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List of abbreviations

AC21	Advisory Committee on Biotechnology and 21st Century Agriculture
AFLP	Amplified fragment-length polymorphism
AGRA	Alliance for Green Revolution in Africa
AIA	Advance Informed Agreements
ANSES	French National Agency for Food Safety
APHIS	Animal and Plant Health Inspection Service
art.	article
ASTA	American Seed Trade Association
BIOS	Biological Innovation for Open Society
BMBF	Bundesministerium für Bildung und Forschung Deutschland
BMG	Bundesministerium für Gesundheit Österreich
Beirat-GR	Wissenschaftlicher Beirat für Biodiversität und Genetische Ressourcen
BSA	Bundessortenamt
BSE	Bovine spongiforme Enzephalopathie
BSWG	Biosafety Working Group
Bt	Bacillus thuringiensis
CBD	Convention on Biological Diversity
CEO	Corporate Europe Observatory
CGIAR	Consultative Group on International Agricultural Research
CEFIC	Council of the European Chemical Industry
CFS	Center for Safety
CFR	Council of Foreign Relations
CN	Contingent Necessitiy
CRADAs	Cooperative Research and Development Agreements
DNA	deoxyribonucleic acid
DoJ	Department of Justice
EA	Environmental Assessment
EASAC	European Academies Science Advisory Council
EC	European Commission
EEC	European Economic Community
Ed.	Editor
EDV	Essentially derived variety
EFSA	European Food and Safety Agency
ETC Group	Action Group on Erosion, Technology and Concentration
EP	European Parliament
EPA	Environmental Protection Agency
EPC	European Patent Convention
EPO	European Patent Office
EPSPS	5-enolpyruvylshikimate-3-phosphate synthase
ESNBA	European Secretariat of National Bioindustry Associations
et al.	et alii/et aliae
EU	European Union

FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug and Cosmetic Act
Fed. Reg.	Federal register
FTTA	Federal Technology Transfer Act
FRG	Federal Republic of Germany
GE	Genetically engineered
GenTG	German Act on Genetic Engineering
Gf	Gene flow
GM	Genetically modified
GMOs	Genetically modified organisms
GRAS	Generally recognized as safe
HT	Herbicide tolerant
HTG soil	Horizontal gene transfer in soil
IAASTD	International Assessment of Agricultural Knowledge, Science and Technology for Development
Ibid.	Ibidem
IFIC	International Federation of Infection Control
IMI	Imidazolinone
IOM/NRC	Institute of Medicine and the National Research Council
IP	Intellectual Property
IPO	Initial Public Offering
IPRs	Intellectual Property Rights
ISAAA	International Service for the Acquisition of Agri-biotech Applications
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAS	Markerassisted selection
M&A	Mergers and acquisitions
MGH	Massachusetts General Hospital
NASDAQ	National Association of Securities Dealers Automated Quotations
NGO	Non Governmental Organization
NIH	National Institutes of Health
NPBT	Novel Plant Breeding Technique
OECD	Organisation for Economic Co-operation and Development
OIG	Office of Inspector General
OSTP	Office of Science and Technology Policy
PA	Patent Act
PBR	Plant Breeders’ Rights
PGR	Plant Genetic Resource
PIPRA	Public Intellectual Property Resource for Agriculture
PITA	Policy influences on technology for agriculture
P.L.	Public law
PPA	Plant Patent Act
PVP	Plant variety protection
PVPA	Plant Variety Protection Act

rDNA	Recombinant deoxyribonucleic acid
RF	Rockefeller Foundation
R&D	Research and Development
RNA	Ribonucleic acid
RNA-i	Ribonucleic acid - intragenesis for gene-silencing
RW	Rootworm resistance
SAGB	Senior Advisory Group for Biotechnology
SBIR	Small Business Innovation Research
SCP	Single cell proteins
SE	Substantial equivalence
SNPs	Single Nucleotide Polymorphisms
SPS	Sanitary and Phytosanitary Measures
STS	Sulfonylurea-tolerant
TBT	Agreement on Technical Barriers to Trade
TFEU	Treaty on the Functioning of the European Union
TIP	The Innovation Partnership
TRIPs	Agreement on Trade Related Aspects of Intellectual Property Rights
TTIP	Transatlantic Trade and Investment Partnership
UBA	Umweltbundesamt Österreich
UK	United Kingdom
UN	United Nations
UNCTC	United Nations Centre on Transnational Corporations
UNU-MERIT	United Nations University – Maastricht Economic and Social Research Institute on Innovation and Technology
UIRRs	University-industrial-research-relations
UPOV	Union Internationale pour la Protection des Obtentions Végétales
US	United States of America
USA	United States of America
USC	United States Congress
USITC	United States International Trade Commission
USDA	United States Department of Agriculture
USPTO	United States Patent Office
VIGS	Virus Induced Gene Silencing
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

An Exploration of the Contingent Necessities of Agricultural Biotechnology

> "*Modernity signifies the transitory, the fugitive, the contingent, the half of art of which the other half is the eternal and the immutable.*"[1]
>
> **Charles Baudelaire**

Technologies have been used and developed by humankind for millennia, but its development has assumed tremendous proportions in the last few centuries. Crucial examples are the capability to split atoms, the applications in aeronautics and the creation of genetically modified organisms (GMOs). Each of these fields is deeply interrelated with political, economic, legal, and social dimensions and can never be understood as a neutral technology that follows objective rules. Like no other technological development, it is modern agri-biotechnology that intervenes in the basic structure of life: the DNA. The genetic constitution of organisms is not arbitrarily transformed, but politicized and economized in various ways. In general, biotechnology should not be mistaken for an autonomous technology with definitely associated branches and disciplines. Rather, it is a collection of scientific techniques with a distinct pluralist and fragmented nature of economic and political patterns of interactions. Modern agri-biotechnology is therefore related to the application of science and technology to living organisms and parts, products, and models thereof. These are used on living or non-living substances in order to produce knowledge, goods, and services. Unlike traditional and conventional animal and plant breeding techniques, modern agri-biotechnology essentially touches the DNA through the in-vitro recombination of the DNA (rDNA). This allows target-oriented gene-sequencing for the development of transgenic plants and animals. One of the most famous examples is the application of the broad-spectrum herbicide *Roundup* on *Roundup Ready* crops that are genetically engineered (GE) to be resistant to the active ingredient *Glyphosate* that is contained in Roundup. This simple calculation is, however, only valid in theory. Since the first commercial application of GE plants in the 1990s, numerous problem areas have evolved. These range from environmental and health hazards to contestable interdependencies between the industry and the academic sector. Due to the systemic character of modern agri-biotechnology, not only farmers, or certain stakeholders, or even just consumer groups are involved, but life, societies and individuals as a whole. This is true since on the one

[1] English translation as quoted in Calinescu (1987) Five Faces of Modernity, p.48. The French original wording: "*La modernité, c'est la transitoire, le fugitive, le contingent, la moitié de l'art, don't l'autre moitié est l'éternel et l'immuable*" (Charles Baudelaire, Oeuvres completes (Paris: Seuil, n.d.l. p. 553).

hand, gene-flows and the environment do not know geographical or manmade national boundaries, and since on the other hand, institutionalization processes take place at the international level more than ever before in human history. To this effect, the international community of states must challenge fundamental and far-reaching agreements and new legal and political regulations. Since there is no right or wrong in decision-making, but rather ambiguity, tentativeness and uncertainty, this work aims to reconstruct a differentiated image of the broad field of modern agri-biotechnology. The analysis is, however, not referred to the conflict between the so-called northern industrial states and the global south, biodiversity issues or distributional conflicts. Instead, the focus lays on the emergence of modern agri-biotechnology and its contingent necessary conditions and occurrences. The specific spatial dimension is therefore applied to industrial societies with developed technologies, namely the US and Europe, paying special attention to Germany. For the analysis, Bob Jessop's concept of contingent necessities (CN) and the corresponding method of articulation are applied. To this effect, occurrences can be viewed as non-necessary interactions of diverse causal chains which become necessary by entering a contingent interaction. In accordance to this, the view on power is relevant: Power is a specific form of causality that produces effects which would not have otherwise occurred under certain other conditions. Keeping these approaches in mind, any kind of reductionism shall be denied. Not one single causal mechanism or the power of one seed company or the narrative of profit maximization define the trajectory of modern agri-biotechnology, but rather a combination of circumstances and social forces which are historically and contextually embedded.

Hence, the hypothesis is that *modern agricultural biotechnology is a contingent necessary occurrence.*

In order to provide an extensive elaboration of the hypothesis, the work is split into a theoretical part and an analytical section. The theoretical part illustrates the conceptual approach and underlying premises. Based on this, the analytical part treats of contingent necessities of modern agri-biotechnology at five levels of abstraction and complexity. Each contains a brief summary at the beginning, except the last chapter, which dwells on specific developments in the US and Europe with a specification on Germany. Due to this structure, there are separate summaries on the US, Germany and the EU.

The first part on the theoretical and conceptual embodiment introduces the concept of contingent necessities and the method of articulation. Thus, occurrences are viewed as necessary products of contingent interactions of differently ordered, causal mechanisms in the past and present. The method of articulation provides the appropriate instrument for the analysis. It is characterized by a dual movement from abstract to concrete, and from simple to complex. This is later applied to the subject of modern agri-biotechnology. Moreover, this section contains theoretical assumptions which constitute a shift from truth claims to plausible reasoning, and imply the Kantian regulative use of transcendental ideas.

The second section contains the analytical work which is subdivided into five chapters. Based on the method of articulation, each chapter operates at different levels of abstraction and complexity. On a highly abstract and simple level, the first sub-chapter introduces in technology as a social process. Hence, the societal dimension of technology is examined as well as historical conditions of economic and technological path-developments. Moreover, dispositions and technology attitudes are considered to be underlying factors that shape technology trajectories and policies or cause technological controversies. Additionally, the concepts of *context-specific depth of intervention* and *sector-specific adaptability* are demonstrated. At last, this chapter dwells on the relation between technology and law, especially Intellectual Property Law. The main goal of this chapter is to show the interlocking relations between various dimensions. Technology is therefore denied as an inherent objective necessity that follows natural law. Hence, it does not function in an isolated momentum, but is rather endogenized and socially constructed and a contingent item.

The second sub-chapter on modern biotechnology reduces the level of abstraction and raises the analytical complexity. A comprehensive picture of modern biotechnology is provided, including specific features of new technologies. Definitions of biotechnology are demonstrated as well as its pluralist and fragmented nature. Essentially, biotechnology is considered to be a collection of scientific methods with broad application possibilities, rather than an autonomous technology. A fundamental contingent necessity of modern biotechnology is the tight relation between science and industry. This causes a far-reaching commodification of knowledge. Furthermore, institutional structures and actor constellations are shifted, and self-perceptions of academics are transformed. Ultimately, systemic risks are explained.

With the third sub-section a great step in specification is realized and complemented by a raised complexity level. The first of four analytical goals is to carve out the specifications of modern agri-biotechnology, particularly genetic engineering. Secondly, the economic dimension is rendered more precise in order to show the correlation between technology development and commercial exploitation interests. This is conducted through the illustration of applied techniques and modification forms. Afterwards, potential risks that are represented in relation to the use of modern agri-biotechnology are illuminated. An important distinction in risk assessment has to be made between the principle of substantial equivalence and the precautionary principle. Finally, it is shown how living organisms are legally regulated and which objections have been raised against the propertization of living material in past times. Legal propertization is conducted with Intellectual Property Rights (IPRs) which signify both patents and Plant Breeders' Rights (PBR).

For the fourth chapter on spatio-temporal modern agri-biotechnology, both the level of analytical specification and of complexity are raised. The spatial dimension implies the global level or more precisely, the international regulation of modern agri-biotechnology. Temporality mainly covers developments since the 1970s. In order to outline developments of IPRs, related occurrences are also considered from the first half of the 20th century. The main aspects in this section are first, the industrial structure, including horizontal and vertical concentration processes, product complementarity, strategies and IPRs in the seed industry. In a further step, IPRs are examined in a broader context. This means considering the WIPO treaties, the UPOV as well as the TRIPs agreement. Moreover, difficulties in biopatenting, product protection and economic inefficiency are specified. In a last step, the two contradicting risk assessment approaches that are explained in the previous chapter are then related to institutional biosafety regulations, namely the Cartagena Biosafety Protocol.

The fifth and very last chapter of the work once more advances analytical specification and the degree of complexity by itemizing specific political territories and economic spaces. Essentially, this section provides two sub-chapters which show certain historical conditions of economic and technological path-developments in the US and Europe. The main temporal dimension contains the time frame from the very beginning in the first half of the 20th century to current events. To this effect, conjunctures are included and not split into a further chapter. Since the US is the main driver of modern agri-biotechnology, it is analyzed first. In a second step, the focus is laid on Europe. Contingent necessities can be best identified with a genealogical access into the corresponding trajectories. Hence, the part on the US starts with the *Division of Natural Sciences* and academic-industrial relations, and continues with the Green Revolution, pre-shaped dispositions in the society, and IPRs. Further, institutional developments are examined. This includes relevant agencies on the one hand and multinational organizations, namely Monsanto, on the other hand. Monsanto is introduced and referred to antitrust cases and farmer trails. Moreover, the sub-part on the US explores struggles in GMO research and attacks on critical scientists. A brief resume of eighteen years GMO planting in the US ultimately sums up the economic benefits and ecologic hazards of its application. Essentially, occurrences of non-necessary interactions have only entered a contingent interaction in the US to become contingent necessary conditions for the development of modern agri-biotechnology. These conditions are dated back to the early 20th century, since a proper analysis requires at least a concrete starting point. In this way legal and financing structures can be explained as well as the transformation of the academic sector. The sub-part on Europe starts with an analysis of the technological and economical structures in Germany. Essentially, the examination of Europe is very complex since national and regional technological trajectories have developed over centuries, whereas the EU is a relatively recent endeavor that is significantly responsible for the regulation of food products and IPRs. The part on Germany, however, contains the traditional chemicals industry, the role of academics, the industrial system, the way the new technology is trying to be adopted, and finally the financing system for venture capital. The analysis continues with the institutional structure in the EU, especially food related legislation and corresponding controversies on the one hand and the IPR regulation on the other hand. Analyzing IPR regulation requires accuracy of discrimination on multiple levels: on the specific relation between PBR and biopatents, and the growing importance of patenting living organisms. In a very last step, the EU is examined in relation to the international legislation, namely the WTO rules. Therefore, GMO controversies in the EU are inquired as well as the related Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT). Both the SPS and the TBT cause legal uncertainties on EU regulations. To complement this, the current situation of GMO controversies in the EU is investigated. All in all, modern agri-biotechnology is broadly opposed in the EU and only little applied by a few states. The motivation behind the comparison between the US and the EU is to show how technological development is interrelated with historical, local, and contextual factors. It is not possible to transfer a technology from one state into another without further ado. Particularly the EU reveals how the negative evaluation of GMO food has ritualized across time and how it complicates possible shifts. This gridlocked situation is the outcome of specific value orientations and dispositions that fundamentally differ from the US.

At the very end of this work, all the results are summed up and complemented by a final outlook on main aspects that have to be focused on in the future.

Part I: The Theoretical Background

The first chapter contains the conceptual approach, the applied methodology and the underlying premises of this work as well as personal reflections about the topic and the research design. Namely the concept of contingent necessity by Jessop is represented, which is linked to the method of articulation. Hence, the method of articulation is first described and later applied to agri-biotechnology. The underlying premises mainly refer to Kant’s argumentation on the regulative use of transcendental ideas as well as the approach of plausible reasoning by Rescher and von Schomberg. Notably, the illustrated premises shall provide a better understanding of agri-biotechnology and are therefore anticipated, but not constantly expatiated on the whole work.

An essential contribution made by the concept of contingent necessity is to broaden the view on research objects, from one dimensional and mono-causal explanation to multi-dimensional and multi-causal argumentation. Contingent necessities are considered to be occurrences of non-necessary interactions of diverse causal chains which only become necessary by entering a contingent interaction. This interaction is however not based on one causal mechanism, but on several interlockings. Significantly, there is not one single theory that could ascertain contingent trajectories of causal chains. This is because of the openness of structure, including unforeseeable future developments which may be uncontrollable and apparently paradox. Jessop underlines that *contingency* and *necessity* are not related to the same conceptual system. Contingence is understood as a logical concept that is concerned with theoretical indeterminability, whereas necessity is an ontological concept which refers to determinacy in the real world. In this context causality as well as the social science's interest in the relation between power and actions, including the determination of the pivotal factor are relevant. Combining these aspects, the concept of contingent necessity enables to examine a specific incident as the necessary product of contingent interactions of differently aligned, causal mechanisms in the past and present. Based on this, power can be identified as a 'specific form of causality that produces effects which would not have otherwise occurred under certain other conditions'. In order to analyze contingent necessities, Jessop develops the method of articulation. This method is particularly characterized by an analytical dual movement from abstract to concrete and from simple to complex. At this point of the work, the method is merely described, but its application on agri-biotechnology follows after the elaboration of the underlying premises. The elaborated premises signify essential parallels to the concept of contingent necessities and can therefore be seen as an enhancement of the Jessopian conceptualization and other socio-scientific approaches. This includes relevant concepts on dispositions, worldviews and latent technology attitudes. The main purpose of devising the premises is to reject the prevailing argumentation of truth in the social sciences and to replace it with concepts of empirical reality and transcendental ideas, plausibility and coherence. In sum, the Kantian differentiation of empirical reality and transcendental ideas and the appropriate notion of a systemizing mind help to understand that contextual, cultural and temporal factors are determinants and that concepts are negligible which represent a rational and logical notions on societal structures and actors. Kant's main benefit for this work is his ascription of a regulative use of transcendental ideas while denying any epistemic contribution of the mind with respect to empirical objects. The mind has no epistemic value in the speculative domain, but a regulative use in practical and ethical concerns. This regulative use thus becomes manifest in the implementation of epistemologically valuable systematizing-projects, that direct our empirical convictions. The reason for integrating this Kantian differentiation is to extent the concepts of dispositions and latent attitudes which are viewed as determinants of technology development. Combined with Kant, these latent positions and dispositions can be understood as a part of the mind which implements systematization-projects and therefore determines the treatment of a society with a technology. This may be an access to the origin of dispositions. Significantly, the regulation activity of the mind is not predetermined but open. Similar to the openness of structure which is explained by Jessop, also the direction of regulation or systematization is not preassigned. These differentiations are very crucial since the best we can achieve as humans is an empirical reality which is subject to our personal state and inner condition. To this effect, structures and institutions are not shaping or producing truth, but only a specific reality. This empirical reality is not understood as being directly related to truth, but rather to plausible reasoning based on coherence criteria, explained by Rescher and von Schomberg. Fundamentally, what is argued for is that coherent hypotheses and theories can be constructed despite missing truth claims and truth indicators. The plausibility of arguments and their conclusions are not defined by an assumed truth of their premises, but are authorized by the reliability of corresponding knowledge sources. Since truth is therefore neither presumed nor aimed, it is favorable to advance a tentative attitude in science, politics, and economics. Plausibility and tentativeness can therefore be highlighted with regard to the frequent blurring argumentation of science and politics. Knowledge and scientific proof are affected in two ways in this work: First, the deference of science in relation to the regulation of high risk technologies, such as agri-biotechnology is addressed and second, my personal socio-scientific approach of representing the complexity of the real world is concerned. Hence, the adequate question is *how plausible can I analyze developments of agri-biotechnology by generating coherent explanations* and not *how true are these developments or my analysis thereof*. In order to achieve the most coherent and plausible analysis of agri-biotechnology, the method of articulation is adopted. The dual movement begins at a simple and abstract level and grows successively complex and concrete.

1. Conceptualization

1.1 The Concept of Contingent Necessity

The analytical framework of the thesis is the concept of ‘contingent necessity’ and the ‘method of articulation’ which are both developed by Bob Jessop in order to improve and alter the theoretical groundwork in the field of International Political Economy. The two referred writings of Jessop are the paper “Kontingente Notwendigkeiten in den kritischen politisch-ökonomischen Theorien”, published in 2009, and his book “State Theory: Putting the Capitalist State in Its Place” from 1990. The concept is related to Post-Structuralism in various ways which cannot be elaborated here in detail.

What links the concept of contingent necessity (CN) to Post-Structuralism is the rejection of a rigid contraposition of structure and actor. There is an emphasis on the contingency of structures and the dispute about dispositions of structures. It is important to understand that contingence is not identical with coincidence, chaos or any kind of arbitrariness (Wullweber 2014: 240). Contingence in Jessop’s concept has to be viewed in its correlation with necessity, which in combination “*indicates both the de facto causal determination (necessity) of events and phenomena and their ex ante indeterminability (contingency)*” (van Heur 2010: 437; Jessop 2009: 150). As Wullweber puts it, there is a *structural uncertainty* (strukturierte Unsicherheit) or in other words, a *failed structuring* (fehlgeschlagene Strukturierung) (Wullweber 2014: 240). However, Jessop himself points out the more general view on the relation between contingency and necessity. Thus, CN signifies the relation between events and structural causality, the *structure-action-problem*, strategic actions and the free will (Jessop 2009: 144). He illustrates that the terms *contingency* and *necessity* are not related to the same conceptual system: “*‘contingent’ is a logical concept and concerned with theoretical indeterminability, ‘necessity’ is an ontological concept and refers to determinacy in the real world.*” (Jessop 1990: 12). Since contingent means “*indeterminable within the terms of single theoretical system*” (ibid.), it is conceivable to put it together with necessity, and therefore premise that each event stands in a causal relation. Similarly, Jessop stresses the inappropriateness of the reduction of all events in the real world to one single causal mechanism. Instead, contingent necessities are considered to be occurrences of non-necessary interactions of diverse causal chains. The necessity comes into play through contingent interaction. However, also this interaction should not be mistaken for relying on one singular causal mechanism. For this reason, there is no single theory that would be able to forecast or ascertain how and why certain causal chains contingently merge or overlap for achieving one particular event and not another (Jessop 2009: 150). There is not just one single theory that explains why a certain interaction occurred or why the outcome of this interaction was actually necessary (Jessop 1990: 12). In lieu of a deterministic notion, interactions on their part are interpreted as results of interactions that are caused by diverse causal tendencies and counter-tendencies (Jessop 2009: 151). Since non-deterministic and anti-reductionist approaches run the risk of providing analyses with an infinite character pertaining to path-dependency, it is highly favorable to examine the beginning of an event genealogically as a necessary outcome of a contingent necessity of diverse constellations of causal mechanisms (ibid.). For understanding this point even more, it is important to stress the characteristically ‘open structure’ of the real world. CN adheres the openness of structure to an unlimited surplus of future possibilities which might be uncontrollable and paradox. Therefore it is required to explore the various determinants within a concrete ‘conjuncture’. Jessop attempts to show how these determinants interact contingent as necessary or sufficient conditions within a variable, causal dialectic of path-dependency (Jessop 2009: 152).

1.2. Causality

Causality can be defined as the *production of effects* and therefore as highly relational to the environment and the society (Jessop 2009: 145). The capacity of a societal force to produce certain effects does not rely on its own causal power. This capacity rather depends on the *force of objects* (Wirkungskraft der Gegenstände) and social puissance. These forces can be and remain latent, but it is also possible that they become reinforced, repelled or deflected in case of activation by other causal forces and dynamics. Built on this background, power can be understood as *a specific form of causality that produces effects which would not have otherwise occurred under certain other conditions* (ibid.: 146). In this context, Jessop underlines the social science’s interest in the relation between power and actions and the question of *how* and *if* certain actions make the pivotal difference. This leads to the question of intended and unintended effects of wielding power. He explains the difficulty in finding explanations with empirical terms that allow defining ‘difference-making’ actors or events. This is caused by the fact that incidents do not know natural borders what in turn allows various interpretations based on different purposes. This analytical blur is highly underscored in analyses of complex conjunctures that are influenced by different temporalities and horizons of time, complex interweavements of different special factors, processes and events, forms of action as well as open and hidden acting social forces (ibid.). Since actors perform under specific conditions and environments, the exercise of power of these actors has to be viewed as conditioned and mediated. Therefore, effects can be caused by a certain actor, the prevalent conditions, non-actor-related structural mechanisms and balance of power (ibid.: 147). For avoiding blurred analyses, the material, societal and spatio-temporal borders of each research object need to be defined cautiously and in an exact manner. An appropriate and deliberate analysis therefore requires the consideration of specific actors, identities, interests, spatio-temporal dimensions and strategic purposes. With this approach it is possible to examine a certain object as a *necessary product* of *contingent interactions* of differently ordered, causal mechanisms in the past and present (Jessop 2009: 148). This can be linked to the permanent but still limited openness of structure. However, this does not mean that there is no possibility for taking a decision in a specific moment, but rather that the structure omit molding a certain decision so that the situation is not decided (Wullweber 2014: 239). Indecisiveness within a specific situation evolves, when there are no unambiguous rules for decision-making that can help the actor to assess his or her position and therefore provide a distinct direction of action (Jessop 2009: 149).

On the whole, the assumptions of the CN concept anticipate any kind of reductionism, functionalism or a rigid notion of determinism. As Wullweber puts forward with regard to Poststructuralism, featuring a function for something means to exist for the performance of certain tasks. Hence, an approach is functionalistic if it explains the presence of specific social systems out of the necessity of its existence for the adoption of certain societal tasks (Wullweber 2014: 237). Thus, Poststructuralist assumptions may be a relational social fabric, but the purposive nature of these relations should be considered. There is a purposiveness within subjects' actions that are ahistorical and antecedent (Laclau 2005: 68). Corollary, it is disregarded that societal institutions are contingent products of historical struggles in principle (Wullweber 2014: 238). Yet, the CN concept rejects functionalist implications since it views causality as well as necessary and sufficient conditions in a broader and more profound way.

1.3 The Method of Articulation

The method of articulation denies subsumption as an analysis method and strengthens the role of contingency through its motion from abstract-simple to concrete-complex. As a result, the method of articulation embodies an analytical "*dual movement*" (Jessop 1990: 11) through combining two forms of theoretical development. First, there is the motion from abstract to concrete across two or more levels of abstraction and second, from simple to complex through the articulation of concepts that belong to more than one level on analysis (Jessop 2009: 155). Further, Jessop adds the significant role of articulation in relation to "*substantive areas*" (Jessop 1990: 11). On this note, he refers to semiotics and the notion of meaning, which is understood as a composition of symbols, discourses and words and thus induced by the "*relations established among them in inherently unstable chains of signification*" (ibid.). Jessop differentiates between three different types of concept-development: The first one runs from general to particular and reverse, the second one runs from abstract to concrete and the third motion takes course from simple to complex. The first type is confined to the ontological level of the contemporary and proceeds inductively, whereas the other two types refer to both, the real and the contemporary. The movement from general and particular is justified if based on the induction of current events and proofs. Presuming a valid generalization and ignorance towards opposing proofs may end up tautologically. It is also conceivable that one deflects the move from abstract to concrete, based on pure ideological terms. Yet, since not all aspects of a specific phenomenon can be grounded on the same level of abstraction, this line of action cannot be favored as well (Jessop 2009: 155). However, the concrete application of the method and used instruments are illustrated below.

2. The philosophical basis

2.1 Kant's concept of the regulative use of transcendental ideas

Remaining within the logic of the current social sciences, empirical convictions mark the personal, constructed truth, which manifests itself into material terms. It is suggested that specific meanings that are acknowledged as societal truth have been constituted through particular and specific ascriptions, which become universal and generalized by the social process of truth making (Wullweber 2014: 234). Against this notion, it is worth to argue that discourse and speech cannot be viewed as a sort of self-propelled force, but rather discourse and speech itself are ordered into systems that are regulated by the mind. These structures are not predetermined but open, yet not infinitely open, but equipped with relative fix patterns of system formation which themselves underlie biological and evolutionary processes. The specific objects that are ordered are various, but in any case it is the mind that ultimately gives the systemizing order. Even though it is not possible to deny or claim the universality of the mind, it is in every sense absurd to reject any systematizing processing of our intellect. In this respect Kant illustrates that *"(o)ur nature is so constituted that intuition with us never can be other than sensuous, that is, it contains only the mode in which we are affected by objects. On the other hand, the faculty of thinking the object of sensuous intuition is the understanding. Neither of these faculties has a preference over the other. Without the sensuous faculty no object would be given to us, and without the understanding no object would be thought. Thoughts without content are void; intuitions without conceptions, blind."* [2] Furthermore, it is the interaction of both, spontaneity and receptivity of thinking and sensuality that is the basis of our knowledge: *"Our knowledge springs from two main sources in the mind, first of which is the faculty or power of receiving representations (receptivity for impressions); the second is the power of cognizing by means of these representations (spontaneity in the production of conceptions). Through the first an object is given to us; through the second, it is, in relation to the representation (which is a mere determination of the mind), thought. Intuition and conceptions constitute, therefore, the elements*

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[2] English version as quoted in Meiklejohn 2013, p.75. The German original reads: „*Unsere Natur bringt es so mit sich, daß die Anschauung niemals anders als sinnlich sein kann, d.i. nur die Art enthält, wie wir von Gegenständen affiziert werden. Dagegen ist das Vermögen, den Gegenstand sinnlicher Anschauung zu denken, der Verstand. Keine dieser Eigenschaften ist der anderen vorzuziehen. Ohne Sinnlichkeit würde uns kein Gegenstand gegeben, und ohne Verstand keiner gedacht werden. Gedanken ohne Inhalt sind leer, Anschauungen ohne Begriffe sind blind.*" Kritik der reinen Vernunft, B74 ff.

of all our knowledge, so that neither conceptions without an intuition in some way corresponding to them, nor intuition without conceptions, can afford us a cognition. Both are either pure or empirical." [3] Thinking ahead, 'transcendental ideals' in fact do not necessarily contradict Post-Structuralist rejection of universal values or even positivist account for reality. Quite the contrary, the assumptions can be combined and profoundly opined. This claim can be substantiated first, by Kant's separation between idea and reality. And secondly, by Kant's argumentation on 'time': *"Each of my images – irrespective of what that image is – is my image and therefore a part of my inner condition."* [4] According to Kant, the inner condition is yet only accessible under the premise of the forms of intuition of time. As a consequence, each image and thereby indirectly, each object (each appearance) is subject to time. As a last consequence, each appearance is ordered within temporal relations (A33/B51; B46/B73). This matches Post-Structuralist notion that values, statements, knowledge and foremost meaning are not unrelated to time, history and context. Anyhow, Kant goes a step further by claiming the mind to systematize things, words and even *their features and forces* (Eigenschaften und Kräfte) (Kant KrV A662/B686) which ultimately shape our empirical convictions (Briesen 2013: 6). Kant ascribes a regulative use to transcendental ideas, such as world, soul, god, etc., whereas he denies any epistemic contribution of the mind with regard to objects that are given empirically. Terms such as nature can be considered to be transcendental as well. Yet, the mind has no epistemic use in the domain of the speculative, but it has a use for practical and ethical issues. The regulative use thus becomes manifest in the implementation of epistemologically valuable systematizing-projects, that direct our empirical convictions (Briesen 2013: 2). In this relation, the positive use of the mind can be identified through the epistemic account of transcendental ideas (ibid.). For the analysis of agricultural biotechnology, Kant's differentiations are invaluable since they contribute to a broader understanding of technology and society. Technology is commonly viewed as being regulated by latent positions, worldviews and dispositions (e.g. in Behrens et al. 1997; Brossard/Nisbet 2006). Combined with Kant, these latent positions and dispositions can be understood as a part of the mind that implements systematization-projects and therefore determines the treatment of a society with a technology. The correlation between these aspects can be best shown with this illustration:

[3] English version as quoted in Meiklejohn 2013, p.74. German original wording: „*Unsere Erkenntnis entspringt aus zwei Grundquellen des Gemüts, deren die erste ist, die Vorstellungen zu empfangen (die Rezeptivität der Eindrücke), die zweite das Vermögen, durch diese Vorstellungen einen Gegenstand zu erkennen (Spontaneität der Begriffe); durch die erstere wird uns ein Gegenstand gegeben, durch die zweite wird dieser im Verhältnis auf jene Vorstellung (als bloße Bestimmung des Gemüts) gedacht. Anschauung und Begriffe machen also die Elemente aller unserer Erkenntnis aus, so daß weder Begriffe, ohne ihnen auf einige Art korrespondierende Anschauung, noch Anschauung ohne Begriffe, ein Erkenntnis abgeben können.*" (Kritik der reinen Vernunft, B 74).

[4] Own translation. German original reads: „*Jede meiner Vorstellungen – unabhängig davon, von was sie eine Vorstellung ist – ist meine Vorstellung und daher Teil meines inneren Zustandes*." (Kant A 34/ B 50).

Kant’s illustration including systematization-projects:

Mind → transcendental ideas → regulative use → systematization-projects

Kant’s illustration including systematization-projects applied to technology:

Mind → transcendental ideas/dispositions → regulative use → systematization-projects → social use of technology

One may criticize the quick step from a singular “mind” to a plural “social use”, since there seems to be a nonobservance of individual and societal developments and interactions. A profound argument against this objection is the general societal development of technology by a society (or to put it more sophisticated, by a *social system of production*). Technology is never developed externally from a society, but always within; particularly technological large-scale systems are embedded into social interactions and usages. I will demonstrate these aspects more in detail in the analytical part of this work, while explaining the interplay between technology and society. This includes the consideration of latent positions, dispositions and worldviews as the underlying determination factors for the social use of technology. These factors are deeply linked to structures and actors as well as their interdependencies. However, as above mentioned the idea of *truth-making* is denied and replaced with reality-making, transcendental ideas, systematizing-projects of the mind, plausibility and coherence. Due to the prevailing anti-universalist and pro-constructivist attitude in the current social sciences, there is little or no consideration of the separation between *transcendental ideas* and *empirical reality* (Kant A35–36/B52). Instead, various phenomena are labelled with ‘truth’, what as a consequence means that also transcendental ideas are constructions of the mind. The point of critique from my side is that it is not possible to verify truth since it would result in an invalid justification. It is far more desirable to maintain the mentioned distinction between transcendental ideality and empirical reality and extent the debate on truth with the debate on *plausibility* or *representation* as shown in the following. This is required because the systematization activity of the mind can be – if at all – understood as a *touchstone of truth* (Probiertstein der Wahrheit) (Kant KrV A567/B595). For anticipating any reductionist criticism that may indicate a functionalistic regulative use, I clarify that there is no predetermined direction that is given to the systematizing-project of the mind. I rather knot to Jessop’s *openness of structure* and claim that a systematizing-project of the mind exists, but its future development is not foreseeable, maybe even uncontrollable and paradox, as said. We cannot forecast in which way transcendental ideas will regulate our empirical realities, but we can say that this regulation is not genuinely based on the production of truth, but on arranging activities of the mind. However, the advancement of latent attitudes based on Kant is premised but not explicitly mentioned during the whole work. I will stick to the terms "dispositions and latent attitudes" which include preceded systematization activities of the mind.

2.2 Plausible Reasoning

The assumed systematizing activity of the mind in Kant's writings can be associated with the concept of *plausible reasoning* (Rescher 1976, v. Schomberg 1995, 1992). This signifies a defendable position out of inconsistent facts despite the absence of truth-indicating factors. Predicated on this rhetoric, it is possible to build hypotheses that are worth examining. This concept provides an explanation for actions and statements of actors, particularly with regard to uncertainty in science and the question of risk, which is relevant to modern agri-biotechnology. A significant alteration has to be made towards epistemic discourses to the extension of all forms of knowledge generation. This is relevant since René von Schomberg reduces knowledge production on science and different disciplines and therefore excludes other knowledge generating events. I defend this claim first, with reference to the heterogeneous character of scientific disciplines and the increasing trans- and interdisciplinary progress. And second, the tremendous role of public's knowledge or the insight of missing knowledge about possible risks in political decision-making processes. It is highly questionable whether scientific evidence extends political actions or whether it is rather "*a resource that is interpreted differently in accordance with diverse political goals*" (Mulkay 1979).

With respect to plausible reasoning, Nicholas Rescher (1976) points out a defendable standpoint out of inconsistent facts that can be deviated into a hypothesis. In this context, von Schomberg illustrates that epistemic plausibility alludes to the plausibility of plausible arguments that are neither deductive nor inductive. They are not on a par with 'traditional formal-logic claims' (von Schomberg 1992: 262). Instead, epistemic plausibility refers to the plausibility of assumptions and premises of non-propositional structure. The plausibility of conclusions is not afforded by the assumed truth of the premises, but is authorized by the reliability of source of knowledge that it is tied in with. Within epistemic discourses it is not the argumentative upholding of truth that is in center of arguments, but rather the coherent construction of theories, hypotheses and assumptions that can reliably open up spheres of knowledge (von Schomberg 1992: 263). The author explicitly distinguishes between *discourse-theoretical truth* on the one hand and *epistemological plausibility* on the other hand and blames countless problems of traditional philosophical truth theories to underlie the disarray of relations of truth with epistemology (Konfusion von Wahrheits- und Erfahrungsbezug) (von Schomberg 1992: 263). The essential difference between plausibility and truth is that plausibility assesses an entirety of propositions, thus of a story, a theory, a domain of knowledge, etc. It thereby relates to claims for knowledge

(Erkenntnisanspruch). This demand cannot be met with only one proposition. For instance, when we talk about the plausibility of certain propositions or hypothesis, then we relate to the plausibility of propositions or hypothesis of an entirety of propositions (von Schomberg 1995: 172). Whereas truth is a predicate for designating propositions. Assertions can be evaluated irrespective of being true or not. We can state the premises for the assessment of the separate assertion (ibid.). However, a proposition that claims to be true requires a criterion for truth so that its claim can be revised. Admittedly, we cannot rely on any truth-criterion but merely the *criterion of coherence*. In high contrast to coherence theories of truth however it is not argued that the coherence of propositions offers valuable clues to the truth of proposition or provides any kind of truth criterion. What is argued for is that we cannot meet truth claims and truth criterions at all, to draw our actions and convictions upon. This is particularly true for political actions and scientific evidence. It is important to understand, that there is no real need for truth in decision-making and action-taking. Rather, science (all science disciplines) would be better off to follow a *tentative* attitude instead of the continuous attempt to the quest for truth. Even though science traditionally seeks for truth, it is not possible to verify theories and hypotheses, but only to falsify these. Also David Hume states in his causal analysis that in empirical terms it is only possible to observe two events that seem to correlate to each other, but the *genuine force* behind these actions cannot be detected. We assign certain characteristics to certain objects, such as power, necessity, etc. but this happens just because it is some kind of a habit to ascribe features to objects after multiple observations of one event. In any case, we cannot achieve a pure and genuine perception. This can be connected with Jessop's criticism on monocausal explanation models. Hence, the infinite complexity of the real world cannot be observed, including the genuine forces that affect causal relations among objects. Being aware of the fact, that 'truth' actually does not express a general relation between speech and the world, it remains unanswered which relation finally exists between true propositions and the world and how this existence can be verified. Truth is neither a genuine relation between speech and the world nor a real predicate as the color *blue*.[5] In any case, this shall not encourage arbitrary claims and hypotheses, but rather demonstrate that it is not truth that we virtually seek for but that it is at most plausibility that we can achieve and ultimately argue with. This can have positive as well as negative effects for political decision-making processes. Normatively spoken, in relation to agri-biotechnology the assumption of tentativeness shall primarily foster a more cautious attitude towards uncertain risks

[5] For an assortment of diverse truth theories see Skirbekk, Gunnar (1989): Wahrheitstheorien: eine Auswahl aus den Diskussionen über Wahrheit im 20. Jahrhundert or Gloy, Karen (2004): Wahrheitstheorien: eine Einführung. A more critical illustration is given by Puntel, Lorenz Bruno (1993): Wahrheitstheorien in der neueren Philosophie: eine kritisch-systematische Darstellung. Also Winifried Franzen's book „Die Bedeutung von "wahr" und "Wahrheit": Analysen zum Wahrheitsbegriff und zu einigen neueren Wahrheitstheorien" from 1982 provides an elaborated lecture for truth theories.

than it is given currently by some actors. This is not only caused by our restricted ability for forecasting possible risks, but also by the inability for indicating the genuine forces behind certain effects that are not totally manageable. As Hume puts forward, *"We have, therefore, no choice left but betwixt a false reason and none at all*." (Hume 1896 [1739]: 269). These considerations will help analyzing different attitudes and motivations in relation to agri-biotechnology since several decisions in this field are made with a strong cultural and social background and furthermore provide an explanation for the difficulty for actors to position themselves within an emerging technological field. In any case it is no longer conceivable to portend to any positivistic rational decision-making model with the assumption of a general resolvability of problems, the availability of information, the completeness of the information, the probability of certain outlooks and a high degree of control and mastering of processes in practice (von Schomberg 1992: 271). Hence, with regard to Derrida's thought about the tension between the finality of decision-making and the ascertaining of truth, the main question here is how to deal with uncertainty while standing under decision-making pressure (Derrida 1996: 53).

