The Global Configuration of the Biotechnology Regime in Comparative Perspective

Daniel Barben

Since the mid-1970s, biotechnology has been established worldwide as a "key technology of the future" – as the core of a new bioindustry. While biotechnology has developed as a transnational technology, it has been subject to existing or emerging arrangements of governance at national, regional, supra-, and international levels. At the same time, manifold and intense social controversies have formed as a reaction to contentious issues. Thus, biotechnology has increasingly become an object of – and a factor in – the global technology race, the international or regional competition between regimes, and a critical public debate.

In the mid-1970s, neo-liberalism has experienced an upturn, too. Since then, neo-liberalism in various forms has become hegemonic, although it has remained disputed. In my view, although the careers of neo-liberalism and of biotechnology are distinct, they cannot be considered simply as separate developments. Their development not only exhibits a contingent simultaneity but it is shaped by interdependent factors. The analysis of the relationship between neo-liberalism and the development of biotechnology is a central aim of my long-term research project – "The Generation and Shaping of Biotechnology: The Neo-liberal Configuration of Functions and Forms of Technological Regimes in Comparative Perspective (USA-Germany/EU)".[1] Surprisingly, the co-evolution

1 I have developed this project over the years, first, when working as a Research Fellow at the Social Science Research Centre Berlin (WZB) (Barben 1997a, 1997b, 1997c, 1998a, 1998b, 1999a, 1999b, 1999c; Barben and Abels 2000), then as a Fellow of the Institute for Advanced Studies on Science, Technology and Society in Graz. Since October 2000, the project has been funded by a "Habilitation" stipend from the German Science

of biotechnology and neo-liberalism has not been sufficiently analysed while, at the same time, business orientation or deregulation – both of which are associated with neo-liberalism – have been prominent issues in the public and academic debate. To appropriately understand neo-liberalism as well as its impacts on the social configuration of biotechnology constitutes a task of considerable theoretical and empirical complexity. Above all, neo-liberalism has to be understood in a non-essentialist way – otherwise it will be nothing but an over-simplifying concept. Thus, it needs to be analysed, how neo-liberal principles related to the "free market society" are constituted and are articulated under specific historical and political circumstances. This requires unravelling the altering meanings of neo-liberalism in different contexts of space and time, in different policy fields and as concerns different actors. It is in the context of such questions that my research project evolves: It primarily aims at reaching a closer understanding of the patterns that govern the biotechnological revolution – patterns that concern technological, social, and political change. The development of biotechnology is being observed in relation to its institutional framing and its social appropriation. As a consequence, the social configuration of biotechnology can be evaluated with regard to the coherence of and the tensions in the emerging technological regime – in other words, in terms of its efficiency, legitimacy or hegemony.

In this paper, the co-evolution of neo-liberalism and biotechnology will remain in the background and surface only occasionally (for a first overview see Barben 1997c, 1998a). Instead, I will unfold the theoretical and empirical complexity of the topic under

Foundation (DFG), and the research has been carried out at the Centre for Technology and Society (ZTG) at the Technical University of Berlin and at the Cenre for Global Chance and Governance at Rutgers University (New Jersey, USA). I am most grateful for the research opportunities provided.

investigation by focusing on selected issues. First, I will expose two main elements of the analytical framework: the approach of social studies of science and technology and that of comparative regime analysis (1.). Second, I will outline some characteristic elements of the governance of biotechnology in comparative perspective – in respect to the historical and political context, the configuration of the biotechnology regime, and the distribution of governance capacities among the different actors (2.). Finally, I will present conclusions as well as an outlook on the future of biotechnology, on transnational technology governance, and on perspectives of social scientific exploration (3.).

1. Elements of the analytical frame work

1.1 Social studies of science and technology

Within the social sciences my project, above all, draws a link between sociology and political science. It contributes to the field of science, technology, and society studies (STS-studies) in analysing the relevance of society for the development of technology and in combining theoretical and empirical work related to a particular techno-science, biotechnology. Alongside the many differences among the inter-/disciplinary approaches of STS-studies, a shared interest and common orientations can be found. Thus, science and technology are not to be treated as given, as "black boxes", instead they must be "opened up" by elaborating how they are socially shaped; the interrelations between science, technology, and society have to be investigated with regard to the question how they determine or influence each other; science and technology are to be regarded as contingent constructions, i.e. as specifically made, and as operating and evolving within a horizon of alternative options

(Winner 1977; Latour and Woolgar 1986; Kohler-Koch 1986; Woolgar 1988; Weingart 1989; Dierkes and Hoffmann 1992; Rammert 1993, 1994; Jasanoff et al. 1995; Martinsen and Simonis 1995).

