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Public Values and Modern Biotechnology in the Dutch Patent System

A multiple case-study of patents on Recombinant-DNA & PCR and CRISPR technologies in the field of green biotechnology.

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Master Thesis

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Abstract

In this study I explored the dynamics of modern biotechnology and the Dutch patent system. The study evaluates how the patent system in the future stimulates biotechnological innovations that are in line with public values. In the recent decades modern biotechnology provided enormous breakthroughs in molecular genetics, with technologies such as Recombinant-DNA, PCR and gene-editing techniques such as CRISPR technology. Modern biotechnology is transforming the green biotechnology industry with constant innovations that can generate public benefits in food security, human health, industry and sustainability and largely influencing the Dutch sector. The societal benefits are promising and therefore these technologies are incentivised by governments through the Intellectual Property system. The patent system is studied due to the increasing importance of patents for this industry. Patents are shaped by the motivation of contributions to the public good. However, previous research identified concerns that signified that these contributions to society were not met. Therefore, this study evaluated these concerns and whether the patent system contributes sufficiently to society, by utilising the public value failure theory of Bozeman (2002). Based on the PVM tool (Bozeman, 2007) and legislation of the patent system, four criteria operationalised the socially desirable functioning of the patent system. The criteria include the effectiveness, efficiency, reliability and inclusiveness of the patent system.

The qualitative abductive approach of this study consisted of two rounds of interviews and a document analysis, conducting a multiple-case study of Recombinant-DNA & PCR and CRISPR technologies. Findings indicate that the Dutch patent system for a large part stimulate biotechnological innovations that are in line with public values. However, current and future technologies in the breeding sector provide several challenges in ensuring wide access to patents on these innovations. In order to sustain innovation in the plant breeding sector, when gene-editing increasingly play a role, patents on plant innovations should maintained accessible to a large population of breeders to ensure biodiversity and inclusivity of the patent system. Recommendations of this study include active initiatives for large scale ethical debate, a search for more inclusive access to plant innovation patents including patent traits and methods to produce these, and lastly, spread of knowledge and awareness on the patent system.

Contents

List of abbreviations and acronyms

CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
DNA	Deoxyribonucleic acid
EC	European Commission
ESC	Economic and Social Committees (European Parliament)
EPC	European Patent Convention, 1977
EPO	European Patent Office
GDPR	Dutch General Data Protection Regulation
GMO	genetically modified organisms
ILP	International Licensing Program
IP	intellectual property
LTO	Land- en Tuinbouworganisatie Nederland (The Netherlands Agricultural and Horticultural Association)
NBT	New Breeding Technology
PBR	plant breeders' rights
PCR	polymerase chain reaction
PINTO	Patent Information and Transparency Online
PVM	Public Value Mapping
RVO	Rijksdienst voor Ondernemend Nederland (Netherlands Enterprise Agency)
TRIPs	Trade-Related Aspects of Intellectual Property Rights, 1994
UPOV	International Union for the Protection of New Varieties, 1961
USPTO	United States Patent and Trademark Office
VBN	Vereniging Bloemveilingen (Dutch Flower Auctions Association)

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1. Introduction

The field of modern biotechnology has known numerous scientific breakthroughs in molecular genetics. Technologies such as recombinant-DNA and gene-editing technologies, of which most importantly CRISPR/Cas (hereafter 'CRISPR'), emerged since the second half of the 20th century. Due to rapid innovation and lowering of costs of technology, it has become a growing and impactful industry for society (Singh et al., 2009; Capps et al., 2017). Nowadays, recombinant-DNA technology dominates biology, medical research and is foundational to genetic modification of agricultural plants (GMOs) such as insect-resistant corn or soy that is herbicide-tolerant (Berg and Singer, 1995; Takeda & Matsuoka, 2008). A more recent development is the emergence of CRISPR, which revolutionises this field of research with low costs and reduced research time because of the easy application and target specificity (Singh et al., 2016). The technology has the potential to enhance plant traits, increase yields, speed up the breeding process and many more (Chen et al., 2019).

Advancements in agri-food biotechnology, which is referred to as green biotechnology, can generate public benefits in food security, human health, industry and sustainability (Capps et al., 2017). The societal benefits of progress in biotechnology are promising. Therefore, the Dutch government aims to stimulate innovation and research in this field (EZ, 2008).

One tool to do so is via the intellectual property (IP) system, which consists of the total of international, especially European, and national treaties, regulations and legislation that determine the entire process of IP. The aim of an intellectual property system is to incentivise innovation by giving protection rights on intellectual work. IP can help to strike a balance between stimulating innovation in the interest of innovators and the wider public interest (WIPO, 2016). For green biotechnology, two main forms of IP are in place.

Most commonly, plant breeders' rights (PBR) protect new plant varieties as a result of conventional breeding processes, which are excluded from the patent system. PBRs enhance the development of new plant varieties without excluding others from evolving them to new varieties. PBRs are organised on the national level and through an intergovernmental sui generis system, the International Union for the Protection of New Varieties of Plants or UPOV since 1961 (Bakker & Minten, 2010).

The rise of innovative genetic engineering introduced patents to the breeder's sector as well. Inventions of genetic engineering meet the requirements for patents, which are the criteria of novelty, inventiveness, utility and sufficient description of the application (EZ, 2008). Patents provide a more exclusive protection than PBRs because others cannot develop the invention without permission of the holder. Since the late 1900s, patents are increasingly used for protecting gene-editing biotechnology, and the impact of patents is expanding with the increasing number of patents on products and processes of CRISPR technology (Strauss, 2009; Singh et al., 2009).

The Dutch patent system is shaped by the motivation of contributions to the public good (EZ, 2008; Karbowski & Prokop, 2013). These contributions to the public good are evaluated by comparing them to societal public values, which can tentatively be defined as the normative consensus on the rights, benefits and prerogatives entitled to citizens and how citizens and governments should behave (Bozeman, 2007). Two examples are economic growth and the development of (expensive) medicines and health cures. Public values research consists of a stream of scholars that seek to highlight and achieve public values as a critical agenda issue for politicians, citizens organisations and society by defining, identifying and classifying public values (e.g., Beck Jørgensen & Bozeman, 2007; Bozeman, 2002, 2007; Nabatchi, 2012). The public value failure theory of Bozeman (2002) helps recognise when values are not achieved and public value failure has occurred. That is defined as the societal consensus that a certain

value is not achieved. As a part of this theory, Public Value Mapping (PVM), a loose heuristic, helps discover if there is a desirable balance of the returns between private parties and society (Bozeman, 2007).

Traditionally, the patent system accommodates this balance by giving, on the one hand, a temporal monopoly for an inventor, and on the other hand, the patent must meet specific criteria. The patent system consists of several safeguards to preserve public values. First, it prohibits patents of any invention that are considered contrary to public policy or morality (Parthasarathy, 2017). Second, the opposition procedure, which is started by external parties, provides possibility to object a patent, within the nine months after it was awarded based on the standard criteria. The last alternative is to issue a compulsory licence, which means that in special circumstances, governments can force a patent holder to allow others to make and sell the invention. In practice, this measure is hardly used because the Dutch government fears impeding the investment climate in the Netherlands (EZ, 2005).

Despite these safeguards, the expansion of modern biotechnology has sparked a debate around ethical considerations and the functioning of economic and innovation components of the patent system. First, the ethical debate on patents on living organisms rises concerns that public values are insufficiently safeguarded in the patent system. Concerning that patents hamper access to natural resources and animal dignity is affected by the commodification of (parts of) genetically modified humans and animals (van Dam-Mieras, 2001).

Second, there is a debate on whether patents can stifle innovation. The concept of 'tragedy of the anti-commons', is presented in this debate and suggests that multiple patents obstruct deployment and may result in an underuse of resources (Heller & Eisenberg, 1998). The concern is that the number of patents will hinder basic research and diminish freedom to operate for commercial parties (Boldrin & Levine, 2013; Karbowski & Prokop, 2013).

Third, there is the concern, that patents are increasing the power of a few multinationals in the agriculture sector, and as a result biodiversity might be reduced. Feared is that small-size plant breeders will disappear with the rise genome-editing techniques, while currently they contribute to biodiversity by providing a diverse range of seeds, while using the protection of PBRs (Louweraars et al., 2009). A doom scenario would be that these multinationals create patent monopolies and reduce access to a diverse pool of seeds causing a reduction of biodiversity and environmental problems (Bakker & Minten, 2010; Louweraars et al., 2009).

The three concerns of the patent system are reinforced with the rise of new gene-editing technologies such as CRISPR and the question arises whether the current patent system is still future-proof from society's perspective, or whether adjustments are needed to allow the patent system to function in a socially responsible manner. In this study, socially responsible functioning of the patent system is operationalised by four criteria that summarise the public values underlying the Dutch patent system. These public values are collected from the scientific literature, treaty texts, reports and principles of good governance. The criteria implying a socially responsible patent system are, as follows:

1. The system is effective. The patent system protects inventions that are socially desirable to incentivise their development.
2. The system is efficient. This criterion has two aspects. Starting with that the system works efficiently when it incentivises investors with a reward for their invention, as a return on their investment, that is of substantial size to stimulate them to innovate, but that is not larger than necessary. Furthermore, this criterion requires that the system operates at minimal 'system costs'.

3. The system is reliable. The system applies the rules consistently and correctly, and it is clear based on which arguments patents are granted. Also, the patent system accommodates legal certainty: patent holders can be assured that their rights will be respected and protected under normal circumstances.
4. The system is inclusive. The patent system does not discriminate between inventors.

Following these criteria, the patent system would produce a balance of returns for private parties and society, which aligns with public values, for example, by facilitating the innovation for research or commercialisation of future technologies to a larger population and not limit it to a small number of multinationals (Heller & Eisenberg, 1998; Karbowski & Prokop, 2013; Boldrin & Levine, 2013). Especially with the emergence of CRISPR technology, the need for such a patent system is essential, whereas this technology has wide societal value and dissemination of the technology is essential (Feeney et al., 2018).

Current research describes the three concerns as depicted above separately and insufficiently shows how these concerns are interlinked with the complete set of public values that are guaranteed in the Dutch patent. For example, research on whether innovation is stimulated by patents often describes exclusively the economic consequences but lacks the focus on other returns to society including public values such as biodiversity (Chu et al., 2012; Merges, 2000). The public values failure theory approach used in this study provides an alternative to the influence of liberal economic thinking in general and market-failure criteria.

Next to that, research lacks on explaining what the effects and influences of the safeguards to protect public values in the patent system are in practice (Feeney et al., 2018; Boldrin & Levine, 2013; Parthasarathy, 2017). Also, research on this topic was popular in the decade after the Biotechnology Directive, but lacks the re-evaluation of these developments. Therefore, the study of the complete set of public values of the patent system for biotechnology inventions by public value mapping contributes to the evaluation of recent technological developments (Welch et al., 2015).

In addition, the public value mapping contributes to policy evaluation and helps provide policy recommendations on patents on future technologies in the biotechnology sector while developing public value theory in this biotechnology sector (Fukumoto & Bozeman, 2018; Welch et al., 2015). Public value theory is further developed by looking at public values in practice, instead of limiting to formal texts such as legislation.

Therefore, the research question is as follows:

How can the current Dutch patent system be tailored to stimulate future biotechnological innovations that are in line with public values?

To answer this main question, I have two sub-questions:

Sub-question 1: To what extent does the current Dutch patent system stimulate biotechnological innovations that are in line with public values?

Sub-question 2: What safeguards for public values implemented in the patent system stimulate biotechnological innovations that are in line with public values, and how is it ascertained that these are enforced?

Empirically, this research takes the form of an abductive qualitative case study of the current Dutch patent system around biotechnology and its underlying public values. The Netherlands is a country with a patent system that is mainly territorial but part of a complex international patent system and represents a typical case of other European countries. Especially in Europe, which consists of many smaller breeder companies, the importance of patents as IP is growing with the emergence of gene-editing technologies and a socially desirable patent system becomes essential. So, implications on the Dutch level could reveal suggestions for on the European scale, which is important for legislation of the European Patent Convention. Subsequent, in the Netherlands, the introduction of new technologies in modern biotechnology will largely influence the green biotechnology sector because of the smaller companies in this sector, whilst this is an economic and social valuable sector for the Netherlands (TNO, 2014).

Furthermore, this study focuses on one country to retrieve in-depth knowledge on the public values, which differ per region but Dutch public values regarding green biotechnology correspond with many European countries because of the similar situation with small-size breeders. That is why the Netherlands is chosen as the object of study.

I study the cases of recombinant-DNA, PCR and CRISPR technologies to zoom in on biotechnology in the Dutch national system. Both recombinant-DNA and CRISPR are foundational technologies with numerous patents. Access of third parties to these patents is essential to research innovation. Other 'New Breeding Technologies' (NBTs) are techniques such as TALENs (transcription activator-like effector nucleases) and ZFN (zinc finger nucleases), of which the range of application is more limited compared to CRISPR are not chosen as object of study because CRISPR plays a more impactful influence on the dynamics in the patent system (Zhang et al., 2020).

This research is executed by document analysis and conducting interviews with IP experts and stakeholders in the biotechnology sector. Finally, the contribution of this research is to understand what adjustments of the patent system help stimulate biotechnological innovations and, next to that, formulate recommendations with guidelines on how to organise biotechnology patents for a balanced system of returns in the Dutch patent system. Additionally, this study contributes to the development of public value theory in evaluating the development of technologies in the patent system and applying Public Value Mapping (Fukumoto & Bozeman, 2018).

The remainder of this research proposal is structured with Chapter 2 introducing and outlining the Theoretical Framework. Furthermore, Chapter 3 presents the Methodology, which clarifies the methodological decisions for this study and how recommendations on possible reconsiderations are developed. Chapter 4 delineates the results of the case study and evaluates public values of the Dutch patent system. Chapter 5 assesses the study with the discussion. And lastly, chapter 6 presents the final conclusions.

2. Theoretical Framework

This section presents the concepts necessary for the empirical part of this research. To perform the research, I define and discuss the key concepts. These concepts form the basic framework to interpret the empirical data. In the first section, I describe the Dutch patent system and specifically clarify the position of biotechnology patents. Secondly, I define public values and illustrate the public values behind the patent system. The last section delineates the concerns on the patent system regarding biotechnological innovations that were identified in previous, which this research will develop.

2.1 The patent system

The Dutch intellectual property system includes treaties, agreements and legislation on the national and international level regarding the processes of the registration, application and awarding of intellectual property. One form of intellectual property is patent protection. Inventors in the biotechnology sector increasingly search for patent protection for their expensive inventions, and therefore I focus on this form of IP protection in this study (Singh et al., 2009). Traditionally, in the Netherlands, patents are exclusively territorial rights, as described in the *Rijksoctrooiwet*, which was most recently revised in 1995. Nowadays, patent regulations are still organised at the national level, whereas since 1977 the European Patent Convention (EPC) influences national patent regulations, and inventors can apply for a patent in all the countries that signed the EPC at the same time (EC, 1973). The European Patent Office (EPO) is the primary organisation responsible for granting patents, which is provided with an autonomous legal system by the EPC.

Another international influence is the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) from the World Trade Organisation (WTO) in 1994 to harmonise patent regulations worldwide in order to stimulate international trade. The agreement is generally recognised as the robust embodiment of IP rights and criteria and resulted from the lobby of the biotech industry for the international enforcement of patent rights (Strauss, 2015). The agreement provides guidelines for governing the patent system but leaves discretion for the implementation on the national level (Tvedt & Forsberg, 2017).

Originally, four arguments that form the foundation of the patent system describe why society should provide this form of IP (Karbowski & Prokop, 2013; EZ, 2008; van der Kooij, 2007; Machlup, 1958). These arguments are *Natural law*, *Reward in the form of a monopoly*, *Incentives created by the monopoly profits* and, *Compensation for revealing secrets*. I will review each of these approaches to patent protection.

1. *Natural law:* is based on the idea that each person is the owner of his or her ideas, and unauthorised use of these is regarded as theft.

This first argument traces back to philosopher John Locke, defender of the 'labour theory of property' (Machlup, 1958). The natural law rights argument marks that it is unfair to allow others to 'free ride' at the expense of others who are taking the effort of inventing. 'Free riders' are people who did not invest time or money in the development of an invention, and therefore it would be unacceptable that they are allowed to compete with the inventor under normal market conditions. Thus, the argument of *Natural law* is used to justify that society grants exclusive rights to the inventions of inventors to protect the 'free riders' phenomenon (Sterckx, 2006).

To add nuance, disagreement with this argument arises because if ideas as property are a function of natural law, why is their ownership limited to a given number of years. Next to that, the use of someone's idea differs from a material item and does not deprive its owner of the possibility to make use of his or her invention (Coquelin, 1873 in Machlup, 1958).

2. *Reward in the form of a monopoly*: asserts that an appropriate compensation should be given to the inventor for the contribution to society in the form of a temporary monopoly.

This line of reasoning is based on considerations of distributive justice, that it is fair that inventors are rewarded because of their services in the proportion of the benefits they provide for society (Sterckx, 2006; Karbowski & Prokop, 2013). Therefore, society should arrange such compensation. Influential economist such as Smith (1776), Bentham (1843), or Mill (1848) endorsed that the most appropriate way to offset such a debt is to grant the inventor a temporary monopoly (in Karbowski & Prokop, 2013; Machlup, 1958).