3. Applying the method of articulation to modern agri-biotechnology

After demonstrating the CN concept, the method of articulation and the philosophical premises of this work, the application of the method of articulation to modern agricultural biotechnology is illustrated. Essentially, the analysis is a literature work with various sources. Scientific books and papers are used for basic insights on technology, society, economy and politics. Moreover, screening scientific papers is necessary for past and current developments. Other sources are reports, drafts, treaties and legal texts. They are examined for gaining information about institutionalization and judicialization processes and latest statuses. Additionally, secondary data is evaluated for precise empirical information. Based on these sources the hypothesis that *modern agricultural biotechnology is a contingent necessary occurrence* is examined. This main assumption is complemented by a number of sub-issues on various abstraction levels. It is thus the fundamental question on the relationship between technology, economy and society and which role is played by dispositions and value orientations. Furthermore, it is necessary to understand biotechnology as a new phenomenon, including specific features. Hence, the question on contingent necessities of modern agri-biotechnology must be related to genetic engineering which is again fundamentally shaped by economic interests. This raises also the question on the legal dimension and applied conflicts. Altogether, modern agri-biotechnology is not independent from time and space and therefore deals with its spatio-temporal embeddedness. This is true for its general emergence, but also for its specification to economic spaces and political territories. As above mentioned, the analysis is conducted with the method of articulation which is based on diverse abstraction levels containing a dual analytical movement from abstract to concrete and from simple to complex, illustrated in table 1. Due to the extensive complexity of the main hypothesis, I develop five analytical chapters which are deeply interrelated. Except of chapter five, each section begins with a short summary of the key aspects in order to facilitate the identification of contingent necessities. Due to the comprehensive extension of chapter five, which contains the analysis of the US and Europe, corresponding summaries are provided separately. The final conclusion of this work compiles the results of the entire analysis with an explicit reference to the hypothesis and the respective contingent necessities.

Agricultural biotechnology: dual movement from abstract to concrete and simple to complex

Technology (*abstract 1 – simple 1*) Technology as a social process
Technology-type (*abstract 2 – complex 1*) Modern biotechnology
Modern Agricultural Biotechnology (*concrete 1 – complex 2*) Genetic engineering in agriculture
Spatio-Temporal Modern Agricultural Biotechnology (*concrete 2 – complex 2*) The international regulation of modern agri-biotechnology
Specific Spatio-Temporal Modern Agricultural Biotechnology (*concrete 3 – complex 3*) Developments and the regulation of modern agri-biotechnology in the US and Europe

Technology *(abstract 1 – simple 1)*

The chosen starting point into the analysis is technology as a social process. This mainly refers to the assumption of a strong bondage of technology to local, historical and context-specific conditions, latent technology attitudes, world views and orienting positions. Significantly, technology as well as economy and law are not viewed as objectively efficient products, but as continuous and contestable political processes. The overall illustration is abstract and simple, defining basic underlying assertions on modern agri-biotechnology development. Explicit references to these assumptions vary during the single analytical sections.

Modern Biotechnology *(abstract 2 – complex 1)*

With this chapter the level of complexity is raised and the degree of abstraction is reduced. The aim here is to create a comprehensive picture of the area in which modern agri-biotechnology occurs. The main insight is that biotechnology is not an autonomous technology field, but a collection of scientific methods with numerous application fields. Another central point implies the scientific-economic relations in biotechnology which cause wide-ranging ramifications and a specific commodification of knowledge, particularly scientific knowledge.

Modern Agricultural Biotechnology *(concrete 1 – complex 2)*

In a step towards rendering precision this section makes the analysis of modern agri-biotechnology also more complex. Four major fields are covered here: First, the specification of modern agri-biotechnology which is in turn its delineation from traditional and conventional breeding techniques. Second, the economization of agri-biotechnology is illuminated; thus the emphasis that there is no "purely technical" side in its development; or in other words, a politically and economically neutral agri-biotechnology development is denied. Third, potential risks that are linked to the application of modern agri-biotechnology, particularly genetic engineering are concerned. At last, the judicialization of agri-biotechnology is discussed. It is examined how living organisms are legally regulated as Intellectual Properties and which objections have prevailed against their juridification for a long time.

Spatio-Temporal Modern Agricultural Biotechnology (*concrete 2 – complex 2*)

This chapter contains the regulation of modern agri-biotechnology at the international level and is purposely not subdivided into single temporal phases. This way of operation is conducted in order to keep the process character of technology development. With respect to the economic side, strong concentration processes can be identified. This is articulated both in the horizontal and the vertical structures of the seed and agriculture market. In fact, only a few multinational operating firms control the seed market. Further, IPRs which are already addressed in the previous chapter are analyzed from the institutional point of view. After an overview on the relevant institutions main organizations, their treaties and major difficulties in biopatenting are examined. Finally, this section refers to biosafety, particularly the two contradicting risk assessment approaches.

Specific Spatio-Temporal Modern Agricultural Biotechnology (*concrete 3 – complex 3*)

Due to its extent, the very last chapter consists of two major analytical parts: the analyses of the US and of Europe. Thus, complexity is raised and abstraction is reduced once again. Significantly, the US is the main driver and promoter of agri-biotechnology. Therefore, the structures and motivations of the US are examined before dwelling on constituted regulation patterns and related problems. Since the previous chapters already contain the economic dimension of modern agri-biotechnology, this sub-chapter focuses on the main historical, social and political developments in the US. Highly important aspects for current structures are the activities of the Rockefeller Foundation, particularly the Division of Natural Sciences and the establishment of the "Green Revolution". Though there were prior given purposes of social control, such intentions of the past seem to be largely replaced by economic interests, working routines of relevant actors and other factors. In order to show current structures, relevant institutional developments, including agencies in the US are analyzed. Ultimately, Monsanto as the market leader in the seed market is deconstructed. In order to stress how one and the same technology emerged under contingent necessary viewpoints in one industrial nation, but not in another, Germany is exemplified. Hence, technological and economical structures in Germany are analyzed first before examining the EU. Adapting the narrative of biotechnology as a key technology triggered fundamental shifts in existing structures and actor constellation in Germany and other European countries. Yet, modern agri-biotechnology has not succeeded to date on a large-scale level in Europe. On the contrary, in the late 1990s, several powerful EU member countries enacted an illegal de fact moratorium on the cultivation and import of GE food and seeds. These national bans widely exist today. Aspects that are analytically elaborated in relation to the EU are GMO controversies, relevant institutionalization processes and the legal development with respect to IPRs. Moreover, the problematic situation between the EU and the WTO is illuminated since several EU regulations violate against legally binding WTO rules.

4. Personal reflections on the topic and the research design

The reason for occupying me with modern agri-biotechnology is due to my personal interest on the subjects of environment, technology and international politics. Since years I am engaged in different projects and organizations which are concerned with environmental and animal protection. Currently it is the *Forum Wissenschaft und Umwelt* in Austria and the evolving food sovereignty movement "*Nyéléni*" in Germany. Academically I pursue to provide a more differentiated understanding of concepts such as "nature" or "environment". Since I consider such concepts to be transcendental ideas, it is my concern to add the Kantian philosophy to generally accepted approaches in the social sciences. Additionally, I share the view of von Schomberg who claims a disarray of relations of truth with epistemology. It appears that *truth* itself or its production is widely applied in concepts of the social sciences while reality and mind activities are heavily underestimated. However, I aspire to build on the terms *dispositions* and *world views* and deepen their meanings in social and institutional terms. The thesis is not solely a theoretical work, but related to the specific issue of modern agri-biotechnology. Due to the difficulty to represent the infinite complexity of the real world, I chose the concept of contingent necessity and the corresponding method of articulation for the analysis. The main reason for this is to elaborate different aspects at various levels of abstraction and complexity. This very challenging task requires comprehensive involvement with technologies and their meanings for societies as well as the international treatment of modern agri-biotechnology and moreover the historical domestic developments in the US and the EU and particularly Germany. Further, a subject which fundamentally crosses both biology and politics requires knowledge and understanding of biological processes. How “life” is institutionalized in various dimensions is still one of the most interesting issues for me. The concept of contingent necessities convinced me with its view on structures, actors and developments. Nothing is necessarily given, but rather moving in contingent spheres and can therefore result in contingent necessary outcomes. I personally feel that all occurrences are contingent necessities with more or less slow movements and not great leaps or overwhelming revolutions that determine path developments and practical decision-making. Thus, as I concentrated on technologies of national states, the embeddedness of social production systems to historical and contextual conditions became clear. With the concept of contingent necessities, reductionism in biological, technological, institutional and ideological terms can be widely avoided. Hence, there is no reduction on only one causal mechanism, but the consideration of an interplay of numerous factors. To this effect, the International Political Economy and its relation to technology development must be outlined. Evidently, the activities of certain multinational seed companies are directed to profit maximization, but I deny purely economic calculation in technology development and the treatment of food. Since far more factors, actors and influences are involved in technology development, I well-considered the systematic character of various pivotal facets.

Part II: The analysis

Chapter one: Technology

Technology as a social process

This chapter enters the analysis on a very abstract and simple level by identifying the political economy of technology as a social process. This signifies the correlation of technology to economic, social and legal aspects, including its embeddedness into local, historical and context-specific conditions. These points are complemented by underlying latent attitudes, dispositions and value orientations. Hence, the examined aspects here are the historical conditions of economic and technological path-development, dispositions and technological controversies, the concepts of context specific depth of intervention and sector-specific adaptability, and ultimately the relationship between technology and law, particularly Intellectual Property Law.

A basic assumption is that technology is determined by economic and political forces which in turn shape societies. Therefore positivistic notions of technology being naturally grown or objectively ruled are rejected. With respect to the international market system, technology is considered to be a result of national path developments and patterns of past technological strength. National trajectories are therefore the necessary product of contingent interactions which broadly determine the application of technology and its institutional consolidation. Further aspects in this chapter relate to technological controversies, including technological lock-in situations. It is argued that these controversies are based on dispositions and latent technology attitudes which cannot be reduced to technology acceptance. Due to this, they are better understood as value conflicts which cannot be solved by refining a technology or improving technical education. Technological controversies are subject to social, cultural and ethical aspects which polarize positions and become ritualized at the national and international level. Whether and how technological controversies emerge is reliant to the identity of a society and its organizational capacities. Thus, the technology evaluation of a society is the necessary product of contingent interactions from basic dispositions, particularly on value orientations, moral acceptability, modernization processes, manageability of problems, the credibility of responsible institutions and trust in political and economic decision and regulation patterns on the one hand and the perception and classification of technology specific information, including situative influences on the other hand. Another contribution of this chapter is the provision of two explanation approaches in order to examine technology development: the *context-specific depth of intervention* and the *sector-specific adaptability*. Based on Dolata and Werle who made up these approaches, it is possible to reach a more appropriate picture of technology development. The context-specific depth of intervention is characterized by the specifications of a technology and its structural and institutional configuration of the relevant sector. It expresses the scope of transformation of a sector, triggered by external or internal pressures. Complementary, the sector-specific adaptability outlines the readiness of structures and institutions to become re-adjusted by external pressure and selection processes. This implies the openness of key structures, institutions and actors of a sector for the anticipation and use of new technological possibilities that are beyond the established socio-technological path of development. At last, this chapter dwells on the constitutional power of law, including the embeddedness of law in International Political Economy as well as to the legal conceptions of property. Similar to the relation of technology and economy also the constitution of property rights is identified as a contestable political and continuous process. Law is never politically neutral, but the shaped by strong interests of powerful actors who define legal contents.

1. The social dimension of technology

Entering the analysis of technology through considering it to be a social process implies the "*discursive-material nature of practices, organisations and institutions*" (Jessop/Sum 2001: 92). These relations rest upon different capacities and commitments within a society's total system. It is thus to examine „*How technology is shaped by social, economic, and political forces alike; and how, in the same process, technologies and technology systems shape human relations and societies.*" (Dolata/Werle 2007: 16). Technology plays a prominent role in the constitution of modern societies and within processes of socio-economic and institutional transformation (Habermas 1981: 117). Therefore, technology is always fed back to economy and administration (ibid.: 113) and in case of modern agri-biotechnology, also to the academic sector. Complex technological systems are not socially, politically and ethically neutral. This is since their construction, implementation and daily use are linked to forms of power and organizational hierarchies and authorities. They imply specific forms of structuring of the social life and are therefore *inherently political* (Winner 1977: 323 f.). In this context, issues of causality in technology development and related interests are important. Complex and expensive technological systems create diverse interests towards the conservation and progression of technologies. These technologies are not merely used for achieving specific other goals. The aspects of its organization and experience are such all-encompassing that these aspects of technology become a new lifestyle by themselves. Technology therefore reflects our societal values and creates new values at the same time – in an intrinsically unpredictable way (Wynne 1983: 162). The genesis of fundamentally new technologies and the substantial enhancements of given technologies promote huge expectations and visions towards its potential usability. These visions and expectations are often linked to controversies concerning structural and institutional modifications (Dolata/Werle 2007: 24 ff.). As Dolata and Werle explain, these promises and future imaginations become refined within the process of continued development and are also regularly revised and renewed. Hence, they are constituted into new action-formative anticipations, condense themselves into principles and become reflected into appropriate strategic re-orientations (ibid.).

However, if technology is viewed this way, it means to deny the picture of technological determinism as it is imagined by several thinkers in past decades. Their assumption is that technical enhancement produces its own unplanned use while it also produces any kind of unforeseen methods at the same time. Technical possibilities force their own practical application. While there were political norms and rules, there are now inherent objective necessities of the scientific-technical civilization which are not understood as earthiness and dispositions and also not as a decision-making entity (Habermas 1981: 116). Of course, this notion cannot be approved since there is no naturally grown technological development without political and social will. At the contrary, technology is highly directed by investments of both, public institutions and in case of modern agri-biotechnology also of private institutions that have strong economic interests. There is no such thing, as an inherent objective necessity of technology that follows naturally given rules without restrictions only based on conscious decisions. Technology is not functioning in isolated momentum, but is rather endogenized and socially constructed and therefore a contingent item (Dolata/Werle 2007: 15).

2. Historical conditions of economic and technological path-developments

For the analysis of economic and technological developments it is necessary to state the institutional embeddedness of these paths. This is because institutions are in a permanent process of transformation, including unpredicted directions of these changes. The types and directions of institutional changes are set into “sharp limits” due to their connectedness with other institutions (Hollingsworth 1997: 266 ff.). Thus, social systems of production can be best understood as systems with specific conditions and principles. In this light, institutional arrangements can enable certain institutional innovative forces just as they can constrain certain others (ibid.). However, the question of system demarcations stands in center of this overall subject since social systems are not necessarily, but predominantly within national borders. These regional and national economies and technologies are engrained in a society’s history and cannot be simply transferred from one state to another (Hollingsworth 1997: 278). As Bartholomew expresses: “*Technology is considered to accumulate in nations along a "natural trajectory" of development and reflect patterns of past technological strength.*” (Bartholomew 1997: 243). Countries have diverse specialties with regard to their sectoral technologies which empirically proved to remain stable for long time periods (Archibugi/Pianta 1992). These “historical compromises” (Barthomolew 1997: 243) have an impact on public institutions, organizational structures and on the bondages of institutions with the industry.

In these terms the forms of economic technology development and of political technology regulation highly depend on the system in which these things happen. Although societies take over regulating principles of foreign management methods and work practices, the virtue of these system-external techniques show strict limits (Hollingsworth 1997: 265). Also the kind of produced goods of a social production system is restricted, particularly with regard to the successful competition in international market system (ibid.). Moreover, it is not only the good that shows restrictions in these terms, but also skills and knowledge that are country and firm specific (Bartholomew 1997: 242). These specifications define the general technological advantage of a country at the international level. Hence, any kind of international technological cooperation is understood as a derivation of complementarity of acquirements and knowledge that are embedded in enterprises from diverse national backgrounds (Shan/Hamilton 1991). Thus, not only the institutional norms and rules of one nation are relevant, but of a social system in the international community since there is an increasing international interdependcy of technological skills and knowledge. However, institutions that constitute a social system of production are not independent. Therefore, changes in one institution normally induce transformations in other institutions, especially in large-scale technology systems.

3. Dispositions and technological controversies

For the analysis of technology it is fruitful to relate to social learning processes which result from discourses (Bandelow 1999; Hampel/Renn 1999) and form hegemonic or controversial principles and narratives (Gottweis 1998). Behrens et al. (1997: 45 ff.) illustrate in a profound manner how latent technology attitudes and predispositions determine the use of a technology and its institutional consolidation. According to their argumentation a specific technology is not the reason for an existing technological conflict, but the related technology can manifest a latent given conflict. Linking this to the first chapter on Kant's transcendental ideas, these latent positions are identified as products of the mind that implement systematization-projects and therefore determine the social use of a technology. Essentially, any reduction of social technology development on technology acceptance should be avoided. Rather, milieu-specific differentiation and ambivalences which are considered to be deeply rooted in normative basic positions towards technology development, usage and societal modernization processes are emphasized (Conrad 2004: 23). The invalidity of a simplistic notion of technology acceptance is based on the false differentiation of technology and the public into two separate spheres (Gaskell et al. 1998: 9ff.). According to this, the public is only able to accept and reject a technology, but not to differentiate more profoundly. This interpretation is problematic since both dimensions are interacting with each other and shape the social system of biotechnology together and not apart. Controversial technologies are not related to technology acceptance, but to a value conflict. Therefore, problems of technology acceptance cannot be solved at the cognitive scientific-technological-economical level, for instance by refining the technology, improving technical education and information or technology impact assessment (Behrens et al. 1997: 46). These problems are rather embedded into value- and norm problems that are connected with psychological, social, cultural, political-judicial, ethical and religious aspects (Behrens et al. 1997: 46). Additionally, the social stabilization and capacity of a technological controversy depends on its organizational, institutional and social anchor as well as its social relevance and inner stabilization (Conrad 2004: 56). Considering this relation helps to understand the triggering factors of technological controversies in certain countries, at specific points of time as well as raised objections against its usage. In general, latent attitudes in biotechnology controversies result out of an interplay of multiple factors at different levels that exclude mono-causal explanations which only focus on area-specific or state-specific aspects (Conrad 2004: 26). In this context it is necessary to consider that technological controversies have the tendency to polarize positions and to ritualize conflicts and thereby manifest and stabilize certain attitudes at the national and international level (ibid.: 54). Furthermore, these controversies contribute to a deeper awareness of problems and to a distribution of information concerning these problem situations, but barely to problem-solving (ibid.: 56). Attitudes towards technology are generally determined by two items. The first one concerns the general value dispositions and technology attitudes in processes of societal modernization. As Zwick emphasizes, criticism against genetic engineering underlines the representativeness of the technology debate for a comprehensive legitimization crisis. As shown below, the debate on genetic engineering expresses a widespread unease of several societies to the current societal situation and its further modernization. The question is not whether modernization is desired at all, but which direction is preferable (Zwick 1998: 87). The second item refers to attitudes which are apart from technology, but deeply correlated to appropriate decision-making, regulation and control procedures. Such factors can be material values, technology optimism, and confidence in actors that are concerned with biotechnology as well as personal activities in biotechnology (Gaskell et al. 2003). As noted, attitudes to technology are predetermined by underlying dispositions on modernization and general value orientation. Although exercising influence on dispositions is challenging, these should not be misinterpreted as totally static and immutable. It is the context that highly determines whether a constellation is assessed as suboptimal and unsatisfying or not. Hence, a changed context may induce a shifted technology evaluation. This correlation of context and assessment, called *lock-in,* is generally attributed as dynamic, not irreversible and not necessarily long lasting (Dolata/Werle 2007: 35; Wieland 2009: 27). Lock-ins illustrate the inefficiency of social institutions, based on the axiomatic assumption of inefficient institutions which are rather understood as a product of habits and customs (North 1991). This explains why a path-dependent process can arise market conform but still entail a suboptimal output (Wieland 2009: 27), even though actors think to make the most efficient decision. The collective societal perception and cognitive processing build the fundament for a social use of technology (Dolata/Werle 2007: 24 ff.). Inefficiency is not only a phenomenon of technological development, but also of economy. An analogy of capital and technology can be found in the insight that their movements are still relatively slow compared to the applied acceleration on them. This can be best demonstrated with a quote of Marx and Engels in the “German Ideology”: “*The movement of capital, although considerably accelerated, still remained, however, relatively slow*.” (Marx/Engels 1968: 7, footnote 3).

4. The context-specific depth of intervention and sector-specific adaptability[6]

Ulrich Dolata and Raymund Werle designate potential sectoral effects of new technologies as '*context-specific depth of intervention'* (Dolata/Werle 2007: 28). This is defined by the specific characteristics of a technology as well as by the structural and institutional configuration of the sector or application area that is subject to the technology. They numerate the most important items in this context which stress the varying influence depending on the degree in which new technologies: a) change the existing technological profile of a sector, expand or destroy given knowledge bases and competences; b) influence existing research, development, productions, distribution and market conditions; c) promote the rise of new actors, set established actors under adjustment pressure and shifts typical actor configuration; d) initiate organizational and institutional re-adjustments; e) expand or open up existing limits of a sector and provoke stronger interpretations of diverse sectors (Dolata/Werle 2007: 29). The context-specific depth of intervention is high when the relevance of the new technology is intense in relation to the reproduction of a sector that produces technologies. It is also high the lesser these relevant new technologies can be used within the established structures and institutions. The consequence of a strong context-specific depth of intervention is an intense sektoral pressure of adjustment and transformation on the existing structures, institutions and action orientations. It is necessary to look for new ways of structural, institutional and organizational alignments and thereby at the involved actors to act beyond their used orientations, familiar rules and accustomed routines (ibid.). As Wieland highlights, technological progress is a cumulative process, carried by concrete actors and therefore always locally and historically bonded (Wieland 2009: 26). It highly depends on the knowledge and know-how of actors for exploring new technological possibilities. Similarly, Dolata and Werle maintain that institutional and structural re-adjustments genuinely depend on quest and selection processes made by actors that are again framed by individually given socio-economic structures and institutions. The authors call this the '*sector-specific adaption ability'*. This concerns the degree of openness of the key structures, institutions and actors of a sector for the anticipation and use of new technological possibilities that are beyond the established socio-technological path of development (Dolata/Werle 2007: 29). In this context, it is important to state the frequently occurring low adaption ability of a sector and its key actors towards new arising technologies. This is not only visible in relation to the pharmacy sector with regard to biotechnology in Germany, but also in the inert approaching to computers in the middle of the last century. The sectoral adaption ability increases parallel to the adaption ability of key

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[6] Own translation. The German original reads „kontextspezifische Eingriffstiefe“ and „bereichsspezifische Adaptionsfähigkeit“ (Dolata/Werle 20071: 28 ff.)

actors, both through transformation and stimulation of structures and institutions (Dolata/Werle 2007: 30). In case of Biotechnology a transformation of the chemical orientation of the pharmacy industry to biotechnology occurred. This example shows the successive change of collective perception and principles that are accompanied by organizational, structural and institutional changes and create new sets of action conditions and options (Dolata 2003: 155 ff.).

5. Technology and law

If one may wonder about the consideration of law in technology issues, it can be pointed out that already Leonardo da Vinci as a creative inventor of new technologies is faced with the problem of copying. His individual trick is to build in an alleged defect in his inventions, usually a mechanical malfunction so that his competitors failed to copy his works. He is reliant on his self-made protection due to a lack of comprehensive inventor protection since first patent law approaches were given in the Venetian Statue of 1474. Today inventors' knowledge, information or ideas can be protected by legal means, mainly through Intellectual Property Rights (IPRs). Hence, the law of IP has to be situated in the field of International Political Economy. Based on this, it is favorable to question any divisions between the "*technically legal and the political, between the definitional and the realm of public policy*" (May/Sell 2006: 16). Similar to North's account for lock-ins in social institutions which are revealed as an inefficient product of habits and customs, also Fligstein claims that the "*constitution of property rights is a continuous and contestable political process, not the outcome of an efficient process*" (Fligstein 1996: 658). Political pressure exerted by strong market actors is subject to economic relations and therefore to institutions and structures. The state's role is to regulate power and control diffusion among actors. Parallel to thoughts of Max Weber in his work *Economy and Society*, also Fligstein underlines that "*political contests over the content of laws, their applicability to govern firms and markets (...) are never neutral*" (Fligstein 1996: 660). In this context, the creation of a market is very influenced and defined by those market actors who are powerful enough to form structures for their own benefit. This, however, shall not relativize the determining influence of prior given structures and the impact of spontaneous events. Just as Dolata emphasizes in relation to rising technologies, also new market creation cannot be viewed as an 'initial period of upheaval' in which "*a dominant perception of control is settled on*" (May/Sell 2006: 24) as it is thought by May and Sell. The approach of contingent necessities understands the emergence of a market as interplaying mechanisms, latent attitudes, value and norms combined with spontaneously appearing events and actor constellations. Thus, the context-specific depth of intervention and the sector-specific adaption ability have to be taken fully into account in relation to market aspects. Also Fligstein emphasizes, that "*a new market is not random, but shaped by existing conceptions* *of control, legal conceptions of property and competition, and the existing organization of related markets*" (Fligstein 1996: 665). This is true for IPRs since the past proved that its development is not caused by one single determining trajectory, but rather several different jurisdictions taking differing paths in context of diverging political argumentations and stipulations (May/Sell 2006: 27). Favorably, interactions between structures and agents are interpreted in a more profound way. In this regard, Margaret Archer (1995) creates an approach for avoiding the reduction of either a determining structure or actor. Hence, Archer explains that providing a causal explanation from the bottom-up notion means "no allowances for inherited structures, their resistance to change, the influence they exert on attitudes to change, and crucially […], the delineation of agents capable of seeking change" (Archer 1995: 250). In the 1930s Walter Hamilton states that "*it is incorrect to say that the judiciary protected property; rather they called that property to which they accorded protection*" (quoted in Cribbet 1986: 4). Similarly, Richard Ely knew the "*power to interpret property and especially private property and to give the concept a content at each particular period in our development which fits it to serve the general welfare*" (Ely 2010 [1914]: 207) is given by certain actors and structures and is not the product of objective entities. It is not the case that property as property predates the governmental apparatus while awaiting recognition; it is rather that the recognition of property sets up its own being in a way men is able to identify (May 2010: 16). Since it is necessary to have a state or any other kind of legal apparatus for viewing property "*in a way other than merely possession by those with the physical ability to protect themselves from dispossession*" (ibid.). Hence, it makes more sense to understand property as a social institution rather than a physical thing. The significant difference lies in the provided protection by the state for certain interests and power relations and not for things that are already considered to be property. Powerful forces of a society can be analyzed as above mentioned since they are able to strengthen and implement their specific interests by mobilizing the legal apparatus in a way that fits their interests and further these strong actors are able to maximize their impact by controlling relevant resources (May/Sell 2006: 32). This is important since property rights not only hold against other excluded groups, but even against state's interventions. However, the legal structures have changed fundamentally with the rise of new technologies and particularly with the new social evolvement of technologies (May 2010: 17).

With the following chapter, the abstract simple debate on technology reaches a higher analytical level in terms of precision. To this effect, the type of technology is specified on modern biotechnology and relevant aspects of technology, society, industry and the academic sector.

Chapter two: Technology-type

Modern Biotechnology

After elaborating the main aspects of the International Political Economy of technology on a simple and highly abstract level, this chapter increases the degree of complexity and also the level of abstraction. The aim here is the exploration of specific characteristics of modern biotechnology in order to ease understanding of modern agri-biotechnology. Therefore, significant characteristics of new technologies are illustrated, followed by the definition of biotechnology and the analysis of the pluralist and fragmented character of modern biotechnology. Subsequently, scientific-industrial relations in biotechnology, the structure and actor correlation in the academic and industrial sectors, including the strategy of discovery exchange are demonstrated. Finally the characteristics of systemic risks are inquired.

What distinguishes biotechnology is its fluid and versatile character, shaped by enormous development dynamics, uncertainties and a barely predictable range of application possibilities. It should not be mistaken for an autonomous technology with definitely associated branches and disciplines. Rather it is a collection of scientific techniques with a distinct pluralist and fragmented nature of economic and political patterns of interactions. On various steps of institutionalization, specific non-necessary networking interdependencies among actors enter contingent interactions and result in contingent necessary contractual and success-oriented cooperation. Essentially, these contacts are contingent necessary results of prior interactions and shape corporatist relations, including institutional structures and actor constellations. This particularly affects the industry steered innovation process that is split into various decentral organized institutions and numerous involved actors. Essentially, biotechnology induces a harsh adjustment pressure on existing structures, actor constellations and actor perceptions in the academic and industrial sectors. This is due to functional interdependencies between both sectors which became contingent necessary in the commodification process of knowledge, especially of scientific knowledge production. In this context, the interdependent correlation between actors and structures of the academic and industrial has to be considered. Referred to Jessop, it can be said that there is a *structural coherence* (Jessop 2009: 168 ff.) between academia and industry. At this point it is important to stress that various occurrences in basic research of biology laid the technical foundation for a potential commercial application of biotechnology, but that a strong interest in social control is given afore. How the industrial use of biotechnology in agriculture is finally realized is related to specific contingent necessities in the technology trajectory. Academic researchers are faced with a highly confusing situation in biotechnology due to its fragment and pluralistic character. At the same time, these actors find themselves in a competitive environment accompanied with economic pressure on the applicability of their research activities. The industry is reliant of academic research results and initiates a market-oriented institutional framework with corresponding incentives to encourage scientists for company foundation. This can be traced back on research activities by certain relevant academic actors who laid the foundations for the establishment of “academic entrepreneurship” in technology development. Hence, even if individual scientists are not genuinely interested in entrepreneurial activities, they can hardly access research without market influence. However, it would be simplistic to interpret researchers and faculty staff simply as profit-maximizing actors. Rather, universities have a social responsibility for the own institution, since they are confronted with financial dependence on federal funding which is in turn reliant on financial support from the industry. Federal funding fundamentally varies with the specific country. Ultimately, companies must adapt specific market requirements which are characterized by major concentration processes in international biotechnological sectors. In sum, the academic sector experiences an essential context-specific depth of intervention by commercialization forces of the industry. The scope of transformation is so high that the universities’ duty in handling broad societal issues is jeopardized to the marrow. Yet, how this will affect future social developments cannot be said. Irrespective of the specific field of application, biotechnological methods affect living organisms. Therefore, the question of risk is raised with respect to environmental hazards and animal and human health. The genuine forces in biological processes cannot be determined empirically and thereby exclude certain scientific evidence on reactions by ‘nature’. To this effect, the removal of boundaries in contiguous ecosystems, including pollution dispersal and gene flow has to be considered. Related risks are best defined as systematic risks with spill-over and ripple effects. In this relation, the social dimension is concerned, namely the ambiguity of systematic risks. Ambiguity expresses lacking objective risk assessment instruments which in turn implies multiple legitimate positions that can define a risk as tolerable and acceptable. As a consequence, it is dangerous for one nation if risks are in large parts socially accepted by another, particularly if risks are assessed as not existing or irrelevant and do not demand further regulation and political intervention.

1. Characteristics of New Technologies

Considering technology to be a socially constructed and contingent item is important with reference to technological large-scale systems that have an impact on relevant areas in societies (Mayntz 1993; Wieland 2009). Such technological large-scale systems are for example the industrial steam engine, telecommunication, but also the new science-based cross sectional biotechnology. These systems lead to fundamental changes and partially to a replacement of the predominant technology system. They create opportunities for change and a tremendous adaption pressure on existing structures and actor constellations at the same time (Dolata/Werle 2007: 20). Biotechnology as a newer phenomenon shows a "*fluid profile*" (ibid.: 35) which reflects its specific cumulative process character that is determined by specific actors and is always historically and locally bonded (Wieland 2009: 26). This means that it is not 'once completed and ready for operation', but rather shaped by developments that are going through long time periods and by new developments and events (Dolata/Werle 2007: 35). Apart from strategic aspects, specific requirement such as complementary products promote the emergence of hierarchical large-scale organizations and sectoral monopolies (Schmidt/Werle 1998). Technological large-scale systems enhance *functional interdependence* and usually stabilize hierarchical institutional coordination forms (Mayntz 1993). The interdependency among these relevant system components hinders the establishment of a fundamental socio-economic change (Wieland 2009: 24). The reaching of equilibria, particularly on the local level, correlates with the introduction of social transformation which is sometimes only realized by an external shock. Established technologies contribute to the consolidation of action regulating socio-technological structures which cannot be ignored or scrutinized. With new technologies also new socially constructed action alternatives and social development directions with unequally attractive options emerge (Dolata/Werle 2007: 20). Thus, biotechnology is even more relevant due to the fact that newer technologies diffuse much faster than older ones (Comin/Hobjin 2010: 2049).

2. Definitions of biotechnology

As a set of techniques and methods, biotechnology already designates industrial production purposes in its official definition by the OECD: "*The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services*." (OECD: 2014). Similarly, the Convention on Biological Diversity from 1992 defines biotechnology as "*any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products for specific use*" (Secretariat of the CBD 1992). These broad definitions imply industrial and medical applications and techniques and tools which are used for agriculture and food production. As a follow-up treaty of the CBD, the Cartagena Protocol on Biosafety narrows the definition of 'modern biotechnology' to (a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection (Secretariat of the CBD 2000). What distinguishes the nature of modern biotechnology is the combination of molecular, microbiological, biochemical, cell-biological, immune-biological, virological and bio-procedural methods. Genetic engineering is a significant technique in modern biotechnology and signifies the direct manipulation of genomes from living organisms with biotechnological means. Commonly, molecular cloning methods are used to generate a specific DNA sequence through isolating and copying the new DNA into the host genome. It is also possible to synthesize the DNA first and insert it into the host organism afterwards. When a plant or animal is modified with modern methods of genetic modification, namely by the recombinant DNA, it is called *genetically modified organism* or GMO. Additionally, when a GMO is still alive, such as a fresh vegetable or fruit or a seed, it is called *living modified organism* or LMO (Husby 2007). Further, the concepts of *genetically engineered* (GE) and *genetically modified* or GM have to be distinguished. However, although there are differences between GMOs, LMOs as well as GE and GM, the terms will be used interchangeable in this work.

3. Pluralism and fragmentation in modern biotechnology

The definition of modern biotechnology has already expressed its versatile character which allows a derivation on its heterogeneous scope of application possibilities. According to this, modern biotechnology is a cross-sectional collection of scientific techniques with a distinct pluralist and fragmented nature of economic and political patterns of interaction. Considering technology to be a social process means to reject biotechnology as a mature technology with an environment of incremental emerging innovations in stable and long-term working conditions. It is rather a paradigmatic new field of technology that is characterized by enormous development dynamics, tremendous uncertainties and a barely predictable range of applications (Dolata 2000: 196). With respect to the International Political Economy of technology, it is undeniable that economic technology development and political technology regulation are highly interrelated (ibid.: 195). Significantly, biotechnology as a whole is determined by a bundle of small-scale techniques not by capital-intense large-scale projects that can only be realized within stable, central organized and networking structured cooperation. Understanding industrial and political networks as the only relevant spaces and mediums of technological trajectories and constituting processes may therefore prove very problematic since pluralistic structures of existing cooperation relations and negotiations are totally underestimated. As Dolata emphasizes, networking interdependencies with their reciprocal and relatively open, but loosely coupled relations among a larger number of autonomous actors can be identified in non-binding, economically non-competitive, politically not directly decision-relevant contexts. These are places for exchanging ideas, value orientations, information procurement and informal agreements. Significantly, bilateral relations with clearly defined borders evolve from these contacts when they turn into contractual and success-oriented cooperation. They further condense to closed corporatist relations between limited amounts of actors when political decision-making becomes relevant (Dolata 2000: 196). In fact, modern biotechnology and agri-biotechnology have undergone these three particular development stages until certain economic structures and actor constellations shaped up. Each phase contains several specific non-necessary occurrences in diverse causal chains that step into contingent interactions before becoming contingent necessary. Yet, the process character has to be regarded despite specific consolidated patterns in biotechnology. Dynamics in academic research, in the market and in the legal regulation system underlie a permanent transformation process, based on technology trajectories of the past. The pluralistic character of biotechnology is further complemented by fragmentation in cooperative exchange of economic and political forms which cannot be brought into one coherent line. These forms are partially in unmediated juxtaposition with each other, including overlapping or time-limited characteristics (Dolata 2000: 195). Crucially, also the industrial process of innovation is split into numerous decentralized evolving biotechnological researches, development and production projects that sometimes compete, but which are usually conducted independent of one another. This is also in accordance with the political constitution of biotechnology (ibid.). Thus, there are several negotiation structures and bargaining arenas, equipped with diverse weights coexisting next to each other. This notion excludes the presumption of an identifiable central actor as it is thought until the early 1980s (ibid.: 196). According to the fragmented nature of biotechnology, Gill compares biotechnology with the classic chicken-egg-problem. It is not clear whether biotechnology is determined by self-preservation interests and market orientation of various disciplines and institutions which shaped its character to multi-purpose methods, cross-sectional science and cross sectional technology or whether it is the reverse case, that biotechnology determines the participation of various disciplines and institutions (Gill 1991: 282).

4. Scientific-industrial relations in modern biotechnology

The necessary components for the consolidation of biotechnology in the agricultural sector are academic research and economic technology development. Or in other words, modern agri-biotechnology could not have developed to the same extent as it is given today, if academic research is not interlocked with the commercialization interests of the industry. Some authors call these interplays "*UIRRs*", University-industrial-research-relations (Blumenthal et al. 1986), others simply term them "*academic capitalism*" (Glenna et al. 2007; Slaughter/Rhoades 2004), or even "*triple helix*" (Etzkowitz et al. 1998), which particularly articulates *new modes of knowledge production*. All these concepts pursue the exploration of new or emerging phenomena such as modern biotechnology as a figure that includes lines of different relevant dimensions. Only the consideration of both academia and industry and their *structural coherence* can provide a proper analysis of contingent necessities in modern agri-biotechnology. The relevance of these relatively new conceptualizations arises out of the fundamentally changed structures of economy, society and politics from distinct local and regional structures to the internationalization thereof. These transformations have a strong impact on the constellation of actors, particularly on academics and their knowledge. Traditional knowledge production and transmission is increasingly outrun through the "*generalized commodity system*" (Kloppenburg 2004: 335) and converts into a significant production factor. At the same time, governments find themselves in entrepreneurial roles and firms have to compete at the international level by implementing strategic alliances, research and development (R&D) strategies and mergers and acquisitions (M&As). This pervasive "*new mode of production*" (Etzkowitz et al. 1998: 69) is both the result and the cause of the interplays between academia, politics, and industry. Particularly in relation to knowledge based growth strategies, the value of human capital increases and networking among scientists, firms and government laboratories (Etzkowitz et al. 1998: 76).

5. The structures and actors in the field of scientific-industrial relations

At this point, it is favorable to throw back the analysis to the CN-related assumption that it is neither only the structure that determines development paths nor solely an actor's decision-making, but the interplay of both. Thus, it is the commercialization of private research funding, federal IPR policies and other external pressures on the one hand and the active participation of certain actors and actor groups in the academic sector on the other hand. The hierarchical industrial structures promote research in targeting patents, trade secrets and exclusive licensing for profit. Significantly, unlike private corporatism, the publicly organized university research is rather oriented on the enhancement and extension of knowledge and solutions for broad social issues (Glenna et al. 2007: 147). Since commercialization increased in modern biotechnology, the capitalization and commodification of knowledge experience a "*profound normative change in science*" (Etzkowitz 1998: 824). Increasingly the regional innovation environment is shaped in order to foster the accommodation of knowledge and scientific innovation, since biotechnological industry depends on academic research. Hence, engineers have opportunities to train business skills or get access to relevant staff, and research institutes have capacities and competences to interact tightly with firms. In this light, students and faculty members are encouraged to cooperate with the industry and to found an own company as a qualified scientist (Etzkowitz et al. 1998: 77). Traditionally, industries view universities as a provider of human capital in terms of potential employees and as a source of knowledge that can promote enterprises. Thus, it is basic research that stands in center of interest so that industry demands academic focus on their actual duty of research and education (Etzkowitz 1998: 825). Knot to the concept of context-specific depth of intervention, a fundamental transformation in the academic sector is introduced by the emergence and profound implementation of biotechnology. Just as enterprises began to extend R&D strategies, the demand for external resources increased and roped universities into specific industrial research with a profound interest in commercialization. This capitalization trend is amplified through active initiation of entrepreneurial activities by certain academics, such as Herbert W. Boyer and Stanley N. Cohen which are commonly viewed as pioneers in biotechnology enhancement. Hence, this new relationship of industry and university requires university and faculty staff to participate in capital formation projects, for instance in real estates and multiple company foundation. This alteration of knowledge into entrepreneurial contexts causes a reciprocal effect of "*cognitive opportunities, institutional rearrangements, and normative change*" (Etzkowitz 1998: 824) which has again cognitive impact on prospective research agendas. This is especially true for the self-perception of academics on their individual role in decision-making processes. Thus, a simplified reduction on an absent debate on responsibility in research projects, as made by Gill has to be rejected (Gill 1991: 285). What he lambastes is the fragmentation of research into numerous single projects which hinders the individual researcher to get a broad idea of the risks caused by certain research activities. Moreover, researchers lack action alternatives since an effective change can only be realized collectively. To this effect, Gill refers to Kant and argues that scientists find themselves in an *unsociable sociableness* of research competition (ibid.). Even though he is on the right track in interpreting this complex and paradox relation of scientists among each other, his notion appears reductionist since the external economic pressure and the determining force of given technological and economic structures are played down. The social responsibility of researchers and a confusing situation in biotechnology are certainly given. However, these conditions have to be linked to the fact that public and academic researchers are carried into a market-oriented environment in which "*they find they must play its rules*" (Kloppenburg 2004: 325). Both the academic actors and the market shaped university structures have to be considered. Researchers and faculty staff cannot be viewed as profit-maximizing actors that are predominantly interested in commercializing research. Rather, they are anxious for articulating the social responsibility of the own university institution since federal funding (in the US) and IP laws exert governmental and financial pressure on them (Glenna et al. 2007: 156). The crucial factor is therefore, the university's appearance as a "*leading participant in the economic development of its region*" (Etzkowitz 1998: 825). As Etzkowitz puts forward, two main dynamics can be identified in these activities: One is the expansion of university research into development activities and the other one is a shift to commercial research objectives, work practices and development concepts (Etzkowitz 1998: 825). It is yet unclear whether and when efforts of one research or development project play an essential role in commercialization. Moreover, dispositional motivations in scientific-industrial relations can be observed in three different ways. The first approach is the idea that "*best commercial interest means that the public is buying it, which means that the public is benefiting*" (Glenna et al. 2007: 155). Thus, in relation to modern biotechnology, the main issues that are included into this practice and thinking are services such as consulting and teaching as well as goods, such as patents, information and publications. The conviction follows the equation of public good and application utilization. Things that are created, but never pushed into the industrial sector fail to benefit anyone and therefore have no value, but a questionable right to exist. However, in this notion, it is not clear why a beneficial usage has to be linked to commercialization and thus excludes any kind of indirect value or alternative value forms. The second motivation relates to the idea of *making good science* and money at the same time, including active participation in business ventures (Etzkowitz 1998: 827). Academic scientists are willing to work in academic laboratories and run an enterprise at the same time. This notion denies a passively receiving or blindsided actor and shows someone who actively attempts to change given paths. This shall not belie the assumption that actors are predetermined to the core by specific cultural and normative backgrounds, and in this case a positive interpretation of entrepreneurship and market orientation. Entrepreneurship and basic research are not seen as contradicting objects, but rather as complementary items that can be symbiotic. In this relation, scientists legitimate their commercially value work with the conviction, that this research will also contribute positively to basic research interests (ibid.). Pivotal developments in this regard are companies' attitudes towards the role of researchers. Private enterprises are not only interested in the expertise for the development of a yet uninvented good, but they are promoting the definition of this product as it is needed by the firm. Thus, the scientist is not only contributing a minor product of academic research, but is integrated into the complete production process (ibid.: 831). The third proceeding concerns strong economic and political pressure by industry and the state. In social systems of production with profound commodification processes, universities are forced to comply with private enterprises through transferred research objections. Universities are reliant from research funding in order to implement and continue research activities. If a university operates negatively according to the economy, state government might reduce or even cancel funding. What is important in this relation is the staffs' decision-making since they cannot merely rely on their own responsibility as an individual, but they need to act for in the university's interest. Thus, the "*university's social responsibility*" (Glenna et al. 2007: 156) significantly influences perception and action-taking. Societies with distinct long-term scientific-economic relations, such as in the US, are usually no longer faced with the question whether universities should conduct knowledge for profit at all, but rather how organizational innovations accommodate industrial connections (Etzkowitz 1998: 831). This raises the fundamental question of political and economic neutrality of science production. With respect to the relationship between the academic sector and the industry, Jessop's approach of *ecological dominance* has to be emphasized. In brief, *ecological asymmetry* articulates the *structural coherence* between economic, juridical and political subsystems which all operate autonomously, but are faced with material interdependencies of capitalistic orders (Jessop 2009: 168 ff.). Thus, academia as an independent institutional order and social living conditions is faced with the *always contingent shadow of ecological-dominant capital accumulation* (ibid.).

