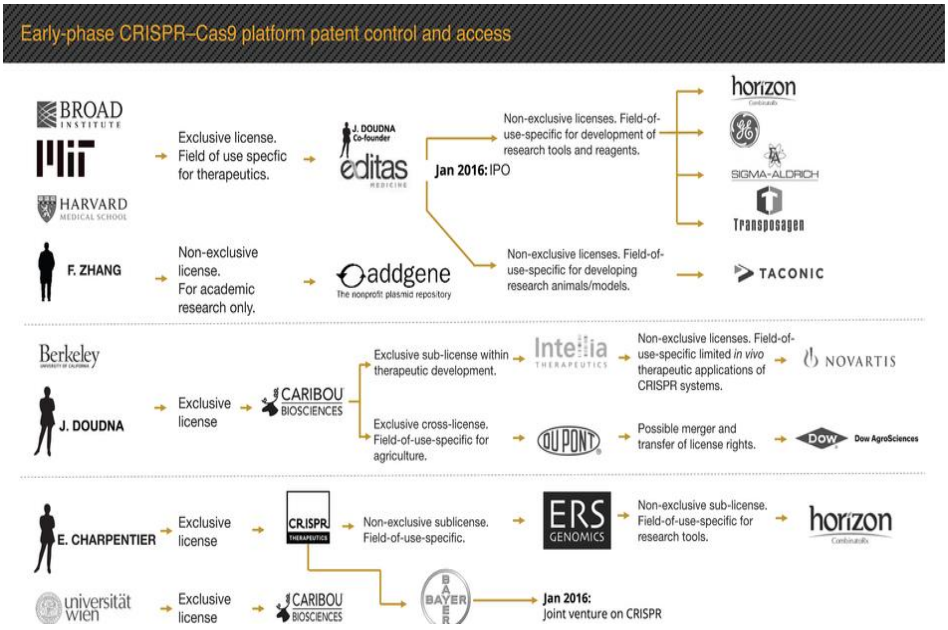

Figure 13: the main patent holders of the initial CRISPR/Cas9 technology and its licensees (Egelie et al., 2016).

It can be asked how likely is it that the commercial entities that are now in control will decide that broad, non-exclusive sublicensing is a viable business model. This is where university and governments should explore access and sharing models in the management of intellectual property.

Biotechnology differs from many other disciplines of technology and science in that it involves a strong general public interest and concern about how the technology and research are conducted and disseminated. Ownership and control of biotechnology knowledge are essential in the commercial utilization of knowledge that is based on publicly funded research and becomes critical in the discussions. Cook-Deegan et al. argue that such discussions include important moral, ethical, and religious questions, as they deal with fundamental issues of human life (Cook-Deegan & Heaney, 2010). James Watson and Francis Crick discovered the structure of deoxyribonucleic acid (DNA) in the early 1950s (Watson & Crick, 1953). Since 1980, when the US Supreme Court ruled that living organisms that are modified by genetic engineering could be patented, there have been many biotechnological breakthroughs in which patent protection has been a major part of the development of the technology (Robinson & Medlock, 2005). I discuss in thesis paper no.2, on the ethics of universities involved in patenting, the balance between the university as an autonomous, self-regulating institution of intellectual

property vs. a model in which the state takes control of access to intellectual property. Figure 14 outlines the balance between a public self-regulative model and the federal regulation model discussed in the paper (Egelie et al, 2018b).

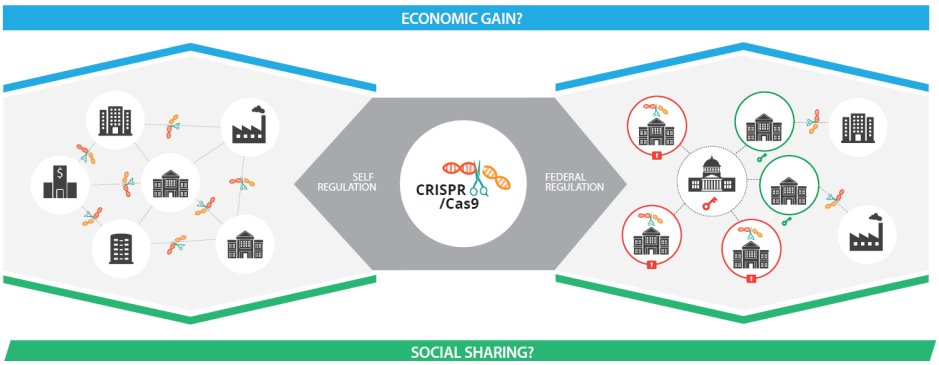

Figure 14: Self-regulation (Public) model vs. Federal regulation (State) model for access to research results need to be explored and developed further for ethical obligations universities have for giving access to research platforms, such as CRISPR (Egelie et al, 2018b).

In a self-regulation model, universities provide access to disruptive research tools such as CRISPR/Cas9 through different bodies such as universities, industries, spin-off companies and ventures without any major interference by federal authorities. In the federal regulation model, access to university-based CRISPR solutions are provided through state decided regulations, policies, and laws because of the long-term importance of maintaining control of and access to these disruptive research tools and appurtenant knowledge. The discussion in this thesis centers on which models provide a more balanced solution between a commercial, economic gain focus and the broader social sharing aspect of access to biotechnology research platforms such as CRISPR/Cas9. There is no clear answer. The case study of CRISPR/Cas9 and the empirical investigations indicate that a stricter intellectual management regime and control of the research prior to collaboration with other organizations might be necessary for a university to maintain access to these research results. This, however, needs to be further explored.

10 Conclusions and suggestions for further research

The university of the 21st century is a highly diverse and dynamic institution. It is debated whether the activities related to industry collaboration can and should reinforce the university missions of teaching and research (Etzkowitz and Leydesdorff, 2000). This thesis makes the case that embedding the 4th mission of knowledge distribution with the other three missions of the university and viewing the four missions as mutually constitutive, is essential for the future coherence of the university in both the first, second, third and fourth mission dichotomy where management of intellectual property is critical. A fourth mission is, as proposed and also expanding the thinking of Petrusson et al.,

emerging that requires these considerations when it comes to intellectual property management. The thesis furthermore provides reflections based on the debate from existing literature of Merton, Etzkowitz, Gibbon, Perkmann, Jakob and others who have discussed the challenges of universities balancing dissemination and sharing knowledge, through intellectual property mechanisms and control to facilitate structured sharing.

10.1 From the 1st, 2nd and 3rd university missions to the 4th - access control by intellectual property management

As figure 15 explains in relation to the four missions of the university, there is a relationship between levels of intellectual property control, open innovation control and the different levels of university engagement in society.

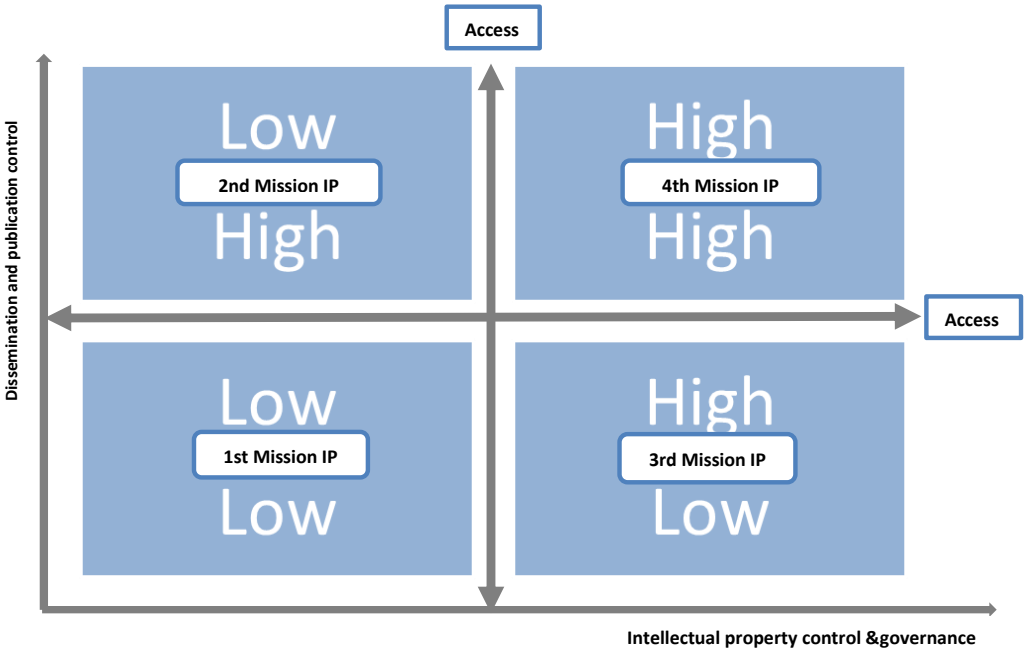

Figure 15: University intellectual property access quadrant is showing the state of intellectual property control in the four different missions of the university.