A counterargument comprises that inventions are a product of developments taking place in society as a whole rather than the result of an individual genius. A successful invention is the result of luck, and thus, there is no need to reward someone for being the first to come up with a given idea (Penrose, 1951, in Karbowski & Prokop, 2013; Sterckx, 2006). However, ideas have to be translated into an invention and this process usually involves further investment of time and financial resources. Only with this additional investment, the invention can be considered as patentable subject matter (Smith, 2019).

The third and fourth arguments are both consequentialist justifications of the patent system.

3. *Incentives created by the monopoly profits:* assumes that inventors without this compensation and profits made from his or her ideas will not produce sufficient innovations to society.

This argument assumes that technological progress is desirable, that inventions and their exploitation are necessary for societal progress, but that inventions and their exploitation will not be obtained to a sufficient degree if inventors can hope only for such profits as the competitive exploitation of all technical knowledge will permit. Thus, to make it worthwhile for inventors and their investors to make their efforts and risk their investments, society must intervene to increase their profit expectations. According to economist including Lyon et al. (1939), Ravenshear (1908) and Wieser (1927), the simplest and most effective way for society to generate appropriate incentives is to grant temporary monopolies in the form of exclusive patent rights to the inventions (in Karbowski & Prokop, 2013; Machlup, 1958). Underlying this idea is that patent protection promising monopoly profits is a key factor determining the human motivation to undertake research works resulting in inventions and innovations (Karbowski & Prokop, 2013).

One of the counterarguments formulated is that it is complicated to determine whether monopoly profits stimulate innovation due to the exclusive rights of patent protection. Dutfield (2017) notes that "it is extremely difficult if not impossible to determine an optimal level of protection for achieving an optimal balance of resources for inventive activities." This difficulty is further intensified "by the task of ensuring that protection is effective but not so strong as to unduly restrict the freedoms of follow-on innovators. Thus a balance between private control over the use of technical information and its diffusion needs to be struck" (Dutfield, 2017, in Smith, 2019, p. 130). In sum, it is essential to determine the optimal level of protection for

achieving an optimal balance of resources for inventive activities. Next to maximising the benefits for society, that requires that a balance is set where the scope of protection does not block competitors from entering the field and thereby allowing them to build upon previous inventions, but prevent the generation of similar inventions (Dutfield, 2017).

4. *Compensation for revealing secrets:* consists of the assumption that the revealing of secrets can help other inventors develop the ideas, and this forms effectively a contribution to society while the inventor profits from the temporary protection.

This final argument justifies the patent system with another consequentialist explanation. It is based on the idea revealing secrets of the inventor is the restitution for monopoly rights provided by society. The patent system encourages inventors to disclose their inventions instead of keeping trade secrets. The economic growth argument includes that technological information disseminates and promotes technological progress, fostering economic development (Sterckx, 2006; Karbowski & Prokop, 2013).

Criticism on this argument takes the direction that society wins little or nothing when inventors are forced to disclose their achievements. Only a few inventors succeed in keeping their secrets for a very long time. Often, similar ideas are developed by a few people within a short time, if not simultaneously. Only the inventor that assumes that no one else comes upon a similar idea would not have a reason to patent his or her invention. So only the information that cannot be kept secret would be revealed against compensation (Machlup, 1958; Karbowski & Prokop, 2013). However, disadvantages of relying solely on trade secret protection include there is no protection against independent creation or discovery and subject matter available in the marketplace can be reverse engineered.

In practice, the patent system provides a temporal monopoly of twenty years to reward the owner for contributing to society. The temporal monopoly should not be confused with ownership or the term property as in IP; a patent right that provides a monopoly includes that others cannot use the invention without the patent holder's permission or a license. In return for the exclusive rights, the inventor must reveal the information and knowledge behind the patent. As a consequence, others can build up on the knowledge to develop new innovations. Patent protection is a passive right, and this means that the patent application, process and legal cases for infringement are the responsibility of the patent holder, including the costs (Harhoff & Reitzig, 2004). In Europe and the Netherlands, a patent is granted to an invention when it meets the standard criteria of novelty, inventiveness, utility and sufficient description of the application (EZ, 2008). In the Netherlands the grant procedure of patents is the responsibility of the RVO (Netherlands Enterprise Agency). The focus will be on the EPO, because through this office the most important patents are applied for and largely influences the green biotechnology industry.

With the emergence of genetic engineering and the first patents on modern biotechnological inventions in 1998, a European-wide discussion originated on whether additional patent criteria were necessary. This resulted in the Biotechnology Patent Directive 98/44/EC (hereafter Biotechnology Directive) that describes criteria for biotechnology inventions to harmonise patent law on these inventions. The directive is implemented in the national laws of European member states and covers four considerations for patents on biotechnological inventions.

First of all, the distinction is made between an invention and discovery, and patents cannot include products of nature or biological processes. Therefore, a discovery of, for

example, a genetic sequence causing breast cancer is excluded from patent rights because it lacks human inventiveness (EZ, 2008; Wood, 2001).

Secondly, patent regulations exclude plants and animal varieties from patenting. However, plant varieties are protected by another form of intellectual property, breeders' rights. Breeders' rights cover a plant variety, but others can utilise the plant variety when developing a new breed without the inventor's permission (EZ, 2008). Breeders' rights are the main form of IP for plant innovation. But with the emergence of gene-editing technologies, patents are taking in a more important place in IP rights in the sector (Bakker & Minten, 2010). The protection scope of patents exceeds the breeders' rights, and therefore the increase in patents changes the role breeders' rights play in this sector.

Thirdly, patent rights prohibit disclosure or commercial exploitation of inventions that are not in line with ordre public and morality. This assessment of inventions occurs prior to the grant of a patent. Earlier versions of the ordre public or morality clause exist since 1910 in the *Rijksoctrooiwet,* but the EPC lastly adjusted it to: (Public) morality denotes the unwritten ethical convictions of a certain (political) community, and; the ordre public stands for the protection of public security and the physical integrity of individuals as part of society (EPO, 1995). Practically, the EPO will decline a patent based on the ordre public and morality when it is conflicting with the norms and values described in the national legislation of one of the associated countries (Mom, 1995).

Finally, the Biotechnology Directive describes the prohibition of patents on specific inventions that are not in line with ordre public and morality. These prescribed standards exclude patents on (parts of) the human body, transgenic humans or a human clone (EZ, 2008; Wood, 2001).

Furthermore, after a patent is granted, two mechanisms make additional changes to the patent or licensing practices of the patent holder possible.

First, on the European level, the opposition procedure of the EPC provides the possibility that patents still are rejected nine months after the awarding of the patent. With an opposition procedure, other parties, e.g., competitors or moral activists, can challenge this patent based on the standard criteria and all the additional exclusions written in the EPC. In practice, this means that the accuracy of the process of awarding a patent is reassessed. For example, the scope of the patent may overlap with previously granted patents or because the patent does not comply with regulations to safeguard public values. As a result, the patent can stay the same, be rejected or modified partly.

Secondly, the Dutch state can deploy a compulsory license in the public interest. A compulsory license is used with reasonable compensation when a patented invention is of necessary value for the public and access is limited by the patent holder (Prifti, 2017; Wood, 2001). Deciding on a compulsory license is the task of the minister of Economic and Climate affairs. This mechanism differs from the judgement of the ordre public prior to the grant of a patent because the patent holder keeps his or her patent. The public interest is a broad motivation and means that a compulsory license can be deployed when public health, innovation and legal security are affected by a patent. For instance, when a critical medicine is not accessible because the patent owner is unwilling to license voluntarily or the prices for licensing are disproportional. However, the compulsory license is hardly used in practice because state ministers see it as an ultimate measure, and most importantly, because it can impede the investment climate in the Netherlands (EZ, 2005).

The additional criteria of the patent system, the compulsory license and the opposition procedure are there to protect public values underlying the patent system. Subsequently, the following section delineates the concept of public values and the public values supporting the patent system.

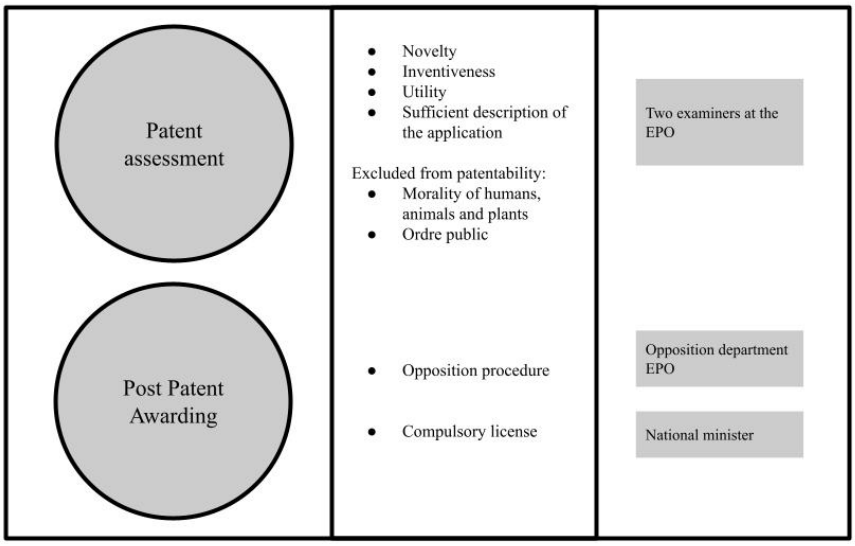

Figure 1. Overview of the process of examining patents, including the standard patent criteria, and safeguarding mechanisms.

2.1.2 Concerns of the patent system

Currently, research on the patent system and specifically for green biotechnology identifies three main concerns on which this research will develop.

First, the ethical debate on patents on living organisms rises concerns that public values are insufficiently safeguarded in the patent system. Since the advent of modern biotechnology, concerns have been expressed about patents on living organisms. The ethical debate about patents on life started on whether the effects of research and industrial application with manipulating gene technologies. Then this debate was followed by an ethical consideration on patents on these technologies (van Dam-Mieras, 2001).

The ethical debate of patents on life remains since the Biotechnology Directive allows for patents on living organisms. The debate is concerned that patents hamper access to natural resources. And that genetically modified animals are patented and are becoming a commodity because of the patent exclusivity. Furthermore, patents can claim genes, organs, germ cells and embryonic cells and enhance commercialisation on these parts of human bodies or animals (Tvedt & Forsberg, 2017; Gitter, 2001).

Second, there is a debate on whether patents can stifle innovation. The concept of 'tragedy of the anti-commons', is presented in this debate and suggests that multiple patents obstruct deployment and may result in an underuse of resources (Heller & Eisenberg, 1998). In particular, the seed industry fears that the cost for breeding will increase because of the number of patents in this field and will create a dense web of patents. The concern is that the number of patents will hinder basic research and diminish freedom to operate for commercial parties (Boldrin & Levine, 2013; Karbowski & Prokop, 2013).

Third, there is the concern, that patents are increasing the power of a few multinationals in the agriculture sector, and as a result biodiversity might be reduced. Currently, small-size plant breeders contribute to biodiversity by providing a diverse range of seeds, while using the protection of PBRs (Louweraars et al., 2009). With the emergence of genome-editing techniques, multinationals strengthen their position with patents and can limit the access to the pool seeds that small-size breeders use. It is feared that these patent monopolies reduce access to a diverse pool of seeds causing a reduction of biodiversity and environmental problems (Bakker & Minten, 2010; Louweraars et al., 2009).

2.2 Public values in the patent system

2.2.1 Public values

Public values are a widely used concept in policy research but often lack a clear definition (Beck Jørgensen & Bozeman, 2007). In this thesis I follow Bozeman (2007, p. 13), who defines public values on the policy or societal level:

> *"A society's 'public values' are those providing normative consensus about (a) the rights, benefits, and prerogatives to which citizens should (and should not be) entitled; (b) the obligations of citizens to society, the state and one another; and (c) principles on which governments and policies should be based."*

Public values comprise specific and identifiable content[1], and therefore public values can be measured and evaluated (Bozeman, 2007). Governments have the position to play a special role in safeguarding public values, but citizens, businesses and non-profit organisations are also crucial in actively solving social problems (Bryson et al., 2014). Underlying the definition of Bozeman (2007) are the following four implications for the use of public values (Bozeman & Sarewitz, 2011). Firstly, public values are not static and immutable. Even though public values are not static, in society public values are stable and only change slowly over time. Changes take place over generations or come with great social change (Bozeman, 2007). Secondly, rarely but in some cases, there may be insufficient consensus to acknowledge public values. For example, during the time of the first environmentalist protecting the environment was not included yet as common public values. Thirdly, public values may conflict with each other, for example, the public values of liberty and security. In such cases, governments can influence the balance between the different public values at stake in public policy. Bozeman (2007) points out that public policy is a reflection of the public values and not the other way around. Lastly, public values may or may not be independent of each other. An example is access to healthcare and a fair return of incentives for companies to do risky and expensive research for new cures.

As stated before, public values research consists of a stream of scholars that seek to highlight and achieve public values as a critical agenda issue for politicians, citizens organisations and society by defining, identifying and classifying public values (e.g., Beck Jørgensen & Bozeman, 2007; Bozeman, 2002, 2007; Nabatchi, 2012).

Public values theory is designed to provide a set of ideas that offer an alternative to the influence of liberal economic reasoning in general and market-failure criteria. A framework to study public values is public value failure theory (hereafter 'public failure theory'). This theory emerged in response to the market-based assumptions to public policy decision making. Public failure theorists argue that market explanations alone do not allow for an expansive public dialogue about policy issues (Bozeman, 2002). Public failure theory argues that if society expresses consensus on a certain value and that value is not achieved, then a public value failure has occurred (Bozeman 2002). The public failure criteria, which are not fixed and exhaustive, include factors such as the insufficiency of mechanisms for articulating and aggregating values in the political and social context, scarcity of providers, and short time horizon (Bozeman, 2002, p. 151; Bozeman & Johnson, 2015). Additional is the health and well-being of the public sphere and the criterion of social and economic opportunity (Bozeman & Johnson, 2015).

Public failure theorists argue that core values can be identified by reviewing a variety of sources, including formal scholarly literature; government documents; agency and program mission statements (Bozeman, 2007; Bozeman & Sarewitz, 2011) but also more informal values that formal forms such as laws and government documents do not explicitly present

[1] A term often used together with public values is 'public interest'. The difference is that public interest describes an ideal, whereas 'public values' comprise specific, identifiable content (Bozeman, 2007).

(Fukumoto & Bozeman, 2018). Public value mapping (PVM) is deployed to determine if public value failures have occurred (Bozeman, 2007). PVM is a loose set of heuristics that allow for the development of analyses of public values (Bozeman & Sarewitz, 2011). PVM consists of four key steps of PVM application.

The first step identifies the core set of public values by analysing relevant data sources such as public laws and national policy reports. The second step of PVM assesses the occurrence of public value failures and successes. This step analyses if government policy or action appropriate and justified according to public value criteria. The third step maps the public values to find relationships among values. The fourth and last step considers the relationships between public value and market failures and successes (Welch et al., 2015).

An example of this would be the ethical and economic trade-off when genetically modified animals are commercialised to decrease costs. At the same time, the modifications do not contribute to the animal's quality of life. The situation conflicts with animal dignity and results in public failure. In sum, this last step assesses the balance between the public value and market failure.

PVM is in its early stage of development and can be applied to the IP policy domain in order to develop a pathway to more systematic considerations of the field of public administration (Welch et al., 2015). The remainder of this chapter contributes to the first step of PVM. It outlines the public value criteria underlying the Dutch patent system and public values regarding biotechnological patents based on (international) treaties, policy document and scientific literature.

2.2.2 Public values in the Dutch patent system

As stated before, the Dutch patents system aims at stimulating economic growth while contributing to the public domain. Public values evaluate these contributions. In this study, I argue that a patent system that functions according to the public values that form the underpinnings of the Dutch patent must meet at least four criteria. These criteria are based on scientific research international treaties, reports and principles of good governance. Specifically, the four arguments that formed the foundation of the Dutch *Rijksoctrooiwet* in 1910, together with the principles and public values derived from the European Patent Convention and the TRIPs agreement form the foundation to these criteria (Karbowski & Prokop, 2013; EZ, 2008; van der Kooij, 2007). When the patent system does not meet these criteria in practice, this indicates public value failure (Bozeman, 2002). Therefore, to function in a socially desirable way the patent system must meet the following criteria.

1. **The system is effective.** The patent system protects inventions that are socially desirable to incentivise their development. The inventions must be, among others, sufficiently new and inventive to make use of the benefits provided by patent rights. Inventions that produce socially undesirable effects or are trivial and do not meet the standard patent criteria are excluded from this protection. Furthermore, this criterion leads to the exclusion of immoral technologies from patentability (EZ 2008; Mom 1995; Van der Kooij 2007). For example, patents on human cloning, on the use of human embryos or on specific processes that pose a threat to human health and the environment.

Accordingly, this criterion is compatible with the third and four arguments of the patent system: 3. Incentives created by the monopoly profits, and 4. Compensation for revealing secrets. Also, the morality of humans, animals and plants and ordre public rules as described in the EPC prevent patents from protecting socially undesirable inventions.