With respect to scientific-industrial relations there is the contestable concept of "discovery exchange" which is developed and implemented in late 1990s at the University of Colorado, Boulder USA. The overall purpose is to achieve significantly higher income by granting venture capital funds that finance a huge portion of university research (Etzkowitz 1998: 831). At that time, this strategy reached a new level of aggressiveness and expansion orientation which then became normal. Patents are carried on a broad range of only potentially useful findings irrespective of existing commercial value, but rather on the expected benefits (ibid.). Research capacities of academic staff have to be encouraged in terms of potential commercialization purposes. Therefore, the discovery exchange concept requires that one of the industrial staff members participates in meetings of research groups for a better identification of potential commercialization of certain knowledge (ibid.: 832). In this conceptualization, the significant uncertainty in biotechnology becomes apparent since strategies are designed to cover only potential benefits which are not based on actually given conditions. This generally illustrates the unconfident treatment of a new technology field with regard to its commercial value which is accompanied by an inefficient treatment based on cultural and social conditions. Since actors face uncertainties with regard to the technological and industrial paths they tread, the ultimate decision-making and strategy application is always predetermined by cultural background, norms and images of future situations.

6. The characteristics of systemic risk

The development and application of biotechnological techniques are deeply related to risks for the environment, animal and human health. This is mainly because biotechnology, irrespective of its specific application field, always affects the modification of living organisms. Due to this, the correlation to Hume's statement becomes apparent since the ultimate question on nature is raised, including uncertain consequences induced by human intervention in natural substances. Essentially, no human being is capable of indicating the genuine forces behind the modification of living organisms. Bringing about changes in the DNA structure means in no way to achieve insights on underlying causal biological processes or impacts on other organisms in ecosystems. Hence, issuing genetically modified organisms must consider the concept of *Entgrenzung*[7], which signifies the removal of boundaries in contiguous ecosystems, including pollution dispersal and gene flow. Risk evaluation is highly controversial since GMOs may interbreed or crossbreed with non-GMOs. Thereby, GMOs are an example for complex risks due to varying ideas on which items matter and the question of which mechanisms to include in the causality analysis (von Kraus et al. 2004). Considering the different assessments towards risk by diverse cultural backgrounds, risk can be identified as "*ambiguous*" (van Asselt/Renn 2011: 438). This ambiguity is typical for systemic risks due to lacking objective measurement for assessment. Rather, multiple legitimate viewpoints define a risk being tolerable and acceptable (ibid.: 437). Ambiguity can be linked to plausible reasoning and the insight that the assessment of a technology is related to cultural and normative values. At large, ambiguity emphasizes the social dimension of risk, particularly technology related risks. According to Krohn and Weyer, "*the risks of research become risks for the society.*" (Krohn/Weyer 1989: 352). Risk issues which are related to modern biotechnology cannot be restricted on sealed laboratory experiments, but have to include the whole human society, animals, plants, and microorganisms. It is technically impossible to prevent interactions and crossbreeding of GMOs with their wild or conventionally bred relatives. The crux in the release of GMOs is that risk taken in terms of technological safety science is frequently understood as the product of incidence rate and measures of damage (Skorupinski 1998: 139). Such definitions premise the quantification of both items. The possible consequences of released GMOs however cannot be foreseen due to a lack of explicit indications. With concepts of the game theory, one would rather speak of decisions under uncertainty than of decisions under risk, since there is no available information about possible consequences (ibid.). Risk means a calculable quantity that can be controlled and regulated whereas 'danger' is externally given and there is no way of influencing the situation. This notion on risk can be traced back on Knight's (1921) definition, who deals risk "*in terms of probability and effects, dose and response, and agent and consequences*" (van Asselt/Renn 2011: 436). As van Asselt and Renn state, this dimensioning of risk is in line with the "*technocratic, decisionistic, and economic*

[7] For a profound analysis of the concept of „Entgrenzung" see Ulrich Becks and Christoph Laus book "Entgrenzung und Entscheidung" from 2004 and also the text "Wie zukunftsfähig ist die Globalisierung? Über ökonomische Entgrenzung und ökologische Begrenzung" by Wolfgang Sachs, published in 2000.

models of risk assessment and management" (ibid.). Simple risks that can be calculated with means of statistics can be explained with the simplistic model of Knight whereas complex risks cannot be captured with a linear probability function. Hence, scholars turn from Knight's notion to a broader and deeper understanding of risk which includes numerically ordered distributions of probabilities. This means to open up for holistic views and the inclusion of societal processes and therefore the embeddedness of risks into contextual matters. Holistic approaches aim the consideration of "*hazard identification, risk assessment, and risk management because investigating systemic risks goes beyond the usual agent-consequence analysis*" (ibid.). Examinations of risk have to regard the several given and increasing interdependencies and spill-over and ripple effects that can be detected in systematic risk issues. To put it briefly, biotechnology as a systematic large-scale technology requires a corresponding notion on potential hazards in large-scale and systematic terms. This insight is shared by the OECD who states a "*growing problem of emerging systemic risks*" that requires to identify a "*set of cross-cutting issues deemed critical for the management of risks in the years to come*." (OECD 2003: 29). The OECD underlines that "*Technological change can reduce some risks while aggravating others or even creating new ones.*" (ibid.: 12). With respect to the 'discursive-material' the highly determining impact of the notion on life is stressed: "*Some emerging technologies change living matter, and represent an unprecedented potential to change the environment. They even challenge the definition of "living" and may change the whole notion of "human": "While the hope is that biotech (for instance) will improve living conditions and the quality of life, it can be argued that the long-term consequences of interfering at such a basic level are impossible to evaluate with the state of knowledge.*" (ibid.). A contestable argumentation is, however, to say that irreversible damage can be done before much is known about the danger or to delay action if risks are in large parts socially accepted by another country that considers risks as not existing or irrelevant and do not demand further regulation and political intervention. Institutional struggles on this can be observed at the international level with the Cartagena Protocol that contains two incompatible risk principles as well as in the EU who challenges food and health security on the supranational and federal level.

After the exploration of the main aspects of modern biotechnology in general, the following section specifies modern agri-biotechnology. A significant analytical advancement is to add the agricultural component to the technological debate.

Chapter three: Modern Agricultural Biotechnology

Genetic engineering (GE) in agriculture

The prior chapter dealt with the specific characteristics of modern biotechnology on a high abstraction and moderate complexity level. Based on this, the next step is to increase both the abstraction level and the degree of complexity in order to examine modern agri-biotechnology. Therefore, this section starts with a brief historical introduction and definition of modern agri-biotechnology, including applied methods which have to be distinguished from traditional and conventional breeding techniques. What follows is the supplementation of the economic dimension by demonstrating applied methods and modification forms in GMO food production. Since the application of genetic engineering on agriculture is limited to a few main crop varieties, relevant risks are signified. These are illustrated in detail and complemented by an explanation of the two relevant risk assessment principles: *substantial equivalence* and the *precautionary principle*. The last part dwells on Intellectual Property Rights (IPRs). IPRs signify both patents and Plant Breeders' Rights (PBR). Finally it is explained which objections prevailed against plant patenting and what patenting motivations have asserted.

Modern agri-biotechnology differs from other modern biotechnology fields, however, also from traditional and conventional breeding methods. Although humankind conducts breeding for over 10,000 years in order to improve growth rates and yields, to create pest and disease resistance and ultimately to enable better nutritional characteristics, modern agri-biotechnology sets a milestone with the application of genetic engineering by recombinant DNA or rDNA techniques. Scientists mainly transfer desirable traits, particular for pest resistances, disease and herbicide tolerances, from one living organism to another. A very important aspect is the focus of GE on only a few plant varieties, namely on corn, soybeans, canola and cotton. As mentioned above, complex technological systems are socially, politically and ethically mediated and not neutral or objective. As a consequence, the application objects of the technology cannot be considered to be neutral as well. These plant varieties are broadly planted partially because of their high yield rates which provide economic benefits. In fact, their dominance is not incidental, but the contingent necessary product of innumerable factors which cannot be exemplified in detail, since humans cultivate plants longer than they use rDNA in agriculture. In this part, it is aimed to examine the main developments that enable modern agri-biotechnology, though agriculture fundamentally underlies geographical and biochemical developments that are not evident or empirically provable. An important element in GE crop planting is the specific type of genetic modification. GMOs are usually either herbicide tolerant, insect resistant or contain stacked genes, which is a combination thereof. The development of herbicide tolerance is pursued in order to make plants resistant to the toxic effects of herbicides that are applied for eliminating weeds. The most applied herbicide is Glyphosate, an active agent in the broad-spectrum herbicide “Roundup” by the enterprise Monsanto.

1. The history of modern agri-biotechnology

Plant breeding can be roughly divided into three major periods. The first implies traditional breeding techniques, the second one conventional breeding and only over 40 years ago the dawn of a new breeding era could be witnessed with the development of the rDNA. Traditional plant breeding began 10,000 years ago as human societies started to domesticate crops and animals and to select animals for breeding and plant materials for reproduction. Nearly 7,000 years later civilizations invented technologies for cheese making, wine fermentation and beer brewing, which are also classified as traditional biotechnology (FAO 2002). The roots of conventional biotechnological plant breeding can be found in Gregor Mendel’s experiments with peas in the second half of the 19th century. He enabled a much better research on genetics, particularly on the heritage of traits in other crops and plants. Based on this, the technique of *hybridization* which is based on cell and protoplast fusion could be developed in the 1930s (Biotechmobil 2014). This method implies a breeding process with plants in which inbred lines are crossed for producing plants that have bigger yield potentials than exhibited by the parental plant. The cell fusion enables the multiplication of chromosome numbers that include the desired traits and can solve restriction of gene transfer through vectorization at the same time (Biotechmobil 2014). What follows is the so called *heterosis effect*. The advanced feature of that hybrid will not be transmitted to the following generation. However, plant breeding methods such as mutagenesis and in vitro procedures (haploidisation, multiplication) give rise to high yielding rates, especially to rice, wheat and other crop varieties (Schenkelaars et al. 2011: 15). The technique of hybridization is closely related to genetic engineering since it uses DNA and same methods, but it does not mix different genes and is commonly uncontroversial (Biotechmobil 2014). During the 1940s to 1960s significant generic interventions are the application of *mutagenesis*, *tissue culture* and *plant generation* as well as the discovery *transduction* and *transformation* (FAO 2002). A fundamental development at this time is the work of James D. Watson und Francis Crick who have discovered the double helix structure of DNA in 1953 (Schenkelaars et al. 2011: 15). In the mid-60s molecular biology discontinued research on the linkages among structures and functions of macro molecules and replaced it with research on tightly focused transfer of single genes among diverse organisms. This is enabled by the discovery of bacterial restriction enzymes which allow the sequencing of DNA at specific desired spots. The discovery of further biological macro molecules which can be applied as instruments as well as the development of various laboratory techniques for the isolation and proof of DNA-fragments opened up the door for selective genetical modifications organisms. The era of modern agri-biotechnology starts with works of Herbert Boyer and Stanley Cohen in 1973, as they constructed a recombinant plasmid and successfully infiltrated it into an E. coli bacterium (Louwaars et al. 2009: 21; Wieland 2009: 214). This discovery led to a progress of several new instruments in plant breeding, foremost to genetic modification (rDNA technology, transgenesis) in the 1980s, and marker-assisted selection (MAS) and some more molecular marker technologies in the 1990s (Schenkelaars et al. 2011: 15). It is 1982 as the first GM plant is produced, namely an antibiotic-resistant tobacco plant. Four years later, in 1986 France and the US implemented first field experiments with tobacco plants with herbicide resistance (Conner et al. 2003). By the 1990s, extensive activities in genetic fingerprinting of a variety of organisms are conducted followed by first field trials of GE plant varieties (FAO 2002). In 1994, the first genetically modified crop variety is approved for commercial use in the US market: The Flavor Saver tomato is released, but soon withdrawn from the market in 1997, since it failed the promised traits and has bad resistance characteristics. In fact, it is not the US with its Flavor Saver tomato, but China that had approved the first commercialization of transgenic plants in 1992 with a virus resistant tobacco plant that is, however, taken off the market in 1997 (Conner et al. 2003). In these early days of modern agri-biotechnology, in 1994 the EU had approved a GMO tobacco plant which claimed to be herbicide resistant. In 1995, the US had approved several crop varieties: canola, maize, cotton, soybeans and some others. In 2000 the highly contested *golden rice* is introduced in the market for fighting a shortage of dietary vitamin A mainly in Asian countries. Research on molecular biology contributes to some essential techniques, such as sequencing and computing that led to the below described breeding technologies.

2. Techniques in agri-biotechnology

2.1 Techniques in conventional plant breeding

Conventional plant breeding can be subdivided into classic and modern methods and is the groundwork of genetic engineering. Classic plant breeding choses plants with certain traits of a certain phenotype and reproduces it. The plant’s hereditary traits, thus the genotype is not considered. One of the modern breeding methods is SMART Breeding („Selection with Markers and Advanced Reproductive Technologies“) and does not refer to the phenotype, but operates with molecular markers. However, since modern agri-biotechnology is the main focus of this work, conventional plant breeding methods are not broadly considered.

2.2 Techniques in modern agri-biotechnology

2.2.1 Genetic engineering

Unlike conventional plant breeding methods, genetic engineering directly concerns the genome of living organisms and thereby the DNA substance. Genetic modification describes the way of DNA transfer either through biological (with soil bacterium agrobacterium tumefaciens) or physical (particle bombardment) insertion of DNA parts into the host body (Louwaars et al. 2009: 22). The commonly announced motivation behind this is to make certain plant varieties resistant against specific pests and to decrease the usage of pesticides by farmers. Briefly expressed, the differentiation between plant breeding in general and modern agri-biotechnology is very important since several methods are similar, but only genetic engineering modifies DNA substance. Modern agri-biotechnology is related to the fields of system biology, biochemistry, process engineering, micro and molecular biology. Genetic engineering is usually applied to plants, foods, feeding stuffs, ingredients of foods, animals as well as micro-organisms in production and treatment processes of food (Conrad 2004: 10).

2.2.2 Molecular marker technology

Marker technologies play a huge role in the genetic make-up of organisms. Louwaars et al. call the AFLP DNA fingerprinting technology, which is developed in 1990 by the Dutch biotech enterprise „Keygene“, and seed companies as a "breakthrough technology" in modern agri-biotechnology (Louwaars et al. 2009: 21; Vos 1995). This enables plant breeders to use DNA images for performing analysis of germplasm of their crops and to find out whether a DNA marker shows a linkage to a certain phenotypic feature. If so, breeders can use this for increasing speed and efficiency in growing processes or for decreasing costs that come along with plant breeding procedures (Louwaars et al. 2009: 22). Moreover, marker-based technologies enable a faster "back-crossing introgression of genes into a desired background" that can be adjuvant for breeding processes with wild relatives as well as for the introduction of new genes from the recent commercial varieties into the breeding programme of an enterprise. Fresher innovations are SNPs (Single Nucleotide Polymorphisms) that can be used for extracting "indigene" markers, which are more closely than "linked" markers and provide an easier way for scaling up and regulating processes at once (ibid.).

2.2.3 Novel Plant Breeding Techniques (NPBTs)

There is a whole raft of plant breeding techniques that genetically modify living organisms. The most important NPBTs are currently Molecular Mutagenesis, RNA-i (Intragenesis for gene-silencing), Reverse Breeding, Grafting on GM root-stock, Agroinoculation as means of selection, Cisgenesis, Intragenesis, Oligo-induced mutation induction, Zinc-finger nuclease induced mutation, Agroinfiltration, epigenetic modification, VIGS (Virus Induced Gene Silencing) and accelerated flowering (Louwaars et al. 2009: 23; Schaart/Visser 2009[8]; Schenkelaars et al. 2011: 15). These NPBTs have been developed in the last decade and are currently enhanced for an improved yield of crop varieties. Since these techniques are a new development in modern agri-biotechnology, it is yet not definite whether corresponding plants are classified and regulated as GMOs (Louwaars et al. 2009: 23).

3. The economization of modern agri-biotechnology

As illustrated above, modern agri-biotechnology is a broadening of conventional breeding techniques which increases *precision* (selecting individual traits) and also versatility (allowing sourcing DNA from a living organism). Since there are various product types in agri-biotechnology, there are just as many economic and technical concerns. In this context, the three generations of crop planting and pest control products are elaborated.

3.1 Crop planting in three generations

By and large, GMO crop varieties are restricted on a few arable crops: soybean, corn, canola and cotton. These and other GE crops are generally classified into three generations:

The first one relates to enhanced input traits which shall induce changes of plants in one or two genes for cultivating its agronomical characteristics, such as herbicide tolerance, insect resistance, and resistance to environmental stresses. The second generation is a way more complex since it pursues the enhancement of quality traits or added-valued output traits such as higher nutrient content of seed for feed by transforming or adding several new genes. Third-generation crops aim molecular-farming. This means to produce pharmaceuticals, bio-based fuels animal vaccines, and products being beyond traditional fiber and foods (Conrad 2004: 10 ff.; Fernandez-Cornejo 2004: 4; Qaim 2009: 666). The second and third generations with output traits (molecular farming) provide manifold application possibilities, including far better market potentials than the first generation. Conceivable fields are functional food, functional fibers, functional feed products, pet food, renewable raw materials, energy providing cultivated plants, biolubricants as well as pharmaceutical substances (Conrad 2004: 70). Hence, herbicide-tolerant (HT) crops are distinguished by resistance to herbicide Glyphosate and insect-resistant GMO crops that hold the soil bacterium Bacillus thuringiensis (Bt). In contrast to earlier years, modern agri-biotechnology in relation to the food processing sector has increasingly focused on the application of GE

[8] For a very detailed explanation of NPBTs and a comparison of these to conventional plant breeding techniques see: Schaart/Visser 2009: Novel Plant Breeding Techniques. Consequences of new genetic modification-based plant breeding techniques in comparison to conventional plant breeding. http://edepot.wur.nl/137009.

enzymes, in food additives, such as amino acids, vitamins, sugar additives, flavorings and flavor enhancers, whereas the application of transgenic substances in starter cultures (cheese, bread, sausage, and vine production) is very rare (Fernandez-Cornejo 2004: 4).

3.2 Pest control products

These refer to herbicide tolerant and insect resistant seeds and their complementary chemical products. These biotechnology innovations are also induced by pesticide policies. The ban or restriction of a certain chemical usually creates market opportunities for substitute products. Additionally, the restricted lifetime of a patent on biotechnology inventions is an essential factor since enterprises need to invest in development of new biotechnology pesticides and herbicides. This however stimulates to acquire start-ups which have developed new products and can provide research and development capacities. It is also conceivable to develop internal research capacities and buy IPRs to university innovations in order to benefit from their basic research activities (Zilberman 1997: 12).

Herbicide tolerance (HT) is developed in order to make plants resistant to the toxic effects of herbicides that are applied for eliminating weeds. In theory, HT crops can continue growing and thriving even when the chemical is applied. Conceivable developments are natural variation or mutation, where plants develop the ability to detoxify the herbicide or to avoid its effects. It is criticized that mutation does not efficiently induce HT for many herbicides. Genetic engineering enables plants to resist the toxic effects of the most relevant herbicide Glyphosate with the incorporation of a single gene from bacteria. Farmers can apply broad-spectrum herbicides over crops and weeds which only kill the weeds not the crops. This Glyphosate herbicide is assumed to be less toxic to other organisms compared to narrow-spectrum herbicides that are applied for weed control in past (UC Davis). The application is mainly conducted to HT-soybeans, HT-upland cotton and also HT-corn (Cowan 2013: 2). Currently, three distinct soybean variety traits provide herbicide tolerance (sulfonylurea-tolerant or STS, Roundup Ready, and a combination thereof) (Schenkelaars et al. 2011: 51). Furthermore, there are ten distinctive biotech traits in maize hybrids except of conventionally grown maize. These are predicated on herbicide tolerance (Liberty Link, IMI, and Roundup Ready), rootworm resistance (RW), including combinations (stacks) of at least two of these traits, and maize borer resistance (ibid). The significance of the complementarity of Roundup Ready and the GE crop varieties in its economic context is explained below.

Insect resistance: Developing insect resistant plants is the second major aim in the application of genetic engineering in agriculture. With genetic engineering the pesticide is transferred into the crop’s DNA in order to control the insect pests. Frequently, these crops are considered containing a plant-incorporated protestant (PIP) (Cowan 2013: 2). Most of the insect resistant plants are genetically modified with the soil bacterium *Bacillus thuringiensis* (Bt) which is known to be very selective, killing with alkaline digestive tracts. Bt is effective against the European corn borer, cotton bollworms (Lepidoptera), tobacco budworm, pink bollworm, control earworm, Colorado potato beetles (Coleoptera), and certain flies and mosquitos (Diptera). It is mainly applied to corn, cotton and potatoes which are commercially profitable. Significantly, Bt does not harm humans, other mammals, birds, fish, or beneficial insects (ACES Illinois 1995). The frequently applied GE trait is the well-known Glyphosate tolerance which is obtained by the expression of an Agrobacterium tumefaciens Enolpyruvylshikimate-3-Phosphate Synthase (EPSPS) and through the production of insecticidal proteins which are derived from Bt crops (Nicolia et al. 2014: 3). Summarized, transgenes that increase the dispersal potential of plants are a) insect, fungi, virus, and disease resistances; b) heat, could, salt, and stress resistances; c) transformed seed lipids; and d) herbicide resistances (UBA 2000: 33).

4. Risk issues

4.1 Environmental and health hazards and control strategies

A crucial aspect is the potential hazard that arises from horizontal or lateral gene transfer from GMOs to organisms flourishing in the surrounding environments. There is a relatively profound knowledge about horizontal or lateral gene transfer among bacteria which is marked as a "*major source of evolutionary prokaryotes*" (EU Commission 2010: 48) whereas the rates and mechanisms of horizontal gene transfer in eukaryotes is almost unknown. This is problematic since any kind of "*potential bacterial-to-eukaryote transfers*" (ibid.) remains potentially hazardous, especially with regard to potential plant to animal transfers. Particularly the issue of coexistence of different production systems is concerned. In fact, it is the *gene flow* that occupies the scientific community (Nicolia et al. 2014: 8). The dispersal of GMOs from one place to another can transfer micro-organisms from unfavorable environmental compartment into an environment with more favorable conditions for survival. Such transportations can be made through running and rain water, wind, and by on things or crop goods affixed organisms. In release experiments GMOs could be proved vertically in deeper soil layers as well as a lateral transports (UBA 2000: 5). Other relevant risks are the replacement of native species from autochthonous micro-flora and hybridization potential, which is an uncontrollable dispersal of transgenic plants. Noteworthy, there is no unitized measurement for the exploration of dispersion potentials of GMOs. Pre-risk assessment primarily relies on the original plant as well as on transmitted genes and gene construction, but yet, the impact of the intended feature modification on the dispersal behavior is broadly unclear. Hence, the vertical gene transfer from transgenes through intra specific and inter specific hybridization into related cultivated crop and wild plant varieties causes controversies (UBA 2000: 6).

The first commercial release of transgenic HT soybeans is in 1996. Since then, various unintended transformations evolved which can be traced back on position and pleiotropic effects. A changed phytohormone balance could be observed and a drastically higher lignification of the caulis. This can induce crop loss when higher temperatures cause a fan out of the caulis (UBA 2000: 7). Just as GE-soybeans, also GE-cotton has induced unexpected problems since its commercialization. In 1997, in some planting fields for HT cotton capsule deformations and a precocious dropping of the caulis are found. Similarly, in certain areas where insect resistant cotton varieties are growing, harsh pest infestation by secondary organisms are proved which have barely appeared to date, and ultimately lead to a higher application of pesticides (ibid.). Due to a lacking observance of significant differences among transgenic herbicide tolerant and conventionally grown rape in their competitive characteristics, an imbrutement is highly conceivable. In Europe this factor is much more relevant than the growing of GE maize since canola originates in Europe, unlike corn. Crossing experiments have already induced a significant gene flow from GE canola to the population of their wild relatives. Potential hybridization partners of *brassica napus* can therefore not be restricted on the immanent genus, but in further genera of the family of crucifer (UBA 2000: 7).

Planting GE plants raises concerns on biosafety and thus the question of Bt resistance of insects and microorganisms, since several studies deliver appropriate observations. One crucial example is the corn borer which frequently returns to crop areas despite applied pesticides. The consequence is an increasing application of pesticides by farmers which thereby impair the environment (TransGen 2014). An attempt to prevent the proliferation of pesticide resistant insects is the establishment of a cultivation concept named "*refugia*" (BMBF 2014). The aim is to avoid harms caused by resistant insects through keeping refuge areas in case of large-scale GMO cultivation. The idea is that varmints can escape if there are fields with conventionally cultivated crops (TransGen 2014). In this relation, it is fruitful to tie up to the lack of information concerning central biological aspects as it is mentioned in the horizontal gene transfer in eukaryotes. This is since there is also a tremendous lack of reliable information about the Bacillus thuringiensis (Bt). Exceptions are toxigenics that are known to be highly movable and whose rearrangements enable multiple genetic combinations (Skorupinksi 1991: 135). The important aspects in this relation and towards the Bt agents in maize are the uncertain and unknown effects on non-target organisms. In case of Bt maize researchers did not find proof for harm on the corn borer while the deltoid moth is evidently endangered (TransGen 2014). It is also commonly known that there is an unwanted effect due to the abolition of the selective effect of Bt-toxins when expressed in the plant. Thus, the toxins lie in the plant in a different order than in Bt itself, so that the effects can change unexpectedly and cause harms to non-target organisms (Skorupinksi 1991: 135). Significantly, when corn borer larvae eat transgenic maize and are then eaten by green lacewing larvae (Chrysoperla carnea) then these green lacewing larvae die (Hilbeck et al. 1998). However, irrespective of the specific insect that becomes resistant, it has to be emphasized that the emerging resistances are generally triggered by a strong selection pressure with native organisms. This could already be proofed in several cases and different territories (Skorupinksi 1991: 136). Concepts for resistance management are numerous, but they fail to contribute to a prevention of these resistances. Rather these concepts pursue only a delay of effects. The success of these concepts depends on the extension of possible cross-resistances. In fact, this question on how to evaluate possible effects on the environment is fundamental for decision-making processes and is subject to the general treatment of GMOs. The evolution of resistant organisms is not beneficial for farmers, since they apply significantly more pesticides and herbicides that aggravate environmental damages in turn. Furthermore, it causes economic harms and health damages for farmers, since they have to buy expensive toxins and are in direct physical contact with these substances. Issuing the use of chemical plant protection products is in fact not more than the attempt to solve a part-problem in an overall problematic situation. This situation is characterized by mechanization and specialization of firms and is accompanied by irreversible soil degradation, harms on ground and land water as well as oust of cultivated plant varieties and wild relatives (ibid.: 137). As a consequence, the development of genetically protected biological pest control can only be viewed as a part solution in the context of conventional high-yield agriculture. Thus, sustainable agriculture as a solution approach is highly questionable due to resistance developments. While sustainable agriculture pursues to avoid pest infestation instead of fighting pests. In case of pest infestation however, it is possible to use non-genetically modified Bt-preparation (ibid.).

4.2 Risk assessment: the substantial equivalence doctrine vs. the precautionary principle

Briefly expressed, the concept of *substantial equivalence* (SE) means that GE crops are compared with their isogenic counterpart and in this sense do not differ from their genotypes; quasi from their non-transgenic counterparts. The SE principal is used for risk assessment of GE crops which are pursued to be commercialized. Thus, a two-step procedure is applied for illustrating SE. First, the GE crop is checked under its morphological, chemical and agronomic features, such as macro and micro nutrients and toxic molecules. The findings from this exploration give information for eventually required analysis on nutrition values, which is thus the second step of the analysis. Commonly, any aberrance which is given within the variability that is considered normal, arranges the crop as being safe (EFSA, 2011). In case of compositional deflections, the crop must be assessed under its safety provision (ibid.). As explained in the previous chapter, risk needs to be considered with its social dimension, particularly ambiguity. The two principles follow fundamentally differing approaches which are incompatible in terms of institutionalization. At this point, the analysis can be thrown back to the argumentation in the very first chapter on plausible reasoning. Both the precautionary principle and the principle of substantial equivalence can be legitimately defended, but essentially the SE principle has to be applied cautiously. This is mainly because of the uncertain effects on the environment as well as animal and human health. Due to this, a tentative attitude is required as explained in the first chapter. The regulation of living organisms confronts decision makers and scientists automatically with the question of biological reactions. Hence, it may end up problematic when reactions such as resistances appear. However, this section aims to focus on the technical sides of agri-biotechnology so that aspects of institutional implementation processes are part of upcoming chapters.

5. The Judicialization of agri-biotechnology

5.1 Intellectual Property Rights for crop protection

The term ‘Intellectual Property’ (IP), appeared in 1855 for the first time, used by the American Liberian Lysander Spooner who argued that inventors and scientists deserve permanent property rights on their ideas (Dutfield 2003: 53). IP describes the branch of law that protects the application of commercially valuable thoughts, information and ideas. Generally, it covers patents, copyrights, trade secrets, trademarks and other similar rights (Cornish 1989). Relevant inventions in agriculture and modern agri-biotechnology are protected with Intellectual Property Rights, which signify both patents and Plant Breeders’ Rights (PBR) or Plant Variety Rights (PVR). IPRs provide exclusive monopoly rights over the creation of a new plant variety for commercial aims over a specific period of time (Dewan 2011: 133). IPRs therefore relate to the techniques used on living organisms or part of organisms in order to modify products with improving features of plants and animals or for developing microorganisms for specific uses. The rise of modern biotechnology, including rDNA, cell fusion and monoclonal antibody technology has induced new requirements for the protection of information, ideas and knowledge, particularly genetic information (U.S.C. Office of Technology Assessment 1990). Biotechnology patents or biopatents are filed for over 150 years. An inventor from Finland issued Patent No. 3 on 8 November 1843 for a novel production technique for yeast cultures. The famous microbiologist Louis Pasteur has enhanced yeast production techniques and granted a patent for this on 29 July 1873 at the French Patent Office. Also the large industrial company BASF has patented a biotechnological invention, named *alizarin* in 1869, which is applied in textile manufacturing (EPO 2013a). In many countries patent legislation emerged in the early 19th century. These legislations provided an instrument for protecting inventions of private individuals. The requirement of an invention to be novel and industrially applicable is similarly present in the most national patent systems. The third demand of non-obviousness – which is essential nowadays – is added by case law in the mid-19th century and is later on amended by legal codifications (Dewan 2011: 131). However, this may not detract from the fact that PBR are established in the first half of the 20th century, whereas patent rights grew in importance with the rise of modern biotechnology in the 1980s, although was applied for a long time. PBR are rights given to plant breeders for the protection of the genetic makeup of specific plant varieties holding the criteria of novelty, distinctness, uniformity and stability (ibid.: 133), thus, PBR protect the variety and not the used method that helped to develop the "*new*" variety. With PBR plant breeders get the right for a new plant variety. Significantly, there are yet several exemptions, for instance the farmers' privilege permitting for saving seeds, the breeders' exemption to use another breeder's protected variety as a base for his further breeding and furthermore, exemption given to researchers allowing scientist to use the protected variety for scientific purposes (Schenkelaars et al. 2011: 21). Significantly, holding a patent means to have an exclusive right as an inventor to exclude third parties from using the patented products and processes, but not for its usage or implementation. If necessary, the patentee has to apply for permission in order to use and market the patented invention (EPO 2014). Unlike PBR, patent right systems do not include exemptions for breeders or farmers, but provide extraordinary strict exemptions for researchers in some states (Schenkelaars et al. 2011: 21). This causes high tensions between patent tights and PBR, visible in several litigations by the US, Canada and Australia against overlapping rights (Rimmer 2003). Their litigations impede a violation of PBR, namely the saved seed exemption as not generating corresponding exemptions from violations of the patents that relate to the same plants. Moreover, violating acts on PBR, e.g. exporting the plant variety do not infringe a patent on that variety that gives the patentee exclusive marketing and distribution rights (Rimmer 2003). Additionally to the patent categories three main patent types are defined for biotechnology: a) structure patents which cover the purified and isolated gene; b) function patents that cover a novel usage for the DNA in question, for instance gene therapies or diagnostics; and c) process patents which are related to new methods of purifying, isolating or synthesizing DNA material (BMEL 2010: 6).

5.2 Objections against plant patenting

In fact, there is a rejection of plant patent protection between 1790 and 1970, based on non-compliance of plant inventions with the legal system of patentability (Dewan 2011: 131). In this context there are five main objections that played an essential role in the patentability debate about living organisms. The first one refers to the "Product-of-the-Nature Doctrine" that reveals the plant breeders' products not to be the result of a creative process which is yet the main requirement of patentability. It is thought that patent protection for plant life is like "*granting patents for the use of natural powers, which would prevent progress.*" (ibid.: 132). A further objection considered plants as living organisms and is therefore not allowed due to ethical reasons. For breeders this did not mean a rejection of plant patents because of the missing creative step, but because the products are given in nature. Another main objection touched the inability of patent protection for plants to comply the requirement of being a novelty. The fourth objection is put forth against plant patents insofar as plant varieties developed with traditional methods did not include inventions and "*new*" varieties and therefore are not non-obvious to an ordinary skill in the variety. At last, the missing industrial applicability is outlined that is generally given in breeders' products. This notion is countered with the idea that agricultural inventions should be included in patent protection because several agricultural products, e.g. machines or fertilizers, could be acknowledged in this category of patent protection. Unlike, in cases of agricultural activities or processes it is thought that patent protection did not fall into this category due to a lacking industrial character (Dewan 2011: 131). These objections have changed fundamentally. The general acknowledgement of issuing patents on living organisms reflects the widespread force of commodification at the global level. However, there is no clear demarcation between men and 'nature'. Concepts such as the Green Economy perpetuate the logic and rhetoric of quantifying earth, nature and life in general. According to North, attempts of quantification and its corresponding legal conduction is however not a sign of rationality and objective measurement. On the contrary, innumerous problematic fields in law and industries evolve since it is not clear how to treat natural resources and immaterial goods, mainly the knowledge about the usage of natural substances. Conflicts are even harsher at the international level if states do not have similar legislations on environmental protection and the exploitation of natural resources.

5.3 Patenting motivations

As objections against patenting living organisms decreased, the motivation for patenting increased. To this effect, the motivation behind the introduction of bio-patents is first, that the protection of biotechnological inventions plays a fundamental role in the industrial development of societies and secondly, the required investment for R&D, particularly in the field of biotechnology can only be profitable if there is an adequate legal protection (BMEL 2010: 6). Immaterial goods such as knowledge and information are not naturally scarce and rivalrous as comparable material goods. Therefore, extracting a price for the usage of non-rival immaterial goods, particularly knowledge is not easily done, but requiring the creation of real prices for marketing opportunities. Transforming information or knowledge into IPRs generates legal benefits for ownership. May sums up three main aspects of these benefits: first, the "*ability to charge rent for use*", secondly, "*the right to receive compensation for loss*" and third, "*the right to demand payment for transfer to another party through the market*" (May 2010: 4). However, IP is permanently in a balancing situation of private ownership against the social use of the public that requires a broad distribution of helpful ideas and knowledge. This debate on public versus private interests becomes increasingly important since private investments accumulate in biotechnology. This is since trade secrets can be viewed as the ultimate type of private property with relation to knowledge (ibid.: 9). At this point however, it is important to understand the issue of legitimacy and political economy on the claim of IPRs. Thus, the cause of the most debates on IP underlies diverse traditions of socio-legal conditions that can be applied and therefore challenges property ownership in general.

Noteworthy, high-throughput technology became faster and cheaper with provisions of data about the genotype. It is assumed that within a few years the entire genome of about 20 crop varieties is completely covered by patents due to the patentability of native traits which are in fact traits that exist in nature (Schenkelaars et al. 2011: 57). High-throughput sequencing shall determine the phenotype of plant varieties while bioinformatics compute all relevant data. Additionally, lawyers are demanded to set patent requirements, which will ultimately result in a "*patent machine for carpet bombing*" (ibid). As a consequence, profound research and development becomes highly infeasible, since access to germplasm and genetic diversity is widely locked. In this relation, the threatened diversification of germplasm is very problematic because plant breeders are reliant on a broad diversity for developments in agricultural biotechnology (Schenkelaars et al. 2011: 57). Relatively new developments are patents that combine biotechnological processes with conventional breeding methods. In conventional biotechnological processes alien genes are inserted into a plant. In contrast to this, there are biotechnological processes that contain genes as instruments without initiating GMOs such as marker-assisted selection processes. What is decisive in this case is the scope of patents through derived protection. Novel biotechnological breeding methods such as molecular marker only serve the sequencing of complete genomes and a more precise definition of characteristics that are given in nature. They do not create new genetic diversity, but merely enable a proper characterization thereof (BMEL 2010: 12).

In connection with the section on modern agri-biotechnology which aims to explore the relatively technical sides, the following chapter adds the spatio-temporal dimension to the research topic. To this effect, relevant institutionalization processes are analyzed, containing economic, political and judicial dimensions at the international level.

Chapter four: The Spatio-Temporal Dimension of Modern Agricultural Biotechnology

The international regulation of modern agri-biotechnology

Together with this section an essential contribution is made in the analysis of modern agri-biotechnology by supplementing the spatio-temporal dimension. The level of abstraction is reduced while the degree of complexity reaches a higher level. It is primarily aspired to identify the unique characteristics of the institutionalization of modern agri-biotechnology at the international level. Main aspects here are the industrial structure of modern agri-biotechnology, the institutional embeddedness of Intellectual Property Rights and biosafety issues.