The Low-Low attention quadrant is describing a state in which intellectual property control and governance for the 1st mission IP and upon dissemination and publication control is in focus. Access is, in this state, fully open and all results are disseminated. There is no attention on protecting, controlling or managing IP. Examples include education, in which institutions have no production of or need for intellectual property control. The focus is on producing knowledge-skilled people, trained to perform elsewhere in society. These organisations are also focussed on controlling the

dissemination of research because their main task is to educate students and perform teaching activities.

The Low-High attention quadrant is a state in which intellectual property control and governance in the 2nd mission IP of research is in focus. This state requires high attention upon dissemination and publication control. Organisations in this state are partly open and disseminate through journals, conferences, and other publication means as part of providing professional science to society. There is some external cooperation which requires some focus on managing and controlling research. There is no focus on protecting these research results through intellectual property rights, as these organisations frequently share research and research results with partners. Examples include research collaborations with external parties that produce joint IP and jointly collaborate on publications.

The High-Low attention quadrant requires a high focus on intellectual property control and governance in the 3rd mission IP, but there is low attention upon dissemination and publication control. Organisations, in this phase, work closely with external parties. This requires a strong focus on IP for external purposes, and for dissemination and confidentiality. Functions for managing IP internally towards external development, such as TTO's and TLO's, are set up. Researchers are, however, to some extent given uncontrolled autonomy to publish and use IP. Confidentiality might, in a number of cases and projects, be challenging.

The High-High attention quadrant is a state in which both intellectual property control and governance focus and dissemination and publication control focus in the 4th mission IP is high. Organisations in this phase are fully in control of IP management. They have a global engagement in science and knowledge development and manage dissemination so that they are able to perform open innovation in collaborations without losing control. They are able to provide knowledge to both external and internal parties in a secure, controlled and transparent manner.

In figure 15 the third mission illustrates university focus on utilization, education, and research. The fourth mission illustrates that universities also outwardly participate through combining activities within education, research utilization of knowledge and proactive economic development. As this thesis has shown, both through the CRISPR/Cas9 case study and the contract management study, the university needs, in this High-High state, an intellectual property focus to function both as a catalyst and engine of the economy. The universities operating in this state are universities made up of a community of experts, researchers and entrepreneurs, which is a result of large international cooperation and networks. The management of these universities is responsible for important strategic and operative activities. Intellectual property and access to and control of this is, in this role, is emphasized. Regulation focus like the proposed self-and federal regulation models, and intellectual property access models like the one proposed in this thesis, is needed to be able to provide booth public funders

of knowledge production and universities as intellectual property producers, with tools to be able to control and make knowledge widely accessible.

Figure 15 and the intellectual property quadrant explains how management of knowledge through clear intellectual property control is essential in providing society with a better option for accessing and making use of research results as the university moves from being only concerned with education and research towards providing contribution in entrepreneurial activities and even further into a 4th mission of being a core provider of knowledge in societal and economic development. How this should be achieved and how to adapt this to the 21st-century fast-growing knowledge economy has been explored in this thesis and the sub-parts of the research publications. This thesis provides studies and suggestions that could improve intellectual property management for universities and other public institutions. The thesis furthermore provides suggestions on how university can control and manage knowledge in a relationship with other parties that broadly integrates with societal needs. The issue of universities' ability to access knowledge through intellectual management has been explored by looking at current practice and developing models of use for the further development of a best practice. The creation and dissemination of knowledge are at the heart of every activity performed by the university. The challenge is realising how this knowledge can best be utilised as an asset in a way that can provide maximum value to the economy, to society, and to the university. Many universities have started to commercialise intellectual property that is built on their research results and know how and to mix this with industry parties and others through collaborations in various forms. These collaborations are often regulated through agreements.

The research problem that is the core theme of this thesis is the intellectual property and collaborations are managed in university-industry research development. This theme opens more areas to explore. The results of the research also indicate that there is a positive correlation between the degree of public funding and public access to the results and publication. It may be important to understand how public funding agencies like the RCN can ensure the best possible social benefits. I have used a method to study the agreements which are furthermore a useful tool for understanding a portfolio of research collaboration agreements. An organization can use this way to view contracts, to assess whether they actually provide the use rights and ownership of research results that they strategically want.

A key conclusion in this thesis is that academic institutions and policymakers must formulate and implement coherent and feasible intellectual property management strategies in the management and sharing of intellectual property within the biotechnology sector. Such strategies must involve a clarification on how the universities, on behalf of the public, utilise knowledge and research results. Access to and academic use of disruptive research tools such as CRISPR are already having an impact on the creation of new knowledge of biological systems. Commercial use of CRISPR tools in health care, agriculture and food will be governed by the interaction of

intellectual property-regulatory-public perceptions. A key contributor to this will be university intellectual property management.

10.2 Further research need

This thesis, to the best of my knowledge, is the first empirical survey that provides empirical evidence of the problems of access to university intellectual property. This is in particular associated with the consequences of exclusive access to intellectual property. Examples include the patent and contract management of collaborative R&D projects with industries and the degree to which they could mitigate negative effects by adjusting the contractual terms for access to and management of intellectual property. It has been explored how universities funded by a public research agency manage access to intellectual property for some technologies. I have developed a model that could be used to analyse collaboration project agreements and how to manage the sharing and access to knowledge-based research results downstream. There is, however, a need to complement this investigation with the results from such project developments, and downstream the collaborations in which project results are possibly to be utilized. One thing is to agree upfront on what is supposed to be the ideal world. But what happens, in reality, might be something totally different.

A tool and model to measure contractually regulated access to research results has been developed for this unique data source and material. The access ontology and scoring model can be developed further and become practical tools for contract management. The tool and result can be furthermore used in evaluations of the effect of policies of funding agencies. It is also believed that the method can be adapted to similar future research into public research public funding agencies similar to the RCN, including in other countries. What it is important to note is that the model does not reflect actual access to research results once the results have been produced. It only reflects the idealized starting position agreed contractually. The empirical analysis investigates the contracts during the initial collaboration negations. It does not investigate how the results of the research collaboration are further utilized and under what terms compared with the terms of the collaboration agreement entered into prior to the project collaboration. This is a possible follow-up action that could further confirm some of the findings the relationship between access and public funding proposed in the thesis.

The discussion, tools, models, and results developed in this thesis is relevant to research and innovation policy-makers, university management and leaders who are discussing strategies, contract management, and knowledge access development. The theses are in particular relevant in relation to the linking of teaching, research, and third mission activities such as commercialization and entrepreneurship. The studies have implications for academic institutional innovation strategies. As shown the university sector is highly diverse and different missions of activities are being pursued as Etzkowitz and others have shown. The way the third mission can mutually reinforce the missions of teaching and research will be different in each organization. This research

demonstrates a way to evaluate such feedback for all parties and organisations involved in collaborative agreements.

The scoring model that has been developed has been used on a unique data set purpose-based established for this research. The data set has been used to analyze correlations between types of collaboration projects, public funding and the regulations on access to the research results. During the work with the model, I realized that additional use of the model could be for studies on how knowledge flows within a university and between universities and industry. The scoring model can be used to predict to what extent there can be contributions from research collaborations to a university's different missions: education, research, and entrepreneurship. The scoring model can also be used by managers in industry to better assess their access to the research results. Thus, the model can also serve as a tool for the parties during negotiations for the establishment of the collaborative project. I am optimistic that the data set, the scoring model and the results will improve the understanding of the trade-off between public, and private sponsorship of academic research involves gauging the impact of disclosure restrictions on the quantity, quality, and evolution of academic research and, ultimately, the influence on innovation and economic growth.

10.3 **Final remarks**

The aim of this has been to improve policymakers understanding of cause and effect between patent data and the use of such data in academic and industrial research and development when it comes to the research collaborations and contractual relationships. The thesis is a suggestion for how to improve the use of collaboration agreements and their framework. It is also a suggestion on how to improve patent data as a source to increase the understanding of managing intellectual properties in the creation of research results. The scope of the thesis have implications for public funding bodies and for science, technology and innovation policy. University managers and leaders must continue to develop solutions for improving access to knowledge and intellectual property in a reality where integration is becoming more important and where application-based research is increasing. As such this thesis is a contribution in the landscape of university intellectual property management where the aim is to create more innovations based on public funded research results while in parallel being able to disseminate the research finding and continue to explore new research.

