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Constructing Openness on Open Innovation Platforms in the Life Science Industry

Creation of a toolbox for designing an open innovation platform

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Foreword & Acknowledgements

The sunshine is shining upon us as we are writing these words of appreciation, reflecting back on our time spent here in Qatar and the adventures that we have experienced together with the friendly people that we have met. The road has been audacious and the authors have been faced with bureaucracy mixed with frustration, which was overtaken by the generosity and hospitability that characterizes the state of Qatar and its inhabitants. The authors have gone from feeling like tourists in another country without a map (literally) to feeling included and welcomed into the state of Qatar. The authors would like to extend their heartfelt appreciation to Bowman Heiden for providing us with the opportunity to come to Qatar and experience its rich culture and for introducing us to numerous interesting people and giving us an experience of a lifetime.

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Abstract

The post-genomic era has lead to a paradigm shift in the Life Science Industry, driven by technological advances and increased upstream patenting, resulting in Open Innovation initiatives to sustain growth in an increasingly competitive, knowledge driven environment. Open Innovation Platforms is a dynamic model for facilitating collaboration, and this study aims to uncover the underlying legal constructions used to regulate openness on Open Innovation Platforms, also creating a tool consisting of the legal and contractual models necessary to support the construction of openness and collaboration on different levels.

The study benchmarks a model for designing Open Innovation Platforms based on general platform governance structures, access, use and cost parameters and takes a theoretical standpoint in the socio-legal approach, viewing regulatory interventions and constructions of contractual and intellectual property law as the legal framework enabling creation of openness, which in turn affects the choices made in the business arena.

The study highlights; the complexity of regulating multi-stakeholder relations, existing structures on Life Science platforms and the many layers of openness created by contractual solutions with the regulatory system as a base.

Keywords: *Open Innovation Platforms, Constructing Open Innovation Platforms, Open Innovation Platform Design, Open Innovation Initiatives, Life Science Platforms, Legal constructions, Contractual Models, Toolbox.*

Abbreviations

ANDI	African Network for Drugs and Diagnostics Innovation
BiOS	Biological Open Source
CC0	Creative Commons Zero
CFA	Constitutional Framework Agreement
DSTT	The Dundee Division of Signal Transduction Therapy
EFPIA	European Federation of Pharmaceutical Industry and Associations
EU	European Union
FRAND	Fair Reasonable and Non-Discriminatory
GSK	GlaxoSmithKline
GSPOA	Global Strategy and Plan of Action
HapMap	The International HapMap Project
IMI	Innovative Medicine Initiative
IP	Intellectual Property
IPR(s)	Intellectual Property Right(s)
JTI	Joint Technology Initiative
JU	Joint Undertaking
MOU	Memorandum of Understanding
PGP	Personal Genome Project
PIPRA	Public Intellectual Property Resource for Agriculture
R&D	Research and Development
SGC	Structural Genomics Consortium
SME	Small- and medium-sized enterprises
WHO	World Health Organization

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1 Background

This section's purpose is to set the stage for the analysis made in the Master Thesis. This section will therefore present the reason why the authors have chosen to address open innovation platform design construction as well as what type of delimitations that the authors have been forced to make. It will furthermore describe the methodology and theoretical approaches of this thesis to finally present the research questions chosen.

The life science industry at large is recognized as being technology intensive and highly innovative, where research specifically within biotechnology has paved the way for genetic engineering and new innovations within drug development based in biological processes. These rapid advances in technology development together with increased dynamicity and accrued competition creates a need for companies within the life science industry to change the way they manage the technological innovation process to meet the demands of the changing external environment. The actors in the field are encouraged to form alliances to fill any voids in upstream knowledge and downstream capabilities.[1] In knowledge-intensive industries, the term "open innovation" has been elaborated upon as a means to allocate risks, pool costs and resources and expectantly increase research and development (R&D) productivity at the same time. The collaborative structure of open innovation is in turn governed by contractual structures that secure and steers the continuous openness between the actors involved as well as with outside parties to ensure a proper construction and outcome. In theory, the idea of collaborative innovation is attractive, but in an industry that is as innovation-dependent as the life sciences industry, the practical implementation of the idea is difficult due in part to the importance put on intellectual property (IP) protection.[2]

Through "open" collaborative channels, life science innovation has prospered and The Human Genome Project is an example of how fruitful collaborative approaches between researchers can be. However, hesitation and skepticism towards opening up collaborations and competitive alliances remains, where the main focus is on unresolved IP protection issues and how to contractually share risks and potential returns.[2] The contractual and regulatory aspects are thus believe by the authors as being prominent in this setting when constructing an open innovation platform.

When researchers come together to collaboratively innovate to create potential leverage, the IP that is created is defined as claimed intellectual constructions of value which, if they have gone through an official administrative process to form legally enforceable properties, are considered as intellectual property rights (IPRs). The structure and conception of an open model towards innovation must then be construed in relation to the concept of "open" as provided for through the contractual structures which govern the continuous openness of IP as constructions of value.[3]

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[1] Allarakhiaq, Wensley p. 115
[2] Next Level Pharma - Open & Collaborative Innovation in Life Science R&D
[3] Petrusson et al (2010) p. 4

It has been proposed that the term "open" is complex and rich with many different implications when utilized in different contexts. The open diffusion of knowledge in different sectors is perhaps most commonly understood as a "means for business development and controlled leveraging through intellectual wealth".[4] The way in which openness is to be interpreted and understood in the context of open initiatives has been found as elaborated upon and the concept has been divided into elements in differing ways so as to come to terms with this imprecision, inherent in the meaning of open. The aspect of how to actually construct openness within a collaborative initiative has then been touched upon primarily through the angle of levels of openness without any specific focus towards tools or concepts on a regulatory level to structure the collaboration and steer the level of openness between collaborators. To have the approach of analyzing the use of tools, concepts and contractual structures to construct openness would according to the authors consequently add another dimension to the way in which openness has been viewed and present complementary features of construction.

1.1 Purpose and Research Question

The purpose of this thesis is to show how open innovation platforms can be constructed through contractual models and with the help of self regulatory tools apparent within the regulatory system. The thesis also aims at describing the interrelations between different constructs of openness and governance over the platform.

The purpose of showing how open innovation platforms can be constructed will help in designing open platform collaborations and serve as a checklist to turn to in constructing different layers of openness and governance. The aim to describe the interrelations between different constructs will help to exemplify how industry collaborations look today and how different choices in governance and openness structures will affect or limit other choices in other layers.

The overarching goal of the thesis is to construct a toolbox which demonstrates the life science industry collaborations governance and openness structures and but also the contractual and regulatory concerns needed to be addressed when constructing openness.

Based on this purpose the authors form the research question: *Based on a tool for constructing open innovation platforms, what constructional tools and contractual structures enable openness in open innovation platforms in the life science industry?*

Having three sub-questions being:

- How are existing legal structures and self regulatory tools used by industry to construct openness?
- Is the tool for designing open innovation platforms fit for evaluating and constructing open innovation platforms in the life science industry?
- Which legal and administrative considerations need to be addressed when constructing an open innovation platform?

[4] Särefjord p.4

1.2 Theoretical and Methodology Overview

The theory which will serve as the fundament for the thesis and provide the authors with the framework for how to analyze and interpret information gathered will be a socio-legal approach which touches upon the interactions of the law and societal behavior, which in turn will lean on a methodology chosen which has most of its base in a tool for evaluating and constructing open innovation platforms. The theoretical approach and methodology will be gone through respectively.

1.2.1 Theoretical Approach

The theoretical understandings of this thesis will be through a socio-legal approach which embeds the implications of how law interacts with the behavior of actors in society. The socio-legal approach addresses the effects that regulations and regulatory interventions have on actors in society. This approach also highlights the construct of law, the implications law has on society and the implications society has on the law, meaning that the social construct of the law is enlightened through the reification process of how law becomes norms that are followed by society.[5]

The authors believe that this approach is appropriate due to the knowledge intense aspects of this thesis since IP and contract law are closely intertwined with the acts of participants on an open innovation platform in the business setting.[6] The socio-legal approach is also applicable on the open innovation platform setting due to the effects that regulations, regulatory interventions and self regulatory tools have on the construction, governance and openness regulations of the open innovation platform, but also the normative behavior of the actors on the platform and how they handle and construct their interactions.

1.2.2 Methodology

The conventional legal method of using primary and secondary legal sources is difficult to apply to this type of thesis that touches upon several different regulatory frameworks and where the interactions and the interventions that law has on the building of social constructions is the primary interest. The law and contractual tools and models that are based on the legal structures have instead been used as a benchmarking point which served as a foundation for further analysis and implementation of a toolbox within the specific context of an open innovation platform.

The steps taken to achieve the constructing of the toolbox could be divided into four main steps which are taken to understand the context in which the thesis operates but also to investigate the industry and the characteristics of the same as well as the existing platform constructions operating within this context and how they are relating to the process of claiming innovation and how they are regulating their interactions and transactions accordingly. The four main steps will be gone through sequentially where a thorough explanation of each step will serve as a foundation and building block for the following step and align the purpose of the thesis with the theoretical and structural framework which has been used to create the toolbox. The steps are the following:

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[5] Mathiesen p. 29ff
[6] Petrusson et al (2010) p. 6

1.2.2.1 Life Science Business Culture

The first step in understanding the context in which the thesis operates the authors outlined the life science and specifically the pharmaceutical sector value chain. The value chain was based in different economical paradigms and the focus was then turned to the operations in the knowledge economy paradigm since this is where most open innovation platforms operate. The authors also saw a need for understanding the business models used by the life science industry to understand the need and receptiveness for open innovation by the industry. The authors then broke down the knowledge economy paradigm to its technology levels, learning the trends and operational environment of an open innovation platform in this setting. The trends within the technology field is also closely related to the industry operations within the life sciences which lead to an analysis concerning the trends in collaboration and the collaborative environment in which a platform must operate. At last the authors also saw that the life science and especially the pharmaceutical industry business climate is very much affected by social structures such as insurance systems and buyers conception of diseases which lead to a brief evaluation of how social structures influence the decisions made in collaborative efforts or more closely being the reason for a collaborative effort.

1.2.2.2 The Platform Analysis using the Tool for Designing Open Innovation Platforms

The authors chose as a next step to utilize a basic tool for construction, evaluation and design of open innovation platforms to enable a following analysis of specific context dependent open innovation platforms. The analytical tool that is being used for designing open innovation platforms is a methodology created by Professor Ulf Petrusson consisting of a subset of questions that one in this context need to consider in an initial stage to be able to construct an open innovation platform. The tool has been utilized as an analysis tool which has served as the starting-point for evaluating and ultimately creating an open innovation platform with the necessary constructional tools and considerations in mind. The tool has been divided by the authors into two basic building blocks for open innovation platform construction, focusing on General Platform Governance and Platform Openness to determine the characteristics of a platform and the tools necessary in order to construct a certain level of platform governance and openness. These building blocks are consequently deconstructed into specific parameters that are serving the purpose of capturing the different levels of construction, which in turn will enlighten the necessary self-regulatory tools derived from regulation and from binding contracts and contractual models present in different manners. Five parameters were chosen for each building block, resulting in five parameters within General Platform Governance and five parameters for Platform Openness which in turn consists of five layers, where the first layer represents the least amount of sophistication and openness whereas the fifth layer consequently represents the highest level of openness.

This tool or methodology has been interpreted by the authors to form the evaluation tool used in the next sequential step of the analysis, where the methodology has been taken and applied to the life science industry platforms and served as a tool for evaluating where on the layers of this tool the platforms operate. This evaluation is based on contract evaluation, understanding the use of self-regulatory tools and the interactions these contracts play with the legal statements. In this evaluation the authors have also used the described methodology to understand the interplay

between the different constructions creating governance and openness on the platform. When applying the tool onto the platforms the authors uncovered that there was a need to further deconstruct the process of claiming in the context of the life science industry, i.e. the claiming of constructions that are in need to be further elaborated upon in order to understand the underlying structures of a platform. The evaluation process would be lacking important elements if this process would not be addressed, since the understanding of the different possibilities of claiming will provide with the necessary fundaments for the interpretation of the self regulatory tools, concepts and models in the context.

1.2.2.3 Legal Implications and Ground Rules

The next step for the authors was to understand the value creation through claiming processes in the life science industry since the knowledge intensity and technological development of the field has lead to industry specific characteristics. This is highly important when evaluating the platform construction having in mind how value is created in the industry. The authors approached the claiming processes from three different questions; *How is value claimed? Where is value claimed?* and *What is claimed as value?* The first question was answered with an approach of benchmarking the three arenas in which an open innovation platform operates in creating valuable intellectual objects for its stakeholders. The second question takes a value chain perspective in focusing of where the value should and is claimed by industry actors and the last question addresses the issues of what is possible to claim from a regulatory and legal dogmatic methodology perspective using primary and secondary sources.

1.2.2.4 The Creation of a Toolbox utilizing the Legal Tools for Construction

In light of the legal implications, the following step for the authors was to use the approach of evaluating the investigated open innovation platforms legal setup and also deconstruct this setup to legal formations to uncover the regulatory and contractual considerations when creating an open innovation platform and a toolbox for enabling further creation. This part has used the methodology tool as a basis for the created toolbox in that the toolbox is an addition to the methodology, adding a legal constructional layer of the tool. The methodology tool therefore served as a starting-point in steering the search for the different contracts, agreements and use of different self regulatory tools, leading to the conclusion regarding the characteristics of each platform and how they have utilized the constructional tools.

1.3 Delimitations

For the authors to be able to shape the thesis according to a proper scope, a number of delimitations have to be made in order to get an appropriate reach for the thesis. The presentation of the delimitations does not imply an order due to relevance or the like, but is merely a recital of the areas which will not be touched upon by the authors at this stage.

1.3.1 The Analytical Tool

The authors have chosen one analytical tool that claims to construct open innovation platforms and have consequently not looked for other tools that claim to do the same. This limits the scope of the thesis. This tool has then impacted what information gathering that has been done as regards analyzing different platforms. Information that has not been relevant in using the analytical tool has not been accounted for.

1.3.2 The Toolbox

The authors would like to emphasize that the created toolbox is not exhaustive but merely a proposition on how one could construct different layers of an analytical tool. The authors have consciously left some constructions that could be made without notice due to the scope of the thesis.

1.3.3 The Life Science Industry Value Chain

The authors have chosen to not specifically address the pharmaceutical value chain in the life science industry as well as the specifics of the market and its regulatory abundance. Nor has any specific attention been paid to the actors within the field since the analysis made have been focused on the legal constructions set by the platforms and not necessarily on the actors present on the platform and their place within the value chain. The industry evaluation merely serves as a benchmarking point.

1.3.4 The Economic Paradigms

This thesis will not describe nor analyze the different economic paradigms that exist, nor specifically address the definition of a knowledge economy. The scope of the thesis operations are within the knowledge economy, however being an analysis of open innovation platforms utilizing a practical toolbox for implementation, a description would not serve a purpose.

1.3.5 The Regulatory System

The thesis will not address the regulatory system as such, its function for society and its role within different areas not related to open innovation platforms. The thesis will have as its primary focus to analyze regulations in relation to IP, competition and contracts regulations as the scope of the thesis is linked to the different constructions done in relation to IP and contracts.

1.3.6 The Evolvement of Open Innovation

The thesis will not address the concept of open innovation and the evolvement thereof, meaning that the authors have not evaluated what open innovation is per se, what is generally known as open innovation since this would not serve the purpose of this thesis and is not within its scope. The term open innovation is a dynamic one which encompasses many dimensions that will not be addressed in this thesis more than when related to open innovation platform constructions.

1.3.7 The Open Innovation Platforms

The thesis does not aim to address or analyze whether the open innovation platforms used as examples are efficient, sustainable, just or financially successful. The thesis neither describe in more detail what an open innovation platform is, except from a constructional perspective.

1.3.8 Constructional Tools

The thesis has only utilized the legal tools which serve as building blocks in the creation and design of an open innovation platform. Therefore, the thesis will not utilize or consider other tools in the value creation process, i.e. the authors have not included an analysis of business strategies, policies or business plans since this is not within the scope of this thesis.

2 Characteristics of the Life Science Industry

The purpose with this section is to introduce the concept of the life science industry and the characteristics of the same to illustrate the transition made from being a field where research has been primarily controlled by large actors to having a more collaborative approach due to the emergence of new technologies and research being made. The purpose is furthermore to go in depth into the structural changes of the industry, principally within the biopharmaceutical field, to demonstrate the constant evolution of the innovation model to meet the requirements made from both private as well as public actors. Finally, the section is intended to exemplify how research results are being packaged as intellectual assets to enable leverage on the investment made in the field.

There has been a distributional shift within the life science industry, primarily as regards the pharmaceutical field, where the key focus of research is no longer on supporting the "blockbuster"[7] model but rather look into the field of biomarkers and diagnostics to further leverage on the evolving knowledge capacity. The role of big pharmaceutical actors in this field has traditionally been that they have done everything from R&D to commercialization, thus covering the entire pharmaceutical value chain with little interference and contribution from smaller actors. However, the emergence of new research areas together with the need to improve R&D productivity, reduce costs and tap the potential of emerging economies puts a pressure on large pharmaceutical companies to collaborate with other organizations to develop effective new medicines more economically. To be able to develop the necessary technology to keep up with the scientific and technical knowledge requirements for the successful development of new medical entities, the larger actors are dependent on smaller knowledge-intensive businesses to feed knowledge into their processes, assisting them in sustaining their economic stability and finding ways to leverage on their products. Thus, there are economic incentives for actors to take advantage of collaboration to enhance businesses.[8]

The way in which innovation is managed today in the life science field is as a result of this bound to be modified due to the emergence of open innovation within the field of biotechnology. The new way in which to administer innovation will encompass the ability to handle the intersection of customer insight and to do comprehensive technology assessments which in turn will provide actors with new ways in how to control their operations and maintain their competitive edge in this highly complex research field.[9]

The authors believe that the intensity of which research is evolving in this area is of significant interest and the next part will therefore focus more in detail on the specific drivers of change in the life science field together with the structural changes so as to get a deeper understanding of why the industry has evolved as has been stated above and will thus shed more light on the specifics.

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[7] The blockbuster model refers to when a company has a strategy to singlehandedly place a large amount of investment in a few molecules, market these heavily and turn them into blockbuster drugs which are then heavily distributed.
[8] Cooke p. 65-80
[9] Fetterhoff p. 14

2.1 Change in the Life Science Industry

As per mentioned in the previous section, the life science industry has faced a paradigm shift and there have been many variables which have contributed to this effect, some of which are intended to be highlighted due to their impact on the field as such. The change within the industry, especially within the pharmaceutical setting, is due to the technological drivers of change as well as policy interventions and structural changes together with a change in demand from the market and the ever-increasing challenge of lack of investment from payers due to the poorly aligned incentives which is an obstacle to the advancement of the industry and its focus on personalized medicine.[10] These different parameters will be handled accordingly in the following sections. The authors would like to emphasize that there are more extensive analysis made regarding the evolution of the life science industry and that the information provided for in this section is merely to illustrate and exemplify the reasons for the life science industry moving towards a more collaborative approach based on certain parameters in its development.

2.1.1 Technology Drivers

The structure of the life science industry including the biopharmaceutical industry has changed during recent years due to a number of pressures and drivers, where one of the key factors has been the rapid developments in the biosciences. This, among other factors, has driven the industry to re-brand itself from pharmaceutical to biopharmaceutical and has done so in order to acknowledge and embrace the more evidence-based approach drawing on the biosciences, genetic sciences and the process technologies used in discovery research;[11] meaning the sequencing of the human genome, the expansion of proteomics research and the emergence of other existing technologies such as functional imaging and computational biology. Through these advances new insights about patients and diseases can inform patient care and treatment through raising the importance and value of the information derived from testing.[12] This information made possible through new technologies could be argued to constitute a "fundamental shift in medical care".[13] As a result of this change, new opportunities were created but also considerable pressures due to the industry facing significant costs in "retooling" for a post-genomic era.[14]

2.1.2 Structural Change Drivers

The industry is also affected by policy interventions, both pre- and post market, within countries that comprise the key pharmaceutical markets which has created additional pressures. The series of structural changes have been implemented to consolidate pipelines, disperse costs as well as to bring efficiency to the sales and marketing efforts of the industry. A structural change that has been acknowledged as in the forefront of the need of the industry is the tendency towards developing strong partnerships with mainly knowledge-intensive small- and medium-sized (SME) biotechnology companies to develop the necessary technology and feed knowledge into the sector. These partnerships in turn take on numerous forms and the overall innovation model continues to evolve as actors within the industry are encouraged to form alliances to fill any voids in upstream knowledge and downstream capabilities. Due to the structural changes in

[10] Davis et al p. 2-3
[11] Petrusson et al (2010) p. 10
[12] US Department of Health and Human Services p.135
[13] Medical Museion, University of Copenhagen Blog
[14] Petrusson et al (2010) p. 10

combination with the opportunities provided for by the biosciences, the historical distinction between basic (largely public sector driven) and applied (largely private sector driven) research has been blurred and the private sector's role in basic research has increased. These changes has subsequently major bearing on the kind of business models that industry actors need to deploy in order to succeed in the ever-changing environment that is the life science industry.[15]

2.1.3 Changing Demand Drivers

The challenging and rapidly changing environment of the life science industry has prompted stakeholders such as shareholders, physicians, patients, payers and regulators to create pressures for change. The change demanded relates primarily to enhancing the efficiency and customization of drug development, modifying the overall eventual costs of treatment and tests and move away from the large clinical trials which are due in part to regulatory hurdles put in place since the regulators are demanding more proof of patient outcomes to justify endorsement, compensation, and prices. These demands from different stakeholder communities needs to be consolidated by the industry through joining forces with a wide range of organizations, from academic institutions, hospitals and technology providers to actors that can provide services tailored to specific biological conditions. The current R&D and innovation model is thus under pressure to evolve, and it needs to do so in order to enhance the productivity of the sector and make it more cost efficient to meet the changing demand of stakeholders.[16]

2.2 Knowledge Intensity and Innovation

As has been shown in the previous section, the life science industry has been acknowledged for having extraordinary technology intensity, a high level of complexity in the innovation process and a heterogeneity as regards the competencies required. Many argue that the rate of innovation in the biotechnology field has been rapid, and the field has because of this become the driving force of radical changes in innovation processes in other sectors of the life science industry as well. To illustrate, the pharmaceutical industry has moved from the traditional chemical paradigm towards the biopharmaceutical paradigm which in turn has important consequences for the structure of the biopharmaceutical innovation system; biotechnology actors are becoming key actors generating new knowledge, tools and substances for the pharmaceutical industry. The IP schemes then have to adjust to new components and compounds, and this will have an effect on how transactions are being managed to promote and leverage on the innovation and knowledge intensity in this new era focusing on biotechnology.[17]

To be able to understand and comprehend the impact of innovation in the life science industry through the biotechnology field in particular, the authors have uncovered the need to look into the intellectual claiming process in order to appreciate that this could have a significant effect on how innovation is being enhanced or suppressed. The use of the claiming process in the life science industry is fundamental for constructing innovations and the following transactions that are to be put in place. The intellectual claiming process therefore needs to be active in order to

[15] Gillespie et al p. 5 f.
[16] Davis et al p. 2ff
[17] OECD p. 9

define the boundaries of innovations that are being developed as well as enable these transactions to shape the industry at large.[18]

According to the authors there is therefore a need to deconstruct the claiming being made within the life science industry to illustrate where in the industry that value is being created, i.e. where in the value chain the claims are being made by the actors and where the claiming process is heading as a response to the new tools and substances introduced to the field. Furthermore, it is also necessary to demonstrate how an actor actually can claim the knowledge being generated, since there are implications when moving from having an invention to utilizing the different means of intellectual claiming, primarily the institution of a patent, as a concept and communicative mean when interacting on different arenas. Finally, an actor will have to be aware of what it is that is to be intellectually claimed within the life science area, since this will ultimately have inference on the control position of an actor as well as the construction of how to manage the intellectual assets that are residing with the actor.

The authors believe that through subsequently presenting and illustrating the different steps to be taken in the intellectual claiming process there will be a greater understanding of how these steps will affect the way in which an open innovation platform will be constructed due to the impacts these processes will have on the content provided for on the platform as well as how the governance of the transactions between the actors will be affected. Therefore, the intellectual claiming process has been analyzed by the authors from the perspective of the life science industry in general, and with the perspective of the development of the potential of claiming property in biotechnology in particular, which will illustrate how to construct claims in different arenas, where in the value chain that value is claimed and also how value could be claimed as property, this to construct platforms and arm them with the right tools to capture value. Furthermore, the claiming of property in this setting will also be determined as whether it is increasing or restricting the level of openness in access and use on an open innovation platform.

2.2.1 The Interface between the Arenas

In the life science industry patenting is an important source of value creation.[19] It is not only important to know where the patent or the value should be claimed but also how value is claimed on intellectual phenomenon. The claiming processes represent the conceptualization of intellectual phenomenon, meaning giving them a value and handle them as property. The claiming process is characterized by the interactions between different arenas, getting normative reification. A claim must be made by someone to be internalized by someone else to be claimed outside the mind of the claimer giving the intellectual phenomenon a value.[20]

A patent, usually used as a value capturer and creator within the life sciences as mentioned above, is a social construct that holds the value of an invention. The actual patent does however not have any value, unless it is given a value; it is just a piece of paper. The construction that gives the patent value is the legal construct being reified as a norm by actors of society. One must understand that intellectual phenomenon does not exist in themselves but are communicative

[18] Petrusson et al (2010) p.10
[19] Petrusson et al (2010) p. 4-5
[20] Petrusson (2004) p. 102ff

actions reified by others.[21] The communicative actions creating intellectual value through intellectual objects must be taken on different arenas; here three (or possibly four) arenas are recognized in the interplay constituting the value of a patent. The arenas are: the administrative arena, the judicial arena, (the political arena) and the business arena.[22]

The administrative arena is where the patent gets granted i.e. the patent office, applying for a patent and getting the value recognized in the administrative setting by the state. When claiming a patent in the administrative arena this is not the only thing that creates value. A patent needs to be claimed in the business arena to be recognized in the business setting where the value of the patent is "constructed through creation of markets and capital transactions"[22]. It also includes defending the patent against infringements in courts which leads to the next arena being the judicial arena. The judicial arena, taking the physical form of courts, has the ultimate power of invalidating the granted patent. The political arena could constitute the lobbying activities by significant actors that possibly change the rules of the game played in the different arenas e.g. what should actually be called an invention defined in the patent law.[22]

The administrative arena is where the reification of an intellectual phenomenon is based on the legal construct that establishes the intellectual phenomenon to be claimed as a tool e.g. a patent or a trade secret. Intellectual phenomenon could also be claimed in the administrative arena in contracts, meaning that two parties reify the object as real and valuable to transact with. The administrative arena works as a recognition center meaning that it filters the intellectual phenomenon that can be reified as tools that are recognized by the parties, state and society as valid transactable objects that hold capital value.[21] To put it in the context of the life science industry, the authors see that an example could be having a biomarker consisting of a cytokine that tells cancer cells to grow. The administrative arena determines if this is seen as an invention in the definition of the patent law, thus if it fulfills the criterion to be recognized as something protectable by a patent.

The business arena is where the intellectual phenomenon is recognized on the market as a claim of value closely connected to the claims made in the administrative and the judicial arena. "Focusing on the business arena, when a designed intellectual structure and/or intellectual building block is communicated, acted upon and trusted, it is constructed".[23] Trust and loyalty among other actors could be built by legal actions such as infringement suits. It is in the judicial arena such suits will be judged. The validation or invalidation of a claimed intellectual phenomenon is what the judicial arena communicates.[24]

If value should be created through a patent, the patent must be recognized in all the arenas. The value created in the life science industry today is knowledge intensive and the value created by the patents is found in the interactions between the arenas, restructuring the industrial paradigm order where the arenas has been more separate.[22]

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[21] Petrusson (2004) p. 102ff
[22] Heiden & Petrusson
[23] Petrusson (2004) p. 116
[24] Petrusson (2004) p. 104-105

The authors conclude that, based on the analysis, claiming actions are needed in all the arenas to enforce the right to the intellectual phenomenon, therefore it is important to understand how the claiming processes in the different arenas are structured to create value from the claimed object. To extract as much value from the claimed object as possible one also needs to consider where in the value chain the object should be claimed.

2.2.2 Capture Innovation through Claims in the Value Chain

In the life science industry, companies are relying on patent protection in order to leverage on their R&D and thus generate profit. To become sustainable in an industry that is as knowledge intensive as this one, these companies have to constantly discover new knowledge and develop new products, leading to heavy investments in preliminary product development while the final product, if not protected, can be reproduced by a competitor at a lower cost. Consequently, in the context of the life science industry, the claiming of intellectual property in research is considered to be essential, both due to the potential investment decisions to be made and due to the necessity of the industry to constantly discover new knowledge and develop new products to profit from R&D.[25] Where this intellectual claiming process is then taking place will, according to the understanding of the authors, have to be based on where in the research cycle that the most value could be extracted for the actors and where knowledge could be leveraged upon.

The claiming of intellectual property is done in different strategic manners in different sectors of the biotechnology industry. Regarding biotechnology SME's, they are reliant on being financed by venture capitalists and private investors to be able to finance their R&D. In this context, the role of claiming IP will serve as a landmark in showing the actors ability to leverage on its plans and carry them out successfully. When claiming IP results through patenting, they could in turn enable the actor with a way of demonstrating the value of their inventions. Depending on these factors, the actors are likely to widen their IP portfolio through submitting patent applications for observatory inventions from the very early stages of research. This is recognized as upstream patenting, the concept or rationale of strategy for patenting that implies that an actor will patent in particular results which are basic research and the focus is on generated research results rather than intended end products or processes of manufacturing in this context, due in part on the possibility to attract investment.[26]

Regarding the more established pharmaceutical companies, which are strong financially and have their R&D dependent on the revenue generated from previous products, they tend to prefer to intellectually claim their inventions through patents at the final stages of product development, since it is downstream in the value chain where the value would be created for them since their budgets for the research are then available for the entire research cycle and they have through this reduced the impact of indirect costs.[26]

The intellectual claiming process will thus create value for different actors in the different stages of the innovation cycle and research process. One more feature is that actors are trying to patent as early in the process as possible, and the research focus of the field has shifted from genes of

[25] Petrusson (2004) p.40-41
[26] Cowan et al p. 23

organisms to the genome.[27] A characteristic approach of biotechnology companies has further been to package the research results as research tools to further leverage on the investment made and generate revenue. Many of the results of research that are claimed in the research process are thus not only discoveries of facts but also the creation of research tools, e.g. gene manipulation, gene mapping and analysis of sequences. To intellectually claim a vital research tool, now treated as an advanced technology in and of itself, through patents could potentially exclude the opportunity for others to pursue research in these fields.[28] There is a notion that diagnostics, drugs and vaccine are likely to build on intellectual tools such as biomarkers, screening systems and packaged research tools which, when patented upstream, could perhaps lead to the blocking of research as well as innovation and thus prevent an efficient outcome since they are on a very basic level which would pose a threat to the scientific progress of the field.[29]

The intellectual claiming process in this field could thus, through the patenting rationale held by the biotechnology actors, be threading the fine line between creating incentives for innovation and the diffusion of knowledge. Within the life science field, many innovations serve as research tools for further knowledge advance, and in biotechnology especially the ability of firms to intellectually claim the results of basic research and outputs that themselves are research tools through patenting can have a significant impact on R&D when moving forward to create and leverage on the value being generated. The higher the number and scope of patent-based claims in this area, the more complex it will become in establishing sustainable structural solutions. Consequently, the new focus of the industry has been more on the genome, which in turn could serve as a research tool and raise the issue of whether there is a possibility to intellectually claim this part of a basic biological part that is so very early stage in the research process not resembling a product or whether this would inhibit innovation.[30] Claims made to reify such a biological part would then have to be accepted in the administrative arena at first, reified by the business arena and upheld by the judicial arena for such a claim to be valid.[31]

2.2.3 Packaging Innovation through Claims

Value capturing in the value chain is very much dependent on the claims of control that can be made for the innovation. In the bioscience industry the patent is a fundamentally important tool in claiming control over the innovation.[32] The claiming of a patent is the recognition of the technology that is being patented as property.[33] Property that can be transacted upon is recognized as capital in the business arena.[34] In this part the authors will discuss "what can be patented" since the life science industry offers technologies and inventions that when the patent law was created was not thought as possible objects to patent.