For the sake of clarity, it has to be stressed that literature on modern agri-biotechnology often contains a division of different temporal phases and institutional developments. What is preferably conducted here is to relate to significant developments at their corresponding time points, which are therefore not restricted to a defined phase. However, this chapter increases both the abstraction level and the degree of complexity while referring to the assumption of a distinct interplay among academia, politics and economy. It must be underlined that the regulation of GE food products struggles with the removal of boundaries (*Entgrenzung*) in two ways: First, the release of GMO crops is an environmental issue with respect to pollen dispersal, gene flow and particularly its threat on biodiversity. Second, its institutional, administrative and legal regulation experiences a diffusion of policies and competencies on *multiple levels* while challenging globalization. Environmental hazards caused by GMOs are analyzed in the previous chapter. Complementary, this section aims to examine the institutional diffusions and complexities of international GMO regulation. Namely, the US fosters the development of GE food products at the international level, including the establishment of relevant institutions and enterprises. Considering the market side of agriculture, seeds have distinct markets and production processes, but plant breeding that applies genetic engineering and other biotechnologies shape the current seed industry. With respect to the economies of scale, there is a dominance of vertically integrated large corporations that rule research and development, distribution, and marketing issues on crop seeds. These relations are widely connected to product complementarity in terms of herbicide tolerance and insect resistance as well as in the challenging implementation of certain IP types. Better defined IPRs usually contribute to joint venture and strategic alliance. These vertical structures are complemented by horizontal mergers and acquisitions (M&As) which are linked to R&D costs, economies of scale and scope made by IPRs and also to regulatory costs. The overall structure of the international seed industry is characterized by a strong market concentration with only a few multinational enterprises that have great market shares. This market concentration is based on the named economic strategies and can be interpreted as the necessary product of contingent interactions in the seed market. Particularly the definition of *power as a specific form of causality that produces effects which would not have otherwise occurred under certain other conditions* must be considered here. Hence, power is given to multinationally operating seed firms that can adopt best R&D strategies and enforce strong IPRs in the seed market. Yet, there is no consent on the regulation of IPRs at the international level. Instead, there are several organizations and their treaties that do not stand in a clear relation to each other. This is supplemented by broad regulations and horizontal overlapping institutional structures. Related regimes overlap in scope, subject and time. Namely the relation between the UPOV and the WTO's TRIPs agreement is unclear. A fundamental change is introduced with the conviction of granting patents on biological inventions rather than to rely on PBR. The TRIPs agreement furthermore established a paradigm shift in legislation. It has substituted domestic competition legislation and carried it to the international level, forcing the presumption of domestic balance to be renegotiated under TRIPs objections. However, it is not fruitful to reduce the commodification of knowledge and information on the TRIPs. It is rather a treaty which contains sets of standards that are developed elsewhere for filling a prior lack of deliberate mechanisms in order to facilitate rearrangements. Crucially, the TRIPs is steeped in industrial interest groups of different countries, particularly of the US and other GMO food exporting countries. This emphasizes the *structural coherence* and interdependencies among the dimensions of law, economy and politics. It further stresses the unclear demarcation between structure and actor, since only a few actors essentially shape the structure and path of modern agri-biotechnology. The importance of causality however remains a fundamental factor. Other coincidences, developments, structures and actor constellation combined with other specific time points would have created fundamentally different occurrences. Going more into detail, the issue on the patentability of living organisms emerges. Currently, law affirms the patentability of natural substances as long as they are isolated by a technical process. Thus, in terms of patent protection, these natural substances are not mere discoveries, but *process inventions*. This can justify a derived patent claim in the isolated natural substance. Biopatents are only describable in functional terms and not in absolute terms. Due to this, the premises of *specificity* and *replicability* are problematic. By the 1980s, the barriers for technology have, however, dramatically decreased. Hence, machine-made gene-sequencing cannot be considered to be an inventory achievement. This is linked to broad patent claims, the meaning of an inventive step and technical processes. Conflictual situations arose from the equation of substances and genes or gene-sequencing. Moreover, the current regulation is confronted with economic inefficiency since the inflation of patents causes a barrier in innovation processes, forces researchers to develop a competitive attitude and requires more investment and R&D projects. The subsequent analysis of biosafety regulations is in line with the prior insights on interlocking dimensions. The Cartagena Protocol on Biosafety which entered into force in 2003 is shaped by market interests of certain industrial lobby groups. There are, however, also struggles on asserting the substantial equivalence principle which is not compatible with the precautionary principle. Disputes on the incompatible principles in relation to the US and the EU are, however, part of the very last chapter. Here, the complex structure, actor and power relations are explored. Significantly, in countries with widely dispersed GMO cultivation, there is no regional long-term monitoring programme on environment and health effects. In sum, the developments show the causal chains of non-necessary interactions which entered contingent interactions and thereby became contingent necessities. Main aspects that correlate to the causality are paradigm shifts and coactions of various social forces combined with commodification processes.

1. The industrial structure of modern agri-biotechnology

Developments as elaborated in the following are not confined to modern agri-biotechnology concern several other biotechnology branches which are not part of this work. In the few last decades, the large seed and pesticide industries are concerned with a significant horizontal and vertical integration, including IPRs. This triggered strong market concentration processes and gross monopolies.

1.1 The worldwide distribution of GMO food products

According to ISAAA, in 2013 GE crops are planted on an estimated 175 million hectare worldwide. This is 3,5% of agriculturally used land (5 billon ha) and 12,5% of arable land. In turn this means that 96,5% of agriculturally used land or 87,5% of arable land worldwide are cultivated without the application of genetic engineering. The majority of GE plants is cultivated in five countries of a total of 27 GMO using countries: US (40%), Brazil (23%), Argentina

(14%), Canada (6%) and India (6%). The four main crop varieties soybeans (47%), corn (32%), cotton (14%) and canola (5%) are equipped with herbicide tolerances (57%), insect resistances (16%), or a combination thereof, named stacked genes (27%) (ISAAA 2013). In addition to these four varieties there are also cultivation activities on a small-scale level: the US plants GE-sugar beets and GE-alfalfa while Hawaii further cultivates GE-papaya. In the US, over 60 GE plant varieties are approved by APHIS for commercial planting in 2005. By 2012, 78 crop varieties are deregulated. Significantly, the development of GE crops multiplies since the first commercial release in the 1990s.

At this point it is highly important to stress the questionable creditableness of these numbers which suggest a constantly growing rate of GMO usage. To this effect, the environmental NGO 'Greenpeace' revealed in 2009 that the ISAAA – International Service for the Acquisition of Agri-biotech Application – exaggerates with the worldwide extension of actual GMO cultivation (Greenpeace 2010). Remarkably, the organization ISAAA is supported by significant biotechnology firms, such as Monsanto or Bayer (ISAAA 2014). Greenpeace explains that ISAAA claims a massive extension of agri-biotechnology in 2009, whereas Greenpeace itself assesses a stagnation of development and cultivation of GE plants since its first commercial release in 1996. The crop area for GE maize in the EU is even decreased by about 10% in 2009 (Greenpeace 2010). The defenders of modern agri-biotechnology are mainly a few seed firms who claim a worldwide "boom" of GMOs for creating a positive image. It is very crucial that the cultivation of GE plants has failed in most countries in various ways: the higher application of pesticides due to resistance developments, the missing profit for GMO farmers, threat to biodiversity and non-target organisms and even large crop shortfalls. The incredible monetary power of these enterprises combined with personnel that switches between law, politics and industries is particularly visible in the results of relevant reports. Even though the extension of GE crop planting should not be underestimated, it is remarkable that states ban GMO products if it is possible for them. Several examples stress the negative position towards GMO food which is often related to political power relations and forces. For instance Africa, where there is planted GMO food at the large-scale, is constrained by pressures from US firms which have historically been intervening into African agriculture already in the first half of the 20th century. Numerous attempts to get rid of GMO food planting are unsuccessful with a few exemptions (ACB 2012). Although this work does not focus on the north-south conflict, it is important to view the general development of modern agri-biotechnology with its embeddedness to international power relations and historical exploitation policies by industrial states, particularly the US. Without the aggressive proceeding and market culture of the US-Americans, there would probably be a small-scale agricultural structure and less environmental hazards caused by pesticides and herbicides.

1.2 The horizontal structure of modern agri-biotechnology

The horizontal M&As are related to R&D costs, regulatory costs and economies of scale and scope, caused by IPRs. As Fulton and Giannakas explain, the structure of the seed and chemical industry is dynamic, due to extensive M&A activities (Fulton/Giannakas 2001: 138). Notably, firm entry in modern agri-biotechnology sector is highest in early 1980s, continued by most important product innovations during the same decade (ibid.).There is a visible increase of M&As in 1996, the year of first commercial release of GMO crops in the US. There is also a higher concentration in specific markets among the relevant economic actors. For instance, Monsanto and Pioneer-HiBred (after acquisition DuPont Pioneer) controlled 15% and 39% of the seed corn market in the US in 1998. Also, both firms controlled 24% and 17% of soybean market in the same year (ibid.). The most powerful seed companies remain dominant since smaller firms still work under licensing and marketing agreements with them. Usually, a new crop variety is contracted to farmers or private firms for production and distribution purposes (Cowan 2013: 27). The status of today's industry is that only a few companies can assert in the seed market. Namely Monsanto, DuPont/Pioneer, Syngenta, Group Limagrain, Land O'Lakes, KWS AG as well as Bayer Crop Science (ibid.: 28). In empirical terms, Useche, Barham, and Foltz (2009) show with a discrete choice model that assessed value devolved to specific biotech traits varies significantly among individual farms and across regions. For a more profound analysis on market power in maize and soybean markets Schenkelaars et al. (2011) designed models of derived demand. The estimated models assume that the price of seed represents the function of the quantity of purchased seed plus the estimated crop price before planting time and controls for trait effects, hybrid life-cycle effects, and regional effects. During the time of late 1990s and early 2000s, there is an integration of the hybrid seeds industry into the agrochemicals industry that fostered commodification and thereby influenced the commodity chain control (Wield et al. 2010: 345). This development is related to the wave of new start-ups which ended in the late 1990s, so that M&As among specialized biotech enterprises had increased and thus show the ongoing development of clear and less diversified structures in biotechnology (Audretsch/Cooke 2001: 49). These developments can be observed in the market share and distribution capacity and the acquisition of access to high quality seed germplasm (Drew 2010; Fernandez-Cornejo 2004; Schenkelaars et al. 2011: 25). In fact, investment in research activities on crop variety, including plant breeding swell on since 1930 and increase productivity from 20 bushels per acre in 1930 to 140 bushels in 1996, which is an increase of 600% (Cowan 2013: 28). A fundamental premise for the establishment of modern agri-biotechnology is venture capital provision in order to support start-ups firms. Taking a view at the international situation of risk investments stresses once more the pivotal role of the US. In 2013, the US covered 68,2% of the global activities, whereas Europe only covered 15,3%, Canada 2,1%, China 7,2% and India 3,7% (EY 2014: 2). Furthermore, the US is the most active market for venture backed IPO (Cowan 2013: 5). The same is true for the increasing number of start-ups, although the numbers are constantly fluctuating in each region of the world (ibid.: 8).

In addition to the applied M&As, the impact of R&D is considerably high. According to the European Academies Science Advisory Council (EASAC 2004), from the introduction of strong PBR in 1960 up to the first commercialization of GMOs in 1996, global expenditure on plant breeding R&D increased 14-fold while the growth of public spending for agricultural R&D activities highly decelerated or decreased significantly (Schenkelaars et al. 2007: 19). Hence, in the late 1990s and early 2000s, the EU Commission made a research project on the "Policy influences on technology for agriculture" – chemicals, biotechnology and seeds (PITA). In detail, this project explored strategies of large and small enterprises in agri-biotechnology, chemicals and seeds and the question of what is shaping these strategies (European Commission 2004). One of the key findings is that R&D and M&A decisions are directly linked to prior given technology paths of individual enterprise cultures. Investment and innovation strategies are thereby very diverse and follow different motives and strategic approaches. The findings are appropriate to the assumptions illustrated in the chapter on technology. Established technology trajectories and path-developments determine the future direction and the way emerging pressures are faced.

1.3 Determining factors in the horizontal structure of modern agri-biotechnology industry

Since M&As are not confined to seed, chemical and agricultural biotechnologies, but are evolving in all industries, the concentration trend can be interpreted as a generally force to cost minimization and rationalization of industry capacities (Fulton/Giannakas 2001: 141). Market concentration is a product of these proceedings and convictions. There are two approaches specifically referring to seed, chemical and agri-biotechnology industries for explaining these concentration processes: sunk costs and escalation strategies.

With respect to sunk costs in concentration processes, the main effects can be traced back on R&D and IPR expenditures on the one hand and regulatory requirements that are introduced by governments prior to R&D outcomes on the other hand (Fulton/Giannakas 2001: 141). Sunk costs for competitive enterprises raise price needs above marginal costs, normally in reducing competition through other firms. Sutton (1991) considers two essential types of sunk costs with an exogenous or endogenous nature. Exogenous are those which cannot be controlled by the enterprise in particular or the industry in general. Examples for this are regulatory costs. Unlike, endogenous sunk costs are strategic variables at firm level. Examples for this are R&D activities as well as advertising. Economies of scale and scope consider large and diversified enterprises as producing lower average costs so that firms have extraordinary incentives to grow larger (Fulton 1997; Lesser 1998). As Fulton and Giannakas emphasize, also IP can create economies of scale since a specific gene with a certain mission, once isolated, can be transferred into several crops and thereby induce lower production costs (Fulton/Giannakas 2001: 143). Firms that fail to follow the force of concentration run the risk of being overtaken by larger firms with lower vulnerability and more economic efficacy. Fundamentally, these developments are not only theoretical, but empirically proven (see Ollinger/Fernandez-Cornejo et al. 1998). Usually, sunk costs and vested interests in combination with technological controversies cause delays and some modifications but seldom a breakdown of an entire technology path (Conrad 2004: 55).

Escalation strategies operate with R&D as it is known from the sunk costs explanation and further relate to M&A activities for achieving market dominance in modern agri-biotechnology (Fulton/Giannakas 2001: 143). The pursuit of escalation strategies can be successful if there is high substitutability of products from other relevant market producers on the demand side and if scope economies stand on the supply side. Since both elements are true for modern agri-biotechnology, escalation strategies are common in its market constitution. With respect to the specific isolated gene, the application of escalation strategies means to find scope economies on the supply side. These scope economies on the supply side enable the usage of technologies that are necessary for the use of these genes. On the demand side, chemical herbicides and pesticides are viewed as a substitution for conventional herbicides, pesticides and seed (Fulton/Giannakas 2001: 143). Notably, in modern agri-biotechnology it remains unanswered whether GE seeds and products are a genuine substitute, a complementary product or even completely rejectable. There are several crops created which are resistant to particular insects, such as cotton, potatoes and corn. Herbicides also refer to these few varieties, such as cotton, corn, canola and soybeans. The new genetic coding however enables a quasi-complementary and substitution relation to conventional and organic food products. This is because for products such as Monsanto’s Roundup Ready, soybean seeds appear as complementary products to the herbicide product which is Roundup in this case (Fulton/Giannakas 2001: 144).

1.4 The vertical structure of modern agri-biotechnology

The vertical restructuring is linked to product complementarity and certain IP which is not well defined. IPRs are also a factor in joint ventures and strategic alliances. Essentially, the combination of seed, chemical and biotechnology activities within one enterprise is one of the most striking developments in the vertical structure of agri-biotechnology (Fulton/Giannakas 2001: 141). This is particularly important for the value chain control (Wield et al. 2010: 343). Although many firms attempt to integrate pharmaceutical and biotechnology elements in the life science model, the bulk of these firms have now spun off their agricultural activities (King 2001). Another important element in this development is the increased implementation of strategic alliances. Formerly, it is usually the case that countries had their own local seed firms which developed appropriate seed for a geographically restricted market and which are also contracted to sales and distribution. A new development is the increasingly purchasing of seed by large biotechnology firms as a "*source of seed material in which to insert the genes for herbicide or insect resistance.*" (Fulton/Giannakas 2001: 141). Examples are found in the acquisition of Morgan Seeds, Argentina's second largest corn seed enterprise, and the Brazilian corn seed company Dinamilho Carol Productos Agricolas by DowAgroSciences in 1998. Another example is how Monsanto acquired a 30% share of the Brazilian corn seed market through the takeover of Sementes Agroceres in 1997 (ibid.).

1.5 Product complementarity and substitutability in modern agri-biotechnology

The illustrated herbicide tolerance and insect resistance of commercially valuable crops in the previous chapter can now be pulled together with economic aspects. The new genetic coding enabled seeds to become complementary and also substitute products for chemicals, which are both economically relevant (Fulton/Giannakas 2001: 143). Monsanto's Roundup Ready soybean seed is a (quasi-)complementary product to the herbicide Glyphosate Roundup and a substitute product for the conventionally applied herbicides for weed control in soybean crops. Buying or selling the seed corresponding to the pesticide is called a package deal. The importance of this production strategy can be outlined with the assumption that the planting of HT-soybeans is linked to little increased assets, variable profits and a decrease in herbicide application rate. Moreover, the cultivation of HT-cotton is associated with increasing yields and variable profits, but also with a lower herbicide use. Crucially, the introduction of HT crops increased the demand for complementary herbicides and in turn decreased the use of non-complementary herbicides (Fulton/Giannakas 2001: 144). Roundup Ready soybean is the most widely utilized HT crop in production, but crops are also developed for other herbicides or multiple herbicides. Since there is an increasing weed resistance to Glyphosate/Roundup, Monsanto announced the development of various *stacked trait varieties,* varieties that are resistant to Glyphosate, but also to the active agents *Dicamba* and *Glufosinate* which are further herbicide products (Cowan 2013: 2). Monsanto's reaction is noteworthy here since it shows the company's path-dependency and cultural orientation. Instead of pursuing a sustainable way of organic agriculture, the company attempts to create more chemicals for fighting resistances. Although it is plausible to assume further resistances against the new active agents or herbicides, it is obviously more plausible for Monsanto to develop products which are in accordance with the former production path. Probably this will be even more problematic in the future since more active agents will result in more resistances and uncertainties. More fatal is the untouched inner attitude towards biological processes. Monsanto would be better off to 'cooperate' with nature and not against appearing natural phenomena. There is a striking increase of HT and insect resistant crops from the period of 1996 until 2012 in the US (USDA 2012). These developments have to be seen in relation to the US seed market that can be separated into two growth cycles since the first market introduction of GMOs in 1996. Hence, the first elemental period is the time between 1997 and 2001 with a slower hybrid sale and a period from 2004 until today with a remarkably fast sell and distribution of hybrids. Next to hybrids, biotech traits introduced in the maize seed market show a similar development. Biotechnology products also imply two phases between 1997 and 2009 since their introduction. Between 1997 and 1999, all biotech products granted combinations of tolerance to IMI and ECB resistance, Liberty and Roundup herbicides (Schenkelaars et al. 2011: 57). Until a second period of offerings in 2003, new biotech products and traits are not developed. Between 2003 and 2007, the US seed maize market is provided with 24 new biotech products which included new traits (rootworm resistance), substitute products for traits which competed with products on the market (Agrisure CB and GT, Herculex I), second generation traits (Roundup Ready II) and various combinations thereof (ibid.). In sum, products in the US seed industry have increased dramatically between 1997 and 2008.

1.6 Economic strategies in the seed industry

Due to the striking concentration processes in the international seed market, it is beneficial to outline the applied strategies of the few dominating firms. The transnational enterprises that widely rule the seed market seem to pursue control over the entire value chain and not only on parts thereof. Such concentration processes and monopolies are problematic in various ways. In terms of environmental protection and food security the reduction on a few arable crops can cause biodiversity loss and a significantly higher dependency on the cultivated crops. With relation to power, democratic structures and transparency can be eroded. This will be elaborated in detail while considering Monsanto. With respect to the economic strategies of the enterprises Chataway et al. (2004) identify three varieties. The first way is applied by Monsanto in early years and from DuPont at a later point. This is to take over Pioneer seeds additionally to their agrochemical portfolio and invest high proportions of shareholder funds in acquisitions. Other companies view this strategy as "*buying the channel to market*" (Wield et al. 2010: 347) for chemicals. The second approach is conducted from other firms, such as Dow and Aventis, later bought by Bayer and also Zeneca and Novartis Seeds, which became Syngenta. In concrete terms, they have invested large amounts in biotechnology and made acquisitions for providing a way to the market, but they failed to invest in seed firms or distribution mechanisms in the same way as realized by Monsanto and DuPont (ibid.). The last strategy is pursued by BASF in the late 1990s. Since German firms did not grow with biotechnology in the same way as US-American or Japanese enterprises, they had to implement catch-up strategies. These catch-up strategies have various forms, but are all linked to the goal of applying genetic engineering. However, in 2012 BASF outsourced its agri-biotechnology line to the US due to public opposition and missing market opportunities in Europe.

1.7 The effects of Intellectual Property Rights on the industry structure

IPRs have a strong impact on agricultural biotechnology industries and show an upward trend in patenting innovations. According to the European Patent Office (EPO), during the time from 1980 until 2006, 41% of patents have been granted to US-based firms, also 41% to Europe-based enterprises and 18% to firms from other states. According to the US Patent Office (USPTO), patent applications are made to 75% by US-based enterprises, 15% by Europe-based firms, and 10% by companies from other countries (Schenkelaars et al. 2011: 21 ff.). The worldwide share of the top ten enterprises is estimated to 75% of all patent application at the USPTO and 42% at the EPO. In general, IPRs shift organizational and contractual structures in modern agri-biotechnology. This is due to the pressure of extending vertical integration or contracting and strategic alliances and particularly for the use of exploitation opportunities. In this context, the IP nature and its appropriate right are important. In case of well-defined IPRs, transaction costs can be kept down and benefit to contracting and strategic alliances. This enables independent enterprises to work "*alongside each other, each focusing on their specialty while at the same time having access to the intellectual property of the other firms through contracts, licenses or joint venture agreements.*" (Fulton/Giannakas 2001: 144). Vaguely defined IPRs, however, usually contribute to vertical integration through M&As. This is probably the reason why multinational seed firms bought out local seed forms in certain states rather than to put license genes to them. A very crucial aspect of creating opportunities for exploitation is linked to vertical integration. IPRs give companies the possibility to make use of their market power against the firms they trade with. This distracts the up or down stream enterprises to invest in new technologies or to develop new products which would be dealt with the bigger company. The main misgiving relates to the appropriation of the beneficial innovation. As a consequence, the dominant enterprise vertically integrates and results in a takeover of the R&D and market development. The integration of marketing systems of local seed companies into their own businesses by multinationals can be partially explained with the fear of local seed companies to fail at keeping their retailing on the long run (Fulton/Giannakas 2001: 145).

2. IPRs in modern agri-biotechnology

2.1 Overview

There is no international consensus on how to treat biotechnology, but a complex of organizations that are related to its regulation and legalization. International organizations such as the UPOV (Union internationale pour la protection des obtentions végétales), the WTO and the World Property Organization (WIPO, the United Nations permanent body primarily responsible for international cooperation in intellectual property) have separately implemented studies and conducted reports, but they only contribute to governments' awareness-enhancement on potential problems and provide various solution suggestions.

At the international level there are several relevant IPR treaties which provide protection for plant varieties. The UPOV had established two important agreements and another one is the WTO's TRIPs agreement. Both systems have broad sets of regulations for the protection of crop varieties with IPRs, which have to be met by the corresponding member states. To put it briefly, the two UPOV agreements contain a sui generis (standalone) protection system specific to plant breeders' demands. The TRIPs agreement instead requests its convention parties of using patents, a sui generis system or a combination thereof for the protection of plant varieties (art. 27.3 (b) TRIPs). The TRIPs agreement contains a broad flexibility in its regulation, but has an unclear relationship to the UPOV regime (FAO 2004). Most states fulfill the requirements with the integration of UPOV treaties into their national legislation. A very crucial aspect is that the TRIPs agreement together with the Convention on Biological Diversity, which will not be explored here, have asserted the conviction of protecting biological inventions rather with patents than with Plant Breeders' Rights. This has far-reaching consequences for a society's treatment with farming and its access to seeds. However, this is analyzed in detail while discussing conflicts between the US and the EU in the last chapter. Three IP agreements are established under the auspices of the WIPO: the Paris Convention for the Protection of Industrial Property (the Paris Convention); the Patent Cooperation Treaty (PCT) and the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (the Budapest Treaty). Since the elaboration of the UPOV system and TRIPs related issues are more comprehensive, the WIPO related treaties are examined first.

2.2 WIPO treaties

As the Paris Convention is originally introduced in 1883 only 11 countries signed, but in the meanwhile the majority of countries who have any form of IP law in their legislation signed it. The convention particularly relates to the national treatment of biotechnology, since it provides protection for an applicant in all convention countries. It mainly covers patents and defines them very broadly in order to enable patent protection to any of the forms of industry patents that are concerned under other convention states' laws. The PCT is first signed in June 1970 and last amended in 2001. The contracting parties to the PCT constitute the International Patent Cooperation Union "*for cooperation in the filing, searching, and examination, of applications for the protection of inventions, and for rendering special technical services.*" (art. 1 PCT). The overall aim is to simplify process of filing patent applications in several countries at the same time. Under this treaty, a single patent application can be filed in one of the receiving offices, defining variable numbers of convention states that can occur in a national patent being issued by each of the designated countries. However, the PCT does not create a world patent and the missing harmonization in patent law therefore remains. Finally, the Budapest Treaty is signed in 28 April 1977 and entered into force three years later, on 9 August 1980. It is regulated by the World Intellectual Property Organization (WIPO) and had 79 member states in 2014. Generally, states that are party to the Paris Convention have also access to the Budapest Treaty which is concerned with the deposit of examples of microorganisms for patent application purposes. The main motivation is to improve invention description since it is hard to provide sufficient definitions and demarcations. Its instrument is a series of International Depository Authorities (IDA) and the recognition by all member countries of a deposit in a single IDA. There are listed 37 IDAs in nearly 20 countries worldwide on 1 March 2008 (WIPO 2014).

2.3 UPOV

UPOV is established outside the system of the Paris Convention, but in close cooperation. The overall purpose is to introduce a Convention that safeguards an acknowledgement of breeders' achievements in breeding novel plant varieties among convention parties. Uniform and clearly defined guidelines guarantee an exclusive property right for the demanding actor. Until the mid-1960s there are only a few states, such as the US and Germany that provided IP protection to plant varieties. At that time plant breeding industries of ten West-European states exerted pressure on their governments to modify their regulations. The result is the formation of the UPOV and its ratification in 1961. The intergovernmental organization is headquartered in Geneva, Switzerland and has currently 71 parties. Relevant revisions of the convention took place in 1972, 1978, and 1991, while the last revision pursues the expansion of protection on new issues in agri-biotechnology (Fernandez-Cornejo 2004: 19). UPOV's essential contribution to IPRs in plant varieties is the creation the "International Convention for the Protection of New Varieties of Plants" which is adopted in Paris, France in 1961 (ibid.). The convention demands from the parties to adopt it into their national legislation to offer at least 24 genera or species protection within 8 years of signing. "*A protectable variety*" is defined as being distinct, uniform, stable (DUS) and novel. Remarkably, there is no obligation to apply the rules to all genera or species so that the system has to be extended gradually. The important principle of reciprocity in the UPOV Treaty leads to disparities in protection. Depending on the various national legislations and the plant species, a patent usually lasts for 20 – 30 years conferring exclusive rights for the patent holder, including marketing and reproduction activities, concerning seed, cuttings, whole plants, etc. A highly controversial issue is the last amendment of 1991 which enables enforcement against farm-saved seed. This means to retain seeds from the previous crop for planting in the next period. Particularly the *Global South* suffers from this regulation, but also US farmers, since powerful multinationals, mainly Monsanto, create dependences for buying new seed each crop season instead of retaining seeds.

2.4 The TRIPs agreement and its impact on patenting biotechnological inventions

Based on the WIPO treaties, the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) represents legally binding common ground-rules for IP protection – thus minimum standards for protection. As May underlines, "*unlike other aspects of WTO members' undertakings, the TRIPs agreement is a set of requirements for positive legislative action to establish the rights and protections mandated by various articles, rather than merely requiring states to refrain from certain actions of practices at the border.*" (May 2010: 74). What is crucial about the TRIPs is that it caused a fundamental change of traditional national and international paradigm. Essentially, the treaty substitutes domestic competition legislation and carries it to the international level, forcing the presumption of domestic balance to be renegotiated under TRIPs objections. However, any reduction of knowledge and information commodification and corresponding protection to the TRIPs agreement has to be denied. Notably, it is rather an overall institution that includes sets of standards that have been developed elsewhere, for a prior lack of deliberative mechanism for facilitating rearrangements (ibid.). The Intellectual Property Committee, which is a coalition of thirteen US corporations, had a distinct impact on the treaty's embodiment. The coalition came off during the Uruguay Round of the GATT in the time from 1986 to 1994. Among the participating companies are Monsanto, DuPont and Pfizer (Sell 2003: 96). This can be related to the chapter on modern biotechnology which introduced the structural coherence between various dimensions. The always contingent shadow of commodification trespasses the legal dimension since specific actors are able to assert their economic interests and constitute them legally. Remarkably, the separation between structures and actors remove and shift existing structures and actor constellations. To this effect, the notion on power has to be considered again as well as the causal conditions. Monsanto and DuPont could articulate and assert their interests due to the specific time points and prevailing mentality on the hand and their state of power at that time. This is particularly related to their impact on political decision-makers, which is explored in the next chapter. The regulations of the TRIPs are broadly contested and frequently criticized by NGOs, scientists, developing countries and others. Though, it plays an important role in upkeeping disparities between states of the *Global South* and those of the north, what signifies industrial states. With reference to biotechnology, the article 27.3 (b) of the TRIPs agreement is important since it requests WTO members to provide protection for plant varieties either by patents or by an effective sui generis system or by a combination thereof. Even though this contested article is highly relevant to the north-south conflict, it is also fundamental for the treatment of biotechnological inventions among developed countries or more precisely articulated, between the US and Europe. This is due to the reason that although plant varieties are treated differently, biotechnological provisions guarantee their integration into the IPR system (May 2010: 81). In sum, the TRIPs sets minimum standards for the treatment of inventions and forces member states to follow and implement WTO rules into their domestic legislation. However, as biotechnology evolved, patenting is brought into the field of plant breeding, since GE plants could hardly be protected with UPOV's Plant Variety Protection (BMEL 2010: 26). Another important article of TRIPs is article 28.1 (b) which defines the extent of a process patent to at least on the patented process and its direct products. This definition is very problematic if applied to bio-patenting. In the field of biotechnology, but also of chemistry and pharmacy the isolated discovery of a substance often allows the prediction on other substances. This can cause too broad patent claims (ibid.: 14). Further, the Directive on the legal protection of biotechnological inventions (98/44/EC in EC 1998) had extended in article 8(2) the scope of protection of derived substance protection on "*a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics*" (see also §9 German Patent Act, art. 64(2) EPC, and art. 28.1 (b) TRIPs). The article 8 (2) has to be read together with the preamble nr. 46, which declares the pursuit of an equivalent patent protection for self-replicating material.

Hence, the scope of patent protection is a result of the interpretation on requirements for an equivalent patent protection. If the *absolute product protection* is replaced by a *functional product protection*, as it is recommended by several scientists as well as politicians, than patent granting could premise an exact description of protein codification of a gene and its functions (BMEL 2010: 15). A specific issue with respect to the derived protection is in the field of animal breeding since breeding contains the steps of selection, cross breeding and mating. Significantly, mating allows animal breeding to be interpreted as a production process, including patent claims on the bred animals (ibid.).

2.5 Difficulties in biopatenting

Biopatenting signifies the patenting on biotechnological inventions and/or discoveries and causes various difficulties with regard to the usage of genetic resources in agriculture. These difficulties concern a shift in Property Rights on genetic resources of plants and animals (BMEL 2010: 12 ff.). Prior to the introduction of IPRs, control over these resources is only provided by the virtual appropriation of these plants and animals. The contained genetic information however was in public ownership or at least not defined as private property. This approach has, however, fundamentally changed in a way that the patenting of genetic information can now exclude third parties from utilization and marketing. Corollary, the demarcation between discovery and invention as well as derived protection and the scope of patenting claims became hampered (BMEL 2010: 12). The current patent law affirms the patentability of natural substances as long as they are isolated by a *technical process*. Thus, in terms of patent protection, these natural materials are not mere discoveries, but process inventions that can justify a derived patent claim on the isolated natural substance. Judicial law refers to the criterion of “technical teaching” (ibid.: 13). The functions of genes are by now understood as being in an interdependent relational system with other DNA-sequences and environmental conditions (relational paradigm). Yet, the function of a gene cannot be defined solely through the specification of the gene-sequence. Another aspect is that in the context of technological developments, requirements for the inventory effort are about to rise (inventive step) (Straus 2001: 1019). With regard to the patentability of DNA-sequences, it is argued that technological barriers have dropped dramatically in contrast to the 1980s. Hence, machine-made gene-sequencing cannot be considered to be an inventory achievement (Krasser 2009: 237). Moreover, the issue of *derived protection* is important. In the field of chemical inventions it is common that the scope of patent protection for a production method can be extended on products that are produced with a patented method as well as on natural substances that are isolated with a technical method. This notion is transferred on the patenting of animals and plants (BMEL 2010: 14). How this proceeding affects legal and political issues is analyzed below.

The current operation praxis is to rely on *absolute patent protection* instead of *functional protection*. Prior, only the production and usage of substances had to be protected as a *process patent*. Unlike this, the absolute product patent pursues *product protection*. The invention is regarded in the isolation and available-making of the corresponding substance. In this light, there is protection provided for the substance itself irrespective of any definition of its usage. Significantly, technological progress and a shift in genetic paradigm are about to force a shift from absolute protection to purpose-bound protection of genes and gene-sequences (BMEL 2010: 13; Wolfrum et al. 2002: 97). Product protection should be restricted in as much as it remains on the given function of the gene-sequence or sequence-segment. The benefit of this is a consideration of the variety of substances, genes or gene-sequences that are essential in shaping patent protection. Furthermore, the judicial scope of patent protection on genes and gene-sequences can be restricted on the linkage of the defined function (Wolfrum et al. 2002: 97). Brief, a defined equation of substances and genes or gene-sequences is problematic.

2.6 Economic inefficiency

It is commonly acknowledged that the application of IPRs on genetic information and thereby on living organisms is accompanied with several impractical ramifications. This is the economic inefficiency that is tied to the so called '*research tool problem'* and the *'reach through problem'*. The research tool problem signifies the case of too many IPRs in basic research tools which block progress in biotechnology (May 2010: 35). The consequence is a missing end product for marketing and thus an increasing demand for more investment and more R&D projects (Wolfrum et al. 2002: 42). The research tool problem also affects the aspect that property held in commons is related to the "tragedy of the commons". In fact, if all valuable scientific data is removed from the intellectual commons by assigning property rights then there would be rather a "*tragedy of the anti-commons*" (May 2010: 35). A lack of resources held in commons restricts the researchers' work since they need source material. In this context, the fragmented system of user rights is a vexed question among researches. Therefore, there are many debates on alternative open source data banks that shall solve these research blockades. Additionally, the 'reach through problem' relates to an end product that does not contain patentable material, but used patented material during the development phase. The patent owner will stake out claims for the usage of his or her invention (Wolfrum 2002: 42). Summarized, these both problems trigger controversies at the international level, since there is a blockade of R&D projects with benefits on the society as a whole and also because the costs for end products are a way to high because of the multiplicity of licensed products (Wolfrum 2002: 42). Serious matters of an inefficient use of the patent system are regarded first, in the research tool being a DNA sequence or a gene, second, in its isolation being rather a routine than the product of a creative innovation process, third, where this is an essential premise for further research projects, fourth, where the research tool is usable without the patent owner requiring for more investment for its availability and its license taker, fifth, when there have to be taken broad debts towards the patent owner (ibid.: 46). The difficulty of an efficient use from patents is further given by the heterogeneous interests within the biotechnology industry, the complexity of the necessary negotiations on patent rights and the inequality among shareholders (ibid.: 51).

The debate on gene patenting can be traced back on a simplifying model of both the research process and its results. This is the notion that one gene codes a certain protein which has a defined function on the corpus. When the gene is isolated, the substance comes out and is patentable if one can define a technological designated use. This simplified model assumes a relatively direct connectedness between the isolation of a gene and the development of valuable products, e.g. pharmaceuticals. The illustrated model is further added by the idea of a positive incentive on innovations in the biotechnological industry by the isolation of one gene (Wolfrum et al. 2002: 34). With regard to the issue of innovation the crucial debate on the use of patents in the development of innovation has to be stressed. It is widely acknowledged that patents rather hamper innovation instead of stimulating and fostering the process (Cukier 2006). An international expert team on biotechnology, hosted by the McGill University in Montreal, Canada has stated that the current IPR system relies on the equation of '*some IP is good but more is better*' (TIP 2008). Therefore, the expert group recommends the implementation of newer and more appropriate IP systems that foster collaboration and cooperation what in practical terms means to have open-source models such as BIOS (Biological Innovation for Open Society) and PIPRA (Public Intellectual Property Resource for Agriculture) (Schenkelaars et al. 2011: 22, 103). BIOS for instance, is initiated by Richard Jefferson who set an alternative to broadly accepted and applied Agrobacterium-based transformation technology (Broothaerts et al. 2005). While the current patent licensing system for Agrobacterium-based transformation technology is very complex, the invented alternative by Jefferson, the so called "TransBacter" is accessible for the international scientific community in a 'protected technology commons'. In this project model there are no commercial restrictions except of shared improvements, regulatory data and relevant safety information (Broothaerts et al. 2005). The main goal remains to enable others to use and improve the technology. Further, PIPRA is initiated by Atkinson and his colleagues in 2003 in order to implement the use of a set of shared principles. These are for instance, the management of a pool of public sector technologies for fostering availability and reducing transaction costs that are caused by transfer action of rights to patented technologies (Schenkelaars et al. 2011: 104). In sum, both projects appear as answers on evolving problem fields that face science directly with legal regulations and shortsighted economic strategies. The very complex situation of innovation support and the unintended hampering thereof is a result of various interests and the interdependencies among the dimensions of technology, economy and science. Furthermore, interlockings in the IP market economy shape certain business relations such as competitiveness and antitrust. Antitrust laws can be interpreted as pursuing a limitation of potential market monopolization, which is frequently realized through patent grants. However, making much more effort to achieve a profound analysis of these relations, means to view them as multidimensional (Leslie 2009) and therefore as standing under high tensions. An example is a patent holder that is able to exclude competitors from market access even though the competitors might provide a significantly more efficient product. This raises two essential questions concerning the balance between antitrust and patent law. First, to what degree can competition be disabled in the short run for fostering intense innovation development in the long run; and secondly, whether "*instances and industries where intellectual property rights are unnecessarily expansive, such that competition is suppressed more than needed to incentivise innovation*" (Schenkelaars et al. 2011: 28) are to be found.

3. Biosafety

In a last step of this chapter, biosafety is examined due to its intercrossing of institutional regulation and ecological processes. In connection to the prior section on the risk assessment approaches of substantial equivalence (SE) and the precautionary principle, it is now possible to lift up the analysis to the institutional level. The SE principle is applied by the US which targets a general implementation of GE crops and struggled over influence on marketing GE food in the European market since the majority of EU member countries deny GE food and engage for the precautionary principle. Furthermore, several African states, as well as Asian countries share the substantial equivalence principle. Also in South America, namely in the GMO exporting countries Brazil and Argentina, this method of risk assessment is used. Crucially, the US followed the precautionary approach before specific forces and powerful actors asserted their interests, of which one is to eliminate strict food controls. In general, precaution in the field of GE crops is understood as an appropriate policy instrument due to the very uncertain knowledge about potential risks for the environment, human and animal health. What is essentially crucial in the conflicting principles is the overall requirement for commonly accepted scientific facts which may carry the precautionary approach to the level of politics and therefore mislead to unrealistic expectations for absolute safety (Nicolia et al. 2014: 6). In fact, the US and Canada, which are the main GE crop exporters, accuse the EU for being protectionist and contravening legal WTO rules with the defense of the precautionary principle. Again, the idea of precaution must be seen as highly paradox in EU regulations since it is neither true for GE feed products and enzymes nor for GE pharmaceuticals. Unlike, New Zealand for instance refuses to grow GMO food as well as the application of GMO medicines which are approved for usage (Ministry for the Environment 2013). An example for the difficulty in decision-making under uncertain conditions is India's refusal to introduce BT-brinjal as the first GE vegetable. Based on the precautionary principle, India desires to protect human health and environment (Ministry of Environment and Forests 2010). This decision is especially remarkable since India does not refuse GMO products in general, but only in this case. It is highly questionable whether it is the actual scientific knowledge and risk assessment which determine the affirmation of biotechnology or whether risk plays a crucial role at all. Particularly with regard to agriculture, there is a question on the ideal conditions for the implementation of biotechnology in this field. Hence, a distinction must be made between the large-scale agriculture systems in the US which enable an application of biotechnology, while small-scale agriculture systems do not allow a comparable implementation, as it is experienced in European countries. Exploring this even more profound, the question of food culture has to be raised and thereby the meaning of food for a society in its broader socio-cultural context. Europeans' identities and cultural values associated with food and agriculture lead to a significantly higher "*cognitive threshold [...] than that of US consumers.*" (Stephan 2012: 120). The consumer behavior of the US-Americans is, however, also a result of past events and probably of the prevailing pragmatism that fostered phenomena such as fast food and convenience food. However, biosafety regulation at the international level is primarily conducted with the Cartagena Protocol on Biosafety, as shown in the following.