Appendix A: Additional statistical tables

Variable	Mean	Std. Dev.	Min	Max
Ownership score	3.135	1.193	1	5
Foreground IP score	2.753	0.886	1	5
Publications score	3.151	0.825	1	5
Confidentiality score	2.827	0.880	1	5
RCN funding share	58.032	21.842	8.48	100
Number of industry partners	4.580	4.067	0	35
Number of university partners	2.212	1.827	0	11
Total project budget (mio. NOK)	32.034	60.127	0.2	384
Biotech	0.231	0.422	0	1
Energy	0.340	0.474	0	1
ICT	0.093	0.291	0	1
Ocean	0.163	0.370	0	1
Other	0.173	0.379	0	1
Year 2009	0.038	0.193	0	1
Year 2010	0.038	0.193	0	1
Year 2011	0.064	0.245	0	1
Year 2012	0.112	0.316	0	1
Year 2013	0.221	0.416	0	1
Year 2014	0.250	0.434	0	1
Year 2015	0.093	0.291	0	1
Year 2016	0.183	0.387	0	1

Table 3: Descriptive statistics

		1	2	3	4	5	6	7	8	9	10	11	12	13	
1	RCN funding share	1.00													
2	Number of industry partners	-0.06	1.00												
3	Number of university partners	0.05	0.08	1.00											
4	Total project budget (mio. NOK)	-0.22	0.54	0.25	1.00										
5	Biotech	0.10	0.01	0.15	0.05	1.00									
6	Energy	0.05	0.17	-0.12	0.07	-0.39	1.00								
7	ICT	0.00	0.08	-0.02	0.03	-0.18	-0.23	1.00							
8	Ocean	-0.06	0.10	-0.14	0.06	-0.24	-0.32	-0.14	1.00						
9	Year 2009	0.03	0.15	0.00	0.28	-0.07	0.17	-0.06	-0.04	1.00					
10	Year 2010	0.07	0.04	-0.06	0.05	-0.09	0.00	-0.11	-0.09	-0.04	1.00				
11	Year 2011	-0.04	0.04	-0.08	0.13	-0.08	-0.02	-0.05	-0.06	-0.05	-0.05	1.00			
12	Year 2012	-0.04	-0.08	-0.06	-0.09	-0.03	-0.09	-0.04	-0.07	-0.07	-0.07	-0.09	1.00		
13	Year 2013	-0.07	-0.11	-0.12	-0.08	-0.05	-0.06	-0.02	-0.01	-0.11	-0.11	-0.14	-0.19	1.00	
14	Year 2014	-0.13	-0.05	-0.10	-0.14	-0.09	-0.09	-0.08	-0.11	-0.12	-0.12	-0.15	-0.21	-0.31	1.
15	Year 2015	-0.08	-0.12	-0.06	-0.13	-0.06	-0.11	-0.01	-0.01	-0.06	-0.06	-0.08	-0.11	-0.17	0.

Table 4: Pairwise correlations (n=312)

	Ownership	Foreground	Publications	Confidentiality	Ownership	Foreground	Publications
Share of RCN funding	0.022***	0.010***	0.006**	0.005	0.021***	0.009***	0.004
	(0.003)	(0.002)	(0.003)	(0.003)	(0.004)	(0.002)	(0.003)
Number of industry partners	0.011	0.023	-0.008	-0.004	0.016	-0.029	-0.059**
	(0.017)	(0.030)	(0.014)	(0.013)	(0.036)	(0.045)	(0.029)
Number of industry partners (sq.)					0.000	0.003**	0.003**
					(0.001)	(0.001)	(0.001)
Number of university partners	0.089**	0.047	0.048	0.056*	0.252**	0.136	0.257**
	(0.043)	(0.042)	(0.042)	(0.033)	(0.101)	(0.108)	(0.124)
Number of university partners (sq.)					-0.019*	-0.009	-0.024*
					(0.011)	(0.011)	(0.013)
Total project budget (mio. NOK)	0.002*	0.001	0.001	-0.001	0.002*	0.000	0.000
	(0.001)	(0.002)	(0.001)	(0.001)	(0.001)	(0.001)	(0.001)
Biotech	-0.121	0.251	-0.152	-0.126	-0.155	0.262	-0.172
	(0.273)	(0.235)	(0.149)	(0.140)	(0.274)	(0.247)	(0.136)
Energy	0.036	-0.436***	-0.388*	-0.021	0.015	-0.422***	-0.393*
	(0.193)	(0.160)	(0.212)	(0.120)	(0.191)	(0.152)	(0.204)
ICT	0.021	0.576***	-0.475**	0.175	-0.021	0.571***	-0.522**
	(0.298)	(0.168)	(0.221)	(0.153)	(0.274)	(0.168)	(0.216)
Ocean	0.182	0.16	-0.19	0.2	0.166	0.169	-0.199
	(0.167)	(0.173)	(0.148)	(0.142)	(0.163)	(0.170)	(0.141)
Year dummies	included	included	included	included	included	included	included
Pseudo R2	0.09	0.09	0.06	0.10	0.09	0.10	0.07
N	312	312	312	312	312	312	312
LR/Wald chi2	250.912	151.997	101.981	667.431	451.061	302.645	125.671
P-value	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Log likelihood	-355.663	-363.323	-356.095	-349.987	-354.476	-361.422	-352.838

Table 5: Ordered probit regression results for the dimensions of access

Publication I

Egelie et al.
The emerging patent landscape of CRISPR-Cas gene editing technology
Nature Biotechnology, 34**,** 1025-1031. 2016
Reprinted with permission from *Nature Biotechnology*

Publication II

Egelie et al.
The ethics of access to patented biotechnology research tools from universities and other research institutions
Nature Biotechnology, 36, 495-499. 2018

Publication III

Egelie, Grimpe, Sørheim and Thue Lie
Public Funding of Collaborative Research and the Openness of Research Results
Published and presented at DRUID 2018
Reprinted with permission from DRUID

Publication IV

Egelie, Grimpe, Sørheim and Thue Lie
Access and openness in biotechnology research collaborations between universities and industry – an empirical study
Submitted for review, Nature Biotechnology, April 2019
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PUBLIC FUNDING OF COLLABORATIVE RESEARCH AND THE ACCESS TO RESEARCH RESULTS

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Abstract

Does public funding of collaborative research between academia and industry associate with the access to project outcomes and research results? To answer this question, we investigate the contractual terms of 312 publicly funded research projects in Norway. We provide an in-depth analysis of the terms on which the partners involved in a project agree to, concerning the ownership of research results, the distribution of rights to all commercial use of intellectual property, the provisions regarding the dissemination and publication of project results, and the degree of confidentiality. Overall, our results indicate a positive, even though weak, relationship between public funding and the various dimensions of access and openness, with the association being strongest with the ownership of research results. Moreover, we show that the institutional composition of the project determines the project's openness and the access to the project's research. Our study has implications for public funding bodies as well as science, technology and innovation policy.

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ABSTRACT

Does public funding of collaborative research between academia and industry associate with the access to project outcomes and research results? To answer this question, we investigate the contractual terms of 312 publicly funded research projects in Norway. We provide an in-depth analysis of the terms on which the partners involved in a project agree to, concerning the ownership of research results, the distribution of rights to all commercial use of intellectual property, the provisions regarding the dissemination and publication of project results, and the degree of confidentiality. Overall, our results indicate a positive, even though weak, relationship between public funding and the various dimensions of access and openness, with the association being strongest with the ownership of research results. Moreover, we show that the institutional composition of the project determines the project's openness and the access to the project's research. Our study has implications for public funding bodies as well as science, technology and innovation policy.

Keywords: Collaborative research projects, public funding, openness, access, intellectual property

INTRODUCTION

Prior research has frequently shown that firms benefit in their innovation performance from collaborating with universities and research institutions (Howells, Ramlogan, and Cheng 2012, Steinmo, 2015). However, these collaborations may suffer from tensions related to different institutional logics, where firms often focus on innovation outcomes. University researchers, on the contrary, are primarily driven toward long-term outcomes and their publication reputations in the international arena (Becher & Trowler, 2001; Steinmo, 2015), i.e. toward disclosure and openness of research results. Researchers will focus on their autonomy and research freedom based on curiosity-driven research. Firms will try to regulate this freedom and drive researchers' actions in the directions of the firms' need (Ankrah & Al-Tabbaa, 2015; Perkmann, King, & Pavelin, 2011).

Previous research indicates that industry funding of academic research is preventing access to public research, especially publication and dissemination of research. It seems that industry prefers secrecy over disclosure to increase the appropriability of the returns from research performed in collaboration with public science (Gans & Murray, 2012). A key issue then is the regulation of access to research results. The firm will impose limitations on disclosure of research results, keep the results confidential and try to protect and control the knowledge developed (Bruneel, D'Este, & Salter, 2010). Thus, the contractual terms of university-industry collaboration agreements will frame and limit the exchange of knowledge, and thus the openness of and access to the research results.