[27] The genome of an organism is all the genetic material in its chromosomes.
[28] Patent Law & Petrusson et al (2010) p.10
[29] Petrusson et al (2010) p.10
[30] Cowan et al. p.29
[31] Petrusson (2004) p. 104ff
[32] Petrusson (2004) p. 40-41
[33] Petrusson (2004) p. 102
[34] Heiden (2010)

Taking one example within the life science industry, where actors try to patent to control the downstream research through the gene sequence. The debate weather gene sequences should be patentable has again taken pace with the court rulings on Myriad Genetics BRCA 1 and BRCA 2 patents on breast and ovarian cancer being invalidated.[35] In the debate of whether sequences should be patentable, not only one of the patentability criterions has been up for discussion but all of them. Over the years the Federal Circuit has judged a few cases which serve as guidelines for patentability on gene sequencing in the US. In 1995 the Federal Circuit ruled genetic sequences patentable based on the non-obviousness of an exact chemical structure of the nucleotide.[36] The Federal Circuit then changed the sails and stated in the *Kubin* case that proteins that have been identified in prior art is preventing the sequencing of the nucleotide to be patentable.[36] This is according to the authors a complex issue that even the court has trouble in knowing how to handle, however the patent office's that handle the issues obviously believe that the sequences of genes should be patentable, so there is a misconception between the judicial and administrative arenas.

The court's decision in the Myriad Genetics trial is "ground-breaking because it basically means that all naturally occurring gene patents are invalid"; the case also implies that tests for naturally occurring genes are no longer patentable (targeting the tests made by Myriad Genetics). However, genes that are created synthetically are patentable.[37] The arguments for those who are against patents in the life science industry are among others that all patents of this kind involve biological processes which is not under the control of the scientists and therefore should not be classified as inventions but merely expropriations from life and should therefore be called discoveries. They also argue that there is no scientific basis for the patenting of e.g. genes.[38]

"Genetic patents are particularly controversial because they lie at the interface between discovery and invention and signal a move away from patenting end products towards patenting basic scientific information".[39] The authors conclude that the debate on what is patentable in the life sciences and especially whether gene patents will be allowed or not is not possible to answer, however as the situation is today gene patents exist and are claimed and accepted in the business arena, approved by the administrative arena however not always upheld by the judicial arena. However, as long as the business arena accepts the patents and court cases do not invalidate or hinder such patents the upstream patenting within the industry will continue.

Leaving the debate regardless whether gene sequence patents will be upheld by the judicial arena, another important issue in the claiming process of a patent must be addressed. There are issues regarding what actually should be claimed by the patent. Claiming the sequence of the gene together with the disclosure criterion might give the patent a very narrow scope making it vulnerable to inventing around the invention because when the patent is granted the sequence including the chemical compounds of the patent will be disclosed. Taking an e.g. from a Japanese court which judged a case with 459 amino acids where one was changed in the infringement suit.

[35] Thomson Reuters, (This court ruling is expected to be appealed).
[36] Gene News
[37] Decker & Weidlich
[38] Ho
[39] Nicol

The case ended up being judged as an infringement due to the doctrine of equivalence, "provided that when the product employed is substituted with the patented invention, the same object and the same effects as those of the patented invention can be obtained". However, claims based on functionality would be deemed too broad and often abused. [40] The authors therefore conclude that the sequenced gene should constitute the claims of the patent and the doctrine of equivalence will make sure those infringers that claim the same functionality as the patent only small alterations of invention must be deemed to infringe on the original patent, even though this solution is not entirely according to the principle of legal security.

To conclude the claiming process, which is about what to claim, the authors believe that there are valid points in both arguments on whether or not patents should be upheld by the judicial arena on genes and gene sequences. The patent system is after all a law that was created to incentivize R&D and award the inventor protection to exploit the invention and also protection of the made investment in inventing the invention; however the authors also see how a patent thicket within the area could give disincentives in the field being forced to navigate through a web of patents when doing research. The authors see that the next challenge of the life sciences in claiming inventions will be what to claim, and how broad it should be claimed to protect the invention and the commercial purpose of the invention.

[40] Japan Patent Office Asia-Pacific Industrial Property Center JII page 57-62

3 The Tools and Concepts as Building Blocks for Contractual structures enabling Life Science Platforms

The purpose with this section is to demonstrate the position of tools and concepts within the intellectual property sphere as building blocks in creating an open innovation platform. This section will address the regulatory and legal frameworks that serve as foundations for designing a platform and specifically the relevant frameworks in the context of knowledge and technology transfer. This section furthermore aims to illustrate how the concepts of Background, Foreground and Sideground will serve as building blocks in platform development and how they have an effect on the restriction or increase of openness in the context of accessing and utilizing specific content on an open innovation platform, that in turn will define the regulatory framework under which the collaborative project will operate.

When wanting to construct a platform that will consist of IP and intellectual assets it is necessary to in the first instance attend to the notion of what different legal tools there are that can be utilized in building a sustainable platform in the life science industry. A tool is the potential claim that an actor can have of something in the knowledgeable reality of an intellectual world. To exemplify, the concept of a "patentable invention" in the patent act is an intellectual tool that can be utilized to claim an explicit patentable invention as an intellectual building block in the construction of an innovation. The legal concepts of IPRs, property and contracts are fundamental tools that are transformable into building blocks that can be used in the design of a platform.[41]

The use of IP as a tool in governing R&D projects and thus in designing innovations in an emerging new sector such as the biotechnology sector is of utmost importance, since its expansion is dependent upon developing and reconstructing an intellectual toolbox that has adjusted property concepts and concepts of offers and transactions. The legal tools "have to be adjusted to operate within an intellectualized economy".[42] The context of an intellectualized economy and the construction of an open innovation platform therein would consequently require new perspectives on how to perceive the role of patents, since the traditional way of analyzing patents would be that they are regulatory interventions in competition and market behavior and not a part of the structurally construction of openness or a tool to build collaboration. Concepts such as the patent, patentable inventions and the patent license could, to be able to adjust to a new emerging economy, be perceived as tools that are to be used to govern strategic partnerships and R&D collaborations and build rather than to merely block others from accessing intellectual property. The perception of the patent and other IPRs would then be that they serve as self-regulatory tools in the construction of platforms where technology is accessed in an open manner rather than to assert a closed position.[43] A self-regulatory tool is the legal text constituting default settings and definitions that is used by actors as building blocks for contractual as well as transaction structures and is used on the open innovation platform to enable open access and to govern the parties' interactions.[44]

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[41] Petrusson (2004) p. 90-91
[42] Petrusson (2004) p. 92-93
[43] Petrusson et al (2010) p. 4-5
[44] Authors' definition

The understanding of the patent and patentable invention as tools that could be used in creating structural order in research will blur the lines between what used to be considered as only proprietary or free and one is able to discuss the different levels of openness that can be constructed through e.g. the use of patents as self-regulatory tools to ensure access to intellectual property and as a means to regulate openness.[45]

The contract is also a tool and building block that, when through the legal framework becomes binding, will qualify as a constitutive tool to use when designing the business phenomena that is an open innovation platform. When constructing commercial relationships of IP within a platform based on research results as the content, the use of a conceptual model such as methods to license and assign IP and IPRs become an important tool. The elaboration on an intellectual toolbox will have to encompass the models of contractual relations and concepts, property concepts and property rights concepts as legal tools to create a contextual framework around the construction of a platform. These legal tools could serve as a framework for aligning collaborative efforts toward a desired objective within a platform. [46]

3.1. The Regulatory System

As a part of understanding the process of constructing an open innovation platform in the life science industry, one has to see how the platform should be designed in relation to the regulatory and legal framework which it operates within. Without this as a foundation, the understanding of the implications that the legal framework can have on a platform construction will be insufficient and not serve the purpose of enabling the sharing of technology on a lawful basis. The regulatory system will also serve as a framework in which the contractual structures can operate, thus affecting the contract as a tool in the construction of a platform.[47]

The regulatory and legal framework will govern the tools utilized on the platform in the construction of openness and serve as an enabler in observing the different models used to construct the open innovation platform. Three different examples of regulatory frameworks have been identified by the authors due to their significant contribution to contemporary open innovation platforms, and they will be presented in the manner of their impact on the platform and its transactions and relations being constructed.

3.1.1 Intellectual Property Law

The IPR regulation and IPRs as such are essentially balancing two sources of value; the first source being that when knowledge is disseminated and widely used it will further public welfare both in production of physical products and also in the production of further knowledge, and the second source being that when an inventor is awarded protection the private incentives to innovate are higher when awards can be reaped due to this construction of protection. Accordingly, IPR legislation is aiming to optimize social welfare and strike a balance between "monopoly" and disclosure. The development of the knowledge based economy where products and services are knowledge-embedded requires IPR policies to ensure adequate protection for new technologies being presented in the field. The IPR regulations are under pressure when it

[45] Petrusson et al (2010) p. 6 ff
[46] Petrusson (2004) p. 95-97
[47] Petrusson et al (2010) p. 19

comes to guarding the technical advancements introduced to the markets, making the owners face difficulties in controlling their property's distribution and use since the developments made are more elaborate than what the legislation has previously faced.[48]

The authors see that the nature of IPR regulation and the way in which IPRs are being used will have an impact on how results from any technology-intensive platform or collaboration can be utilized and protected. It will also shape the tools that an actor can use to make claims in relation to other actors on the platform in regards to the collaborative output. The collaborative structure will also be impacted by the IPR legislation thus determining the constitutional criterion for protection and therefore impacting the collaboration structures because it is a central building block in protecting the output value. The IPR regulations will also impact the transactions and be used as a tool to share through the use of license structures on the platform.

3.1.2 Competition Law

The authors acknowledge that the relationships that are structured on a platform will consist of collaborative exchanges which is governed by competition law and other regulation that can determine whether these exchanges become threatening to the functioning of the free market. When a major collaborative effort is constructed and acted upon, particularly development platforms that consist of substantial technology collaboration and trade will need to be specifically designed to comply with competition law since the implications suggest that the transactions may be scrutinized and the platform as such could be subject to further investigation, ultimately having its privileges revoked. Even though the competition law is ensuring a functioning free market meaning that competitors should not collaborate to block the market there are certain collaboration within the field of R&D that are recognized as beneficial to the society which has been exempted from the rules of competition law.[49] When designing the platform, depending on which parties found as stakeholders in the platform the authors believe that one should consider the implications that competition law suggests to construct the platform in accordance with them.

Competition law can also be utilized by the platform so as to shape its internal policies and sanction mechanisms so that in the next step compliance is ensured. The need to comply with competition law and also use it as a mechanism to shape policies between the actors is particularly apparent when developing an open innovation platform within biotechnology when talking about the construction of a patent pool, which have met significant competition law obstacles and interventions.[50] The pooling of IP owners and their IPRs needs to be precompetitive and thus not create a blocking position and instead promote the dissemination of technology.[49] The design of a platform within life science would, based on the legal analysis made, have to consider the level of exclusion it actually operates with when openness to access and usage is constructed through the intellectual tools available such as licensing models and agreements on the allocation of rights and access to technologies. Competition law will thus as seen by the authors also have an impact on the contractual structures which are implemented in the area of life science in particular, due to the different platforms having content that could

[48] Cowan & Harison p. 2
[49] EU Commission Regulation 2659/2000
[50] Petrusson et al (2010) p. 20

potentially become a large part of an actor's R&D and thus the innovation market could be hindered.

3.1.3 Technology-specific Regulations

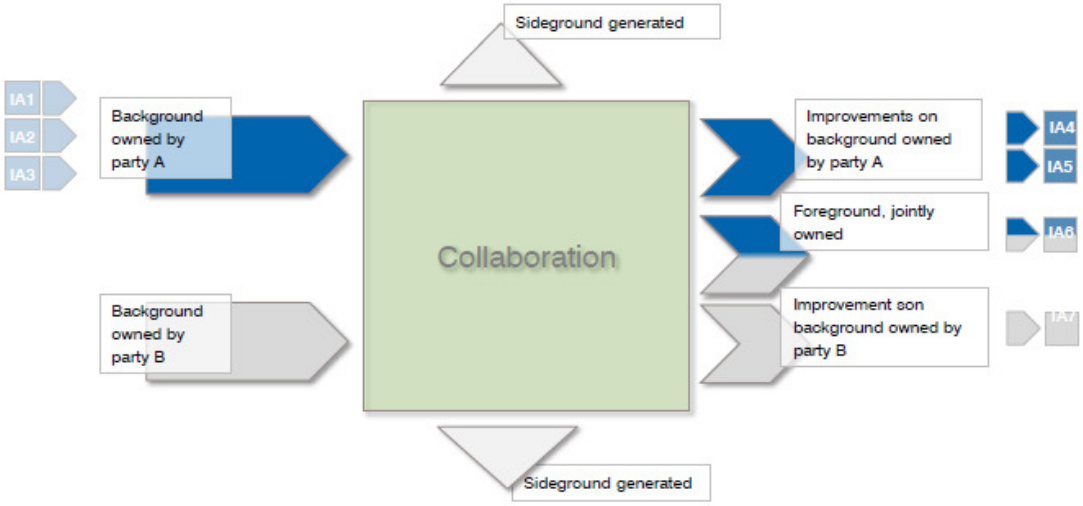
The design of an open innovation platform will also have to conform and take into consideration the technology specific regulations and rules which are particular to the domain that the platform will be constructed in. In the context of the life science industry, regulatory compliance is a core part when wanting to keep a competitive supply chain and research environment and at the same time enable profitable growth. There are different regulatory requirements to consider in this setting, and the most prominent ones to consider are the requirements on clinical trials for new pharmaceuticals and the certification of products to be released.[51] As the authors see it, these prerequisites will thus naturally have an effect on how the output and exploitation of results from pharmaceutical development collaborations will be constructed, since if a research result should not comply or reach the technological requirements set forth by regulation then the potential for utilization will thus become limited. The construction of an open innovation platform in the life science industry would then have to consider the different regulatory steps to comply with. The outcome is to some extent depending on the nature of the field and what the reasoning behind the platform is, but the technology-specific regulations are definitely a large part of the construction of the platform.

3.2 Contractual Structures

In building an open innovation platform the contractual structure is the foundation for the creation of the platform and will define the interactions between the participants. The contractual tool is based in the legal system but is mostly up to the parties to use as they like; the legal system is the last resource and resort to which the parties can turn in case of misinterpretation and assertion of the contract as such. The contract between the parties defines and clarifies the roles of the parties in their interactions and is the ultimate expression of the party's interests. The contract is also the creator of transactions in which certain clauses must be defined to structure the collaboration.[52] The contract is therefore seen by the authors as a fundamental tool in the platform development.

The contract also constitutes certain concepts and regulates the interactions between the parties but also ownership. A concept that is created based on the normative acceptation and the reification of tools, such as the "patentable invention", is that of Background and Foreground.[53] "Background IP" and "Foreground IP" is expressions of concepts that have been made popular through their usage in the European Seventh Framework Programme for research and technological development.[54]

[51] Petrusson et al (2010) p. 20
[52] Petrusson (2004) p. 165 and 202f
[53] Petrusson (2004) p. 156
[54] Petrusson et al (2010) p. 16



Visualization 1: Background, Foreground and Sideground Visualized in a Research Project

Background is the construct of what one party to a collaboration effort brings into the collaboration in terms of IP or other intellectual assets necessary for the collaboration. Foreground is what comes out of the collaboration that is defined in a project plan or otherwise. Sideground is valuable results that come out of the collaboration but which do not fall inside the objectives of the collaboration, i.e. was not needed for undertaking and completing a project.[55] In the collaboration that is visualized, one can see that the actors have divided the ownership of the foreground that is not an improvement on background jointly and kept background improvements owned by the initial parties. Often there is another layer adding to this having complex licensing structures for accessing each other's background and foreground.

The background, foreground and sideground regulations and constructions are thus very important in research and innovation because it will define the regulatory framework under which the open innovation platform will operate. An open innovation platform with IP as a tool in transactions and as content will rely on the concepts of background, foreground and sideground since once the scope of these have been defined, the rights of other parties to access and use the background of initial parties and the foreground created in the projects will follow and serve as a framework in the contractual structure of a platform.[56] This framework will according to the authors consequently serve as a foundation for shaping the level of openness chosen for each platform, due to the characteristics of background, foreground and sideground as determinants for how the platform content should be divided and utilized by the actors present on the platform, thus leading to determining how one should have access and usage rights to background, foreground and sideground which will set the level of openness. In sum, the authors have found that the claiming of intellectual property in the shape of these concepts is then done through the construction of a contract such as the license agreement, or a collaboration agreement could also be utilized. The contractual structure of the platform is then built upon constructions that are to be governed and the contract itself serves as a tool and building block in the construction of the platform.

[55] Telles
[56] Petrusson et al (2010) p. 16

4 The Tool –"Construction of Open Innovation/IP Platforms"

Professor Ulf Petrusson has created a tool or a toolset of questions that one needs to consider when constructing an open innovation/IP platform. The purpose of this section is to explain this tool in terms of what parameters and layers that he is proposing in the construction of the open innovation platform. A more detailed explanation of each layer will be found in Appendix 1. The purpose of explaining the tool is that the following study will apply this tool in analyzing life science platforms and further on give the possibilities in how each of these layers can be constructed from a legal point of view creating a toolbox for how to construct an open innovation platform. The chapter will as a result present an overview of the tool which should be kept in mind to understand the analysis performed with the tool in the following chapter.

To be able to build and leverage on an open innovation platform it is important to understand the context in which one is operating and the characteristics of the same, since the decisions to be made and relationships to be structured are dependent on the stakeholders that are present in a field as well as what is actually driving and influencing the development of the field. The life science industry characteristics introduced in the initial chapter will thus serve as the fundament for where and in what way an analytical tool for constructing open innovation platforms could be implemented, finding the proper context and adapting the analysis and information to be gathered to the contextual framework that the characteristics create. Furthermore, to be able to utilize the tool once the setting has been determined and the attributes of the same have been addressed, an introduction to the tools and concepts that serve as building blocks for the contractual structures that the analytical tool aims to uncover will give the necessary setting for how to deconstruct the different parameters and layers and what it is that they are actually looking to expose and how they have been constructed. The analytical tool in itself with the parameters and layers must consequently be introduced with the necessary considerations of the context and fundamental building blocks as complementary aspects that will help in interpreting and explaining the different parts of the tool.

These complementary aspects have also influenced the authors in deciding on which parameters in the tool to use when analyzing open innovation platforms. The division of the tools main building blocks has therefore been done in accordance with what the authors believe as accommodating for both the context of the life science industry and the specific tools and concepts used in the setting to properly build the toolbox that this thesis will present.

The parameters chosen within the General Platform Governance building block are focusing on what the actual content of the platform is, i.e. what kind of content that the platform operates with and how this content is leveraged i.e. controlled and used through the IPR claims which are made by the stakeholders on a platform. The parameters are further focusing on how this content is being developed on a collaborative scale and the interests of a platform and how structurally controlled the platform is. The parameters chosen are related in part to general characteristics of a platform as well as platform governance, which the authors are aware of and have chosen to implement due to the parameters specific suitability for the analysis within the context of the life science industry. The parameters chosen will add another dimension to the analysis due to the context in which it has been implemented, demonstrating the complexity of the life science industry as such. The authors have chosen to specifically include the level of

system/tool leverage that, even though on a general platform characteristics scale, still serve the purpose of illustrating the multiple and variable alternatives there are to content in this field. The description of platform content will furthermore serve the purpose of helping in dividing the categories of platforms based on their specific content.

The parameters chosen within the Platform Openness building block is in part focusing on a platforms ability to facilitate different levels of openness, i.e. access and use of content on a platform. The parameters are relating to how accessible the content on the platform is, how open the platform is for actors to include content, how an actor can use the content in R&D and innovation and how much it would actually cost to utilize the content. The parameters chosen are revealing the underlying constructions chosen for enabling and facilitating openness and the sub-set of questions serves as a direction for uncovering information that is relating to the tools and models for constructing the different layers of the parameters. These parameters have been chosen due to their relevance for the life science industry and their potential for application within this field.

4.1 The General Platform Governance Parameters

The general platform governance parameters will uncover how the parties have constructed their relationship in terms of what content that will be primarily shared on the platform and how this value is protected and leveraged upon. These parameters will also touch upon which stakeholders the platform consists of, how they have chosen to collaborate and what primary purpose the platform will have.

4.1.1 Level of System/Tool Leverage

An open innovation platform can take several forms depending on the central components being platform technologies. The value of the open innovation platform in this sense is the sharing of platform technologies.[57] These technologies or created concepts make it possible to transform knowledge into transactable objects packaging it with the help of IP and virtual products. This phenomenon is the basis for the knowledge based businesses driving the knowledge economy.[58]

This parameter, as has been interpreted by the authors, focuses on the purpose of the open innovation platform and measures the leverage of the content on the platform which is often the focus and the incentive of creating the platform. To distinguish between platforms and to evaluate this parameter one could ask "to what extent each platform is constructed to leverage developed value, from simply collecting and opening up access to valuable knowledge, to sophisticated systems that regulate and enable access, development and transactions of knowledge".[59] There are several different types of content or leverage systems which a platform could be built around, the tool that the authors have chosen talks about five layers;

[57] Merges p. 14
[58] Heiden (2010)
[59] Petrusson et al (2010) p. 15

1. gathered data/ R&D results etc.,
2. packaged content and/ or features,
3. systematized toolbox,
4. operational system and
5. a multilayered system, where one layer generates a market like platform for the next layer.

4.1.2 Level of Collaboration

The Level of System/Tool leverage is according to the authors a good way of starting an analysis of an open innovation platform in seeing the object of the platform. Taking the next step and seeing the form of the platform one should turn to the stakeholders of the platform and in which environment the platform is being constructed.[60] The authors therefore conclude that dependent on the stakeholders, their incentives and needs of the platform, the regulatory framework for operations on the platform will be established through access and right structures, meaning that the collaborative actions and relationships of the stakeholders will be dependent on the purpose of the platform or collaboration and the incentives of stakeholders in combination with negotiation skills.

This parameter will be the structure of the platform, determined by access and usage rights resulting in competitive relations, pre-competitive relations or collaborative efforts of developing the object of the platform. The relations presented by this tool are:

1. competitive relationships where each actor develop their own contribution and compete in having it included in the platform,
2. competitive relationships where collaboration exist in pre-competitive areas,
3. collaborative relationships controlled by one or few actors (cluster logic),
4. collaborative relationships with more or less equal parties, or
5. a multi-stakeholder collaboration/community

4.1.3 Level of Public Responsibility

This parameter will show how the platform shoulders public responsibilities. This is affected by the stakeholders of the platform, whether they are public or private, competitors or join in collaboration. The purpose of the platform will also play a role in how much public responsibility will be shouldered as will the openness regulations.[61] The platform could based on the analysis made be instituted by the public for the benefit of society or through private actors in a public domain or all for commercial/private purposes, not having the public interest in mind. The layers of public responsibility are:

1. only of private interest,
2. primarily of private interest, but there is a public interest that competition is not restricted,
3. a platform where interests of the open society is included,
4. a constructed public domain, or
5. public infrastructure

[60] Petrusson et al (2010) p. 16
[61] Petrusson et al (2010) p. 16-17

4.1.4 Level of Platform Governance

The platform governance will influence the control of the content that objectifies the platform and be influenced by what level of collaboration that exists in the platform. The more formally strong the platform is the easier it is to transact valuable objects, packaged without IPR protection among the stakeholders of the platform.[62] This parameter will indicate how formal the organization or governance construction of the platform is, and the different layers are:

1. project oriented and controlled ad hoc in project contracts etc,
2. driven by network control according to a contractual model implemented in a web of contracts,
3. controlled by a jointly created and relatively informal organization,
4. controlled by a formally strong and hierarchical organization, which presents policies and enters into contracts with stakeholders, or
5. a formally strong structure supported by the public and acknowledged in public policy/regulation

4.1.5 Level of IPR Claims

Platforms have different objects, platform technologies or content that they provide through the platform, meaning that the protection for the different objects of the platform will be different, however in the field of life science it is mostly about patent protection and even copyright protection due to the emergence of the bioinformatics industry. The level of protection of the platform objects influences how open access on the platform could be managed and the level of usage that other participants can have to the platform; the more protection of objects on the platform that the platform uses the more structured can transactions be on the platform and therefore become easier to handle.[63]

This parameter measures the claims on the platforms in the form of ownership of IPR's but also if the platform requires protection of objects for the objects to be recognized on the platform. The protection levels that exist are:

1. not patented or protected by other IPRs,
2. rarely patented or protected by other IPRs,
3. protected to a large extent,
4. patented in a systematized way, or
5. has to be patentable or patented if to be included?

[62] Petrusson et.al (2010) p.15
[63] Petrusson et al (2010) p.18

4.2 The Platform Openness Parameters

The different levels of general platform governance, as described above, will be complementing, complemented by and interacting with the platform openness level, which will be defined by how the platform has chosen to handle the access, inclusion, usage and cost of the platform objects, platform technologies or content it provides.

4.2.1 Level of Access to the Platform

The level of access to the platform is a part of governing the rights of the stakeholders on the platform, and will distinguish between which stakeholder that will have the right to use the content or rights to see the content of the platform or have the right to become a participant on the platform, and thus determine how the actors will in practice be able and incentivized to participate in the platform as well as which transactions that will take place in practice due to the platform openness.[64] When discussing the different levels of access the authors acknowledge the fact that it is important to recognize that the content on the platform in this setting is usually sophisticated and contains multiple objects and platform technologies, which could be divided and access could be granted to some but not all parts of the content. Therefore, the authors believe that access can be regulated through different means for the purpose of diversifying among the actors of the platform or carrying out transactions of research results under certain terms.

This parameter consequently measures how accessible the content/data on the platform really is through a level of restriction between the platform and its stakeholders. The levels that exist in terms of access are whether the access is:

1. restricted to the developers,
2. restricted to a group, cluster etc,
3. restricted to a closed community,
4. restricted to an open community, or
5. open to everyone

4.2.2 Level of Openness to Include Content etc in the Platform

The openness of an open innovation platform could further be determined by the way in which the platform allows the inclusion of content onto the platform, i.e. how open the platform is for actors to include content/data. The opportunity for an actor to include parts to a platform is further enhanced or restricted by the IPRs existing on the platform and the way in which they have been handled in terms of whether there is an environment which considers IPRs as being a binding commitment to openness as the right to include or as a right to exclude and restrict.[65] Thus, the authors have seen that this parameter is affected by the level of IPR claims that exist on the platform, and together these parameters indicate how sophisticated the platform is in terms of leveraging openness with the help of IPRs. The right, or opportunity, to include content in the platform is according to the authors a construction that, depending on the level, could incentivize actors to jointly develop and share platform technologies.

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[64] Petrusson et al (2010) p. 18
[65] Petrusson et al (2010) p. 7-8

This parameter then measures which opportunity actors have to include content in the platform, and the different levels that exist are:

1. restricted to a development group (venture),
2. restricted to a cluster,
3. restricted to a closed community
4. restricted to a open community, or
5. open to everyone.

4.2.3 Level of Open Usage in R&D

The platform technologies, objects or content that is presented on an open innovation platform should to some extent be utilized and further developed by the actors that are a part of the platform. The research that is being done will in the context of the platform be packaged and controlled with a certain level of sophistication depending on how willing the actors are to let the results be leveraged upon by others, and then whether the utilization comes with an agenda, as found by the authors analysis. The agreement on how the use of the technologies should be managed is primarily done through a contractual structure, since the intense IP transactions that will take place in the system require regulatory tools to be administered properly.[66] The authors have seen that the interests of the actors on a platform could differ and thus affect how they have decided to divide the utilization paths of generated results between participants, since it is important to allow for a flexible allocation system to support the individual interests of the actors while at the same time incentivize contribution to the platform. The division of utilization of the content on the platform for R&D purposes will as seen by the authors also be affected by the level of access which has been given in a prior state to results on the platform, and in turn this result can be divided into the content which has been brought in to the platform as well as the results which are generated in collaboration between the actors.

This parameter will then indicate the different options available for actors in terms of dividing the utilization of research results in R&D, i.e. how open the platform is for content to be used in R&D. The different levels that exist are:

1. no right to use the content in R&D,
2. an opportunity to negotiate the right to use,
3. a right to use the content under restrictions,
4. a right to use the content with a grant back, or
5. fully open usage R&D

4.2.4 Level of Open Usage in Innovation

In the same way in which the level of open usage in R&D is handled, the division of the utilization path for the research results of the platform could be selective in terms of how the actors could further the content in terms of production, business modeling and sales. The platform could have determined an end-goal with the research where commercialization is key and thus open up the usage of the content in innovation to further that goal, or the platform could consist of competing actors that collaborate on a pre-competitive state where

[66] Petrusson et al (2010) p. 10

commercialization is not the end-goal. This in turn creates a need for access to certain content on the platform depending on the purpose of the collaboration, thus showing the interdependence between the different parameters. The allocation system is based on the rights conferred by the parties to the platform and the access right obligations specified; an actor could have the right to commercialize results within a certain sphere without having any access right obligations, due to the way in which content is included and separated between the actors. The level chosen in this field will decide how the development of the content will proceed and be used to leverage the content and create value for the actors involved.

This parameter thus indicate the different options available for actors in terms of dividing the utilization of research results in innovation, i.e. how open the platform is for content to be used in innovation. Is there:

1. no right to use the content in innovation,
2. an opportunity to negotiate the right to use,
3. a right to use the content under restrictions,
4. a right to use the content with a grant back, or
5. fully open usage in innovation

4.2.5 Level of Costs

The value of being able to get access to and use the content of an open innovation platform is further derived from the principle the platform chooses to implement in terms of payment and sponsorship. This parameter, relating to the level of costs on the platform, is as could be concluded from the analysis related to which construction the platform has decided to implement regarding the transactions being done on the platform, i.e. whether licenses are being used, IP policies are in place stipulating the terms of the joint development and so forth. The more the costs are directed to the commercial setting and negotiation based terms the more they suggest that the results being generated are to be decided on a case-by-case basis or whether there is a fixed rate to be followed. On the other hand, the more the costs are directed towards using acknowledged principles that support open sharing of information, the more it suggests that the results generated should be accessible to anyone, not letting the level of costs be a significant factor to take into consideration.

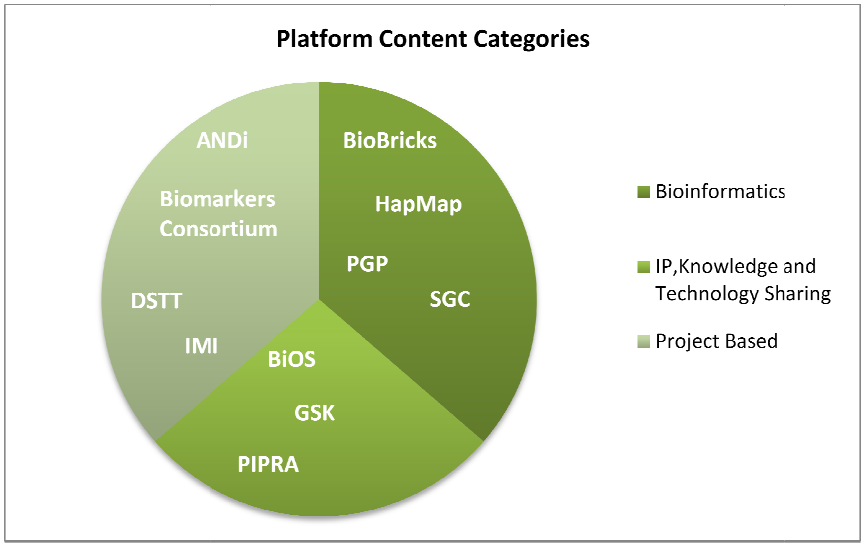
This parameter then indicates how expensive the access and usage is. The principles are:

1. commercially negotiated,
2. fixed commercial terms,
3. fair and reasonable terms,
4. publically or otherwise sponsored, or
5. free access and usage?