3.1 Biotechnology Safety Regulations: The Cartagena Biosafety Protocol

The Cartagena Biosafety Protocol is a follow-up agreement of the Convention on Biological Diversity and came into force in 2003. It has undergone the same pre-negotiation processes as the CBD itself. These negotiations are primarily implemented by CBD's Biosafety Working Group (BSWG) in six meetings which took place from 1996 and January 2000. After the Earth Summit 1992 in Rio de Janeiro, Brazil, the BSWG turned to be the main deliberation and negotiation forum on biosafety subjects (Segarra/Fletcher 2001: 4) that let the Protocol finally enter into force on 11 September 2003. In this context it is important to outline the role of the US with regard to the Biosafety Protocol. In the forefront, it worth mentioning that the provisions in the Biosafety Protocol shape market rules and US agricultural interests in biotechnology trade. Further, the

CBD treaty has not a legally binding character, but relies on voluntary measures. Thus, the treaty is in accordance with the current US law, although the US failed to ratify the CBD. The US, as the largest GMO exporter and producer, is not an official part of the proceeding, yet they attended the negotiations as a part of the so called *Miami group*, a group which developed drafts and positions during the negotiations. The Miami group is driven by the leading agricultural exporters: USA, Argentina, Canada, Australia, Chile and Uruguay. The intervention of the Miami group into the negotiations can be traced back to their interest in a consistent relation among the protocol and other bilateral and multilateral trade agreements, particularly the WTO agreements, such as the Sanitary Phytosanitary-Standards (SPS) accord as well as the TRIPs agreement. Hence, the struggles about the SE principle and the precautionary approach are dominant within this period. The "savings clause" thus seemed to be an appropriate position on which the conflicting attendees could agree (Segarra/Fletcher 2001). The protocol's preamble thus expresses that "*nothing in the Protocol implies a change in the rights and obligations of governments under the WTO or other existing international agreements.*" (Biosafety Protocol 2003). Further, it is emphasized that the Biosafety Protocol is by no means subordinated to other accords, but rather mutually supportive. However, the US continued rejecting CBD participation and thereby the ratification of the Protocol. This does not deter the US to send observer delegations to the negotiations for their agricultural and biotechnology interests. In fact, in 1992 President Bush denied to sign the CBD agreement arguing with a lack of IP protection. One year later, as Clinton became President the treaty is signed and sent to the senate for advice and further consent for ratification. The Clinton administration, together with industry analysts came along and conveyed a new notion on the savings clause. They took it in the sense that "*disputes originating from Protocol implementation could be handled through existing mechanisms, such as the WTO dispute settlement agreements and its appellate review bodies*." (Segarra/Fletcher 2001: 8). Unlike, EU decision-makers emphasized that the Protocol is neither subordinated to any other agreements nor that it is necessarily extendible to future agreements or already given agreements that are not linked to the Protocol (ibid.). However, the Clinton administration had added a statement of interpretation to the treaty to conciliate detractors' concerns (Fletcher 2003). Remarkably, the Senate Foreign Relations Committee argued in favor of ratification in 1994, but the full Senate is not willing to agree until the 103rd Congress ends. The Senate continued to deny attention on the treaty in 1995, so that the treaty remains in the Senate Committee on Foreign Relations until today (ibid.). In any case, the Clinton administration has accepted the inclusion of the precautionary principle and is therefore harshly criticized by several voices of the US Congress. These actors argue that this event sets the future GMO trade on thin ice, even when merely a minimum of labelling requirements are allowed. Yet, article 10 and 11 and even the preamble of the Biosafety Protocol approve the prominence of the precautionary principle. Notably, in this regard the precautionary approach means the option of rejecting GMOs if there is missing scientific certainty, for instance in scientific data, information or analysis. For the consideration of the SE-principle, risk assessment and risk management issues are included at the same time. It is regulated that the exporter of GMOs is responsible for the costs of risk assessment as well as for the required mitigation actions. Moreover and very significant is the Protocol's allowance of socio-economic factors in the importation of GMOs into the party's state. Another relevant aspect of the Biosafety Protocol is the establishment of the application of "Advance Informed Agreements" (AIA) between importing and exporting parties which effectively refer to the first transboundary movement of GMO products. The original rationale of the AIA is set in article 19.3 of the CBD, which relates to the possible impact on the environment caused by international trade of GMOs. This expresses the conviction that specific trade good shall not be induced without the consent of the receiving country. Hence, the Biosafety Protocol demanded the potential importer country's agreement before the first shipment of a GMO is released into the environment (applied to seeds, microorganisms for environmental bioremediation, fish or field release). Additionally, the mentioned article 11 requests that bulk shipments of GMO commodities which are used as food, feed, or for processing, have to be accompanied by clear declarations, for instance "*may contain*" GMOs and are "(n)*ot intended for intentional introduction into the environment."* (Segarra/Fletcher 2001: 5). The struggles at the international level reflect the complexity behind the regulation of genetically modified organisms. Due to the highly uncertain economic output it is not even possible to state a clear commodification of life, although there is an offensive push by the US. Based on the argumentation of this work, that reactions of nature cannot be genuinely measured. It is also not clear which consequences the application of GMO food will have on all living organisms.

In sum, this chapter dwells on the economic and legal dimension at the international level. Fundamental contingent necessary occurrences are concentration processes at the international seed market and paradigm shifts in property claims and patenting approaches. However, the following chapter is much more concrete and contains developments in the US and Europe.

Chapter five: The Specific Spatio-Temporal Dimension of Modern Agricultural Biotechnology

Developments and the regulation of modern agri-biotechnology in the US and Europe

This section on specific spatio-temporal developments reaches the highest level of complexity and specification. To this effect, the US as the main driver of modern agri-biotechnology is illuminated and Europe is cited as a counterexample of modern agri-biotechnology development and broadly an opponent thereof. This oppositional position has to be distinguished from general catch-up ambitions in biotechnology. For an adequate analysis, this chapter provides separate summaries on the corresponding contingent necessities of the US and the European trajectories. In both cases, main occurrences are accessed genealogically. Due to the nature of the CN concept, key occurrences are defined with consideration of causality and make previous chapters more comprehensive from the retrospective.

Literature is full of analytical approaches spreading the claim that some (industrial) countries are open for new technologies and some others are rejecting those. It is, however, not beneficial to reduce national technology trajectories on openness or a lack thereof, but to consider events as contingent necessary. Institutional arrangements may block specific institutional innovations and facilitate others. Essentially, the analysis on a certain country can be linked to the plausible reasoning approach, since it shows that justifiable positions can evolve from specific argumentations which are at the core based on coherence and plausibility and not on discursive-theoretical truth. This is also true for the different dispositions, value conflicts as well as technological controversies. Since there is a lacking objective measurement on technology development, economic decision-making and potential risks for organisms, the only alternative is to consider ambiguity among decision-makers of all kinds.

Part I: The contingent necessities of modern agri-biotechnology in the US

This sub-part contains aspects of the historical biotechnology development in the US, significant dispositions, the emergence of IPRs and institutional developments, including agencies. However, the economic dimension is mainly covered in the previous section while political and social effects are centered in this part. Although this sub-chapter examines key aspects under the appropriate dimensions, the summary explains the contingent necessary occurrences interrelational.

Briefly expressed, the US is characterized by a strong imperialist attitude, a pragmatic tenor and extraordinary strong economic interests. As already mentioned, the US is the main driver of modern agri-biotechnology worldwide. It provides the highest amount of venture capital and the corresponding legal regulation framework for promoting GMO food products. Technology clusters have emerged over decades under very specific conditions and lead to a very close network of academics, pharmacists, patent attorneys, venture capitalists, specialized consultants and politicians (Müller 2002: 287). But these conditions are built on former trajectories containing arrangements that facilitate the development of GMO food. Hence, as a first relevant contingent necessity, the eugenic activities of the Rockefeller Foundation (RF) can be identified which are motivated by the capability of social control. Essentially, the RF acted within a newly emerging system of international relations combined with the rising narrative of economic productivity after World War I. The US reached to a new historical bloc with first approaches of an internationalized finance market and short term profit orientation. Introduced by RF's Warren Weaver, the Natural Science Division triggered the shift from the physico-chemical field to experimental biology, including the emergence of molecular biology. This happened parallel to the Wall Street crash of 1929 and the 1932 collapse of the finance market. Weaver established small short-term funding which are complementary to the effects of the Clayton Antitrust Act from 1914. This Act forbade relations between big banks and trusts and thereby hinders investment banks and firms to develop long-term financing strategies. These incidents built the foundations for academic-industrial relations and the current financing of modern agri-biotechnology since numerous start-ups can be equipped with high venture capital investments. As a result of the reorganization of the RF in 1928, the concept of "Green Revolution" arose. Officially developed for fighting world hunger, the Green Revolution mainly supported a few companies such as Monsanto. Crucially, the transformation of small-scale agricultural structures into large-scale production systems and the enormously high amount of applied chemicals widely destroyed sustainable local agriculture in the countries concerned, mainly Africa. However, hunger is little diminished and historical dependency structures among industrial states and developing countries broadly remain until today. Apart from the Green Revolution, first steps towards plant resource propertization are made in 1930 with the Plant Patent Act. As prior explained, after the discovery of the DNA double helix in 1953, an important CN happened in the 1970s with the foundation of the first biotechnology enterprise *Genentech*. Remarkably, the US followed strict regulations for human health and environmental protection between 1960 and 1980. By the 1980s then, strong economic interests grow in importance and shifted prior policies into industrial-friendly terms, instead of adhering to the precautionary principle. Important occurrences are subsequently in 1980, with the two fundamental Acts that led to a more intense cooperation between industries and universities. Recently before the first commercial release of

GMO food in the US in 1996, biopatenting regulations are modified into industrial-friendly terms, namely for biotechnology and biochemistry firms. Also the substantial equivalence doctrine is institutionally adopted by the FDA who is responsible for the approval of GMO food. Although the principle of sequential equivalence is highly contested related to environmental harms and health hazards, it reflects the plausible reasoning for specific actors to enforce it, in order to raise profits. That regulations introduced in the 1990s are not appropriate for risk assessment is criticized by various actors of which one of them is the USDA's AC21 group. To draw a comparison to the EU it has to be stated that US states and specific actors have little say in decision-making processes of federal regulatory agencies, whereas EU member states are both the principal agents of enforcement, and assume formal political roles in European regulatory committees and in the EU Council. At last this sub-chapter dwells on Monsanto as the most powerful company in the seed market and seminal for the agri-biotechnology path. Its power is a contingent necessity of certain conditions and occurrences combined with self-driven aggressiveness at the market, in politics and against consumers in its homeland and abroad.

1. Institutional developments in the US

1.1 Establishing new financing structures

The previous chapters have already shown the relationship between the academic sector and the industry. The International Political Economy of modern agro-biotechnology is, however, examined without the consideration of the imperialist impact of the US. Now, these relations can be linked to the influence of the Rockefeller Foundation which was already active in the early 20th century. It is important to understand that molecular biology cannot be reduced to a social control strategy of the RF or on research works of some scientists (Gottweis 1998: 47). Rather, the role of the RF has to be viewed as a part of complex contingent necessary developments which enables the production of GMO food products. In fact, "*Geneticization – the farming of central dimensions of humans in terms of biological factors (genes) – provided continuity behind the surface appearance of discontinuity between the "old" eugenics and the "new" biology.*" (ibid.: 45). What remains from the shift from interventions into population to the subcellular level, is the idea of *social control* (ibid.) and in case of agri-biotechnology, the vision of *food control*. It is important that RF activities are embedded into a system of international relations which newly evolved at that time. The re-organization of forces, structures and actor-constellations fundamentally increased economic productivity and social stability. This allowed the RF to follow activities of social control and interception. Defining biotechnology as a key technology and promoting this idea occurres as a part of the social control vision. Crucially, molecular biology is developed at a time as the Pax Americana becomes the prevailing political, economic and social doctrine containing a multinational liberalism (Gottweis 1998: 47). Related to Jessop, in molecular biological research and its social consolidation the *always contingent shadow of capital accumulation* can be identified. Hence, it is assumed that genetic engineering is developed strategically in order to gain social control and for industrial purposes at the same time. In turn, it is denied that there is first basic research and then commercial interest. As Gottweis expresses, the RF's "*influence on society was as much tied to the authority of knowledge of molecular biology as the conditions for scientific work in molecular biology were connected to the power and resources of the Rockefeller Foundation and its embeddedness in the international capitalist order*." (Gottweis 1998: 47). The RF begins to focus on the "New Science of Man" (ibid.: 46) near the end of WW I. The international constellation of powers starts to shape rival imperialist political and economic territories. At that time, the Wall Street crash in October 1929 introduces a long-lasting economic crisis. This occurrence is complemented by an international collapse in the finance market in 1932. The contingent necessary result is the evolvement of a novel historical bloc in the US. This bloc is characterized by an increasing internationalization of the finance market, including short-term profit orientation. Corresponding importance of investment banks rises as well as the influence of capital-intensive industries. Significantly, the capital-intensive Rockefeller enterprise Standard Oil is less reliant on human labor and therefore less vulnerable to possible turbulences. This enables the accommodation of numerous workers despite the great depression (Gottweis 1998: 46). The capital market system generally hinders the evolvement of broad employee skills since there are many incentives for enterprises to engage in short-term profit maximization projects (Hollingsworth 1997: 293). In the US, by the end of WW I, the equity markets are extraordinarily institutionalized. Corollary, big enterprises are not significantly reliant on commercial banks for financial support. The industrial fields that are supported by the US-American system are mainly steel, railway, telephone, oil, cooper, and also electrical products industries in the late 19th and early 20th century. This is made possible through channeling investment capital into these various industries. Namely, the Clayton Antitrust Act of 1914 forbids folded relations between big banks and trusts. As Hollingsworth states, this Act reduces "*the ability of investment banks and firms to carry out a long-term strategy of promoting a community of interests among firms either in the same or in complementary industries*." (Hollingsworth 1997: 293). The US-government in 1933 fosters a separation between investment activities and commercial banking. These crucial events lead to the US-American non-financial corporations' dependence on financial markets and not on banks for raising capital. Further, managers of corporations are increasingly dependent on decisions and strategies of stockholders and bind owners (Hollingsworth 1997). Briefly, due to the predominant incentives for short-term projects of big enterprises, these events hindered an eventual development of long-term stable relations between employees and employers, as in Germany and other European countries. The consequence is a work mentality with high skills and broad training, and thus a "*flexible or diversified quality social system of production*" (Hollingsworth 1997: 293). Recognizing this is essential for the reasoning of the US-American style of supporting start-up firms. The genuine difference in societies with big venture capital stocks and those who rely on banks for capital can be seen in these developments (Hollingsworth 1997: 293). Taking a view at the international level, the US dominance in venture capital provision becomes highly apparent. In 2013, the US covers 68,2% of the global activities, whereas Europe covers only 15,3%, Canada 2,1%, China 7,2% and India 3,7% (EY 2014: 2). These numbers varied during the past decades, but the leading role of the US and the comparably low amounts of venture capital in the EU remain the same. Furthermore, the US is the most active market for venture backed IPO (Cowan 2013: 5). The same is true for the increasing number of start-ups, although the numbers constantly fluctuate in each region of the world (Cowan 2013: 8).

1.2 The Division of Natural Sciences and scientific-industrial relations

Another important development in the early 20th century includes the RF announcement of a new policy with a "Division of Natural Sciences" after the Rockefeller Board's reorganization in 1928 and 1932 (Abir-Am 2001: 66). A significant role in these developments is played by the mathematical physicist Warren Weaver who becomes the director of the Natural Science Division. In line with the spirit of the times, it seems to be plausible for Weaver that technology is the foundation of scientific progress and shifts the focal point from prevailing physico-chemical sciences to experimental biology (ibid.). He is inspired by the Nobel laureate biochemist Frederick G. Hopkins who considers biology as "*the science of life, which held the promise of helping with the increasingly violent 'social unrest' that was caused at that time by the Great Depression.*" (Abir-Am 2001: 66). On the other hand, Hopkins views physics as the science of death. A highly significant issue which proved pivotal for later financing structures is Weaver's funding approach for research projects. Similar to the Clayton Act for regulation requirements for investment banks, Weaver denies the application of a few large and long-term grants for academic research. Rather, he prefers the funding of many small grants in order to support short term projects (ibid.). Although Weaver is criticized by colleagues from the RF, namely Allan Gregg, he insists on short term funding and therefore laid foundations for the financing approach that promotes finance for innumerous start-ups. In other words, Weaver's funding approach is originally a non-necessary interaction of diverse causal chains that becomes necessary by entering a contingent interaction. In fact, Weavers decision triggers a shift in academic research which makes academics adapt the role of entrepreneurs and therefore establish a "*synergistic relationship with business firms*" (Hollingsworth 1997: 294). This is particularly true for Herbert Boyer who is seen as a pioneer in entrepreneurial science making. After the discovery of the rDNA with his colleagues Stanley N. Cohen and Paul Berg in 1973, Cohen and the investor Robert A. Swanson found the first biotechnology company *Genentech* in 1976. Genentech remains in the market until today and is a member of the Swiss Roche Group since 2009 (Gene 2008). Academic-industrial relations are promoted by the state which causes a deep involvement of scientists into university activities, government agencies and an overall dynamic network. The US-American government retreats intense support in network activities, giving entrepreneurs and academics the freedom to engage themselves in commercial purposes. Unlike in other sectors such as computing or mechanical engineering, university research plays an integral role in agri-biotechnology (Glenna et al. 2007: 145). This deep interaction between academia and industry is also caused by certain economic, political and social forces. Particularly developments that rose since the end of World War II as a process of economic competitiveness in the US Congress fostered the promotion of a commercialization of academic research. This development that started in US policy with a coalition in the Congress, gains international influence and exerts external pressure on several European countries as well as on the Japanese nation. Namely the MIT engineering professor Vannevar Bush indirectly establishes state funding for science with grants provided to engineers and scientists (Slaughter/Rhodes 2004). Essentially, he "*proposed a division of scientific labor in which the government agreed to fund some science done in universities (basic), some done in government laboratories (development), and some done in corporations (applied).*" (ibid. 47).

1.3 The Green Revolution

The Natural Sciences Division also established agriculture with the Board reorganization of 1928. Known under the term "Green Revolution", RF is engaged during the time from 1940 until 1970. Officially the Green Revolution signifies the promotion of high yield crops in order to fight world hunger in third world countries (Rockefeller Foundation 2006). During that time, traditional farming methods are replaced by capital-intensive, industrial large scale farming methods (The Thistle 2001). Since there is a deep correlation between the RF and the few significant agro multinationals Monsanto, Syngenta, etc., the application of chemical fertilizers and pesticides significantly grow in importance. In fact, higher yields are achieved, but world hunger could not be reduced significantly in several countries and regions (The Thistle 2001). Whether calling it *agro-capitalism* (Hoering 2010) or not, world hunger must rather be seen as a problem of food distribution and not caused by a lack of food production. Hence, the Green Revolution partially contributes to a reduction of starvation in Asia, but it causes enormous environmental damages because of the increased application of fertilizers and pesticides (The Thistle 2001). As a consequence, local crop varieties could not survive so that farmers are forced to buy seeds from large seed firms. This unsustainable agriculture remains problematic until today. However, the first initiative starts in 1941, as Mexico gains small funding grants by the RF in order to conduct research on corn. Then, vice-president of the US Henry Wallace officially claims his desire to help people in Mexico by increasing the yield per acre of corn and beans (Rockefeller Foundation 2006: 2). Another significant motivation behind the engagement is to inhibit communist infiltration by stabilizing the Mexican state. This is important for the protection of family investments (Dowie 2002). Apart from Mexico, several other South American countries as well as Asian states are targeted by RF, such as India, Pakistan and the Philippines. Particularly Africa is targeted by the Green Revolution.

In order to initiate a second Green Revolution, the Alliance for Green Revolution in Africa (AGRA) is found in 2006 and is financially supported by the RF and the Bill and Melinda Gates Foundation. Significant actors of the AGRA are US-American groups such as the Citizens Network for Foreign Affairs (CNFA) and the International Fertiliser Development Centre (IFDC). Both groups contain interests of Monsanto, Syngenta Crop Protection, Dow AgroSciences, Bayer CropScience and DuPont Crop Protection in selected African countries (Mayet 2010). At this point the philanthropic approach of the Rockefeller Foundation has to be questioned. RF activities are in line with their interest in social control and food control. According to this, the official assertion of fostering genetic engineering and microbiological research for fighting poverty has to be relativized drastically. An important aspect in this regard is that the new narrative on science policy is not restricted to the US, but is aimed to be diffused at the international level (Gottweis 1998: 46). In fact, biotechnology can only be understood as a key technology if the ideological construction of the lock is accepted, namely that life is widely determined by the DNA of the individual organism (Gill 1991: 279). As Gottweis emphasizes, the more institutions and actors are involved in the process of knowledge exchange and technology transfer, the more the new doctrine can be "*consolidated, disseminated, and legitimized*" (Gottweis 1998: 46). To this effect, the sudden appearance of external pressure on the German economy and technology development can be seen as a US strategy to spread this new notion. Yet, it is important to stress the attempt of US enterprises to gain access to the European market with more or less success at the beginning of GMO commercialization and an ultimate failure in implementation. Still, European companies realize the general pressure through US and Japanese developments in biotechnology and begin to catch up development in the general application. However, these forces are driven by two particular motivations that still have an essential weight. The first is to generate "*a revenue stream for universities in exchange for the transfer of research discoveries to the private sector*" (Glenna et al. 2007: 143). The second goal is to subsidize the private sector through increased effectiveness in private public research (ibid.). A crucial aspect is that basic research directly linked to commercial application opportunities can cause dubious moral and legal issues such as conflicts of commitment, scientific misconduct in academic research as well as conflicts of interest. The integration of research and commerce runs the risk of a larger focus "*of basic research on treatment rather than prevention*" (Bartholomew 1997: 254) since biotechnology enterprises primarily pursue profit maximization. Moreover, these developments may cause a loss of creative power of academics since the orientation to commercial utilization restricts possibilities for experimenting. Endeavoring profit accumulation with agricultural products has thus "*overwhelmed the public sectors ability to focus on research with broad public benefits.*" (Glenna 2007: 269). Expressed in Kloppenburg's words, *''(t)he besetting sin of the biotechnology industry seems to be its lack of interest in solving for pattern as opposed to identifying partial, temporary, and commodifiable solutions to narrowly defined problems*" (Kloppenburg 2005: 318). Conflicts of interest are an important aspect with regard to RF activities. Popularly known under the term "*revolving door*", history shows innumerous examples of individual actors that work for the government and the food industry. Examples are Ann Veneman who is the first female agriculture minister of the USDA under the Bush Jr. administration and prior serves in the Board of Directors of Monsanto's Calgene Inc.. This company develops the Flavor Saver Tomato which is then purchased by Monsanto (GMWatch 2000). Another example is Michael R. Taylor who was Monsanto's Vice President for Public Policy and FDA Deputy Commissioner for Policy and also active during the Obama administration. Crucially, Taylor assisted agricultural activities in Africa, promoted by the RF (Organic Consumers Association) (GMWatch 2000). Other important persons are Clarence Thomas, Donald Rumsfeld, Tom Vilsack, Linda Fisher, Marcia Hale and Michael Friedman. All in all, this personnel carrousel is a phenomenon of the structural coherence between different dimensions. This causes problems at various levels and dimensions. It is problematic since the relation between the private sector and the government melts. The common welfare is endangered by the collective detriment which is based on privileges of a few. As a consequence this blurred relationship can culminate a regulatory capture.

1.4 The deference of science and pre-shaped dispositions in the US society

Certainly, not every individual US-American citizen is steeped in imperialism, particularly not to the degree as identified in the RF. What has to be considered is the systemic nature of biotechnology, especially of academic-industrial relations. In this context, a general deference of science and a prevailing positive technology attitude in the US population can be identified. As the leading exporter of agricultural biotechnology products, the majority of American scientists, industrialists and political decision-makers has a positive view on GMO food or are not significantly aware of its consumption (IFIC 2008). This is based on the plausible conviction that it helps to fight world hunger, improves sustainability and provides commercial advantage (Brossard/Nisbet 2006: 25). At this point it is important to stress the temporal embeddedness of the industrial use of modern agri-biotechnology. In the US the significant time is by the 1980s and 1990s, as the society raised basic trust and belief in private enterprises and therefore into biotechnology firms. This time is decisive for the establishment of GMOs in this extent and may not have been possible to another point in time again (Vogel 2003). Today, parts of the US population grow skeptical towards GMO food and particularly farmers are losing conviction in GE seed farming. However, the general positive public opinion about GMO food in the US is "*'pre-shaped' by a strong deference to scientific authority, a basic value predisposition cultivated by the nature of the American educational system.*" (Brossard/Nisbet 2006: 29). When academic research is concerned, the scientific community is convinced to be best operating without regulation policies and other intervention or even control. This can be linked to the entrepreneurial attitude of academic researchers in the US who pursue patenting on their discoveries and inventions. In this relation, Jasanoff explains that the scientific community in Europe differs from the American thinking and acting, since academics view themselves more likely as servants to the state and are therefore subject to regulation and political control (Jasanoff 2005). In the US educational system the primary and secondary education fundamentally contribute to the public's belief in the "*functional authority of science*" (von Schomberg 1991: 262). Irwin explains how the system helps to depict science as politically neutral with lesson plans and textbooks (Irwin 2001). It is taught an objective and positivistic notion of science which gives an understanding of the natural world. There is little education in history and in politics of science or even in scientific disagreements and scandals (Brossard/Nisbet 2006: 29). This deference of science is rooted in the *pragmatic style of thought* (Harwood 1993) which is not only given in the development of technology with industrial purposes, but in the shaping of the corresponding legal framework.

The overall positive position towards GMOs can also be observed in media. As a part of technology attitudes the role of media has to be examined with relation to food, particularly to GE food affairs. In some respects, the represented occurrences in media are related to the perception and the classification of GMO specific information and other food related issues. The situative influences and the sector-specific cognitive perception concerning GMOs are affected and therefore fed back to general value orientations, moral acceptability, societal modernization processes, manageability of problems as well as to the credibility of responsible institutions and trust in political and economic decision and regulation patterns (Conrad 2004: 25). The fundamental differences between the US and the EU in these terms can be best articulated with a quote of Stephan: „*While European consumers may also be susceptible to a logic of utilitarian benefits—such as lower prices, environmental or health advantages—the cultural values and identities associated with food and agriculture mean that Europeans' cognitive threshold is higher than that of US consumers*." (Stephan 2012: 120). The differing reactions on food and GMO food issue both countries and are visible in various events. In 2000, the US is faced with the *StarLink contamination affair*, which reveals the contamination of taco shells by a GE corn variety exclusively approved for animal feed. Even though this event creates a policy window for reforming GMO regulation by inducing a debate over biosafety, crop segregation and coexistence, the public does not effectively react (Stephan 2012: 110). This is accompanied by the moderate reaction of relevant news organizations which does not create a negative frame or contribute to a generally higher problem and risk awareness. The press presents the affair as an industrial and regulatory issue mainly reported by business and science reporters. Respectively, there is little known about the general media coverage of this specific affair, in terms of interpretation, extent of input, and so on. The striking event is that major news organizations did not define this event as surprising or even consider it to be a scandal (Nisbet/Brossard 2006: 31). Apart from the contamination affair, there are two crucial studies in 1999 and 2001 proving the negative impacts of the toxicity of Bt corn to caterpillars of Monarch butterflies, a non-target species. But also these studies fail to trigger a shift in GMO policy or in any other relation (Nisbet/Brossard 2006: 31). Remarkably, people's faith in food safety and food supply remains positive. Media is usually most effective when creating frames that strongly touch public values (Gamson/Modiglinai 1989). Examinations of media coverage on GMO food in the US have shown that those frames predominate in journalistic interpretations which underline the scientific progress and economic development. Conceivable benefits are thereby much more stressed than possible risks, what leads to an overall positive image of GMOs (Nisbet/Brossard 2006: 31). General tendencies in media coverage on GMOs have not changed significantly since the millennium. Other issues such as the Chandra Levy disappearance, energy prices and rolling blackouts or debates on stem cells and other food issues such as bacterial food poisoning get more media attention than GMO food issues (Nisbet/Brossard 2006: 46).

2. Intellectual Property Rights in the US

2.1 Creating the legislation for the protection of plant varieties

For the sake of clarity, before analyzing the legal system of plant variety protection in the US it is fruitful to stress that *vegetatively propagated plants* are protected with the Townsend-Purnell Plant Patent Act from 1930, while *generatively propagated plants* are protected with the Plant Patent Amendment of 1998 and the U.S. Plant Variety Protection Act from 1970. In line with the elaborated occurrences in the 1930s, first approaches towards "propertization" can be found in the introduction of the US Plant Patent Act (PPA). This new act permits patent protection for asexually reproduced plants, or usually asexually reproduced cultivars (except tubers). As Dewan stresses, this novelty has "*removed the product-of-nature objection related to plants*." (Dewan 2011: 132). Corollary, the changed conditions allowed new industrial seed companies to usurp the state funded research in maize breeding (Schenkelaars et al. 2011: 24). A significant outcome of this is the technological breakthrough which rendered the possibility of hybrid maize seed. As a further consequence of the advancement of crop yields lead, the plant breeders protected their IP with patents to prevent imitations. The usage of new hybridization entails several advantages for farmers, such as higher yields, tolerance lodging, greater uniformity in maturity, and the possibility for large-scale mechanization processes. The new method was beneficial since hybrid seed does not exhibit its lineage and therefore offers proprietary control to firms over the home developed seeds. Moreover, the upgraded vigor is not transmitted to the own offspring, so that farmers need to purchase new seed for each coming season to have a safe continued vigor (ibid.).

In 1952, the very essential Patent Act (PA) set new rules in patent rights to agricultural innovations under a significantly broad definition which implies "*any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvements thereof*" (35 USC § 101, in USITC 1995: 16). This wide understanding of patent protection includes innovations in biotechnology and genetic engineering from patenting and is therefore one of the central events in the institutional framework in modern agri-biotechnology. It is remarkable that neither the PPA of 1930 nor the PA of 1952 use formulations that provide IPRs to seed and tuber propagated crop varieties (Fernandez-Cornejo et al. 2004: 20). However, the crucial factor of the profound change in the treatment of plant genetic resources and IPR is given by the rise of biotechnological developments, especially of genetic engineering in the 1970s and 1980s

(Raustiala/Victor 2004: 283). The decline of the *common-heritage system*[9] began with the invention of the recombinant DNA in the 1970s and events in 1980 at the national level in the US. This is realized by the Bayh-Dole Act from 1980 (or 'Patent and Trademark Law Amendments Act'), which replaced the *Vannevar Bush model on public goods* (Slaughter/Rhoades 2004: 46). Briefly articulated, the Bush conception understood public good as a sum of private and public goods. Unlike, the Bayh-Dole model interprets public goods from universities as a waste of financial and personal efforts unless it is supported by private actors. As a consequence, public goods need to be translated into private goods for contributing to the public (Glenna et al. 2007: 146). However, this shall not disable university's basic research, but is rather an additional mission for the universities. It is expected from now on that universities also do research with an immediate commercial application pursue. The Bayh-Dole Act is built on the intention to incentivize innovations through university research and private enterprises to strain for property rights on publicly funded research. Prior there are lacking possibilities for setting research incentives and technology transfer with the pursuit of profit. Another aspect is that scientists themselves are rarely motivated to occupy themselves with the legal processes of achieving state's approval for patenting government funded research inventions and discoveries (ibid.: 145). Under the former notion on public and private goods, it is more common to release discoveries to the public sphere. A crucial consequence of the Bayh-Dole Act is that from now on private enterprises are allowed to make investments in university research projects and have a direct impact on the academic work. In fact, the U.S. Supreme Court had strengthened breeders' rights with the Act, since it extends patent rights to genetically engineered microorganisms which is a significant instrument as well as a product of biotechnology (Fernandez-Cornejo 2004: 19). The amount of patent grants that are raised since 1980 at six land-grant universities makes the quantitative influence of this Act apparent.[10] The Bayh-Dole Act leads to a whole slew of laws, executive orders, and judicial decisions which caused renegotiations to the social contract to deliver autonomy to universities for creating public-goods science. Further it stressed academic research in order to use it for the knowledge based economy (Slaughter/Rhoades 2004). These events initiated a legal system that fosters technology transfer at the federal level.

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[9] The common-heritage principle: "*Common heritage of mankind is a principle of international law that states that the elements of the earth and cosmos are common to humankind. Common heritage of mankind includes ocean floor and its subsoil and also outer space. The principle states that areas of Antarctica, the sea bed, and outer space cannot be monopolized for the benefit of one state or group of states alone, but should be treated as if they are to be used for the benefit of all mankind.*" (US Legal Definitions 2010)

[10] For a detailed analysis of the land grant universities and their relations to private investment, see Rhoten/Powell: Public research universities. From Land Grant to Federal Grant to Patent Grant Institutions, in: Knowledge matters. 2011.

In accordance to the basic assumptions on law and society in this work, Demsetz understands the development of property rights as a sign of *changing values*. Since there are evolving "*desires of the interacting persons for adjustment to new benefit-cost possibilities*" (Demsetz 1967: 350), these changes require new property rights. Further, the main causal forces of the emergence of property rights can be observed as the "*pluralistic interests of economic actors*" rather than "*aggregate efficiency concerns*" (Raustiala/Victor 2004: 282). Expressed in concrete institutional terms, it is the American Seed Trade Association (ASTA) that has demanded the Breeders' Rights Study Committee for exploring questions of property protection in relation to agriculture and thus achieved the resolution of the Plant Variety Protection Act (PVPA) in December 1970 (Fernandez-Cornejo 2004: 20). The very meaningful PVPA issues a Certificate or Protection to breeders and gives them exclusive rights to market a new plant variety for 18 years from the day of granting (ibid.: 19). These exclusive rights are related to a *research exemption* and a *farmer's exemption*. The research exemption permits the usage of the seed to develop new plant varieties while the farmer's exemption allows farmers who primarily work in crop breeding for selling, to save seed from a protected plant variety to plant on the farmer's land. For these farmers it is allowed to sell seed to another farmer who is also primarily working on crop growing (Schenkelaars et al. 2011: 20). Briefly expressed, the variety that has to be protected is demanded to be stable, uniform, and distinct from all other varieties. The PVPA excluded fungi, bacteria, first generation hybrids and varieties which are sold or used in the US for more than one year or more than four years abroad (Dewan 2011: 132). The new PBR with their introduction of IPRs on GE products initiated innumerous M&As and R&D activities by pharmaceutical and petrochemical multinational enterprises. Thus, one decade after UPOV and the introduction of the PVPA in the US more than 50 US seed firms are acquired by these multinationals (Schenkelaars et al. 2011: 18). What has changed since that time is primarily the ownership structure in the seed industry: Expressed in absolute numbers, within the period of 1998 to 2009, the annual sales volume of the global markets increased from 18 billion $ US to 44 billion $ US (ibid.). By 1985 the most powerful nine seed firms shared 12,7% of the global seed market and only four of them are owned by pharmaceutical or petrochemical multinationals. One decade later, in 1996 these enterprises shared 16,7% of the global seed markets whereas only one is owned by a multinational firm. Notably, in 2009 the most influential ten seed companies shared even 43,8% of the global markets while five of them are owned by agrochemical multinationals (ibid.). In 1982, PVPA certificates are held to 50% by 14 conglomerates of firms (Drew 2010). Remarkably, the US accede the UPOV Convention with its PPA, but did not adopt the UPOV requirements into the PVPA before 1984. The US Supreme Court's decision in the Diamond vs.

Chakrabarty case by 1980 led to strengthened breeders' rights, with an extension of patent rights on GMOs (Fernandez-Cornejo et al. 2004: 19). In 1994, the PVPA is extended with an amendment that came into effect in 1995. The PVPA is brought in line with international standards that are established by the UPOV and enabled the US to ratify the International Convention for the Protection of New Varieties. An important novelty is the extension from 18 years patent protection to 20 years protection for the commercially important crops and 25 years for trees, shrubs, and vines (Fuglie et al. 1996: 35). A significant change through the amendment is the extension of protection to tuber-reproduced plants, such as potatoes and the introduction of an "*essentially derived variety*" (EDV) category. The profound change with the protect-ability of these varieties refers to technological advances achieved through genetic engineering and biochemistry. These achievements entitle plant breeders to create varieties that can differ on the basis of a single gene or micro-molecule in its DNA composition (Fernandez-Cornejo 2004: 20). The main thought of this extension through adding the definition of distinctiveness is to inclose GE plant varieties whose characteristics and unique features are determined by miniscule levels and thus provide IPRs to breeders for extraordinary subtle genetic manipulations in the varieties (USC, 1970, § 2401, 2541; USITC 1995: 16). Ultimately, the amendment set prohibitions for farmers who want to sell saved seeds of protected varieties without prior permission of the variety owner (Fuglie et al. 1996: 35).

3. Institutional framework at the federal level

Noteworthy, biotechnology in the US is not regulated by one specific statutory, but by several agencies (Vogel/Lynch 2001). The institutionalization process and evolved regulatory framework distinctively outline the growing economization of the *always contingent capital accumulation*. In 1984, the White House decided to make the Cabinet Council on Economic Affairs responsible for biotechnology regulation instead of the EPA (Environmental Protection Agency). Significantly, since White House activities are not necessarily publicly available, it is enabled to convene a working group under its own auspice and without public participation (Lynch 2001: 6). The Working Group, with personnel from USDA's APHIS (Animal and Plant Health Inspection Service), the FDA (Food and Drug Administration), the NIH (National Institutes of Health) and EPA constitute an administrative "Coordinated Framework for Biotechnology Regulation" in 1986 (Cowan 2013: 8). This still remains the key document on biotechnology. The framework then established a working group on biotechnology, the Biotechnology Science Coordinating Committee and declares the EPA, USDA and FDA to become the heading agencies involved in the regulation of biotechnology (Cowan 2013: 8; Lynch 2001: 6)

3.1 Agencies in the US and the institutional crux of GMO regulation

The regulation of biotechnology products is significantly transposed through the Coordinated Framework for Regulation of Biotechnology (51 Fed. Reg. 23302) published in 1986 by the White House Office of Science and Technology Policy (OSTP 1986). This framework is introduced for improving safety regulation of products and research activities of biotechnology through the application of given statutory authority and agency knowledge with conventional breeding methods (Cowan 2013: 8). In the same year the Federal Technology Transfer Act (FTTA) (P.L. 99-502) is introduced as an amendment to the Stevenson-Wydler Technology Innovation Act of 1980 in order to establish a Federal Laboratory Consortium and to enable federal laboratories to ingress into Cooperative Research and Development Agreements (CRADAs) and also to bargain over licenses for patented inventions, which are made at the laboratory (U.S.C. 1986). Since the main issue is technology transfer, the appropriate follow up legislation promoted joint ventures with the Small Business Research and Development Enhancement Act (P.L. 102-564) of 1992 and the reauthorizing Small Business Innovation Research (SBIR) program until 30 September 2000 (SBIR 2000). The rationale behind these developments can be best exemplified with a quote by the SBIR coach Roland Tibbetts: "*The US leads the world in three areas important to economic growth - basic research, small high tech firms and venture capital. SBIR pulls them together*." (SBIR 2014).

The FDA primarily works under the Federal Food, Drug and Cosmetic Act (FD&C Act; 21 USC §301 et seq.) and the Public Health Service Act (42 USC §201 et seq.) and is responsible for the regulation of food, animal feed additives, and drugs for humans and animals, genetically engineered products included. The main mission is to ward off human health risks that can be caused by these products and substances. Unlike today, US policies on environmental and health relied on the precautionary principle. In these terms, the Delaney Clause to the Food, Drug and Cosmetic Act is important since it prohibited the use of food additives if experiments proved carcinogenic effects in laboratory animals or humans, based on the fear of irreversible hazards (Lynch 2001: 3). In 1996, the same year as the US began with the commercial use of GMOs, pesticide use is removed from the Delaney Clause by the amendment to Title IV of the Food Quality Protection Act of 1996 (P.L. 104-170, Sec. 404). In its own words, the FDA requires to safety and well labelling for all food and feed manufacturers of the domestic and imported products which are marketed. Same standards have to be equally applied to domestic and imported foods and feeds irrespective of being genetically engineered or not. This means that no food additive can be marketed unless FDA gives approval. An exception is given for additives that had been declared as "*generally recognized as safe*" (GRAS), since they do not demand FDA approval (Cowan 2013: 9). In accordance to industrial-friendly proceedings, the FDA invites sponsors of genetically engineered food and feed products to participate at the voluntary consultation processes. A crucial development takes place as biotechnology stocks performed badly in the late 1980s and early 1990s. Slow approval rates are caused, since the newly evolving biotechnology is confronted with given regulatory agencies at that time which are not yet prepared to manage the situation. Thus, under the Bush administration asserted a lax regulatory framework in order to eliminate trade barriers for the promotion of the biotechnology industry. As a consequence, in 1992 the FDA rules the doctrine of substantial equivalence which is explained above. In fact, this new ruling means that genetically modified crops do not require specific risk assessment and a precautious approval system (except from transferred genes induced for human allergen) (The Thistle 2001). Notably, on 15 January 2009, the FDA had published its final guidance on the regulation of genetically engineered animals and products. The general treatment is characterized by an equation of genetically engineered food products and non-GE food in labelling proceeding as long as the nutritional composition remains the same. Developers of GE animals and GE-derived products instead need to gain pre-market approval from FDA (Cowan 2013: 10).