2. **The system is efficient.** This criterion has two aspects. First, the system works efficiently when it incentivises investors with a reward for their invention, as a return on their investment, that is of substantial size to stimulate them to innovate, but that is not larger than necessary. The level of protection is fair when it does not block others considerably from innovating and thus is beneficial for both the investor and society. Second, this criterion requires that the system operates at minimal "system costs". Not only costs of applying for and registering a patent are low, but also the costs of patent disputes are minimal.

As such, the second criterion is in line with the first and second argument underlying the patent system: 1. Natural law, and 2. Reward in the form of a monopoly.

3. **The system is reliable**. The system applies the rules consistently and correctly, and it is clear based on which arguments patents are granted. Also, the patent system accommodates legal certainty: patent holders can be assured that their rights will be respected and protected under normal circumstances. Reliability and legal certainty relate to good governance principles and facilitate (international) trade, which is an important objective of the World Trade Organisation (WTO, 1994). The TRIPs agreement for intellectual property rights contributes to good governance by providing large-scale direction on public values, ensuring predictability, and settling disputes more systematically (WTO, 1995). A reliable system in practice is the responsibility of the EPO, national patent offices and courts. However, society must be able to rely on the government in case of excesses and emergencies to intervene with a compulsory license in the interest of the public (EZ, 2008).

4. **The system is inclusive**. The patent system does not discriminate between inventors. To get the most out of society's creative potential, as many inventors as possible have access to the patent system, and as many people as possible can benefit from an invention. Private inventors and large corporations enjoy equal protection in the patent system. An inclusive patent system also ensures that less purchasing power consumers, for example, in developing countries, are not excluded from essential innovations such as life-saving medicines (Henry and Stiglitz 2010; Maskus and Reichman 2004). This last criterion is emphasised in the 2001 "Doha Declaration on the TRIPS Agreement and Public Health" for the TRIPS treaty in the field of health (WTO, 2001).

The above criteria imply that the stakeholders around patents behave in line with public values prominent in the patent legislation and treaties. Public institutions are expected to use the patent system and patent rights appropriately and fairly for all (potential) patent holders, committing to socially responsible functioning of the patent system. Patent holders, in their turn, are expected to apply for patents that cover inventions that are socially desirable and charge a reasonable price for innovations and not make improper use of patent rights.

However, the four criteria might not always be straightforward, and tensions between public values can arise. For example, patents on genetically modified animals can incentivise innovations that, on the one hand, contribute to society, with better medicines, diagnostic tests or enhanced food products. But, on the other hand, these innovations can impair animal dignity because of the patent exclusivity, which conflicts with criterion 1, defining an effective patent system (Tvedt & Forsberg, 2017; Gitter, 2001).

Another example illustrating tensions between public values is that large companies often have better resources to produce innovations and protect those with patents in the green biotechnology field. These patents strengthen their position, and so only a few multinationals play are the leading players in this field. The inequality in access to patents leaves behind the smaller and traditional breeders because of the high licensing costs. It is feared that these patent monopolies reduce access to a large and diverse pool of seeds. Thus, causing a reduction of

biodiversity and environmental problems, which is a socially undesirable outcome and not in line with criterion 1 (Habets et al., 2019; van Dam-Mieras, 2001). Also, the inequality in access conflicts with criterion 4 of inclusiveness. On the contrary, the strengthening of the position of large multinationals makes it possible for these companies to develop high-cost innovations in the biotechnology field that benefit society. Therefore, in this case, criterion 2 of providing a reward in the form of a monopoly is attained. To find out whether these tensions are affecting the functioning of the Dutch patent system, in dept analysis is necessary to identify whether these tensions are out of balance and for example result in better provision for larger companies than the public.

3. Methodology

This section first presents the research design. Secondly, section 3.2 discusses the data collection and analysis methods. Finally, the planning of this research is presented.

3.1 Research design

This study is conducted as a part of a larger research on public values in the Dutch patent at the Rathenau Institute together with five other researchers. This study investigated whether development of new promising technology fields was accommodated in the Dutch patent system in a socially responsible way. It looked at development of medicine and specifically the Covid-19 Vaccines, Artificial Intelligence and Biotechnology in relation to IP. The study was aimed at finding overarching conclusions applicable to a broader range of technology fields in the Dutch patent system. For this master thesis, I strengthened the work on Biotechnology with additional data and analysis. This methodology section describes the decisions made for the biotechnology topic in this master thesis, for the further methodological considerations of the overarching research can be referred to the Rathenau report (2021).

In this study the theoretical framework identified three concerns for biotechnology regarding the protection of public values in the patent system. However, more understanding is necessary if these concerns are still valid and how the developments of CRISPR technology compared to recombinant-DNA will amplify the interference of public values. This study applies the public value mapping tool of Bozeman (2007) to identify if the presented tensions are apparent in the Dutch patent system, identify new public value failures and evaluate them in practice. The Dutch patent system is object of study, because the Netherlands has a vital (green) biotechnology sector that is expected to be largely shaped by CRISPR technology innovations and represents a typical case for other European countries (Berkhout et al., 2019).

Therefore, an abductive qualitative research design is adequate to capture a thorough picture of biotechnological inventions in the Dutch patent system. This research takes an explorative research approach in order to gain in-depth understanding of the shifting position of the biotechnology patents because of new technologies on the public values in the patent system. The units of analysis are the public values in the Dutch patent system.

The technologies, Recombinant-DNA & PCR and CRISPR, were studied in a multiple case-study. The multiple-case study explored how the emergence of these fundamental technologies in the biotechnology shaped the patent system. The recombinant-DNA & PCR case has similar characteristics to CRISPR but started in 1970s and therefore analysing lessons from this case are valuable for understanding the current system and how technology currently will evolve.

The aim of qualitative research is not to provide generalisable conclusions. This research contributes, corresponding with the observations and information in these case-studies, to literature concerning problems in the patent system in general and provide recommendations on how to tailor the patent system in order to stimulate future technologies in line with public values. Additionally, this study aids the development of public value theory and specifically the development of the PVM tool for technology (Welch et al., 2015; Fukumoto & Bozeman, 2018).

3.2 Data collection and analysis

To secure the *external reliability* of this study this chapter follows with an extensive description of how the data collection and analysis was depicting a systematic approach qualitative research for possible replication.

Data collection is based on document analysis and interviews. Both approaches focus on public values in the biotechnology cases and in the (Dutch) patent system in general. The document analysis includes academic, grey literature and policy documents on laws and international treaties. These documents were collected via experts from the Rathenau Institute and in the biotechnology and IP field, and search engines such as Google Scholar and Web of Knowledge. Initially, the keywords used were e.g., biotechnology; recombinant-DNA; CRISPR-Cas (and all variations); New Breeding Technologies; patents; public values and social justice. Further documents were retrieved by forward and backward citations, and snowballing with new keywords that arose.

Furthermore, data was collected by interviews with key actors in the Dutch patent system. The interviews were conducted in two phases. In the period from December 2020 and January 2021 40 interviews were held as a part the Rathenau research, of which 13 were specific for the biotechnology study. In April and May, the second phase was performed independent of the Rathenau institute. In this phase an additional number of 11 interviews were conducted and further document analysis was completed until no new information came to light and theoretical saturation for the biotechnology study was reached.

The respondents cover the stakeholders of the (green) biotechnology sector in the Netherlands and experts on IP or biotechnology, were selected by purposive sampling (Bryman, 2012). First, interviews were conducted with experts in order to identify the main stakeholders of the Dutch biotechnology sector and confirm knowledge about the complexities of the patent system. After that, snowballing was used to select further respondents that help serve this study by providing insights on the explained tensions in the Theoretical Framework and help identify possible other tensions. The interviews concerning the Recombinant-DNA & PCR case were planned before the interviews for the CRISPR case. However, several experts and stakeholders are involved in both case-studies and can provide insights for both.

In Table 1 the respondents interviewed are presented. Examples of stakeholders are breeders' companies, biotechnology researchers, ethical activist and large corporate biotechnology companies. Experts for this study are researchers of the case-study technologies, sometimes with a public value perspective, including patent specialists, lawyers, ethical researchers and political scientists. The respondents are distinguished in five stakeholder groups, which are also depicted in Table 1.

For the second phase interviews respondents were identified during the data analysis of the first phase. These respondents consist of stakeholders in the green biotechnology sector such as small breeder companies in the Netherlands, activists that have ethical considerations for patents on CRISPR technologies and the Dutch or European patent office in order to form a more comprehensive picture of the Dutch patent system.

The interviews with experts and document analysis contribute to the *external validity*, by confirming if results are applicable for patents on other technologies or in other countries (Bryman, 2012).

The interviews were structured with topics of the interview guide, which is based on public values and the described concerns regarding the patent system. The interview guide, see Appendix 5.1, describes a topic list with questions that are applicable for both cases and the research at the Rathenau Institute. In this way the questions for the cases and the other topics are similar and make systematic comparison between interviews possible and contribute to the *external validity*. In addition to the structure of the interview guide, the semi-structured nature

of the interviews allows for deviation and new themes to emerge such as new public values or tensions in the patent system (Jacob & Furgerson, 2012). In preparation for each interview the topic list of questions in the interview guide was adapted for the specific interviewee to effectively ask for information that was expected by the interviewees' expertise.

Respondent number	Occupation	Stakeholder group	Abbr.
1.	Researcher	-	R
2.	Researcher	-	R
3.	Patent Attorney (EU)	Multinational	M
4.	IP specialist: Breeder company interest association	Multinational/Small-size breeders	sB/M
5.	Researcher	-	R
6.	Researcher	-	R
7.	Multinational	Multinational	M
8.	Scientist	Knowledge institution	K
9.	Researcher	-	R
10.	Researcher	-	R
11.	Patent Attorney (EU/NL)	Multinational	M
12.	Executive and scientific director	Social organisation	S
13.	IP Specialist	Multinational	M
14.	Patent Attorney (EU/NL)	Multinational/Small-size breeders	sB/M
15.	Patent Attorney	Multinational	M
16.	Patent examiner	EPO	E
17.	IP Specialist	Multinational	M
18.	IP Specialist	Small-size Breeders	sB
19.	Patent examiner	EPO	E
20.	IP Specialist, Biotech interest association	Biotech companies Interest group NL Biotechnology multinationals/start-ups	sB/M
21.	IP Specialist	Small-size breeder	sB

Table 1 List of interviews; R 1-21 refers in the text to respondent number. In the code table the abbreviations are used; M = multinational, sB= small-size breeder, K= knowledge institute, S= social organisation, E= EPO, R= Researcher.

Because the global COVID-19 pandemic is still limiting people's movements, interviews were held online (e.g. Zoom/Teams) or by telephone. The interviews were held in Dutch and English dependent on the native language of the respondents. Previous to the interview the interviewee was asked for consent on recording the interview and a form that describes the Dutch General Data Protection Regulation (GDPR) which is a standard procedure at the Rathenau Institute. Respondents 16 and 19 preferred if no quotes were used in the results and the recording of the interview was refused by respondent 19. During that interview extensive notes were taken.

Subsequently, the interviews were transcribed and coded in Atlas.ti. Starting after the first interview transcripts and documents were attained. The coding process was based on the qualitative Gioia Methodology, but consists of more iterative comparing between theory and the data (Gioia et al., 2013). The first step was to assign open codes to the data in order to

identify new information. As part of the iterative process these codes were then compared with theory and category codes were assigned to the data.

As an intermediary step, after the data was collected, a table in excel was composed with the four criteria and quotes of each respondent on different aspects of the patent system. With the help of this table, a systematic analysis could be performed of the different perspectives on the functioning of the patent system for different stakeholders. Overlapping views were linked with the help of this table. For a summary of this table see Appendix 5.2. The complete table consisting of all quotes is upon request.

The constant comparison of the data to theory pursues *internal validity* of the study. The final step was to develop themes from the categories relating to the research questions and linked to existing literature. Also, the cases were compared for cross-case patterns and strong indications for similarities or differences were contributions to the theory generation (Eisenhardt, 1989). Throughout the process of data analysis there was consistent use of concepts and regularly the process took a step back to the literature, to ensure *internal reliability* (Gioia et al., 2013).

Another contribution to *internal reliability* was the regularly discussions about concepts and themes from the data and literature with other researchers at the Rathenau Institute. The data analysis was finalised when no new information related to the research questions was found in interviews and from the document analysis.

4. Results

The following section presents the results of this research. This chapter links back to the data of this study by quotes and referring anonymously to the interviews with (R) and the number of the specific interview as listed in Table 1.

Firstly, the context of the Recombinant-DNA case is delineated. The context characterises the technology, the ethical debate, and the technology development in relation to IP. This is followed by the background of the CRISPR case. The context of the technologies depicts five main stakeholders in the green biotechnology industry, which are knowledge institutions, social organisations, multinationals, small-size breeders and, the main patent governing institute, the EPO. The respondents are also accordingly characterised in Table 1. Thereafter, the results chapter evaluates the public values that support the Dutch patent system by assessing whether it meets each of the criteria for a socially desirable functioning of the patent system.

4.1 Context: Recombinant-DNA and PCR case

This section discusses the developments of Recombinant-DNA and PCR technology, during the first period of modern biotechnology. The historical insights extracted from this case, help understand the dynamics of IP and the unfolding of new technologies. Further, this section identifies factors that characterise modern biotechnology. The case depicts events that are related to the broad field of modern biotechnology to portray the discussions and dynamics of the patent system, for example the ethical debate about patents on life. Thereupon, the case specifies on practices for green biotechnology and IP, specifically patents and plant breeders' rights.

4.1.1 Technology and application characteristics

To start with the technologies in this case and the associated characteristics. The field of modern biotechnology modifies the genetic code, the DNA, of organisms using contemporary techniques. By adding or modifying specific characteristics, organisms are suitable for several (commercial) purposes. The transformation of the biotechnology sector can be traced back to the invention of Recombinant-DNA technology. Recombinant-DNA was the first technology to bring knowledge on DNA into practice in the 1980s. Recombinant-DNA is a technique that allows the modification of the DNA of bacteria or animals to produce, for instance, proteins for medical or commercial purposes. The method combines DNA material from genetic sources from different plants or animal species. Recombinant-DNA is thus used to add transgenes to an organism and the organism is subsequently referred to as transgenic.

PCR is the second technology that also played a significant role in the historical development of modern biotechnology. PCR stands for 'Polymerase Chain Reaction' and with this technique, pieces of DNA can be multiplied until there is sufficient material to analyse the DNA. This DNA is used to gain more insight into, for example, the possibilities for modification, or diagnosing and monitoring (hereditary) diseases.

Inventors and patent strategies

At the onset of modern biotechnology, private companies were the only parties using patents. Recombinant-DNA was the first technology of important societal value that was

patented by a public institution. Back then, the public feared that the access and spread of this technology would be limited by this patent (R 2, 5, 8).

Recombinant-DNA is an invention of Stanley Cohen (Stanford) and Herbert Boyer (UC San Francisco) in 1973. In 1980, a US patent was granted to Stanford University, known as the Cohen-Boyer patent. Despite the patent, the university guaranteed accessibility to the technology with a non-exclusive licensing program, which was titled the Stanford University Licensing Program. A non-exclusive license means that any applicant could obtain a license if reasonable fees is paid. As it was new, back then, for scientists and public organisations to apply for patent protection, in particularly on such a fundamental technology, scepticism existed on if the use of patent protection would be beneficial to society and if the technology would be sufficiently developed and available for social purposes.

Conversely, this licensing program was recognised for encouraging innovation (R3, 4, 6, 7; Feeney et al., 2018). The licensing program did not seek profit but aimed at meeting public values by encouraging innovation and providing an income only for research and education. The licensing terms asked commercial companies for a fee and royalty. A royalty is a percentage of the profit of the product for which the license is required. Moreover, non-profit organisations were given a license for which no royalties were charged.

PCR was invented in 1983 by Kary Mullis, who worked at the private company Cetus. In 1987, the US patent office awarded Cetus a patent. The private company's initial strategy was to grant exclusive licenses. Licenses were granted at high fees and included royalties. This strategy limited the spread of this foundational technology. Soon Cetus sold this patent to the pharmaceutical company Hoffman-La Roche. The pharmaceutical saw that the restrictive licensing criteria of Cetus insufficiently stimulated the use of PCR. Therefore, the company set up new licensing conditions, which ensured that the patent was non-exclusively accessible and only demanded affordable royalties from commercial companies. In addition, research and R&D applications were exempted from royalties. This renewed strategy promoted the technology and created the widespread use of PCR in research and private purposes (R 3, 4, 6, 7; Feeney et al., 2018).

These two foundational technologies are examples that show that a patent on a fundamental technology does not prevent innovation and diffusion of that technology. The licensing strategies of Stanford and Roche did actively encourage the diffusion of technology and research. However, the Cetus strategy demonstrates that limited dissemination of technology is also a possible outcome of patent rights.