5 Analysis of Existing Platform Structures

This section aims to analyze different forms and structures of platforms that are prevalent around the world within the life science industry. When using the tool for analysis of platforms the authors categorized the platforms according to system/tool leverage parameters, collaborative structures used and governance formats to give an overview of the platform constructions of certain fields. This section will show the common denominators or variations of platforms within similar fields, drawing conclusions and discussing why the platforms are constructed in the way that they are. This leads to a constructive analysis pointing out interrelations between parameters constructing the platform and further on also discussing how these platforms have created the governance structures and openness that they want their platform to have based on the contractual structures and regulatory systems present. This section will also highlight when the tool has been difficult to apply to the life science industry setting.

The authors have included a number of platforms to analyze for the purpose of giving examples[67] but also to see if the applied tool would be able to differentiate between platform structures. In choosing the platforms to analyze the authors started out with some more commonly known platforms within the field such as Innovative Medicine Initiative (IMI), African Network for Drugs and Diagnostics Innovation (ANDI), Public Intellectual Property Resource for Agriculture (PIPRA) and Biological Open Source (BiOS). Taking this standpoint the authors found more internet based platforms focused on the sharing of bioinformatics, choosing to analyze BioBricks, The International HapMap Project (HapMap), Personal Genome Project (PGP) and Structural Genomics Consortium (SGC) further. The authors also wanted more physical content based platforms and therefore analyzed Biomarker Consortium, The Dundee Division of Signal Transduction Therapy (DSTT) and GlaxoSmithKline (GSK) as further analysis objects, now having a differentiated and adequate number of platforms to perform an evaluation.



Visualization 2: The Evaluated Platforms divided in Categories

Performing the analysis of the platforms, evaluating each parameter and layer constructed in the platform, the authors have been able to categorize the platforms according to their structures with the tool as a basis for the categorization. The classification has been based on the

[67] The platforms are introduced in the Reference list (Chapter 8)

system/tool leverage structures, collaboration and openness regulations evaluating the platform, placing the platforms with similar intentions and purposes within the same category. Thus the Bioinformatics category has been formed based on the content and collaborative openness measures included in the platform. The IP, Knowledge and Technology sharing category is built around the concept of having a body of IP, knowledge or technology that is shared and in some way enhanced through collaboration or used for the purpose of sharing. The third category is constructed after the governance or way of collaboration and sharing on the platform having the purpose of network building, which is designed in a project structure thereby constituting the Project Based category.

In each of the categories a brief introduction to each category will be made followed by a review of the platforms and their patterns of construction and approach towards governance and openness. The common denominators and similarities will be addressed and how the platforms have used different mechanisms in order to handle the construction of their platform in the separate categories. When the category is somewhat aligned specific platform examples will not be addressed separately, however platforms that have specific characteristics or are differing in a noticeable way will be addressed.

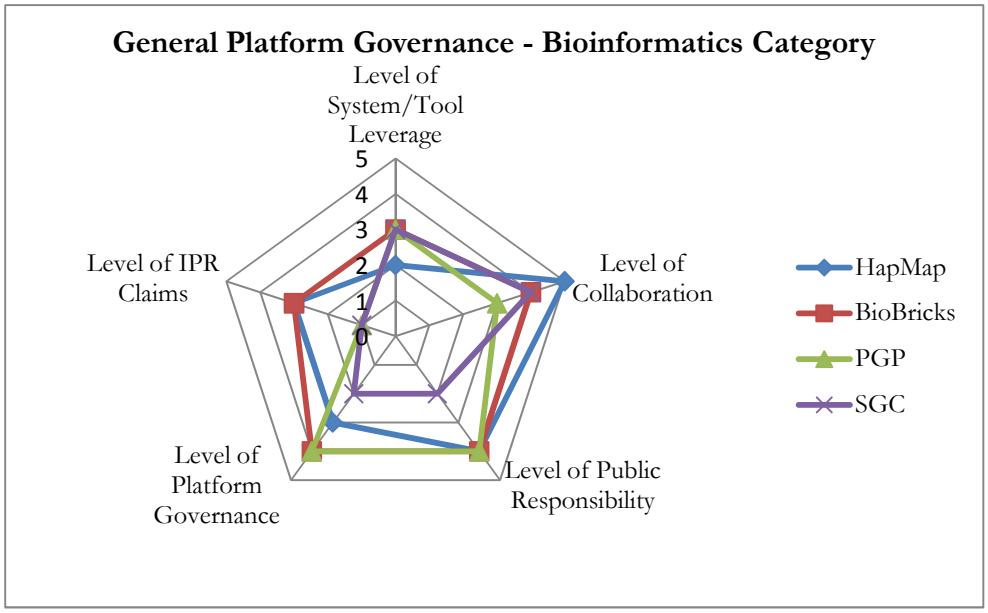
5.1 Bioinformatics Category

The Bioinformatics category is created by the authors based on the content provided for through the platform and collaborative efforts that exist. The common denominator for these platforms is that they are providing web-based material in the form of sequences of the genome or 3-D based visualizations of proteins etc., all where the logic of supplying the material through the internet is possible. The evaluation shows that the value created on the platform is through the sharing of research results that actors can build upon, and that will enable the research conducted and development of products or systems.

The development of a database that store biological information consequently involves highly complex interfaces whereby researchers could both access the existing data and information and also submit new and/or revised data. The logic behind the category of Bioinformatics is then centered on the concept of open source and its potential implementation in the biotechnology field. The reasoning behind open source lies within the copyright protection, which has enabled it to share proprietary information through general licenses to serve the public with information through the internet. Thus, the open source licensor "forgo the value of the technology as a private good in order to establish—or reestablish— it as a public good".[68] In the biotechnology field, the implementation of an open source model would suggest having to take further steps from having proprietary collaborative licenses based on patent protection to place knowledge and technologies in the public domain and invite the broadest possible range of participants through computer science to help realize the technology's full potential.[69]

[68] Hope p. 153
[69] Hope p. 156

5.1.1 General Platform Governance in the Bioinformatics Category



Visualization 3: General Platform Governance diagram for the Bioinformatics Category

As stated above, the content of these platforms has as a common denominator that all content on the platform is possible to supply through the internet, in this case in the form of sequenced genes or 3-D based structures of e.g. proteins, i.e. a form of bioinformatics information. The analysis shows that most of the Level of System/Tool Leverage parameters are deemed to be packaged content and/or features (2) or most commonly a systematized toolbox (3). When the authors have evaluated on which layer one or another platform is existent it sometimes has been hard to make the distinction between a systematized toolbox (3) or if it is merely a database which would be a packaged content/feature (2). This has been particularly hard when considering the multi-features of a biomarker, even though it is in a database structure it could also be provided and used as a tool for further research depending on the business model of the platform. There is also a possibility for bioinformatics data such as the sequence of a genome to be deemed as a multilayered system (5) due to the similarity with this being a basic layer which could provide a market like structure in the personification of medicine. However, the market for personalized medicine is still young[70] and even though the foundation is being set, the market layer might take several years or decades to create. This means that when looking at a platform structure it is not a static picture that should be evaluated but the dynamics and the interrelations between the collaborative structures and governance, resulting in the value propositions of the platform which must be taken into account to set the Level of System/Tool Leverage. This parameter is also dependent on the IPR claims made due to the control that is needed or wanted to leverage on the platform content.

Further elaborating on the protection needed in a platform structure this category is characterized by using the copyright protection rights as control mechanisms. Databases that are web-based and supplying a layer of information that is possible to build and choose from is protected as

[70] The Basics on Personalized Medicine

databases with copyright protection as the foundation.[71] The analysis of each platform shows that most platforms could have protection through copyright, but some platform actors have chosen to surrender all rights, e.g. through a Creative Commons Zero (CC0) license. This suggests that they in the evaluation are deemed as not IPR protected at all (1), since this is the underlying reasoning for surrendering those rights; this is shown in the Level of IPR Claims. Even if the platform as such is protected through IPR's and some rights from the copyright protection is exercised in connection with the platform, all results in the database are let free to the public domain (see below regarding Platform Openness).

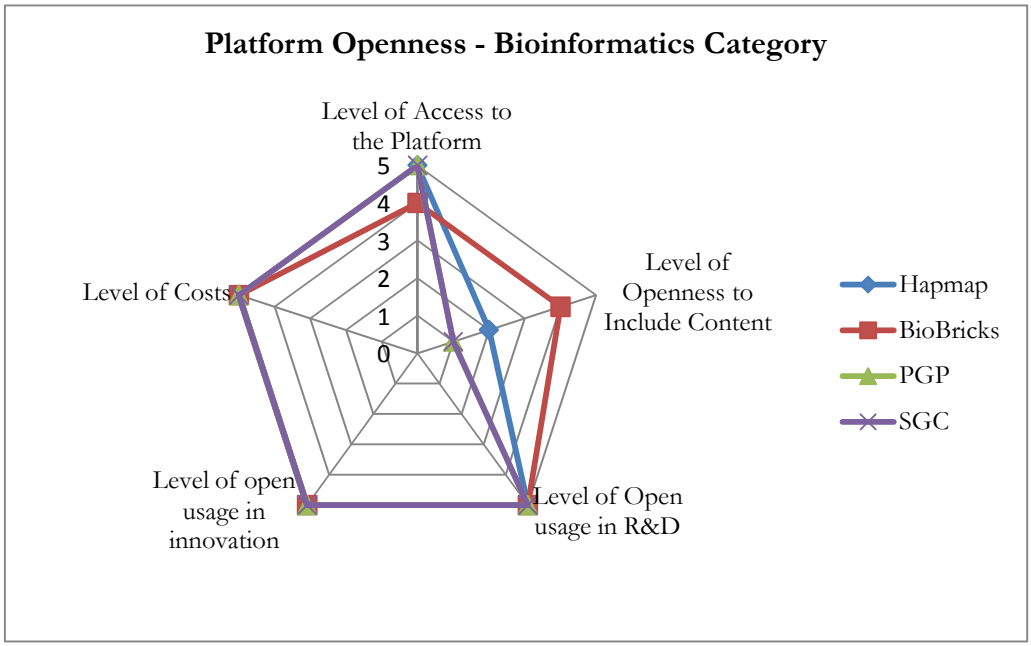
The evaluation shows that these types of platforms are typically run by some kind of formal organization, consortia or board; however, how the initiation of such governing structure has come about is quite different, indicated by the Level of Platform Governance. The platforms are either governed by network control through a web of contractual agreements between the participants (2), or through a contractual model were an informal organization is created jointly to govern the platform (3) or a formal organization that governs the platform and by itself introduces new policies and enters into contracts with stakeholders (4). Governing procedures are also often connected to the type of Level of Public Responsibility that the platform encounters due to the purpose and initiating parties of the platform. Shown by the analysis is that the more public interests that a platform shoulders the more strict governance structures are implemented in the platform, often depending on involvement from public actors that often require more bureaucracy and more control by a governing organization, consortia or board, therefore also affected by the collaboration structures and stakeholders of the platform.

This category of platforms is characterized by openness when it comes to collaborative partnerships, joint development and contribution to the platform for the good of the public domain as a common feature. The collaborations could be relationships controlled by one or a few actors (3), with equal parties (4) or a multi-stakeholder/community partnership (5) where the same goal is not competitive with one another's, shown in Level of Collaboration. The collaboration structures of these platforms are built on the notion of having a forum where information is shared between the stakeholders of the platform to create a standard or enhance the information in the public domain, often not collaborating on R&D together. Therefore, the layers of the tool used for the analysis are not optimal in evaluating the collaborative efforts of Bioinformatics category platforms.

In general the platforms analyzed in this category, content and internet-based platforms, has similar patterns of construction; a high level of collaboration together with basic research projects where most of the actors aim at freely releasing content into the public domain where many actors have an interest in openness and therefore also has a high level of public responsibility, ensuring that upstream research results are made public. The governance of the platform is differentiated but in general one could say that an organization or the like will govern or have the responsibility of the platform and the activities carried out by the platform. The content on the platform is made available to the public; however, the platform as such is often protected as a database with copyright protection, more or less enforced by the actors.

[71] The Swedish Copyright Act

5.1.2 Platform Openness in the Bioinformatics Category



Visualization 4: Platform Openness Diagram for the Bioinformatics Category

There are several kinds of openness and there are several ways for a platform to open up and to be called an open platform; however the Level of Access to the Platform might be one of the things regarded as an especially important parameter for openness, having access to the platform content. For the bioinformatics category, the access to the platforms is very open, as can be seen from the analysis, and this is a trend that could be recognized from the open source movement. However, even though the access to the content is open the authors can see a more restricted approach when it comes to inclusion of content on the platform; a characteristic recognized from e.g. Linux.[72] The Level of Openness to Include Content could also be more restrictive because the platform, when opening up results etc., want to be able to control the quality of the platform content and therefore restrict the development either to a group of developers (venture) (1) or a group/cluster logic (2) or maybe to a more open community (4) still having some restrictions on who could contribute to the platform (3).

The Level of Openness to Include Content on the Platform is very much intertwined in the web of governing structures set up by the platform. This parameter will be affected by the public interest which the platform shoulders because of the nature of participants having diverse interests in the distribution of access to content which is needed when wanting to have a larger group of developers. This is also very closely connected with the IPR claims made by the platform being proprietary or less proprietary which in turn is dependent on the public responsibility and the collaborative efforts by the platform. Openness to include content is also interrelated to the access of the platform structure because in some instances one must be granted access, as a first step in the process of including content on the platform.

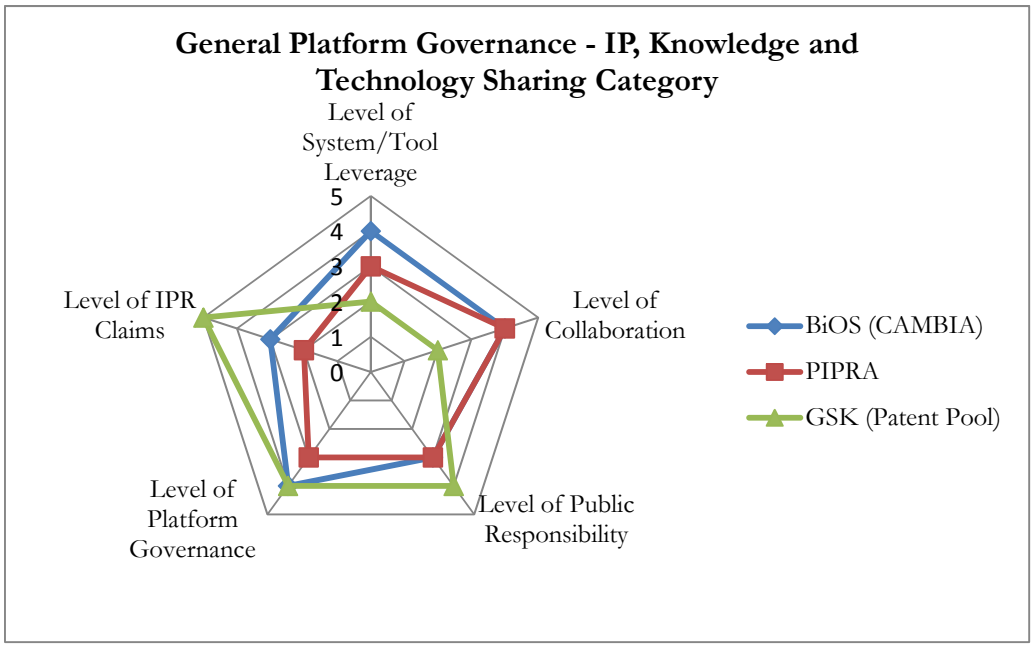
[72] Linux Website

The Level of Open Usage in R&D is fairly high in investigated platforms and their content is free to use by the public in R&D. One of the reasons for this is that the gene sequences or 3-D protein visualizations are very basic building blocks that are needed in downstream research and many actors agree that these kinds of structures needs to be in the public domain for the good of the research society as a whole. Many of the investigated platforms do not only release the content for R&D purposes but also for innovation, meaning use for commercialization and in business models etc. shown in Level of Open Usage in Innovation that is also fairly high. The cost for using the content is low and therefore indicates a high openness on the Level of Cost parameter. The openness for usage on the platform is also as the level of openness to include content very much dependent on the collaboration setup between the participants of the platform, the purpose and the IPR claims made on the platform because of the hurdle of controlling unprotected research results in a commercial setting, which in turn is intertwined with the public interest of the platform due to the stakeholders active on the platforms interest in taking on public responsibility.

5.2 The IP, Knowledge and Technology Sharing Category

This category include IP, Knowledge and Technology sharing pools or platforms, meaning that the value creation and the emphasis is not on joint development but sharing of rights/knowledge or information together with service providing platforms. This category was created based on the purposes with the platforms but also based on the Level of System/Tool leverage in combination with the Level of Collaboration. This category is diversified in the point of having different structures in many of the different parameters discussed which could be a result of having different IPR claims influencing the Level of System/Tool leverage. Below these differences and some similarities will be elaborated upon.

5.2.1 General Platform Governance in the IP, Knowledge and Technology Sharing Category



Visualization 5: General Platform Governance Diagram for the IP, Knowledge and Technology Sharing Category

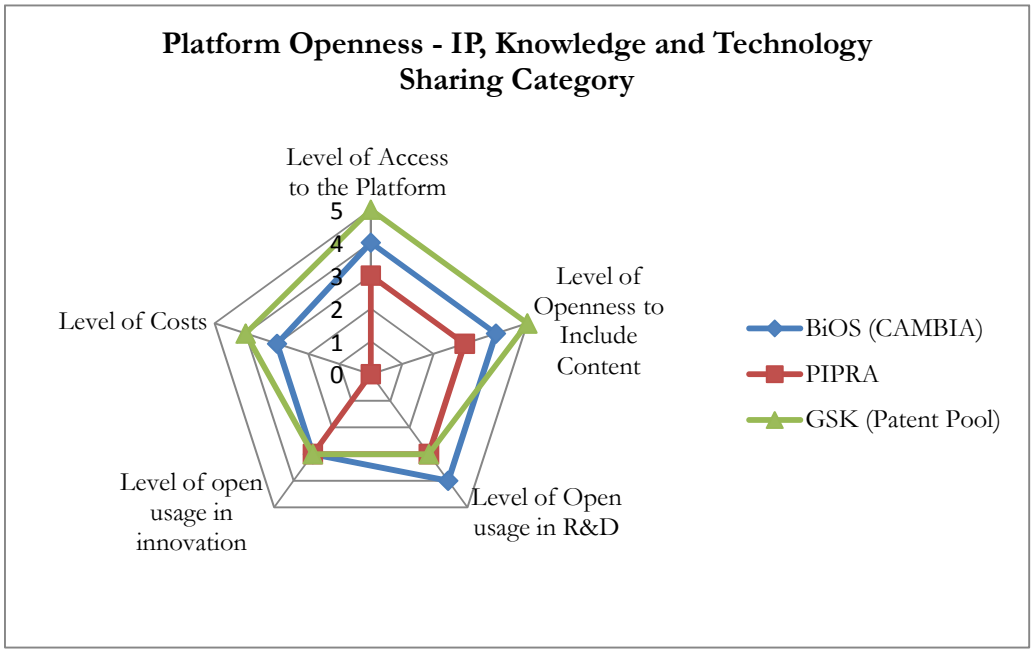
The IP, Knowledge and Technology Sharing category has the characteristic in common that content on the platform is separated mostly because of the IPR claims made in relation to the content. A patent pool like GSK consists of patents which are packaged content (2), also meaning that the level of IPR claims must be patented to be included in the platform (5); however, this is not entirely true since there could be a certain amount of know-how also floating around being licensed in connection with the patent, however this level of IPR claims is the most preferable for this kind of platform to achieve its purpose. Other platforms with more sophisticated content like systematized tools (3) or operational systems (4) are not as controlled with IPR's, probably not depending on the level of protection wanted but the characteristics of the content and material provided through the platform. These correlations can be seen in Level of System/Tool Leverage and Level of IPR Claims. The analysis has shown that the Level of System Tool leverage is highly dependent on the control mechanisms implemented around the content on the platform meaning among others IPR claims which is one of the most important building blocks in construction of the System /Tool leverage. The control mechanisms are also affected by the governance structures that the platform has chosen.

The investigated platforms are to some extent organized under a governing organization, informal (3) or formal (4), created jointly or by one actor meaning that these kind of platforms might be difficult to control ad-hoc since the basis for these kind of platforms are some kind of governing figure. In the GSK case one actor needs to provide the patent licenses, in the PIPRA case someone needs to be the service provider, database builder and manage the connections. BiOS is also structured around a technology pool like GSK, demanding a governing figure entering into contracts on behalf of the platform. There are always solutions that are better than others and the authors do not want to pose the assumption that platforms like this could not be governed ad-hoc or through contractual webs; however, the study shows that more actors are strategically choosing other ways of governing structures for this types of platforms.

The Level of Public Responsibility indicates if there is a private or public interest as the purpose of the platform. The study shows that the investigated platforms have more or less a public interest of not restricting the use of the content on the platform, either a limited interest or are aiming to shoulder higher public responsibility. Even though the public responsibility is influenced by collaboration structures and the governance of the platform, there are no trends to be seen on how these are constructed throughout the investigated platforms, meaning that the platforms have not chosen the same structure of regulating the three parameters. The PIPRA and BiOS platforms have participants that develop their content together while GSK content is developed in competition but supplied as content on a market where actors are not competitors. All of the three platforms take on relatively high levels of public responsibilities.

In general these platform structures are built for different purposes and consequently have different structures; the PIPRA and the BiOS platform are the most alike even though they do not have the same content nor purpose, therefore no conclusion can be drawn that even if a similar purpose is found or not, the platform structures must be fitted to each platform to reach the goal of that particular platform and not follow standard solution.

5.2.2 Platform Openness in the IP, Knowledge and Technology Sharing Category



Visualization 6: Platform Openness Diagram for the IP, Knowledge and Technology Sharing Category

The platforms in the IP, Knowledge and Technology sharing category are aimed at assembling content in one place for stakeholders to view and finally implement in their own R&D but also for utilization by society. The nature of collaborations being centered on the sharing of rights, knowledge and technology makes the Level of Access to the platform highly important. The platforms are however not coherent in their choice of level of access, which is primarily dependent on the different levels of memberships which they have chosen to implement as structures for the collaborative sharing of information. The platforms have generally chosen a solution that is based on acceptance where one, if one wants to be a part of the community, have to agree on the terms and conditions set forth, which then differ between the platforms.

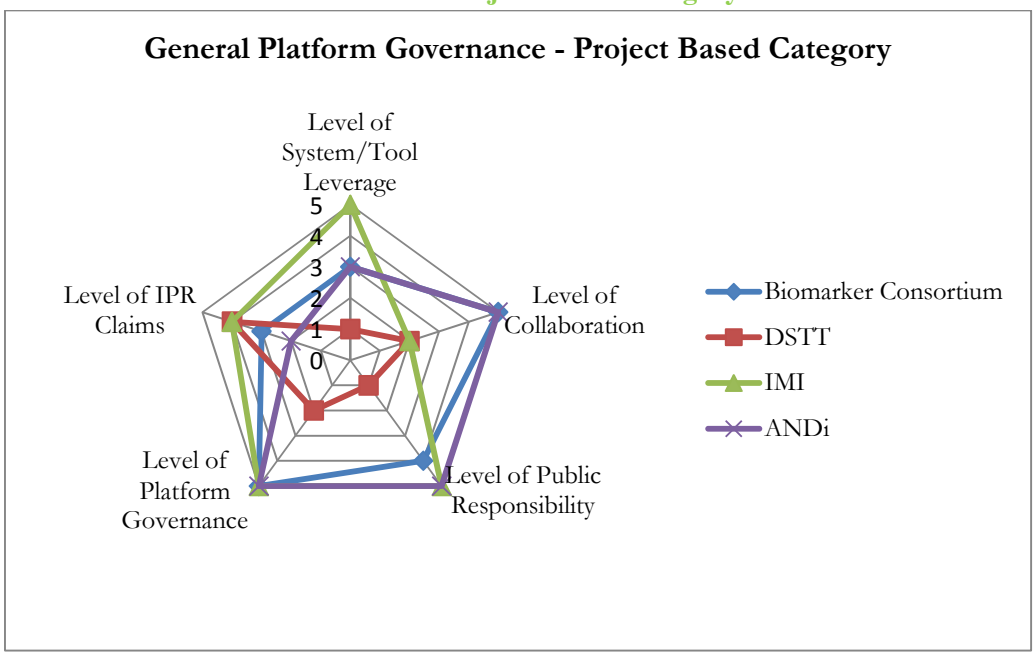
The inconsistency between the platforms is further shown in the Level of Openness to Include Content, where structures are differing based on what model the platforms have chosen. An explanation for these discrepancies could be the significance put on the information and IP being shared through access to the platform. However, the trend that can be seen is that despite their inconsistencies the platforms have put emphasis on the ability of participants to use the IP and knowledge in their R&D. The reasoning behind this is in part because of the platforms intentions of not blocking other parties from doing R&D which they can achieve through utilizing their IP, knowledge and technology to open up research efforts so that they as well as others can benefit from it. This is thus a reflection of the Level of Public Responsibility taken by the platforms. Actors are aiming at finding new ways to stimulate research that might otherwise not happen, and they are doing this through their sharing of IP, knowledge and technologies in different ways. The same principle goes for their Level of Open usage in Innovation, since the platforms to some extent ensure that the participants, through a few restrictions, still have the opportunity to use content in commercialization and at the same time give back to the platform.

To conclude from the made analysis, the IP, Knowledge and Technology sharing category all have the common denominator of using their assets to create value for themselves as well as others through open sharing on platforms. They have however different approaches towards the actual construction of the sharing of information, but one can see that the trend is to use the platforms to move away from using the primary feature of patents (the right to exclude) towards a usage of its status to regulate openness and ensure access for others constructed as intellectual building blocks. The platforms are similar in terms of providing open usage in innovation and R&D, but are positioned on different levels in terms of access and opportunity to include content on the platform. In this aspect GSK primarily stands out as they have chosen to employ an open approach in both access and ability to include, but have a rather strict term when it comes to fields of use for the research and so forth. This clearly indicates the dynamics of this field and the very different levels that a platform can employ to create and sustain openness to promote innovation and research.

5.3 Project Based Category

The Project Based category is characterized by the platforms having elements to them that represents different actors coming together to form projects on the platforms, thus having the value created through the platforms enabling and facilitating the collaboration through certain means and providing the basis for the actors to construct their networks. The common denominator between the stakeholders that are present within these platforms is that they have utilized the existence of a platform structure where e.g. academic researchers and industrial actors can come together and have a broader focus or relate to an area of technology where they have mutual interests. The role of the platform can then be to support the development of the content of a specific project through either funding or enabling knowledge transfer and joint development efforts and so forth.

5.3.1 General Platform Governance in the Project Based Category



Visualization 7: General Platform Governance Diagram for the Project Based Category

The analysis shows that the Level of System/Tool Leverage on Project Based platforms is not coherent. The value created through the platform is thus the content created by the platform, however the platform can be seen as a value creator itself e.g. in the multilayered system (5) where the platform as such creates value to the market created which then is the content on the platform. Project Based platforms can therefore contain several different layers of content meaning that openness constructions must be adapted to each layer of content, as must the other parameters so that most value can be created from the content i.e. also the purpose of the creation of the platform. When it comes to determining which level of System/Tool leverage that is existent on platforms there has been a challenge due to the project based nature in which the content could take many forms but also to some of the projects infant nature. This is the case with the ANDI platform due to the fact that no projects have been initiated meaning that a judgment had to be made on the information on what will become content on the platform. When it comes to the IMI structure the challenge was to see the complexity from a holistic perspective since the leverage structures in the platform are highly sophisticated, correlating with the goal and public responsibility shouldered by the platform to enhance the process of drug discovery to market meaning that a new market is created that was not possible earlier due to the obstacles in the process; however, the difficulty here is to take the overview perspective seeing all infrastructures built to support the Level of System/Tool leverage.

The Level of IPR Claims that a platform could make is depending on the content of the platform. A common characteristic of life science research is that patenting has been more upstream[73] and therefore could cause patent thickets which could be a significant problem. In the platforms analyzed, research is of a basic characteristic and therefore IPR protection is more directed towards having the content on the platform protected and/or patented in a systematized way (4), since the level of basic research is a field where patenting nowadays is considered as being more of a strategic way of ensuring that the commercialization path is clear and thus not hindering the use of the technology in downstream markets.[74] The authors believe that the purpose of doing biotechnology research in a project oriented setting is most certainly to generate research results that are of such prevalence that it should be subject to IP protection. The proximity to commercialization may perhaps not be that significant, but the protection is to be leveraged upon at a later stage and therefore needs to be handled in a more sophisticated manner.

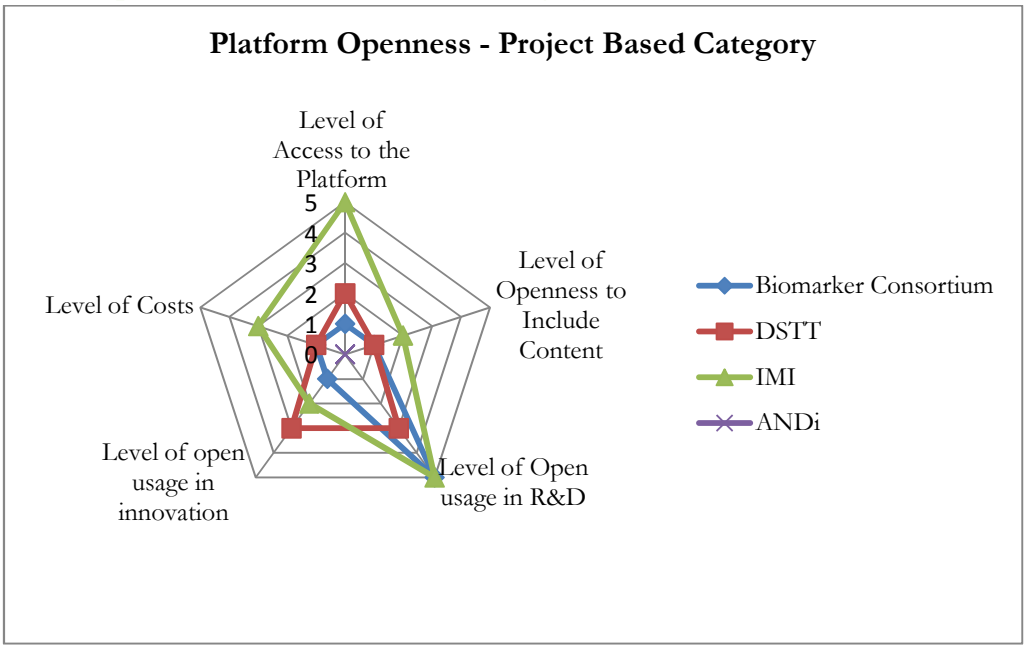
The existence of a formally strong structure which is supported by the public is prominent within the project based platform, as indicated by the analysis in the parameter Level of Platform Governance. This in turn correlates to the Level of Public Responsibilities shouldered by the platform, since the majority of the platforms are public infrastructures (5) or public domains (4) that are created to oversee a public interest and is then in turn governed by a supported strong structure such as a public actor (5) or another strong and hierarchical organization (4). This would suggest that a platform based on projects that has as a high-reaching aim of solving public interests often is governed through a formally strong structure.

[73] Petrusson (2004) p.41
[74] Petrusson et al (2010) p. 29

However, as can be seen by the analysis there are other possibilities, e.g. to create an ad hoc governing structure where contractual models are used to drive the network control; this can consequently be done when the private interest of the parties to the platform are more prominent than the public interest which is shown by the DSTT structure. Here, the parties to the platform are primarily private companies funding projects initiated through a university division to enhance their own research. However, this could suggest that the Level of Collaboration could be based on competitive actors coming together in collaboration on the platform in pre-competitive areas or areas in which they are separated by interest in the platform. Other platforms within this category that works with a common goal are either based on multi-stakeholder communities (5) (as seen with the investigated platforms) or could be collaborations between equal parties (4) or collaborations controlled by one party (3) having the common goal of collaboration with no conflicting interests. Both DSTT and IMI has parties with conflicting interests in the commercial setting collaborating in a pre-competitive setting to consolidate the businesses or for the common good of research.