My research – as well as most of STS-studies – is levelled against technological as well as against social determinism or reductionism, which implies that both the technological and the social dimensions have to be considered in their connectivity. Yet, as with every postulate, one must examine critically whether its methodological requirements are actually met in a particular research approach, or in its findings. For instance, the strong opposition against technological determinism can lead to severe problems of social determinism, which – contrary to the initial intentions – arise in the case that the factors shaping science and technology are attributed in a one-sided way to social processes. Accordingly, social constructivist perspectives, which are most influential among STS-studies, occur in quite different articulations – with respect to the characteristics of and the relations between science and technology, institutions and organisations, action and interactivity, or nature and culture. While cognitivistic and sociological exaggerations have occurred, social constructivist science and technology studies have made an important contribution in putting objectivism and positivism epistemologically as well as empirically into relative terms. Yet, it remains a crucial task to reveal the discursive nature of science and technology and to acknowledge scientific truth claims. Additionally, instead of reducing the interest in science and technology to that of the corresponding set of knowledge or tools, the various substantive and practical aspects of science and technology have to be conceptionalised (Heintz 1998; Lenoir 1997; Pickering 1992).

Instead the analytical dimensions of science and technology, institutions, discourses, and practices need to be integrated. In

correspondence with the subject and the analytical perspective of my project, conceptual interfaces with science and engineering thus have to be adopted. For together with biotechnology, an institutional framework has evolved that has been a matter of strategic importance for the shaping of biotechnology and has been a source of manifold conflicts. Thus, on the one hand, it is the process of institutional framing that decides how biotechnological potentials and applications unfold. On the other hand, it is biotechnology itself and its potentials that set requirements and limitations for the institutional framework.

1.2 Comparative regime analysis of biotechnology

When investigating the social configuration of biotechnology one needs to deal with the specific articulations of science and technology, of institutions and organisations, of discourses and practices. For this purpose, I propose a regime analytic approach. In a first instance, the regime concept refers only to the basic sociological notion that institutionalised social structures, practices, and meanings are *mutually determined and re-shaped*. Although this seems to be a simple idea, it is crucial to overcome the (all too often assumed to be clear-cut) distinctions between structures and actions, between facts and beliefs, or between interests and ideas. In other words, regimes are arrangements of regulated as well as regulating institutional structures, practices, and discourses. The notion of a biotechnology regime refers to such dimensions and supposes that they are shaping biotechnology while, at the same time, being shaped by biotechnology. This implies that biotechnology itself can be interpreted as a regime, by presenting it as the *result and starting point of structuring effects* – one need only think of the inclusion of bio-scientific processes in the insurance business or of the socio-economic implications of agricultural technologies. Biotechnology and the biotechnological regime are thus not simply opposed to each other

(in the sense of technology versus institution): they are interwoven. They mark an articulation that is open to contradictions, tensions, and alternative possibilities. The significance of biotechnology is therefore determined by a set of factors, which effect in different functional dimensions and stages, marking the generation, regulation, and enculturation of biotechnology.

Comparison is an important analytical tool (both with regard to science and technology and to politics or social institutions), which helps to avoid essentialist assumptions. My project is designed as an *international comparison* between the USA and Germany (or the EU where necessary). The USA has been the leading country in almost every relevant aspect of the biotechnology development and therefore constitutes a prominent case of reference. Germany, in contrast, is an important country that has been trying to catch-up in this specific scientific and industrial field. In addition, the project aims at reconstructing *international and transnational developments*. Under the condition of a globalising economy this is a necessary complementary step, one of the reasons being that global transformations in general and the case of biotechnology development in particular cannot be understood adequately without taking into account the global South.