4.1.2 Debate on patents on life

As mentioned, patent offices granted patents on these technologies, but other patents on molecular genetics, which became increasingly apparent, were not granted without large-scale debate. In 1980, the US Chakrabarty patent caused lots of controversy in the developments around patenting modern biotechnology and was the first-ever patent granted on a living organism (USPTO, 1980). The invention included a genetically modified bacterium that can break down petroleum, invented by the researcher Chakrabarty at the company General Electric. The patent offered protection on the production of the bacteria and the composition of both the bacteria and other working substances. The US ruling made it clear that ‘anything under the sun that is made by man’ fell within US patent law and that living organisms were not exempted from patent protection (USPTO, 1980). Consequently, the commercialisation of the latest DNA techniques within biotechnology took off.

Among the European Patent Convention member states, this US ruling created uncertainty about how living organisms should be interpreted. Also, it was observed that

European law was out of date, given the rise of biotechnology (Parthasarathy, 2017). In order to harmonise the interpretation of biotechnology and patent law, in 1988 the European Commission started an initiative for the Biotechnology Directive (Wood, 2001). The EPO decided to abide by this directive voluntarily to stay aligned with national patent law. Surprisingly, the European Parliament challenged the European Commission's approach to the new patent directive. The Economic and Social Committees (ESC) of the European parliament were asked, a standing assembly made up of representatives from employers' organisations, trade unions, and other interest groups, to review the draft Biotechnology Directive. In Europe, this led to a debate over life forms that shed new light on old concerns about patents' moral and social implications due to the rise of bioethics and concerns about biotechnology. Four main concerns arose from this (Parthasarathy, 2017).

First, there were worries from most ESCs, small-size breeders and social organisations in Europe that the socioeconomic costs for farmers, breeders, and consumers would increase and not outweigh the benefits of economic growth at a broad scale (R 4, 9, 12, 18). Argumentation for this was that if life forms were patentable, 'Independent breeders will no longer be able to use varieties and races freely for further innovation as their access to patented genetic information and techniques will be subject to delays, three to four years after the grant of the patent, according to the draft Biotechnology Directive, and payment of royalty fees for the whole patent period. The economic strain on the breeding sector will be such that most independent breeders will simply go out of business if they are not bought up by multinational firms first' (Parthasarathy, 2017, p. 65). This was likely to happen because European farms were comparatively small, and those companies would not be able to bear the costs of buying patented seeds each year. Respondent 4, a representative of the Dutch breeders, describes the motivation for a lobby against this draft of the directive back then:

"*And it is also true that, because of the number of smaller companies in the sector, there is also a bit of a concern that this is very much in favour of the larger multinationals with a lot of legal capacity, and that it is therefore much more difficult for small companies to handle these negotiations successfully. So that is also a, yes, motivation.*" (R4).

Second, a broader concern is that strengthening the patent regime would lead to the consolidation of agriculture worldwide, harming the environment, society and public health (R 4, 5, 7, 9, 12, 18). If patents on seeds were allowed, this would provide a competitive advantage to patent holders, which would reduce the number of plant varieties. Ultimately, this would hurt global biodiversity and become more problematic if one pest wiped out a variety, leaving large regions without access to a particular crop. An analogy of this is the US plant-patent system, where there are no breeders' rights and thus no breeder's exemption, only five companies have applied for 75% of the biotechnology patents on technologies that develop new seeds (Habets et al., 2019; van Dam-Mieras, 2001). These patent monopolies reduce access to a large and diverse pool of seeds, causing a reduction of biodiversity and environmental problems (Habets et al., 2019).

"*From our perspective, it's working very good for the big companies but not in the interest of farmers, smaller breeders, consumers and the environment because these bigger companies might not have the intention to serve regional, environmental of specific consumer needs or farmers' needs. So that's why we're opposing this patent on seeds."* (R 12)

Third, various social organisations for animal rights and three ESC committees worried about allowing patents on animals. Some feared that such patents would encourage the production of animals that would experience considerable suffering (R 2, 10, 12). The issue is

if a patent system allowing patents on transgenic animals would promote a monopoly by large multinationals on living organisms and result in more transgenic animals than socially necessary. A monopoly on an animal with genetic modifications for medical purposes or product improvement, such as transgenic salmon, encourages the genetic modification of animals because the costs can be earned back. Respondent 12 illustrates this situation for practical example of patents on transgenic chimpanzees.

"*If you have a business with genetically engineered chimpanzees, you will try to engineer as many chimpanzees as you can and sell it on the market. That is something that is pushed by patents. If you have a patent on a chimpanzee, you will try to make profits with it, and that's a very extreme example. It's why we were also using these kinds of patents, but we chose the incentive which is created by a patent can have ethical implications, for example, usage of genetically engineered animals which are used in pharmaceutical research. Yes, we also think that in the future, animals will be used in pharmaceutical research, but they should not become a business on its own. Experiments should only be performed according to the law if there is a need, evidence for a need that these experiments are performed. Patents are a commercial incentive to perform experiments*." (R 12)

Next to that, there was a clear consensus that the Biotechnology Directive needed stronger articulation to protect human dignity by excluding human beings from patentability. Or even more extensive exclusions on isolated or manipulated parts of human beings, including human genes, cell lines, organs, and tissues.

Finally, the ESC committees and several researchers raised concerns that the Biotechnology Directive would stifle innovation in Europe by restricting the free exchange of scientific resources and information (Heller & Eisenberg, 1998; Karbowski & Prokop, 2013; Boldrin & Levine, 2013). Even though research exemption allows researchers to use patented products or processes in research in Europe, committees were worried that with the Biotechnology Directive, this exemption would be weakened. Research institutes and commercial parties are increasingly collaborating, making the distinction between research and commercial application more complex (R 3, 9). In the end, this would directly affect public research institutes and universities, but also farmers and breeders who developed improved agriculture through generations of plant innovation (R 3, 4, 5, 7, 9, 18).

"For the biotechnology patents, two discussions have been and still are apparent. The questions of whether patents on biotechnology inventions are ethically acceptable, for example, are specific cases considered in this patent system and the standpoint that patents in this field might stifle innovation, which is maybe more a general patent discussion. Because of overexpansion of the system and including basic research and diminished freedom to operate. The ethical discussion is about whether patent offices should be making moral decisions while granting a patent and if they have the competencies for this. While on the other hand, civil society groups say that patents are an incentive and a grant is in need of ethical considerations." (R 9)

Finally, in 1998 the European Parliament approved the European Commission's proposal, and in this directive was decided that biotechnological inventions had to be assessed using the existing patent legislation as much as possible. It became apparent that living organisms were no exception to patentability in Europe. However, an interpretation was devoted to animals and humans as described in the exceptions to patentability described before in Chapter 2.1. Parliamentarians redefined the ordre public clause to focus on concerns

regarding the commodification of life and validating controversial and potentially unethical research areas. But they also addressed other social and environmental impacts beyond ordre public. This was in addition to weakening patents on plants and animals by excluding plant and animal varieties. Mainly because farmers in Europe were concerned about the socioeconomic effects of intellectual property for agriculture. Also, the directive ensured farmer's privilege, which allows farmers to continue to reuse seed over generations without fear of patent infringement, just as the breeders' right system allowed. Lastly, the parliament proposed an explicit exemption for researchers to use patented materials.

This debate interlinked with the resistance to the use of biotechnology. Churches and other social organisations supported small-size breeders in their objection to the Biotechnology Directive, who were trying to limit the use of molecular genetics in biotechnology practices (R 2, 4, 9). These organisations' moral and ethical principles turned against altering the DNA of living organism (R 12). They joined the debate against patents on life. This brought confusion, and sometimes, because there was little awareness about the patent system, the debate failed to recognise that this was not entirely in the hands of the patent system. Patent regulation can only prevent inventions to be patented and preventing the application of technologies lays outside the scope. Europe has different authorities that regulate genetic modification, regardless of whether there is a patent on the invention (EC, 2001). A patent can therefore be granted when the European safety authorities have not yet approved the product. Thus, the patent legislation has a limiting effect on the ethical control of products and processes, but it has given rise to public discussion about Genetically Modified Organisms (GMOs). However, this drift of the debate weakened the reputation of the patent system at the time (R 16).

4.1.3 Developments of the technologies and IP

Oncomouse

During the advances of the Biotechnology Directive, an ethical discussion about the first patents on life emerged. One patent that played an important role in the ethical considerations of patents was the Harvard Oncomouse (EPO-BA, 2004). Before the EPO granted the patent, a complex juridical case on this patent resulted in two decades of controversy. This process contributed to the ethical review of patents at the EPO. The Oncomouse was one of the first transgenic animals, developed by researchers at Harvard in 1980, to be used in research and to be patented. Scientists created the Oncomouse for cancer research, and they genetically modified this mouse to contract cancer. The patent on it was eventually granted to Harvard college in 2004, where two things became clear. First, the EPO decided that the Oncomouse was not an animal variety and thus was within patent protection. In addition, morals and ordre public were assessed for the first time through a utilitarian balancing test (R 10). In this case, it was a trade-off between the suffering of the mouse and the expected medical benefits of cancer research, under the condition that there was no other way to conduct this research without transgenic mice (Salvi, 2001). In addition, the EPO judged that in Europe there generally was no moral disapproval for the use of mice in cancer research. Thus, it was decided that the medical benefits were such that they outweighed the suffering of the animals (WIPO, 2006).

Later, in another patent case, a patent with the same utilitarian consideration was rejected. It concerned a mouse that lost its hair to treat hair loss in humans. The medical contribution was not sufficient here, according to the EPO. A necessary consequence is that the formulation took the place of the different interpretations of exceptions to patentability, specifically for biotechnological inventions. Such as the ban on patenting human cloning and thus the utilitarian balancing test.

The Oncomouse formed the start of the use of opposition procedures by social organisations to oppose patents of the EPO. As the opposition procedure addressed the

Oncomouse case, the EPO faced criticism from civil society over its decisions to allow patents on plants (R 2, 4, 5, 9). Greenpeace and the Green Party, among others, had begun to use the EPO opposition procedure to challenge patents that they considered morally and socially problematic on grounds of the ordre public (Parthasarathy, 2017). In the end, around twenty groups, including animal rights organisations, religious associations, environmentalists, the Green Party and even the German Ministry of Youth, Family and Health, were active in filing several official oppositions to patents of the EPO (R 19). This group of social organisations aligned their ideas with small-size breeders that feared patents on seeds, and these two groups took in a position against patents on life for the next decades (R 4, 12, 18). Next is described what the subsequent controversy of patents on plants was about.

Broccoli-tomato case

After modifying and implementing the Biotechnology Directive, the small-size breeders in Europe were still concerned about the effects of increasing the use of patents for their practices (R 2, 4, 14, 17, 18, 21). Most plant varieties in the EU today are solely covered by plant breeders' rights. They rely on the practices of plant breeders around the breeder's exemption, which includes that when breeders' rights cover a plant variety, others can utilise the plant variety when developing a new breed without the inventor's permission (EZ, 2008). Thus, freedom-to-operate is easy to manage and to obtain also for small-size breeders. The Biotechnology Directive made it possible to patent living organisms and thus to patent plant traits or methods to make these traits. The patents on living organisms must meet the standard criteria through innovative genetic alterations and proof the difference with organisms occurring in nature. When this patented trait is then included in a new plant variety, breeders must obtain a license for this patent to use it for developing a new variety. While the use for breeding is allowed, commercialisation requires a license if the resulting plant is still covered by the patent because, for example, it still includes the trait protected by the patent.

After implementing the Biotechnology Directive, the legislation was not clear on what the scope would be in terms of patent protection for processes to obtain plants and crops. Several court cases have clarified this over time. It concerned the possibility of acquiring a patent on products resulting from traditional breeding with conventional breeding. In 2009, parties applied for patents on plants or crops resulting from traditional breeding, which did not involve genetic modification. According to the applicants, the innovative step was the use of PCR technology in preparation for conventional breeding processes, which made it possible to identify gene sequences more quickly and thus speed up the process of conventional breeding (R 14, 15, 17).

From 2010 till 2020, there was unclarity about the patent protection on gene-editing. Two famous cases strongly influence the discussion, Broccoli/Tomatoes I (2010) and II (2015), decided by EPO's Enlarged Board of Appeal concerning marker-assisted breeding. It was decided that article 53b of the EPC did not exclude plant and animal products produced by essentially biological processes from patentability. Marker-assisted breeding uses DNA markers, often based on PCR, associated with desirable traits to select a plant or animal for inclusion in a breeding program early in its development. Marker-assisted breeding reduces the time required to identify varieties or breeds that express the desired trait in a breeding program (R 4, 13, 17). The Broccoli/Tomato cases were both products of marker-assisted breeding, but the crops were yet still produced via conventional breeding and therefore these cases were discussed in the opposition proceedings.

The EPO decided in 2015 that plants and other agricultural products that were previously protected only with plant breeders' rights could be covered with patent rights. Zimmer and Grammel (2015 in Parthasarathy, 2017) summarised the outcome of the different hearings as follows. First, the so-called product claims included plants or plants parts, such as fruits or seeds as patentable, as long as the subject matter of the claim is not limited to one or more specific plant varieties. Second, plants or parts of plants can be claimed independently of whether they can only be produced by using an essentially biological process to produce plants. Third, there is almost no restriction on obtaining product protection for plant-related inventions at the EPO.

As the EPO grants these patents, there is a division in the seed industry. Disagreement with the decision comes from the seed associations in Europe and they are joined by most of the earlier mentioned social organisations that turn against the use of patents on life (R 2, 4, 12, 18, 19). For these stakeholders, this decision would mean that more patents would be applied for that would cover plant traits and that might interfere with developing new plant varieties. The fear of the breeder's and social organisations was that freedom-to-breed would be limited. Therefore, this decision problematic according to the Dutch organisations Plantum, LTO (Agricultural and Horticultural Association) and VBN (Dutch Flower Auctions Association The Netherlands) (R 2, 4, 12, 18). The Dutch government also disagreed with this ruling because The Netherlands entails many of those smaller breeding companies like the rest of Europe that cannot afford patents (Schouten, 2020).

"Yes, exactly, so of course you can get a licence for such a [plant] property, then you have to negotiate with the patent holder. Only, look, if it concerns one characteristic, well, maybe that is still possible, but the more characteristics are patented, of course, and in a breed, you must always have a combination of all desired characteristics, then it is a bit of a worst-case scenario that you will soon have to make agreements with five parties, so to speak, before you can start working with that material again. And it is also true that, due to the number of smaller companies in the sector, there is a bit of a fear that this will be to the advantage of the larger multinationals with a lot of legal capacity, and that it will therefore be much more difficult for small companies to conclude negotiations properly. So that is also a, yes, motivation [to prevent the emergence of patent blockades]." R 4

In response to this, the 'International Licensing Platform' (ILP) was set up in 2015 for patents related to vegetable crops. It was an initiative by Dutch vegetable seed companies, including the help of the Dutch government and other international breeding actors like Syngenta, to continue encouraging development by creating access to patents on vegetable crops or methods necessary (R 2, 7, 12, 13, 17, 21).

The ILP, which falls into the broad scope of a 'clearing house', and officially it is a foundation that creates a platform bringing together patentees and licensees of patents and patent applications covering biological material needed for vegetable breeding purposes. All companies working with vegetable crops can become members with or without a patent (Kock & ten Have, 2016). Becoming a member of the ILP gives you access to all the patents held by ILP members for a reasonable fee. These fees are mutually determined, and if two companies do not agree, there is an independent arbitration board to solve this (R 4, 7, 21). The platform has a broad coverage of the sector representing over 60% of the commercial vegetable seed companies. This platform aims to prevent the fragmentation of patents on plant properties from preventing further development. Free access to plant material is important to maintain innovation and avoid monopolisation (R 4, 13, 18).

Another initiative was the PINTO database of the European Seed Association (ESA), which was started in order to provide transparency. PINTO, Patent Information and Transparency Online, database publishes information on the presence and ownership of patents withing commercial varieties. Currently, the database gives a good indication of what patents are there. However, it is a voluntary initiatives and patent holders have to add their patents to the database themselves.

In addition, the Netherlands, as part of their European Presidency, organised in 2016 a symposium on the plant breeding sector. At this symposium, an opinion was formulated with EU countries on the Broccoli and Tomato cases and their interpretation (R 4, 13, 18). Shortly after that, the European Commission followed with an interpretative statement on how improved crops should be assessed in patent law. After political support from the EU Council of Ministers and the European Parliament, this statement led to changes in the EPO's implementing rules as of July 1, 2017. As of that date, patents are no longer granted on the products of conventional breeding.

In 2019, a Technical Board of Appeal of the EPO ruled in a different case, G 3/19 Pepper, that the interpretative statement of the European Commission has no legal value and that the amended interpretative document is not in line with the European Patent Convention. Finally, on May 14 2020, it was decided in the EPO Enlarged Board of Appeal that interpretation of the Biotechnology Directive based on the dynamic interpretation is valid and all patents on improved crops filed are no longer valid. However, patents filed before 2017 retained their validity (EPO-BA, 2020).

The EPO's revised view on this is explained by the unanimous position of member states and the importance of harmonised interpretation for EPO members. This decision is a relief for the breeding's sector after the decade-long ambiguity (R 2, 4, 18).