In general the analysis shows that the project based platforms are controlling whatever content that is leveraged on a rather high level, having strong governance where public actors support the platform or having more private interests and are less formally governed. A platform that has a high involvement from public actors in the governing structures often also has a high public responsibility in shouldering gains for the open society. Project based platforms with less involvement from public actors often takes on less public responsibility and are created for private interests. Whether the platform is public, private or a combination, the Level of Collaboration is a result of which actors are participating, their gains in the platform and what kind of research in these cases that is performed under the projects on the platform.

5.3.2 Platform Openness in the Project Based Category



Visualization 8: Platform Openness Diagram for the Project Based Category (ANDI platform has been left without values due to loss of information and the infant stage of the project)

The Level of Access to the Platform on a project based platform can, as shown, be either very limited, i.e. only to a group (venture) (1) or cluster (2) or open to all (5). The access to the platform is generally influenced by the governance and the collaboration structures of the platform. In a private setting, the access to the platform will often be more limited than in a public and the purpose, influenced by the Level of Public Responsibility, of the platform being set up is therefore most important in determining the level of access constructed by the platform. This is also connected to the cost of access and usage, seen in Level of Cost; private platforms seem to negotiate on commercial terms (1) meanwhile more public platforms have pre-set terms of a Fair Reasonable and Non-Discriminatory (FRAND) agreement (3) and sometimes even free information or content (5) from the platform to access and use due to public funding or sponsorship by the private sector (4).

In the Level of Open Usage in R&D and Level of Open Usage in Innovation one can again see how the purpose and private/public domain setting of the platform distinct between the levels of openness in these regards. More public platforms tend to open up for open usage of platform content in R&D while private platforms seem to have openness but with restrictions. When it comes to the access to platform content for usage in innovation the same pattern can no longer be seen, the level of usage in innovation is ranging from only the developers are allowed to use the content (1), the members or free to everyone (5) (not represented here). These patterns are closely linked to the incentives for members of the platform to participate in the platform; private stakeholders would (most often) want this parameter to be on a low level of openness to gain competitive advantage and a reason to develop content within the platform. The Level of Open Usage is closely connected to access in certain platforms, e.g. the IMI platform which controls both access and usage through licensing rights to content.

Since the project based platforms are characterized by individual projects being initiated, the Level of Openness to include Content on the platform is shown to be fairly closed due to the nature of the collaboration structure chosen. The platforms typically have the structure where anyone can apply for participating or initiating a project but have to go through a process deciding their eligibility to be able to include content on the platform; a structure that supports development done by contributors in a more closed, secluded manner.

Based on the analysis general conclusions that one could see is a clear focus on the Level of Open Usage in R&D within this category; however this is a trend that can be seen over all categories, mostly reflecting the early stage of this research field meaning that several, even private, actors are supportive of a basic research structure that is open to the public. The nature of how these projects are run will determine the openness level; often a general guideline is set and then implemented within the projects of the platform, having some freedom to determine the level of openness. This indicates that both Level of Openness to Include Content and Level of Open Usage in innovation will be rather closed due to private interests in having the project team develop qualitative research results that will, in a commercial setting, benefit the developers of such results.

5.4 Existing Platform Structures Combined

In the setting of life science and biotechnology, the emerging new way of managing innovation through open innovation platforms have through this evaluation proven to be a dynamic model where actors can merge and form collaborations in differing ways based on diverse purposes and incentives. These parameters are thus taken into consideration when a platform is to be constructed; the value to be created is done through different models in order to accommodate for the purpose of creating the open innovation platform and aligning the incentives for the participants on the platform. The categories presented above have either chosen to let the platform as such be the value creator in connection with the content and structured their platform around this purpose, or have their IP and knowledge being the driving force of the platform to open up the research path towards stimulating innovation or even let mature models in other fields such as open source serve as a starting-point in sharing information across borders.

The categories discussed above all have in common that they are shouldering public responsibilities on a rather sophisticated level, which is due in part to the nature of the life science field as being an important part of the development of society, in combination with being an early research field and the fact that the field is facing high demands from the global public which results in the platforms having to meet the requirements of providing value-added information and knowledge to societies in an open manner.[75] The platforms high marks on the scale could further suggest that they are willing to let society benefit from the research being done through constructing their information sharing in a more open manner, which is held to be true for the case of the bioinformatics category especially.

The comparison of the platforms further reveals certain trends in moving forward and managing open innovation platforms in these different categories. In the Project Based category, the trend is to move toward having the value created on the platform be patented in a systematized way or protected to a large extent, whereas the Bioinformatics category is more focusing on creating fully open platforms and have the value created protected through as minimal means as possible which leads to the IPR claims having to take a back seat. This in turn could facilitate the construction of openness in the Bioinformatics platforms, since the claims in relation to the IP being provided for on the platform would not be that strong or present at all and thus creating a platform for open sharing in terms of both access and usage of the research on the platform. The IP, Knowledge and Technology category reveal a desire to open up their platform to enable the spread of their collaboratively developed assets, but have not fully implemented the vision when it comes to open usage in innovation which suggests a more proprietary way of collaboration. The Project Based category illustrate great differences from both the Bioinformatics category and IP, Knowledge and Technology Sharing category, adapting a more closed manner in terms of access and usage, apart from the usage in R&D which would then serve as a starting-point for them to build upon. The nature of the collaboration in this setting, projects being set up to reach a common goal, can most certainly be a factor to consider which could explain this.

[75] Davis et al p. 2

The overall trend that could be extracted from the diagrams representing the three different categories is that they are all constructing their openness towards ensuring an open usage of their content on the platform in R&D for those that gain access to the platform. There is however a discrepancy when it comes to the Level of Access and open usage of the results, especially when considering the Project Based category, which could suggest that there are mechanisms in place that serves the purpose of the platform to promote research in a more open setting to spur development and innovation but that is still restricted on the platform. Thus, one can through this comparison see the multiple ways in which an open innovation platform can be constructed.

In conclusion, there are several parameters to consider, requiring the necessary tools in order to be realized according to the purpose and vision of the potential participants on the platform. The authors believe that there is a need for clarification as regards the different ways in which to construct open innovation platforms through the means of regulation and contracts, and the next section therefore aims to take a starting-point in the different parameters and layers of openness and present the legal tools to put in place in order for a construction of an open innovation platform.

6 Regulation and Contractual Models for Constructing Openness

The purpose with this section is to, on a structural level, demonstrate the different parameters that are to be constructed when designing an open innovation platform. The parameters will be deconstructed into their different building blocks, demonstrating the utilization of regulation used by other platform initiatives to govern and construct openness in the life science field and how each layer within a parameter can be constructed with the support of the regulatory system and contractual structures present. A checklist of what to think about when constructing each layer is to be found in Appendix 2. The aim with this section is to develop a structure for how an actor can construct an open innovation platform through the usage of the tool parameters and their different layers of governance and openness in association with the intellectual concepts that are used and can be used in research and innovation to ensure the level of openness chosen by an actor.

The evolvement of the biotechnology sector has brought with it many new emerging technologies which could materialize into IP concepts which are to be used in research and innovation. There are structures which are developing around these concepts which involve multiple stakeholders, and the interactions among the stakeholders are becoming complex and they are then represented through the open innovation platforms which have been addressed in this thesis. The IP concepts are what constitute the content on these platforms, which then are to be claimed by the stakeholders through evolving mechanisms which are managing their different interests and interdependencies in the structure that is the open innovation platform. These mechanisms are structured with contractual models and the regulatory system as a basis for how to determine a certain degree of openness through the extent of control the stakeholders maintain through access and use of the gathered and developed platform content.[76] The investigation in the previous chapter show an overall pattern of utilizing a more or less integrated system which is based on legal tools that aligns the collaborative efforts to serve the purpose.

The conclusions drawn from the above analysis of the different platforms in the three categories are related to how a platform is constructed or can be constructed both on a general platform governance level as well as an openness level. Through the starting-point of seeing how issues of primarily IP are managed through contractual structures and specifically how the platform structure is governing the content on the platform, one can see how the designed solutions for this can create the basis for how openness is established and designed on the platform. Through this understanding the authors have gathered and evaluated how contracts and IPRs operate and are used as tools on open innovation platforms in the life science industry which has contributed to the development of a toolbox that is aiming to provide insight in how to construct an open innovation platform with the use of regulation and contractual models.

This toolbox will first be addressed in relation to general platform governance parameters, determining how a platform is being governed and how a layer in the different parameters can be constructed to protect and regulate the content on the platform. The tool will then be addressed in relation to platform openness parameters and will demonstrate how contractual models and regulatory systems have been used to enable openness in the different layers. The review of the toolbox will also provide a demonstration of the necessary considerations to be taken when designing the platform on the substantial level through highlighting what different mechanisms that are of utmost importance and that should be addressed.

[76] Petrusson et al (2010) p.3

6.1 How to Construct Open Innovation Platforms - General Platform Governance Parameters

General platform governance structures are what constitute the actual platform; without setting these parameters, the platform would not exist or would not be called a platform. The purpose of this section is to give a thorough analysis of each layer in each parameter of general platform governance and explain how such a layer can be constructed with the support of the regulatory system and contracts and demonstrate the actions that need to be taken in order to design the different layers of each parameter. This section will explain the legal means of how to control the governance parameters on different layers on the platform. Each parameter will be addressed and existing platforms in the life science industry using different layers within the parameter will be discussed from the perspective of how they have chosen to construct that layer.

The general platform governance parameters help in governing the development process on the platform, the ownership of research results and the development of products, systems or tools. The governance structures set up in these parameters are furthermore to be constructed to govern the packaging of these tools and systems and their development towards the intellectual construction of a product. The governance structures of the platform will also create or direct the stakeholders of the platform towards a technology and knowledge market and impose a value proposition to customers. When creating structures that are built on the concept of governance there are also constructions in these parameters that will govern the transactions of IP which could take place on the platform, and the platform governance parameters will also serve as a tool to govern the level of openness on different layers to be implemented by a platform. A platform which is to be present in a setting such as the life science industry where knowledge is considered as a key component in the furtherance of research and technology development also is in need of acknowledging parameters that take into account the constructions to be put in place to govern the distribution of knowledge in a platform. [77] According to the authors these parameters are thus to be considered as the foundation for how the platform will be run, setting the stage for the different stakeholders and their transactions and collaborative efforts to ensure that the platform will be leveraging on the capabilities that are brought in.

The parameters have been analyzed in connection to the different governance structures and solutions present within the different layers to govern the systems, tools and collaboration as well as public responsibility and the IPR claims that are present on the platform. The main focus is thus on the legal tools as value creating factors that constitute governance.

6.1.1 Level of System/Tool Leverage

This parameter is dependent on the objects of the platform i.e. the platform technologies being shared among different actors. The platform technology is "defined by the degree of collective access, development, usage and control that it allows".[78] The platform Level of System/Tool Leverage parameter is determined by the leverage potential of the developed value, meaning that the potential leverage on the platform is the determinant of the parameter. Usually the control aspect is highly involved when evaluating the leverage potential of the developed value on the

[77] Petrusson (2009)
[78] Petrusson et al (2010) p.15

platform.[79] What content that is present on the platform is also, as shown by the analysis, dependent on the purpose of the platform meaning that different steps in the value chain have equivalent layers of content to be chosen.

Gathered data or R&D results is the first layer and has the lowest leverage potential on the platform according to the analytical tool; however, the results could be patented or be a part of a database then constituting a packaged content and/or feature. Even more leverage potential has the systematized toolbox due to its characteristic of e.g. using a biomarker both as a research tool and valuable result/product in itself. An operational system has even higher leverage potential due to the building possibilities on the operational system, making it possible to draw value from others´ inventions due to the foundational nature of the operational system, an e.g. is a standard biological part functioning as a fundamental part of a more complex biological part. The layer which has the highest leverage potential is the multilayered system, creating a market through the platform and leveraging on both the platform as such and the market created as a result.

Moving further up the Level of System/Tool Leverage scale one can according to the analysis see how the means of regulations and contractual models becomes increasingly important to enable control of the value created on the platform, either for commercial purposes or for the public good; however, from the authors perspective, openness always needs to be regulated because if that regulation is lacking, the platform will perhaps not stay open for long.

6.1.1.3Enhancement of Content through Control

Research data is the least leverage friendly kind of content presented in this parameter due to the low protection and transaction abilities of the kind. However, the authors' analysis show that this can be a good degree of content if one has stakeholders of the platform being competitors and sharing result in a pre-competitive arena. Leveraging further on the research result or gathered data one could choose to have content packaged, also often meaning to package the results through an IPR making the control aspect higher through recognition of ownership and external control, making it a transactable object and thus having the leverage potential higher. This does not necessarily mean that packaged content or features needs to be IPR protected but one needs to constitute the result, constructing property, which could be done in agreements recognizing the results. This means that a clear ownership structure should be put in place on the platform that can facilitate the development of collaboration where the object in question is to be transacted upon.

Leveraging even further on packaged content or features one could, if the results allow it, include business models as a means of protecting and leveraging on the results. A systematized toolbox could consist of content constructed through packaging it either as a product or a service at the same time. Taking the example of a biomarker which can be leveraged as a patentable invention used as it is or through a different business model, meaning that it could also have the value proposition of a research tool. This leverage potential layer of content on the platform is characterized by choosing the right business model to leverage on the control mechanism but also on the multilayered assets meaning that there are several pathways to leverage on the results.

[79] Petrusson et al (2010) p.15

A more sophisticated system/tool leverage content mechanism is the operational system which benchmarks the systematized toolbox but uses the content to create the foundation for the platform, thus using the biomarker as a research tool and gather results from that research tool on the platform, making the biomarker the constitutional tool or the parts that makes the other possible, demonstrating interoperability between different technologies and parties. The content of the platform is therefore enabling technologies, services or other things that are gathered or work together.[80] The basic layer that is to be built upon must here be protected and one could either choose to improve on the operational system as such, or determine how the access and implementation in the operational system should be constructed. The intricate part is to regulate access to and implementation of innovation onto the operational system or with the help of the system and the leverage potential as such; controlling the enabling technology. The authors therefore conclude that a protected first layer is good, either through an IPR right or through a contractual model imposing certain conditions to add to, and access the system.

The latter step is not far from the multilayered system which constitutes a market like structure for the next layer. Taking the biomarker as an example; to construct this kind of content one would need the basic structure which enables a market in the next layer, e.g. a standardization body which determines a standard for usage of a certain biomarker for a certain type of cancer and the market being created through actors competing in having their invention as the standard. IMI is a body operating to solve the problems of a specific industry, meaning that it determines the priority of the issues, then letting project actors compete in who gets to do the project on that specific issue, and then the rights to use the technology or results coming out of such a collaboration, meaning that in accordance with the analysis the basic layer provides an opportunity in the next layer being the solution to the set problem, as a standardization body.

As the content of the platform gets more sophisticated the regulations on competition law or antitrust law tightens, meaning that collaboration further up the system/tool leverage potential latter creates more obstacles to the free market meaning that one has to consider these kinds of legal implications choosing on which layer one should collaborate.

6.1.2 Level of Collaboration

When constructing an open innovation platform the authors believe that, based on the analysis made, one of the fundamental structures to be implemented relates to on what layer the stakeholders of the platform are collaborating in development of content; either through competitive relationships where collaboration is determined by the categorization of inclusion of content, or development in separate areas, or through collaborative relationships between parties with similar rights. This parameter is therefore investigating the creative relations set up between the platform stakeholders.

The relationships which are set up will constitute the collaborative structures of the platform. These structures are measured, on the one hand, on the collaborative or competitive nature of stakeholders, who the stakeholders are, and on the other hand also on the level of control. When constructing the collaborative structures of the platform, the analysis show that the nature of the

[80] Mail correspondence with Ulf Petrusson, 8th of April 2010

parties will influence how rights are distributed through negotiation and the rights of the parties to the platform content, inclusion etc which will become the regulatory framework. "The outcome of these discussions establishes the typical R&D collaboration and will define the regulatory framework under which the collaborative project will have to operate". [81]

There are, as the analysis shows, multiple structures to consider when constructing the level of collaboration; it could be the gathering or sharing of data on a basic level, or the stakeholders could do research collaboratively through a more sophisticated structure or share IP in an IP pool where others can enhance the technology. The level of collaboration is as a result determined by the way in which the stakeholders have constructed and chosen to implement their collaborative efforts; either through a competitive setting where categorizing content and research areas become prevalent as when competitors compete in having content included in the platform or where the platform is set up not to restrict competition even though competitors are collaborating, or more collaboratively where the level of control on the platform is essential, meaning either controlled jointly by stakeholders on the platform, or controlled by one or a few parties. There could also be multi-stakeholder relations on the platform indicating different kinds of actors coming together to collaborate to achieve the same goal.

6.1.2.1 Where is the Collaboration taking place: Competitive Relationships

When operating an open innovation platform where stakeholders are to come together and serve the purpose of that specific platform, the relationship that is to be established between them are according to the authors crucial in further constructing and regulating a platform. In setting up the platform, the analysis shows that consideration needs to be taken as regards to how the stakeholders should relate to each other and how their contributions to the platform should be handled. To have the relationships between the stakeholders on the platform as competitive and use the contribution of content and the intellectual categorization of content into different areas of research could suggest that there needs to be a sophisticated construction regarding the content of the platform that takes into consideration the research being done and the areas in which to utilize the outcome of the same. The level of collaboration will then be ignited through either having the competitors stay competitive even in the contribution of content and let that be what defines the collaborative state or have the collaboration be set in an environment where the competitors can still have collaboration where the research area is not imposing a directly related threat to the businesses to be further conducted.

6.1.2.1.1 Standardization Bodies

The stakeholders who are active within a certain area of research or development could define their collaborative efforts through letting their competitive relationship still serve as the foundation and develop their own contribution and consequently compete in having it included in the platform. This structure has been implemented by standardization bodies, which regards the development of a cluster of an industry. In this context, stakeholders are regulating and agreeing upon what standards that should be prevalent in the industry.[82] This will create a platform where parts can be made compatible with each other, thus creating a standard. Even

[81] Petrusson et al (2010) p.16
[82] Mail correspondence with Ulf Petrusson, 8th of April 2010

though everyone is granted access there is still competition regarding having one's own technology implemented as a standard and for it to be accepted on the platform.

A way in which to approach this method of determining a competitive relationship is to have agreements in place that stipulate that all the stakeholders involved are accepting the standard or the like that is chosen by the platform and that everyone is welcome to supply technologies that they would like to be introduced as standards. Furthermore, the authors believe that there is also a need to implement regulations regarding the sharing of technology standards on fair and reasonable terms, this to not lock an industry into a standard that is not open for everyone. The relationships between the stakeholders are thus based on a competitive structure but that could still ensure a level of openness in terms of the outcome.

6.1.2.1.2 Competitors Joining in Pre-Competitive Areas

In the life science industry there are certain areas in which the public could gain from having results being open but that are also possible to build businesses on at a later stage. In this context the relationships could be competitive where collaboration exists in areas that have been categorized as pre-competitive to enable further business and value creation. In the case of IMI, the platform hosts competitors that collaborate with academia and SME´s and share the ownership of their inventions. The platform is constructed in a pre-competitive phase for many of the industry stakeholders since the platform is planning to enhance pre-clinical research and the process of getting the trials of drugs faster to market. The platform has thus intellectually categorized the utilization of their research results to have them included in these pre-competitive areas; the access to the enabling tools that will emerge at the later stage will then facilitate the competitive relationship.[83]

The DSTT is another platform which is supporting certain areas of research where it is shared among industry stakeholders to build on which ultimately enhances their business.[84] Another approach is implemented by GSK, who is including patents that are pre-competitive due to a "non-existing market" in neglected diseases.[85] The utilization of these patents in this area will then consequently support and further build the businesses of the competitors that are collaborating at the same time as the technologies could be accessed for use in an area where they do not compete.

Should the potential platform structure indicate that the level of research will have to be done amongst competitors but through a pre-competitive state, the ones constructing the platform would, based on the analysis, have to consider and conform to an area of research where the stakeholders can build on their businesses at the same time as it is enhancing information sharing, such as e.g. IMI and DSTT who are looking after the interest of the stakeholders at the same time as the purpose of the platform to enhance productivity is being met. What the authors believe is of further significance is whether and how the platform should categorize the use of the content on the platform by the stakeholders, since this will determine the areas in which the results can be utilized and steer the collaboration and innovation towards the pre-competitive

[83] Petrusson et al (2010) p.29
[84] Division of Signal Transduction Therapy Website
[85] GSK Patent Pool

areas. This part is according to the authors of utmost relevance due to the incentives for competitors coming together in pre-competitive areas, meaning that the life science industry as a whole or the stakeholders of the platform must gain from the platform collaboration to be incentivized to join the platform and collaborate.

6.1.2.1.3 Competition Law Considerations

When stakeholders to a platform come together to collaborate and create a structure where there will be collaborative exchanges, there is a need to consider competition law due to its role as governing the trade that is taking place so that they will not become threatening to the functioning of the free market and ultimately be considered as illegal. The platform that is constructed based on competitive relationships where the actors compete in including content to the platform should be specifically designed to comply with competition law, meaning that competitors should not collaborate to block the market. Thus, the actors need to consider whether their collaborative undertakings will constitute an agreement amongst them that could be anticompetitive, such as having the stakeholders raise or lower their prices at the same time due to the climate of the platform. The stakeholders that are present within such a platform could also as shown by the above analysis be owners of substantial IP and then compete with others in pooling this IP and IPRs onto the platform; these undertakings by the stakeholders must be precompetitive according to law and thus not create a blocking position and instead promote the dissemination of technology to comply with competition law since a stakeholder through the platform could be considered as being in a dominant position.[86] Should a platform furthermore create licensing structures that are similar to licensing pools, where the competitors grant each other licenses but on a restricted basis, this could create higher barriers for other stakeholders and create a monopoly type situation which is not in compliance with competition law.[86] Therefore, competition law considerations must be taken when constructing a platform and special notice must be taken when competitors are horizontally integrated in the value chain.

6.1.2.2 Collaborative Relationships determined by the Level of Control

The relationships between stakeholders that come together to collaboratively solve a specific issue or problem and that are not leveraging on its competitive relations are as concluded from the analysis defined by the level of control which could be exercised by either one or several stakeholders that have the correct influence to characterize the relationship of the stakeholders and steer the distribution of research being done. The construction of these collaborative relationships could then be constituted through the negotiations set forth regarding how the platform should be set up in terms of governance and content, which has been emphasized through the above made analysis on the interdependence between the general platform governance parameters. The structure that is to be created should consequently be responsive to determining on which level that the stakeholders should be considered as present on, whether they should have a few prominent actors exercising control over the platform, having the stakeholders share rights to the platform in an equal manner or letting a public-private partnership where the public domain serves as a prominent stakeholder and facilitate collaboration between both public and private stakeholders for the sake of research be prevalent. The construction of the different alternatives ultimately comes down to on what level the control

[86] Commission Regulation (EC) No 772/2004 of 27 April 2004

of the stakeholders to the platform should be executed and the different ways in which to create it, which as discussed will be the result of negotiations among the stakeholders.

The control through the collaborative relations could be given through regulating the ownership of results properly in agreements to allocate how much control each stakeholder possesses over the platform or further agree that one stakeholder should have the right to represent and enter into agreements with outside parties, thus giving that stakeholder control in the sense that he has the decision-making power and the ultimate saying regarding the activities of the platform and the research being made. The PGP is an example of such a collaboration initiative where Harvard University is the driving and controlling research group but where there are research groups around the world adding information to the same platform. Harvard University controls the adding of the information to the platform and so controlling the members of the platform.[87]

The creative relations of stakeholders on a platform is thus determined primarily through the purpose of the platform as well as whether the collaboration should have its foundation in the competitive setting of the stakeholders or whether the relationships should be built on collaboration where the stakeholders either have certain obligations and rights that are either giving certain stakeholders a few privileges or whether a community is set up to serve civil society. The regulatory aspects of constructing the collaborative setting of the platform is then according to the authors focused on letting the area of research and the state of the stakeholders be the foundation for how to allocate rights to the separate parties. To intellectually categorize between certain areas of research and distribute the rights accordingly would also serve the purpose of the platform and leave room for letting the stakeholders conduct their businesses on top of the platform collaboration.

6.1.2.2.1 Collaborative efforts determined by Access and Usage Rights

The collaborative relations could also be determined by on what level the platform regulates how the stakeholders to the platform should have the same rights as regards access and use of the platform and its technologies, but also determining if there is one party controlling the other parties in their collaborative efforts or not. This conclusion could be drawn through the analysis made on the mentioned platforms and the interdependence between platform governance and openness. This interaction is what ultimately in this setting will decide on the structure.

A more equal structure would be considered as an open approach as regards the level of collaboration, due to the dynamic transactions that could take place through the regulation of access and use among the stakeholders. The platforms of investigation are usually represented through having a generous distribution of rights and letting the collaborative relationships be based on equality. PIPRA is such a platform where all the stakeholders on the platform have the same right to the services provided at the platform since they are accessible to those that would like to be a part of the platform.[88] BiOS has constructed their equal parties in a way so that everyone that wants to be a part of the platform have equal conditions where they sign an agreement with certain restrictions which they ultimately can or cannot comply with.

[87] Personal Genome Project Website
[88] PIPRA MOU

6.1.2.2.2 Public Actors defining the Collaborative Structures

To create relational structures on a platform requires the consideration of the necessary stakeholders to include when designing the platform according to its purpose such as when having a collaborative relationship where multiple stakeholders from both the private and public sector are present that in combination with civil society are working to attain a shared goal and expand the reach and improve the quality, supply and accessibility to content identified for communities.[89] This multi-stakeholder community is then characterized by a public involvement in the platform, either as a part of the platform, constructed by the public or having goals that are in the interest of the public also making it rather particular to regulate according to the authors.

The construction of a platform which consists of a multi-stakeholder community is usually created through initiating projects that have a broader focus or that relate to an area of technology which academic, industrial and public actors have a mutual interest to accommodate for all the stakeholders on the platform.[90] The analysis conclude that to reach this level of collaboration the regulatory aspect of construction is not as prevalent as when it comes to choose the suitable set up of the platform with the proper stakeholders' assembly and an accurate purpose with the platform that will serve as the foundation for the collaborative projects that are to be initiated at the later stage. Platforms that have created these kind of multi-stakeholder communities are IMI, ANDI and the Biomarker Consortium which have been initiated by the public sector which has expressed a desire to collaborate with universities, SME's and industry in setting up the platform.

6.1.3 Level of Public Responsibility

Platforms can be constructed in different ways in different settings depending on the level of public responsibility which is sought for the platform to uphold, i.e. the public involvement and purpose of the platform or if it is driven by purely private interests. When talking about an open innovation platform in general and the life science industry in particular one must be able to identify some kind of openness in the sharing and usage of content on the platform to talk about an open innovation platform at all; meaning some type of public responsibility.[91]A platform could state that it exercises a certain amount of public responsibility, but in this setting the authors suggest that it will be other regulations within the platform that will determine which public responsibilities that the platform actually will shoulder. Therefore the authors conclude that this parameter is closely connected to how open a platform have constructed their terms on whether a stakeholder can access and use the information/content that constitute the platform; it is through this that the level of public responsibility will be measured. The analysis further suggests that the level of public responsibility shouldered by the platform can be said to depend very much on the stakeholders constituting the platform and how they are incentivized to unite and join the platform.

[89] Swarts p. 2
[90] Weigelt p. 942
[91] Petrusson et al (2010) p.16

6.1.3.1 Who the Stakeholders are

In the context of an open innovation platform there are certain interests of stakeholders that need to be considered when constructing the platform and these will in turn be a part in setting up the structure for how the level of public responsibility will be handled and shape the collaborative efforts and the outcome of how a platform chooses to handle the content of the platform. This parameter is thus a construction of the stakeholder's interest when forming the platform, in line with the analysis made regarding the different platforms and their respective stakeholders. The authors therefore believe that it is important to reflect on the different stakeholders and their category in society and their interests when creating a platform.

6.1.3.1.1 Private Interests of Stakeholders

A platform could according to the analysis consist of merely private stakeholders where the platform consequently shoulders the private interest of the stakeholders involved. The demands for making the platform open in terms of information sharing and content providing could then be limited, since the interest in sharing information is constricted to the private actors setting up the platform. To create this level on a platform, the authors see the possibility that stakeholders could construct their ownership and distribution of rights to be held strictly between the private stakeholders and not let information be distributed to the public for them to access or use; however, this does not need to be the case to serve the interest of the private stakeholders. When constructing the platform there is according to the authors an opportunity for a platform to create regulations that promote the platform as doing something that is beneficial for society as a whole and not principally for the stakeholders as such, e.g. let the information on research results and progress become public to illustrate the advances made. Therefore, the influence that a private stakeholder and their interest have on the platform is according to the authors not critical in the construction of whether the platform actually will or could fulfill a public interest.

The control that the interest of the private stakeholders exercises is connected to the actual regulation of ownership and access as well as usage of the content of the platform. This could based on the analysis be implemented when e.g. there is a public interest that competition is not restricted, where primarily private stakeholders can regulate the ownership; access and usage of the content in a way that would not restrict the competition on their market due to the development efforts made by the parties together. Here, the interest is thus to foster competition on the market, letting the transactions taking place on the platform not affect the way in which business and research is being conducted elsewhere. In general, the authors believe that the public will benefit from the new effectiveness of research through the introduction of new or improved products or services from an open innovation platform where collaborative R&D is taking place; however, the competitive state between the stakeholders to the platform and their development efforts could have an effect on the market and consequently the public interest.

The stakeholders on the platform have the inherent right to compete with each other; however, the practices which they are undertaking must not in some instances infringe on the public interest that competition is not restricted. The platform could then be constructed through letting the agreements which are set forth regarding ownership; access and usage not restrain competition, meaning that the distribution of these rights should promote the dissemination of knowledge and through this not hinder competition. This could pursuant to the authors be done

through regulating that each participant on the platform should be free to exploit the results of the joint R&D effort and any background that is necessary for the purposes of such exploitation. This could then be limited to certain technical fields of application, where the stakeholders are not competitors at the time. This construction could when executed properly maintain the interest of the public society to not restrict competition at the same time as the interests of the private stakeholders will be looked after due to a possible separation of research fields.

6.1.3.1.2 Interest of Open Society

To construct a platform that would include the interest of open society could suggest that a certain level of openness to the public in some way should be implemented; this does however not mean that the stakeholders cannot have the openness restricted to members or merely having a limited interest or a specific target to share with the public. The platform constructed could also share most of its results with the public and serve as an entity similar to a public actor.[92] This further strengthens the notion of having the choice of the level of public responsibility affect the choices made regarding regulating other matters of the platform. Should the stakeholders choose to implement a structure where the interest of open society is included they could keep the level of access to the platform high as well as the level of usage for the public domain, resembling the structure of a public record.[92]

Based on the analysis made, the authors have uncovered a range of structures to implement which in turn could serve the interest of open society at the same time as the research that is being done is leveraged upon in the business arena. To construct this level of public responsibility, actors would have to consider how much information and what type of information that they would like to share with society as a whole; in what category should the information be kept public? When this has been decided upon, the way in which to construct the level of access and usage will according to the authors become more apparent; the division of information to disseminate will be reflected upon when constructing access to specific content through either background and foreground regulations and furthermore let the licenses be on an exclusive field of use basis to steer the collaboration and support the interest of the platform.

6.1.3.2 Incentive for Joining the Platform

The preference when discussing the level of public responsibility implemented by the platform will based on the analysis made be dependent on the way in which the sharing and distribution of information has been handled by the platform. This in turn will determine the incentive for whether a stakeholder will join the platform or not, i.e. what the purpose of setting up the platform is. There are consequently different ways in which the platform could share information which the analysis shows is based on the purpose in constructing the platform as such. When regarding private stakeholders and how they come together to construct their collaborative efforts, the analysis suggests that the choice of implementing a closed way of sharing information through restricting access and usage of rights could serve as an incentive to choose the structure depending on the purpose that the stakeholders have in creating the platform. There are different structures to consider, implemented by the analyzed platforms, that would be deemed as closed

[92] Mail correspondence with Ulf Petrusson, 8th of April 2010

in terms of not letting the sharing of information and distribution of rights be available for the open society, thus affecting how the platform could incentivize stakeholders to join the platform.