However, studies of actual contractual terms and how these influence access and utilisation of research results are scarce. There is a dearth of studies on how access to research results is regulated in contracts between universities, public research institutions and industry

partners. Moreover, university-industry collaborative research is often sponsored by public funding bodies. Intuitively, we would expect an increasing share of public funding to be associated with a higher degree of the public's access to the research results. However, little empirical evidence exists on this relationship despite its obvious interest and relevance for science, technology and innovation policy. This gap is also recognised in previous research as the need for research on real contracts regulating knowledge access is called upon (Perkmann et al., 2013).

This paper builds on unique data from 312 research projects and includes agreements between 2507 partners. These are projects funded by the Research Council of Norway, RCN. The degree of public funding in the 312 projects is between 19% and 100%. Our exploratory study investigates the correlation between the degree of public funding of collaborative research projects, the participation in the projects from academia and industry, and the extent to which restrictions to the openness of research results are imposed. We focus on four dimensions of access and openness: the ownership of research results, the distribution of rights to all commercial use of intellectual property, the provisions regarding the dissemination and publication of project results, and the degree of confidentiality.

Overall, our results indicate a positive, even though weak, relationship between public funding and the various dimensions of access, with the association being strongest with the ownership of research results. Moreover, we show that the institutional composition of the project determines the public access to the projects' results. Specifically, we find access and openness to be driven by the number of industry partners and universities in the projects. Our results have implications for public funding bodies as well as science, technology and innovation policy.

BACKGROUND AND RELATED LITERATURE

In industry-university collaborative research projects, the tension between the institutional logics is reflected in the agreements they do for openness and access to the research results. Openness is a term for to what extent the knowledge is available, and not kept confidential. Access is a term for to what degree the parties can utilise the research results, commercially, for further research or in education. Collaborative research projects are framed by agreements with contractual elements regulating access. The agreements define different concepts, such as ownership to the results, the right to publish and the need to keep information secret. We see the tension between the parties reflected in how they agree on sharing, publishing and giving access to the knowledge (Thune & Gulbrandsen, 2014).

The projects in our study all relate to the project development process at the RCN as explained in figure 1.

[Figure 1 about here]

The figure explains the three typical phases of a research collaboration project funded by RCN. In the first phase, the project is established by agreeing on a framework between the different parties. Between the phase of establishment and the project phase, the collaboration agreements are discussed, negotiated, prepared and agreed before the project begins in the second phase. The third phase we have named “Dissemination and Use”. In this last phase, it will be of importance what the parties have agreed contractually in the collaboration agreements. However, what is agreed contractually might not be what the parties do. The focus of our study is the period between Establishment and the Project phases. This is when the partners negotiate the details of the collaboration agreements. Our study and models concerning what the parties agree contractually before the actual research collaboration has started. As such it is possible that

the degree of access evaluated in our study differ from the next two phases where the collaboration agreements are set into practice.

There is a rich literature on university-industry relations. A thorough review of academic engagement is in (Perkmann et al., 2013). These relations are broader than the contractual relations, the agreements, that we study. However, in our evaluation of the agreements, we focus on the managerial aspects and not on the agreement as a legal document. The agreements will have details on how the parties expect one another to act, who owns and control the research results, who may have access to results and background needed for utilisation, and how the parties will resolve possible conflicts. Research may have a high degree of uncertainty about the possible utilisation of the results. The agreements that we study can in many cases be part of a long relationship between the parties. The agreements are also records that "represent an ideal source of information but are not readily available because they are often considered commercially sensitive …" (Perkmann et al., 2013, p. 411).

The results from university-industry collaborations can be the basis for new industries and platform technologies. The access to the research results is balanced with the control mechanisms. The control can be in the form of appropriation mechanisms such as patents and trade secrets, and it can also be agreed contractually. As examples, this balance of control and access is discussed for the development of DNA technologies in (Cook-Deegan & Heaney, 2010) and the recent development of CRISPR-Cas9 in (Egelie, Graff, Strand, & Johansen, 2016). A difference between these two technologies is to what extent the universities had control over research results and how they gave access to others, e.g. by licensing to industry.

The industrial partners in university-industry collaborations may wish to restrict publication of the research results. They may thus use the contractual control to keep proprietary

benefits and reduce public access to the results. A survey-based study of German academic researchers shows that higher industry sponsorship means increased publication delay and secrecy (Czarnitzki, Grimpe, & Toole, 2015). That study looks at the industry sponsorship with reference to OECD showing a shift from public to the private sponsorship of research. This shift is an aggregated shift for all countries surveyed. Now, as examples, for Norway, Germany and the USA, government spending increase, whereas in Denmark there is increased industry sponsorship (OECD, 2017). For policymakers, it is then of interest to understand how the degree of funding relates to what extent the public gets access to the research results.

We opinion that there are instances where the active ownership of universities is crucial for the public benefit from research. An example is how the universities with control over the intellectual property managed the utilisation of technologies, such as the essential patents concerning rDNA and PCR, versus how the emerging CRISPR technology is managed (Egelie et al., 2016, p. 1025). Thus, in this study, we have assessed the universities ability to give the public access to research results. This does not mean that industry control is always negative for society. In some cases, industrial control over the research results is needed for the successful utilisation of the research results from university-industry collaborations. A measurement system for such collaborations, seen from the firms' perspective, could include our way of assessing and scoring the agreements (Perkmann, Neely, & Walsh, 2011). Thus, our model proposes a tool that innovation managers can use for analysing collaborations.

Over the past decades, universities have widened their activities beyond teaching and academic research. University research provides knowledge inputs to private-sector innovation. Universities have implemented entrepreneurial activity, and commercialisation often referred to as their "third mission" (Etzkowitz, 1998; Salter & Martin, 2001). The source of funding for the

universities can have an impact. A study of German universities shows that industry funding has a positive impact on the quality of applied research, and a negative impact on quality and quantity of publications (Hottenrott & Thorwarth, 2011).

Transfer of knowledge and technology from higher education institutions to the private sector can be performed in several ways. Research conducted by university researchers for the industry is one such. The value of such collaborative research for the innovation performance of firms is considerable (Cohen, Nelson, & Walsh, 2002; Mansfield, 1995, 1998; Zucker, Darby, & Armstrong, 2002). Cohen et al. find that firms, therefore, are funding collaborative research projects to seek direct access to the universities' knowledge. Policy makers may argue that the potential for universities to foster and accelerate industrial innovations is not yet fully exploited. The societal returns from academic research can be increased (Dosi, Llerena, & Labini, 2006): From a private-sector perspective, the benefits of collaborating with academia are found to be unambiguously positive, whereas the effects on the scientific sector are not as clear-cut.

The Triple Helix is a model explained as a relationship between universities, industry, and government, to generate new knowledge, innovation, and economic development (Etzkowitz & Leydesdorff, 2000; Ranga & Etzkowitz, 2013). The creation and flow of knowledge will often be regulated in collaboration agreements similar to those we study.

There are few examples of research on how contractual agreements on the interface between organisations affect research and development. In the study "Government Support Programmes to Promote Academic Entrepreneurship", the researchers (Rasmussen & Gulbrandsen, 2012) uses the framework of Agency theory to analyse contractual relationships. The analysis gives an understanding of the roles of the parties and how they decide on funding.

Templates for written agreement are used in many countries' framework for funding of university-industry research collaborations (Eggington, Osborn, & Kaplan, 2013, p. 33) . Together with policies and regulations, this constitutes the formal framework for university-industry collaborations. For our study, it is the Norwegian framework, as managed by the Research Council of Norway, that governs the projects we study.

The Norwegian innovation policy changed in 2003 by new legislation corresponding with the trends internationally and in the USA. The Norwegian change was inspired by the Bayh-Dole Act in the USA. In the article "Technology transfer and public policy: a review of research and theory" there is a thorough review of the following evolution of the Technology Transfer Organizations (TTO) that the universities set up as a result of the policy changes (Bozeman, 2000).

There is a typology of university-industry links in (Perkmann & Walsh, 2007, p. 263 ,table 2), which discusses the organisation and management of collaborative research. Transfer, e.g., licensing of intellectual property is categorised as a low relational involvement. Relationships, e.g., research partnerships imply a high involvement. Our study regards the framework to the access for the results from these high involvement research partnerships.

(Nelles & Vorley, 2010, p. 173) discuss the implications of funding schemes on universities. They address the need for models to be able to understand how public funding schemes are influencing such university-industry collaborations.