In addition to the national, supranational and international levels of regime analysis (with nation states, supranational and international organisations being the main political units), the comparative approach carves out yet another layer by considering the different areas that constitute the biotechnology regime. Generally, the biotechnology regime comprises elements that are biotechnology specific respectively non-specific such as regulations that are relevant to biotechnology but are not exclusively directed at it (for instance regulations regarding trade or environmental issues). According to my analysis, the following areas constitute the biotechnology regime: *innovation, risk management, patenting, bioethics,*

biodiversity, and acceptance policy. These areas represent substantially different articulations of technological, institutional, discursive, and practical elements. At the same time, they portray complex issue-areas, i.e. bundles of the questions that are at stake. The areas are obtained by observing the conflicts around biotechnology; thus, they are not simply given and self-evident. Correspondingly, it is of fundamental importance to ask *whether* the list of *regime areas* is *complete* and *how* their *arrangement* is to be conceived of. All areas affect the generation and shaping of biotechnology as well as the way it is embedded in society. How the areas contribute to the generation, regulation and enculturation of biotechnology is an empirical question that depends on how they are organised and working. A basic analytical idea consists of asserting that *primary functions* are articulated in the areas of the biotechnology regime, and that *functional interdependencies* link up the different areas. It is a task of social theory to determine the general importance of a specific regime area. As a consequence, the reconstruction of the biotechnology regime has to be carried out by unfolding, both, arguments from social theory and observations from empirical research (see 2.). This procedure is intended to perform a fundamental methodological task: to enable a *functional analysis that moves beyond functionalism* – i.e. to reconstruct functions and their realisation instead of presupposing and deducing them.

Moreover, another level of comparison refers to biotechnology itself in two different ways, firstly by addressing the *different sectors of biotechnology* and secondly by comparing biotechnology with other technologies. In the project presented here, besides considering biotechnology as a unifying concept, I refer to its two main sectors, namely biomedicine and agricultural biotechnology, depending on the issues that are relevant to a particular regime area. Comparison between biotechnology and *other high or low technologies* is not carried out for practical reasons (for a comparison

between biotechnology and information and telecommunications technology see Barben and Behrens 2001).

A regime analytical approach starts out from the observation that "regimes" occur in a variety of contexts; the different concepts that come into play have neither been synthesised nor have they been brought into a more comprehensive perspective. Thus, in the context of social development, regimes are spoken of as "urban regimes" or as "national modernisation regimes"; when distinguishing between forms of political rule, "democratic regimes" are contrasted with "authoritarian regimes", for example; with respect to regulation of the global economy, one refers to the "global currency regime", e.g. the Bretton Woods system as established after World War II, or the "global trade regime" as currently represented by the WTO (World Trade Organization); with regard to forms of business organisation, "company regimes" are differentiated, for instance, according to various types to combine functional and scalar hierarchies; in the face of international conflicts or global problems, forms of negotiating and managing disputes have been established as regimes, as in the case of the nuclear arms race between the USA and the USSR during the Cold War or in the case of "environmental" or "climate regimes".

The predominance of the regime concept of international relations in social science is a source of common misunderstandings. Correspondingly, despite the multifarious contexts of use, regime analysis is frequently restricted to international politics in political science, and, in other disciplines, it is presented as being of relevance primarily to political science. When applying the idea of a generalised regime analysis a set of categories is needed to integrate the different thematic and conceptual contexts. Since there exist various theoretical traditions of regime analysis, divergent concepts and perspectives can be employed, but these must be adapted to specific purposes. As any analysis that is not sup-

posed to be a general theory, regime analysis relies on the subject of inquiry with the consequence that the design of the theory has to be outlined according to its peculiarities.[2] With regard to the analysis of the biotechnology regime, the approach of theory building consists of *generalising and of specifying* regime analytic concepts. The fact that the biotechnology regime concerns different levels and areas and, thereby, different configurations of actors, can be reflected by referring to a variety of theory traditions. I propose reference to the following approaches in particular:

The concept of a "technological regime" has been developed above all within *evolutionary and institutional economics* (Nelson and Winter 1977; Dosi 1982; Dosi and Orsenigo 1988; Freeman and Soete 1997) where it co-exists with the concepts "technological paradigm" and "technological path". Thus, the importance of technologies is seen in terms of certain production methods, of technological change along certain development paths and of technological revolutions – which are caused also by paradigms whose productivity and innovative capacities have been exhausted, for example. Also of interest is the "*techno-economic paradigm*" concept (Perez 1983) which does not refer to a particular industry, but to groups of industries or branches, especially applying to electricity or computer technology, but also to biotechnology. A great number of new applications arise from such paradigms, at the levels of both product and process; they are based on views of technological

2 In the following section I do not attempt to evaluate existing approaches of regime theory and develop them further towards a general theory. Instead, by using the biotechnology development as an example, a heuristically revealing and theoretically extensible analysis can be sketched out. Biotechnology policy is a suitable subject for reflecting on an integral frame of regime analysis, as biotechnology, due to its characteristics as a cross-sectoral technology, involves a series of further policy areas, such as health, agriculture or the environment, and also covers various areas and forms of regime. Thus, the contexts of earlier regime theory discussions – regional or national development regimes, forms and styles of government, trade, production and environmental regimes – can be examined at the same time.