The way in which a platform could incentivize stakeholders to connect to a platform could also have its foundation in a more public way of sharing information and content that is connected to the platform. The analysis further suggests that the presence of a public stakeholder, which could have constituted the platform or been involved in the creation of the same as a primary stakeholder could, suggest that the public interest and way of sharing information more openly is implemented, but yet preserving the rights of the private stakeholders and thus incentivizing them to contribute and expand the portfolio of the platform. IMI is a platform which was constructed based on the purpose of benefitting the industry as well as the public combined. The platform has managed to create a structure where the research being done is not blocked, which benefits society and the spread of information is accommodating that level of public responsibility at the same time as it preserves the interests of the industry stakeholders in that they are regulating the ownership composition so as the results being generated are kept within the organization[93] to a certain extent. The platform has thus managed to incentivize both public and private stakeholders in collaborating on the platform. This enhances the notion that the aim of the platform must not target the public sector completely and the usage of the content must not be made freely available for everyone on a commercial level to be called open within public responsibility.[94]

6.1.4 Level of Platform Governance

The governance of a platform is according to the authors an important decision in the construction of platform, based on the analysis made. The platform governance i.e. formal organization of a platform "is very much the fundament that generates the new logic where more or less all creative activities can become IP transactions".[95] The platform governance is as seen by the authors in the analysis made often constructed through negotiations where the stakeholders would like to impose their interests or through an initiating organization which creates the structure which other actors then join. The contract is in this setting a fundamental tool for construction of the platform since a platform is a collaborative effort and self-regulatory tools could play a supporting role in how platforms are structured and governed.

6.1.4.1 Controlling the Platform from a Network Driven Structure

When platforms are driven from a network structure there are primarily two ways of constructing such a structure based on the application of the analytical tool. The first one is when stakeholders are coming together to form a platform in which contracts are drafted ad-hoc, meaning that actors determine the conditions on which they want to collaborate in contracts set up for every transaction or collaboration on the platform. The contract is here, as interpreted by the authors, the mechanism to construct the platform and the participants are here more or less free to agree on what terms of collaboration they want on a case by case basis. There is consequently no constructional framework agreement (CFA) in place which determines the overall structure of the

[93] Innovative Medicine Initiative (IMI) IP Policy (2007)
[94] Innovative Medicines Initiative (IMI) Call and Evaluation Process (2007) and Innovative Medicines Initiative (IMI) IP Policy (2007)
[95] Petrusson et al (2010) p.17

platform and the authors conclude that the network themselves will determine how different parameters on the platform will look. The CFA is a founding agreement for the platform constituting the governance and openness on the platform. The CFA is a legal instrument which supports the development of project agreements regulating the mechanisms of the platform.

The second structure of how to construct a network driven platform is based on the analysis to determine among the stakeholders an overall contractual model which is implemented in a web of contracts between the participants of projects on the platform, meaning that all actors through the platform structure implement the same model contract within their own negotiated agreements on a project basis, this constructing the platform logic according to the authors. In this structure the authors have interpreted it as that there is no single entity controlling the CFA but the CFA is the controlling structure of the platform and implementation in the project agreements is on a voluntary basis for the project to become a part of the platform structure.

DSTT has such a structure where the model contract, constituting the platform, constitutes the consortia which form the platform. All actors are collectively responsible for the governance over the platform through the implementation of the model contract.[96] SGC has a structure where contracts constitute a board which then creates a scientific committee which governs the research projects. Funders then have separate agreements with the participants of the project governing the research targets, meaning that the model contract constitutes the board which is the governing structure; however the actual governance over the research projects lies with the network through governing the research being done on the platform.[97]

These structures are pursuant to the authors hard to exemplify since there are many different network driven structures that could be valid in attaining the platform structure fulfilling the wants and needs of the platform stakeholders.

6.1.4.2 Controlling the Platform from an Organizational Structure

Organizational structures are often structures that are recognized by society as entities which gather more than one actor; it could be a legal entity recognized as taking on economic responsibilities for a group or a person acting under the same name.

6.1.4.2.1 Informal Organization

In constructing different layers of organizational governance over platform structures there are mainly three structures that ought to be considered according to the authors. The informal structure is represented by a non-legal entity that is recognized by the stakeholders of the platform as the governing structure. The legal structures where the entity of governance is recognized through claims in the legal arena are companies, NGO's or foundations, and at last the structure where the public plays a big role in governing the platform[98].

The most informal organizational structure as shown by the analysis is recognized in agreements between actors giving a steering committee or a board the legal powers to govern the platform through the constituted permission from the platform participants. This platform governance

[96] King p. 14
[97] The Structural Genomics Consortium - An Overview
[98] The Swedish Company's Act

structure builds on the sovereignty each entity entering the platform has, having the right to surrender governance aspects to another entity by acceptance. Agreements among the stakeholders should then constitute the board or the steering committee and accept it as the governing structure over the platform. The PIPRA and HapMap platforms have this kind of structure. They are formed by coalitions of entities recognizing one or more entities as governmental boards, teams or project groups to steer the platform objectives.[99]

6.1.4.2.2 Formal Organization

The next structure is the more formal legal governing structure meaning that the structure that is governing the platform is a recognized legal entity either formed by the participants of the platform or being the initiating body of the platform. As climbing the ladder of structure based on the analyzed platforms the hierarchical order is more prominent and more formal structures are implemented to govern the platform. In this way of governing the platform the legally recognized formally strong organization is the center point steering the platform. This entity will then take on responsibilities against stakeholders on the behalf of the whole platform, and also institute policies valid for all platform members. The authors consider that the legal benefits in having such an organization must be weighed against having a more informal organization.

The strong legal organization will be governed through shareholders agreement (concerning a limited liability company) controlling the legal entity which controls the platform.[100] This in turn will be one of the things stakeholders needs to constitute in constituting a legal entity determining the governance over the platform. In the case of foundations or NGO's there are board seats that have the ultimate power of steering the platform through the legal entity.

BiOS is such a structure which is initiated and run by the organization CAMBIA being an NGO which enters into agreements with stakeholders of the platform on behalf of the platform BiOS itself.[101] GSK patent pool is run by BIO Venture which is also a NGO, which in turn is a recognized legal entity under the UN Charter and International law. [102] The BioBricks and PGP are foundations which govern their platforms, created by the stakeholders or founders of the organizations.[103] Foundations are also legal entities that administer the property it is set up to govern. This organization can enter into agreements with other parties and imposes policies on the stakeholders of the platform as the governing structure that constitutes the platform body. The organization thus has the overall mandate to enter into agreements with existing and potential stakeholders on the platform and consequently have an influence on the transactions being made on the platform. The governance over such a structure is also important to regulate among the stakeholders of the platform since the board of the NGO or Foundation will govern its purpose.[104]

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[99] Memorandum of Understanding (MOU) PIPRA & International HapMap Projects – Initial Planning Groups and International Hapmap Projects - groups Participating in the International HapMap Project
[100] The Swedish Company's Act
[101] CAMBIA DRAFT Health Technologies BiOS 2.0 Agreement
[102] GSK – Open Innovation Strategy and Peoples
[103] Personal Genome Project Website and BioBricks Foundation Website
[104] The Swedish Law on Foundations

6.1.4.2.3 Publicly Characterized Organization

The structure which has more of a public characteristic can be seen through the analysis made by the authors as instituted by the government, recognized in one of the governmental policies recognizing the organization or projects existence and somewhat regulates the purpose or the goal for the project. The strong formal structures are typically structures subordinated governmental report structures. These projects are also often funded by public money meaning that both transparency and firm governance structures often are implemented. This type of layer is as seen by the authors often regulated by the public how it should work and which government structures that should be implemented. A board which is controlled by the public together with other stakeholders is the model primarily used in the platforms that the authors have benchmarked.

The IMI platform is a platform supported and created out of the Seventh Framework Program supported by the European Union (EU) Commission, EU public actors together with SME's (Small and Medium sized Enterprises) in collaboration with European Federation of Pharmaceutical Industries and Associations (EFPIA). These actors constitute the board of the platform which governs the platform which formally is set up by a council decision which is the legal entity responsible for implementing the IMI Joint Technology Initiative (JTI). [105]The initiative is supported by several legal instruments.[105]

ANDI is another initiative taken by the public as a pan-African not-for-profit organization that aims to promote sustainable product R&D and access through collaborative networks and partnerships. The initiative is instituted by the World Health Organization (WHO) through their Global Strategy Plan of Action (GSPOA), and is supported by the public on the governmental level in Africa. Resolutions from WHO is also supporting the work. The board of the ANDI project is formally strong and all policy decisions are taken by this entity. Governance over calls and projects will also be taken from this body and contracts will be gone through this body. They are a formal organization with a strict structure for how to govern the platform.[106]

6.1.5 Level of IPR Claims

When operating a research platform one has to consider what type and on what level results of the platform should be protected. This is closely linked to the type of content but also to the value proposition that the platform wants to convey. "The level of IPR claims within a platform will have significant impact on the degree of freedom for actors to use the developed content, but also on incentives for actors to participate in and contribute to the platform, as well as on the opportunities for the platform to exert central governance over content".[107] The author's logic is to present three kinds of structures in regards of protecting valuable knowledge or results i.e. assets of the platform.

[105] Petrusson et al (2010) p.26
[106] African Network for Drugs and Diagnostics Innovation (ANDI), Strategic and Business Plan for the African Network for Drugs and Diagnostics Innovation (ANDI), 2009
[107] Petrusson et al (2010) p. 18

6.1.5.1 Non Protected Content

When operating a platform which will generate assets that cannot or are on an early stage meaning that no IPR protection is possible the authors find it important to emphasize that it is of relevance for the actors on the platform to know how to handle and leverage on these kinds of assets. A rather commonly known and very important aspect of the asset management is secrecy or confidentiality in the sharing of research results and taking measures for the results to keep being secret if one wants to have the possibility of patent protection or first mover advantage in the market place. Secrecy and confidentiality agreements therefore need to be constructed and accepted by the platform participants to protect the non-protected assets. "Contracts are obviously fundamental in these instances but are limiting in the sense that parties are bound through mutual bilateral consent resulting in a complex nexus of contracts where multiple parties are involved".[108] Assets that are not protected does not need to be protected to be value adding; if one wants to block others from patenting a certain path one could publish the results and therefore have freedom of operability in that particular invention.[109]

The governance over results that are not IPR's is more complex to handle for the platform participants than that of handling IPR's which are property constructs and recognized as value creators. IPR policies are only recognized by assets that are IPR's and other generic ways of handling results are more complex.[110] The authors consequently conclude that transactions on the platform are in this case more likely to be handled ad-hoc due to the various forms that non protected assets can take e.g. being knowledge or a technique since it is hard to generalize how to transact such an asset.

Based on the authors' understanding, to be able to control this kind of results, policies and regulations in the actual R&D would also need to be implemented, e.g. publishing policy for the researchers, restrictions on who one can talk to in the laboratory if several departments are using the same laboratory, how results should be handled and reported etc. This means that there needs to be instruments put in place that are supporting and implementing the legal instruments that are to be constructed, such as the publishing policy. These supporting mechanisms could in turn constitute a framework which preferably aligns the researchers´ behavioral pattern with the overall objective of the platform and what the intentions are with doing the research in the first place. The authors further believe that to protect R&D results or gathered data from being public is a process or procedure starting in the laboratory and going through the "packaging stage" when agreed upon meaning that as the parties identifies it, it is a technology package and easier to protect as a trade secret (since that must be clearly defined) also meaning that the statues of the platform content has become a packaged content.

[108] Petrusson et al (2010) p. 5-6
[109] The Swedish Patent Law - Novelty Criterion
[110] Petrusson et al (2010) p. 18

6.1.5.2 IPR Protected Content

When operating platforms with mostly IPR protectable or IPR protected assets, which in the life science industry mostly consist of patent protection (due to the nature of the objects invented)[111] the platform transactions begin to become easier to handle due to the property nature of such a construct. The IPR laws are typically laws under which rights can be packaged into transactable objects. As a conclusion, the authors see that leaning towards the concept of an IPR, transactions can be generalized and agreed upon in overarching agreements by the construct of background and foreground which is easier to define when IPR's are present, meaning that ownership is also easier to define due to the self-regulatory tool that is constituted through the patentable invention, copyrighted material or the trade secret. When looking at the open source biotechnology field copyright protection is often considered for created databases with information. Even though the result in the database is not protected as such[112] it is for most of these the value of the gathered information that is leveraged. Copyright protection is claimed through the business and judicial arena but is of no need to claim in the administrative arena since the protection arises without a formal application process or the like. The trade secret could be used in collaborations but it takes more effort due to the secrecy demands of the protection.[113]

The HapMap project is using the copyright protection for databases and packaging their research results in a searchable way, constituting a database. Regulations between actors are in this stage as shown by the analysis of the platforms often licenses to the packaged results; here GPL licenses are a common tool to use to regulate the use of the object, through having a click and accept deal like the one utilized by HapMap prior to their restructuring of the platform, or when using information one agrees to certain conditions kind of policy. The packaged results and R&D could thus according to the analysis performed be governed through the medium of different licensing mechanisms which will serve as the structure under which the transactions of intellectual property and the promotion of openness in access and research will fall. The usage of certain terms and conditions in a licensing structure is one contractual mechanism that according to the authors could meet the purpose of the stakeholders and define borders of the collaboration itself.

6.1.5.3 Patent Protected Content

When having a platform where platform content is patented in a systematized way or has to be patent protected to be included on the platform the transactions between the platform participants are to some extent easier to handle. The patent as such also functions as a self-regulatory tool when it comes to claiming ownership and sharing[114]; policies on platforms must therefore according to the authors take the standpoint in the ownership and characteristics of the patent. GSK patent pool uses the self-regulatory mechanism of the patent to share their patents with others through their platform. They are as the owner of these patents allowed to waive their rights to use the patents, to license the right to use the patented invention etc. which is used to construct the transactions on the platform.[115]

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111 Texas Law Firms - Life Sciences Industry Bringing New Frontiers For Law Firms
112 The Swedish Copyright Law
113 Petrusson (2004) p.114f
114 Petrusson et al (2010) p. 7
115 GSK Patent Pool

6.2 How to Construct Open Innovation Platforms – Platform Openness Parameters

This section aims to present the different parameters relating to platform openness which forms a basis for assessing which level of openness a platform can choose to implement. Furthermore, the section aims to exemplify the different layers of openness for each parameter, illustrating how the construction of openness can be done with the regulatory environment and contractual models as a base. The purpose of this section is consequently to present the different choices of legal construction tools to be implemented when designing open innovation platform openness structures which should ultimately serve as a model tool an actor can utilize when creating their open innovation platform, shedding light on the considerations to be taken and examples to regard when implementing their strategy for managing innovation.

When designing an open innovation platform there are, as has been mentioned previously in this thesis, considerations to be taken which will have an effect on the way the platform is to be constructed. The by the authors suggested toolbox which to construct openness with will consist of many different layers which correspond to the structures developing around multiple stakeholders that collaboratively develop, package and build transactions around technology. The degree of openness will in this setting be determined by the extent of control the collaborators can have over access and utilization of the gathered and developed platform content through contractual structures. The way in which the platform choose to manage and design solutions for the use of their IP in relation to technology and content on the platform will create the foundation for how openness is established, designed and incentivized within a platform.[116] The toolbox will as its main purpose help in creating structural solutions for open innovation and distributed innovation and will take a starting-point in the different contractual models and regulatory mechanisms that will create a foundation for joint development. The parameters have been analyzed in connection to the contractual structures and solutions present within the different layers to control access and utilization of the platform content. The main focus is thus on the legal tools as value creating factors that govern openness.

This qualitative analysis was initially based on looking at the tools that have been used by the platforms analyzed in the previous sections; tools used in the construction process of the platform, and also the tools that have played a role in the construction regardless of whether the actors have actually acknowledged them or not. This has served as a starting-point and will enhance the depth of the analysis made and go beyond merely seeing the recognized and probably accepted tools utilized by the actors through also seeing the underlying norms that has built the platform structure. The platforms are further characterized by using instruments that has served as a framework within which further contracts will be established, e.g. IPR policies and membership fees and financing policies which have been taken into consideration to elucidate how to govern openness through different mechanisms. Furthermore, consideration has been taken to the dependence that a platform has on what the different stakeholders' wants, such as access to technology, access to new innovations or access to a position of control, and how this will affect the way the IP is used in a contractual setting and ultimately the way in which to construct the platform.

[116] Petrusson et al (2010) p 18

6.2.1 Level of Access

The way in which stakeholders will be able to access the content on the platform could ultimately determine how the stakeholders in practice will be able and incentivized to participate in the platform. The authors would therefore conclude based on the analysis made that access is an important part in designing the platform structure. When discussing the level of access to an open innovation platform, there is thus a need for determining the actual implication of the concept of access and what it is that an actor actually obtains access to. Access could be defined in many ways as has been seen by the authors when conducting the analysis, meaning it could include rights to use content, rights to see content, rights to participate in the platform and therefore be able to see and/or use content. Access could also mean becoming a member of the platform or mean how accessible content is for outside parties, a structure implemented by certain analyzed platforms. Therefore the authors believe that one must determine in which way access should be regulated both internally on the platform and externally for third parties. How access is regulated is also dependent on the characteristics of the content on the platform, shown by the interdependency patterns among the governance and openness parameters constructing the platform.

There are several layers of access that eliminates participants of the platform to access content, but more commonly, access is more shared on the platform since the contribution, collaboration and co-creation are the fundaments for open innovation platforms.[117] When designing the concept of access the internal access of the platform is what comes first to the authors' minds, which entails regulating the transactions between the participants; however, it is important to also regulate how content could be or is possible to access for external parties which otherwise could be governed ad-hoc and the authors see that this may or may not be preferable for the platform.

6.2.1.1 The role of Managing IP in constructing access

The life science industry, particularly the biotechnology field, is typified as being IP intensive where it is starting to become a strategic tool used by actors to leverage on knowledge and patenting is done primarily on generated research results as opposed to end products.[118] The content of a platform could thus be protected through IPRs and the stakeholders rely on the IPR administrative system to confer rights to them which will enable them to use those rights as they deem appropriate. The different stakeholders thus claim their IP on the platform, which in the case of life science is primarily patents or patentable inventions, and this claiming of IP could in turn be used in order to create and steer the collective research platform and the construction and enabling of access. IPRs in the shape of patents and patentable inventions that are claimed could be managed as property which then is transacted upon more or less openly depending on the purpose of the platform and the interest of the stakeholders.[119] The use of IPRs to construct and enable open access could allow the owner of a patent to make valuable technology accessible openly, without being required to do so free of charge, or without control. "The patent can be

[117] Petrusson et al (2010) p. 10f
[118] Petrusson et al (2010) p.10
[119] Petrusson & Pamp (2009) p. 156-157

used to contractually govern the level of openness, as well as under which commercial conditions the inventions may or may not be used".[120]

Also depending on the characteristics of the content there are different ways in which access can be managed. Content could be IPR protected or not, content could be physical or virtual. When access to content is managed there are very specific tools to use depending on the nature of the content. The access to content will therefore be managed from a few different perspectives elaborating on how access is managed when IP protection is present or not, but also taking into account where and how access to content will be managed. Managing content is highly dependent on the content itself, meaning on which form it exists; in some cases when the platform is gathered around a biobank the content will be physical meaning that access to such content could be controlled through actual physical blockage. However, content on platforms exist more likely in a virtual form to some extent, at least written down by someone, meaning that there is a challenge to distribute such material in a protected manner since virtual information flow has almost no transaction costs.[121]

Having virtual content the authors have found two approaches which a platform could utilize; one could distribute the content through the internet, either in a free or in a closed way meaning restricting access. In a free way one could put the result on to an accessible website or not being so accessible choosing an intranet for platform participants, representing a more closed approach.

6.2.1.2 Constructing Developers and Group/Cluster Access Restrictions

The way in which to construct open access could, based on the analysis, be elaborated on as different means to restrict stakeholders to the content of the platform, both internally as well as externally. There are collaborative arrangements that could be constructed where openness could be restricted through using the means of regulation to maintain the competitive advantage of the stakeholders. The stakeholders to a platform could then maintain their competitive advantage towards external stakeholders at the same time as they are leveraging on the knowledge and development provided for on the platform by other stakeholders, which could result in a structure where knowledge and technologies are accessed in a restricted fashion. This could be materialized through keeping access to content on the internal level and even restricted within the platform for merely the developers or a group/cluster of stakeholders to access. The usage of different contractual models and control mechanisms with the regulatory system as a base could then according to the authors be used in creative ways to facilitate the interests of the stakeholders as well as incentivizing them to contribute to the platform through their opportunity to access the content on the platform. This could thus be used to both expand the number of stakeholders and participants that could gain access to the platform and let open access be created on different levels when regarding internal and external stakeholders.

[120] Petrusson et al (2010) p. 5
[121] Petrusson (2004) p. 36

6.2.1.2.1 Using Agreements to stipulate Access Restrictions

Ownership and access to content is in the different projects that are set up by the Biomarkers Consortium governed by an IP policy, serving as an instrument to further the establishment of a project plan that will set the framework for how ownership and access should be handled.[122]The authors then find that the reasoning is that the specific participants in a project, as defined by the IP policy, are the ones establishing a content access plan which suggests that the ability to access the data and IP for others could be restricted by the participants for the participants in the specific project, leading to the conclusion that one have to be a project participant in order to access and decide the outcome of research results and the like. Furthermore, the IP policy the authors have analyzed sets up the initial terms and conditions of access rights and licenses with regard to the IP introduced into or generated by participants in a project. The participants in the project agree to grant each other licenses to use each other's pre-existing data, which does not elaborate further as regards any external parties getting access to the content of the platform. The conclusion drawn by the authors is that the purpose of these licenses is thus to further research among the participants, letting the access remain restricted and on the terms and conditions set forth by the participants in a project. This structure is thus focused more on how the participants on the platform could regulate the access to their information, which is according to the authors model an internal approach towards external stakeholders.

The use of the contractual structure around the IP of stakeholders as a means to construct access to a specific group or cluster has been done by the platform DSTT. The DSTT consortium is governed by a pioneering agreement, which stipulates that the pharmaceutical companies that are present within the platform share access to all the unpublished results, technology, know-how and reagents in the participating laboratories in the platform, and have the first right to license the IP that they generate. The publications of the division, which is a part of the University of Dundee, are placed on a closed website, only accessible to each company. In effect, each company has access to the research output of a large amount of scientists provided for by the university that will generate IP to be accessed by the companies through a licensing structure.[123] The DSTT consortiums way of utilizing the university's and companies IP to further research is rather illustrative in this setting; the IPRs are tightly regulated where the industrial partners' interests are protected to a large extent. Should new technologies or information be introduced by a company to the DSTT which is based on IP or information gained by using reagents, this remains confidential to each company and any IP generated through the use of a proprietary compound becomes the property of the company providing it. In turn, the University of Dundee has the right to any IP generated from academic research conducted by DSTT-linked scientists on University contracts, and the Medical Research Council (MRC) has the right to any IP generated from academic research conducted by DSTT-linked scientists on MRC contracts.[123]

The stakeholders on the platform as developers or group and cluster should then based on the analyzed constructions put forth above consult the option of implementing a license structure that facilitates the sharing of the rights within the group, e.g. use a first right to license and implement the confidentiality obligations and rights to enable parties to choose as they deem

[122] Biomarker Consortium IP Policies
[123] Division of Signal Transduction Therapy Website

appropriate when to actually publish any results outside of the group. The important aspects in this instance is then according to the authors to create a mechanism that takes into account on what level the rights should be transacted upon; should works that are based on the content being accessed be proprietary for the developer, should the IP generated from each of the stakeholders, e.g. researchers, remain with them and so forth.

In designing a platform where the access should be restricted to developers or a group of stakeholders, the use of a CFA where the necessary definitions regarding who it is that is actually considered as a participant and a part of a group or cluster is seen by the authors as highly relevant. The CFA could be constructed as either an IP policy or a pioneering governing agreement which stipulates the terms and conditions to be used; a supporting framework for the management of the rights of the stakeholders.

6.2.1.2.2 IP as a constructive tool to Restrict Access

In a platform that merely hosts the IP of stakeholders and does not take on a strong central ownership to completely control the research result, the analysis conducted suggest that the IPR legislation and the construction of proper allocation of rights between the participants becomes very important. IPRs can in this setting be used as constructive elements when building a model of open innovation when the interest of the participants is to keep information proprietary and closed for developing participants or a specific group.

The analysis furthermore shows that there is a need for an active claiming process to be able to reach this level of open access, where the claiming of IP is to be used as a control mechanism to ensure that access is kept within a development group or in a cluster as such. This process could be materialized through regulating proper ownership and title clearance through contractual governance between the parties involved in a sophisticated manner as well as ensuring proper restrictions on how to make data publicly available so as to not defeat the purpose of the platform. In this setting it is therefore, according to the authors, in line with the analysis preferable to keep the IPRs controlled tightly, utilizing the rights which have been conferred to the stakeholders to further research at the same time as competitive advantage is secured.

6.2.1.3 Constructing Community Access Restrictions

When constructing access restrictions to a community the analysis suggests that the internal access is not regulated as much as the external; the authors thereby conclude that the internal access is implicit meaning that all community members consequently have access to the content on the platform. In this setting it is therefore the joining of the community that becomes the internal access regulations, meaning that the external access regulations aims at describing which actors that are outside the community that could access the content on the platform.

When talking about communities the regulatory tools to be used to ensure access will need to adapt to a larger amount of actors that creates the community. In this setting the analysis reveals that there are different approaches towards determining whether a platform is restricted to an open community through their structures or restricted to a closed community. When restricting access to content on a platform to a community of actors, whether open or closed, the authors believe that one should consider implementing structures to define the community; when it is a

closed community a certain type of actor or organization could be a prerequisite and when talking about an open community the analysis of the existing platforms show that there are often demands on the stakeholder which could be chosen to go along with, such as constructing a community which demands waiving of IPR's which is a choice that an actor can make to become part of the community.

6.2.1.3.1 Using Membership Structures as Restrictions

There are several ways in which access could be restricted to communities. PIPRA has chosen to restrict their access to a closed community using excluding membership terms. The membership structure is based on the fundamental requirements of members agreeing to populate the PIPRA database and also being not for profit organizations, public agencies or universities active in the agricultural industry.[124]

The membership structure used by PIPRA which is shown through the analysis is a way to construct a community design, imposing different conditions constructing an open or closed community platform depending on the inflicted conditions. To have such a membership structure with the complement of certain fundamental requirements could define whether an actor will be able to fulfill the same and have the ability to access content. Thus, a community is established which does not let outside parties access the platform without actually surpassing the hurdle of becoming a member. A membership structure is to be considered as a framework within which further contracts can be established, letting the importance of contracts as tools used by the participants in the construction of the platform become prevalent. This could also supply the platform with a control mechanism through letting a requirement of membership decide the outcome of access to content and the distribution thereof, thus setting the stage for further contractual mechanisms imposing other conditions of e.g. use on the members. The authors furthermore believe that what is important to remember in designing a community restricted access layer is to define who it is that can become a member, how that stakeholder should become a member and what prerogatives the member should have.

6.2.1.3.2 Elaborating on Contracts as Restrictions

Another approach using contractual measures in creating the community has been adapted by BiOS, a platform which has implemented an open source like structure based on a protected commons which lets the IP on a common based technology stay with the inventor. The platform, which is perhaps more accurately described as a technology pool, consists of enabling technologies that is available to anyone who agrees to the terms of the mutual non-assertion agreement set forth between the platform and the user. The access to content on the platform is governed by a more or less two-tiered contractual structure where a mutual non-assertion agreement sets out the terms and conditions for the sharing of IP and a material transfer agreement asserts this when the use of materials transacted between the parties is connected to the IP and technology. To access the content, a participant would have to voluntarily set their proprietary rights aside for the benefit of all who have agreed to share in the same way.[125] Furthermore, they introduce a shrink-wrap solution where, when biological materials have been

[124] Boettiger & Bennett p. 86-91 and PIPRA Webpage
[125] CAMBIA DRAFT Health Technologies BiOS 2.0 Agreement

transferred, a party through opening any package displaying the agreement or using the materials agree to have read and agreed to the mutual non-assertion agreement.[126] The authors then conclude that BiOS is consequently not using a membership structure and is more characterized as an open community platform structure in accordance with the definition set forth through the analysis.

When designing a platform which is aiming to implement a level of openness that responds to many actors having the opportunity to be a part of the platform, the analysis shows that the use of IP legislation becomes more dynamic in the sense that the platform would use the legislation not to assert any negative rights in the sense that the actors can block each other to enhance their own position but rather to use the legislation to encourage people to use the rights conferred to them and waive these for the purpose of generating research results that are open to the community.

6.2.1.4 Access is open for everyone

The idea of letting research be exposed to the public domain without any restrictions is in the life science industry encouraged by extending the public sphere in biotechnology, thus not imposing any requirements on who can be able to access the content that is developed by a platform. In this setting one can talk about complete exposure and availability, and the management of the transactions are thus of interest to see how platforms have ensured openness in terms of access. An accurate description of the initiatives implementing this would be "open access", referring to letting the understanding of human biology become public. The idea of extending the public sphere in human genome sequencing research has been implemented by the PGP, which is making research data is made freely available for those that show interest; there are no requirements of membership.[127] The same construction is implemented by the SGC, which is committed to an open access policy and does not let anyone, funders or other sponsors receive rights to any results before the public gets the results. As a result, both funders and non-funders have contemporaneous access to the results generated by the SGC. The data is shared openly among the consortium members and made publicly available. Here, no IP transactions are taking place and thus no IP is used in the collaboration between the stakeholders.[128]

Another initiative known as the HapMap Project wants to determine the common patterns of DNA sequence variation in the human genome and to make this information freely available in the public domain. Before the project utilized a "click-wrap" agreement on the internet, where users agreed not to reduce others' access to the data and to share the data only with others who have made the same agreement, however registration is no longer required and their data access policy has thus been altered and does not govern the sharing of data more than ensuring the open access approach.[129]

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[126] CAMBIA DRAFT PMET BiOS 2.0 agreement
[127] Personal Genome Project Website
[128] The Structural Genomics Consortium – An Overview
[129] International HapMap Project – Access to Database

6.2.1.4.1 Value Leverage through Open Access

The perhaps most prominent and sophisticated initiative in the sphere of constructing a high level of access is the IMI. There are some interesting constructions in regards to access when elaborating on the concept of internal and external access to content on the platform. To be able to participate in a project on the IMI platform, which also gives access to content, there is an open call process implemented which states that an organization or the like can access the possibility of being included in a project.[130] Projects are governed by a two-tiered contractual structure, a grant agreement between IMI Joint Undertaking (JU) and the individually chosen projects setting up appropriate arrangements for research activities and rules relating to IPR's. Then the project agreement between the parties governs the relationship, consequently also the conditions of access rights to generated IP and content by the participants in the project. Project agreement participants undertakes to disseminate and allow the use of content both by other project members but also to supply licenses (access and usage rights are here interrelated) to content for R&D purposes. The contracts set up between the different stakeholders are furthermore governed by an over-arching IP policy which serves as the legal instrument from where the contracts can be steered and further developed. [131] The IMI platform is therefore using the concept of IP introduced to a project as intellectual building blocks to regulate and control the access to content through a license structure. Content that is not defined as an output of the projects on the platform "sideground"[132] which is used as a building block in enabling a completely private and closed domain where access rights are not defined. [131]

The analysis shows that in the life science field there are not many initiatives that can speak of utilizing their IP to leverage on value created on a platform through open access, since most of the initiatives spoken of are not including IP in their collaborations, or have chosen not to address the issue through means that could be accessible. However, the IMI initiative illustrates how IP is considered as intellectual building blocks in enabling access for all through contractual instruments and legal tools such as IP policies to establish a foundation for sharing and availability. Patenting in this context, i.e. the use of the patent as an intellectual building block, can be used in order to ensure that research results shall be available to as large an extent as possible and that it should also be used by everyone who wishes to do so. In this setting the authors conclude that it is thus important to view the ability to create open access domains through utilizing the results brought in to the platform as well as what has been generated. To be able to create a platform where the access is open for everyone, one could regulate how the generated results (content) should be handled, i.e. who has the right to access these results and how can they access these results; through licenses or should the information be put in the public domain and not having any rights asserted by the parties to the platform, or should the actors on the platform not have any rights to the results being made at all.