Another important institution is the Animal and Plant Health Inspection Service (APHIS). Main duties of APHIS refer to the importation, interstate movement, and field experiments of GE plants and organism that are or could possibly be plant pests under the Plant Protection Act (U.S.C. PPA 2000: §7701 et seq.). In this light, a regulated plant is not allowed to be released into the environment, or be tested in field unless APHIS has not provided authorization. This can be implemented either with permission or notification of the process. APHIS understands GE plants that are or might be plant pests as "*regulated articles*" under the regulation of 7 CFR 340 - 340.9 (APHIS 1997). The required authorization has to be effected prior to interstate movement, environmental release and field testing as well as importing. Generally, permission shall impose restrictions on movement and planting for the prevention of plant material which potentially pose pest risk. The indicated goal of APHIS is the guidance on testing and movement of GMOs which may harm human health, agriculture or the environment (Cowan 2013: 9). Notably, the bulk of other GE crops are developed under the notification option which is an enhancement of the usual procedure and thus less strict than permitting. However, the usage of notification can only be implemented when the plant variety is not considered to be a noxious weed (or weed which is in the released field) and further APHIS standards are achieved (ibid.). Irrespective of the applied process, the next requirement is that a developer needs to pervade is the "*non-regulated status*" by APHIS for the commercialization of GE products. Therefore, the developer has to give relevant information on plant biology and genetics including possible environmental and plant pest hazards, which may be caused by its modification. Under the National Environmental Protection Act, APHIS implements a formal Environmental Assessment (EA) and further has regular periods of public comment before a decision is taken on approval for "*non-regulated status*" (Cowan 2013: 9). Crucially, defining non-regulated status terminates any federal regulatory control of the GE plant. The aforementioned global extent of GE crop planting also showed the increasing amount of HT and Bt resistant GE crops in the US. Respectively, APHIS approved over 60 GE plant varieties for commercial purposes through 2005. By September 2013, APHIS deregulated already 96 crop varieties of received 145 petitions for deregulation (AG Professional 2014). The deregulated GE varieties are mainly cotton, corn, soybeans, and canola and to a lesser extent tomatoes, potatoes, sugar beets, papaya, squash, alfalfa, plum, rose, chicory, flax and rice (AG Professional 2014). As explained above, nearly all industrially usages are beneficial for the supply side of agriculture due to the application of complementary products for HT and Bt resistances (Cowan 2013: 2). The U.S. Congress traditionally promotes GE products despite political struggles and skeptical positions of several members on the adoption and regulation of GMOs. Usually the Congress funds biotechnology projects by the USDA with regular annual appropriations. These programs cover various types of research activities that are primarily implemented through the Department's Agricultural Research Service and the National Institute for Food and Agriculture. APHIS assessed BRS budget for FY2013 is $ US 16.7 million. In contrast to FY2012, this is approximately $ US 1.4 million less spending. In 26 March the Congress decreed the same sum for FY2013 as it is given for FY2012 which is $ US 181 million (USDA 2012; USDA 2013).

3.2 Criticism of institutions

A significant development with respect to US authorities takes place as the USDA publishes a status report by its Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) in August 2006. The committee consists of the biotech industry, agricultural, consumer and scientific representatives. AC21 states that "*U.S. regulations evolve slowly and many governing statutes were written before modern agricultural biotechnology was developed. That system may not be optimal to meet the needs of producers and consumers.*" (AC21 2006). Moreover, the AC21 stated a "*clear, comprehensive federal regulatory system to assess the environmental and food safety of transgenic animals before they are commercialized.*" This has to be viewed under the question on the appropriateness of current FDA regulatory system under PPA in order to provide safety and public acceptance for transgenic crops (Cowan 2013: 12). The idea is to establish a new Biotechnology Regulatory System (BRS) office and the creation of a compliance and enforcement unit. These advancements had to improve the developers' adherence to the rules and further the publication of significantly stricter permit conditions for GE-derived plants (Cowan 2013: 13). An important critic passed on APHIS current biotechnology regulation comes in 2005 from USDA's Office of Inspector General (OIG) in relation to the over 10,600 applications for GE experiments at over 49,300 field sites (ibid. 14). The OIG stated that "*the Department's efforts to regulate those crops have not kept pace."* There are innumerous weaknesses in the approval and inspection process which *"increase the risk that regulated genetically engineered organisms will inadvertently persist in the environment before they are deemed safe to grow without regulation.*" (USDA OIG 2005). In 2011, the OIG further published an audit of APHIS control regulation system on GE animals and insect research. It declares that APHIS fails to issue regulations with regard to the introduction, interstate movement, or field release of GE animals or insects, which are in fact the main aspects in APHIS mission (USDA OIG: 2011). Another fundamental aspect are APHIS missing recordings of containment protocols and its failing provision of information about their field tests, including exact locations and the later destiny of crops after testing. This is disturbing since a report by the University of Arizona and Texas A&M University (2004) found out that GE corn had spread around in the near environment. This study proofs that GE-grass pollen spread to non-GE grass to 13 miles away. This is much more than prior studies show (Watrud et al. 2004).

Also, the Institute of Medicine and the National Research Council (IOM/NRC) denounced APHIS current regulatory system for biotechnology in its 2002 NAS/NRC report. The critic primarily refers to the missing distinction between the types of environmental risks which are posed by GE plants and conventionally bred crops. Moreover, the lack of transparency in working proceeding and public input are criticized (Cowan 2013: 37 ff.). Significantly, the report explains that some GMOs are able to exist in natural ecosystems and breed with their wild relatives. Therefore, certain biological techniques such as induced sterility are recommended in order to prevent transgenic organisms from their escape into the natural environment. This is due to missing reliable and secure bio-confinement methods.

APHIS released a draft programmatic environmental impact statement in July 2007 in order to demonstrate the assessment of its regulatory structure (USDA: 2007). Notably, this is the first revision since its establishment in 1987. As above described, under the current regulation GMOs are regulated when they are plant pest or potentially become a plant pest. Essentially, the revisions lead APHIS emphasize that technological developments on GMOs are not in line with the plant pest definition, but can cause environmental or other physical harm by the definition of a plant pest under the PPA (Cowan 2013: 15). APHIS established a permitting system in accordance to environmental releases of GMOs which includes two major risk factors: the first is "*the ability of the unmodified recipient plant species to persist in the wild*" while the second one refers to "*the potential of the GE trait to cause harm based on the plant pest and noxious weed definitions.*" (ibid.). The Union of Concerned Scientists decries the revised regulation rules of APHIS for failing appropriate protection of the US food supply. Bio-pharm crops can be potentially contaminated by cross pollination, but also through seed mixing between bio-pharm food crops and food crops for consumption (ibid.: 16). A notable event took place as in March 2009 about 80 advocacy groups have signed a letter besetting Tom Vilsack, the Secretary of Agriculture in US, to stop the approval of GE crops until APHIS had changed the new regulatory approach to biotechnology. Another event referring to APHIS is its relation to Monsanto since the deregulation of Monsanto's GE-alfalfa illustrates a legalization challenge in US courts. This is because according to US District Court for the Northern District of California in San Francisco, APHIS had failed to appropriately factor environmental impacts of the GE-alfalfa for issuing approval as it is described under the PPA (APHIS 2008). Thus, famers, environmentalists, and consumers joined forces for filing suit against the GE-alfalfa as creating "*"super weeds" resistant to herbicide, hurt production of organic dairy and beef products, and cause farmers to lose export business due to risks of contamination to natural and organic alfalfa*" (Cowan 2013: 12). Thus, the debate on GE-alfalfa is important in relation to the question on co-existence between conventionally bred and genetically engineered products.

4. Monsanto

4.1 The contingent necessities of Monsanto's rise

Indisputably, the most important and powerful enterprise in the seed market is Monsanto, who holds far more patents (647 in 2003; Kimbrell/Mendelson 2005) on GMOs than competing firms in the sector and who had a total net sale of 14,9 billion $ US in 2013, with a net income of 2,84 billion $ US according to own reports (Monsanto Annual Report 2013). Hardly any other company in the world is so contested as the former provider of the highly toxic herbicide *Agent Orange*, which caused irreversible damages on the environment and people's health in Vietnam. In 1901 Monsanto is founded in St. Louis, USA as a chemistry firm. It extended its agricultural branch with fertilizer and pesticides in the 1960s. Companies in the seed industry usually differ in the investment activities in GM technology since they either aim to use it additionally to other technological paths and product lines or as a total replacement for conventional or organic breeding methods. Monsanto is subdivided into two business domains: *Seeds and Traits and Crop Protection* (Monsanto Corporate Profile 2013). The domain '*seeds and traits'* compasses the entire seed business as well as genetic engineering, including biotechnology, breeding and genomics, which is more than 70% of the total profits. GM seeds for corn, cotton, soy, canola and sugar beet are sold by Monsanto itself and its affiliated company Seminis in more than 150 countries in the world. This leads to the pole position in global shares of GE soybeans, corn, cotton and canola. By 2005 Monsanto's global share of GE-Soybeans is by 91%, GE-corn by 97%, GE-cotton by 63,5% and GE-canola by 59% (ETC Group 2005). The second domain, *crop protection* produces the complementary chemical products for the GM seeds, mainly the famous broad-spectrum herbicide Roundup. Monsanto pursues a R&D strategy for the development of GE crops which are tolerant to Glyphosate and also develops GE insect resistant crops because of its important share in the herbicide market and a very little activity in insecticides (Schenkelaars et al. 2011: 27). The R&D strategy to develop GE crops which are primarily based on Bt-genes fitted well to its expansion plans (Wield et al. 2010: 346). Notably, Monsanto could only gain technological leadership since it applied a very aggressive acquisition strategy which displaced numerous competitive firms off the seed market within a very short time. In the time from 1996 to 1999, Monsanto acquired a group of seed and biotechnology enterprises with an investment of more than 8 billion $ US (Schenkelaars et al. 2011: 27). The crucial factor here is that most other multinational enterprises had a higher risk with the application of technology for less chemical use, since these firms are primarily chemical firms with broad inventory of agro-chemicals whose sales volume run the risk of becoming decreased if GM technology proved to be valid (ibid.). In contrast to Monsanto, these enterprises acted much slower in various ways. Monsanto has a narrow product base and few chemical technologies with a broad proportion of its profit resulting from merely one chemical: the Glyphosate herbicide Roundup Ready. This caused a minor risk for Monsanto to fail in case of investing in biotechnology in contrast to other large agrochemical enterprises (Wield et al. 2010: 346).

4.2 Antitrust cases against Monsanto

In relatively early years of GMO commercialization, in 1998, Monsanto acquired the company DeKalb for about 2.3 billion $ US and thereby unintentionally lead to an Antitrust Division through the Department of Justice (DoJ) about competition in agri-biotechnology, particularly the maize seed market (DoJ 1998). The main concern of the DoJ is to provide access to transformation technologies to other biotech-companies with competition purposes for the development and introduction of new traits in maize seed. Primarily, the DoJ raised concerns about the combination of DeKalb's IPR on the leading method of maize transformation which is called "biolistics" and IPR claims of Monsanto to evolving Agrobacterium-transformation technology (Schenkelaars et al. 2011: 108). As a consequence, Monsanto spins off its IPR claims on Agrobacterium-transformation technology to the University of Berkeley (ibid.). Almost one decade later, in 2007, the DoJ raised concerns about Monsanto's acquisition of Delta and Pineland, a major US cotton and seed company. The DoJ requests Monsanto to purge stacking prohibitions in its cotton trait licenses. Hence, Monsanto sold its Stoneville cotton seed brand and related business assets to Bayer for 310 million $ US as well as certain conventional cotton parental lines that it had acquired from Delta and Pine Land's cotton breeding program. A non-exclusive license to the same parental lines have been retained by Monsanto and Bayer's FiberMax brand and the Stoneville brand remained licensed for the usage of Monsanto's cotton trait technologies (ibid.). In general, the various antitrust cases show Monsanto's aggressiveness and desire to control all relevant parts in the value chain control. Relating these cases to the revolving door effect, which is mentioned above, Monsanto's influence should not be underestimated. Increasing concentration processes in the seed market and in power relations are highly dangerous for democratic values and biological as well as institutional diversity. In fact, Monsanto is an enterprise, but due to its actions and decisions it could rather be viewed as an organism that attempts to subordinate "weaker" institutions and actors. Hence, the creation of several anti-Monsanto movements, such as the "March against Monsanto" is not surprising. Monsanto's negative impact on the social and ecological environment is visible in many countries, such as India, some South-American and African states, but also in European countries. Even more crucial are the trials against Monsanto that come from US farmers.

4.3 Farmers against Monsanto

Due to its aggressive proceeding and out crowding of competitive market actors in the seed industry, Monsanto is regularly criticized, judged and observed by various instances. Hence, in September 2006, a class-action suit with more than 100.000 farmers had filed against Monsanto in the US District Court in Wilmington, DE (U.S. District Court 2007). The accusations referred to the monopoly on Monsanto in the US market for Glyphosate. Since Monsanto owns patents on GE seed lines of cotton, soybeans and canola, the plaintiffs accuse Monsanto to keep in product exclusivity "*by acquiring seed companies that were developing modified seed technology, eliminating those products that could have led to the development of genetically modified seeds that could be used with non-glyphosate herbicide.*" (Cowan 2013: 30). However, Monsanto subdued the farmers' plaintiffs for class certification in July 2007, so the case is refused without prejudice for Monsanto, and is refiled in the Missouri courts (Cowan 2013: 30). Essentially, while all enterprises have technology agreements with farmers that are planting their seed, Monsanto holds a technology agreement which needs to be explored profoundly since it delivers important control over the patented seed after the farmer had purchased, planted and harvested the obtained crop. When a farmer is not able to fulfill the company's terms of agreements, then he can be enforced to certain actions by Monsanto. Highly severe is that even farmers, who have never purposely planted Monsanto's seed or any other kind of GE varieties, can be financially and legally screwed by Monsanto if traces of seed of the patented GMO are found (CFS 2005). The lawsuit from the Trade Association and the Organic Seed Growers and over 80 plaintiffs are the latest action against Monsanto in this relation. They concern Monsanto's aggressive patent claim of GMO seeds and the suing of farmers whose fields are contaminated by GMO seeds (RT 2014). To the regret of the farmers and plaintiffs, in January 2014, the US Supreme Court adheres Monsanto's claim on GMO seed patents and its suing of farmers whose fields are contaminated by Monsanto's seeds (Supreme Court 2014). The success of Monsanto in the lawsuits and trials can be related to the revolving door effect. Famers and Associations can accuse Monsanto and their claim of contamination is more than comprehensible. On the other side, it is not clear why a famer can be sued despite a missing will in planting GMOs. This is a highly important legal issue that must be observed on the long run.

4.4 Struggles in GMO research and attacks on critical scientist

As already noted, particularly in GMO research, scientific knowledge enjoys some strong legitimization with its functional authority. It is extraordinary important that there is in fact no clear notion on given and potential risks related to GMOs. The very contestable aspect in this is that advocacies are usually members of the industry whereas critical voices often come from scientists, environmentalists, or consumer rights defenders, but also from political parties. In the past there are several cases of scientists who published GMO critical studies. Remarkably, for many of them the consequence is to be dismissed or set under pressure by specific industrial enterprises, organizations or even the own academic institution. In fact, there is a long history of attacks on risk finding studies. Examples are Ignacio Chapela, a former Assistant Professor at the University of Berkeley who had published a paper on GM contamination of maize in Mexico (Quist and Chapela 2001) and is then discredited by the Bivings group, a public relations firm hired by Monsanto. Also Arpad Pusztai, a biochemist who occupied himself with contradictory findings in GE potatoes (Ewen and Pusztai 1999) and who is attacked by the British Royal Society. A Professor of Molecular Embryology at the University of Buenos Aires, Andres Carrasco (Paganelli et al. 2010) even had to sample physical violence, since he found health risks from Glyphosate of Monsanto's Roundup Ready (Independent Science News 2012). The last prominent case is the Séralini affair which began in September 2012 triggered by a study of an experiment that is published by a group of scientists, headed by Gilles-Éric Séralini. For over two years the group examined health effect on rats which are fed with Monsanto's Roundup resistant

NK 603 maize (corn) and also with the herbicide Roundup (Séralini et al. 2012). Ultimately, the study illustrated alarming results with tremendous health risks, such as tumors[11]. However, the study is retracted and the EFSA which is highly affected by industrial lobbyists explains that the study does not meet scientific requirements. The accused deficits are "*typical method deficits*", such as the husbandry conditions, statistical methods for data evaluation, and even the overall test design. The allegation of disregarding scientific standards appears ironic since studies related to certain industrial organizations, frequently neglect scientific standards as they are actually forward-spaced by the French National Agency for Food Safety (ANSES) or by the EFSA (NIH 2007), or also by the NIH's Conduct of Research (GMWatch 2011). The treatment of critical scientists can be related to the growing scientific-industrial relations, as explained in the third chapter of this work. This can have harsh consequences on the independence and credibility of scientific knowledge and academic research work. However, this affects the question on application-oriented research that automatically requires actors who have a specific interest in the research results.

5. Resume of 18 years GE plant in the US

A USDA study of 2013 on "Genetically Engineered Crops in the United States" (Fernandez-Cornejo et al. 2013) shows that highest yield increase could have been realized with stacked genes, which contain several herbicide and pesticide resistances in their genes. There is a striking increase of stacked crops, a reduced application of pure Bt traits and a steadily increasing usage of HT traits. During the last years, these crops have established in the market much more effective and show increasing rates in case of maize and cotton on about three-quarter of total acreage. Moreover, the study shows that the planting of Bt crops usually does not lead to higher yields and higher net profits for famers, particularly when high pest pressure is given. Also the planting of herbicide tolerant plants does not necessarily increase farmers' yields and net profits. A highly significant point is the declined use of herbicides per planted acre in the beginning of commercial utilization of GMOs which had turned to an increase of herbicide use in later years (USDA 2013). Almost all herbicide tolerant GE plants which came into market became resistant against the broad-spectrum herbicide Glyphosate which is the active ingredient in Monsanto's Roundup, as explained above. The long lasting application of Glyphosate caused tolerances of numerous pest plants which in turn lead to significantly higher usage of herbicides. Partially, older herbicides are applied since due to lacking research in new active agents for 25 years. Seed

[11] Séralini et al. used animal experiments with rats for their study. As an animal rights defender, I want to emphasize the cruelty that animals have to suffer from such experiments, irrespective of the issued outcome. Apart from this, results from animal experiments cannot significantly be transferred to the human body. There are several examples, such as Penicillin, Insulin or Aspirin, which prove that animal experiments are bad science and in-vitro methods and other techniques have to be promoted at the large-scale level.

firms have developed GE plants which are tolerant to 2,4-D and resistant against the older active agents "Dicamba". Due to this, scientists demand for a broad base of weed control. In sum, the cultivation of GMO crops have to be viewed differentiated although the real "winner" seems to be the multinational seed firms and not farmers.

In sum, basic contingent necessities are the historical relation to the Rockefeller Foundation, domestic GMO regulation and the role of Monsanto. The approval method of the FDA and the unsuccessful trials from different actors against Monsanto are essential. This is since the revolving door effect grows in importance and subordinates democratic participation and rights of farmers and relevant organizations.

Part II: Developments and occurrences in Europe

The reasons for examining Europe not only as a whole, but to specify one specific EU member, namely Germany, is because the EU is still a relatively young project while technology trajectories proceed at national and regional levels for a long time. Thereby, the first part contributes to the understanding of biotechnology development and basic structures for agri-biotechnology in Germany. With the section on the EU, the analysis enters the area of food regulation, IPR policies and inner-European GMO controversies and international struggles. There are separate summaries provided for both Germany and the European Union at the very beginning of each sub-chapter. The analysis of the German legislation on plant protection is combined the analysis of the European GMO legislation.

1. Germany

Germany is an industrial state which maintains its position in various international markets, but failed to develop modern agri-biotechnology. Thus, this section explains which specific occurrences prevailed and failed to enter a contingent interaction. Essentially, Germany does not provide comparable amounts of venture capital as the US. Moreover, the *comprehensive style of thought* in combination with the Humboldtian idea of *pure science* which is dissent to the US-American pragmatism dominates in Germany for a long time. By the 1970s, scientific-industrial relations increase and Germany catches up development in several biotechnological fields, but applies little in agriculture. Once again, plausible reasoning is emphasized in order to show cultural and national differences. Thus, there is a lack of a Natural Science Division, incentives for short-term small funding grants and effectively of an intrinsically motivated shift from physico-chemical to experimental biology. Germany makes efforts to apply the newest technology on the production of traditional products rather than to the development of entirely new technologies and industries. Unlike, the US aims to construct fully new technologies and industries (Hollingsworth 1997: 289). Germany’s industrial system is characterized by a long-term funding approach and stable employment. It seems that German chemistry considered biotechnology to be a temporary solution which has to be replaced by the organic-chemical synthesis (Wieland 2009: 203). This is complemented by a weak institutionalization of academic subjects that are necessary for biotechnology development, namely microbiology, molecular biology and genetics. Additionally, academic biologists have crucial reservations on a practical application of their research projects. In sum, these structures shape the national technology trajectory and corresponding economic aspects in Germany and remain until the 1970s, as an external shock confronted the country. Hence, internationalization processes overrun national technology development and intervene in production processes. With respect to modern agri-biotechnology, the shock is particularly triggered by the US technology development and partially by Japan. New narratives on life and directions of development begin to shift the institutional configurations and actor constellations in Germany. Although Germany adapts the notion of biotechnology as the new key technology, initial catch-up strategies conducted by industries and the government are at the core marked by uncertainty. Efforts in developing biotechnology finally fructify in the mid-1990s, but modern agri-biotechnology is yet neglected. Venture capital provision is subject to fluctuations, reflecting a small importance at the international biotechnology market. Though, nowadays there are rising interrelations between the academic sector and the industry for research in plant biotechnology, but the applied technology is hybridization, not genetic engineering with rDNA. In sum, the scope of transformation was and is large in relation to biotechnology, but not in case of agricultural breeding methods. The context-specific depth of intervention increases in the 1970 with the extensive changes of international relations and growing external pressures. In turn, the strong resistance of chemistry and the academic mentality reflects the restricted readiness to accept emerged forces. Hence, the area-specific adaption ability has to be considered with its deep social and historical background. With a few exemptions, Germany generally refuses to plant, distribute, import or sell GMO food products and relies on its corresponding national ban on GMOs in agriculture. Crucially, scientific-industrial relations increase in Germany, but the absolute number of institutional cooperation is yet manageable.

1.1 Technological and economical structures in Germany

1.1.1 Germany's traditional chemicals industry

Until the 1970s, the chemicals industry in Germany is dominated by the mentality of industrial chemists which head the development departments and rule the executive management (Wieland 2009: 212). Essentially, the chemicals industry is a prototype of knowledge-based industries. Its success can be traced back to the tight connection of academic basic research and industrial production. The high degree of scientification influences the self-perception of salaried chemists and shapes their idea of theory and practice (ibid.). According to traditional linear thinking, technological progress is achieved through scientific knowledge which is gained by pure basic research and subsequently translated into technical application. In contrast, the roots of biotechnology are a *manual-empiric tradition* which exerts adaption pressure on the German chemicals industry. Biotechnological processes are barely touched with theoretical issues. Hence, it is presumed that commercially relevant microorganisms are found and not developed, and processes are improved through systematic testing and not derived from models. As Wieland underlines, German chemists must have considered biotechnology to be a low-tech sector since it stands in a great contrast to their established chemicals culture (Wieland 2009: 212). On this note, it falls into place why financial incentives by the state failed in research and technology policy since the German chemicals industry reaped the public subsidies and engaged itself in SCP-Projects[12], but refrains from changing its paradigm of organic-chemical synthesis and thus remains on its traditional self-perception (ibid.). Germany does not contend with real economic problems, but is gripped by the fear of uncertain industrial competitiveness in the long run. This fear triggers a changed self-perception and action-taking (ibid.: 199). The restricted influence of public management exposes in path development processes by the mentality and dispositions of actors in the innovation system. Significantly, the fundamental transformation in German chemicals industry and those from other European countries is neither provoked by the state nor by real economic problems, but by an external shock in terms of a rapidly developing biotechnology field in the US (ibid.: 200) and partially in Japan. These external effects are accompanied by great promises of financial benefits so that stock jobber already attune to a new market situation (ibid.: 238). Linking these developments to the explained sector-specific adaptability, it becomes clear how dramatically this gridlocked situation was at that time. A long industrial tradition which is grown over centuries of academic basic research and successful technology development is suddenly faced with a new technology, compelling it to adaption.

[12] SCP signifies a process for "*single cell protein*" cultivation. The idea is to produce local food from waste. Scientists and policy-makers in the late 1960's viewed the possibility to grow microorganisms on oil as a possible solution to fight worldwide hunger (Bud/Cantley 1994: 133).

Despite real problems, this leads to one fundamental change: the self-perception of chemists had to be re-positioned in order to withstand in the international market. The pressure on the cultural and technological development direction influenced the existing dispositions and required new values and inner convictions.

1.1.2 Academics

The German education ideal is traditionally determined by the Humboldtian idea of pure science and knowledge production. To this effect, molecular biology which is the basic natural science in agri-biotechnology is understood as pure science until the 1970s (Wieland 2009: 224). Furthermore, German academic researchers never had serious incentives to make efforts in patent gaining. This is since the German law imputes full Intellectual Property to employees of public universities which again precludes the share of knowledge with an employing institution (Giesecke 2000: 211). Mainstream authors call this an "*obstacle to the overall innovative performance of German universities*" (ibid.). Crucially, academics must carry the costs of filing and sustaining patents on their own without financial support by institutions. It is untypical for Germany to run technology transfer offices as profit enterprises. This stands in contrast to the US system in which university technology transfer offices bear all costs and "*in return get a share of the royalties*" (Giesecke 2000: 211). For a long time, Germany is characterized by a small number of innovative start-ups in biotechnology and dominant large-scale pharmaceutical enterprises that have little incentives and potential for competing with global modern biotechnology (ibid.). Thus, small start-ups as known from the US-system are put out as direct spin-offs from universities that lead to an extraordinary economic advantage (UNCTC 1988). The fundament of these start-up firms are the "*entrepreneurial academics*" that gain a lot of venture capital based on the idea of the American "self-made man" (Bartholomew 1997: 252). Unlike, in Germany this idea of the self-made man induces bad associations and is not pursued. This cultural difference is fundamental for the business strategies between both countries. It can be also lifted up to a higher level in as much as Germany provides significantly more welfare services in contrast to the US.

1.1.3 The industrial relations system in Germany

For understanding main industrial and technological developments, it is fruitful to consider the time around World War I, since the foundations for important aspects of the German social system of production are laid at that time (Hollingsworth 1997: 285). A significant factor for the strategic thinking in terms of long-term periods is the industrial relations system. As Hollingsworth expresses, it is this industrial relations system that contributes to the recent success of economic catch-up process in German industry. This system is characterized by a "*highly developed centralized employer and business associations as well as trade unions*" (ibid.: 286). In fact, Germany does not make much efforts to develop *entirely new technologies and industries,* but into the *application of the newest technology* on the production of traditional products. Unlike, the US aims to construct fully new technologies and industries. According to Bartholomew's statement of "*natural trajectory*" of national technological strength, Germany is specialized on automobiles, machine tools, chemical products and traditional industrial products from 19th century production lines. Furthermore, the Germans gain a good reputation in the application of the newest micro-electronic technology for the production of traditional products and to new production methods. Newer industries, such as computers, consumer electronics and semiconductors are not on the list of successfully applied technologies. Germany fails to promote products that require mass advertising and a fast development of entirely new products (ibid.: 289 ff.). The fast resurgence of the German chemicals industry after World War II leads to the establishment of a well-assorted tool box of tried and tested innovation and production strategies (Wieland 2009: 203). This specific restriction on certain application areas causes an essential specialization that impedes the break out of established patterns. In particular, organic-synthetic processes compete with evolving biotechnological processes and finally have to make way for biotechnology. The external shock forces enterprises and academics to change their self-perception and their research strategies. Thus, actor constellations and given structures began to transform in the 1970s.

1.1.4 Facing the new technology

In the 1970s, the top chemistry and pharmacology enterprises in Germany (Hoechst, Bayer, Boehringer, Merck and Schering) as well as some academic institutes and large research facilities (e.g. Society for Biotechnological Research) participate in a two year study on issues of public promotion policy for the creation of a programmatic framework (Wieland 2009: 209). Already to this early date, biotechnology is defined as *application-oriented science* which contains the adoption of biological processes within the frame of technological processes and industrial productions. The initially used technical definition implies biological reactions with living cells (ibid.) and stands in relation to a huge amount of diverse processes in food production and wastewater treatment as well as the production of antibiotics, enzymes, and other complex substances. The authors try to set an economic and social component next to the purely technical definition of this new technology. Hence, biotechnology is defined as the future key technology which fundamentally contributes to the German economy (ibid.: 210). This shows that the representatives of science are focused on their own debate forum with purely scientific discussions at the beginning, before they participate in public debates considering value orientations and public technology attitudes (Bremme/von dem Bussche-Hünnefeld 1999: 164). Crucially, this shift comes from the insight that technology can only be established with the will of the people. Of all time, it is this first period in which people lose their trust in scientists' integrity. It might have been the decisive time at which there could have been created a basic consent on the usage of genetic engineering that was destroyed instead (ibid.). A study of Hampel and Renn at that time shows a dramatic misbelief in scientists' law-abiding behavior and of self-restraint of scientists based on moral reasons (Hampel/Renn 1998).

In May 1981, Hoechst establishes a cooperation relation with the MGH (Massachusetts General Hospital) and explains its strategy with the low amount of highly qualified task forces, the lacking readiness of German scientists to work tight with the industry, and the bureaucratic difficulties for such cooperation and the huge uncertainties which prevail towards biotechnology (Wieland 2009: 227). The Research Ministry (BMBF) shows sympathy for Hoechst's decision on the one hand and is disturbed on the other hand. Therefore, it initiates the German chemistry and pharma firms BASF, Hoechst, Bayer, Boehringer Mannheim, Schering, and Thomae to write a report about the situation of biotechnology in Germany. Ultimately, all the participants agree on the high potential of biotechnology which cannot be assessed clearly (Wieland 2009: 227). In 1985, the Federal Government in Germany adopts the program "Angewandte Biologie und Biotechnologie" with the aim to foster knowledge transfer from biological basic research into industrial application purposes. In this relation, the implementation of promotion for joint research projects which combines universities' and industries' engagement is planned as well as the attempt to set incentives for the foundations of specialized biotechnology enterprises with tax reduction and financial aid (ibid.: 231). This period in the mid-1980s is accompanied by the implementation of an Enquête-Commission on the chances and risks of biotechnology which ends up with an amended gene-technology law (Enquête-Commission 1987). The regulation and regulation of biotechnology is negotiated in closed actor circles until a publicly and very controversially held debate becomes noteworthy. It triggers a general debate on the chances and risks of biotechnology and ends up on the question if Germany is the future industrial location for biotechnology. During the 1990s and later, research funding in the food sector is not related to one particular ministry, which could promote the diffusion of technological novelties in the food industry. Rather, development and diffusion of novel technologies are based in the areas of ministries of agriculture, environment, research and economics. Thus, due to a lack of coordination, the extent of public affirmative action is little. Moreover, the food sector is the only branch of economy which is not administered by the Ministry of Economics, but the Ministry of

Agriculture (!). Though, in the Ministry of Agriculture, the dominating issues are primarily regarded to agriculture and have only an indirect impact on the food sector (Behrens et al. 1997: 52). However, the catch-up attempts of Germany finally fructify in the second half of the 1990s. The appropriate tremendous profit outlooks draw attention of venture capitalists and stock jobbers as well as from the dominant chemical-pharmaceutical industry (Wieland 2009: 238 ff.). Hence, the challenge for the research and technology policy are no longer the chemical industry's close attitude towards profound innovation, but rather the lack of knowledge transfer from academic basic research into industrial application. In this relation, two problem fields become evident: On the one hand it relates to the weak institutionalization of relevant subjects such as micro biology, molecular biology and genetics which are all together with other disciplines the scientific basis of biotechnology. And on the other hand, the cultural skepticism of academic biologists towards a port of their research for potential application purposes, particularly in industrial contexts is concerned. Fundamentally, it seems to be nearly impossible that a deep cultural imprint of a universal and application-distant scientific ideal which innumerous researcher generations had incorporated, could all at once found firms and act as entrepreneurs without profound changes in their value systems (Wieland 2009: 241). Due to this, in 1997 the BMBF implements a study concerning the attitudes towards biotechnology in Germany towards biotechnology with 1500 participants. Crucially, there is a high acceptance towards biotechnology for pharmaceutical products, but not for food production (Bremme/v. d. Bussche-Hünnefeld 1999: 162). This can be understood as latent given opinions and attitudes to technology, based on moral defensibleness and less on scientific knowledge which is very uncertain anyway (ibid.). In detail, the fears are related to increasing allergies and the creation of transmitting resistance genes from one variety to another as well as the linked uncontrollable dispersion of features which are foreign to one species and uncertain impacts on the environment (ibid.: 166). Although the state and the industry have agreed on the weak position of the German molecular biology and the implementation of efforts for promotion, it is unclear which common proceeding to choose for basic research fostering (Wieland 2009: 229). The German Federal Ministry of Education and Research endeavors to accommodate the industrial interests of the three major German chemical enterprises, BASF, Bayer and Hoechst. However, the Ministry also knows to hinder the industry's pursues for an exclusive access right to the knowledge in basic research which is compiled at the universities Heidelberg and Cologne (ibid.). For the decade of 2000 to 2010, the BMBF finally introduces the framework programme "Biotechnologie – Chancen nutzen und gestalten". The aim is to secure international work effort in German bio sciences and to foster national innovation. For the time of 2001 until 2005 around 980 million

Euros are provided for biotechnology projects. After a new notification by the European Commission, in 2006 the programme is prolonged for further five years and equipped with one billion Euro appropriations (BMBF 2010: 5). However, the general focus lays on pharmaceutical, industrial and platform technologies or services. Plant biotechnology is not represented to the same extent, but restricted on a few facilities. Today's plant biotechnology includes research on plant genomes and agriculture as well as nutrition science and partially bio-energy. Academic research is highly diffused in Germany, visible in nearly forty universities and thirteen non-university research facilities (ibid.: 30). One of the most important institutions is the Leibniz Institute of Plant Genetics and Crop Plant Research (IPK) which is a nonprofit research institution and a member of the Gottfried Wilhelm Leibniz Association (IPK 2014a). Furthermore, the majority of these institutions conduct Departmental research for plant biotechnology, e.g. the Julius-Kühn-Institute or the Johann Heinrich von Thünen Institute or the Max-Rubner Institute (BMBF 2010: 30). That research facilities and the industry are approaching subsequently can be stated also in Germany. Thus, the Boehringer Ingelheim Ulm University BioCenter (BIU) is the result of a tight cooperation between the University Ulm and the pharmaceutical company Boehringer Ingelheim. Also Bayer has a strategic alliance with the German Cancer Research Center in Heidelberg. Moreover, Berlin's Charité cooperates with the French pharmaceutical company Sanofi (BMBF 2010: 33). Germany adopts the idea of a more application-oriented position towards plant research as well as the focus on molecular biology. Hence, plant research is conducted under this light, but the overall aim is not the production of GMOs. Instead, the aim is to develop processes for efficient productions of hybrid seed. This shall increase yields, yield stability and quality of seed and their traits (IPK 2014).

1.1.5 The financing system for venture capital

The externally induced adaption pressure to Germany leads to various context-specific adjustments in the existing technology structure and corresponding financing system. As a result of the *New Economy*, in 1997 Germany follows the US-American example of the NASDAQ and creates the new market segment *Neuer Markt.* The purpose is to support the German biotechnology sector, telecommunication sector, environmental engineering and internet-based enterprises. Particularly the stock market for young high-tech and high risk firms is aimed. The *Neuer Markt* aims to become the dominant facility option for venture-backed biotechnology firms and created at least 17 German biotech firms in 2000, compared with over 400 firms at the NASDAQ (Müller 2002: 289). From 1997 till 2000, the *Neuer Markt* experienced a rapid growth, but stagnates already in 2003 (Die Welt 2013). From the very beginning, the Initial Public Offering (IPO) is seen as the best strategy at the stock exchange (Müller 2002: 289). IPO, however, loses importance since 2008. In general, venture capital providers are faced with two major risks. The first one signifies business risk which is generally calculable and a part of day to day work for venture capital providers. The second major risk includes exit-risk. The difficulty here is to calculate whether and when a share can be sold. A functioning IPO market would, however, provide a solution through the enabling of standardized exits for venture capital providers. The incalculable exit-risk could be reduced to a minimum (wallstreet-online 2014). The striking point in the established biotechnology financing system of Germany is that "*venture capitalists are involved in one in three of all dedicated companies*" (biotechnologie.de 2010). The very strong fluctuations in the last years mark an instable financing of biotechnology activities and contribute to an overall uncertain investment business of biotechnology in Germany. Since there is no functioning IPO market in Germany, German firms remain unattractive during the growth period for venture capital. The complaint over insufficient venture capital is justified because Germany is able to catch up biotechnology development to a certain extent, but the situation of the IPO market proves problematic for a serious innovation support (wallstreet-online 2014). In 2009, only 24 firms are active in plant biotechnology issues and the sector tends to diminish (biotechnologie.de 2010). Though, there is a sharp increase in 2010 with a strikingly higher amount of investment in biotechnology compared to the previous years, investments dramatically slump in 2011 and reach the relatively low level that was given before. However, there is no stable venture capital provision, but rather a strong fluctuation which probably remains in the future biotechnology sector (German biotechnology sector 2014).

2. The European Union

In relation to the EU it is important to say that the draft of the European Union is endorsed almost parallel to the Green Revolution which is established by the US. Significantly, the topic "GMO" enters the EU agenda not before the mid-1990s. Due to the very complex situation, the EU Commission is given no alternative to enact a *de-facto moratorium* on the cultivation and importation of GMO food in 1998, coming into force in 1999. With this moratorium several nation states, including Germany and Austria, ban GMOs from their territories. Corresponding Directives legally support their skepticism, namely the Release Directive of 2001 which enables member states to restrict or prohibit a product's use or sale if risk for human health or the environment is assumed (art. 16). The broad oppositional attitude towards GMO food has not significantly changed since the 1990s. Essentially, regulations set in 2003 and 2007 create a blockade situation that lasts until today. Lastly, in July 2010 the EU Commission established new guidelines for national coexistence regulations. With this, national GMO bans are even strengthened and simplified in their implementation. Yet, there is neither a genuine demand for

GMO food, nor a relevant economic benefit linked to the usage of modern agri-biotechnology in Europe. Also, there are no inner-European alliances and start-ups, but an orientation of firms to the US market and businesses. Due to this, German BASF outsourced its agri-biotechnology line to the US already in 2012. However, no matter how strong the oppositional position from the most EU countries is against GMO food, Monsanto and other relevant companies continued lobbying for their products. Their behavior on GE crops that are not even yet approved is an extremely serious matter. One of the most crucial cases nowadays is the GE-corn 'SmartStax' by Monsanto and Dow AgroScience. The industrial-friendly European Food Security Authority (EFSA) assesses the corn in 2010. It is then approved in autumn 2013 for the European Market. The critical point relates to the illegal imports from the US into the EU during the time in between the assessment and the official approval. This is since the Directive 1830/2003 that demands for retraceability of plants is violated heavily in cases of GE plants with gene-combinations. The practical difficulty of identifying certain genes and plants causes problems of institutional regulation and monitoring. Especially since the EU relies on the precautionary principle, European institutions have to be strengthened in relation to monitoring and approvals. Furthermore, the rising numbers of biopatents increase its importance for European breeders who traditionally operate with Plant Breeders' Rights. There is an unclear relation between biopatents and Plant Breeders' Rights and a wide row of conflicts, such as the scope of patent claims. Around 2007 one of the largest patent offices in the world, the European Patent Organization (EPO) officially admits the necessity "*to undergo substantial changes to fulfil its function and gain the legitimacy necessary for its future work*" (Then/Tippe 2009: 5). With this, it becomes clear how an emerging patent inflation challenges current organizational systems in their given capacities as well as inventiveness in general. In this context, the Biopatent Directive of 1998 is important, particularly the industrial-friendly and woolly definition of "*essentially biological processes*". In accordance to EPO's European Board of Appeal, plants are patentable "*if the technical teaching of the invention is not limited to a specific plant variety or varieties*" (EPO 2013a). A pivotal decision was taken in 2010 with the '*broccoli and tomato case*' (G 2/07 and G 1/08). The Board rules that a process for the breeding of plants containing the steps of crossing and selection is exemplified from patentability even if comprising a further step of technical process, such as the application of molecular genetic markers. Currently, the Board is demanded to decide whether the products of such processes are also excluded from patentability (EPO 2013b). Moreover, in May 2012 the European Parliament adopts a resolution appealing to the EPO to end issuing patents on conventional plant and animal breeding. In sum, there is a general tendency in the EU to strengthen national GMO bans and PBR. The EU catches up biotechnology in various fields, but the application to agriculture is opposed from the beginning. Therefore, the very last part of this section dwells on the conflicts between the EU and the WTO regulation. Main aspects concern the different principles of substantial equivalence and the precautionary approach, labelling issues and uncertainty in the judicialization of GMOs. The GMO controversy at the international level evolves since several countries, mainly the US bring accusations to the WTO's Dispute Settlement Body, indicating non-conformity of EU actions with WTO rules. Since the EU insists on the labelling of food products, several GMO food exporting states, especially the US accuse protectionism. In fact, the US-American and European situations have reversed with respect to policies on human health and environmental protection. The strict US regulations remain until the 1980s and become successively lax, whereas various regulations in the EU are loose until the 1980s and grow stricter since then. The reasons of the charges are a failed implementation of the EU Release Directive 2001/18, the definition and regulation of bio-patents (Directive 98/44), and the political conflicts in 2004 on liability regulation according to co-existence of agriculture with and without biotechnology. All in all, Europe adopts the narrative of biotechnology as a key technology, implements new structures and extensively converts funding possibilities. Notably, biotechnology is supported in various industrial fields, but the food sector widely remains untouched; or in other words, the legal framework is modified in a way which frankly conserves conventional agriculture and food production. This has to be interpreted cautiously since GMOs cannot be completely denied in agriculture. At the contrary, adjustment pressure on agricultural structures is triggered indirectly by high feed prices, relevant for animal breeding farmers. Today it is the case that non-GMO feed is much more expensive and hardly available in comparison to GMO feed, particularly soy bean feed which is most applied. These circumstances force farmers to buy GMO feed and contribute to GMO pollution on this way. Furthermore, farmers are confronted with pressures to transform their traditional small-scale production to large-scale farming. These forces are particularly severe for smaller family farms that do not have significant financial and personnel resources.