There have also been investigations on the relationship between industry sponsorship and restrictions on disclosure in research collaborations between university and industry. The studies of Czarnitzki & al. support the perspective that industry sponsorship jeopardises public

disclosure of academic research (Czarnitzki, Grimpe, & Pellens, 2015; Czarnitzki, Grimpe, & Toole, 2015). These two studies use individual-level data on German academic researchers. The studies indicate that there is a lack of understanding of the mechanisms in the actual contracts. Joint research projects involve the sharing of research knowledge and potentially withholding or even banning the publication of research results by academics. Contract research involves only the sharing of well-defined research information. As a result, firm employees and academics may have different preferences for the types of collaboration.

Access to the intellectual property is one of the possible indicators when evaluating the output from research collaborations (Bozeman & Dietz, 2001, p. 390). The conclusion from (Perkmann & Walsh, 2007, p. 275), citing the previous paper, is that "*Research is also needed on the appropriate indicators and measures to account for the impact of* [research] *partnerships both organizationally and for society as a whole."*

As indicated by the literature there is a need to understand the mechanisms of how university-industry collaboration projects funded by the public are performing, and how public funding schemes are acting on these collaborations. It is interest from the cited literature to develop models that can evaluate the impact of regulations and policies on the access to knowledge created in collaborative research. However, as the literature indicates, there is a lack of models for measuring how contract regulations influence the access to knowledge in industry-university research collaborations. As explicitly stated by (Czarnitzki, Grimpe, & Toole, 2015, p. 255 note 4): *"…we did not find any studies that systematically analyze the contractual terms of scientific or military-oriented contracts from state sponsors or private foundations.*"

The literature points to academic engagement being distinct from the commercialisation of research, e.g. there are different priorities. In collaborative research, the parties negotiate the terms of the projects and contractually agree on the priorities. This negotiation includes the control over the research results. Regulations and policies, from the participating and the funding parties, frame and influence the agreements.

The industrial partners in university-industry collaborations may want to restrict publication of the research results. They can then use a contractual control to keep proprietary benefits, appropriate the innovation and reduce public access to the results. The university partners may want to use such control to increase public access, allow for publication of all results and thus for use in further research and education. There is an overview of such measures in (Perkmann, Neely, et al., 2011 table 2). These measures can be used by university and industry managers alike. There is a systematic review of the literature on university-industry collaboration in (Ankrah & Al-Tabbaa, 2015). Both these articles synthesise theoretical literature, and their conclusions call for empirical studies to validate their models. Our study addresses these calls with data from collaborative research with public funding.

DATA AND METHODS

Data

We used data from 312 collaborative research projects funded by the Research Council of Norway (RCN) during the period from 2008 to 2017. Norway is a wealthy country in Scandinavia, with around five million inhabitants. Norway is not a part of the European Union but participates in the European Research Area. The RCN annually funds research with one

billion EUR per year given to around 5000 projects. In 2016, public allocations to research comprised more than one percent of Norway's gross domestic product.

Our sample is randomly drawn from a total population of 21838 projects funded by the RCN during that period. A criterion for selection was that the project would have at least one university and one industrial partner. We have been granted access to the full data that the RCN keeps on those projects, including the participants, the funding amounts and the collaboration agreements that the partners have signed with the RCN and among each other. Research institutes are identified separately. We use "academic partner" as a term for universities, university colleges and other public educational institutions. Industrial partners also encompass some public bodies that mainly have an operational focus, and some companies set up to research profit. RCN is the public sponsoring body for all the projects and the source for all the collaboration agreements. Institutes are defined as an organisation endowed for doing research for a particular defined purpose, usually organised as a foundation or as part of the government.

All these research programs are subjected to the RCN contract management program. This management includes a policy document, general terms and several template agreements for collaborative research projects. Our study investigates the results of contract management in RCN projects. We understand the agreements as a mechanism to govern public access to research results. Collaboration agreements in public research projects are central mediators in exchange of data and research results. Such agreements may restrain or facilitate sharing and access to data and research results. In the context of research policy and knowledge management, we aim to investigate the role of agreements in publicly funded research projects as a mechanism for establishing robust and sustainable access to research results and knowledge in the context of

the responsibility of the public to disseminate knowledge broadly through both education, research, and entrepreneurial activities.

The structure of projects and agreements in our data set

The agreements are managed by a project owner that is responsible vis-à-vis the RCN, and that manages the collaboration contract among the involved partners. The RCN does not review or monitor the content of the consortia project agreements (between participants), except for a few large and prestigious projects [identifying reference omitted]. The agreements are confidential, as is the identity of the projects we have studied. Our research needed special permission from the Norwegian Ministry of Education and Research. A premise is that the selection of projects and contracts in the study is only known to the principal investigators. Contact with the project participants is not allowed.

We selected projects across multiple research programs that span over the last decade. There were several practical difficulties in finding and accessing the agreements, due to archival issues. As a result, we removed projects we initially had selected because the agreements were in poor quality or not available from the archive. Also, we discarded a small number of selected projects, as they were not real research collaborations, but other grants.

In the case of projects involving partners, the project owner must enter into written collaboration agreements with all partners. Collaboration agreements are to be completed at the latest within three months after RCN has sent the contract to the project owner. RCN will not disburse any funds until they receive the collaboration agreements.

Agreements based on contract templates constitute a large body of our data set. Such templates are often initiated by the RCN or the academic institution as well as the industry

parties (to a lesser extent than the public institutions) but then subjected to negotiations between project managers and legal staff from the parties involved in the projects.

The basis for drawing up collaboration agreements

The collaboration agreements are to regulate the reciprocal rights and obligations of the project owner and partners in the project. RCN communicates directly with the project owner alone and is not a party to the collaboration agreements. RCN does not stipulate special requirements for the content of the collaboration agreements, except about certain aspects involving the distribution of rights in the project. It is up to the parties to determine the appropriate format for and content of the collaboration agreement for the individual project. Unless otherwise specified, the project owner may choose to draw up one common collaboration agreement or individual collaboration agreements for projects with multiple partners. The project owner is responsible for ensuring that the collaboration agreements comply with the terms and conditions of the contract. Partners are institutions, companies and other types of enterprise (as well as any designated individuals) that RCN, in its contract with the project owner, has stipulated are under obligation to provide professional or financial resources for the implementation of the project. The partner is responsible vis-à-vis the project owner, and the project owner is responsible vis-à-vis the RCN (The Reseach Council of Norway, 2015).

Regulation of rights to project results

The Research Council stipulates specific requirements for the regulation of ownership and rights to project results in a collaboration agreement. These requirements build on the Principles for the Research Council of Norway's Policy on Intellectual Property Rights and are set out in Sections 7.2 and 7.3 of the General Terms and Conditions for R&D Projects. Figure 2

shows the RCN contract management framework. The figure describes how the RCN contract management framework creates a baseline with its General Terms and conditions, the policy on IPR and contract templates. This is seen in relation to the subsequent collaboration research project agreement framework where the parties are creating its own set of collaboration agreements intentionally based on the RCN baseline.

[Figure 2 about here]

The agreement framework of the RCN

After a research project has been granted a pledge of funding, contract negotiations will be initiated between the Project Owner and the Research Council. The contract sets out the terms and conditions for the use of the research funding and the parties' rights and obligations about the implementation of the project. It is frequently the case that certain aspects of the grant application must be revised and updated before a contract can be signed. The contract between the Research Council and the recipient of the research funding consists of the following documents at a minimum:

- an **agreement document** that contains specification of the project's objectives, management, budget, financing, progress plans and reporting requirements;
- the **project description** that was submitted by the Project Owner together with the final, often a revised, version of the grant application;
- the **General Terms and Conditions for R&D Projects**, which are the Research Council's standard terms and conditions.

If the provisions of the various contract documents conflict with one another, the agreement document will take precedence over the General Terms and Conditions for R&D Projects and the project description. When it comes to the parties to the contract, they are the Research Council and the Project Owner (The Reseach Council of Norway, 2015).

Measures

Dependent variables - building an ontology and scoring model

We use four dependent variables that we argue to reflect the openness of a collaborative research project: the ownership of research results ("Ownership"), the distribution of rights to all commercial use of intellectual property ("Foreground IP"), the provisions regarding the dissemination and publication of project results ("Publication"), and the degree of confidentiality ("Confidentiality"). The variables are the result of a scoring model which in turn is based on an initial ontology derived from a subset of the research data. The variables capture dimensions related to the extent of openness and are defined on an ordinal scale from 1 (no openness) to 5 (full openness).

The term ontology has two connotations. The first is that of the philosophy of science. Here an ontology deals with what exists. It is a broader term than taxonomy, which means mere classification. In this first sense, (Courvisanos, 2007, p. 53) discuss and ontology of innovation in the view of critical realism. The objective is to develop a model of innovation decision-making and action.