When constructing a platform with content that is openly available for many parties to access and in certain cases also use the content that is supplied through the platform one has to ensure that

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[130] Innovative Medicine Initiative (IMI), Rules for submission evaluation and selection of Expressions of Interest and Full Project Proposals Stage 1, (2009)
[131] Innovative Medicines Initiative (IMI) IP Policy, (2007)
[132] Sideground definition by IMI, Innovative Medicines Initiative (IMI) IP Policy (2007)

access should be kept. Openness always needs to be constructed to be open in the long run.[133] With this in mind, the authors suggest that this could done through imposing restrictions on how to further the use and access of content thus the aspect of whether or not an actor that has access to the platform is also free to patent improvements or modifications becomes important. If a platform supplies gene sequences as content, and modifications that limit the use of the platform content is made and patented, one could require grant-back licenses to ensure freedom of the platform content from patent blockage, however then also restricting the usage thus not the access to the content. Even if access is open for everyone, the analysis imply that this openness has to be built on the platform through contractual structures between the platform members ensuring access to everyone or based on IP structures or publication.

6.2.2 Level of Openness to Include Content on the Platform

The parameter openness to include content on the platform has been interpreted by the authors as describing how stakeholders of the platform are allowed to contribute to the development of platform content. This is a steering mechanism for the founders of the platform in steering the development of both the platform content as such but also steering the platform development as in means of who will be interested as a stakeholder in the platform both from a contribution but also a collaboration perspective. This section will attend to the legal mechanisms that govern the openness structures needed to construct different layers of openness to include content on the platform.

6.2.2.1Statements in the CFA

The CFA, a term constructed by the authors based on the analysis made, will govern the level of openness to include content on the platform through clauses that states the prohibition and process of including content on the platform (depending on the governance structures of the platform the CFA will be constructed by different participants). Through such an agreement the classification of stakeholders in who is considered to be a contributing or developing participant of the platform will be defined. The restrictions that are possible to make in such a classification could limit the contributing or developing participants to a group, cluster, open or closed community or not limit the contribution of content at all, having inclusion of content open to everyone. It is according to the authors important to define what is meant by the groups, clusters or communities, meaning that definitions and criterions of those who could be part of the platform must be clearly expressed.

A platform that has constituted such an agreement is e.g. DSTT which includes in their pioneering agreement that only selected universities (i.e. on a development group/ cluster level) can include content on the platform.[134] The HapMap Project has a similar structure consisting of six universities around the world setting up the project and being the only ones including content on the platform.[135] IMI has used a sophisticated governance structure which constitutes that through a call and evaluation process, projects will be chosen, and only project participants will be able to include content to the platform.[136] GSK has on the other hand used another structure

[133] Petrusson (2004) p. 177ff
[134] Dooley & Kirk p. 316 f.,
[135] HapMap Will Help Identify Genetic Contributions to Common Diseases
[136] IMI Call & Evaluation Process, IMI IP Policy, IMI Grant Agreement

having conveyed that everyone is allowed to include content onto their platform or "donate relevant small molecule compounds or process patents for neglected tropical diseases, and allow others access to develop and produce new products and formulations for use in those least developed countries".[137] The analysis then reveals that actors use these CFA's to convey their intended actions in who can contribute to the development of content on the platform.

When selecting the participants to such a group, cluster etc. the authors believe that, based on the analysis, one must be specific in defining who actually has the possibility of entering such a group and on what terms it is possible to enter such a group. There are different ways of defining and administering such a restriction in participants or stakeholders that are allowed to include content on the platform; one such administrative mechanism is the different membership structures that could be built.

6.2.2.2 The Membership Structure

A membership structure will administer the openness to include content on the platform through determining what requirements there are for a stakeholder to become a part of the platform and ultimately include content on the platform. The regulations that constitute the membership structure should then as more of a supporting legal instrument lay down the requirements for how a stakeholder can actually become a member or participant; limiting and defining the boundaries of the platform. The membership structure of the platform will according to the authors also help in enforcing other governance and openness choices made by the platform stakeholders. If enforcing a membership structure to control the openness to include content on the platform the membership structure could also stipulate other requirements in terms of access and usage. If one chooses to have a completely open structure without any membership terms enforcement of other requirements could be struggling.

Based on the analysis the authors have uncovered that there are several ways in which membership mechanisms could be attained; there could be a model where one includes content and therefore becomes a member or a model based on a review and application process administrated by the platform that approves the membership of participants. The dynamics in creating a membership structure and its ability to structure collaboration has been acknowledged by platforms in the life science field and have been implemented to facilitate the interests of the participants. The Biomarkers Consortium has implemented a contributing membership program where organizations are welcome through the program to support biomarker development and can then apply to become a member of the development group.[138] In this instance the authors find that the platform has put forward restrictions to the contributing membership structure in terms of letting the requirement of eligibility be prevailing, which intellectually separates and categorizes different stakeholders and the pre-requisites that need to be fulfilled in order to be able to contribute to the platform through the membership structure.

The authors have through the analysis made located another model of utilizing restrictions through a membership structure as a means to regulate openness; a model that is employing a structure where a certain field within the industry is separated and included on the platform, e.g.

[137] GlaxoSmithKline Patent Pool
[138] Biomarker Consortium – Join the Consortium

imposing restrictions that stipulate that the platform can only have participants that are present and doing research within genome sequencing to include content on the platform, which will naturally eliminate a significant amount of actors and thus create a community which is closed to all other actors which do not handle these research areas. There are then regulations which are set by the platform as such, being a closed community inflicting restrictions on the ability of an actor to contribute with content onto the platform. The PIPRA platform has implemented a structure where they have defined certain criteria for a stakeholder to become a member to the platform such as being in a specific industry or business environment and to be a specific type of organization or the like. Through these requirements the platform have defined the community which they are intending to create through restricting their inclusion to members and the community defined is the only parties that can become members.[139]

The authors found that to implement a structure which supports the contribution of its members is applied by the BioBrick Foundation and BiOS, two initiatives that through fairly similar structures coordinate the research efforts of their platforms and thus steer the level of contribution. The BiOS initiative has through its terms and conditions in their Mutual Non-Assertion agreement set forth between the platform and the user constructed a demand that to be able to contribute you have to waive your ability to assert your proprietary rights in favor of the platform and the research community.[140] The BioBrick foundation has a similar structure in place, where they have constructed a Contributor Agreement that stipulates that a contributor to the platform can ”list and submit as many different materials as the Contributor wishes”; however, the contributor must be able to agree to not assert or threaten to assert IPRs in connection to the material that they are transferring to the platform.[141] Based on the analysis, the authors find that there are thus requirements to consider that through the contractual structure implicitly limit the ability to contribute to the platform and in turn shape the platform.

The boundaries of the platform to be set through a membership structure could then be closely intertwined with the contractual model of a contributor or mutual non-assertion agreements, which the authors call CFAs, which will stipulate obligations and requirements that will shape the level of openness to include content to the platform. The structure of the agreements mentioned in the analysis is to a large extent based on a stakeholder´s capability of administering their IPRs and the context in which the membership structure is presented. As regards a more open model, where the openness to include is restricted to a more open community like in the case of BiOS and the BioBricks Foundation, they have put forth restrictions that a stakeholder can address and try to comply with in order to be able to contribute to the platform. In this context the authors conclude that a stakeholder can actually affect the outcome of whether or not he will be able to contribute to the platform since the restrictions or criteria put forth are not entirely done by the platform as such but will rather put the responsibility on the stakeholder to alter his operations in order to comply with the restrictions.

The restrictions set forth in this setting are according to the authors relating to a structure where IPRs are used as a tool in constructing which level to utilize as regards the ability to include

139 PIPRA MOU
140 CAMBIA DRAFT Health Technologies BiOS 2.0 Agreement
141 BioBrick Public Agreement

content on a platform. The structure of using an agreement that stipulates that the relinquishing of rights to assert IPRs is then transferred into determining who it is that can actually contribute to the platform, shaping the membership structure of the platform. The purpose of utilizing this construction is to enable a control mechanism that can be structured through imposing conditions through membership terms.

The authors believe that the contractual structure presented can thus regulate the shape of the community sought for, letting the participants that are members of the platform relinquish their inherent right to assert their IPRs as a way of ensuring the possibility of including content. The agreements that are in place to govern the contribution should also stipulate definitions regarding the rights that should be surrendered in order for a stakeholder to contribute to the platform. The agreement implemented to shape the membership structure should then stipulate whether the non-assertion of rights should be connected to all IPRs that are relating to the content that is to be included, or should contributed content be intellectually separated into different layers, i.e. should rights in relation to only patents be required to be non-asserted or should more intellectual assets such as technologies and the like as patentable inventions also be included.

The institution of membership structures can also help in dividing members into more than one category also meaning that members of the platform can have different rights to include content to the platform. The authors therefore conclude that membership structures are one way of administer who can be part to include content on the platform.

6.2.2.3 Type and Structure for Including Content

When it has been determined which stakeholders that could include content to the platform and how to administer the process of determining who could include content, the authors believe that one must turn to the next challenge addressing what kind of content that can be included in the platform and how (touching on the Level of IPR Claims).

The regulations on what could be included in the platform could be either on a high level including a lot of content or more specific. The analysis suggests that it could be on a protection and leverage potential level or on a research arena level. Another option is also to constitute a review board that determines through qualitative assessment what could be included on the platform. This is however very much dependent on how one could include the content; also depending on what the content of the platform is which according to the authors asserts the notion of the interdependency among the parameters. If one determines to include IPR's as content on the platform the how part would mean supplying licenses to other parties through license structures set forth in the CFA or utilizing the waiving of rights. If the platform content is determined to be uploaded virtually, will there be a process of revising content or would one be able to do it ad-hoc, also influenced by who could include how extended the process must be. If the content of the platform is physical the analysis made suggests that the CFA must address who should hold the physical material of the platform and also naturally what rights the sender vs. the holder has to the material.

The authors have found that many of the issues arising regulating the inclusion of content on the platform also has to do with the rights that stakeholders of the platform will gain and the

including party will withhold to the content of the platform. Incentives for joining and including content on the platform is dependent on the rights still held to the content when included or the value gained which in some cases can be higher when included and in some cases better off as a secret by one actor (this touching upon the access and usage rights of content, again showing the interdependency among the different parameters).

6.2.2.4 Division of rights

The analysis made implies that one important parameter to consider is furthermore the legal instrument of IP legislation and the rights which this confers to inventors of specific content to be put on the platform. The platform will have to consider the implications of the rights of the researchers and how the distribution of the rights should be contractually structured. The platform would have to address whether to create a strong ownership structure or create a license structure that allows more flexibility when it comes to including content, based on the level of openness which would like to be pursued.

The division of IPRs will in this stage be initiated when the stakeholders are to be accepted onto the platform as contributors, thus being interrelated with the membership structure set forth as a mechanism to administer the content on the platform. When a stakeholder is to be able to include content on the platform, there needs to be regulations in place in the CFA that will govern the allocation of rights to the background material, information or the like which will be contributed with by the different stakeholders onto the platform. The rights to the background should according to the authors then be administered appropriately, and based on the understanding from the analysis there are multiple levels to consider which should fit the overall purpose of the platform in terms of level of openness to include content.

The division of rights will ultimately help in establishing control on different layers on the platform and will thus help in ensuring the level of openness sought for. The license mechanisms to be put in place are thus supported by the CFA which is addressing the allocation of rights and especially the rights to the background which is to be included onto the platform. The rights which are conferred by the parties will also have further implications on who it is that can actually enforce the rights, which will give the participants an opportunity to negotiate the terms and conditions based on their acquired rights. The authors therefore conclude that the interaction between the licensing structure and the CFA will pave the way for the control aspect in the collaboration.

6.2.3 Level of Open Usage in R&D and Innovation

Usage of the platform content is one of the most important things in regulating the openness of a platform. The regulations on usage often work as good incentives for actors joining the platform. When talking about usage in R&D, what is meant by the authors is usage that does not constitute products or other types of innovations used in business models or for commercialization purposes, also meaning that usage in innovation is just that, results (foreground or background) used for commercialization. IMI has gone as far as defining their "Research use" as clinical trials

and non-commercial development activities, while their usage in innovation is called "Direct Exploration" and includes all commercial activities beyond that point.[142]

When regulating the usage of results in R&D and innovation the authors believe that it is preferable to consider for whom the results should be made available. If all usage is open for everyone in this parameter there are few incentives for commercial actors to join the platform due to no first mover advantage or leap in innovation to other competitors not being in the platform would be gained. The authors will in a first step talk about the layers of constructing open usage for the platform participants.

How usage can be controlled is reliant upon the content of the platform meaning that if the platform content is protectable or protected through IPR's and especially patents there is a possibility to claim ownership of the content making it easier to determine the structure of how usage rights should be handled and distributed throughout the platform. If the content is not an IPR, one has not the self-regulatory mechanisms apparent in the legal system to back up claims made that the usage is restricted if such usage is not regulated through agreements. This analysis would then imply that the protection of the content is the first step in constructing open usage structures, meaning that one could rely on the legal system through claiming IPR's or one must regulate the unprotected assets in the platform agreement to claim the ownership of such result.

The next step in construction of usage rights is to determine the rightful owner of the result that will be distributed on the platform. When constituting the platform one must determine either that parties on the platform (on network driven platforms) determine of their own how the ownership of results should be regulated, or a CFA could govern the ownership issues of the platform such as an IP policy that is imposed and accepted by all the members of the platform. There are different methods for different models of content that could affect how one could implement such a contract, meaning that if the content is internet based a "click to agree" structure is often implemented, due to the nature of openness on these platforms, however in more sophisticated platforms this is one of the key issues negotiated on the platform.

Once the ownership of results is determined the access to the results and the possibility to use it in different settings is regulated through contracts between the participants. Here, as the authors have mentioned in previous sections, there are different governing structures of how this is regulated and in the layers of this parameter the authors will point at some examples of how regulations are done in platforms today.

6.2.3.1 Protection and Ownership of the Content

The first step in constructing the usage layers of a platform is the protection of the content. The analysis reveals that depending on the nature of the content if it is IPR protected or not, internet based or research results one has to think in different ways. If content of the platform is IPR protected there are certain self-regulatory tools to use in the construction of usage rights and if there is not one has to construct such rights on the platform to be able to control the usage. When having determined the protection level and content of the platform one needs to use the

[142] Innovative Medicines Initiative (IMI) IP Policy (2007)

structures to sort out the ownership claims that actors on the platform has to the content. If having IPR's present the ownership is self-regulated but if no IPR's are present the ownership structures needs to be determined through negotiations and agreements where foreground and background is stipulated with an owner.

6.2.3.2 Regulation of Usage in CFA

When the owner of the platform content is determined one could start looking at how one wants to regulate the usage of other actors on the platform or by external actors. There are several constructs possible to make. If one wants a more closely regulated usage meaning that no one other than the owner(s) should be able to use the content one has to state this in the CFA, however these kinds of structures letting no one on the platform use the content is rare and often occurring in a private setting. Taking the Biomarker Consortium as an example they construct rights to use the result or content (foreground) for the project participants through (by law the inventors would be the only ones having a using right) the IP policy saying that all project team participants, regardless of who owns it (the inventor who invented it or his employer) has the full right to use the content in both R&D and innovation, meaning that other platform stakeholders does not have a right to use the content for innovation, however, everyone (even others outside the platform) has a right to a license to use the content for research purposes.[143]

Opening up the platform one could talk about a right to negotiate a right to use the content. This layer is constructed through the CFA or implemented on the platform through network control choosing such a governing structure, stating that whoever owns the content needs to give others on the platform a right to negotiate a right to use the content, a first right to negotiate could be used or negotiations on FRAND or commercial terms depending on the interests of the stakeholders. One also needs to determine who will have such a right to negotiate; are there different categories of participants and what about third parties from outside the platform? IMI is an example where there is an opportunity for outside parties to achieve a research license on FRAND terms and direct exploration licenses through commercial terms, regulated in the IP policy of the platform. Participants within the platform have a right to use the results (foreground) for research purposes without having an option to negotiation however FRAND terms apply and are given an opportunity to negotiate the right to use under direct exploration or commercial terms.[144]

Even more open usage could be designed in giving participants, stakeholders or others a right to use content under the CFA; however, such a right could be restricted or come with a grant back clause. As regards the restrictions they could be on anything from that the platform participants needs to pay for the usage to that the usage is restricted to certain areas or certain fields. The GSK platform is a platform where usage of user rights under restrictions is applied. GSK grants everyone who wants a license to do research with their patent rights on the restriction that they commercialize in a third world country (listed) where the neglected disease that the patent concerns is a problem. They have also special terms that need to be agreed upon. There is also a

[143] Biomarker Consortium IP Policies
[144] Innovative Medicines Initiative (IMI) IP Policy (2007)

possibility to get a license for commercial terms in other geographical fields however this is negotiated with GSK on a case by case basis.[145]

As regards the cases where usage is allowed but stipulated with a grant back clause this is a solution built on the software movement and a copy of the "copyleft" license, meaning that one is able to use content, however if one makes any modifications or enhancements of the content one needs to provide licenses, under the same conditions as the first license to the content. This is a more complex structure than when this was used in the GPL format because copyright protection is automatically occurring when software code is created while the code of genes or other enhancements in the life sciences often must be protected through patents[146], meaning that the incentive for using this structure is much lower in a commercial setting than in the software movement and the GPL license had due to payment of patent fee's which are released to the originating source. However, if this is a platform where others also share there is a greater incentive than building on the GPL which is a public license. What can be said by the authors is that a construct of this is that the research use of such a grant back might be a limit to keep the incentives of commercial actors to use the platform content in their business. When constructing this type of usage for the platform the CFA must not only stipulate the right to use the content to the platform in combination with the grant back license but also what should be considered a modification or improvement and on what terms such a grant back must be made. To implement a CFA in the internet based setting a "click/use to accept" kind of a shrink wrap model could be utilized, meaning that if you start using the component or if you enter the database, become a member etc. then you agree to certain terms when having seen the material on the platform. This model and this type of content is the most frequently seen by the authors using grant back usage licenses.

BiOS is a platform using this type of open source thinking in sharing technology. They have constructed an agreement so that the users of the technology and IP licensed under the agreement if patented or otherwise IP protected in expansions or improvements of the technology the rights given by such a claim will be set aside for the participants who has signed mutual agreements respecting the same principle.[147]

If one wants everyone to be able to use the content without no restrictions and no restrictions on keeping improvements or such open, a regulation on the platform stating that all content that is provided at the platform will be open for everyone to use without any restrictions needs to be implemented in the CFA. However there could be restrictions when talking about actors outside the platform. The common denominator is however the intention of letting research being made on the platform available to contributors as well as outside parties through contractual means to maintain a certain amount of structural control. IMI has a construct where background that is necessary to be able to use foreground and foreground is licensed on fair and reasonable terms, non-exclusively to everyone for the purpose of research. This is included in their IP policy which is recognized by all actors of the platform.[148] The PGP platform has no restrictions for using

[145] GlaxoSmithKline License Terms
[146] Hope p. 10f
[147] CAMBIA DRAFT PMET BiOS 2.0 agreement
[148] Innovative Medicines Initiative (IMI) IP Policy, (2007)

their content in products or development efforts etc. it is actually encouraged. However when it comes to ownership of the material the provider of the material (the test owner) owns the actual sample, however if alterations are made it is possible to patent those since there are no restrictions on the use of the content, the only restriction is not to patent the content of the platform. Even if the usage is free and open there is still an agreement to sign when using the material since rights might not be totally surrendered from the rights holders side even though a promise of not imposing the rights on your usage is agreed.[149]

6.2.3.3 Licensing Structures

When having stipulated what kind of usage one wants to the platform content the practical matter of designing structures to let such things happen can be done in practice through the legal means of a license. When having IPR's on the platform the license structures the authors see that this clearly benchmarks the rights of the owner to license out or to abandon the right to take legal action gained through patent, copyright or design rights law. The authors consequently find that the law is here the backbone of such a construct. The same rights could also be stipulated through agreements as stated earlier when deciding ownership of the content.

To have a rather generous level of open usage in R&D seems to be the trend in life science platforms, since the majority of the platforms analyzed have decided to include a contractual structure where licenses or CFA's are implemented that in turn creates a structural solution for the openness giving all parties of the platform fully open usage in R&D and Innovation.

6.2.4 Level of Costs

To determine the level of costs to deploy on a platform is complementary to other parameters which have been presented in this thesis and it will serve a role in determining how competitive the platforms are, which in turns is dependent on the stakeholders who are present on the platform and their relevant status within the research field; the life science field as analyzed in this case. The authors have, based on the analysis made, concluded that the level of costs that should be arranged by the platform, between the participants of the platform and any outside stakeholder thus letting the focus become divided to both internal and external transactions are to some extent determined by where in the value chain the stakeholders to the platform are positioned and their creative relations to one another; should there be a platform with the purpose of creating a standard (through a set up standardization body) then this would be reflected in the level of costs, since this body would perhaps not use costs that are commercially negotiated since that would defeat the purpose of creating and contributing to the standard in the first instance.

The level of costs is also reliant on the content of the platform; the authors have seen through their analysis that in the life science field there exists a range of material as well as merely unstructured data that passes as content and has implications on how the costs should be regulated, e.g. are there license structures implemented then the platform would have to consider whether to let access to the rights be on a commercial basis or on fair and reasonable terms. The level of costs is found to have a two-fold purpose of both regulating the terms of transaction among the participants on the platform and also regulate the relations that the platform has with

[149] Science Commons Material Transfer Agreement

any outside stakeholders that would like to receive access or make use of any content coming out of the platform.

To set up a proper structure for level of costs that would adequately reflect the stakeholders relation on the platform as well as the content of the platform to ensure the other structures of the platform, the analysis implies that there are different alternatives that could be divided into more or less three categories; terms of payment that are set by the industry without any regulator interference that could be commercially negotiated or fixed, terms set by a regulating body or governmental body that have been stipulated and formally implemented and finally the lack of terms of payment to reflect an overall openness to the platform without any payment.

6.2.4.1 Terms set by the industry

The concept of costs being commercially negotiated has as interpreted by the authors the inherent meaning to it that the price or cost is negotiated and set by the industry as such. This means that it relates to a more privately negotiated rate and is thus not dictated by regulators and implemented as standard of payment. The price regulation is then as understood by the authors left for the commercial parties to discuss, and in this setting it is possibly done on a more case-by-case basis should the need for access to a specific part of content be present or the platform has primarily private interests to adjust to.

When determining a level of cost that would conform to the purpose of the platform and the stakeholders that are participating, multiple dynamic ways are to be found in the setting of commercially negotiated terms. Should the purpose perhaps be for private companies to share rights to exploit the platforms technical know-how and also keep their proprietary compounds while paying to license the IP emerging from the basic research projects, like the DSTT platform[150], then the terms of payment could be held on a commercial basis since the licenses are given on a semi-exclusive basis which could indicate that the private companies on a platform would like to negotiate should a request for a license be present. The license would then through the negotiations probably be given to the highest bidder, which according to the authors would indicate the relevance of having commercially negotiated terms when the first right to a license could be withheld should they not pursue it.

The level of costs can be dependent on the actual intellectual separation between the members of the platform as opposed to the external actors in terms of access to the content on the platform. In the Biomarkers Consortium, there is a requirement that you have to be a member and a part of the program agreement in order to access results and have the costs as a part of the agreement. Should you however be an external party wanting to gain access then the terms regarding costs is to be commercially negotiated due to the distinction made.[151]

The commercial terms made could also be fixed in the sense that they have been decided upon by the industry on a high-reaching level but that are fixed as opposed to negotiated, which makes it less flexible and not entirely subject to negotiation regarding the level of costs. The terms regarding the costs are then not done on a case-by-case basis but the concept of fixed also

[150] King p. 5
[151] Biomarker Consortium IP Policies

suggests that since they are set the stakeholders would have to comply or otherwise not be a part of the agreement. The authors have then seen that a starting-point to employ when discussing fixed commercial terms could be collected from international bodies that address suggestions on how the terms could be laid down.

To construct commercially negotiated terms should require having to regulate the licenses and have the terms regarding payment as complementary to the level of access and usage that has been decided upon through the distribution of rights. To have the costs commercially negotiated suggests that the process could according to the understanding of the authors be biased, should an industry actor exercise their favorable terms against a smaller actor and thus reach an unfair outcome. The platform would have to address these issues as well when constructing the obligations of costs, including mechanisms such as having the parties negotiate on equal terms. The construction and regulation of costs in relation to the platform are inherently connected to the licensing structure which has been created by the platform, again shown by the analysis and its interdependencies. The licensing structure could in turn be subject to separation as regards both access and use of the platform content, and also be subject to separation when it comes to external stakeholders and internal participants, as will be shown in the next section.

6.2.4.2 Terms set by the Public

The use of standard terms which have been implemented by a governmental body as a means to ensure a reasonable market and allocation of ownership could serve as a mean to regulate the level of costs to be applied on a platform and the transactions to take place. The concept of Fair and Reasonable Terms (FRAND) have been introduced as a way of enhancing the pro-competitive character of the industry where it is applied. The foundation of the concept is to prevent members on a platform or collaboration from engaging in licensing abuse where a stakeholder uses his situation to impose unfair, unreasonable and discriminatory licensing terms that would damage competition and increase their own relative position. There is no real legal precedent that spells out specifically what the terms actually entail, which means that the interpretation of the terms have to be done based on acclaimed legal scholars and persons knowledgeable within the field. What could be extracted is that the term "Fair" relates mainly to the underlying licensing terms and them not being anticompetitive and that they would not be considered as unlawful should a stakeholder impose the terms on a relative market. The term "Reasonable" refers mainly to the licensing rates, which is of primary interest in this setting since this parameter is discussing the level of costs which are employed through a licensing structure. A reasonable licensing rate is a rate charged on a licensee that would not result in an unreasonable aggregate rate if all licensees charged a similar rate.[152]

When discussing the concept of FRAND the authors would like to raise the issue of whether the "Reasonable" licensing price should include the value that a technology captures when it has been adopted more widely than when it was one alternative among many; however, to have a license price that captures the additional value is perhaps not "Reasonable" because it does not to a certain extent reflect the intrinsic value of the technology being licensed. This is a discussion that the authors think should be considered when realizing the licensing of a technology and

[152] Ruikka

setting the appropriate terms as regards payment in connection to this. The concept of FRAND imposes many reflections when it comes to the limitations that they inflict on the platform stakeholders when they are willing to implement it. To have a platform that uses the FRAND as a milestone for their payments the authors see the need to consider the stakeholders that are thought to be given access or usage rights through licenses and thus their positions as well as the platform itself and the market in which the platform and its stakeholders are operating within. The licensing structure to be set up in this case could then give the stakeholders an opportunity to separate between when to use the concept of fair and reasonable terms and when to impose other terms of payment.

In the case of IMI, there are differences in the deployment of the level of costs, which shows the diversity that can be applied when constructing openness on a platform through the cost mechanism. The platform has intellectually separated between the use of the content in R&D and innovation, where the usage of the content in R&D is subject to fair and reasonable terms, whereas the usage in innovation is subject to commercial terms which are negotiated upon.[153]

Based on the analysis made and the conclusions drawn regarding different standard terms available, the authors believe that as regards the construction of this layer in the level of costs there are many considerations to be taken which will have legal implications should they not be managed in a proper manner. When one considers a fair and reasonable price in terms of licensing, the platform cannot use a rate that would significantly increase the cost to the industry and make the industry uncompetitive and unreasonable, since this would not comply with the imposed FRAND concept. In the case of the life science industry the platform should avoid putting a high rate on certain patented materials or the like that would stifle the development, particularly downstream research, since the analysis suggest that the development of the industry is dependent on not blocking research being done in order to promote innovation. Furthermore, as has been demonstrated by the IMI example, a licensor can package their licensing terms on different terms; however, all licensing rates must be reasonable to be acted upon legally. To conclude, the authors suggest that to regulate the terms for costs with fair and reasonable terms imposes many considerations and a platform would have to be aware of the implications a wrongfully constructed obligation could have on the rights of the stakeholders. The regulation of the fair and reasonable terms is thus controlled on a regulatory basis, which makes it differ from the underlying layers regarding commercial terms, which puts demands on the platform to conform and adjust their terms to avoid litigation.

6.2.4.3 Terms set through Sponsorship

The research being done on a platform could furthermore be sponsored either partly or fully through public funds which could be run by the government, corporations or foundations that allocate scarce funds to research projects or the like. When the government is involved in the process, the funding is usually carried out through universities and specialized government agencies, whereas corporations also play a major part in funding research through their R&D departments.[154] When a platform would like to exercise a more open approach towards the access

[153] Innovative Medicines Initiative (IMI) IP Policy, (2007)
[154] The Swedish Research Council - The Swedish system of research funding

and usage of the platform content, the authors believe that the platform would still need to have leverage on the value that is being created on the platform, i.e. there needs to some extent be a financial return that will make the platform sustainable and create a return on the investment being made onto the platform. The usage of external funding and sponsorship can most certainly create a platform that through these financial means can sustain an open access policy and create benefits for the research community but you would still need to leverage on the platform to be sustainable.

When a platform is sponsored by either the government or the corporations that are a part of the platform, the notion of having external funding as a level of costs could impose requirements on letting the access to the results become more open towards the actor that is actually sponsoring the platform, due to their contribution of paying for the costs related to the research. In a situation where the platform is being sponsored for its efforts in research and to ensure its openness, there is according to the authors a need to initially regulate how much a sponsor will have to contribute to the platform, i.e. the amount of money that is to be put into the platform as a sponsorship or grant. This could be done through a research agreement which could detail the terms of the award.

Furthermore, the authors believe that there needs to be clear guidelines or agendas as regards on what type or field of research that the money should be spent, this to keep the sponsor involved in knowing where the money is being transferred to. The contractual aspect could further be enhanced through regulating the influence that a sponsor may have over the platform and the content that is being generated and contributed on to the platform. The sponsor could have an advisory mechanism which could serve the purpose of ensuring that the money is being spent primarily on a research agenda that would benefit the sponsor as such and the goal that it has on its own agenda as well. There is furthermore based on the analysis made a need to regulate the type of members that a sponsor would like to have included on the platform; this has naturally to do with the level of influence that the platform has negotiated to give to the sponsor in question. The contractual tool could thus limit what type of actor that is to access the platform, or more accurately, depending on the research agenda the platform has been sponsored for the members would naturally gravitate towards this due to the investment being made in that specific area. The agreement will then reflect how willing a sponsor is to support all the participants on the platform, since there may be an agenda that the sponsor will follow that is not in compliance with certain participants on the platform.

The authors have furthermore drawn the conclusion that the agreement set up between the sponsor and the platform should also regulate whether there should be milestones to be reached by the platform; the requirements of a sponsorship could be to review the agreed upon milestones to ensure its efficiency. Through regulating and describing the milestone, the sponsor will know what he can expect to receive in exchange for the support of the research. In the life science field the authors have seen through the analysis that the milestones could relate to having test parameters being validated in human clinical trials and thus letting the platform move forward in its validation process. The agreement should further regulate the budget that the platform is working under, i.e. the expected costs that are to be spent and also what they are expecting in return.

6.2.4.3 No terms of payment

To enable a platform to be fully open even in terms of costs a level of free access and usage could be utilized, where the actors that are granted access and usage can exercise these rights without having to pay for it. The realization of this layer of openness has been done by the PGP which is posting their content through a database which is accessible on the internet and could be utilized by everyone without incurring any costs.[155] The information is then not to any cost for a participant or external actor which would make the access and usage free. The same principle has been adopted by the HapMap Consortium, which is committed to rapid and complete data release, and to ensuring that project data is made freely available in the public domain at no cost to users.[156]There is thus according to the analysis a way of practically ensuring that the content is made freely available at no cost to users and participants on the platform and thus the regulations regarding the costs could then be stipulated by the authors as being non-existent in this context. The regulation aspect should then be that the platform should insist on being compliant with a fully open policy and that they are not imposing any costs on the ones that would like to access and use the content on the platform.