or investment decisions, which have become common currency to the extent that, on the one hand, alternative paths of development become excluded while, on the other hand, efficient large-scale production is made possible within the chosen framework. The power of techno-economic paradigms relies on the influence of standards and textbook knowledge, on the availability of inexpensive components and raw materials, on effective infrastructures and education systems, on large-scale production, experienced management, technological expectations, and trends. Once all these elements have been successfully established and are supported by a series of political and social institutions, they may become a *technological regime*. Such a regime can predominate for several decades (Freeman 1993: 313) up to the point where it enters an epochal crisis and is gradually replaced by a new regime. Since this is a structural crisis of regime compatibility, the emergence of a new techno-economic paradigm goes hand in hand with broader institutional change. From the perspective of this theoretical approach, patterns and aspects of biotechnology's early stages of development can be illuminated. For example, it allows to address the extent to which bioscientific and biotechnological approaches constitute a new technological paradigm (which encompasses the various fields of application) or in how far they are able to do so only for certain fields of application or for certain lines of research and development (R&D) alone. Furthermore, it enables to ask which are the options that are realised instead of others, which paths are thus taken and which alternatives are excluded. Finally, the nature of the connections with other high-impact technologies such as information and communications technologies can be observed, as well as the accompanying new divisions of labour and institutional innovations or transformations which start to emerge. Another important focus of research is the concept of "National Systems of Innovation" (Nelson 1993) which has the disadvantage

that social as well as cultural determinations are not considered adequately with regard to an integral analysis.

Concepts for the analysis of regulatory regimes in particular are provided by *actor-centred institutionalism*. These analyses are fruitful inter alia because they are often drawn up in comparative perspectives and address the relationships between the political and the economic along with their specific institutional and organisational manifestations and their mediation with collective or individual actors (such as corporatism, neo-corporatism, etc.). This approach aims at determining the specific functions, capacities, and limitations of regulatory regimes (Mayntz 1995; Mayntz and Scharpf 1995; Scharpf 1988, 1996). The main analytical interest of actor-centred institutionalism, however, lies in a conceptualisation of the ways in which actors from different social areas develop networks of negotiation and co-operation across area boundaries in the light of certain problems, an approach that aims at drawing conclusions concerning capacities of problem solving or political control. While this particular focus is not of central importance for my project, I will refer to the typologies of regulatory systems and styles as provided by comparative policy analyses. These are increasingly developed with regard to the theme of regime competition in the context of globalisation and the subsequent reconfiguration of the "varieties of capitalism" – for instance the "Rhine" or "Anglo-Saxon" model of capitalism (Crouch and Streeck 1997).

In addition, the discussion of regimes in *international politics* is profitable above all in cases in which a need for international regulation is asserted (Krasner 1983; Keohane and Nye 1989; Kohler-Koch 1986; Rittberger 1990; Keeley 1990). In the case of biotechnology, this primarily holds in the context of negotiations and agreements on trade, biosafety, biodiversity, and bioethics. International regimes are concerned with more all-embracing problems, in cases where the actors involved exhibit differing or opposing interests,

preferences and expectations, and where problem management is oriented around certain principles and procedures, norms and goals. Since the concept of regimes as developed in international politics predominates, this is problematical for theorising, insofar as a more general validity is then given to a sub-disciplinary concept, above all with respect to reality; as a consequence, conflicts with the potential to escalate into war influence our understanding of regimes far beyond their original context – that of the Cold War (Kohler-Koch and Schaber 1994; Sakamoto 1994). In these cases, it is in the form of the regime – i.e. certain negotiation and co-operation structures aimed at reaching compromise – within which it appears desirable to integrate the conflicting actors. In most other cases, including international politics, it is rather the specific properties of regimes on which their description with respect to functional performance and effect depends.

Since there are still deficits with regard to the conceptualisation of the global level, recourse must be made to *international political economics* and *world systems analysis* (Cox 1987, 1997; Gill 1997; Gill and Mittelman 1997; Altvater and Mahnkopf 1996; Amin et al. 1982). Important contributions have been made with regard to both a better theoretical and empirical understanding of global economic and political transformations, and the reconfiguration of the capitalist world order. After all, developments in individual societies cannot be adequately understood without bringing in the world system as the highest, all-embracing level of analysis.