Patent attorneys see that this decision is not of much value at this point, and the EPO lacked retroactivity (R 13, 14, 15, Kock, 2020). Patents on improved crops were already almost non-existent, and there is more demand for patents on newer technologies (Kock, 2020). In addition, the problem for breeders, who were very much fighting for this, has not been solved with the future role of 'New breeding Technologies', which will make patents play a more prominent role for the breeding sector (R 7, 13), which is discussed in the next chapter.

Position of the EPO

The European Patent Office plays an essential role in granting patents in Europe. The EPO is the executive body of the European Patent Convention (EPC). Changes to the legislation of the EPC are possible if a majority of EPC member states are in favour. Another way is that the EPO identifies when the national patent law of the member states shifts for a specific rule and the general consensus of the EPC has changed. An example of this is the Biotechnology Directive in 1998, which has also been incorporated into EPC legislation because there was a clear consensus on this issue among member states of the EPC.

Another example is the broccoli-tomato case, on which clarity was rejected in 2020 with the G 3/19 pepper case. The general consensus is measured through national legislation (R 19). For example, the EPO does not provide patents on inventions that are related to euthanasia. Among member states of the EPC, there is no clear consensus on the acceptance of euthanasia, and therefore the EPO excludes inventions related to patentability (R 19). In the end, the EPO's value is to provide consistency and equal access in patent applications, and they try to distinguish the changing consensus from the changing political trends (R 16, 19).

The EPC states that inventions that violate good morals and public ordre are excluded from patent law. This legislation gives room for interpretation and depends on the country where the patent is granted. The EPO always works with three people on a patent application for over a year. If there is any ambiguity or doubt in this group about whether the patent should

be granted, the patent is labelled with SeCa, which stands for Sensitive Cases System (R 19; Forsberg & Groenendijk, 2019). These cases are registered and handled independently by examiners who have more knowledge on these topics. This often goes beyond the technical assessment of the patent but has ethical, social, environmental and economic implications. The SeCa system is used frequently for biotechnology patents, but also in other technology areas, additional assessment is necessary (R 19). Parthasarathy (2017) describes after in-depth research of the European patent system that the EPO has done a lot of work on improving their reputation and how the examiners assess ethical concerns of the patent system since the Oncomouse case. However, respondents (3, 6, 9, 12), Forsberg & Groenendijk (2019) and Parthasarathy (2017) criticise this SeCa system for its productiveness for society and that still economic benefits are chosen over public consequences. This concern arises from the more technical approach that EPO examiners take in when granting patents.

"I think patent examiners very much prefer to see their actions as merely technical and not as political or regulatory. The European Patent Office is a public agency which has to be aware of granting patents in the public interest. The public interest and the interests of the applicants do not necessarily have to be the same. There may be conflicts of interest, and the Patent Office has to be aware that it is a publicly entrusted institution which has to take care of other interests, of the sources, of the users, of other publicly set goals and not solely the interests of the applicants and their competitors." (R 9)

The representatives of the EPO note that the institution has been struggling with its reputation and the reputation of the patent system (R 3, 9, 19). An often-mentioned reason for the criticism on the EPO by respondents was explained by their financial incentives. The incentives for the EPO are to grant patents rather than to refuse them because of financial incentives (R 4, 6, 7, 9, 11, 12).

"There are some inbuilt mechanisms within the patent system which may lead towards a bias for the applicants. For instance, the self-financing mode of the EPO means that there is an incentive to grant, and there is less incentive to refuse patents. The whole system works mainly through the interaction between applicants and the Office." R 11

As mentioned previously, often patent legislation is confused with problems that do not fall within the reach of the patent offices, such as the safety regulations for GMOs. They see that there is lacking information on the patent system and what exclusion from patentability practically means. The awareness of possibilities with patents is low in some parts of society, which must be improved (R 19). For example, university students do not learn about the patent system in their (technical) studies, while patents play an important role in their future work. Also, often when small size companies are sued for infringement, this is sometimes the result of lacking knowledge on patents. The EPO representatives (R 19) say the EPO aims to be as transparent as possible and creates initiatives to inform more people about the patent system.

4.2 Context: CRISPR

The second case portrays the current situation of modern biotechnology and identifies what challenges lay ahead for actors in the green biotechnology sector.

4.2.1 Technology applications characteristics

CRISPR is a gene-editing technique that modifies the genome of living organisms and to alter DNA in humans. The first version of CRISPR technique was the CRISPR-cas9 system, which is traced back from a natural gene-editing system in bacteria that constantly combats viruses. The acronym of CRISPR stands for Clustered Regularly Interspaced Short Palindromic Repeats and forms together with the enzyme cas9 the basis for CRISPR/cas9. Meanwhile, research has shown that other enzymes are also working with the CRISPR system such as Cas12a, Cas13 and MAD7 (R 7, 8, 14, 17, 20; Zhu et al., 2020). The performance of these enzymes is currently studied and the enzymes are still competing for which one has the best and efficient performance in different applications (R 7, 8, 16).

The CRISPR system enables targeted cuts of the DNA, modifying the existing genetic material or inserting external material in the DNA. However, the technology is researched and the precision of targeting DNA is under still development (R 3, 8). Scientists and companies follow the advances of the CRISPR with great interest because the technique promises to be faster, cheaper, more precise and more efficient compared to other gene-editing techniques. Other techniques such as previously discussed Recombinant-DNA and the NBTs have not such a broad application as CRISPR and do not enable such complex targets such as climate resilience (R 7, 8). In addition, CRISPR offers the possibility of changing the genome of the organism in places without the need for foreign genes. This is a step forward compared to Recombinant-DNA. Sometimes it is the case that the changes made with CRISPR are not identifiable in the genome because the modifications can also potentially occur in nature through mutations or through selection and crossbreeding (R 13, 17; Smith, 2019).

As a result, CRISPR is also seen as a key technology that is fundamental to a large number of societal challenges (Feeney et al., 2018). An important one is medical application where the focus is on human treatment or drugs. The potential of CRISPR is now being explored in a wide range of diseases from disorders of a single gene, such as sickle cell disease or more complex conditions such as cancer or HIV. In addition, a potential area of application lies in research tools involving animals. Finally, it offers many possibilities in agriculture and food supply (Feirrera et al., 2018). The role of CRISPR in agriculture and food supply is the focus of this case study.

4.2.2 Ethical and safety concerns

The progress of CRISPR has not gone unnoticed by some civil society organisations and is for these organisations a cause for concern. Similar organisations as in the previous case, are critical towards the development of the technology. The same ethical and safety concerns come into play with CRISPR, such as the possibilities to adapt germline cells that will pass the modifications on to the next generations. Additionally, the characteristics of making simple, precise and cheap modifications are amplifying the concerns. For example, there is the dreadful scenario that CRISPR is used for improving natural human traits, such as height and intelligence.

"A lot of concern over the last number of years from people who would look at this egalitarian issues. Or effects of new biotechnology. Would be that it would create hitherto, unseen inequalities between people. That people would have access to something that would make them stronger - some people - stronger, fitter, healthier, longer living. Stronger, more

intelligent. If we were talking about enhancements, and so on. Than other groups of people who wouldn't have access." R10

This kind of situation is prohibited in Europe with the genetic modification directive. However, some parties feel that misuse is expected. A controversial Chinese publication in November 2018, is an example of this. The publication revealed that the scientist, who went against national law, created the two designer babies Lulu and Nana with genetic engineering. In China and in the rest of the world his action was received with abhorrence. This scientist was convicted for his actions, but the harm was done and, it resulted in enormous global turmoil about genetic engineering of human germ-cells. From some advocates of CRISPR technology, this action was disruptive for the social debate on GMOs (R 8, 9, 19). Because on the contrary, CRISPR does not have the ability to simply design the genetic makeup and the designer babies were developed against all legislation in China but also would not be allowed in Europe. In general, its feared in the biotechnology field, that the largest determiner for successful commercialisation of gene-editing technologies is the acceptance of the public (R 16, 17, 18, 19).

At the moment, application of CRISPR technology is still strictly regulated in the EU under the GM Directive 2001/18/EC (EC, 2001). Commercial use of the technology is therefore not yet feasible in Europe due to the costly and lengthy safety protocols. Some scientists and breeders would like to see this change for gene-editing techniques that are limited efficiently add traits to a plant species that are species-specific. In other words, gene-editing results in the same plants as when conventional breeding is used, but a lot of time is saved and it is simpler to combine traits (R 7, 8, 13 17, 18, 20, 21). Advocates for changing GM law say that it carries less risk than the transgene traits added with Recombinant-DNA and therefore the regulation should make a distinction between species specific traits and transgenic trait.

"And why the breeding sector in particular that [GM directive] is not relevant to gene-editing is because you stay within the genome and the mutations that occur can also occur in nature. They could just as well occur when you cross two tomatoes with each other." (R 17)

In a recent report, the European Commission confirmed this distinction between the use possibilities of gene-editing technologies such as CRISPR and the transgenic results from Recombinant-DNA technologies (EC, 2021). However, no further action points have yet been formulated to control CRISPR through alternative routes than GMO legislation. The process of deregulation of the GM protocols for gene-editing techniques will still take some time and that means that commercialisation of gene-editing technologies has to wait. Currently, the larger companies in the breeding industry are testing what the possibilities for CRISPR, among other techniques, are for them and to prepare for when more is possible (R 13, 17).

4.2.3 Developments of CRISPR and IP

Inventors

The invention of CRISPR/cas9 can be traced back to 2012, when Jennifer Doudna (University of California) and Emmanuelle Charpentier (Max Planck Institute) were the first to publish on this technology. Recently, they received the Chemistry Nobel Prize for this. Another important CRISPR/cas9 scientist is Feng Zhang. For the Broad Institute, he published in 2013 a method to modify the genome in humans and mice with CRISPR/cas9.

At the time, the University of California was the first to file a patent in 2012. This contained a broad description of the technology without yet a clear application of the technique. A year later, the Broad Institute applied for a patent with a fast-tracked procedure that allowed them to

receive a US-patent before the patent applicants from California. This patent stated the application of the technique in eukaryotic cells of mice and humans. Since then, there has been a battle over the scope of these patents.

The University of California has not acquiesced in the decisions of the United States Patent and Trademark Office (USPTO) and the Supreme Court that their patents describe separate inventions and do not overlap with the California patent. At this point, the patent holders are still waiting for further developments, but there is little chance that the Broad Institute's patent will be rejected. It is likely that the University of California will lose the entire patent or will have to share it with the Broad Institute, because in September 2020 it was decided that the patent with the described application of eukaryotic cells will not be rejected (Cohen, 2020). In Europe, the patent of the University of California has more chances, due to a mistake in the application of the Broad Institute. Recently, this patent was rejected due to an incorrect inventor's name on the patent. What the consequences of this will be for Broad is still unclear, but there is a chance that the positions of the two universities will be reversed in Europe.

There has been criticism of the role of these universities in the 'battle' over CRISPR patents. The IP costs incurred could have been avoided by coordination between the two parties. Meanwhile, the cost to the Broad Institute for protecting CRISPR/cas9 has been estimated at least $81.6 million.[2] Due to the ambiguity of the patents, investors wait for further developments and in the fear that they bet their money on the losing patent (R 3). In addition, the patent pool set up for CRISPR/cas9 is not getting off the ground because the patent holders do not want to participate in it. Thus, the public role of these public universities differs compared to the Stanford licensing program of the recombinant-DNA patent and the current actions of these universities does not contribute to the public. This infighting between them can be explained mainly by protecting or upgrading the reputation of the universities.

"Yeah, yeah. So, I think patents nowadays, they have many different functions. It's not just about having a glorious invention. And having a genius and then giving him a monopoly for a limited time. Timespan. It's very much about reputation. It's very much about showing off, that you are an innovative University. So, it's, it's a lot about reputational factors as well." (R9)

"Especially, now with the Nobel Prizes being given to Doudna and Charpentier, which is what part of this is obviously all about." (R3)

Also, some argue that private institutions would never have been able to put so much money into the litigation that has been going on. The public parties are not depended on the profit and wide spread of the technology, as private companies would be (R 7).

Another criticism and concern from Europe are the IP strategies of the two universities with the core patents for CRISPR/cas9. The licenses are granted to a few large multinationals like DuPont and spin-off companies like Editas Medicine from the Broad Institute and CRISPR Therapeutics from the University of California. Corteva Agriscience is a company supported by the Broad Institute and on paper they promise open innovation (Corteva, N.D). In practice, their license terms turn out to be non-transparent and there are quite a few conditions attached to using the license. Corteva holds the most important patents for agriculture.

However, research can take place without too many problems. Also, therefore, there are already several enzymes that can work with the CRISPR system. For many parties it will become more attractive if an enzyme other than cas9 turns out to be good for use in order to

[2] (R 13): See 10-K reports of Editas Medicine available under: https://ir.editasmedicine.com/static-files/fcdbc9e0-a378-4020-846a- 8013ff5fbe75. https://ir.editasmedicine.com/static-files/bd9916b8-4cca-41c9-ba27-d362c131fda0.

avoid the cas9 patents. The future will show whether this costly battle over cas9 has been worth it. The other enzymes offer hope for good function with the CRISPR system.

"The best thing, for the entire field, is for the parties to reach a resolution and for the field to focus on using CRISPR technology to solve today's real-world problems" (Cohen, 2020).

In recent years, the patent landscape for CRISPR technology has evolved rapidly and is referred to as a so-called minefield for CRISPR users due to the number of patents and its complexity (R 3, 7, 13). Notably, the landscape of numerous patents on CRISPR/Cas9 is complex and dominated by five universities (Ferreira et al., 2018). But as noted before, other enzymes have proofed to work with the CRISPR system and are currently studied for their performance.

"It is good that there are different enzymes on the market that work with the CRISPR system. They have different applications and the scientists have preferences for specific ones with certain applications. You would have to ask them. This variety in enzyms gives you a better position in the negotiations for the licenses. And look, the essential patents will be free for all to use in 10/11 years. We'll really have to deal with it in the coming decades. But there are also advantages to it, so then you have to look for other ways to collaborate" R 17.

This development is beneficial to the situation since it will bring competition among the patents, and when more knowledge is retrieved on these enzymes, the Cas9 patents might not be the only important patents in the field.

New dynamics for plant innovation

Now I will continue to develop the situation for plant breeders with the current situation for plant innovation and what the predictions are for these stakeholders. Currently, PBRs are still most commonly used in this sector. The IP tool provides sufficient protection and leaves room for innovation because of the breeders' exemption. The gene-editing techniques will make it possible to patent traits that are modified by these techniques. If the patented trait is used in a new plant variety, a plant breeder needs permission from the patent holder to use it in a new variety. For this reason, the patents on traits make that the plant breeders' sector is more and more interfering with patent rights. As noted before, most of the plant breeders do now not have the knowledge or resources to deal with patent rights. Often these plant breeders have no IP specialist to propose patent strategies, and next to that they do not have to money to go to court for infringement cases. The emergence of gene-editing technologies will therefore limit the freedom-to-operate for small-size breeders. Breeders are concerned that there will be reduced access to genetic material to develop new varieties due to the rise of patent thickets.

These technologies will affect this sector more than in the previous case of recombinant-DNA and PCR. Also, because no comprehensive solutions like the ILP, or patent pools are initiated for these technologies. In addition, to develop characteristics, breeders often need various methods that are also protected by patents. In some countries these patents also protect the resulting product and can therefore also determine the commercialisation of a new variety. This may also require complicated licensing negotiations for developing a new species.

Next to that, traits play an increasingly important role for the development of new plant varieties.

Plant varieties with Complex Traits

Plant innovations have the unique innovation character, that the complexity and degree of integration is continuously increasing. Unlike other areas of innovation, new plant innovations

do not replace the former, but rather build upon and improve upon them, forming increasingly complex ‘stacks’. The complexity of traits contributes to genetic diversity (Smith, 2019).

Studies indicate that future yield gain will almost exclusively be contributed by improved genetics, to achieve the challenges agriculture faces of raising productivity while ensuring sustainability and improving resilience (OECD, 2018). To live up to this reality, breeders have to work with increasingly complex challenges. Breeders must combine an increasing number of traits in one breed, to ‘stack traits’ (R 7, 13, 17). One driving force for this is (local) climate change to which plants have to be adapted. For example, traits can lead to effective use of water and other plant resources of the plant. To prevent plagues three to four new traits, have to be used, to be able to protect the crop to be eaten by different insects and herbicides. Another factor is that, there is increasing environmental and public scrutiny against pesticides, which makes it more attractive to create natural resistance genes in plants (R 7).

The more complex the characteristics of a plant, the less likely it is that these varieties can be bred within a feasible timeframe using conventional techniques, and genetic engineering is therefore essential for the development of new varieties (R 21). As a result, the development of new varieties also requires large investments that can be recouped through intellectual property protection.