The practical application of ontology in information science is the second connotation. Here academics describe an ontology in the form of formal statements and computer languages, with diagrams that show how the terms of the ontology are associated. A well-known example from management science is the ontology of the Business Model Canvas (Osterwalder, 2004). Such ontologies are also used in law, in knowledge management, and innovation studies. A thorough review and ontology for innovation management is provided by Bullinger (2009).

[Figure 3 about here]

Figure 3 describes the relations of all the different elements of an openness ontology in relation to a university-industry research collaboration framework. We extracted contractual terms from templates, sample agreements, bilateral and consortium agreements. These terms are related to access to research results in different ways. Based on this we built an ontology. An ontology is a sound basis for a scoring model. The ontology makes it clear what the different concepts and terms in the scoring model encompass. Also, the orthogonality of the terms, to what extent they overlap or interconnect, will be more precise. The scoring model uses concepts from the ontology. We followed the three-step methodology from (Rosemann, Green, & Indulska, 2004).

We base our ontology on common terms and expressions used in research collaboration agreements between the university and industry parties. We used our own dataset from projects funded by RCN. Also, we investigated common clauses, terms and terminology used in template agreements from public collaboration agreements used within the European Research Area:

- EU Horizon 2020, EU Framework 6 and 7, DESCA model templates (DESCA, 2017)
- The Lambert Toolkit, as discussed in (Eggington et al., 2013)
- University collaboration agreements known to us, [identifying reference omitted]
- RCN agreement templates (The Reseach Council of Norway, 2015)

The ontology was then adapted to a scoring model. The scoring model included parameters we found in RCN project agreements, parameters that are related to our research question and the wider concept of "access". We initially chose eight concepts we found in collaboration agreements that all are related to openness in their broad definition. We defined these openness concepts as briefly discussed in the following clauses.

An example of the discussions is that the definition for IPR (Intellectual Property Rights) is not a definition in legal terms, and is not ontologically unambiguous. First, we merged the terms IP and IPR. From a legal theory point of view, there is a distinction between the property and the rights to the property. There could be one invention, one property, covered by several IPRs, e.g. patent and copyright and design rights. Then we considered existing legal ontologies. As an example, the ALIS ontology shows that there are nine types of legal, moral rights, such as the "rights to reconsider right to or withdraw assignment to exploitation " (Cevenini, Contissa, Laukyte, Riveret, & Rubino, 2008, p. 173). Our decision was not to detail the evaluation at this level. Another example is that one RCN template uses the term "academic rights" as something the university or researcher will keep (The Reseach Council of Norway, 2015 "Simple Collaboration Agreement"). The term has no legal definition but is connected to the discussion on academic freedom (Wright, 2016, p. 70). We decided to leave it out of the ontology. As the difference between IP and IPR makes little difference on the discussion on access, we decided to treat the terms as equivalents, and use IP. We then defined IP and IPR, in line with many contractual definitions as:

"Intellectual Property" "IP" or "Intellectual Property Rights", "IPR" means all industrial property and property rights including patents, utility models, rights in inventions, registered designs, rights in designs, trademarks, copyright and neighbouring rights, database rights, moral rights, trade secrets, and rights in confidential and proprietary information, all whether registered or unregistered and including any renewals and extensions thereof, and all rights or forms of protection having equivalent or similar effect to any of these which may subsist anywhere in the world and applications for registrations of any of the foregoing.

We need these types of formal and normative descriptions in a complete ontology, but we do not need them in full for our discussion here. The important concepts are therefore briefly described further. “Access rights” is a term related to IP. The term means those rights (e.g., licenses or user rights) to use knowledge or Background IP given by the owners of the knowledge or pre-existing knowledge to others. Another term for this is the right to “Utilisation”. We used that term, as it better gives associations to rights for commercial and educational use, as well as for further research.

“Ownership” is regulations about who owns the relevant Foreground IP. “Foreground IP” means IP or project results generated or developed during the lifetime of the project. The term used for EU-funded research is now “Result”. “Publication” regulates the partners’ ability to publish information and results from a collaboration project. Academic researchers publish the results of their work to disseminate knowledge to the public. Universities rigorously want to protect the rights of its researchers to publish. On the other hand, companies may be concerned that publishing could reveal their confidential information or cause a loss of IP, such as patents or trade secrets, resulting from the research. “Confidentiality” regulates what information is deemed to be confidential and what is not. Clauses on confidentiality will regulate the time frame the confidentiality obligations will be in force, and what clauses will survive the termination of the agreement.

The scoring model

We grade each of the parameters in the scoring model from 1 to 5 according to different descriptions of the ontology terms. The details of the four main ones are in Table 1, below. A score of 5 represents the highest degree of openness. The university will own the results, and they will be public available. This does not preclude patents owned by the university. It may,

however, preclude the universities from using trade secrets as an appropriation mechanism unless the industry partners agree.

A score of 3, indicates a balanced situation. All foreground IP is jointly owned. It will normally be published, but the university can agree to it being kept secret. There are no provisions on further use in education and research, as the university is a joint owner. (Note that the laws on joint ownership of intellectual property are very different from country to country, see (Belderbos, Cassiman, Faems, Leten, & Van Looy, 2014) for a discussion and references.)

A score of 1 indicates that the industry has ownership and can require that all results are kept confidential forever. The university partners are liable if a confidential result is published.

[Table 1 about here]

Scoring

We analysed the projects over a period of six months and scored according to Table 1. The agreements were extracted in batches by RCN employees from the RCN archives. The initial selection was random. We then selected programs with projects extending over around ten years. We selected programs spanning different topics and technologies, such as energy, aquaculture, and nanotechnology. Around half of the projects selected initially were not available or could not be scored due to lack of contracts, erroneous files scanned or unreadable scans. Due to constraints on confidentiality, we could not go to the archives and look them up manually, nor could we contact the project managers or parties to get their copy of the agreement.

In parallel with developing the ontology, we initially scored a small number of projects. We discussed the scores and updated the scoring guides. We then worked individually. Both principal investigators are researchers who are familiar with contracts and contract terms. They

both have more than fifteen years of experience with IP and contracts. Each project has an average of around ten parties. Many of the agreements are similar, but each must be checked. First, we evaluated all projects to see how many had individual, bilateral contracts, and how many had similar consortium agreements signed by all parties. In this review, we also removed some projects were the agreements were only formal declarations without content, e.g., "We hereby agree to be a partner in this project". We then read and scored the agreements of the 312 projects.

Explanatory variables

We use several explanatory variables that we assume to be associated with the extent to which the project data and outcomes are publicly accessible. First, we include the total project budget (in millions of NOK) to capture the overall size of the project. The project budget includes the funding provided by the RCN and the contributions by all project participants. Second, we include the share of the total budget that was funded by the RCN (in percent) to investigate the role of the degree of public funding for accessibility. Third, we are interested in the institutional composition of the consortia and include the number of industry partners as well as the number of universities in the consortium while taking the public research institutes as the reference group. Additionally, we include the squared terms of these two variables to investigate a potentially curvilinear relationship. Finally, we control for technology area of the project (biotech, energy, ICT, ocean, with other technologies being the reference category) and the year in which the project started.

Model

Since the dependent variables are measured on an ordinal scale that can range from 1 to 5, we estimate ordered probit regressions for the relationship between the dimensions of

openness and the explanatory variables. We cluster the standard errors by RCN research program, which is organised around technologies such as biotech, energy, ICT, health and ocean.

RESULTS

Table 2 shows the descriptive statistics for the 312 projects under study while Table 3 shows the pairwise correlations. The correlation coefficients and the mean variance inflation factor (VIF) of 1.55 do not indicate that our data analysis is complicated by multicollinearity problems (Belsley, Kuh, & Welsh, 1980).

[Table 2 about here]

[Table 3 about here]

The four variables measuring the dimensions of openness take integer values between 1 and 5, and their mean values vary closely around 3. Hence, the variables indicate that projects exhibit on average a moderate degree of openness. The average project budget is 32 million NOK (around 3.3 million EUR). There are also considerably smaller and larger projects. 58% of that budget is on average provided by the RCN. The projects include on average 4.6 industrial partners, but there are also projects with many more industrial partners and projects without any firms. Moreover, there are on average 2.2 universities in the consortia, with a minimum of no and a maximum of 11 universities. Most projects are in the energy area, followed by biotech and other areas, and most projects started in the years 2013 and 2014.