Contributions from the (French) *regulation theory* implicitly contain a concept of technological regimes while the black box of science and technology remains closed. The reference to this research approach, whose emphasis lies more on economics, sociology or political science, is motivated above all by its potential in terms of social theory. This results from its analysis of specific phases of the

capitalist social formation, of the relationships between economy, politics and policy, culture, etc. with respect to their organisation and dominance, of their epochal crises and transitional processes (Lipietz 1985, 1993; Hübner 1989; Demirovic, Krebs, and Sablowski 1992; Jessop 1995; Hirsch 1998; Lipietz 1998). This approach works with a central distinction between *regime of accumulation* and mode of regulation: The regime of accumulation is characterised by the distribution of wealth between capital and labour, the distribution between consumption, saving, and investment – i.e. the determination of volumes and the composition of the effective demand – and the connections between capitalist and non-capitalist forms of production. The *mode of regulation* is characterised by a series of institutional forms, concerned with credit and other financial relationships, types of competition and property law, the link between labour and wages, the relationships between state and economy and to the international economy. Together with the "*industrial paradigm*" concept, which refers to the dominant principles of organisation of labour, of management methods and technologies, those two concepts constitute a "*development model*". These concepts – the mode of regulation being the central one, enclosing the others – are directed at the changing relationships and in-/compatibilities between the development of the forces of production and the work force, the modes of production and consumption, the institutional forms and political or economic strategies – in order to draw conclusions about the specifics of the social formation, for example, or to compare transformations from Fordism to post-Fordism in individual nation states.

In comparison to regulation theory, a shift in emphasis consists of drawing a more clear distinction between *the generation, the regulation, and the enculturation of biotechnology*. Although they have been applied at a different level, the distinctions drawn in regulation theory tend to neglect the cultural dimension as well as, up to a cer-

tain extent, the dimension of state regulation by subsuming both under the term "mode of regulation". State regulation is a constitutive element of biotechnological industrialisation, while, at the same time, it shapes the legal and institutional framework within which biotechnological applications are introduced into society. Since this is not the same process as enculturation, enculturation consists rather of a variety of forms of adaptation and appropriation. The analytic emphasis on state regulation and enculturation thus also addresses the reasons for the long, hard struggle over the If and How of national, supra- and international regulations, as well as the fact that biotechnology is, on the one hand, not yet encultured in practice but that, on the other hand, it receives its social significance in the enculturation processes.

In a form similar and appropriate to regime analysis, the approach of *governance analysis* emphasises the existence of interrelations between social structures and actions. Unlike the traditional approach of political analysis, whose subject matter is *government* in the sense of organisation and functions of state ministries and administrations, the focus of governance analysis is wider. Generally, governance refers to processes of governing, controlling, directing, or shaping; it is not restricted to activities of state organisations but gives rise to the question of what actors in which social contexts dispose of what capacities of action and power. In other words, by analysing governance the fact is emphasised that government is neither a given nor exclusive to state organisations; instead, it is oriented towards the reproduction of power and the social distribution of government powers.[3] The discourse on *global governance* became widespread in the early 1990s (Global

3 "Governance" is an English term that has also found its way into German, not merely as a fashionable concept, but simply as one that is not easy to translate. Since, in general, basic concepts both in reality and in the social sciences – like "government" or "state" – often denote very different things in different languages, this causes particular difficulties for comparative research.

Governance 1995; Rosenau 1992; Messner and Nuscheler 1996; Brand et al. 2000; Mürle 1998). First of all, it refers to the major global problems of humanity such as the degradation of the environment, disease and poverty and, after the end of the bipolar world order of the Cold War era it deals with the search for a new, sustainable world order. Thus, the "global governance" approach is oriented towards a configuration of actors and institutions that – in one way or another, in different social contexts, and from the local to the international level – is concerned with the government of problems. As in other influential and appealing discourses, different lines of argument and options for action encounter each other. It certainly makes a considerable difference whether global governance is approached predominantly from an empirical-analytic, a normative-emphatic, or a political-strategic perspective (Brunnengräber and Stock 1999).

2. The governance of biotechnology in comparative perspective

2.1 Historical and political context

Within the last thirty years, two *historical points of transition* bundle major events that have had repercussions also with regard to the social configuration of biotechnology.