2.1 GMO crop planting in the EU

The application of GE crops is moderate from the beginning and has even decreased in the last years. The limited extension is due to the conflictual situation which is mainly characterized by political uncertainty, a precautious attitude towards potential environmental and health hazards and a broad opposition by various organizations of the civil society. This is accompanied by the negative dispositions on food products that are produced with genetic engineering. Hence, the assumed economic benefit is significantly low in most cases (Götz 2005). However, the first commercial approval concerns Monsanto's GE-maize MON-810 in 1997. This is first approved and soon banned by Germany, France, Greece, Luxembourg, Austria, Poland, Bulgaria, and Hungary (FoEE 2013). The major acreage in the EU remains GMO free, thus the acreage for MON-810 in the entire EU is about 0,13% in 2013 (FoEE 2013). Currently it is the case that some Eastern European countries plant GE seeds while Spain and Portugal have the major GMO fields: they plant on a total of 145,133 ha acreage in 2013 (ibid.). The Czech Republic and Slovakia experienced a drastic decrease of the commercial cultivation of this variety. Poland announced its national ban on MON-810 in January 2013 and also of the GE-potato *Amflora* which is approved in 2010. Amflora is used from 2010 until 2013 by Germany and Sweden, but not anymore in 2012 even though its cultivation is still legal for one more year. Amflora is developed by German firm BASF who declared in January 2012 to outsource its agri-biotechnology activities to the US because of the tremendous public opposition and the missing marketing opportunities in Europe (Spiegel 2012). Similarly, in spring 2013 Monsanto announced to cease lobbying in Europe due to the broad public refusal against GMO food (taz 2013). This ceasing includes the application for approving new GMO crops and new field trials with this seed (ibid.). Significantly, Monsanto's announcement has to be skeptically viewed as a strategic PR-campaign and not as a serious withdraw from the EU market. Several applications are withdrawn, but the cultivation of MON-810 continues (Süddeutsche Zeitung 2013). Even more remarkable is the case of the GE-corn SmartStax by Monsanto and Dow AgroScience which is approved by the EU Commission for food and feed in autumn 2013. SmartStax is assessed by the EFSA in 2010, but not yet approved. Since the plant is already brought from the US to the EU before its official approval, this importation is illegal. The EU Commission failed to take legal measures against these imports. This is crucial since benefitting industries can rely on the fact that EU authorities cannot detect illicit supplies. According to EU regulations, each EU approval application demands a clear verification procedure for the corresponding GE plant. According to the Directive 1830/2003, products which derive from these plants must be retraceable. This Directive is violated heavily and regularly since the GMO plant is approved with gene-combinations (stacked events) which are also in other plants. Significantly, several plants are approved for food and feed which contain gene-combinations that complicate its practical identification. The case of SmartStax reveals to which extent the corn already exists at the market and the difficult monitoring circumstances for authorities (Testbiotech 2012). In combination with a lacking regional long-term monitoring programme for environmental and health hazards, future consequences cannot be determined. The more it is necessary to reform and strengthen institutional approval requirements and monitoring systems in the EU. As long as there are lax regulations and broad legal blind spots, the precautionary principle will have only a low impact in practical terms.

2.2 Food scandals and dispositions concerning food

The different dispositions of the US society and European societies emphasize the cultural embeddedness of attitudes. Getting deeper into the matter means to relate this to the systematization activity of the mind. Food is not considered to be a transcendental idea, but the image of genetics and potential dangers that can evolve if humans actively intervene in this "part of nature" causes indisposition and mistrust in several European societies. Awareness for food and the metabolism between the own body and the environment is essential in this regard. Moreover, value orientations, moral acceptability of GMO food and the confidence in EU institutions are directly affected. This can be observed in the trust in political and economic decisions as well as regulation patterns. Unlike in the US, food scandals in the EU lead to profound shifts in the EU policy of food and feed products. One of the most influential events is the BSE scandal in late 1990s and early 2000s which is not directly related to the issue of GE crop plants, but generally opened up the dispute about food safety question in the European Union (Gaskell/Bauer 2002: 61). What follows is a significant shift in the way policy makers had treated risks. Fundamentally, they have the insight that regulation on such a sensitive issue like food should not be predominantly controlled by the industry and that expert committees are usually likely to fail in their risk assessments. Corollary, the UK government as well as the European Commission are admonished for their usual procedures to date. The European Parliament particularly excoriated the "*secretive decision-making procedures and the complex and undemocratic system of scientific committees*" (Gaskell/Bauer 2002: 62) in the EU. While the above illustrated food scandals in the US had no impact on the later applied policy, the EU remarkably strengthened consumer rights in DG XXIV (Consumer affairs), more transparency, and also a say of the parliament in decision-making of the Commission (ibid.). The cases stress the ambiguity of food related risks and the overall attitude towards food. It reflects the different food cultures and the great importance that is attached to food.

2.3 Institutional developments in the EU

The EU policy for biotechnology is mainly characterized by a regulatory framework pinned in between two conflicting paradigms: fostering economic growth and competitiveness on the one hand and protecting the environment and human and animal health on the other hand (Falkner 2007: 513). This can be illustrated with the regulation of biotechnology in Germany, which is characterized by both *promoting policies* which have the mission to develop a key technology for safeguarding international competitiveness and protection of business location as well as *regulation policies* which pursue the establishment of a legal framework for the usage of the new biotechnology and regulation and channeling conflicts with the evolving technology (Conrad 2004: 36). A very crucial difference to Europe is that US states have little say in decision-making processes of federal regulatory authorities, whereas EU member states are the principal agents of enforcement and take over political roles in European regulatory committees, and the Council of Ministers at the same time (Stephan 2012: 108). Europeans are traditionally used to organize around products and not around industrial processes. Hence, the biotechnology sector has a fragmented structure with small and medium-sized firms which hinder European biotechnology firms to create EU-level associations for lobbying in European institutions in the probably most decisive time period (Behrens et al. 1997: 12; Falkner 2007: 515). The fragmentation of diverse usage interests in the food industry dramatically determines technology development and the course of diffusion (Behrens et al. 1997: 12). A typical feature of European sub-industries is its heterogeneous association structure which demonstrates the diverse interests of the overall food industry towards agriculture (ibid.: 51). This fragmentation is one of the reasons that prevent European famers from using genetic engineering techniques (Falkner 2007: 518). To view this much broader, the ankle has to switch to the general "*delicate balance of power*" (Bauer/Gaskell 2002: 52) which is constituted by clearly written and unwritten regulations as well as different structural premises of European countries. Fundamentally, since negotiations and decision-making have to be made in Brussels and no longer at the domestic level, the national structures, norms, and rules change profoundly. This primarily affects interest groups which have to change their strategies with the emerging biotechnology development. Hence, they do not retain their powerful influence on policies unless they have participated at the European level and thus at European institutions which are characterized by several various rules and actors (Bauer/Gaskell 2002: 52). Remarkably, not before 1989 the Council of the European Chemical Industry (CEFIC) establishes the Senior Advisory Group for Biotechnology (SAGB) which is in fact the first European industry organization in biotechnology sector (Cantley 1995: 633 ff.). Shortly after this, in 1991, national biotechnology associations congregate in order to create the European Secretariat of National Bioindustry Associations (ESNBA) (ibid.: 635). In 1996, appropriate industrial groups organize themselves in Brussels and create an entirely new common institution, called Europa-Bio which acts towards the powerful European Commission and some other actors (ibid.). EuropaBio turns to be the main biotechnology group, but still fails to implement a strong industrial purpose of modern agri-biotechnology, since the usage possibilities at that time are not explicit. This can also be seen in the German Act on Genetic Engineering (GenTG 1990) with its uncertain, fragile and highly politicized notions and rules. These conditions can be traced back to the missing experience with the emerging technology and uncertainty about potential hazards for humans, animals and the environment. Therefore, the prioritized rule-making procedure is to choose rather rigid laws than to cede regulation to industry and science (Conrad 2004: 40).

2.4 The legal framework of GMO regulation

2.4.1 EU legislation on GMOs: The Release Directive 2001/18/EC

The main legal regulations on biotechnology in the EU are built on the Release Directive 90/220/EEC and the System Directive 90/219/EEC which are merged into the Release Directive 2001/18/EC in 2001. The Release Directive 90/220/EEC is related to the release of GMOs whereas 90/219/EEC regulated GMOs within sealed systems. The amended Directives 94/51 and 98/81 on the one hand and 94/15, 97/35 and 2001/18 on the other hand become updated and tightened. The Directives 258/97, 1829/2003 and 1830/2003 have to be directly transferred into domestic legislation since they regulate approval, identification and the traceability of GMO food and feed products. Furthermore, the Directive 178/2002 regulates the general principles and requirements of food law, established the European Food Safety Authority and lays down procedures in matters of food safety (EC 2002). Since its establishment, the biotechnology law is amended almost every year, lately in 2011 (BMG 2014a; BMG 2014b). Both Directives contain so called "*technology specific or horizontal regulations*" which are based on the conviction of potential risks being caused by the application of certain technologies (Behrens et al. 1997: 106). In fact, the additional Deliberate Release Directive of GMOs explicitly advises of public participation in national decision-making on specific issues (EP 2001). However, since this covers merely voluntary implementation, only a few countries decide to adopt it into their domestic legislation (Bauer/Gaskell 2002: 52).

2.4.2 The Novel Food Regulation

The Novel Food Regulation 258/97 (EC 1997) is introduced in May 1997 and relates to the regulation of novel foods and novel food ingredients. In this relation, also the Regulation 1829/2003 on genetically modified food and feed as well as the Regulation 1830/2003 (EU Parliament and Council 2003) on traceability and labelling GMOs are relevant. The followed principle of the Novel Food Regulation is a product-oriented or vertical approach and therefore not focused on the applied technology, but rather on the product and its related organisms itself (Behrens et al. 1997: 106). The conflicts linked to the Novel Food Regulation are examined below with respect to the WTO rules.

The Novel Food Regulation implies a strict labelling regulation for all new food products, including biotechnology products which are actually covered by the Directive on Deliberate Release. Such a regulation is already planned in 1992, since the Release Directive is in dispute. An essential contentious point is the missing specification of labelling, so that there are various differences between the already issued approvals for GE-maize and GE-soya and the question on future approvals (Bauer/Gaskell 2002: 63). On this account, the European Commission agreed on mandatory labelling as long as certain conditions are fulfilled. This means whether the new food product is explicitly recognizable distinct from existing equivalents, or whether the product raise concerns in terms of ethical or health issues, or in other words, whether the GMO is present in the food product (Bauer/Gaskell 2002: 63). In general, the regulatory burdens in the EU for GE crop approval are hard to overcome. Hence, the amount of test releases dramatically decreases and causes the abandoning of GMOs by large enterprises (Nicolia et al. 2014: 9).

2.4.3 GMO controversies in the EU

The European biotechnology sector is characterized by asymmetrical power relations and the influence of involved non-state actors. This is reflected in an asymmetrically structured pluralism of political decision-making and interest bargaining (Conrad 2004: 50). The difficulty in the political regulation of GMOs concerns the *principle of the free movement of goods* which implies the remove of national barriers of the free movement of goods within the internal EU market. This is problematic with respect to the environmental since ecosystems, pollution, and gene flows do not stop at on manmade national borders. As illuminated above, the issue of *Entgrenzung* is concerned since GMOs may interbreed or crossbreed with non-GMOs. The national scope of action in the EU is very little which formally allows national bans exclusively when approved by scientific proofs on threats caused by GMOs. The Deliberate Release Directive adopts the precautionary principle in order to avoid potential risks resulting from GMOs. Based on this, applicants who desire to implement field trials with GMOs are called for applying an environmental risk assessment to the "*competent authority*" of the corresponding state. Moreover, it has to apply to each other EU member state for marketing GMO products and the permission to "*object to such marketing within their borders*" (Lynch 2001: 10). With article 16 of the Release Directive member states "*may provisionally restrict or prohibit' the use of sale of a product if it has "justifiable reason that an approved product poses a, risk to human health or the environment.""* (ibid.: 30). In the mid-1990s and early 2000s, the EU is faced with critics from various relevant regional and national actors. Several member states, namely Austria, Ireland and Greece banned the import and cultivation of GMOs for food products (Bauer/Gaskell 2002: 66). Unlike, the situation in France seems to be beneficial for GMOs at the beginning of the 1990s, with an open attitude and the engagement for an EU-wide marketing of GE-soybeans and GE-maize from the US. After a relatively short time, also France opposes the distribution of GE-maize (Bauer/Gaskell 2002: 66). By the end of the 1990s, the government at that time, environmental organizations, agricultural organizations and the green Ministry for the environment militate against the use of GMOs. France finally puts a two year moratorium on marketing approvals for specific plants (Bauer/Gaskell 2002: 67). Many EU member states effectively campaign against GMOs, initiated by consumer and environmental groups. Also the European Parliament argues for stricter regulations and a strengthened framework; and ultimately, food retailers retract GMO products from the market which have already been approved (Falkner 2007: 518). Based on the Release Directive, the GE-maize MON-810 is approved by the European Commission in 1997, despite a strong lack of support by the member states. The approved GE variety is exported from the US into the EU in November 1996, although the approval applied for December. Crucially, the US "*denied that its initial shipments of corn contained genetically-modified varieties*" (Lynch 2001: 11). The triggered media attention induces an increases awareness of the public and subsequently a stricter risk assessment. The consequence is a strengthened precautionary approach in the regulation framework (ibid.). Yet, the process of authorization has broken since the member states in 1999 relied on the Directive's savings clause which implies a preventive treatment with GMOs and thus, their approval in the single member states (Falkner 2004: 518). For instance, Austria perpetuates his ban of GE maize until today despite the Commission's decision and verdicts of the European Court of Justice. At this time it is an official petition which initiates a moratorium on GMOs and appropriate patents. This applies pressure on the Austrian government and administration (Bauer/Gaskell 2002: 66). In sum, the Commission's efforts to create one overall coordinated biotechnology policy based on several biotechnology programs in the 1980s fail. This can be traced back to the dominant national biotechnology policies of powerful member states, such as Germany whose biotechnology enterprises preferred alliances with US domiciled biotechnology firms instead of investing in inferior alliances and for fostering biotechnology start-ups in Europe (Bongert 2000; Senker 1998). Due to the very complex situation at that time it seems to be the best alternative to execute a *de facto moratorium* on planting and marketing GMO foods in Germany, Austria, France, Greece, Italy and Luxembourg in 1998, coming to effect in 1999. This can be understood as a reaction of the EU to calm down the situation for gaining time for revising the regulatory framework on biotechnology (Skogstad 2003: 327 ff.). The de facto moratorium underlines the tension between the finality of decision-making and ascertaining of truth which is articulated by Derrida. The relevant European actors hardly take a position in a fundamentally uncertain policy field despite being under decision-making pressure. Evidently, most actors do not assume a general resolvability of problems, the availability of full information, and the confidence in mastering processes in practice. The de facto moratorium is based on the common notion of the EU member states of an incomplete EU biotechnology law. Therefore, it is planned to remain valid until the given legal situation is updated and complemented. In fact, the moratorium is not formally legal, but the result of complex political structures and events which need to be understood within its historical conditions at that time. This is the key moment for the implementation of the precautionary principle in the European regulation of GMOs which could not find a solution for an evolving technology sector from abroad. Additionally, a significant impact is made by the 1997 and 1998 election's political power, with center-left governments in France, the UK and Germany (Bauer/Gaskell 2002: 65). The time from the late 1990s is a contributing factor for the later path of GMOs in Europe. Corollary, by 2000 Europe is characterized by massive promotion programs for competition, the implementation of legal-bureaucratic regulation drafting and a partially restricted usage of biotechnology innovations. With respect to causality, this time frame has to be considered essential. Thus, it can be said that the non-necessary conditions did not enter a contingent interaction which could benefit the usage of GMO food products. It is, however, also conceivable to say that a non-necessary interaction entered the contingent interaction which hinders the development and application of GMO food. However, the most important conditions are related to the institutional embodiment of the EU and the dispositions and value orientations.

2.5 Intellectual Property Rights in Europe

2.5.1 Overview

Intellectual Property Rights mark both biopatents and Plant Breeders' Rights (PBR). Unlike the US with its prevailing Plant Patent regulations, European countries usually develop PBR. Compared to patents, PBR developed much later, though the protection and the usage of biopatents subsequently grows in importance. This is not least because Monsanto pursues control about the entire food chain and biomass production and does not merely raise property claims to single plant varieties and seeds (Greenpeace Germany 2008). Yet, the interfaces among PBR and patent protection are not clearly defined and thereby cause conflicts. The application of patent law to plant and animal breeding is difficult in relation to the reproducibility of biological material. Until the Diamond vs. Chakrabarty case in the US in 1980 enables the granting of patents for microorganisms, it is generally asserted that living material, namely plants, animal and microorganisms are not viewed as patentable due to the lacking inventive step. Supposed inventive components refer to several methods such as MAS, genetic fingerprinting, evaluation of plant traits, or description of compounds (Then/Tippe 2009: 26). Hence, the narrative on the patentability of natural substances if isolated through a technical process also reaches the EU. In this relation, genetic engineering and new legal modifications confront the EU with structural and institutional transformations. Though, the EU is embedded in a net of legal regulations, it starts the dispute on a new Directive for more than ten years and finally comes up with the Biopatent Directive (98/44 EC) that is adopted by the European Parliament in 1998 and by the European Patent Organization in 1999 (Then/Tippe 2009: 26). A highly contestable issue is the application of patents to conventional breeding processes, particularly with respect to farmers' and breeders' privileges. Nevertheless, Then and Tippe counted more than 70 patents on conventionally bred plants and 40 patents on animal breeding in 2009 (Rentenbank 2010: 10). In 2008, almost 25% of total patent applications to seeds and plants include conventional breeding techniques while it is less than 5% during the time from 2000 to 2002 (Then/Tippe 2009: 3). Patents on conventional breeding harm European farmers rather than US-American farmers, since GMO crops are little grown in Europe. Hence, the Biopatent Directive creates the industry-friendly patenting exemption on "*essentially biological processes*". In this regard, crossbreeding and selection are determined as *natural phenomena* that are excluded from patenting similar as defined for natural substances (BMELV 2010: 5). Although PBR shall conduce to plant breeding and breeding advancement in agriculture and horticulture (BSA 2013), particularly the achievement of innovation is in question. Similar to patent regulations, PBR appoint that only the patent owner or his successor is legally allowed "*to produce, trade or import propagating material of the protected variety on a commercial basis.*" (ibid.). As ruled by UPOV, PBR are issued if the plant variety is distinct, uniform, stable and new. Further, it needs to have a variety denomination (ibid.). In order to problematize the influence of biopatents, this part dwells on the main aspects in the European biopatenting regulation and contains also specific developments in Germany.

2.5.2 IPR regulation at multiple levels

In Germany biopatents are granted since the 1980s, but require new legislations since biological material becomes an important issue. The § 2a (3).1 of the German Patent Act defines biological material as material that contains genetic information which can reproduce itself or can be reproduced within a biological system. Because genetic information is contained, the issue of Intellectual Property is affected. Main acts in this relation are the amended German Patent Act from 2005, the European Patent Convention (EPC) from 1973 and its amended version from 2000, the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, called Biopatents Directive, the TRIPs agreement that comes into force in 1995 as well as the Convention on Biological Diversity (CBD) which comes into effect in 1993 as well as the ITPGRFA. International and European regulations, namely the TRIPs agreements and the CBD as well as the EPC precede national legislations. Hence changes in national law have to be adequate to the preceded legislations.

Already in 1895 Germany had systems available for controlling and approving seeds. The first draft for a Seeds and Planting Material Act is submitted in 1929 (Bette/Stephan 2009). With the ‘Saatgutgesetz’ from 27 June 1953 Germany achieves the worldwide leading position in plant breeding protection (Bundesgesetzblatt 1953). Since Germany’s accession in UPOV in 1968, its PBR’s are conducted by the Federal Office for Plant Varieties under the plant varieties protection law (Sortenschutzgesetz SortSchG) with a technical control process (Bette/Stephan 2009: 6). This SortSchG is private-law and similar to patent regulations. The amendment of 1968 causes a separation of the legislation on the marketing of seeds and plant propagation materials due to the abolition of the value for cultivation and use. Another amendment follows in 1985 and induces revision of given procedural regulations. The amendment of 1997, the so called Sortenschutzänderungsgesetz considers a novel version of the treaty from 1991 as well as the relevant Community regulation. The Council Regulation (EC No 2100/94) from 27 July 1994 on Community plant variety rights in conjunction (GemSortV) generates a Community’s autonomous property right. As a consequence, two property rights systems became valid at the same time, in Germany and in other European countries that face the same collision problem. The rights of the property rights owner are defined in the German national legislation, namely in art. 10 SortSchG. The corresponding regulation is in art. 13 GemSortV and similar to the articles 9, 19 and 14 of the German PA. The protection is, however, not as comprehensive as the property right gained through patents. Just as required by the international legislation, also here the patentee has exclusive right to prohibit third parties’ production, distribution and safeguarding of the patented product. The last relevant revised version of the national Patent Act in Germany is from 1980 and is last amended in 2013, coming into effect in 2014 (WIPO 2009). In the context of biotechnology only in 2005 the Patent Act is effectively revised, in terms of biological material and relevant aspects of product claims.

2.5.3 Granting patents: premises and legal consequences

The Convention on the Grant of European Patents, commonly known as European Patent Convention is ratified in 1973 and enters into force in 1977. It is an international treaty, constituted by the European Patent Organization for the regulation and granting of European patents (EPO 2013). According to its preamble, the EPC is “*a special agreement within the meaning of Article 19 of the Convention for the Protection of Industrial Property, signed in Paris* *on 20 March 1883 and last revised on 14 July 1967, and a regional patent treaty within the meaning of Article 45, paragraph 1, of the Patent Cooperation Treaty of 19 June 1970*". However, a European patent is not considered to be a unitary right, but rather a group of patents being autonomously enforceable and revocable by the member states at the national level. This bundle of rights is related to countermand or subject to two types of post-issued procedures. First, a temporary opposition procedure, being induced by everyone but the patentee himself, and second limitation and countermand procedures that can only be initiated by the patentee himself. The European Patent Organization however should not be mistaken for competences of the EU. The EPO is rather an intergovernmental organization with two bodies, the "*European Patent Office and the Administrative Council, which supervises the Office's activities*" (EPO 2013c). The 38 members are demanded for adopting the EPC into their national Patent Acts. In this context, it is remarkable that patents are granted by the EPO despite a missing rule on its application for other member states. There is not even a consensus on how to regulate patents best in the EU. However, since the patent package sets up a single and specialized patent jurisdiction in December 2012, there is a *European patent with unitary effect* in the EU. This widens patent protection from single EU member states to 25 nations.

As explained above, patents can be granted for processes or products. Production claims allow the exclusion of third parties "*from making, offering, putting on the market or using a product which is the subject matter of the patent, or from importing or possessing said product for such purposes*" (section 9 (1) German PA) without the owner's permission. In relation to "*biological material*" the PA claims that it "*shall denote any material containing genetic information and capable of reproducing itself or being reproducible in a biological system*" (2a.3.1 German PA). Moreover, in accordance to section 8.1 of the European Patent Convention, section 9a.1 of the German PA rules that patent protection is effective for generative and vegetative reproduction as long as the features that are related to the invention still exist. As it is defined in section 9.2 of the German PA, a process patent excludes third parties "*from using a process which is the subject matter of the patent, or, when said third party knows or it is obvious from the circumstances that use of the process without the consent of the patentee is prohibited, from offering the process for use within the territory to which this Act applies*" without the content of the patentee. Additionally, "*offering, putting on the market or using or importing or possessing for such purposes the product produced directly by a process which is the subject matter of the patent*" is not allowed for third parties without permission (section 9.3 German PA).

A significant distinction is between working processes and manufacturing methods, since manufacturing methods ultimately have a product as an outcome, such as a substance, biological material, or gadget whereas working processes do not have comparable results. The scope of protection for a manufacturing method is covered by section 9.2.3 of the German PA and section 64.2 of the EPC in relation to the process as well as to directly produced products (derived protection). According to section 9.2.3 Patent Act and 64.2 EPC, patents for working processes have the same scope of protection as manufacturing patents, but the product protection is rejected since working processes do not have products as a result. The very contestable derived protection is already examined in the previous chapter on the TRIPs article 28 (1) b. Since the TRIPs regulation causes problems for follow-up generations, namely the value of process patents becomes eliminated or reduced. Therefore, section 9.a.2 of the German PA asserts an extension of derived protection on "*the biological material possessing the same characteristics and directly obtained through said process and shall extend to any other biological material derived from the directly obtained biological 13 material through propagation or multiplication in an identical or divergent form.*"

The European Patent Convention excludes patenting of animals and plants while follow-up regulations and practical implementation requires conceptual precision. Thus, only plant varieties and animal races are excluded from patenting. It is, however, allowed to grant patents on processes that are applied to several plant varieties as well as on animal races. As a consequence, plant and animal genetic material is patentable and corresponding processes for the production thereof (BMEL 2010: 10). Furthermore, a prohibition of patenting is given for *essentially biological processes* which are defined as relying entirely on natural phenomena such as crossing or selection. Ultimately, in accordance to article 2.2.4 German PA it is forbidden to grant patents on "*processes for modifying the genetic identity of animals, which are likely to cause said animals suffering without any substantial medical benefit to man or said animal, nor shall patents be granted for animals resulting from such processes*". This article expresses moral reservations towards animal cloning.

In accordance to the German PA, section 11.2, the effects of patent shall not extend to "*acts done for experimental purposes relating to the subject matter of the patented invention*". Fundamentally, since 2005 section 11.2.2a excludes the usage of biological material with the purposes to breed, discover or develop a new plant variety from patentability. However, if the breeder wants to market the variety after successful development, and one or more patentable components exist in the developed variety, the patentee can raise claims to prohibit the marketing or he can demand license fees. Farmers in fact are exclusively allowed to conduct new processes and breeding within their own firm, but not in industrial matters. According to section 2a.1, 2a.3 German PA and EPC article 53.b and regulation 26.5 of the Implementing Regulations to the

EPC and also to article 4.a.b of the Directive 98/44/EC, "*essentially biological processes for plants and animals*" are exempted from patentability. Such an exclusion is enabled by the article 27.3 (b) of the TRIPs agreement. This formulation is linked to industrial interest groups who aim room for interpretation (Then/Tippe 2009: 26). Essentially biological processes are legally defined as relying on "*natural phenomenon such as crossing or selection*" (art. 27.5 EPC), which is based, inter alia, on EPC of 2006 and 2a.3.3 German PA. The EPO Board of Appeal then ordered the enlarged 27 Board to interpret the definition of "*essentially biological process*". In the decision T83/05 the Board of Appeal admits "*The wording of Article 2 (2) Biotech Directive and Rule 23b (5) EPC is, in the view of the board, somewhat difficult to understand. On the one hand, only processes which consist entirely of natural phenomena are considered to be essentially biological processes for the production of plants. On the other hand, crossing and selection are given as examples of natural phenomena. This appears to be self-contradictory to some extent since the systematic crossing and selection as carried out in traditional plant breeding would not occur in nature without the intervention of man.*" (p. 336/337, § 53, in Then/Tippe 2009: 27). In Germany, the economy in the field of plant growing is extraordinary strong rooted on plant variety protection. This is because breeding privileges enable the application of entirely protected varieties for breeding new varieties and independent from the content of the patented variety.

2.5.4 *Essentially biological processes* in question: The broccoli and tomato case

An overall point of debate is that mere discoveries from nature are not patentable, but natural substances if isolated through a technical process. In 1998 the case of G-01/98 Novartis/Transgenic plant is carried out at the Board of Appeal of the European Patent Office. The case induced that processes are patentable if their technical application concerns more than one plant variety or animal race (BMEL 2010: 12). Unlike, biotechnological processes which treat genes as instruments without changing the genetical constitution of an organism must be distinguished from those processes related to the case. This also concerns new biotechnological methods, such as marker assisted breeding methods. Specific cases in modern agri-biotechnology relate to the Biopatent Directive and the difficulties in demarcating classic breeding, crossbreeding, selection and modern breeding methods with biotechnological techniques. In 2002, Plant Biosience granted a patent (EP1069819) for selection processes based on marker-assisted selection (MAS) that are applied for modifying a specific ingredient of a broccoli plant variety. Although this process contains conventional breeding steps, EPO did not consider MAS to be a technical and therefore patentable process. One year later, in April 2003 Syngenta Participations AG files a protest against the patent. Their position is that patented selection processes are *essentially biological processes* and therefore not patentable under the relevant regulations of the EPC (EPO 2010). Similarly, the *wrinkled tomato case* develops. In 2000, the Israeli Ministry of Agriculture applies for the patent on a breeding technique for tomatoes with less water content, including corresponding products of the technique (EP1211926). By 12 August 2004, Unilever N.V. lodges an appeal and demands for revocation of the patent on the same accounts as given in the broccoli case (EPO 2010; Tippe 2012).

Both cases come to EPO's Board of Appeal in July 2010, followed by a fundamental judgment. By December 2010, the EPO finally decides that the application of biological processes for crossbreeding plants is not patentable (G1/08). Yet, it remains unclear whether the plant, the seed or the eatable components of the plant is patentable (Informationsdienst Gentechnik 2010). Later on, in December 2011, the EPO announces that patent claims on production processes are refused, but the broccoli itself, including its seed and eatable components are patentable (Tippe 2012). However, the EPO only inspects whether a patent application signifies a novel, industrial applicable technical development while complying with the inventive step. Impact assessment on social, economic or ecologic issues exceeds its scope of authority and competencies. These issues are related to the legislator or responsible European and national authorities (EPO 2010). In this relation, NGOs, namely "No Patents in Seeds!" require governments to "*take a first step in the upcoming decision on the so-called new Unitary Patent*" (No patents on seeds 2012).

At large, there is one predominant issue in the legal regulation on GMOs. This is the dominant legal uncertainty on claims for future breeding and also for disclosure requirements. In the field of breeding it is often not possible to disclosure the invention completely in terms of retraceability of the substances. Biopatents however cannot be described exactly, but are merely describable in their functions. Therefore, the requirements of specificity and replicability occur to be fundamentally problematic premises of patentability (art. 83 EPC). Because of this, these premises have been replaced by consignation mechanism in plant variety and patent law. Crucially, they fail if claims are raised on future breeding so that there is legal uncertainty as a consequence. Until today, in disclosure issues of biopatents there is no adjudication given (BMEL 2010: 23). Remarkably, the impact of patents is usually checked in processes of breach which cause legal uncertainty on eventually due license fees for breeding and production decisions of famers and breeders. This may lead farmers and breeders choose less appropriate varieties and races with higher legal certainties (ibid.). The accrued costs caused by verification and rescission procedures are so high that a systematic usage of these patents is in fact only possible for well-resourced actors. Moreover, the length of these procedures is a significant cause of legal uncertainty. Additionally, traditional breeding methods can be rejected from general availability and instead be privately possessed. Crucially, a once achieved monopoly can be consolidated in perpetuity with strategies, such as "*evergreening*"[13].

Subsequently to political and legal issues at the domestic level in Germany and at the European level, the following part dwells on the conflictual situation of EU regulations for GMOs at the international level, namely struggles with the WTO.

2.6 European GMO controversies at the international level

Disputes concerning GMO regulations of the EU primarily affect the WTO regulation of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT). These challenge the EU's savings clause and the Novel Food Regulation, including labelling, but also the general treatment of scientific evidence.

2.6.1 The sources of conflicts

The crucial factors in these debates are strong export purposes of the US and some other countries with their desired harmonization of EU standards. In detail, they defend the principle of substantial equivalence and maintain that GMOs and conventionally grown products are *like products*, thus fundamentally containing the same product characteristics and merely differ in terms of their production basis. The US argues for this notion since under WTO rules, discrimination among like products is not allowed. In fact, it is unsettled whether GMOs genuinely belong to this category or not (von Schomberg 2000: 123). Thus, the controversy of like products refers to the incompatibility of the principles of substantial equivalence and the precautionary approach, which is pursued by the EU. Briefly, the case concerns nine national measures, such as the import ban on GMOs by the six EU member states Germany, Austria, France, Greece, Italy and Luxembourg (Knirsch 2007). By 13 May 2003, the biotechnology lobby exerts pressure on the US government and relocates the conflicts to the WTO's Dispute Settlement Body. The US is supported by the GMO planting countries Argentina, Canada, Egypt, Australia, New Zealand, and Mexico. Egypt and Honduras later withdraw their appeals due to failed consumerism. A significant aspect is the extraordinary duration of the conflict. The statutes of the WTO define a regular deadline of six to nine month for the Dispute Settlement Panel to reach a judgment. This case has, however, span over thirty month (!) with the ultimate outcome of the non-approval of 27 biotechnology products during the time of June 1999 and August 2003 violating the WTO rules. Moreover, the body counts 24 cases of illegal authorization delays. Also

[13] Evergreening is pursued with two strategies: with market strategies that conclude long-term license agreements with potential patent users and even the buying up of imitator enterprises or their products; and with technical processes that create *patents on addition* on process components and also with application or incremental innocation whose novelty, inventiveness and added usage is questionable (BMEL 2010: 6).

the nine rejected national measures are defined as non-conform to the WTO regulations (ibid.). An important aspect is the WTO's requirement to provide scientific evidence of risks caused by GMOs. The current system relies on the Commission and of the European Council for risk management and the EFSA as the single institution being responsible for scientific risk assessment. Yet, the majority ratio demands for the agreement of all ministers if they want to accept or reject a proposed decision of the Commission. The procedure of risk management is based on a cooperatively made agreement of the Commission together with the Council and not separately on one statement. These decisions are formally taken on the basis of scientific risk assessment of the EFSA whose independence is highly questionable. This is since the Corporate Europe Observatory (CEO)'s report "Unhappy Meal", published in October 2013, exposed that some 59% (!) of EFSA's scientific panels members had direct or indirect connections to firms with activities under EFSA's remit (CEO 2013). What is crucial in this regard is the confusion of scientific knowledge with political decision-making. As mentioned above, the US educational system is characterized by a strong deference of science, namely the "functional authority of science" (von Schomberg 1991: 262). This contradicts with any kind of non-evidence based legitimation and is therefore inconsistent with the WTO regulation which only approves national regulation being apart from WTO rules in case of evidence based prove of environmental and health hazards. Hence, European member states are called to stand to the WTO rules which forbid discrimination, including the free movement of goods. A significant factor here is that member states can rely on "*legitimate factors*", such as economic, social or ethical considerations as well as societal traditions such as food culture. It is, however, problematic to prove these factors so that scientific risk assessment or public participation are defined to be a control instrument against arbitrary treatment in public administration of GMO food. However, the aspect of public participation is questionable since the EC failed to define the treatment of public comments on GMO issues (BMG 2014a).

2.6.2 Sanitary and Phytosanitary Measures (SPS)

Related to the trade and environment issues and the agreement on the application of the WTO's Sanitary and Phytosanitary Measures (SPS) there is discordance whether the SPS can be applied to modern agri-biotechnological products or not (WTO SPS 1994). This is since the SPS is not product focused, but risk focused and therefore addresses the potential impacts of the use of products on "*human, animal or plant life or health*" (art. 2.1 SPS). To this effect, the article 5.7 of the SPS is questionable since it allows WTO members to justify measures which may prohibit products made on precautionary considerations. Under this article, members are requested to set up "*additional information necessary for a more objective assessment of risk*" (art. 5.7 SPS) within an appropriate time period. This is for the avoidance of arbitrary regulation and for encouraging members to seek scientific evidence to confirm or refute real risks, set restrictive measures with terminable character. However, the precautionary principle is articulated in the SPS even though the principle's meaning is not really met. Crucially, the WTO's Appellate Body emphasizes that the precautionary principle, which is not merely defended by the EU, but also by several states, cannot constitute a basis for the justification of SPS measures that otherwise show inconsistencies with other WTO objectives and obligations. In this regard, article 3.3 of the SPS must be considered since it allows member states to establish their own desired level of sanitary protection. These issues reflect the difficulties of harmonizing different values and risk approaches at the international level. Once more it is emphasized that it is not possible to reduce occurrences and political or legal decisions on pure economic reason and profit maximization. It is more fruitful to consider cultural and historical backgrounds and latent dispositions.

2.6.3 The Novel Food Regulation vs. the TBT agreement

The EU's Novel Food Regulation stipulates compulsory labelling for GE-soya and GE-maize and therefore falls under the WTO Agreement on Technical Barriers to Trade (WTO TBT 1994). Briefly, this mandatory labelling regulation forces producers to set up separate production alignments for markets that demand labelling. This can be understood as unjustified trade barriers. The main aspect in this regard is that WTO rules do not consider the EU's labelling and traceability regulations. Since the EU demands for a different treatment of GMO products and non-GE products, including an appropriate documentation, US agricultural lobby groups view this as a decisive trade barrier even if GMOs would have been approved in the EU market. These interest groups argue that such a separation misleads consumers to view GE-derived products as inherently and substantially different from non-GE food products (Hanrahan 2010). Remarkably, the US has suspended WTO sanctions for now even though there is still the pre-dominant notion on discrimination of US food products since EU remains stricter rules for labelling and tracing GE-products. The case may return to the WTO's Dispute Settlement Body if no progress is made. This gives the US the opportunity to ask for compensation for the annual value of lost US food exports, royalties and licensing fees from GE crops. In turn, the US may carry extra tariffs on EU imports or even lift other WTO agreements regulating agricultural products or health and safety (Cowan 2013: 24). The question yet remains on how to calculate the loss of potentially sold product since the EU population is extraordinary skeptical towards GMOs what is stressed in polls and surveys (European Commission 2010).

2.6.4 The current situation of GMO controversies in the EU

The European parliament and the national governments in early 2000s lay the foundations for the current regulation framework and working style. Particularly the decision-making processes in 2001 and 2003, including the majority ratio generate a blockade situation that lasts until today. This appears to be an inappropriate way for achieving effective political decisions and turns to be a profound point of critique by later governments. In July 2010, the EU Commission introduces new principles for national coexistence measures. The aim is to provide a basis for member states to decide autonomously for restricting or prohibiting GE plants, to hinder accidental traces of GMOs in other products. It is planned to simplify and extent national planting bans with the amended Release Directive. The Commission follows two strategies for its implementation: on the one hand the principles on coexistence which are prior at best applied in exceptional cases are loosen, and on the other hand a new savings clause is introduced into the Release Directive 2001/18/EC which allows full flexibility and almost unlimited scope for the establishment of GMO-free regions. In fact, *coexistence* is understood as providing a choice between conventional, organic, and GE-agricultural production systems, and is ousted with this regulation extension on national total bans. What is important in this regard is that the Commission must give a legally unbinding statement on the definition of coexistence in the Release Directive. Whether or not coexistence is genuinely given must be decided by the European Court of Justice in case of a clash. This second strategy means to allow general bans of GMOs irrespective of the coexistence principle, although it is not explicitly articulated by the Commission. Rather it refers to socio-economic arguments. These socio-economic considerations are for instance the partial protection of small-scale agricultural structures, freedom of choice for farmers, or even aspects of consumer protection which have to be subdivided into ethical and religious concerns on GMOs. However, this stands in contrast to legally binding WTO rules and is once more a sign for the predominating two conflicting paradigms Falkner mentions, namely the promotion of economic growth on the one hand and the protection of the environment, animals and humans on the other hand. Noteworthy, the European Court of Justice understands exploitation bans has a clear inhabitation or restriction of the freedom to move goods. Apart from the accusation of the US and Canada, the European Court of Justice itself admits an illegal protective ban on GMOs, even though the rule of law in this case is obviously less powerful than other factors that maintain these national bans on GMOs. If a member state declares itself a GMO-free region, it is against international WTO regulation, but it is also against the TFEU principle of the freedom to move goods. As long as there is a violation of TFEU law, the Commission itself is responsible for conducting treaty violation proceedings. Another possibility is to find a claimant at the national level who wants to check the legal position of courts of the appropriate member state. The courts in turn are able to question the conformity with the European law at the European Court of Justice (BMG 2014b). A very important aspect related to GMO planting restrictions is the principle of proportionality which affects issues of coexistence. Particularly the EU's refrain from providing definite tolerances for GMO traces or the application of best practices by GMO farmers, such as coated seed or distances between GMO and GMO-free fields are concerned. An effective reason to implement GMO-free regions is the seed production itself since it has to be kept pure in a special way. There are already certain practices, such as sealed producing areas which exclude the cultivation of certain plants that may crossbreed with non-GE plants. Thus, the definition of GMO-free regions has to be limited to specific GMOs and not on GMO planting in principle, particularly when these GMO-free regions are stretched across whole national territories (BMG 2014b).