“I was just talking about the trait to prevent 'corona' among tomatoes, but that is only one aspect. You also want the variety to yield a lot. That it is drought-resistant, so it can cope well with little water. Apart from the 'corona', there are also insects that damage the plant e.g., the white fly. Besides that, you want it to be a tasty tomato, with a sweet taste, you want it to have a long shelf life, etc. There are dozens of characteristics that a breeder ultimately wants to combine in a variety. That means that developing a variety according to the different objectives the breeder has set, is a time-consuming process of ten to fifteen years. Breeders are therefore now working on the varieties that will be on the market in two decades' time. With some it goes a bit faster, like lettuce or spinach. With onions, however, it takes a long time. They are a variety that has to grow two years, and it can sometimes take up to thirty years before a new variety is on the market.
That is why you see far fewer patents for onions and asparagus, because before you are on the market, your patent has already expired.” R 17

However, some parties are more concerned about the amount of licenses that will be needed and the complexity of plant patents due to the expected growth in this field (R 7, 18, 21; Contreras, 2018). This will be able to lead to more use of trade secret in the industry. Trade secret is just something that should be avoided from a public policy perspective because it prevents the spread of knowledge. The possibility of reverse engineering is simple with the PCR technique by sequencing DNA for plants obtained by simple techniques or classical breeding or keeping the parental line of plant varieties secret. Hybrid plants are not stable and therefore a second generation of the plants will not result in the same plants with the same characteristics (R 13, 17). Also, for plant varieties obtained from a more complex process, it is more complicated and often laborious processes to retrace the genetic basis (R 13, 21).

4.3 Evaluation of Public values underlying the Dutch Patent system

The following section evaluates the Dutch patent system according to the four criteria of effectiveness, efficiency, reliability and inclusiveness, as depicted in the theoretical framework. The review of the criteria also addresses the reassessment of the safeguard mechanisms;

biotechnology directive: the exclusions of patentability, ordre public, morality; opposition procedure, and; compulsory license.

Finally, this section compares the three concerns established in previous research to the results of this study. These concerns included (1) the ethical debate whether to patent living organisms, (2) the concern that patents hinder innovation (tragedy of the anticommons) and, (3) the concern that patent reduce biodiversity in this field.

4.3.1 Criterion 1. The system is effective

The patent system protects inventions that are socially desirable to incentivise their development.

This criterion looks at whether the patent system protects innovations that are socially desirable. Modern biotechnology has contributed to society with Recombinant-DNA, PCR and CRISPR, as discussed in this study, and many more technologies. The patent system has contributed to stimulating these technologies and contributed to the spread and further development of Recombinant-DNA and PCR.

The introduction depicted the concern that research and commercialisation of biotechnological innovations would be stifled with the rise of patents in this field (Boldrin & Levine, 2013). In the first case these fears have not been realised. The patentholders of Recombinant-DNA provided a socially desirable licensing program that was beneficial for private companies, while contributing to society. PCR technology initially started with a narrow licensing program, but it soon became apparent that this was not successful for dissemination of the technology and for the company itself. Later, the strategy of Hoffman-La Roche proved that a non-exclusive licensing program for a technology with such a broad application was beneficial for both the company and the public (R 3, 5, 10, 21; Feeney et al., 2018).

Research of Contreras (2018) studied the phenomenon of tragedy of the anticommons, the second concern, twenty years later in practice. The study concluded that up to present time, the problems resulting from complexity of patents in this field have stayed limited. Respondents from this study from the different stakeholder groups have confirmed this (R 3, 4, 7, 11, 13, 14, 15, 18).

The tragedy of the anticommons was prevented because the number of patents needed for plant innovation have remained manageable, together with the initiatives providing access to patents and transparency. The ILP and PINTO are two successful examples of voluntarily collaborative initiatives that were started to ensure access and transparency. Clarity on patent ownership associated with commercialised varieties and technologies facilitates improved legal access and licensing (R 13). Also, organisations conducting plant breeding and technology development have learned how to manage IP much more effectively during this time when the first patents were entering the arena of plant variety improvement (R 4, 7, 13, 21; Smith, 2019). However, improvements can be made for some breeders in the sector. Because knowledge and awareness about the patent system are still limited in some cases. Due to limited resources, but also because their traditional attitude towards patents and the new technologies (R 4, 15, 18). Also, some factors in the patent system indicate that incentives for innovation within this field might not be the obvious result in the future (R 4, 7, 13, 18). For example, the ILP is now limited to the vegetable crops and is as well as PINTO based on voluntarily participation to provide success.

The technology of the second case, CRISPR, has not completely unfolded yet. First because the technology is relatively new and due to ethical and safety regulations in Europe the technology cannot commercialise. Second, the patent dispute between the University of California and the Broad Institute is not settled yet. The first patents on CRISPR/cas9 were

granted in 2014 to The Broad Institute. So, years have passed and it is expected that the EC will take some time to adapt GM directive (2001/18/EC), so gene-editing technologies are exempted from these regulations in Europe. Duration of the patent expires. However, companies and researchers prefer to access the licenses for research and development practices. Also because developing of new plant traits are time-consuming process. This is limited to large companies that have the resources and negotiation position to attain licenses for CRISPR

At the same time many patents on CRISPR/cas9 and other enzyme combinations are applied for. So, there is a wide interest in working on advancing this technology. And currently, the licensing programs for the foundational patents of CRISPR/cas9 are not contributing to a wide spread of the technology, in contrast to the previous case study.

"The ability to exclude people from using a really powerful research platform is, I think, socially extremely worrying. The two other examples we've had in the past are recombinant-DNA where Stanford generally licenced it, and PCR where eventually it was generally licenced. The question is whether Broad and Berkeley will go that route and make it relatively easy for newcomers to investigate to try and develop new products, or whether they will keep the [patents], the key areas, to themselves and their friends?" R 3

The patent battle between the two universities create uncertainty and have hold off initiatives to form a patent pool.

"It seems that it is especially the University of California which is blocking a "patent pool". Reputation is certainly one element ("we are the first inventors"). However, most likely also the fact that the universities (both UC and Broad) have granted exclusive licenses to start-up companies is a key factor. For the start-up their future and likely the majority of the valuation depends on the exclusivity. This again shows that it is a fundamental policy flaw if public institutes are allowed to grant exclusive licenses. It should be by law that any innovation resulting from publicly funded R&D should only be out-licensed non-exclusively. Here the greed of the tech transfer office managers is actually destroying public value instead of creating it." R 7

Today, there are also other enzymes that offer potential for the CRISPR system. the development of these enzymes offers competition and it remains to be seen in the future which enzyme will have the greatest contributions. Also if this will result in more competition and therefore reduce the monopoly power of current patent holders (R 14, 16, 17, 20).

Next to the foundational patents of CRISPR, there are many overlapping patents that could indicate patent thickets (R 7, 21; Smith, 2019). Yet there are no large-scale consortia to make access possible.

The criterion of effectiveness also covers the first concern, the ethical considerations of the patent system which are delineated in the following section.

Ethical considerations of the patent system

This criterium assesses whether the patent system also prevents inventions to be granted when this protection is socially undesirable. As described before in the context of both cases, modern biotechnology has forced humans to reconsider ethical and moral borders. During the drafting of the Biotechnology Directive the ethical debate found its general consensus on some of the aspects of modern biotechnology application. Special exceptions of patentability were composed for modifications of the human gene and cloning and are described in article 53(a) in the directive.

During this time, the large-scale debate contributed to adaption of patent legislation to the new technology developments. This was possible because the debate resulted in consensus on some of the ethical aspects and influence of stakeholders throughout Europe. Which made it possible to include these new rules into the legislation of the EPC.

The execution of the examining of ethical concerns in the patent system is still a concern for respondents. The approach of the EPO has improved, but take into account the social consequences will be necessary. This will remain important, since the use of recombinant dna will still be prevalent in the patent system

The developments of CRISPR are going fast. So, more ethically questionable patents are applied for in the future. The fast developments of this promising technology and the characteristics of easy and cheap application require a new debate on how access to this technology should be regulated. The main tension is that because of the pace of adoption there is limited time for a large-scale ethical debate. Therefore, the inventions will develop faster than that European consensus will arise, so an improved mechanism is necessary to examine these patents. To create more clarity on this initiative must be taken for large-scale debate. To bring the debate further for CRISPR, then only limiting to anti GMO advocates. Because the public is scared for the consequences of GMO, and labelling GMO will reduce profits for companies. Even though this is not falling under the scope of the patent system, this is an often named factor influencing the development and dissemination of the technology.

Compensation for revealing secrets

One of the pillars on which the patent system is based, is that in return for a monopoly, patent holders have to reveal their invention. So, this information can help other inventors develop the ideas, and this forms effectively a contribution to society. The other way, which is not preferable from a policy perspective, is the use of trade secrets.

In the field of biotechnology patents are an often-used tool to protect new products and processes. In the field there is an increase of patents because of the high competitiveness in the field. For instance, patents are favourable for inventors when several others are making similar discoveries at the same time. The perfect example of that is the development of CRISPR. The inventor that assumes that no one else comes upon a similar idea would not have a reason to patent his or her invention. This trend of increasing the number of patents, also ensures the revelation of information, so others can develop this.

The patent system is said to encourage inventors to disclose their inventions instead of keeping them secret. But in some situations, practice proves differently. In general, it is the case that only the information that cannot be kept secret is revealed against compensation (Karbowski & Prokop, 2013). There is increasingly a trend of using trade secret as a way to protect IP (R 11, 13, 15, 17; Holman, 2016; Contreras, 2018). In contrast what previous literature suggests, the shift towards trade secrets might be in favour of the large companies than small start-ups and universities (R 16, 17, 20; Holman, 2016). Particular the academic field emphasis on publication for open innovation and sharing information (R 5, 9). For start-ups patents play a critical role in fundraising and as a means for validating technology for licensing (R 14, 20, 21). The patents are important for these companies to convince investors choosing for their companies.

In the biotechnology field, trade secrets can be used for protecting methods, certain formulae, and 'know how'. Trade secrets are used as a complementary option or are used with appropriate measures such as restricted access, secrecy agreements and physical security measures (R 17; Smith, 2019). There are two reasons that contribute to the increase in trade secrets in this field. First, the knowledge embodied in non-hybrid seeds shares the non-excludable and non-rival characteristics of a public good. The possibility for 'free riders' is to replant harvested seeds of varieties. In contrast, hybrid varieties are endowed with a biological form of IP rights, which incentivises farmers to purchase seed annually and which can allow parental lines to be maintained as trade secrets by the developing company, and thus do not have the non-excludable and non-rival characteristics of a public good (R 13, 14, 15, 17; Smith, 2019). Consequently, regarding hybrid crops, this form of trade secret can provide a very high level of protection. In such a case the use of patents facilitates better to society in terms of licensing and revealing the secrets behind the gene editing of the product.

Second, according to respondent (7), when the complexity of plant patents increases to a point that it is virtual impossible to have all of the right licenses, parties will move towards trade secret. This situation of complex patents landscape is a feasible result with the rise plants as a result of gene editing. Also, Contreras (2018) supports this and sees the increase of trade secrets as a threat to the socially responsible functioning of the patent system.

4.3.2 Criterion 2. The system is efficient.

This criterion has two aspects. Starting with that the system works efficiently when it incentivises investors with a reward for their invention, as a return on their investment, that is of substantial size to stimulate them to innovate, but that is not larger than necessary. Furthermore, this criterion requires that the system operates at minimal 'system costs'.

To start with the first aspect, the IP system provides two forms intellectual property to the green biotechnology sector. The PBRs are a sufficient reward for the current plant innovation when it comes to conventional breeding. This IP instrument stimulates innovation by providing certainty that the time spent developing a new plant variety will be recouped (R 4, 7, 12, 14, 17, 18). This has resulted in a diverse sector of small-size breeders in Europe and in the Netherlands (R 4, 7, 13, 14, 18). Small and large breeder companies that develop new plant varieties, characterise the sector as a highly competitive sector. In order to, compete in the market, the companies have high reinvestment rates. According to respondent 17 and 18, this is possible because of the IP possibilities in the sector.

> *"The high investments are necessary because the NL market is very competitive. Most vegetable companies in NL reinvest about twenty percent, which is no big secret, of their turnover in new R&D. If you are not sure that you can still innovate tomorrow, you would not reinvest so much."* R 17

The larger companies complement their PBR portfolios with patents on processes and traits derived from biotechnology advances. These advanced breeding's technologies are costly technologies and demand skilful people, is argued by R 17. The company related to R 18, is more a middle size breeder, but they position themselves in the 'anti-patent' group for plant innovation. R 18 describes that these patents are blocking access to traits and hinder plant breeding. This company does apply for patents, as a defensive patent strategy, but use a non-exclusive licensing strategy. So, other parties can access their patent in return for a reasonable price. The company fears that the existing balance for plant breeders will be disturbed with the

use of patents and development of new plant varieties will become less, because all traits will be covered by patents from multinationals (R 4, 12, 18).

A solution to this would be a breeders' exemption for patents on plant traits. That gives breeders the possibility to develop new varieties with patented traits, without the permission of the patent holder. So in other words, the breeder pays a license to patent holders for patented traits, the breeder combines them in a new plant variety and can protect this variety with PBRs and sell it.

The second aspect of this criterion requires that the system operates at minimal "system costs". Regarding this aspect, a concern arises when the costs for innovations become higher than necessary to reward the inventor. From this perspective, transaction costs and patent disputes should be prevented as much as possible. First, in the first case-study patent thickets where mostly prevented because of collaboration initiatives to provide access to patents. With the increasing number of patents in the field of CRISPR and other NBTs, there are many overlapping patents (Feirrera et al., 2018; Smith, 2019; Egelie et al., 2016). This means that patent thickets are apparent in this field of study. The characteristics of plant innovation of stacking traits, will make the situation for patent thickets worse. Patent breeders will have to combine patents on these traits and with methods for these NBTs.

Therefore, the number of licenses necessary for developing new plant varieties might go up to four or more. This will bring about higher transaction costs, which were previously not needed in the plant innovation. In return, the public will gain plant varieties that contribute more optimal to disease resistance, herbicide resistance, increasing yield and improving quality, that might contribute to adaption to climate change and water drought (Zhu et al., 2020). However, the transaction costs for these patent thickets can be reduced, as is visible in the electronics industry. The initiatives for patent pools are therefore necessary and a widespread voluntary participation in these patent pools.

The last costs that are socially undesirable is the patent dispute between the public organisations about the CRISPR/cas9 patents. The roles of universities and public organisations have changed in the patent field in the past years, with different outcomes as a result. Universities have more patents nowadays and universities also play an important role in the development of foundational technology CRISPR/Cas9. The licensing program of the main patents of this technology are controlled by a few patent holders and they license the patents exclusively to specific companies under secretive terms and their spin-off companies (R 3, 4, 7, 17, 20). This is contrary to their role as public institutions and the fundamental role of this technology for society. The natural law argument relates differently to publicly funded institutions. Next to that access to this this foundational technology is limited, the institutions are part of the costly patent disputes. The reimbursement of IP costs to the Broad Institute alone has now amounted to $81.6 million (R 13). Normally in such a situation private actors would argue for a patent pool. Despite some attempts a holistic patent pool is not (yet) foreseeable (R 21; Neville, 2020; Smith, 2021).

4.4.3 Criterion 3. The system is reliable

The system applies the rules consistently and correctly, and it is clear based on which arguments patents are granted. Also, the patent system accommodates legal certainty: patent holders can be assured that their rights will be respected and protected under normal circumstances.

This criterion evaluates whether the safeguarding mechanisms in the patent system are implemented in a socially desirable way. During the first case, rapid developments in modern

biotechnology challenged the patent system and the implementation of these mechanisms. This section evaluates the safeguard mechanisms one by one.

First, the mechanism depicted in the Biotechnology Directive to excludes inventions from patentability because they are not in line with the criteria of the patent system such as ordre public and morality. The EPO describes that whenever new technology developments, but also social issues occur, it takes time to set the boundaries for these new issues. A recent example presented, is the social issue of euthanasia and patents on the medicine that can support this process (R 19). The EPO will in this case not grant patents for a medicine for this because a majority of the EPC member states does not allow for euthanasia and this is not in line with their public values. The EPO will wait until more consensus on this topic arises, which then should be reflected in national laws, before granting patents. This shows that the patent office nowadays includes public values more into their governance of patents. The Oncomouse case taught that decision making regarding ethical considerations should be transparent.

However, the concern depicted for the ethical considerations of CRISPR technology were that the rapid development of the technology does not allow for a large-scale debate and the patent system now is opened to granting patents on this technology. The ethical balancing tests are criticised by social organisation, to be too much in favour of the economic benefits and limited room for animal suffering. Therefore, initiative for large scale debate on the boundaries of the patent system and ethical issues related to animal dignity, is essential for proper further development of the technology and its effects on the public. Also, the EPO improved on how they handle ethical and other concerning issues with the SeCa system, however respondents argue that the approach still a technical assessment is rather than a assessment of the public values underlying the patent system.

"The question whether patents on biotechnology inventions are ethical acceptable (are specific cases considered in this patent system). The ethical discussion is about whether patent offices should be making moral decisions while granting a patent and if they have the competencies for this. While on the other hand, civil society groups say that patents are an incentive and a grant is in need of ethical considerations." Q R9

The approach of the EPO itself is more that other regulations should provide restriction on the ethical issues. The EPO see the patent system more as a technical examination including the aspects of article 53(a) (R 3, 6, 7, 10, 12, 16, 19). In their view other legislative mechanisms should make clear whether inventions are ethically tolerable and should be allowed (R 16, 19).