[155] Personal Genome Project Website
[156] International HapMap Project Article

7 Conclusions

This thesis had posed one prominent research question; What constructional tools and contractual structures enable openness in open innovation platforms in the life science industry? This main research question had three sub-questions, them being: How are existing legal structures and self regulatory tools used by industry to construct openness? Is the tool for designing open innovation platforms fit for evaluating and constructing open innovation platforms in the life science industry? Which considerations need to be addressed when constructing an open innovation platform? This section will show how the authors have answered these questions.

This thesis has been able to show what constructional tools and contractual structures there are that enables openness in open innovation platforms in the life science industry through creating a toolbox which is providing an actor with the necessary tools and concepts to be able to initiate and create an open innovation platform. The toolbox has its foundation in the regulatory and contractual aspects of the management of innovation, derived from existing legal structures and self-regulatory tools that have been found to be used by the life science industry in constructing openness, taking the standpoint in the investigation and analysis made of the existing platforms. The identification of these tools and concepts have furthermore been obtained from the tool for designing open innovation platforms created by Professor Ulf Petrusson, a tool which consist of a subset of questions which has served as the starting-point for the authors in gathering information and in creating the practical framework of the toolbox. The suitability of the tool in relation to the life science industry has been addressed throughout the thesis, letting the differences between the life science industry context and the open source context serve as an example in how the utilization of a tool have to be altered and customized to a specific context. The understanding of the life science industry and the analysis made on the existing open innovation platforms have furthermore served as the foundation for determining what considerations to take in order to construct an open innovation platform. The considerations have been addressed both when analyzing the platform constructions as such as well as when discussing the practical toolbox accordingly.

The thesis has thus shown that the construction of openness in open innovation platforms have many dimensions to it, leading to the development of a practical toolbox for visualizing the many faces of open innovation platforms. The thesis has furthermore shown that open innovation platforms offers a variety of new opportunities for value creation compared to other models, using the constructional tools and contractual structures present steer the development. The thesis has furthermore proposed a conceptual exemplification for how open innovation platforms are structurally built and accompanied this with a practical toolbox of platform construction tools. Through this toolbox, an opportunity for structural creation of open innovation platforms has been provided for.

The main conclusions that could be drawn from the analysis made that will assert and support the above mentioned statements regarding the thesis will be presented below with an emphasis on how a platform in the life science industry could be constructed through legal tools and the interdependency of the platform parameter building blocks.

7.1 Evolution of the Life Science Industry Innovation Model

The structure of the life science industry has been subject to numerous changes in recent years due in part to the technical advancement of the field which are embracing the more evidence-based approach where the genetic sciences and process technologies are in the forefront of research. The field of biotechnology that encompasses genomics development is a highly complex and early field of research in life science where actors have made the transition from patenting at the final stages of development to patent particular results from basic research, and the focus has shifted from intended end products to generated research results as the value creator.[157] The development of the research field and the discovery of new research areas are opening up the possibility for medicine to become more personalized; thus not utilizing the blockbuster model where big pharmaceutical actors invest in a few molecules that are turned into a large amount of drugs that are distributed without being tailored to the specific need of a patient.[158] These new knowledge requirements, together with policy interventions made to disperse cost in the development of drugs, has created a demand on actors in the life science field to advance their innovation model and create new collaborative partnership structures to fill voids in upstream knowledge and downstream capabilities.[159]

Open innovation platforms have as a result emerged in this field to fulfill these requirements, and this new way of administering innovation can provide the actors with the necessary means to control operations and keep their competitive edge. The development of open innovation platforms in the life science industry, as has been seen through the analysis made, is however not only focused on the advancement of businesses but rather to let information related to the research being made be released to the public for the sake of further research, leading to different structural approaches to manage the level of openness aspired for.

7.2 Platform Construction through Legal Tools

The fundamental structures when constructing an open innovation platform is the legal framework that the platform is built upon, meaning the contractual tools, concepts of background and foreground but also the legal framework around IP.[160] The legal framework is used in the construction of the platform as the basis for how to construct the contracts and what defaults that are set. The contract structure is the most fundamental in constructing the platform due to the conformity among actors that are created i.e. the actual collaboration structures and terms.[161] Other structures that are also important in the platform construction and in particular in the life science industry is the self-regulatory tool found in the patent construction. This construction which in this setting is used to build the platform structure through the mechanisms of the patent given by patent law, mostly the right to exclude others, which is elaborated upon in the construction of distribution of rights.[162]

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[157] Petrusson et al (2010) p. 10
[158] Cooke p. 65f
[159] Gillespie et al p.29
[160] Petrusson et al (2010)p. 19ff
[161] Petrusson et al (2010) p. 31
[162] Petrusson et al (2010) p. 4-5

When talking about the mechanisms of the patent, that could be used to construct the platform, one must notice the importance of claiming the patent characteristics and mastering the different arenas which to operate in. The platform as well as the patent construction must be recognized in the administrative setting, through registration and approval, claimed in the business arena to earn the respect of the business community but also uphold the rights in the judicial arena which represents the ultimate power of the state.[163]

When mastering the arenas, the authors conclude that one can make claims that constitutes the platform and negotiate the background and foreground of assets due to the property character given when claims has been made and recognized by others. The open innovation platform is therefore a collaborative tool, set up by contractual structures which form the foundation for the functions on the platform and shaped by the IP framework legislation from which claims are made to distribute rights of the platform.

7.3 The Interdependency of Platform Parameter Building Blocks

When considering the proposed way of building a platform structure with the help of the tool created by Professor Ulf Petrusson one must see the interrelations between the parameters and see that they are not separate structures but intertwined with each other. This has been emphasized by the authors throughout the analysis and has consequently been proven to be a valid point. Using the proposed toolbox to construct the different levels of openness and governance over the platform the authors suggest that the starting point must be taken through seeing the overall construct that one wants to create with the platform. Taking the example of creating the public responsibility that the platform will take on, one cannot according to the authors construct this layer without considering the consequences of how access and usage rights are distributed and created in that layer. The consequences of choosing a closed structure, which of course is dependent on the stakeholders, will determine the level of public responsibility shouldered by the platform.

When using the tool created by Professor Ulf Petrusson one must also remember that this tool is not constructed to fit the life science industry in particular but is a tool that, based on the authors' interpretation, is constructed to fit many fields and especially constructed in the context of the open source movement. The tool has therefore been a challenge to apply in the collaboration and system/tool leverage parameters due to the characteristics of the life science industry. The collaboration parameter has proven difficult to apply for the authors due to the fact that R&D in the life sciences is costly and often demands physical laboratories with sophisticated equipment to join in the research as has been declared based on the industry analysis. Collaboration is therefore more existent in the physical setting or through sharing of research results, while the open source movement was more of a community effort of development. The system/tool leverage, as mentioned, handles another type of content than in the open source computer software setting, but has similarities to the gene sequencing; however, the analysis conclude that the protection levels used to leverage content is connected to patent protection or trade secrets meaning protection that needs to be administered which is not the case in the open source setting. Despite difficulties the tool has been applied without alterations.

[163] Petrusson (2004) p. 102ff

7.3.1 The Categorization of Platform Structures

When using the analysis tool, evaluating platform structures from the way that they are designed, the authors conclude that the tool helps in choosing the relevant information making it possible to categorize the platform structures depending on their content, governance and collaboration level, which of course is built on the grounds of the openness chosen by the platform. The categorization that the authors have done with investigated platforms shows examples of how the platform parameters work together to construct the framework in which the platform is able to operate.

Addressing the Bioinformatics category of platforms the level of system/tool leverage has been the deciding factor in the construction of this category by the authors. The level of system/tool leverage, which has been seen as being closely connected and influenced by the level of IPR claims, can be seen to be fairly low due to the nature of the bioinformatics field as being early stage and actors having incentives not to block the development therefore taking on a high public responsibility, sharing content with the public. This is also something that has influenced the level of collaboration that in these platforms are fairly high. This has according to the authors in turn influenced, or is a consequence of the level of access, usage and cost levels that are implemented on the platform taking on highly open structures to facilitate the collaboration on the platform. The level of openness to include content is however found through the analysis to be more closed due to the control mechanisms that this parameter possesses in terms of development of the platform.

Turning to the IP, Knowledge and Technology Sharing category which is categorized based on the level of system/tool leverage, meaning which state the content on the platform takes, also naturally dependent on the IPR claims made by the platform. The categorization is also based by the authors on the collaborative nature i.e. the sharing of content not meaning developed together but shared through the platform structure which is seen in the level of openness to include content on the platform. These structures are governed by organizations or boards recognized as leading the platform decisions and the platforms takes on a high level of public responsibility due to the sharing of content and highly open access structures used by the platform. The category lets more actors use their content in R&D than in innovation which according to the authors indicate more private interests by platform stakeholders.

The Project Based category is built on the governance structures and collaboration base the platforms have chosen. The analysis show that the governance structures are formally strong structures with either high level of collaboration where the public is involved or that the collaboration structure is limited to the project teams also influenced by or influencing the openness to include content on the platform. The involvement from the public also points at a high level of public responsibility taken by the platform. This is also shown through the open ways in which usage is regulated for the purpose of R&D. However, the incentives for private actors have been kept through restricting the use of results in Innovation.

What can be said overall is that all platforms shoulder a pretty high level of public responsibility, and a reason for this could according to the authors be the nature of the life science field. What is also concluded by the authors is that even if the public gains from the collaboration private

stakeholders are still interested in joining the platform when preserving some of their interests in openness regulations and in particular usage in innovation. To keep control over the platforms most actors also seem to choose a more formal structure in governing the platform than an ad-hoc approach. This could be correlating with the IPR claims of the platforms which are not exaggeratedly high, leading to the the authors concluding that the construct of the patent is harder to use as a control mechanism and building block in the governance construction of the platforms.

7.4 Utilizing the Toolbox in Constructing an Open Innovation Platform

The toolbox that has been created to set up an open innovation platform consist of a set of constructional tools that, when mastered and elaborated upon, will serve the purpose of structuring a collaboration between stakeholders, taking on the necessary considerations when building the platform and leveraging on its content. The toolbox created by the authors then proposes a structural approach to how actors can create open innovation platforms to collaboratively leverage the opportunities of this transition to create or maintain a competitive advantage. To be able to seize, understand and eventually utilize openness, the traditionally dual conception of open or closed (proprietary) have been developed into a continuous scale and multifaceted concept compartmented into a toolbox based on the contractual and regulatory systems as building blocks in designing an open innovation platform. The analysis made have thus identified the specific concepts and tools that are essential in the creation of openness in open innovation platforms and the authors have, based on these, developed a practical toolbox intended to provide a practical foundation in the creation of open innovation platforms.

As a structural approach to developing and understanding the concept of constructing openness in the context of an open innovation platform, this thesis has utilized a division of the concept into two substantial elements; Platform Governance and Platform Openness. The structures within the respective elements are set up with the primary goals of facilitating the transactions taking place on the platform; the governance of the platform and the governing structures are set up as interpreted by the authors to oversee the level of collaboration created by the stakeholders and the system/tool which is to be exchanged or transacted upon within the platform, the level of public responsibility and interests of the stakeholders and the level of IPR claims which are present on the platform. These structures are in turn affected by the arrangement chosen for how openness should be constructed on the platform, i.e. how accessible is the content on the platform, who can include content on the platform, what is the level of open usage in R&D and innovation, and what does it all cost. Through this theoretical model, where elements are interrelated and thus addresses the dynamics of constructional tools to be utilized, a practical tool for creating open innovation platforms is built.

The proposed practical framework and the platform construction tools that have been identified through the analysis made are not claimed to be a complete set, since this would be incomprehensible and not possible when analyzing a limited number of open innovation platform initiatives within the life science industry. However, the toolbox proposes the required platform construction tools and actions to take on every layer of the platform in building the platform based on their distinctiveness and in the theoretical framework provided for through the evaluated tool for designing open innovation platforms created by Professor Ulf Petrusson.

The authors now intend to conclude the actions taken to utilize this toolbox in constructing an open innovation platform through sequentially go over the steps that are to be taken when constructing the layers in the different elements of the structure and consequently what considerations to take in the design process. The section will further express and exemplify the necessary constructional tools and concepts to be utilized when designing the platform, which will serve as the framework which will shape the platform. This will according to the authors add a practical dimension to the theoretical framework which could move it one step further into becoming operational for open innovation platform design.

7.4.1 Content on the Platform

Content on the platform is represented in the parameter structure trough the level of system/tool leverage potential. This does not only represent the content on the platform but also the control that exists over content i.e. what potential leverage there is. The leverage potential is however, as concluded by the analysis, not only based on the control mechanisms as in IPR claims made on the content, but also relating to what type of business model that is used when creating the value proposition out of the content. When constructing the level of system/tool leverage the authors acknowledge that one need to consider what value proposition that should come from the platform i.e. data and R&D results, a systematized toolbox or a multilayered system etc. to stakeholders. In constructing this value proposition, the level of control over content is, as stated previously, important to consider since the leverage potential and the value that is possible to create for stakeholders is dependent on the control exercised over content.

The analysis made by the authors suggest that there are several considerations to take when designing the content on the platform, who are the stakeholders, how do they relate to each other and what do they want to get out of the platform collaboration? These questions are according to the authors highly relevant in designing the platform system/tool leverage potential due to the enhancement of the results that will be done by stakeholders, or should the platform as such be considered as the commercialization vehicle for the content. When considering having R&D results and data as content this should be used in their own businesses meaning that the level of protection could be low and regulated with secrecy on the platform. Enhancing the content and packaging it is interpreted by the authors as recognizing the content as a transactable object often through using the legal IPR framework and the patent protection or through contracts among the stakeholders. Leveraging on the content even more, business models could be used to package the content in different means, designing a systematized toolbox. When the toolbox becomes a gathering point for other data, constructing interoperability between technologies or parties, more leverage could be seen in the operational system constructed through the usage of the toolbox in creating other relevant data etc. This is similar to the multi-layered system which creates a market like structure for the second layer of the platform.

In constructing these layers of content, the level of protection is, as seen, important to consider in relation to the level of system/tool leverage. The level of protection must according to the authors' analysis also be fitted to the stakeholders of the platform, meaning how they want to leverage and control content. There are also certain benefits and drawbacks in having content protected or unprotected which has surfaced through the analysis made. Unprotected content of the platform must be handled through contractual structures on the platform. Unprotected

content must also be recognized in transactions to constitute property of one stakeholder, which is then used in determination of ownership. The authors have found through their analysis that ownership is often determined in negotiations using the concepts of background and foreground. As the authors have further understood it from the analysis, unprotected assets must also be handled on the platform on a fundamental level constituting secrecy and confidentiality policies implemented in IP policies and routines followed by researchers to protect the content from outside sources.

The authors can, based on the analysis made, conclude that IPR and patent protected assets are easier to handle due to the self-regulatory nature of the packaged content. Through the legal framework ownership is determined which is then elaborated upon on the platform structure to distribute ownership. Once ownership and protection is sorted out, contractual structures generalizing content from the protection level makes it possible to support the system/tool leverage potential structures wanted on the platform.

7.4.2 Collaboration on the Platform

The collaboration on the platform is represented through the structure of whether the relationship on the platform has its base in either a competitive, collaborative or community context. This categorization of stakeholders is based on the analysis dependent on what kind of stakeholders that are relevant to the platform, leading to the assumption of the authors that it is of importance to know what type of stakeholders there are that could potentially become a part of the collaboration on the platform, which will affect the way in which the collaboration will be structured. It is furthermore according to the authors essential to be aware of the relation between the stakeholders to the platform, since this will determine on which level and in what context the stakeholders will be able to collaborate and leverage upon the content that is present on the platform. The relationship between the stakeholders to the platform will furthermore give a sense of what their purpose with joining the platform really is, constructing the foundation for the collaborative structure from which the constructional tools and concepts can be extracted.

The analysis has shown that the relationship between the stakeholders on the platform is dependent on what it is that they are actually coming together to collaborate on, i.e. the content of the platform. When coming together to serve a common purpose, the stakeholders relationship on the platform will further be influenced by who it is that can actually include content on the platform, i.e. what structures there are put in place to restrict or open up the ability for stakeholders to contribute with content to the platform. The authors have detected multiple structures to consider when constructing the level of collaboration, and it will be determined by the way in which the stakeholders have chosen to implement their collaborative efforts; should it be through a competitive context where the categorization of content is prevailing, or in a more collaborative context where the level of control of the content becomes more essential.

In a context where the relationship between the stakeholders is competitive and they develop their own contribution and compete in having it included in the platform, the structure will according to the authors have to take into consideration the underlying assumption that the competing stakeholders have an interest in having content included on the platform to be able to

further leverage on others contribution. This structure is implemented by standardization bodies, which provide stakeholders with the opportunity to investigate opportunities and develop innovations based on the accrued pool of knowledge of the participators of the platform that is available for everyone contributing to the platform. The objective of letting society benefit from innovation is approached through different methods in this context based on the analysis made, and the relation to IPRs as tools in constructing this level is then fairly clear. The authors acknowledge that there needs to be a balance between utilizing the IPRs as tools to create and maintain a monopoly situation of a stakeholder at the same time as the structure should support the diffusion of technologies. When constructing the competitive relationship as the model of a standardization body, the ability to include content should according to the authors be limited to a group or developers that regulate the sharing of technology standards, determined through the constructional tool of a CFA that classifies the stakeholders and thus creates restrictions on who it is that can actually be a part of and contribute with content to the platform.

To intellectually categorize the content of the platform through determining different paths of research results could enable competitors to come together and collaborate in pre-competitive areas of research. In this context, the authors can see through their interpretation of the layer that the relationship between the stakeholders is still competitive and their interests are facilitated through letting the platform content be subject to pre-competitive areas. These are then the merger of fundamental basic research and proprietary research conducted by the stakeholders, i.e. content which, depending on protection, is to be contributed by the stakeholders to the platform.

The collaborative structure to be created is, as mentioned, dependent on the relationship they want to have with each other on the platform; should they have a few prominent actors exercising control over the platform or share the rights to the platform in an equal manner or let a multi-stakeholder community set the stage. In this context, the construction comes down to on what level of control the stakeholders are exercising on the platform, a control that as found by the authors being connected to the content of the platform. The control that is to be sought for could be constructed through implementing a membership structure as has been done by the analyzed platforms, which is done through certain regulations that serve as a legal instrument that lay down the requirements for how a stakeholder can become a member of the platform and contribute with content. These structures can, as found by the authors, take on numerous models, dependent on the interest of the stakeholders on the platform, e.g. letting certain eligibility requirements become relevant to restrict the platform to a closed community, require activity within a certain area of research to separate between the stakeholders that are to populate the platform or having the relinquishment of IPRs be a requirement. The IPRs are then what could constitute the level of control exercised by the stakeholders, constructed through regulating the ownership of results in agreements or agree that one stakeholder should have the right to represent the platform. This approach could then be concluded by the authors as relating to the division of rights between the stakeholders of the platform, letting the IP legislation serve as the fundament when allocating rights to stakeholders, letting them decide whether to create a strong ownership structure or share them more openly with each other and the public.

7.4.3 Incentives for Platform Stakeholders

What type of content, what leverage potential there is, what kind of relation to other actors and who are the actors that are collaborating to include and create the content of the platform will according to the authors influence if stakeholders want to join the platform due to the stakeholders interest and relation to other stakeholders on the platform. The incentives for joining the platform however are as found by the analysis very much dependent on the access, ownership and usage of content on the platform that the stakeholder will gain or having to share with the platform participants. The authors recognized through the analysis that the economics of joining the platform could influence the decision for a profit making stakeholder, meaning that the costs must be weighted with the benefits. Access, usage and costs could in turn determine the level of public responsibility shouldered by the platform, i.e. how the sharing with the public is and what benefit could the public draw from the platform.

When constructing the access to the platform there are located considerations to make in incentivizing actors in joining the platform. If access is constructed in a narrow way, through agreements of the platform and IP constructs only letting development groups or clusters access the platform content, private actors looking for competitive edge are probably more interested, however the public responsibility of the platform will be deemed lowered. Constructing a more open platform, access could be restricted to communities which through membership structures are included, accepted or reviewed when joining the platform. The mechanisms of a contract could according to the analysis made also work in stipulating requirements for becoming part of the community having the possibility to access content. Depending on requirements the community becomes open or closed. The most openly constructed access structure is open access, meaning that access is open for everyone. The challenge in having open access is according to the authors to leverage on the content even though it is accessible to everyone.

Access and usage is sometimes intertwined but could be kept separate to leverage more on content on the platform using the mechanisms to control usage as a value creator. To control the usage of the content there are some considerations to make, the protection of the content must be regulated so as to that an owner of the content can be determined (this must be regulated through agreements in distributing the rights of foreground, and access to background, when doing research collaboratively). Once ownership is determined the authors believe that there should be statements in the CFA stating who should be able to use the content on the platform. To restrict usage as much as possible until there is no usage of results on the platform could occur regulated among the parties of the platform. Opening up the usage a bit more one could in the CFA state that other actors on the platform have the right to negotiate a right to use the platform content, however on which terms could also be negotiated talking about the level of cost which could either be constructed through negotiations on commercial terms which are fixed or non fixed, FRAND terms, sponsored by the public or the platform or free, meaning no cost for the participant. The costs in relation to a negotiated usage or access licenses could be stated as complementary to these structures in the CFA. These cost structures could, based on the analysis, be implemented for different members and different parameters of the platform. Costs for usage of the results plays a large role in the incentives for a stakeholder to join the platform and also influences the public responsibility being either accessible to many parties

through a low cost structure which is negotiated on equal terms by industry. The right to negotiate a license could therefore be more or less beneficial depending on the cost structures set by the platform.

There could, as shown by the analysis, be other restrictions imposed by the platform for usage of the content, one such structure is the grant back which imposes that one could use the content (with or without cost) but is forced through contractual mechanisms, constructed by the platform for keeping the content on the platform open, to grant licenses to improvements or alterations of the content licensed from the platform back to the platform on certain conditions. These conditions could be determined by the platform and stated in the CFA. Other regulations that the authors acknowledge as relevant in relation to this are also what an improvement or alteration should mean and on what terms the grant back should be done. If the platform should take on the most public responsibility the usage of content could be free to use for everyone, meaning that there are no restrictions when it comes to the usage of results made available through the platform.

When handling the usage there is a distinction between the usage in R&D and innovation which is made by the tool. This distinction is, based on the interpretation of the authors when utilizing the tool, made to keep incentives for private and public actors in supporting the public interest making content available to use in R&D but to keep the rights of the usage in innovation used in the commercial setting. In this way it is believed by the authors that the private actors can contribute to the public domain without losing their competitive advantage.

When having decided what type of usage rights that the platform should facilitate for participants and third parties the management of how to solve such usage needs to be addressed. Through licensing structures the owners of the content (either the platform or separate actors) could, through the CFA, be obliged to provide licenses under certain conditions stated in the CFA in combination with choosing the level of usage rights for other participants. The authors could therefore conclude that a proper management will be constructed through the contractual structures available having conditions be put on the participants to allocate proper usage.

7.4.4 Governing the Platform

Other structures that are acknowledged through the analysis as being considered by stakeholders when joining the platform is how the platform is governed i.e. what will that particular actor have a say in. This is also important when setting up the platform because the platform governance forms the structure of the platform and makes up the platform body. The authors have found through the analysis that there are primarily three ways of constructing the governance over the platform, the first is through a network driven structure which encompasses two structures of steering the platform. The second structures are the organizational structure which has the informal and the formal organization as steering mechanisms, and finally there is the public character organization.

The network driven structure which has an ad-hoc approach to governance is interpreted by the authors as encompassing that the platform is governed through agreements constituted among the stakeholders whenever a platform project is conducted. The agreements include the structure

of the parameters of the platform from a case to case basis. The network of actors will determine the conditions for collaboration in an ad-hoc governed platform, which is also the case of the next model being that the platform is driven by network control through an overall contract which is implemented among the contract between actors. This governing structure means that a constituting CFA which is implemented in the collaboration agreements between stakeholders is the determining factor if the project is in the platform structure. The platform is therefore governed by the contract and the terms stipulated in the CFA.

The next approach that the authors found is the organizational structure, often recognized by a body that is determinant in the platform structure. Either recognized by the stakeholders on the platform as the governing body, constituted through the CFA, or being a recognized legal structure forming the body of the platform through the CFA or being the founder of the platform. In these structures the authors can conclude that the actual governance over the governing body becomes crucial in having a say in the platform activities, meaning that board seats and shareholders agreements should be considered.

The last governing structure that is found as an approach which could be constituted is the public character organization which is an organization that is supported by the public and acknowledged in legislation or public policy agreements. The analysis implies that the public often wants a role as a governing body or at least a governing board where more stakeholders are included. The public stakeholder often has an agenda to follow meaning that the governing structures are set by the public stakeholder, often controlling the platform formally and in a bureaucratic way, which the authors have been able to see through their analysis of the platforms present in the life science industry.

The governing structure of the platform is constructed through the contract solution, constituting the fundament of the platform. This tool is also found as being supported by legal self- regulatory tools in building the body of the platform especially targeting the rules of the legal entity. The authors could therefore conclude that there are regulatory and contractual solutions that are found as being fundamental in constructing the platform, which as a result will provide the toolbox with the necessary elements in order to be utilized as a complement in designing open innovation platforms in the life science industry.

7.6 Further Research

This thesis has, as per mentioned in section 7.1, accomplished the primary goal of answering the research questions through demonstrating that openness on open innovation platforms can exist in various different forms and it offers a variety of new opportunities. To extend value creation however relationships should be governed properly. The thesis has furthermore given a framework of the legal constructional tools necessary to consider in order to create a certain level of openness on the open innovation platform, and this has emanated into a proposed conceptual toolbox for how open innovation platforms could be structurally built through using these tools.

However, these accomplishments are not to be considered as fully complete according to the authors, since delimitations had to be made at an initial stage which was seen as outside the scope of the thesis. The authors would therefore like to propose recommendations on further research

which could serve to complete the structure and let the recognition and practical implementation of the toolbox be at the forefront.

The identified platform construction tools from the analysis made of the different categories of open innovation platforms, as classified by the authors, provided a large number of useful tools that when analyzed served as a foundation for the conceptual toolbox. However, the authors suggest that the toolbox may not be complete at this stage, and further analysis of even more initiatives could enrich the toolbox and make it a bit more comprehensive.

Moreover, the aspects of further verifying the tool should also become a part of further research, since the authors have conducted their analysis based on the contractual tools and models of the platforms, and there could be more features that the platforms would like to add to get more of an inclusive view. Therefore, the authors suggest that further research should be conducted on a more practical level where the platforms should be approached to verify or deny their current position which has been decided by the tool and receive input so as to where they would actually like to be positioned. This could help in confirming the utility of the toolbox at the same time as the potential limitations of the toolbox could be addressed.

As a result of this, the authors additionally recommend that further research should be made on the theoretical framework and practical toolbox for open platform design as regards their practical implementation. Through applying the toolbox in a real-life setting and contexts, extensions and complementary aspects are most likely to be found. To practically apply the tool and use the theoretical framework as a foundation would add more depth to the analysis and identify which platform concepts and tools that are the most essential in a specific context, which ones that are most complex, the interrelatedness between the parameters, which ones which are the most time-consuming etc. The authors believe that these aspects are very valuable in making the tool practical and operational.

The authors would furthermore like to emphasize that the evaluation and design tool which has been used as the tool for building and finding contractual and regulatory structures have been proposed by Professor Ulf Petrusson and is not claiming to be the only tool available in evaluating and analyzing open innovation platforms. The authors therefore suggest that further research could be made regarding other proposed tools for conducting an analysis on open innovation platforms, since the authors believe that there may be other initiatives or suggested models for the purpose of uncovering the underlying structures of open innovation platform. To investigate this possibility would add another dimension to the research conducted so far, since a comparative study between the different models would serve as a complement to the study made as well as put the tool in its preferable context and furthermore verify whether the toolbox is optimal for its purpose.

The authors would like to wish eventual researchers good luck and an interesting time furthering researching this subject. The authors have had a great time and learned a lot through writing this thesis.

8 References

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Below the information and references used for the analysis of the platforms will be stated.

8.6.1 African Network for Drugs and Diagnostics Innovation (ANDI)

The ANDI network is initiated by the African Union and is a result by a number of calls by among others the World Health Organization. ANDI is set up to promote and sustain an African-led R&D innovation through the discovery, development and delivery of affordable new tools for the treatment of diseases in Africa. ANDI maps out the capabilities of Africa to through the platform come together to create the tools needed to solve the burdensome diseases of the African people.

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8.6.2 BioBrick Foundation

The BioBrick Foundation is a not-for-profit organization founded by engineers and scientists from MIT, Harvard, and UCSF. The organization encourages the development and responsible use of technologies based on BioBrick standard DNA parts that encode basic biological functions. The platforms is aiming to develop and implement legal strategies to ensure that BioBrick standard biological parts remain freely available to the public at the same time as they provide scientific materials to allow the public to use and improve existing BioBrick standard biological parts, and contribute new BioBrick standard biological parts.

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The Division of Signal Transduction Therapy (DSTT) is a unique collaboration between scientists in the MRC Protein Phosphorylation Unit and the College of Life Sciences at the University of Dundee and five of the world's leading pharmaceutical companies, namely AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Merck-Serono and Pfizer, which is dedicated to accelerating the development of specific inhibitors of kinases and phosphatases for the treatment of disease, as well as for the study of cell signaling. The consortium is utilizing different IP licenses and facilitates the knowledge transfer to the pharmaceutical companies within the platform.

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Innovative Medicine Initiative (IMI), *Rules for submission evaluation and selection of Expressions of Interest and Full Project Proposals Stage 1*, 2009, [Online] Innovative Medicine Initiatives. Available at:
http://www.imi.europa.eu/docs/imi-gb-071v1-05112009-rules-for-submission-stage1_en.pdf
[Accessed 18th of April 2010]

8.6.8 International HapMap project

The goal of the International HapMap Project is to determine the common patterns of DNA sequence variation in the human genome and to make this information freely available in the public domain. An international consortium is developing a map of these patterns across the genome by determining the genotypes of one million or more sequence variants, their frequencies and the degree of association between them, in DNA samples from populations with ancestry from parts of Africa, Asia and Europe. The data is gathered in a Data Coordination Center and deposited in another database which is accessible to everyone that would like to see it.

HapMap Will Help Identify Genetic Contributions to Common Diseases [Online] Available at:
http://genome.gov/10005336
[Accessed 13th of April 2010]

International HapMap Project Article, Available at:
http://deepblue.lib.umich.edu/bitstream/2027.42/62838/1/nature02168.pdf [Accessed 13th of April 2010]

International HapMap Projects – Groups Participating in the International HapMap Project (Online), Available at: http://hapmap.ncbi.nlm.nih.gov/groups.html -
[Accessed 13th of April 2010]

International HapMap Projects – Initial Planning Groups (Online), Available at:
http://hapmap.ncbi.nlm.nih.gov/initial_planning.html -
[Accessed 13th of April 2010]

International HapMap Project – Access to Database
Available at: http://hapmap.ncbi.nlm.nih.gov/cgi-perl/registration
[Accessed 13th of April 2010]

8.6.9 Personal Genome Project (PGP)

The mission of the Personal Genome Project is to encourage the development of personal genomics technology and practices, and to be able to achieve this mission they have constructed a framework for prototyping and evaluating personal genomics technology and practices at increasing scales. The platform is promoting openness and collaboration from the very start to ensure that the different threads of personal genomics are all individually addressed and reinforce each other as they come together. At this point the platform welcomes any individual that would like to donate their personal genomic profile and they make the content freely available on their website.