Conclusion

Built on the concept of contingent necessities and the underlying philosophical assumptions, the method of articulation is applied to the subject of modern agri-biotechnology. To this effect, the hypothesis that *modern agricultural biotechnology is a contingent necessary occurrence* was examined at five levels of abstraction and complexity. Altogether, contingent necessary structures, events, and actors are identified at various points of time. As a philosophical assumption, the frequently assumed social process of truth making in the social sciences is denied. Discourse and speech are not considered to be a self-propelled force, but rather embedded into systems which are regulated by the mind. Activities of the mind, however, should not be understood as predetermined, but relatively open and complex processes. They shape dispositions and systematize the order of information. In this context, this work sticks to the term *disposition*, while relying on the regulative use of transcendental ideas and the systematizing activities of the mind. In addition, a clear distinction between discourse-theoretical truth and epistemological plausibility is emphasized. It is asserted that argumentations and statements can only rely on coherence-criteria, but not on truth-criteria. Thus, since truth is not decisive for political actions, it remains unclear how to make decisions under uncertainty. To this effect, it is not evident which forces genuinely lay behind societal developments, but it is possible to evaluate institutionalization processes which combine both discourse and corresponding material consolidation.

With a very abstract and simple access into technology in the first analytical part, the strong correlation of technology development to local, historical, and context-specific conditions, dispositions and orienting positions are exemplified. Technology is viewed as a continuous and contestable process that is determined by economic and political forces. In this regard, also law – or more specific – the constitution of property rights is linked to and defined by economic and political structures and interests. National or regional technology trajectories are deeply rooted in cultural and traditional path dependencies which shape structures and actor constellations. These trajectories are interpreted as the contingent necessary product of past development paths that build the base for new contingent necessities. Across time, internationalization processes have amplified and impact on the international market system and related national technology strengths. Good approaches for analyzing these changes are the concepts of *context-specific depth of intervention* and of *sector-specific adaptability*. The first one expresses the scope of transformation of a sector that is triggered through external or internal pressures. The second concept articulates the openness of structures and institutions to become re-adjusted by external pressure and selection processes. In other words, it concerns the openness of key structures, institutions and actors of a sector for the use of new technological possibilities which are beyond the established socio-technological development path. Triggered technological controversies may emerge at an early stage and ritualize at the international and national level. Controversies are based on dispositions and latent technology attitudes that cannot be reduced to technology acceptance. They are rather understood as value conflicts which are hardly solved by technology refinement or an improved technical education in a society. Thus, a society's technology assessment is the necessary product of contingent interactions from basic dispositions, particularly value orientations, moral acceptability, modernization processes, manageability of problems, the credibility of responsible institutions and trust in political and economic decision and regulation patterns, as well as the perception and classification of technology-specific information, including situative influences.

Based on this very abstract simple sub-section, the subsequent part specified the technology-type of modern biotechnology. Since modern agri-biotechnology is a part of modern biotechnology, it is fruitful to develop the broader context. Yet, extensive spatio-temporal references are neglected in order to operate on a relatively abstract analytical level. In accordance to the view on technology as a socially constructed and contingent item, this section first explores the characteristics of new technologies by considering their systematic large-scale nature. Main features are their fluid profile and the functional interdependence between various dimensions. Economic technology development and political technology regulation are inseparably connected. Significantly, biotechnology is not an autonomous technology, but rather a cross-sectional set of scientific methods with a pluralist and fragmented nature of economic and political patterns of interaction. This is already exemplified by the definition(s) of biotechnology, which refer to the application of science and technology to living organisms and parts thereof on the common ground of achieving material and immaterial benefits from its usage. However, both the fragmented cooperative exchange of economic and political forms, and the various application fields and uncertainties shape modern biotechnology. It is, however, hard to define whether biotechnology is predetermined by market-oriented positions of disciplines and institutions that shape its nature to multi-purpose methods, cross-sectional science and technology, or if biotechnology itself defines the participation of various disciplines and institutions. Hence, it is beneficial to consider this to be a contingent necessary interaction of both in the meaning of a conjoint development. In each case, there is a strong relation between science and economy in biotechnology development that is conceptualized variously in the social sciences. Main results of increasing interlockings are the commodification of knowledge which then turns knowledge into a new production factor, on the one hand, and an enhanced networking among scientists, companies and governments on the other hand. Non-necessary structures and actors in both the academic and the industrial sector enter a contingent interaction and become contingently necessary for the development of biotechnology. One of the fundamental changes is the shift from publicly organized university research on the improvement and extension of knowledge and research on solutions for broad social issues to private corporatism which calls for application-oriented research and narrowly defined goals. The increased cooperation among academics and industrials shifts former structures and actor constellations as well as the self-perception of academics and university staff. To this effect, together with biotechnology the entrepreneurial academic is born. Universities are faced with new economic and educational conflict situations since they have adopted the leading role in economic development. Combined with Jessop, academia as an independent institutional order is faced with the *always contingent shadow of capital accumulation*. That these scientific-industrial interrelations profoundly affect the cognitive level reflects the assumption on dispositions that direct social trajectories. Further, it shows epistemological plausibility based on coherence criteria which should not be mistaken for discourse-theoretical truth due to failing truth criteria. For concerned academics, university staff, industrials as well as governments the increasing commodification process appears as a plausible occurrence, but not as a social truth. Similarly, the risk assessment of a society can be viewed under its ambiguous character. There is no objective measurement for risk evaluation, but only different plausibly legitimate positions on defined political subjects. In accordance to the philosophical assumptions, these positions and dispositions are systemized by the mind and related to plausible reasoning. Conflicts may arise in case of disagreements at the international level, among countries at close quarters or within larger unions, such as the European Union. Specified on biotechnology, the question of risk touches the systematic point of view and the challenging institutional treatment thereof. Pollution dispersal and gene flow do not prevail at manmade national borders, but follow rules that are not genuinely apprehensible for mankind. Remarkably, this insight reached the OECD, which acknowledges the *growing problem of emerging systematic risks*.

Bearing in mind the general characteristics of modern biotechnology, modern agri-biotechnology is specified in a next analytical movement. With this section sought to generally explore the technical aspects without a broad consideration of institutional implementation processes. These aspects are, however, not politically, socially, or economically neutral, but related to a wide variety of contingent necessary interests and actor constellations. While similar breeding techniques are applied in conventional and organic agriculture, the application of genetic engineering with rDNA is characteristic of modern agri-biotechnology. An important aspect in modern agri-biotechnology is the focus on only a few high yield rates, namely corn, cotton, canola and soybean. Another crucial aspect is that crops are genetically modified for being herbicide tolerant (HT) and insect resistant. These specifications are related to strategies and past developments of powerful actors, particularly of seed companies such as Monsanto. That the broad application of pesticides and insecticides cause resistances is highly disturbing, particularly since one of the official arguments for planting GMOs is a reduction of applied pesticides. As paradoxical as it may seem, the application of certain pesticides ultimately leads to higher expenditures for farmers since they have to buy even more pesticides. The increased use of pesticides additionally stresses the environment and also the farmers' health. With respect to risk assessment and its social dimension, this section dwelled on the two prevailing principles: the principle of substantial equivalence (SE) and the precautionary principle. SE exemplifies genetically modified organisms which are considered to be substantially equivalent to their non-transgenic counterparts. This means that they are not different from the genotype of their isogenic counterpart. On the other hand, the precautionary principle expresses a precautious attitude to the commixture of GMOs with non-GMOs. The application of the principles is relevant in relation to international regulations, since controversies are triggered by labelling issues. In addition to risk assessment the basic legal dealing of inventions with Intellectual Property Rights (IPRs) is relevant. These signify both patents and Plant Breeders' Rights (PBR). IPRs provide the patent owner with exclusive monopoly rights over the creation of a new plant variety for commercial purposes over a specific period of time. The criteria for issuing a patent or PBR on an invention, namely novelty, industrial applicability, and non-obviousness crystalized over different points of time during the 19th century. PBR were introduced in the first half of the 20th century, while patents effectively grew in importance with the emergence of biotechnology and related legislation in the 1980s. PBR are only granted if the plant variety is novel, distinct, uniform, and stable. Therefore, PBR protect the variety, but not the applied method or process. However, for a long time in humankind objections have been raised against plant patent protection. These are based on ethical reasons and a totally different position towards nature as given nowadays. It was thought that patent protection for plant life or living organisms were the attempt to issue patents for the use of natural powers. Unlike today, life was not widely measured and quantified into economic terms, based on biological reductionism. Establishing the doctrine of profitable patents on life is, however, necessary for the development of modern agri-biotechnology. With the growing industrial exploitation of biological material on the one hand, and immaterial goods, particularly knowledge and information on the other hand, motivations in stricter legal regulation arose. Although the legal protection on these issues is driven by the aim to foster innovation, the patent inflation causes various conflicts in research and development activities.

With the subsequent section, modern agri-biotechnology was supplemented by the spatio-temporal dimension. This includes the international political territory and corresponding economic spaces as well as the space of time from the second half of the last century until today. The focus was laid on three major analytical issues, namely the industrial structure, IPRs and biosafety regulations. The main results of this section include a fundamental vertical and horizontal integration in the international seed market. The structure is shaped by market concentration, a few multinational seed companies, numerous mergers and acquisitions, strategic alliances and R&D activities. Monsanto is the largest seed company worldwide in terms of market shares and the amount of granted patents. A remarkable development in the past decades is the combination of seed, chemical, and biotechnology activities in one enterprise, which is true for Monsanto. The distinctive factor is its aspiration to control the entire food chain and biomass production, and not only the raise of property claims on single plant varieties and seeds. This is in stark contrast to former structures and distribution purposes. Apart from a few exemptions, it is no longer the case that one country has its own local seed enterprises, which are responsible for the development of seeds for a specific territory as well as the corresponding market distribution. These proceedings are widely replaced by the activities of the multinationals and their international distribution network. Monsanto, however, is a good example for outlining technological and economical path developments. It develops the genetically modified “Roundup Ready” crops and the suitable herbicide “Roundup”, which contains the active agent Glyphosate. Monsanto increases its sells and venues, but numerous farmers are confronted with the formation of resistances of organisms against Glyphosate. This forces farmers to apply even more chemicals which in turn cause additional pressure on the environment. Now, the pivotal point is that Monsanto announced to carry more effort into the development of various stacked trait varieties that are resistant to Glyphosate, but also to two further herbicides Dicamba and Glufosinate. Instead of changing the path and relying on organic farming, Monsanto continues its usual strategy. Essentially, Monsanto does so despite an expectable resistance formation on the new herbicides. However, the interests of the few multinational firms are also visible in the legislation, particularly the general propagation of the narrative of biotechnology being a key technology. As there is no international consensus on the general treatment of GMOs, there is not one specific legal regulation. Instead, there is a complex of organizations that are committed to the regulation thereof. This is supplemented by broad regulations and horizontal overlapping institutional structures. These regimes overlap in scope, subject, and time. Relevant organizations are the UPOV, the WIPO, and the WTO with their respective treaties. The WTO's TRIPs agreement as well as the Convention on Biological Diversity, which were established in the first half of the 1990s, assert the conviction that biological inventions should rather be protected with patents than with Plant Breeders Rights. Crucially, the TRIPs provides broad flexibility for regulation, but has an unclear relation to the UPOV regime. The UPOV regime aims to safeguard an acknowledgement of breeders' achievements in breeding novel plant varieties among convention parties. However, the TRIPs essentially triggers a paradigm shift in so far as it substitutes domestic legislation and carries it to the international level, forcing the presumption of domestic balance to be renegotiated under TRIPs objections. Yet, there is no reduction of knowledge and information commodification to be blamed on the TRIPs agreement. It is better considered to be an institution which contains sets of standards that are developed elsewhere and were previously lacking in deliberative mechanisms in order to facilitate rearrangements. The TRIPs was shaped by the Intellectual Property Committee whose members are, inter alia, Monsanto and DuPont, which are two of the few powerful multinational seed firms. These occurrences emphasize the interlockings among different dimensions, as explored in previous chapters. Moreover, it can be linked to the diffuse separation between structure and actor, since developments are constituted together. With respect to contingent necessities it can be emphasized that the strong market concentration processes and the distinctive impact of a handful firms is a result of past market activities, a growing interest in expanding and the contingent causal junction. Incidentally, at the time when environmental problems entered the international arena, these firms were already so powerful that they could yield power on the formulations of the international legislation on IPRs and on environmental regulations. Before IPRs become the dominant protection type, genetic information is in public ownership or at least not defined as private property. The paradigm shift causes harsh legal problems since it is unclear how to define patents on living organism and how to state inventions on life. Current law affirms the patentability of natural substances if isolated through a technical process. Thus, in terms of patent protection, these natural substances are not mere discoveries, but process inventions that can justify a derived patent claim on the isolated natural substance. Biopatents are in fact only describable in functional terms and therefore not in absolute terms. Due to this, the premises of specificity and replicability are problematic. Crucially, since the 1980s, the barriers for technology have decreased dramatically. Hence, biotechnological actions such as machine-made gene-sequencing cannot be considered to be inventory achievements. These issues derived protection as well as regular legal struggles on broad patent claims. Another aspect affects product protection, since only processes and the usage of substances are formerly protected, whereas absolute product protection asserts across time in order to achieve product protection. In this development an inherent reductionist equation of substance and genes or gene-sequences is cognizable. Fundamentally, the economic dimension plays an integral role in IPR regulation. Although IPRs are issued for supporting innovation, empirical developments often show the contrary. It is thus, that innovation is hampered by restricted research possibilities as well as the competitive mentality of researchers. The research tool problem describes the situation where too many IPRs in basic research tools block progress in technology. The consequence is a missing end-product, increasing investments, and also more R&D projects. Additionally, the reach-through problem is conflictual since researchers who work on a product while using a patented substance have to consider licenses patent owners. In order to fight these restrictions, several projects have been initiated that contain free gene banks for instance. With the last part on biosafety, this section built on the previous chapters on risk, particularly the two incompatible principles on substantial equivalence and the precautionary approach. Notably, in countries with widely dispersed GMO cultivation there is no regional long-term monitoring programme on environment and health damages. From the institutional point of view, biosafety is constituted in the Cartagena Protocol which entered into force in 2003. This Protocol is a follow-up agreement of the UN Convention on Biological Diversity and was therefore made by the CBD's Biosafety Working Group. In accordance to the TRIPs, the provisions of the Protocol also shape market rules and US agricultural interests in biotechnology trade. A very critical impact on the CBD and the Biosafety Protocol is exercised by the Miami group that represents, inter alia, the interests of the US agriculture lobby. In this way, the US attended negotiations and brought the regulations in accordance to the US law, while refusing to ratify the agreement.

In a very last step, the analysis dwelled on specific political territories and economic spaces, namely the US and the EU, focusing on Germany. Hence, the contingent necessary conditions are illuminated more precisely with relation to country-related histories and societies. Notably, this work refuses a separation of specific periods in the path of modern agri-biotechnology, but rather choses a genealogical way, starting with the last century. The US is the main driver of modern agri-biotechnology on its own territory as well as at the international level. In addition to developments in the international arena, it is required to examine contingent necessities for the creation of modern agri-biotechnology within the country. Germany is chosen as an example to outline that industrial states are not like one another, but that technological, economic, and political trajectories are embedded into historical and contextual conditions and specifications of a society. Significantly, nation states and societies are not considered to be homogeneous entities, but complex constructions, including various interests and dispositions. From the macro-perspective, it is, however, needed to simplify attitudes and political decision-making as well as historical causalities. However, European nation states no longer stand alone, but are widely integrated into the European Union. Since the EU regulation has an essential impact on the national and regional legislation of every single member states, explorations of inner-European controversies as well as those at the international level are provided. Essentially, the analysis on a certain country can be linked to the plausible reasoning approach, since it shows that justifiable positions can evolve from specific argumentations which are at the core based on coherence and plausibility, but not on discursive-theoretical truth. Due to a lacking objective measurement on technological development, economic decision-making and the treatment of risk, including the effect of ambiguity is considered. A main result in the analysis of the US is that technology clusters have evolved over decades under very specific conditions, which created a close network of academics, pharmacists, patent attorneys, venture capitalists, specialized consultants, and politicians. The US provides the highest amount of venture capital and a legislation which supports GMO food production. Looking back into the history, the eugenic activities of the Rockefeller Foundation which are motivated by the capability of social control can be assigned as a contingent necessity for modern agri-biotechnology. The Rockefeller Foundation operates within a new international relations system that is characterized by a rising narrative of economic productivity after World War I. The US turns into a new historical bloc with first approaches of an internationalized finance market and short term profit orientation. At that time, Warren Weaver, who worked for the Foundation, introduces the Natural Science Division, which triggers a shift from the physico-chemical field to experimental biology, including the emphasis on molecular biology. This overlaps with the Wall Street crash of 1929 and the collapse of the finance market in 1932. With his initiative, Weaver paves the way for small short-term funding, which is partially opposed by his colleagues at the Foundation. Contingently, this new approach is similar to the effects of the Clayton Antitrust Act from 1914. Based on this, relations between big banks and trusts are prohibited and as a consequence, the creation of long-term financing strategies of investment banks and firms. In a retrospective, these events are defined as the contingent necessities for scientific-industrial relations and the current financing of modern agri-biotechnology. This is true since numerous start-ups can be equipped with high venture capital investments. However, a crucial event is also the Foundation's introduction of the *Green Revolution* concept after its reorganization in 1928. The actual conduction took place during 1940 and 1970. The officially claimed aim is to fight world hunger, but it is strongly driven by economic and political interests of specific enterprises, particularly those of Monsanto. Apart from the fact that hunger has hardly been reduced in the corresponding developing countries, the former small-scale agricultural structures are widely transformed into large-scale structures. Although today the motives of social control are no longer given in the meaning of eugenics, the multinational firms seem to pursue food control. This is reflected in their intention to control the entire value chain of food and biomass production. An essential event for biotechnology is the discovery of the DNA double helix in 1953, since it is the necessary condition for the construction of the rDNA in 1973. Shortly afterwards, one of the involved researchers founds the first biotechnology enterprise "Genentech" and sets a cornerstone in scientific-industrial relationships. It takes less than ten years until former precautious regulations for human health and environmental protection fall into the always contingent shadow of commodification. In the 1980s, two legal events take place which foster a tight cooperation between industries and universities. Furthermore, recently before the first commercial release of GMO food in the US in 1996, biopatenting regulations are modified into industrial-friendly terms, mainly for biotechnology and biochemistry firms. Parallel to that, certain firms convinced the U.S. Food and Drug Administration to adopt the substantial equivalence principle, since the FDA is responsible for the approval of GMO food. Although the principle of substantial equivalence is highly contested with respect to environmental harms and health hazards, it reflects the plausible reasoning of specific actors who aim for profits. The principle, which is introduced in the 1990s, is in many ways inappropriate for risk assessment, and therefore criticized by various actors such as the AC21 group of the U.S. Department of Agriculture (USDA). Fundamentally, US states have little say in decision-making processes of federal regulatory agencies, whereas EU member states are both the principal agents of enforcement, and assume formal political roles in European regulatory committees and in the EU Council. Hence, whether some actors or states are not satisfied with the situation, it is hard to trigger a change in the old development path. Another aspect is the deference of scientific knowledge which is particularly shaped by the US educational system. Such a positive attitude towards technology and a broad application of modern agri-biotechnology may end up in a critical situation for the entire population and the environment. However, this emphasis of science can be found in several regulations at the international level such as the WTO treaties. Of course, the positive view on technology and modern agri-biotechnology should not be generalized, since there are also critical voices which seem to increase. To this effect, the rising trust in private enterprises during the 1980s and 1990s is distinctive. It is highly questionable whether GMOs would receive the same degree of support if introduced nowadays. In relation to IPRs, there has been a successively intensifying process of propertization since the 1930s. With the US Plant Patent Act of 1930, patent protection for asexually reproduced plants or usually asexually reproduced cultivars could be realized. With this Act, industrial seed companies are allowed to usurp state funded research, which practically result in the development of hybrid maize seed. Hybridization is economically beneficial for farmers as well as seed companies which continue activities with this background. The subsequently applied Patent Act of 1952 conducts a very broad definition for patent protection of agricultural innovations which is essential for the protection of innovations in biotechnology and genetic engineering. Some decades later, in the 1970s and 1980s, as international relations and the economic system profoundly changed, the legislation for biotechnological innovations has also tightened. Namely, the Plant Variety Protection Act of 1970 issues a Certificate to breeders which gives them exclusive rights to market a new plant variety for 18 years. Briefly expressed, the variety that has to be protected is demanded to be stable, uniform, and distinct from all other varieties. The Act is amended in 1994 in order to become harmonized with the international standards. One of the most contested issues is the creation of the "essentially derived variety" category. Based on this, broad protection is provided for varieties that are achieved through genetic engineering and biochemistry. Fundamentally, the amendment establishes a prohibition for farmers to sell saved seeds of protected varieties without prior permission of the variety owner. With the Bayh-Dole Act of 1980, cooperation among universities and industries is tightened extensively. Universities are demanded to do research also with an immediate commercial application aim. A crucial difficulty that arises out of these scientific-industrial relations is that studies and research results are often formulated in a way that is beneficial for the industrial sponsor of the research project. Hence the results are often biased and slanted. Since Monsanto is one of these industrial sponsors, there are regularly critics on its proceedings and treatment of humans and the environment. The firm is then faced with several antitrust cases, numerous accusations by farmers, and is held responsible for attacks on scientists who criticized the application of GMO food.

The analysis of the EU begins with a specification of Germany since technology development is mainly realized at the national and regional level. Essentially, Germany adopts the notion of biotechnology as a key technology and therefore upgrades existing structures and actor constellations. However, Germany refuses an extensive application of genetic modification to food products. With this in mind, it can be either said that occurrences of non-necessary interaction never entered a contingent interaction, meaning there are no contingent necessities in the development and application of modern agri-biotechnology in Germany, which is a logical negation; or it can be said that there are contingent necessities which took another trajectory, namely in the manner of conventional and partially organic agriculture, which is an affirmation of contingent necessities. In each case there are completely different circumstances and value orientations which hinder its establishment. One of the reasons is the comprehensive style of thought which is in line with the Humboldtian idea of pure science that is dissent to the US-American pragmatism. By the 1970s, scientific-industrial relations increase and Germany catches up development in several biotechnological fields, but little in plant breeding. However, there is no comparable Natural Science Division, incentives for short-term small funding grants and an intrinsically induced shift from physico-chemical to experimental biology. Historically, Germany develops traditional products by applying the newest technology instead of developing an entirely new technology or industry, as the US does. Germany fails to promote products that require mass advertising and a fast development of entirely new products. In this regard, it is remarkable, that the German chemistry considers biotechnology to be a temporary solution that needs to be replaced by the organic-chemical synthesis. At the same time, there was a lacking institutionalization of subjects that are relevant for the development of biotechnology. As a result, microbiology, molecular biology and genetics are confronted with the reservations of academic biologists on application contexts of their research outcomes. Additionally, the German industrial system is characterized by a long-term funding approach and stable employment. Altogether, there is a low area-specific adaption ability to change existing structures, actor constellations, and above all, the deeply rooted mentality and cultural identity. To this effect, shifted paradigms and readjustments are not based on a self-propelled societal force, but related to an external shock, triggered by the US, and to a certain degree, Japan. This is induced during the readjustment of international relations and forces in the 1970s. New narratives on life and development approaches begin to alter national institutional configurations and actor constellations. Despite general uncertainties, also big enterprises, such as BASF find themselves forced to impose new strategies and assimilate along the lines of the US model. After decades of catch-up strategies and attempts to institutionalize biotechnology, recognizable success is gained in the mid-1990s. Significantly, the application of genetic engineering to food is, however, not efficiently aimed, but steepened in uncertainty. Politicians hardly know where to position themselves and which decisions to take. The situation in the European Union was similar. In fact, the subject comes up in the mid-1990s, with the first commercialization of GMO food. Since the EU is a relatively young project which is faced with numerous various interests, it is difficult to find consensus on sensitive topics such as food. This comes up in between two conflicting paradigms, namely the support of economic growth, and competitiveness and the protection of human and animal health and the environment. In fact, most EU member states oppose GE food, but a few countries, particularly Spain and Portugal plant GE crop varieties. Yet, the major acreage in the EU is GMO free and not economically attractive for seed firms. However, the fragmentation of diverse interests in the food industry determines technology development and the path of diffusion. Typically, European sub-industries have a heterogeneous association structure which demonstrates the various interests of the overall food industry towards agriculture. This fragmented structure effectively prevents European farmers from applying genetic engineering. The "delicate balance of power" challenges the regulation of the new field of biotechnology. Negotiations and decision-making have to be made at the EU level and no longer at the domestic level. As a consequence, in 1996 appropriate industrial groups organize themselves in Brussels and create a completely new common institution. With respect to the EU legislation, the Release Directive from 2001 is important due to its functions of regulating approvals, identification, and traceability of GE food and feed products. The Directive contains "technology specific or horizontal regulations" that are based on the conviction of potential risks being caused by the usage of certain technologies. One of the main contributions of the Directive is to enable states to restrict or prohibit a product's use or sale if risks for the environment or humans are assumed. Another essential regulation is the Novel Food Regulation which is introduced in 1997 and causes conflicts at the international level. Technological controversies within the EU evolve during the same time with the approval of a GE-maize variety by the European Commission. After several struggles, many countries finally rely on the precautionary principle and assert national bans on the cultivation and importation of GMO food products. This de fact moratorium comes into effect in 1999 and is applied by some states still today. Essentially, the de facto moratorium underlines the tension between the finality of decision-making and ascertaining of truth, which is articulated by Derrida. European decision-makers hardly take positions within uncertain policy fields despite the pressure to take action. In this relation, the de facto moratorium is based on the common sense of the EU states on the incompleteness of the European biotechnology law. The plan is to keep the de facto moratorium valid until the legal situation is updated and finalized. In a complementary way, the lacking demand for GMO food causes a lack of inner-European alliances and start-ups. Due to this, after years of lobbying, recently some of the few multinational enterprises have announced to quit the European market and corresponding lobbying. With respect to IPRs, it is important that the increasing usage of biopatents has a fundamental effect on European plant breeders who mainly work with PBR. Especially the US and EU legislations are concerned with the uncertain relation between biopatents and PBR that cause various conflict fields, such as uncertainty about the scope of patent claims. The patent inflation of the last decades applies pressure on institutions with organizational functions, particularly the European Patent Organization (EPO) to adjust. Evolving relations and narratives require the extension of given capacities and a re-organization of inventiveness. In this relation, the Biopatent Directive of 1998, including its industrial-friendly definition of ‘essentially biological processes’, plays an important role. The current state of the patentability of plants is that the technical teaching of the invention should not be restricted to a certain plant variety. After a long process, in 2010 the EPO’s Board of Appeal finally made a decision in the broccoli and tomato case. It ruled that a process for plant breeding, which comprises the steps of crossing and selection is exemplified from patentability, despite containing the step of a technical process. The Board has now to decide whether the products of such processes are also excluded from patentability. Another crucial action is taken in 2012 by the European Parliament which adopts a resolution in order to stop granting patents on conventional plant and animal breeding. This EU facilitated strengthening of PBR and of national bans on GMOs leads to a wide row of international conflicts, particularly with the US. Considering ambiguity in risk assessment, the incompatibility of the principles of substantial equivalence and the precautionary approach becomes apparent. Notably, GMO controversies of the EU primarily affect interests of the US. In the meantime, these disaccords have ritualized at the international level. The US brings accusations to the WTO’s Dispute Settlement Body in the late 1990s and early 2000s, maintaining on the inhibition of discrimination. They refer to the legal harmonization of ‘like products’, despite uncertainty about GMOs belonging to this category. It is argued that such a separation misleads consumers to view GE-derived products as inherently and substantially different than non-GE food products. Mandatory labelling on food products is ruled by the EU’s Novel Food Regulation of 1997. The WTO considers this to be an unjustified trade barrier. Ultimately the outcome is that the missing approval of several biotechnology products during the time of June 1999 and August 2003 are not in conformity with WTO rules. Additionally, the national bans are defined as violating WTO regulation. Fundamentally, WTO members are allowed to rely on ‘legitimate factors’ such as economic, social or ethical considerations as well as societal traditions such as food culture. Since it is difficult to define or quantify these factors, the reliance on scientific risk assessment remains the primary approach. It is also formally planned to include public participation in order to avoid arbitrary treatment in public administration of GE food products. The European Commission has, however, failed to define the treatment of public comments in GMO related fields. The current system for risk assessment in Europe relies on the Commission and the European Council as well as the European Food Safety Authority (EFSA) as the only institution that is responsible for scientific risk assessment. These relations are highly contestable since the majority of EFSA’s scientific panel members have direct or indirect connections to enterprises with activities under EFSA’s remit. However, the current situation in the EU regulation is best described as a deadlock that was made by decisions of governments in 2003 and 2007. This also affects the regulation of coexistence, which is revised lastly in 2010. As a consequence, national bans are strengthened and the coexistence of conventional, organic and GE agricultural productions is ousted. Despite the conflicting situation with the WTO, the European Commission refers to socio-economic arguments such as the (partial) protection of small-scale agricultural structures, freedom of choice for farmers, or consumer protection.

In sum, there is permanent inner-EU struggle on the treatment of GMO food which has by now largely gone well for GMO opponents. Fundamentally, it is unclear whether an economic benefit is truly provided for the EU if one takes into account the low estimated economic benefits and the costs of environmental and health hazards. Just as several actors stress, the economic benefits of using transgenic plants drastically vary with the plant variety, the agricultural type of farming and the external (regulative) circumstances. An important aspect in this regard is the increasing impact of the economies of scale and scope, which support the transformation of small-scale agricultural structures into large-scale formations. While EU subsidies are directed to economic growth and international market pressure, these pressures are fundamentally on the farmers’ expense. Thus, more and more farmers are confronted with the large-scale decline of farming (Bauernsterben). This can be linked to another crucial aspect: feed products. Although GMO food products are widely denied in the EU, feed usually has genetically modified content. This affects two aspects. First, in accordance to *Entgrenzung*, GMOs are not out of the food chain, especially not if contained in feed. Second, low prices on GE-feed subsequently push non-GE feed out of the market; though it is still possible to buy non-GE-feed if required. Further, the contamination of non-GE food is related to legal and monitoring aspects both at the national and the international level. One refers to the institutional blind spot at the EU level, namely the illicit supplies. Currently, each EU approval application requires a clear verification procedure for the respective GE plant. According to the Directive 1830/2003 the retraceability of these plants must be ensured. The regular violation against the Directive is enabled with approving GMO plants that contain gene-combinations, called stacked events, which are also in other plants. In practical terms, it is almost impossible to identify these gene-combinations. The recent case of SmartStax reflects this difficulty. Authorities responsible for monitoring, currently lack in appropriate instruments. This is accompanied by a missing political decision for a stricter legislation. Another source of criticism is a lacking monitoring system at the international level. To date, in countries with widely dispersed GMO cultivation, a regional long-term monitoring program for environmental and health hazards is missing. In the absence of a monitoring program, the precautionary principle will only have a low impact in practical terms. This is not only true for Europe, but also for several nation states that aim to preserve people from potential hazards. Additionally, the attacks on scientist that are critical towards GMOs have to be discussed more in the scientific community and in the public sphere. This is because primarily scientists have the appropriate know-how and capabilities for conducting monitoring programs, while these attacks also compromise the independence of academic research, which is accompanied by increasing scientific-industrial relations. One of the most crucial aspects in the establishment of modern agriculture is the application of pesticides and herbicides. Particularly the active agent Glyphosate is addressed. According to German BUND (2013), almost everyone in Europe has Glyphosate in their body and is also affected by other hazardous chemicals that are used in agriculture. It is needed to reduce the application of chemicals both in conventional agriculture and in agri-biotechnology. Glyphosate triggers various diseases, such as Alzheimer’s, diabetes, and cancer. Moreover, it can cause depressions, heart attacks, and infertility. Apart from these diseases, it has a highly negative impact on soil fertility (Samsel/Seneff 2013). Another aspect is its correlation to chronic Botulism, a disease that affects cows. This is very crucial, since cows in Europe are regularly fed with GMO feed that is usually treaded with Glyphosate. The affected cows are mostly high performing dairy cows (Shehata et al. 2013). Significantly, this is a result of a wider dimension: the huge amounts of food production and the idea behind it. Keeping the tremendous amounts of wasted food and problems of obesity in mind, it is highly questionable whether we need so much food at all. While starvation is rather an issue of distribution and not of a lacking amount of food in general. With respect to the EU, the debates on the Free Trade Agreement TTIP between the US and the EU must be observed in the nearer future. Negotiations on TTIP, inter alia, concern the sensitive fields of food and agriculture and can cause extensive damages in the EU, which has stricter health and environmental regulations than the US. Recently increasing resistances by various NGOs to TTIP emphasize the opposition to GMO food in Europe and thereby the different dispositions and value orientations. In the end, if people and natural ecosystems are not treated with respect and goodness, for both biological and social reactions, the slogan may be *respect existence or expect resistance*.

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Abstract (deutsch)

Die vorliegende Arbeit nimmt sich den kontingenten Notwendigkeiten der modernen landwirtschaftlichen Biotechnologie an. Kontingente Notwendigkeiten werden verstanden als Ereignisse nicht-notwendiger Interaktionen verschiedener Kausalketten, die erst durch die kontingente Interaktion notwendig werden. Das Konzept trägt dazu bei spezifische Ereignisse als ein Zusammenspiel vieler verschiedener Faktoren zu betrachten, wodurch Reduktionismen ausgeschlossen werden sollen. Konkret wurde moderne landwirtschaftliche Biotechnologie vor allem in den USA entwickelt, u.a. mit dem Resultat gentechnisch modifizierter Nahrungsmittel (Gen-food). Daher können wesentliche kontingente Notwendigkeiten in der vergangenen Technikentwicklung des Landes gefunden werden. Europa hingegen setzt vornehmlich auf konventionelle und teilweise organische Landwirtschaft. Das Thema der modernen landwirtschaftlichen Biotechnologie, vor allem die Frage nach Gen-food führt in Europa regelmäßig zu Konflikten. Dies ist nicht zuletzt auf die unterschiedlichen Wertevorstellungen und Dispositionen zwischen Europa und den USA zurückzuführen. Ein Ziel dieser Arbeit besteht in der Untersuchung der Frage, warum Ereignisse nicht-notwendiger Interaktionen in den USA eine kontingente Interaktion eingegangen sind und warum Europa eine andere Entwicklung erfahren hat, die von einer breiten Ablehnung gegenüber Gen-food geprägt ist. Mit der Methode der Artikulation werden kontingente Notwendigkeiten auf verschiedenen Abstraktions- und Komplexitätsebenen untersucht. Die Analyse beginnt mit einer einfachen und abstrakten Untersuchung von Technologie. Technologie wird als sozialer Prozess verstanden, der historisch und kontextual eingebettet ist und somit auch die entsprechenden ökonomischen und technologischen Pfadentwicklungen. Mit der anschließenden Untersuchung besonderer Charakteristiken moderner Biotechnologie wird die Analyse spezifischer und konkreter. Diese wird allgemeinhin aufgefasst als eine Sammlung verschiedener wissenschaftlicher Methoden mit breiten Anwendungsmöglichkeiten und nicht als eine eigenständige Technologie. Zudem gilt es die weitereichende Kommodifizierung von Wissen, insbesondere von wissenschaftlichem Wissen zu berücksichtigen. Im dritten Schritt analytischer Konkretisierung werden die technischen Seiten der Technikentwicklung moderner landwirtschaftlicher Biotechnologie erleuchtet. Diese werden zusätzlich auf ihre ökonomische Verwertbarkeit hin untersucht. Dabei sind der Entwicklungsfokus auf einige wenige Hochleistungssorten wesentlich sowie die Entwicklung von Resistenzen gegen spezifischen Herbiziden und Pestiziden. Im Anschluss gilt es die technischen Aspekte auf die Internationale Politische Ökonomie hin auszuweiten. Ein wichtiger Punkt hierbei ist die industrielle Struktur, die durch horizontale und vertikale Konzentrationsprozesse geprägt ist. Der internationale Saatgutmarkt wird von einigen wenigen multinational agierenden

Konzernen geleitet. Monsanto beispielsweise zielt auf die Kontrolle der gesamten Wertkette der Lebensmittelproduktion sowie der Biomasseproduktion ab und grenzt seine Eigentumsrechte nicht auf wenige Pflanzensorten und bestimmtes Saatgut ein. Des Weiteren werden in der Arbeit geistige Eigentumsrechte und die Schwierigkeiten mit Biopatentierungen erörtert. Das letzte Kapitel der Analyse widmet sich schließlich den unterschiedlichen kontingenten Notwendigkeiten in den USA und in Europa. Beide werden mittels eines genealogischen Zugangs in Bezug auf ihre technologische Entwicklung und ökonomische sowie akademische Strukturen hin erforscht. Da die Europäische Union eine jüngere Erscheinung ist als nationale und regionale Technikentwicklungen, wird letzteres am Beispiel Deutschlands veranschaulicht. Insgesamt ist die Arbeit eine Literaturarbeit, sodass empirische Daten vornehmlich aus Sekundärquellen bezogen werden. Bücher, Artikel aus Zeitschriften, Berichte sowie Zeitungsberichte und Internetseiten bestimmter Akteure bilden die wesentliche Bezugsbasis für Quellen. Darüber hinaus dienen diverse Abkommen und Gesetzestexte als Quellenbezug.

Abstract (englisch)

This work examines the contingent necessities of modern agricultural biotechnology. Contingent necessities are occurrences of non-necessary interactions of various causal chains which become necessary by entering a contingent interaction. The concept allows viewing specific subjects as interplays of several factors in a causal relation, while avoiding reductionism. In concrete terms, modern agri-biotech is mainly developed in the USA. Hence, contingent necessities of modern agri-biotech can be found in its past technology development. In US history, various causal occurrences finally resulted in the development of biotechnology with the usage of genetic engineering (GE) and its application in agriculture. In contrast, Europe primarily relies on conventional and partially organic breeding methods. The application of modern biotechnology in agriculture causes conflicts in Europe due to fundamentally different values and dispositions between the US and European states. One essential aim of this work is to examine why non-necessary occurrences enter a contingent interaction in the USA and why Europe experiences another development including a broad opposition towards modern agri-biotech and GE food. With the method of articulation, contingent necessities are assessed at various levels of abstraction and complexity. The analysis begins with a simple and abstract elaboration of technology. Technology is understood as a social process which is historically and contextually embedded similar to respective economic and technological path-developments. Subsequently, the analysis becomes more specific and less abstract by specifying modern biotechnology. Modern biotechnology is considered to be a collection of scientific methods with broad

application possibilities rather than an autonomous technology. Additionally, the far-reaching commodification of knowledge, particularly scientific knowledge is addressed. In a third step, modern agri-biotech is specified. The technical sides of its development are examined and related to economic interests. The development focus on a few high yield crop varieties and their resistance against specific herbicides and pesticides is a crucial aspect. In the following, the technical aspects are extended to the International Political Economy of modern agri-biotech. An important aspect is the industrial structure which is characterized by horizontal and vertical concentration processes. Hence, the international seed market is ruled by a few multinational companies. For instance, Monsanto strategically targets control of the entire food chain and biomass production and does not merely raise property claims to single plant varieties and seeds. Moreover, the analysis dwells on Intellectual Property Rights and related difficulties in biopatenting. The very last chapter examines the different contingent necessities in the USA and Europe. Both are accessed genealogically concerning technology developments and economic and academic structures. Considerably, the European Union is a more recent project compared to technology trajectories that are rather observable at national and regional levels. Thus, this work also inquiries into relevant developments and structures in Germany. The thesis deals with empirical data from secondary sources. Books, papers, reports, newspaper articles and webpages are the main sources as well as treaties and legal texts.

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2013	**Universität Wien** INEX Sustainability Challenge Service Learning Project in Kooperation mit Riskexperts Thema: Klimawandel Leitung: RCE Vienna http://www.rce-vienna.at/sustainabilitychallenge/home/teilnehmerinnen/
2013	**Universität Wien** Forschungspraktikum Thema: Internationale Politische Ökonomie – Handel und Umwelt Leitung: Prof. Dr. Ulrich Brand und Dr. Werner Raza
2010/2011	**Universität Siegen/Universität Karlstad** (Schweden) Binationales Lehrforschungsprojekt Thema: Unemployment and the Welfare State Gefördert durch den DAAD http://www.uni-siegen.de/start/news/international/361400.html

Nicht-Akademische Tätigkeiten

Seit 2014	**Nyéléni in Deutschland:** Bewegung zur Ernährungssouveränität in Deutschland Tätigkeiten: Pressekommunikation, AG Finanzen. http://nyeleni.de/
Seit 2013	**Mitbegründung des Magazins „engagée“:** Das Magazin für eine neue Kultur der Partizipation Tätigkeiten: Inhaltliche Konzeption, Koordination, Vertrieb, Administration des Social-Media Bereichs.

	http://www.engagee.org/index.html
Seit 2013	**Forum Wissenschaft und Umwelt**, Wien Tätigkeiten: Administration des Social-Media Bereichs http://www.fwu.at/
2013	**Global2000/Friends of the Earth Austria** Praktikum/Projektassistenz - Projekte: “MarketWatch” und “Dirty Energy” - Lektorierungsarbeiten, Daten- und Literaturrecherche
Seit 2012	**Universität Siegen** Career Mentoring-Programm des Alumniverbunds Kontaktnetzwerks

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engagée: Das Magazin für eine neue Kultur der Partizipation.

Publikationen
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