Furthermore, controversies like the Oncomouse and the Broccoli/tomato case are creating long times of uncertainty for inventors, which is not in line with this criterion of reliability. The large-scale debate should result in pre-defined boundaries that provide clarity. So, the Ordre public and morality, two very broad and vague terms should be more predefined. he articles regarding these issues are widely interpretable and the EPO took standpoints in a more 'free market' or liberal point of view (R 12).

Patent offices could provide a more reliable system if they increase to open to the public. Encouraging public discussion to social balance patents and finding a better space to determine what is the right balance in the patent system between patent holder and society, by identifying what is favourable for innovation and for social welfare and what is not.

The public controversies must not be seen as threatening the reputation and the image of the European patent system but as supportive in terms of social balancing of patents and in terms of determining what is the right equilibrium in the patent system, what is favourable for innovation and for social welfare and what is not. These controversies have to be taken very seriously. It is important to create forums for the discussion of patentability criteria, of patent

scope, of inventive step requirements. It would be helpful for instance to have a public conference every year or every two years for emerging technological fields and to discuss with experts in the field, not only with legal scholars and not only with technicians, but also with economists, with social scientists, with ethicists, and with civil society organisations and interested citizens.

The European Patent Office is undergoing a process of transformation. It has become more open to the public than it was in the past. My impression is that compared with the European Commission there is more sensitivity about the possible crisis and more productive irritation about whether patents really equal innovation or whether patents may in some respects be unfavourable to innovation processes.

Secondly, opposition procedure has been used increasingly since controversies arose around the first modern biotechnology patents. Social organisations found this mechanism to correct the awarding process of the EPO. However, sometimes the process is not decided before the patent expires. Also, the opposition procedures create uncertainty that is not beneficial for investors for the patent.

"The opposition procedure is one mechanism for bringing a counterforce into the system, used by civil society groups and researchers through interpretation of the law, but this is post-grant and has not been very successful (and very slow process)." R9

Lastly, the compulsory license is the mechanisms that is implemented by a national minister, therefore the decision to apply a compulsory license becomes a political one. During the interviews, compulsory licenses were hardly mentioned as a tool to correct the shortcomings of patent strategies regarding public values. However, it was mentioned that the compulsory license has more effect as a negotiation tool, to prevent companies from asking unreasonable prices for their licenses.

"It's a negotiating tool. If I go to [a large multinational] and say I want a licence and they say, okay, 60 percent, and I say that's ridiculous, I couldn't sell on the market. 'Very well, that's why we say 60 percent.' If I can then turn around and say if you give me a licence for this, I will give you a licence under this patent of mine that you want to use. 'Oh, okay!' Then it's no longer 60 percent, it's 2 percent. If I haven't got anything to licence, I could say if you won't give me a licence I'll go and ask for a compulsory licence and in the process it will become public just what obscene profits you're making and just how difficult you're making it for new, important, useful things to reach market just because you want to protect your market for your 50-year old machine which should've been scrapped years ago. The existence of the possibility of compulsory licencing is and of itself part of an arsenal you have when you're trying to get access to someone's technology." R3

If the compulsory license officially should be applied more often is hard to identify. The effects of the compulsory license as a negotiation or oppressive tool, are hardly studied because the effects are not measurable this way. Only behavioural studies could contribute to how companies determine their licensing strategies and what the role of the compulsory licensing mechanism is in those decisions.

4.3.4 Criterion 4. The system is inclusive

The patent system does not discriminate between inventors.

Through this study, five main stakeholders were identified for the patent system for green biotechnology. The data indicate that multinationals profit the most from the patent system with their resources and IP expertise and therefore also will benefit more from the developments with NBTs. The ownership power of patents has increased for multinationals. In the period that modern biotechnology emerged, the importance of patents has increased for this field for both researchers and commercial parties. This has resulted in a higher power concentration of large monopolies, which include mainly Syngenta, Monsanto, BASF/Nunhems, Limagrain, KWS. These seed companies that have access to the licences of NBT developing tools and have the possibility to already entail the new genetic engineering tools for research and development. For example, the patents for foundational patents of CRISPR/cas9 are now only accessible for larger companies, because licenses for a commercial use or to commercial entities are only available under non-disclosed terms which are likely quite onerous and therefore not feasible for smaller companies.

The multinationals can build a leading advantage compared smaller companies for this technology and therefore might have more control over these plant patents in the future. However, at the time it is not sure yet how detrimental this is for society because the commercial roll out of the CRISPR in Europe is still unclear and additionally there is still uncertainty on which enzymes will work the best with the CRISPR system in the future.

"In that respect we are in, I don't want to say, eh, luxury or comfortable position, but we are a big company and we have a large IP department. Therefore we are in a position to have access to the patent of CRISPR. So you do research as IP departments on what do I need, what processes am I going to apply, what do I need basically. And in this case, a number of institutes emerge that have what they call, essential patents for the CRISPR technology. And you sit down with them and say, hey I want to apply this for these conditions and then they come up with a licence proposal, with an agreement. On the basis of which that technology is licensed to us. That's actually how we obtain, what they call, the freedom-to-operate. And sometimes that means that you have to talk to three, four, five parties in order to settle the license." R 17

Furthermore, knowledge institutions are increasingly using the patent system for protecting their inventions. The results have shown that this can be beneficial to both the universities and the public, depending on the licensing program. The patents serve as an income for research at the universities. At the same time research is becoming increasingly interlinked with commercial application and with patents they can control the patents and get a fair reward for their research practices. Respondents suggest that universities work more often together with companies and start-ups or set up a surrogate company themselves (R 3, 9, 13, 15). The participation of universities in the patent system are an opportunity to steer in the direction of socially desirable innovations.

Social organisations have since the emergence shown an increasing role for controlling the practices of the EPO and patent legislation (Parthasarathy, 2017). Through the opposition procedure, social organisations influence patent cases and through this way they try to correct decisions made by the EPO. However, this has not always been very productive because the opposition procedures take a lot of time and sometimes the patent is expired (R 9, 12).

Lastly, the results signify that the common small-size breeders' in Europe, have the least benefits from the shift towards patents in this sector. Currently, the PBRs provide Small-size breeders do not have the capabilities to adapt to this shift to patents and gene-editing. However,

they have a vital function for society, by providing biodiversity and adaptation to local climates (R 4, 7, 18, 21).

The breeders participate in the group of anti-patents on living organisms. The inequality in access to patents leaves behind the smaller and traditional breeders because of the high licensing costs. It is feared that these patent monopolies reduce access to a large and diverse pool of seeds causing a reduction of biodiversity and environmental problems (Habets et al., 2019).

When no adaptions are made to international patent law, it is expected that the division between small-size breeders and multinationals will become larger. An often-made suggestion by respondents was that the transformation to a patent dominated plant breeders' sector is similar to the change in terms of use of IP that many other sectors have already experienced, including the pharmaceutical and electronics sector where new ways of managing the number of patents were established (R 3, 9, 11, 14, 15). In the electronics sector, patent pools are now a common form of managing patents. However, the lessons learned from these other sectors is that not all benefits generated will immediately preclude the provision of benefits to all stakeholders, including farmers and society at large (Smith, 2019). Determining mutually acceptable licensing terms therefore becomes the immediate concern to resolve to allow either commercial or humanitarian use of protected technologies (R 21). Ensure the wider availability of patent access to enhance innovation practices optimally to satisfy this argument of an effective patent system.

5. Conclusion

In this study I explored the dynamics of modern biotechnology and the Dutch patent system. The study evaluates how the patent system in the future stimulates biotechnological innovations that are in line with public values. In the recent decades modern biotechnology provided enormous breakthroughs in molecular genetics, with technologies such as Recombinant-DNA (1970), PCR (1980) and gene-editing techniques such as CRISPR/cas technology (2012).

Modern biotechnology is transforming the green biotechnology industry with constant innovations that can generate public benefits in food security, human health, industry and sustainability and largely influencing the Dutch sector. The societal benefits of progress in biotechnology are promising and therefore these technologies are incentivised by governments through the Intellectual Property system. Two main forms of IP are used in this industry, Plant Breeders Rights and Patents. Due to the changing innovation practices of modern biotechnology, the balance between the two IP tools is shifting. Partly, because patents are taking in a more extensive role for the industry. Patents provide monopoly rights to the inventor, as a reward for their contribution to society and in return for revealing the secrets so others can develop on this. Patents are shaped by the motivation of contributions to the public good.

However, previous research identified three concerns. First, whether the patent system sufficiently considers animal dignity and other ethical considerations. The second one is whether the patent system does not stifle innovation due to the number of patents. Finally, there was the fear that patent monopolies can reduce the number of breeders and therefore this will reduce biodiversity.

This study evaluated these concerns and whether the patent system contributes sufficiently to society. By utilising the public value failure theory of Bozeman (2002; 2007), by first mapping public values from formal documents and then by analysing data from interviews with stakeholders and experts in the green biotechnology industry. Finally, the public values are evaluated according to the four criteria of a socially desirable patent system: effectiveness, efficiency, reliability and inclusiveness.

Furthermore, the study explored what future adaptations could improve the safeguarding of public values in the Dutch patent system for biotechnological innovations. Accordingly, the research question guiding this research was as follows:

How can the current Dutch patent system be tailored to stimulate future biotechnological innovations that are in line with public values?

And the two sub questions:

Sub question 1: To what extent does the current Dutch patent system stimulate biotechnological innovations that are in line with public values?

Sub-question 2: What safeguards for public values implemented in the patent system stimulate biotechnological innovations that are in line with public values, and how is it ascertained that these are enforced?

In conclusion, the respondents and data collected in this study indicate that the Dutch patent system stimulates innovation in the field of biotechnology that benefits society, but that current and future technologies in the field of biotechnology may hamper the contribution of patents to society to some extent. Subsequently, challenges determined for each criterion are depicted.

Firstly, the criterion effectiveness consists of two main challenges. First of all, the effectiveness of the patent system is challenged in the future by the possible limits to access of plant innovations such as processes to develop plant traits and plant traits itself. Additionally, access to essential patents of a foundational technology such as CRISPR, is hampered by the patent dispute between the two initial patent holders of CRISPR/cas9. Until now, access to patents in this field was safeguarded because of socially responsible licensing programs and collaboration initiatives such as the ILP and PINTO.

The second challenge is the ethical consideration of the patent system. Mainly, the considerations of animal dignity in the patent system are found questionable by several social parties. But also, the rapid developments in the field of CRISPR demand for a reconsideration of the ethical boundaries aligning with the characteristics of this technology. Large scale ethical debate can help define clear boundaries of the patent system for the NBTs in the future.

Secondly, the criterion of efficiency determines if the patent protection provides a proper and reasonable reward for the inventions and if the costs of the system are efficient. In this study. The results of this study indicate that patents provide proper protection for molecular genetics technologies and innovations if you take in to account the risk, knowledge and costly labs that are needed to work with these technologies. In the case of foundational technologies, the right to exclude other might be against societies interest to disseminate this technology as much as possible. The patents on CRISPR/cas9 illustrate such an example. However, future developments of the technology will show whether the cas9 enzyme is the most effective combination with the CRISPR system and how the monopoly power of the current patent holders enfolds.

Additionally, to the criterion for an effective system, this criterion entails the goal to ensure freedom-to-operate, and centres around the reduction of transaction costs to prevent unnecessary costs for innovation. In the case future plant breeding, the number of patents in this field will continue to increase. Innovation processes could then include the situation that up to ten different licenses are needed to commercialise this innovation, for example a plant breed that has the characteristics of efficient water use and resistance to several plant illnesses and herbicides. To make these innovations profitable, transaction cost need to be maintained low through reasonable licensing negotiations. Other industries, e.g., the electronics industry, have shown that collaboration is helping to bring these transaction costs down, while benefitting to both society and innovators. However, the process towards a collaboration platform or patent pool requires careful consideration of governments to guarantee inclusiveness of the industry.

The third criterion of reliability covers the safeguarding mechanisms for public values in the patent system. The governance of these mechanisms can be improved to provide transparent and clear set boundaries for ethical assessment of the patent awarding process. The post-grant mechanisms seem not to have a direct contribution in correcting for public values. However, in some cases the compulsory licences provide a pressure to companies to give reasonable access and prices to licenses. Also, the opposition procedure contributes to the role of social organisation in the patent system, by giving those organisations a voice to correct social issues regarding patents.

Lastly, the inclusiveness criterion sees that patents contribute to the trend of multinationals strengthening their monopoly power with patents. But most importantly, the knowledge and awareness of the patent system is a way, not the way to completely solve it, but to improve this. Action from patent organisations, provide education as a government

Therefore, the findings of this study carefully conclude that the Dutch patent system incentives innovation related to green biotechnology that contribute to society, but several challenges could be adopted to ensure this in the future.

The following recommendations devote to solving these challenges. First, to contribute to the challenges of providing access to licenses in the green biotechnology field and limiting transaction costs for obtaining these licences for example plant innovation, two things could improve this. First, private initiatives such as the ILP for vegetable crops could be extended to other fields of plant breeding. What the International Licensing Platform does, is it brings together patentees and licensees of patents and patent applications covering biological material needed for vegetable breeding purposes. All companies working with vegetable crops can become members with or without a patent and this gives you access to all the patents held by ILP members in return for a reasonable fee. Secondly, national governments enhance this by supporting the formation of these collaboration initiatives and can lobby for protection of breeder's innovation in patent law. The Dutch patent legislation describes already that breeders should not be prohibited in their development of new varieties because of patent protection. However, currently this kind of exemption is limited in other European countries which include markets of breeders.

Second, large-scale ethical debate, between EPC members states, can contribute to the boundary setting of patent legislation regarding ordre public, morality and other exclusions to patentability. As the EPO can change legislation and assess patents in this field according to the results of a large-scale debate. This contributes to the last recommendation on improving knowledge and awareness of the patent system.

This point helps improve the knowledge of small stakeholders on how the patent system works and how to make profitable use of the system, which can supply the enhanced inclusiveness of the patent system (but not solve this problem). Next to that, a better understanding of what the aims of the patent system are and what safeguarding mechanisms are in place, can promote the reputation of the patent system and the EPO.

Practically, with this study I hope to contribute to the increase of knowledge and awareness of the patent system and the foundational values related to this system. This study provides an overview for stakeholders with limited practical experience in this field and specifies the philosophical and public values underlying the patent system. It is a first step to comprehend the complex interactions within the patent system and how the patent system contributes to innovation, to develop further policy on the patent system and have productive debate about (ethical) considerations of patents.

6. Discussion

This chapter provides a critical reflection on both the theoretical framework and the empirical results. Furthermore, it reviews theoretical contributions of this study. Lastly, future research directions are presented.

6.1 Limitations and alternative explanations

Due to the exploratory nature of this study based on qualitative data, several limitations of the research need to be taken into consideration, mainly regarding the internal validity, the measurement validity and generalizability.

The first part of the data collection was executed as a part of a larger research. During this part of the data collection, interviews were conducted together with other researchers and so was the data analysis, which was carried out in close collaboration. However, the second part of the data collection and analysis were conducted by a single researcher, reducing measurement validity and internal validity of the study. This concern was addressed in three ways: by performing data triangulation, by holding iterative rounds of expert validation and by documenting the empirical and analytical approach in all stages of the research process.

First, the highest possible measurement validity was addressed through data triangulation. The rich contextual data gained through 21 interviews was complemented with the document analysis. The interviews allowed for the emergence of new themes during the conversations, in addition to discussing pre-identified topics. Interviews were conducted until the point of theoretical saturation, meaning when no new themes appeared during additional interviews and findings from previous interviews were repeatedly confirmed in the last few interviews. The concepts and symptoms identified during the interviews were supported by the internal documents, publications of the stakeholders of this study, the scientific and grey literature examined as part of the document analysis.

Second, to compensate for low internal validity, the empirical and analytical approach was closely documented in all stages of the research process. The interview guides, and coding framework can be found in the appendix (Appendices 5.1 and 5.2). Transcripts of the interviews and the complete coding framework consisting of all the quotes can be obtained on request. Additionally, both in the beginning and at the end of the research process, experts from the field of study (namely plant breeders and IP specialists) provided validation for the theoretical framework, as well as identified concepts and findings. At different times in the process of developing the results I contacted respondents for verification. First, after I conducted the first part of the interviews, I verified most of the 13 interviews via email and identified what new respondents were beneficial to the further development of the study. In total I contacted

fourteen of the respondents to discuss the interview transcripts and more general results from this study. Mainly, information on how the patent system functions was validated by IP experts and patent attorneys that have years of experience, to compensate for my knowledge on IP law.

Third in order to increase the internal validity of the research, repeated discussion rounds with several of the respondents were held during the second round of interviews and while composing the results of this study. Also results were discussed during the weekly meetings with the researchers from the Rathenau Institute also during the second part of the research process, both amounting to investigator triangulation. This allowed to validate the identified concepts, their interrelations and the theoretical implications of the empirical findings.

Nevertheless, replicability for this type of qualitative research is difficult to the dynamic and constantly changing social nature of the studied social environment. Next to that, the perspectives on biotechnology and the patent system differ extremely. In this study I have aimed to find a group of stakeholders that represent these perspectives. However, with this number of interviews it is not possible to represent the complete the field of modern biotechnology in the Netherlands. The rapid evolving industry and a different group of respondents might change conclusions of this research in the future.