Personal Genome Project Website, (Online) Available at: www.personalgenomes.org
[Accessed 13th of April 2010]

Science Commons Material Transfer Agreement [Online], Available at:
http://mta.sciencecommons.org/agreements/sc-ou/2.0/legalcode
[Accessed 14th of April 2010]

8.6.10 PIPRA

PIPRA is a non–profit initiative striving to make it easy for developing countries to access new technologies. This collaborative consortium, or collaborative IP management model, have as a goal to create a common database which displays patent information as well as license information which will be accessible and searchable for anyone. Through this the platform wants to decrease intellectual property barriers, improve commercialization strategies, and increase technology transfer. They would also like to help public institutions more broadly by supporting them in getting their technological innovations to those who need it most.

Boettiger, Sara, Bennett, Alan - *PIPRA – A Resource for Collaborative Intellectual Property Management in Agriculture,* Journal of Intellectual Property Rights, Vol 12. January 2007, pp. 86-91

Memorandum of Understanding, Public Intellectual Property Resource for Agriculture (PIPRA) (Online), Available at: http://www.pipra.org/documents/PIPRA%20MOU.pdf
[Accessed 11th of April 2010]

PIPRA Webpage about [Online] Available at: http://www.pipra.org/about/
[Accessed 12th of April 2010]

8.6.11 Structural Genomics Consortium

The SGC is a public-private partnership to promote the development of new medicines by carrying out basic science of relevance to drug discovery. The core mandate of the SGC is to determine three-dimensional structures of proteins of biomedical importance and proteins that represent potential drug targets. The mandate of the SGC prescribes that all protein structures be placed promptly in the public domain, and not even the project sponsors receive any prior rights or exclusive access to data and results. The consortium includes laboratories at three institutions—the University of Oxford (UK), the University of Toronto (Canada) and Karolinska Institutet (Stockholm, Sweden)—and three pharmaceutical companies—GlaxoSmithKline (Brentford, UK), Merck (Whitehouse Station, NJ, USA) and Novartis (Basel, Switzerland) which are supporting the project. The operations of the SGC are overseen by a Board of Directors and a Scientific Committee.

The Structural Genomics Consortium overview OCTOBER 2009 – an overview [Online] Available at: http://www.thesgc.org/about/SGC-overview.pdf
[Accessed 14th April 2010]

Structural Genomics Consortium – About [Online] Available at: http://www.thesgc.org/about/faqs.php#faq_1
[Accessed 15th of April 2010]

Appendix

Appendix 1: Explanation of the Tool

Level of Platform Governance Parameters

Level of System/Tool Leverage

Number	Name	Explanation	Example
1	Gathered Data / R&D Results etc	Results that represent valuable knowledge without structure.[164]	Results from laboratory testing-antibody responses profile to certain H. Pylori Antigens.
2	Packaged Content and/or Features	Content in the form of valuable knowledge with a structure based on: metadata, theoretical relations and connections, the solution to a problem, visual representation or instructions and codes.[165]	A Database including antibody responses to H. Pylori Antigens.
3	Systematized Toolbox	Valuable knowledge which can be leveraged upon through serving several purposes.	Biomarkers which are content as such but could be leveraged as a research tool or standardized contracts that are content between the parties but could also be leveraged through supplying to others.[166]
4	Operational System	A platform like structure where value is created through operability. An enabler or an assembling point system for different platform technologies connecting the use of gathered technologies.	A standard biological part that is providing the necessary means to make other parts work and make them work together - software like content.
5	A Multilayered System , where one layer generates a market like platform for the next layer	System that is constructed in two layers where the first layer is a value creator in itself constituting a source of information (and transactions) working as a driving force to the second value creating layer which is characterized as a market to complement (inclusion) the first layer.	A standardizing body where value lie in the information and decisions of that body but value is also created through the development processes including technology to the determined standard.[167]

[164] Lindgren, 19th Oct 2009
[165] Lindgren, 19th Oct 2009
[166] Mail correspondence with Ulf Petrusson 8th of April 2010
[167] Petrusson et al (2010) p.15

Level of Collaboration

Number	Name	Explanation	Example
1	Competitive Relationships where each actor Develop their own Contribution and Compete in having it Included in the Platform	*N/A*	A standardization platform where a standard is set through competition among the participants technology.
2	Competitive Relationships where Collaboration exist in pre-competitive areas	*N/A*	An area where actors that normally compete are doing development together due to the early stage of the research and taking profits only from a product level of the value chain.
3	Collaborative Relationships Controlled by one or a few Actors (cluster logic)	*N/A*	A development effort where one actor takes on the responsibility of distributing the results to the other actors
4	Collaborative relationships with more or less equal parties	*N/A*	Collaborations with stakeholders that when acting on the platforms are treated as equals.
5	A multi-stakeholder collaboration/community	A collaboration where government parties join the private sector and civil society to attain a shared goal, and to expand the reach, improve the quality, increase supply, and/or improve accessibility of services to identified communities. [168]	A public-private partnership where multiple stakeholders come together from the industry and academia to enhance productivity within drug development, creating new enabling technologies which could be leveraged upon in a new market, e.g. research resulting in a diagnostic tool which would be used in a different setting.

[168] Swarts p. 2

Level of Public Responsibility

Number	Name	Explanation	Example
1	Only of Private Interest	A platform where private interests is the priority	A platform constructed by private actors, or by the public where the goal of the platform is to benefit the commercial actors
2	Primarily of Private Interest, but there is a Public Interest that Competition is not Restricted	A platform where private interests is the priority, however taken into consideration is the competitiveness of the market.	A platform consisting of private actors but that are complying with the implicit and explicit laws relating to the notion of a free market, not letting their transactions become anti-competitive.
3	A Platform where Interests of the Open Society is Included	A solution similar to the library where information can be gathered but the public interest could be more limited.[169]	A platform where stakeholders are conforming to letting the information flow be open for society, but could also be limited to a specific area or the like, materialized through agreements on the platform.
4	A Constructed Public Domain	A construction where the information/research results are similar to a society where there are public records for people to get access to when needed.	A platform which is open for society where everyone has the right to access content.[170]
5	Public Infrastructure	A platform constructed by the public which also shoulders the responsibilities against the public domain.	A platform where it has gotten directives from the EU to comply with initiated and governed by public actors that are accountable for making sure that the public gain access to the information.

[169] Mail correspondence with Ulf Petrusson 8th of April 2010
[170] Mail correspondence with Ulf Petrusson 8th of April 2010

Level of Platform Governance

Number	Name	Explanation	Example
1	Project Oriented and Controlled Ad Hoc in Project Contracts	A platform governed, from time to time, with contracts between the project actors	The platform is divided into different projects where there are project agreements governing the separate projects that are initiated by the platform.
2	Driven by Network Control According to a Contractual Model Implemented in a Web of Contracts	A platform governed by a group of actors controlling the platform through a model contract which is then implemented in separate contracts	The model for how to govern the platform is implemented in the contracts between the actors so that they all agree on the same governance structure and the agreements between actors in the network are structured according to a contractual model.
3	Controlled by a Jointly created and relatively Informal Organization	The platform is governed by an organization constituted and controlled by the actors of the platform.	A platform where the stakeholders have come together and agreed on a structure but that has not necessarily been materialized in agreements or the like.
4	Controlled by a formally Strong and Hierarchical Organization, which Presents Policies and Enters into Contracts with Stakeholders	An organization which governs the platform with hierarchical and formal structures. This organization also is the platform in that it enters into contracts on behalf of the platform.	When a platform has created a company structure which enters into agreements on behalf of the platform.
5	A Formally Strong Structure supported by the Public and Acknowledged in Public Policy/Regulation	A platform that is instituted by the public or standardization organizations that is based on a public initiative basing in regulation or policy decisions by the public.	When the EU institutes a platform through their policy decisions which are recognized by the Council.

Level of IPR Claims

Number	Name	Explanation	Example
1	Not Patented or Protected by other IPRs	*N/A*	Research results that are in a too premature state to patent.
2	Rarely Patented or Protected by other IPRs	*N/A*	A database where separate results are not protected, but the platform as such is protected.
3	Protected to a large extent	Any IPR protection could cover the objects of the platform, and most of the content on the platform is covered.	A patent pool where knowledge is included where the main results are protected but not the following knowledge.
4	Patented in a Systematized way	The platform has a patent policy determining how things are patented on the platform or there is a logic behind the patenting.	A platform that has created an IP policy which is followed by all actors which states what and when something is to be patented to create patent strategies for further protection of the content.
5	Has to be patentable or patented if to be included	*N/A*	A standardization platform where the chosen standard must be patented so that access for everyone can be guaranteed

Level of Platform Openness Parameters

Level of Access to the Platform

Number	Name	Explanation	Example
1	Restricted to the Developers	The content/data on the platform can only be accessed by the ones developing the content, i.e. closed to outside parties.	When a platform is based on projects and the access is restricted to the participants in the project developing the content.
2	Restricted to a Group, Cluster etc.	The content on the platform can only be accessed by a specific group or cluster that is created by the platform. The criteria for being a part of the platform are fairly closed.	A platform in this category could be set up between a university and companies, where access is restricted to the research group and the companies that request the services of the group.
3	Restricted to a Closed Community	The content on the platform is restricted to a larger set of people defined by clear borders of access, limiting links to other communities which are set up outside of the platform. Only a few can fulfill the criteria of becoming a part of the platform.	A platform which could have a certain membership structure, where to be able to access the platform one must fulfill the criteria for becoming a member. This will provide access to the platform. There are limitations to who can become a member; certain demands need to be met e.g. to become a member you have to include certain content.
4	Restricted to an Open Community	The content on the platform is restricted to a large set of people but maintains strong relations with outside communities and let them have access to the content. The criteria for gaining access are loose.	Platforms which could have a certain membership structure, but on terms that are more easily accessible, but the requirements could be specific. The access is restricted due to the fact that almost anyone can become a member, only if they sign the terms and conditions of the platform.
5	Open to Everyone	The content is open for everyone, so that everyone can access the information provided for on the platform.	Here a platform does not pose any restrictions on who can have access to the content. Anyone is free to access. The platform usually publishes their results and content immediately when the results have been generated, to ensure public access and benefit.

Level of Openness to Include Content etc in the Platform

Number	Name	Explanation	Example
1	Restricted to a Development Group	The content/data on the platform can only be included by developers, i.e. closed to outside parties.	A platform which allows only the constructed (through agreements on the platform) development group to include content on the platform.
2	Restricted to a Group, Cluster etc.	The content on the platform can only be included by a specific group or cluster that is created by the platform. The criteria for being a part of the platform are fairly closed.	A platform that restricts inclusion of content could be created through a group of participants that through contractual arrangements limit the possibility to include content to only a determined cluster to the platform to prevent outside obstruction.
3	Restricted to a Closed Community	The openness to include content on the platform is restricted to a larger set of people defined by clear borders of inclusion, limiting links to other communities which are set up outside of the platform. Only a few can fulfill the criteria of becoming a part of the platform.	Here a platform could be built upon a membership structure where you have to become a member to be able to include content on to the platform. There is thus the hurdle of actually becoming a member in order to include, which makes it restricted but more open since a larger group of people can participate.
4	Restricted to an Open Community	The openness to include content on the platform is restricted to a large set of people but maintains strong relations with outside communities and let them include content. The criteria for including content are loose.	Here a platform could have a certain membership structure, but on terms that are more easily accessible, but the requirements could be specific. The inclusion is restricted due to the fact that anyone can become a member, only if they sign the terms and conditions of the platform.
5	Open to Everyone	The inclusion of content is open for everyone to contribute with.	Here a platform does not pose any restrictions on who can include content in the platform. Anyone is free to include, and the platforms usually supports open collaborative sharing.

Level of Open Usage in R&D

Number	Name	Explanation	Example
1	No right to use the Content in R&D	The participants on the platform are not permitted to use the content in the platform in R&D; they have no right to exploit the results in their own research.	An agreement among the actors on the platform could stipulate that the content should be held strictly for platform purposes and not be included in the actors own pipeline of ideas and research.
2	An Opportunity to Negotiate the Right to Use	The participants on the platform are given a right to negotiate a right to use the content in R&D.	Here, the agreement gives the participants and opportunity to negotiate the right to use the content, which opens up the process but still does not leave any guarantees, depending on the strength of the actors' ability to negotiate is.
3	A Right to Use the Content under Restrictions	There could be a right to use the content explicitly stated, but with limitations which could be of different nature e.g. royalty or narrow field of use etc.	Here an agreement could provide the actors with the right to use the content; a license agreement where one actor's background could be available for usage but only if the other actors agree on licensing their background as well.
4	A Right to Use the Content with a Grant Back	There is a right to use the content on the platform, but there is a requirement that one have to give the participants on the platform the right to the further development one have done on the content.	Here an open source model could be implemented, where the purpose is that everyone should be able to have a right to use the content; an open general license is used and the developers of the content on the platform have to "give back" improvements made to the platform for access to the general public.
5	Fully Open Usage in R&D	Here there are no restrictions as to whether a participant can use the content in R&D.	Here there are no contractual limitations as to how the content could be used in R&D; on the contrary, the field of use is not restricted in terms of R&D and the purpose with the platform is to have everyone use the content in R&D to spur research. However, one have to regulate what R&D means.

Level of Open Usage in Innovation

Number	Name	Explanation	Example
1	No Right to Use the Content in Innovation	The participants on the platform are not permitted to use the content in the platform in commercialization; they have no right to exploit the results in their commercialization path.	An agreement among the actors on the platform could stipulate that the content should be held strictly for platform purposes and not be included in the actors own pipeline of commercialization.
2	An Opportunity to Negotiate the Right to Use	The participants on the platform are given a right to negotiate a right to use the content in innovation.	Here, the agreement gives the participants and opportunity to negotiate the right to use the content, which opens up the process but still does not leave any guarantees, depending on the strength of the actors' ability to negotiate is.
3	A Right to Use the Content under Restrictions	There could be a right to use the content explicitly stated, but with limitations which could be of different nature e.g. royalty or narrower field of use or payment structures for the products.	Here an agreement could provide the actors with the right to use the content; a license agreement where there is a right to use the content in innovation, but merely for certain products within certain areas.
4	A Right to Use the Content with a Grant Back	There is a right to use the content on the platform, but there is a requirement that you have to give the participants on the platform the right to the further development you have done on the content	Here an open source model could be implemented, where the purpose is that everyone should be able to have a right to use the content; an open general license is used and the developers of the content on the platform have to "give back" improvements made to the platform for access to the general public.
5	Fully Open Usage in Innovation	Here there are no restrictions as to whether a participant can use the content in innovation.	Here there are no contractual limitations as to how the content could be used; on the contrary, the field of use is not restricted in terms of innovation and the purpose with the platform is to have everyone use the content and bring it through commercialization.

Level of Costs

Number	Name	Explanation	Example
1	Commercially Negotiated	The terms of payment are to be negotiated on a case-by-case basis in a commercial setting.	When two parties to an agreement or to a platform come together to negotiate the price to be put on the content or research results.
2	Fixed Commercial Terms	Pre-determined, fixed cost rates that are not subsidized.	Here, the costs are referred to a fixed rate which has been negotiated in a larger setting such as terms used in international commercial transactions and could be utilized by the platform as a standard.
3	Fair and Reasonable Terms	Terms that is not anticompetitive and includes reasonable licensing rates.	The terms could be used in a licensing setting to enhance the pro-competitive character of a platform. As regards cost, the term reasonable could be understood as when a rate is charged on a license which would not result in an unreasonable aggregate rate if all licensees charged a similar rate.
4	Publically or Otherwise Sponsored	The costs are under a sponsorship or otherwise served and supported through public means.	Here the costs are covered by a public body or through sponsorships. The platform could also be sponsored by the private parties, i.e. companies, which are a part of the platform itself.
5	Free Access and Usage	Here there are no costs for access and usage, meaning that no financial means will be charged for access or usage of platform content.	Here the situation of a Creative Commons structure could be discussed, where the access and use of the content is completely without any cost and is thus open in terms of payment.

Appendix 2: Checklist for the Constructional Toolbox – Layer Specific

General Platform Governance Parameters

Level of System/Tool Leverage	
1. Gathered Data/ R&D Results	• Institute a bilateral agreement of CFA on the platform to regulate the content. • Publishing policy framework to ensure that valuable research results are being handled appropriately so that there will not be a dissemination of information and that the gathered data or R&D results can be leveraged upon at a later stage. • Confidentiality and discretion needs to be implemented and understood in the research sphere, and the implementation of a mentality in which to consider different options when deciding on making content publically available. • A clear purpose with the platform will determine the object that the platform will facilitate and in turn set the stage for how the object should be handled and where it belongs on the platform. • Regulate the ownership through foreground regulations to know who will control the results
2. Packaged Content and/or Features	• Package the content through appropriate IPR legislation which are adjusted to the characteristics of the content and serve as intellectual concepts that could be utilized on the platform to protect the content and its features, or package content through recognition. • Utilize the medium of different licensing mechanisms as a way of governing the packaged content to be transacted upon; the licensing structure should then address the different levels that are available when it comes to how the content and features should be distributed, accessed and used. • The object should be clearly defined, and the IP which could be derived from the object should have a clear ownership structure • Policy with terms and condition where one agrees to certain conditions in order to be able to use the object in question/the results within the platform

3. Systematized Toolbox	• The presence of IPR protection and IP law as tools in constructing this layer is important since they will ultimately determine what rights there are existent on the platform and this will then serve as the foundation for any mechanisms that are to be implemented by the platform and also help in determination of ownership.
	• Use a different business models through both services or physical products to leverage on the value of the research result.
	• There needs to be a division into two different types of protection when discussing a systematized toolbox; protecting the toolbox from being used and protecting it from being patented.
	  o When protecting the toolbox from being used, one has to use the concept of IPR protection to restrict access and consequently usage of the toolbox
	  o When protecting the toolbox from being patented, one has to use the concept of patents as a means to protect information from being patented – however, this does only

	translate to what is being made public

4. Operational System	• The basic technology should be protected through regulating how the restriction on improvement should be handled, or how the access and inclusion of content onto the platform should be handled.
	  o Use the IPR as a means to regulate the protection of the technology
	  o Use a contractual model that imposes conditions to be met to be able to access and improve on the technology
	• Regulate ownership to the enabling technology.
	• Remember the implications of competition law when close collaboration between stakeholders

5. Multilayered System	• A multilayered system consists of a core system that should be protected to some extent to enable the possible restrictions on access to the system and for an actor to further build on the system. • Contractual models and IPRs should be utilized to come to terms with how to leverage on the system. • Regulate ownership of the rights to use content/the ownership of the content and the right to include content onto the second layer. • Access and inclusion of content is important for the second layer construct to give as much value as possible.
Level of Collaboration	

1. Competitive Relationships where each Actor Develop their own Contribution and Compete in having it Included in the Platform	• This layer is characterized by standardization bodies where actors come together and regulate and agree together on what standard that should be prevalent in an industry.
	• To protect the collaborations, agreements are needed that are stating that
	  o Everyone accepts the standard that is chosen by the organization,
	  o Everyone is welcome to supply technologies that they would like as standards.
	• Regulations regarding sharing of technology standards on open and fair terms (determine cost conditions) are also important so that the industry does not get locked into a standard that is not open for everyone.
	• The competitive relationship is on the level of being able to include and contribute to the platform, which separates it from the regulation of how to access the content once it is on the platform. This is the next stage, regulating the access to ensure that it is open for everyone.
	• Respect competition law regulations

2. Competitive Relationships where Collaboration exist in Pre-Competitive Areas	• Categorize the utilization of the content on the platform to steer it to pre-competitive areas of research or development.
	• Incentive structure that ensures that industry collaborates
	  o Ownership regulations that are kept closed to the collaborators to enable them to pursue their interests.
	  o Requirements on whether to patent and protect or publish, since the results could be early-stage and should therefore be considered as important to regulate since patenting could block the continued research by others.
	• Respect competition law regulations

3. Collaborative Relationships Controlled by One or Few Actors	• Control could be handled through a CFA that
	  o divides the ownership of results.
	• CFA statements that divides the responsibilities on the platform
	  o Who should be able to enter contracts with outside parties etc.
	  o Who is the spokesman of the platform?
	  o Who will be conducting negotiations with outside parties?
	• Depends on the level of control the platform participants want to have
	  o Control when including content
	  o Control how someone can access
	  o Control how someone can use the content
	  o Control who owns the content

4. Collaborative Relationships with More or Less Equal Parties	• This layer is dependent on the access, usage and ownership rights of the platform that will determine whether they are deemed as equal in terms of the access, usage and ownership of the platform content. • Determine what actors should be able to regulate the inclusion of content, control over access and usage rights. • Collaborators that are more or less equal o Depends on the restrictions set forth regarding access to and usage of the content • Consider the research phase.

5. A Multi-Stakeholder Collaboration/Community	• Regulatory issues are not prevalent when building a multi-stakeholder community in the first instance of constructing the platform
	  o The purpose of the platform is negotiated
	  o The public is involved and inclusion of many different stakeholders are prevailant.

Level of Public Responsibility	

	• Take into consideration which stakeholders the platform should host and incentivize.
	• Regulate the Public Responsibility through regulations of access, usage and cost. Where Public Responsibility is equal to dissemination of information.
	• In Private interest
	  o Ownership and usage should be restricted
	• Primarily of private interest, but there is a public interest that competition is not restricted
	  o Regulate access, usage and ownership that is tailored to not restrict competition in the area of operations
	• A platform where interests of the open society is included
	  o Could be restricted to the members of the platform as long as public interest is included
	• A constructed public domain
	  o Results to be shared with the public
	  o Access to the platform and usage of the content must be kept high
	• Public infrastructure
	  o The public actor will be a part of the constituting

	agreement which structures the platform
Level of Platform Governance	

1. Project Oriented Controlled Ad-Hoc in Project Contracts	• Regulation of platform governance is made through separate agreements among the participants in the separate project
	  ○ Project plan
	  ○ Project agreement which divides responsibilities and sets up the structure of the platform

2. Driven by Network Control According to a Contractual Model Implemented in a Web of Contracts	• Contractual model that will be used by the constituting network
	• Regulate how the platform should operate
	  ○ Which projects should be initiated and accepted on to the platform
	  ○ What information should be made publicly available
	  ○ Distribution of research results
	• Constituting agreement that creates a board structure
	  ○ Hierarchical system where an overarching contract will be implemented in each of the separate contracts.
	• Separate agreements among the project participants
	  ○ Regulate the influence on research targets, ownership and collaboration conditions.
	• Funding of the platform projects.

3. Controlled by a Jointly Created and Relatively Informal Organization	• Agreement where rights are surrendered in favor of the continuation of the platform research and governance through creating a joint, board or consortia like structure which has the governance over the platform. • Agreement with a formal acceptance of a governing board or the like that will supervise the platform

4. Controlled by a Formally Strong and Hierarchical Organization, which Presents Policies and Enters into Contracts with Stakeholders	• Legally recognized entity which could include stakeholders on different levels
	• Non-governmental organization
	  ○ Choose their own board structure
	  ○ Agreement where the board have the mandate to enter into agreements
	• Limited Liability Company
	  ○ Shareholders agreement
	  ▪ Stipulate the participants of the board
	• Foundation
	  ○ Choose their own board structure
	  ○ Agreement where the board have the mandate to enter into agreements

5. A Formally strong Structure supported by the Public and Acknowledged in Public Policy/Regulation	• A structure where the public is involved in the creation of the platform and has certain conditions of governing the platform
	• A structure where a board is created to govern the platform or other structures that stakeholders surrender their sovereignty to.
	  ○ Stakeholders are a part of constituting the board
	  ○ The platform is constituted due to a policy decision
	  ○ Platform stakeholders should agree on the terms of the platform

Level of IPR claims	
1. Not Patented or Protected by other IPRs	• The content on the platform need to be regulated through agreements not associated with IPRs and IPR regulation.

	• The content could however turn into IPRs ○ Policy on how to value research result or whether to patent or publish • Protect the results through secrecy or confidentiality
2. Rarely Patented or Protected by other IPRs	• Patent strategy that determines what and when something should be patented
3. Protected to a Large Extent	• Patent strategy that facilitates the determination of what and when something should be patented
4. Patented in a Systematized Way	• Clear ownership division, which will make it easier to govern the rights to the content on the platform • Patent strategy that determines what and when something should be patented
5. Has to be Patentable or Patented if to be Included	• Already clear set patent policy and agreements regarding ownership, already handled in an earlier stage prior to entering the platform.

General Openness Parameters

Level of Access to the Platform	
1. Access is Restricted to Developers	• IP Policy framework agreement or other CFA structure restricting access to content as wanted, recognized by all actors of the platform also constituting policies or rules to restrict the actors in actions and relations outside the platform e.g. confidentiality • Through usage of the IPR regulatory system, the protection and exclusive rights / Ownership and rights based on platform agreement for non IPR assets/ are used as control mechanisms to steer access to content • Licensing structures makes sure that the right actors gains access to the content • Licenses must be on an non-exclusive basis if more parties are involved
2. Access is Restricted to a Group/ Cluster	• IP Policy framework agreement or other overarching structure restricting access to content as wanted, recognized by all actors of the platform also constituting policies or rules to restrict the actors in actions and relations outside the platform e.g. confidentiality • Through usage of the IPR regulatory system, the protection and exclusive rights / Ownership and rights based on platform agreement for non IPR assets/ are used as control mechanisms to steer access to content • Licensing structures makes sure that the right actors gains access to the content • Licenses must be on an non-exclusive basis if more parties are involved
3. Access is Restricted to a Closed Community	• A policy agreement constituting the platform must set the structures for what the closed community is, what restrictions the party wanting to access the platform must fulfill • Through a membership and review structure one could control the closed community constituted by an agreement on the platform • Content on the platform is controlled through usage of the IPR regulatory system, the protection and exclusive rights / Ownership and rights based on platform agreement for non IPR assets/ are used as control mechanisms to steer access to content
4. Access is Restricted to an Open Community	• A policy agreement constituting the platform must set the structures for the open community, meaning what is necessary to be part of the community and on what conditions. • Through a membership structure one could control the open community knowing what actors is part and has agreed to terms of membership and therefore getting

	access to the content. • IPR regulatory system /ownership and rights based on platform agreements for non IPR assets are used as control mechanisms steer access to the content
5. Access is Open for Everyone	• Policy stating that content will be accessible to everyone. • Publication is used as the control mechanism for continuous openness of results or database protection • Two licensing structures to control next steps of content development – GPL, meaning in the future and free content to build on proprietary. o GPL – ensure agreement with all users to continue to grant back all improvements and modifications to be free under same conditions as content o Ensure freedom for content through agreement not to patent parts of the content made available under the license
Level of Openness to include Content on the Platform	
1. Openness to Include Content is Restricted to the Development Group	• A policy agreement constituting the platform must set the structures for only allowing certain parties as granted to include content on the platform. • Membership structure with agreement to fulfill certain criterion which is through a review board constituted through CFA. • In a CFA or within a review board the type of content to include must be specified. • The mechanisms to include content such as publishing or putting on a platform. • The distribution of IP rights on content when included in the platform in CFA also defining the boundaries of the development group.
2. Openness to Include Content is Restricted to a Cluster	• A policy agreement constituting the platform must set the structures for only allowing certain parties as granted to include content on the platform. • Definition in CFA of the cluster or the cluster logic, which actors that could be included. • In a constituting agreement or within a review board the type of content to include must be specified. • The mechanisms to include content such as publishing or putting on a platform. • The distribution of IP rights on content when included in the platform in constituting agreements also defining the boundaries of the cluster.
3. Openness to Include Content is Restricted to a Closed Community	• A policy agreement constituting the platform must set the structures for only allowing certain parties as granted to include content on the platform. • Definition in CFA of the community or creating the community and define relations to other communities. • Membership structures with review boards could regulate the parties allowed to include content on the platform • In a CFA or within a review board the type of content to include must be specified. • The mechanisms to include content such as publishing or putting on a platform. • The distribution of IP rights on content when included in the platform in constituting agreements also defining the boundaries of the community.
4. Openness to Include is Restricted to an Open Community	• A policy agreement constituting the platform must set the structures for only allowing certain parties as granted to include content on the platform. • Definition in CFA of the community or creating the community and define relations to other communities. • Membership structures being in place to have enforcement possibilitie. • In a constituting agreement or within a review board the type of content to include must be specified. • The mechanisms to include content such as publishing or putting on a platform. • The distribution of IP rights on content when included in the platform in

	constituting agreements also defining the boundaries of the community.

5. Open for Everyone	• A policy agreement constituting the platform must set the structures for allowing all parties to contribute to the platform
	• Keeping the platform open
	  o Regulations on all members not to restrict openness
	  o Grant-Back Licenses for improvements (restricting openness?)
	• Mechanisms to include content in a structured way so that ownership rights are possible to secure
	• The distribution of IP rights on content when included in the platform in constituting agreements

Level of Open Usage in R&D and Innovation	

1. No Right to Use the Content in R&D/ Innovation	• Determining in the policy that no right to use the content is established
	  o Ad-hoc in projects
	  o CFA
	• Claiming IPR through legal system or protect content through the constitutional agreement and gain control over content through self-regulatory tools
	• Determining ownership over the content in the platform
	  o Background
	  o Foreground
	  o Sideground

2. An Opportunity to Negotiate the Right to Use	• Determining in the policy for a first right to negotiate a license is established (certain conditions on members etc. for a right to negotiate a license?)
	  o Ad-hoc in projects
	  o Through CFA
	• Claiming IPR through legal system or protect content through the constitutional agreement and gain control over content through self-regulatory tools
	• Determining ownership over the content in the platform
	  o Background
	  o Foreground
	  o Sideground

3. A Right to Use the Content under Restrictions	• Determining in the policy under which restrictions of the right to use content should be available, established
	  o Ad-hoc in projects, or
	  o Through CFA
	• Claiming IPR through legal system or protect content through the constitutional agreement and gain control over content through self-regulatory tools
	• Determining ownership over the content in the platform
	  o Background
	  o Foreground
	  o Sideground
	• Set up licensing structures for platform stakeholders with restrictions on usage regulated on a higher level than party to party if all licenses and usage should be the same over the platform e.g. IP policy

4. A Right to use the Content with a Grant Back	• Determining in the policy under which usage with a grant-back should be available, established
	  o Ad-hoc in projects, or
	  o Through an Overarching structural agreement
	• Claiming IPR through legal system or protect content through the constitutional agreement and gain control over content through self-regulatory tools
	• Determining ownership over the content in the platform
	  o Background

	○ Foreground ○ Sideground • Set up licensing structures for platform stakeholders with restrictions such as the grant-back regulated on a higher level than party to party if all licenses and access should be the same over the platform e.g. IP policy • Overarching agreement regulating what content has a grant back, when a grant-back becomes valid e.g. when improving or modifying, also specifying what the concept of modification is. – Enforcing for all actors on the platform to keep content open in the next step.
5. Fully Open Usage in R&D/ Innovation	• Determining in the policy under which usage open to everyone, established ○ Ad-hoc in projects, or ○ Through CFA • Claiming IPR through legal system or protect content through the constitutional agreement and gain control over content through self-regulatory tools • Determining ownership over the content in the platform ○ Background ○ Foreground ○ Sideground • Set up licensing structures for platform stakeholders regulated on a higher level than party to party if all licenses and usage should be the same over the platform e.g. IP policy
Level of Costs	
1. The Costs are Commercially Negotiated	• Constituting or overarching agreement deciding what should be paid for ○ The price ○ Terms of payment • Agreement on each actor is free to charge the price they want and is not restricted by the platform negotiating costs.
2. The Costs are on Fixed Commercial Terms	• Constituting or overarching agreement deciding what should be paid for ○ The price ○ Terms of payment • Agreement on the terms of payment or price which is fixed for all actors but is valued according to market terms – agreement stating how valuation should be done.
3. Fair and Reasonable Terms	• Constituting or CFA deciding what should be paid for ○ The price ○ FRAND terms • Enforcement clauses for not following the FRAND terms
4. Publically or otherwise sponsored	• Contributing or CFA deciding what should be sponsored and how the sponsorship should relate to the parties on the platform i.e. what is the money for. Regulating, ○ When should money be paid ○ What milestones should be reached ○ By whom and with whom is the agreement with ○ What is the gain for the funder • How should these money be distributed on the platform • Payback clauses when breach of contract
5. Free access and usage	• Constituting agreement making all actors agree to supply the content on the platform and that they include freely available to all parties of the platform and also to the public if agreed upon.