Table 4 shows the results of the ordered probit models. The first four models include the full set of explanatory variables while models 5 to 8 additionally include the squared terms of the two institutional composition variables measuring the number of industry and university partners. We find a statistically significant positive relationship between the degree of funding

from the RCN and the ownership, foreground IP, and publication scores. While small in size for all three outcome variables, the association is strongest for the ownership score, indicating that higher public funding is associated with more open ownership of the project results. Overall, this finding shows that public funding indeed facilitates openness. In turn, this finding is consistent with prior research that substantiates a positive relationship between the degree of industry funding and the restrictions in the form of publication delay or secrecy imposed by industry sponsors (Czarnitzki, Grimpe, & Pellens, 2015; Czarnitzki, Grimpe, & Toole, 2015).

Next, we turn to the institutional composition of the consortia. We find no statistically significant relationship between the number of industry partners and the openness scores. However, we find a significant positive relationship between the number of university partners and the ownership and confidentiality scores. For these two dimensions of openness, more university participants apparently propel openness – a finding that reflects the universities' traditional mission to promote open science.

This picture changes once the squared terms are taken into the models. We find a U-shaped relationship between the number of industry participants and the publications score. Openness in that regard is highest with a low and with a high number of industry partners while an intermediate number of industry partners seems to be associated with restrained openness. We attribute this finding to coordination problems within the consortium. When a higher number of industrial partners is involved, individual firms will have difficulties restricting access and steering the project in a direction that mostly benefits their commercial interests. The industrial partners in the consortium are more likely to agree on common interests and consequently also on non-exclusivity of the results so that openness increases.

Contrary to this, we find inverse U-shaped relationships for the number of university participants and the ownership and publications scores. Nevertheless, the coefficients suggest the relationship to be rather concave than inverse U-shaped. In that sense, openness increases with increasing participation of universities.

We do not find a systematic relationship between the total amount of project funding and the four openness scores, indicating that the budget size itself is not a relevant determinant of openness. Concerning the different scientific areas, we find a few statistically significant relationships between energy and ICT area projects and openness. However, these only concern the scores for the use of foreground IP and publications. Finally, we find the year dummies to be jointly significantly related to the openness scores. There are indications for an increasing extent of openness over time. Particularly projects started in 2014 turn out to be associated with a higher openness which may indicate that the university administration has become more aware of the need publicly to disclose project data and results over time.

[Table 4 about here]

CONCLUSIONS AND IMPLICATIONS

There are limitations to our study. One limitation is that we have used only Norwegian data. Another limitation is that the data set may be skewed. We still do not know the reasons for some agreements being unavailable to us. The lacking agreements may be due to, e.g. scanners not working from time to time, and affecting the data randomly, or there could be systematic errors.

The study uses Norwegian projects only. There are foreign parties to several of the agreements, but the project responsible is Norwegian in all the projects. The agreements are in

English or Norwegian language, with standard European contract terms. Some are inspired by English or US contract tradition. Almost all are using Norwegian law. However, the method and the ontology use common English terms and expressions for intellectual property regulations. The method can thus be adapted to similar future research, also in other countries.

The collaboration agreements regulate fall-back positions if the practical cooperation between the R&D partners breaks down. The persons working on the project will hardly consult the agreement whenever knowledge is exchanged within the project. Nor will the agreements reflect every possible situation or problem that can arise. Our scores do not reflect the actual access to the results and the background, but the idealised position in case of further negotiations.

Furthermore, the study concerns innovation management, intellectual property management and results from initial negotiations of contractual terms. We do not follow up the results of the research projects and how that is used further in research or utilisation.

With reference to figures 1 and 2, we show that it is possible for a funding agency to evaluate the results from a policy that favours public access. Our method for evaluation opens for funding policies that can reward negotiations that end with a high degree of public access, or that can reward high access for industry partners. Our ontology and the scoring model can be developed further and become practical tools for contract management. Such tools can also be used in evaluations of the effect of policies for funding agencies.

The agreements and contracts are where researchers best can initially study the intentions of the parties and the framework of the project results. Further research can study how and when restrictions are created and their impact on the actual results.

The statistical analysis of our data confirms prior research results on the correlation between funding and publication of research results. We have used a very different method from (Czarnitzki, Grimpe, & Toole, 2015), but we see similar conclusions: There is a positive correlation between the degree of public funding and public access. We see variation across technology areas, but more restrictions on use rights than restrictions from ownership. Our results indicate that the budget size of a research project itself is not correlated to access.

As we did not find a systematic relationship between the total amount of project funding and the four access and openness scores, this indicates that total funding of projects does not matter significantly for neither ownership, foreground IP, publication or confidentiality. However, we find significant results for the RCN funding share with the different score variables. This shows that the model we developed is useful for investigating a relationship between the degree of public funding and the ownership, foreground IP, and publication scores. The association is strongest for the ownership score, indicating that higher public funding is associated with more open ownership of the project results.

There are differences between technology areas in our study. In energy and ICT, there are significant relationships between a larger degree of access and openness for the public when it comes to using of foreground IP and the freedom to publish the results. This finding is in particular relevant for projects starting in 2014 and after. It may indicate more matureness within the universities' administrations to negotiate the contractual elements that are of more importance for further research. To explore this further, we need to study the post-project period.

Finally, we see indications that grants to the large, prestigious research centres, implies a higher correlation between public funding and public access. These are topics for further research, as is our most interesting result, the U-shaped correlations: There is a U-shaped

correlation between the numbers of industry participants and the public access to the results. There is also an inverted U-shaped correlation between the number of participating universities and the public access.

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TABLES

Table 1: Details of the scoring model

	Ownership	**Foreground**	**Publication**	**Confidentiality**
Access Grading				
1	Industry owns all IPR and project results	Industry has exclusive user rights to all commercial use of IPR and project results.	All dissemination of project results is strictly controlled. No publications allowed.	All Information is by default confidential if not already public. No specified time limits or other limitations.
2	A specific party owns Project Results if based on own background, dominating contribution or own commercial interests. Otherwise jointly owned.	All parties have by default exclusive (within specified field of use) or non-exclusive, world-wide, royalty free User Rights to any utilization of all the Project Results,	Project results must be published but could be delayed according to participants needs. Not specified publication veto for academics.	All Project results and background information disclosed is by default confidential if not already public, limited in time.
3	All Project results are jointly owned. Separate agreements for Access rights	All parties granted non-exclusive user rights to all Project results to be able to utilize own Project result.	Results shall be published, but publication must be sent to Steering committee which could object and request modifications before publication.	Project Results and Background information is confidential if marked and justified for particular reasons and limited both in content and/or time.
4	Ownership of all Project Results is individually owned. Where several Parties have carried out work generating Project Results and where share of the work cannot be ascertained, they have joint ownership,	All parties have royalty free user rights, but only during the project period to results that are needed to perform utilization of own Project result, further user rights may be given upon request.	Publications could be delayed due to patent or other justified grounds, but according to Norwegian laws. Must be clearly stated that results must be published within a time frame.	Project partners have to specifically call for confidential information. Must be marked Confidential, time limited and approved by a Project Board. Parties could refuse.
5	Academic institution owns all Project results.	Only academic partner has specified user rights of Project results.	No publication restriction. Specified that results must be published	No confidentiality conditions specified

Table 2: Descriptive statistics

Variable	Mean	Std. Dev.	Min	Max
Ownership score	3.135	1.193	1	5
Foreground IP score	2.753	0.886	1	5
Publications score	3.151	0.825	1	5
Confidentiality score	2.827	0.880	1	5
RCN funding share	58.032	21.842	8.48	100
Number of industry partners	4.580	4.067	0	35
Number of university partners	2.212	1.827	0	11
Total project budget (mio. NOK)	32.034	60.127	0.2	384
Biotech	0.231	0.422	0	1
Energy	0.340	0.474	0	1
ICT	0.093	0.291	0	1
Ocean	0.163	0.370	0	1
Other	0.173	0.379	0	1
Year 2009	0.038	0.193	0	1
Year 2010	0.038	0.193	0	1
Year 2011	0.064	0.245	0	1
Year 2012	0.112	0.316	0	1
Year 2013	0.221	0.416	0	1
Year 2014	0.250	0.434	0	1
Year 2015	0.093	0.291	0	1
Year 2016	0.183	0.387	0	1

Table 3: Pairwise correlations (n=312)