A further limitation is linked to the generalizability of the research. Overall, it can be said that due to the contextual specifies of the breeder companies in the Netherlands the conclusions drawn from this research might not automatically generalize to a larger population. This is mainly caused by composition of the plant innovation sector in the Netherlands. Not everywhere a similar composition is visible, but larger countries in Europe such as France and Germany match with this structure of companies and carefully conclusions can be compared to the situation in those countries.

The sampling strategy for the Netherlands as an object of study, was chosen because the patent legislation is still based on territorial rules and reviewing multiple countries in this explorative study was not feasible. Also, public values are mostly related to nationalities and bounded to nationalities. However, with the patent system increasingly being international a larger study would be useful to identify public values on a larger scale.

The interviewees were sampled based on their knowledge, experience and stakeholder positions in the green biotechnology industry in the Netherlands or Europe, with the aim to gain the most insights on the topic from different perspectives on the role of the patent system for plant innovation. Because of the limited possibilities to use CRISPR technology, this study bases its conclusions on a prognosis of the situation around CRISPR technology safety regulations and patents.

In addition to the stakeholders of the green biotechnology sector in the Netherlands, interviews with experts on public analysis of the patent system provided additional insights in how the patent system functions and what elements are of play. Interestingly, the interviewees in the sample repeatedly referred to each other for further insights, and it appeared that the most knowledgeable and active individuals for both cases in the research of the patent system have been included in the sample. One limitation is that during the first part of this research my knowledge on how the patent system worked and what the dynamics of different actors were, was very basic and the complex system is hard to understand as an outsider. One of the experts verified this by arguing that complete understanding of the patent system is only possible with at least ten years of experience.

Another point which could increase the validity of this research regards the novelty of the theoretical construct used. In literature PVM is used for small case studies such as perspectives

on GMOs. In this study, the mapping tool is applied on the patent system which comprises a larger group of stakeholders and number of events determine the public values, which make it more complex than in previous studies. To further solidify the extension of PVM applications could prove insightful.

Alternative explanation for the results presented in the previous chapter is that the 'concerns' identified will be solved by market solutions. Arguably, a more economic perspective would not take into account for example, criteria four of inclusivity. From an economic perspective the road to only a few multinationals dominating the plant innovation sector would not be problematic. Therefore, taking a more economic perspective could provide additional insights in what market solutions would solve the complexity issue in the patent landscape. However, as stated this study follows the arguments that underly the patent system and include both a public value perspective and economic perspective.

6.2 Theoretical contributions

This study is set out to examine the patent system and its ability to safeguard public values and stimulate biotechnology innovations.

In this study, I aimed to go beyond the more traditional studies and determinants of a successful patent system, that covered a more liberal economic thinking. A contribution of this study is the operationalisation of the four criteria for a socially desirable functioning of the Dutch patent system based on the philosophical arguments of the patent system and additionally to the public values portrayed in legislative texts and treaties considering the patent system. Evaluating the patent system with the complete set of public values that are assigned to the patent system sets out to examine the patent system beyond this liberal thinking and at the same time, study the ability of the patent system to safeguard public values and stimulate biotechnology innovations.

The overarching approach includes the dynamic interactions of the five stakeholders in the field green biotechnology, contrary to earlier studies addressing the issues separately, results in the finding on the lacking knowledge and awareness of stakeholders. The lacking knowledge of the patent system is not without consequences for political and social debate. The complex dynamics of the patent system make it hard to understand and in debate often incorrect functions are awarded to the patent system, such as the demand to ban GMOs in the ethical debate, which make productive debate to improve issues of the patent system difficult.

A theoretical novelty is that this study tried to shed new light on the application of public value theory. By combining Public Value Mapping with a contextual case study of the developments in modern biotechnology, this reveals the discrepancies between written legislation and public values in practice. This combination appeared as a useful approach to get a better understanding of public values, but also understand the dynamic interactions between stakeholders in the patent system that maintain the public values.

6.3 Directions for future research

Considering the limitations of this research and theoretical contribution, several suggestions for future research can be derived.

With regards to future research, given that the green biotechnology industry is highly dynamic and that number of patents in this field is still immensely growing, future studies could continue to assess the four criteria for a socially desirable functioning of the system in order to

detect if balances in the patent system are compromised and intervention by public or private parties is necessary.

Focus points could be on how the organisation of large-scale ethical debates contribute to a socially desirable patent system by setting clear boundaries for legislations such as ordre public and morality. During such a debate, governance of the patent assessment should be covered as well. The same applies to studying the assessment of patents might conflict with public values, by analysing the patent awarding process in detail and consider this process and the decisions made, from a social and ethical perspective.

Additionally, a focus of future studies could explore the collaborative initiatives to ensure access to patents in the field of plant innovation. Initiatives such as the ILP could form as an example, and studies can identify what the challenges for up scaling such a platform would be.

Lastly, knowledge and awareness of the patent system is one of the challenges for the socially desirable functioning of the patent system. Future exploration could focus on how knowledge on the patent system and awareness can be improved and become more widespread among stakeholders, to improve the use of the patent system by stakeholders without discriminating on resources. This can decrease the discrepancy between stakeholders and improves efficient use of the patent system.

To conclude this with the theoretical direction for future research, the last point depicts the public value theory used in this study. The public value theory and the public value mapping tool provide grounds for further research and can be further matured. The public value failure theory is still limited in its applications and currently the theory is only applied to case studies of a smaller scope. The application of public value theory in this study by developing criteria to evaluate if public value failure occurs in practice provided additional insights on public values. Further research could delve deeper in the evaluation of public values in practice to provide more guidance on operationalising criteria to improve internal validity of future studies.

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9. Appendix

9.1 Interview Guide

Interview Guide: Rathenau Institute "Future proof Intellectual Property" Biotechnology

The interview questions cover the main themes of the research on Future Proof Intellectual Property, and this guide is specified for the Biotechnology topic. The interview guide provides a template for structuring the interview, but the semi-structured approach allows for deviation to deepen the focus on certain questions. There is no distinction made between the Recombinant-DNA case and the CRISPR case in the interview guide because respondents might have knowledge of both cases. In preparation for each interview, this interview guide is adapted to the respondent.

Introduction:

- Introduction of interviewer and the Rathenau Institute
- Shortly discuss the aim of the research project
- Duration is about 60 minutes
- Research ethics
- Confidentiality, statements and conclusions cannot be traced to the respondent
- Recording of the interview (repeat that permission was requested by mail)
- Communication afterwards with the transcripts or results for verification

Opening question:

1. Could you give an introduction of yourself and your relationship with IP/biotechnology?
Goal: open the conversation and assess the credibility of the respondent

Content related opening question: IP in the biotechnology field:

2. How do you define the IP in the domain of biotechnology?
Goal: open the conversation on the topic, get an idea of what topics/direction the respondent is knowledgeable of and try to make clear what the boundaries of the topics of the interview will be.
3. To what extent is it possible to protect a creative performance/invention in the current IP system for biotechnology?
Goal: Verify what is protected by IP and whatnot, ask for examples of IP tools.

Historical background IP protection Biotechnology

4. Could you briefly summarise the reasoning behind the decision to protect biotechnology technologies via this IP system or the decision not to do so? (Ask specifically to the Recombinant-DNA and CRISPR technology)
Goal: Identify or verify public values underlying the IP protection.

5. Could you briefly summarise the most important discussions (in the public debate) concerning IP protection of biotechnological inventions?
Goal: Identify stakeholders in these discussions and their arguments, how and where the discussions took place and how they might have been settled.

Scope of protection and strategy of IP (private interests):

In this part of the interview, I would like to discuss the role of private parties and their interest in IP protection.

6. What strategies and combinations of IP do inventors in this field use nowadays to protect their inventions?
Goal: Identify how inventors are making use of the IP protection. And what sort of companies/inventors are making use of the protection, and do they use different strategies.

7. What are the most important functions of IP in the domain of biotechnology?
Identify if functions such as reputation, tax benefits or protectionism are apparent reasons to use IP.

8. To what extent is IP-protection effective for private parties (e.g. big and small firms)?

9. To what extent is it necessary to adapt IP protection to make it more effective for private parties?
Goal: Steer in the direction of practical measures or adjustments of the organisation of IP.

IP and public values:
Now I would like to discuss the public interests of IP in this sector.

10. To what extent does the current IP protection stimulate or limit innovation in the field of biotechnology?
Goal: Identify how the respondent describes the role of IP in incentivising innovation in the Biotechnology sector.

11. To what extent do current IP protection have undesirable social effects or desirable consequences?

12. To what extent is it necessary to change the current IP protection to enhance desirable effects and to reduce undesirable effects?
Goal: Try to make the respondent think out-of-the-box and identify what are difficulties in making new/adjusted measures in the IP field and why are these difficulties.

The end.
Thank you for your time.
Do you have any further comments or questions?
Any suggestions for further respondents for interviews on this topic?

9.2 Code framework

	Code	Subcode	Example quote
1.	*Effectiveness*	1.1 Ethical considerations : Animal patents	R(12) (S): I*t's a little bit with the chimpanzee issue. If you have a business with genetically engineered chimpanzees you will try to engineer as many chimpanzees as you can and sell it on the market. That is something which is pushed by patents. If you have a patent on a chimpanzee, you will try to make profits with it, and that's a very extreme example. It's why we were also using these kinds of patents but we chose the incentive which is created by a patent can have ethical implications, for example, usage of genetically engineered animals which are used in pharmaceutical research. Yes, we think also in the future animals will be used in pharmaceutical research but they should not become a business on its own. Experiments should only be performed according to law if there is a need, evidence for need that these experiments are performed. Patents are a commercial incentive to perform experiments. It's something we try to explore whether this difference can be made to patent law and to some extent, the European Patent Office in its last decisions was following our arguments.*
1.	*Effectiveness*	1.2 Ethical/safety considerations gene-editing	R9 (R): *The question whether patents on biotechnology inventions are ethical acceptable (are specific cases considered in this patent system). The ethical discussion is about whether patent offices should be making moral decisions while granting a patent and if they have the competencies for this. While on the other hand, civil society groups say that patents are an incentive and a grant is in need of ethical considerations.*
1.	*Effectiveness*	1.3 Argument 3: Incentives created by the monopoly profits	R10 (R): *What a patent system will likely bring about. One of the ideas behind it is that an invention will bring wider social benefits. That a patent system is a way of incentivizing that. And some degree controlling that. It moves away from secrecy over ones inventions. contribute towards incentivizing the people to develop these inventions and innovations. And spend time and resources on them. So, it'd be a kind of a utilitarian argument.*
1.	*Effectiveness*	1.4 Patent thickets	R7 (M): *Access to licenses for CRISPR technology is limited and complicated. There are around four players with many patents on this technology. The overlapping patents results in a patent thicket and legal uncertainty. It is virtually impossible for a user to negotiate all 4 licenses. Not only for costs, also because certain terms are not compatible.*
1.	*Effectiveness*	1.5 Coorporation for access	R17 (M): **Translated**: *Unfortunately, in the electronics sector, where I previously worked, you saw patent pools develop at a certain point. There you had a kind of consortium, a cooperation, between different patent holders. These parties then say, okay, there are hundreds of thousands of patents for this technology. Then they agree on this royalty price that you will pay per product. Then that royalty is divided among all the patent holders. As far as I know, that is not yet very common in biotechnology. So it's not that you can buy a simple package, but really on the basis of different licensing agreements. This is then about what we need to be able to apply the technology. That is different from the ILP.*
1.	*Effectiveness*	1.6 Recommendations	R3 (M): *My preference would be for a short period of exclusivity followed by a period of licence of right where anybody can use the technology but they still have to pay a licencing fee.*
2.	*Efficiency*	2.1 Argument 1: Natural law	R10 (R): *Patent control is something that rewards someone for doing something. The problematic part of this is that so many people are involved in creating this new thing and the reward only goes to one person. This is thing in capitalism, patents are something rewarded by a government and therefore can be controlled in who and what can get this monopoly.*
2.	*Efficiency*	2.2 Argument 2: Reward in the form of a monopoly	R17 (M): **Translated**: *The high reinvestments are necessary because the Dutch market is very competitive.* *Most vegetable companies in NL reinvest about twenty percent, that's no big secret, of their turnover in new R&D. If you are not sure that you can still innovate tomorrow and earn this back, you would not reinvest so much. Secondly, it's not just a patent, by having a patent you are also disclosing something to society. So people can learn about it, instead of us keeping it secret. Other researchers can use it, in that sense it's a kind of flywheel.* *We do it because we get the exclusive right in return, otherwise we wouldn't give it to everyone for free.*

3.	*Efficiency*	2.3 Patent battle	R11 (M): **Translated**: *No, this is unique for two reasons. Firstly, because it is about universities, which are really just educational institutions, and what they certainly don't do [is] litigate for large amounts of money. Because in America, patent litigation costs millions. But that's what they do here, and that's the second reason why it really is a unique case. Look, it only happens once every few years that you have a truly groundbreaking new development. What generally happens, of course, is that several universities or companies work simultaneously on the same new innovative concept. That's just how innovation works. But what often happens, one company gets a patent on a specific improvement, another company on another specific improvement. They make an agreement with each other saying 'you can use my patent and I can use yours and we'll go on with our own business', and all the others they just wipe off the market so that the two of them can use that invention. That's what the standard picture is, whether it's universities or companies. But in this case there is little improvement and little collaboration is foreseen. Here it's a kind of totally new, groundbreaking research field. Thus, there is a lot at stake, so in that sense it is a unique case.*
3.	*Reliability*	3.1 Compulsory license	R5 (R): **Translated**: *It is not because [compulsory licenses] are not applied that they have no effect. .... The idea that they exist, however, cause companies to behave differently. ... The fact that companies know, if we offer our medicine on unreasonable terms, put our diagnostic test on the market, then we run the [is this being said? 00:38:53] risk of a compulsory license. Also with the risk that they lose their reputation, because the previous prices will probably become public. that's what the government very often uses to do price negotiations and say, look if you don't lower the price, then it just becomes a compulsory license.*
3.	*Reliability*	3.2 Governance EPO	R21 (sB): *Actually it is engrained in the EPC that it is the mission of the EPO "to grant patents". The EPO sees that as a direction to rather stay on the pro-patent side. And this again results in an eroding quality in the examination. Today the "real" examination is happening in opposition and appeal which in my view is dead-wrong. However, the EPO sees this rather as an excuse to stay quite liberal especially on the requirement of inventiveness as "the critical patents will be anyway challenged". As the opposition devision is part of the examination, they also rarely deal with inventiveness. So eventually the board of appeal has become the decision making instance for inventiveness of important patents. This is not how the EPO was originally intended to work.*
3.	*Reliability*	3.3 Oppositon procedure	R12 (S): *The European Patent Office you have nine months to file opposition. In some cases it took us ten years to come to a decision. A patent from day of application to end is just 20 years so some of these patent opposition cases took longer than the patent has power.*
4.	*Inclusiveness*	4.1 Division small-size and multinationals	R4 (sb/M): **Translated**: *Look, if it is only about one characteristic, well, you can still do that, but the more characteristics are patented, of course, and in a breed you must always have a combination of all desired characteristics, then the doomsday scenario is a bit like that you will soon have to make separate agreements with five parties, so to speak, before you can start working with that material again. And it is also true that, due to the number of smaller companies in the sector, there is a bit of a fear that this will be to the advantage of the larger multinationals with a lot of legal power, and that it will therefore be much more difficult for small companies to conclude negotiations properly.*
5.	*Stakeholders*	5.1 Knowledge institutes	R3 (M): *Academic institutes look good. They give royalty-free licences for basic research and if they charge a relatively small royalty on any product that comes out of it they look good, and they generate income. There are a handful of universities in the world that actually make a profit out of licencing their patents, not many. Most university TTOs are loss-making operations but there are some which have made fortunes.*
5.	*Stakeholders*	5.2 EPO	R7 (M): *The picture of the EPO that is drawn in the media is very negative. The epo has to deal with the misunderstandings that arise from this.*

5.	*Stakeholders*	5.3 Multinational	**Translated**: R17 (M): *About access to CRISPR technology R: In that respect we are in a eh, I don't want to say luxury or comfortable position , but we are a big company and we have an IP department out there and we are therefore in a position to talk to the patent owners of that technology. So what you do is, researching as an IP departments on what do I need, what processes am I going to apply, what do I need basically. And in this case, a number of institutes emerge that have what they call essential patents for the CRISPR technology. And you sit down with them and say, hey I want to apply this for these conditions and then they come up with a license proposal, with an agreement. On the basis of which that technology is permitted for use. That's actually how we obtain, what they call, the freedom-to-operate. And sometimes that means that you have to talk to three, four, five parties in order to obtain the licenses.*
5.	*Stakeholders*	5.4 Small-size breeders	**Translated:** R15 (M): *Sometimes the plant breeders distract the discussion about patents, because they just have no knowledge on the patent system and take in a very negative attitude of patents, more the anti-patent group. There are some ways out for patents in the Netherlands, such as cross-licensing and a breeder's exemption, I think article 53 in the Rijksoctrooiwet. To my knowledge this is hardly used, and why is that? They have no interest in things changing. However, I think that is unimageable.*