		1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	RCN funding share	1.00													
2	Number of industry partners	-0.06	1.00												
3	Number of university partners	0.05	0.08	1.00											
4	Total project budget (mio. NOK)	-0.22	0.54	0.25	1.00										
5	Biotech	0.10	0.01	0.15	0.05	1.00									
6	Energy	0.05	-0.17	-0.12	-0.07	-0.39	1.00								
7	ICT	0.00	-0.08	-0.02	-0.03	-0.18	-0.23	1.00							
8	Ocean	-0.06	-0.10	-0.14	-0.06	-0.24	-0.32	-0.14	1.00						
9	Year 2009	0.03	0.15	0.00	0.28	-0.07	0.17	-0.06	-0.04	1.00					
10	Year 2010	0.07	0.04	-0.06	0.05	0.09	0.00	0.11	-0.09	-0.04	1.00				
11	Year 2011	-0.04	0.04	0.08	-0.13	0.08	-0.02	-0.05	-0.06	-0.05	-0.05	1.00			
12	Year 2012	-0.04	-0.08	-0.06	-0.09	-0.03	0.09	-0.04	-0.07	-0.07	-0.07	-0.09	1.00		
13	Year 2013	-0.07	-0.11	-0.12	-0.08	-0.05	-0.06	-0.02	-0.01	-0.11	-0.11	-0.14	-0.19	1.00	
14	Year 2014	-0.13	-0.05	-0.10	-0.14	-0.09	-0.09	-0.08	-0.11	-0.12	-0.12	-0.15	-0.21	-0.31	-1.00
15	Year 2015	-0.08	-0.12	-0.06	-0.13	-0.06	-0.11	-0.01	-0.01	-0.06	-0.06	-0.08	-0.11	-0.17	-0.18

Table 4: Ordered probit regression results for the dimensions of access

	Ownership	Foreground	Publications	Confidentiality	Ownership	Foreground	Publications	Confidentiality
Share of RCN funding	0.022***	0.010***	0.006**	0.005	0.021***	0.009***	0.004	0.003
	(0.003)	(0.002)	(0.003)	(0.003)	(0.004)	(0.002)	(0.003)	(0.004)
Number of industry partners	0.011	0.023	-0.008	-0.004	0.016	-0.029	-0.059**	-0.021
	(0.017)	(0.030)	(0.014)	(0.013)	(0.036)	(0.045)	(0.029)	(0.032)
Number of industry partners (sq.)					0.000	0.003**	0.003**	0.001
					(0.001)	(0.001)	(0.001)	(0.001)
Number of university partners	0.089**	0.047	0.048	0.056*	0.252**	0.136	0.257**	0.222*
	(0.043)	(0.042)	(0.042)	(0.033)	(0.101)	(0.108)	(0.124)	(0.121)
Number of university partners (sq.)					-0.019*	-0.009	-0.024*	-0.019
					(0.011)	(0.011)	(0.013)	(0.012)
Total project budget (mio. NOK)	0.002*	0.001	0.001	-0.001	0.002*	0.000	0.000	-0.001*
	(0.001)	(0.002)	(0.001)	(0.001)	(0.001)	(0.001)	(0.001)	(0.001)
Biotech	-0.121	0.251	-0.152	-0.126	-0.155	0.262	-0.172	-0.152
	(0.273)	(0.235)	(0.149)	(0.140)	(0.274)	(0.247)	(0.136)	(0.133)
Energy	0.036	-0.436***	-0.388*	-0.021	0.015	-0.422***	-0.393*	-0.033
	(0.193)	(0.160)	(0.212)	(0.120)	(0.191)	(0.152)	(0.204)	(0.115)
ICT	0.021	0.576***	-0.475**	0.175	-0.021	0.571***	-0.522**	0.136
	(0.298)	(0.168)	(0.221)	(0.153)	(0.274)	(0.168)	(0.216)	(0.146)
Ocean	0.182	0.16	-0.19	0.2	0.166	0.169	-0.199	0.189
	(0.167)	(0.173)	(0.148)	(0.142)	(0.163)	(0.170)	(0.141)	(0.142)
Year dummies	included	included	included	included	included	included	included	included
Pseudo R2	0.09	0.09	0.06	0.10	0.09	0.10	0.07	0.10
N	312	312	312	312	312	312	312	312
LR/Wald chi2	250.912	151.997	101.981	667.431	451.061	302.645	125.671	759.654
P-value	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Log likelihood	-355.663	-363.323	-356.095	-349.987	-354.476	-361.422	-352.838	-348.638

* p<0.10, ** p<0.05, *** p<0.01

FIGURES

FIGURE 1

Our study concerns the phase between establishing and running the project.

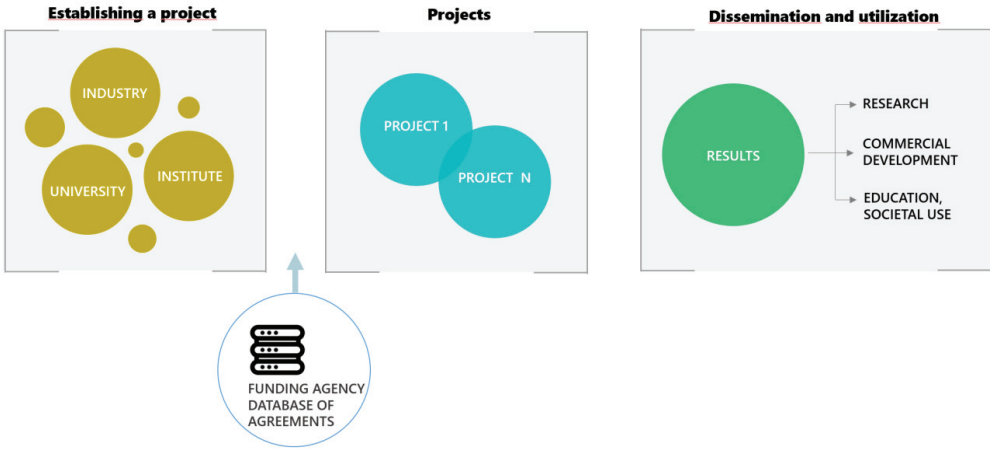


FIGURE 2

The RCN contract management framework and baseline and the subsequent collaboration research project agreement framework

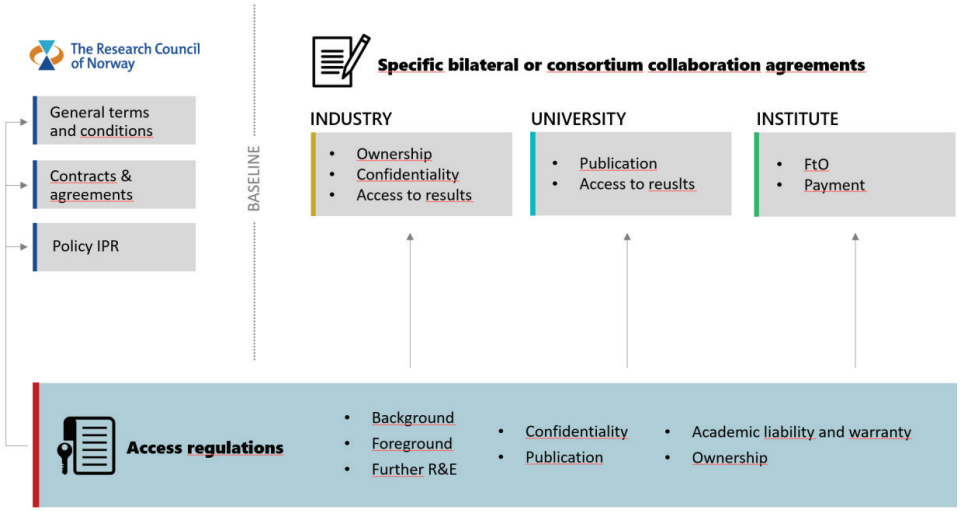
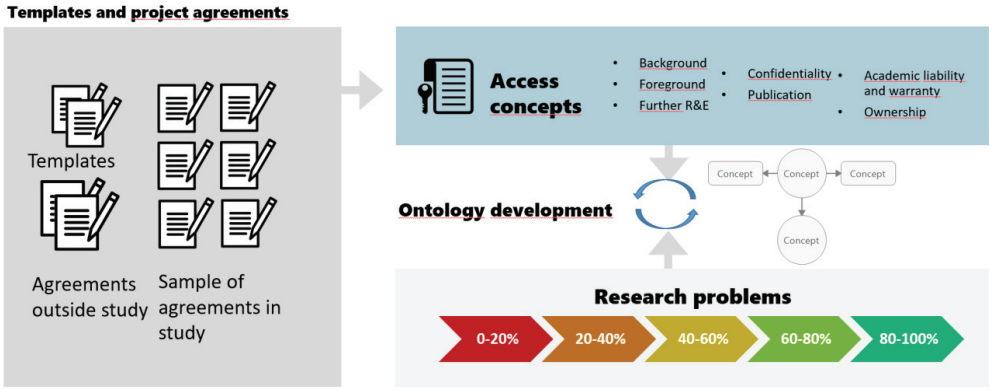


FIGURE 3

The Ontology creation with contracts, access concepts and the research problems



Paper IV