The economic crisis that emerged in the years 1973 to 1975 turned out to be of a systemic nature. The crisis was followed by deep social transformations and reconfigurations as indicated, for instance, by the end of the Bretton Woods world currency regime, by the "crisis of the Fordist welfare state", and by the "end of the social democratic age". By way of the "limits of growth" not only the economic limits of a particular social model but also the insu-

perable ecological limits to growth-oriented economics became articulated. It was during this period that the upturn of neo-liberal political strategies took place, initially in Great Britain and the USA, aiming at a restructuring of societies driven by the "free market". Simultaneously, the new social movements acquired an increased significance by criticising predominant modes of production and by propagating alternative ways of life. Against this backdrop the first experiment of "gene manipulation" succeeded, and the famous Asilomar conferences took place, dedicated to the assessment of the risks inherent in genetic engineering as well as of appropriate safety measures. The period 1973-75 marks the first context in which biotechnological innovation and risk management became shaped. Biotechnology worked as a paradigmatic technology with respect to which contradictory perspectives were applied regarding the "limits of growth" and the "growth at limits".[4]

In the period between 1989 and 1992, the post World-War-II world order came to an end with the collapse of despotic state socialism. Market-oriented social transformations, which seemed to be without any alternative followed both in the former socialist countries and in the "Third World". Correspondingly, a boost in economic globalisation involved intensified competition between nations and regions regarding their competitiveness. However, this period of accelerated social change has also experienced important initiatives towards a globally sustainable development (i.e. concerning environmental protection, economic development, and

4 Accordingly, the significance of biotechnology is projected by its ability to shift the limits of the predominant model of social development from inside by eliminating the problems accumulated and by opening non-problematic perspectives for future expansion. On the other hand, biotechnology is perceived not only as a wrong answer to, but rather as an expression of the pending catastrophe, which will fail to achieve a sustainable social model and, instead, produce a latge number of follow-up problems (Barben 1999a).

social justice) as represented above all by the United Nations Conference on Environment and Development in Rio de Janeiro. This development gave rise to a partial reorganisation of the arenas and actors in international politics, including an increased recognition of non-governmental organisations (NGOs) and of actors on a local level. As a consequence, the course of economic globalisation and global politics marks a battlefield for neo-liberal strategies and strategies of global governance. Biotechnology has become interwoven with this constellation in many ways: as a contested "key technology of the future" linked to many areas of science and the economy and therefore of importance to the future position of countries; or with regard to the access to, the use and protection of biological diversity or the global patent regime. The period 1989-92 marks another expansion of neo-liberalism by liberalisation and deregulation policies both at the international and national levels. At the same time, it represents an increased promotion of problem solving and dispute settlement mechanisms.

The arguments in the biotechnology debate up to date have been shaped by three seemingly irreconcilable positions: First, the primary aim of the *position of the neo-liberal market-oriented release of biotechnology* is to allow the scientific and technological exploitation of biology to proceed as fast and as unhindered as possible. This involves the existence of excessive expectations of the unique feasibility and commercialisation potential of genetic engineering. Second, the *position of environmentally or ethically motivated demands for the restriction (or even prohibition) of biotechnology* initially refers to experiences from the conflicts around nuclear power (where for a long time the risks had been denied) and is supported by symbolic associations such as equating "splitting the atom" and "splicing the gene", both of which are symbols of an infringement of a sacrilege. Excessive expectations of the unique risk and feasibility potential of genetic engineering thereby fuelled apocalyptic vi-

sions. Third, the *position of searching for technological, economic, and social alternatives* is above all inspired by the efforts to promote sustainable development. This position is dedicated to a broad range of tasks and combines social with technological approaches. In this perspective, both a sustainable biotechnology and sustainable alternatives to biotechnology are envisaged. In historical practice, these positions are articulated differently depending on balances of power, time, and regional context.

2.2 The social configuration of the biotechnology regime

Against this historical and political background, the configuration of the biotechnology regime will be outlined by sketching the basic functions and characteristics of the various regime areas – innovation, risk management, patenting, biodiversity, bioethics, and acceptance policy –, and by exploring how biotechnology governance has been shaped on the national (USA-Germany), the supranational (EU), and the international level.

A widely held definition of biotechnology, which has been in use since the mid-1980s only, emerged, above all, at the instigation of the OECD (Organisation for Economic Co-operation and Development) to simplify *international comparison and co-ordination*. According to the definition established, biotechnology is the integrated application of a wide range of scientific and technical disciplines – such as molecular biology, microbiology, cell-biology, biochemistry, and engineering – to utilise the metabolic processes of organisms, cells or parts thereof to provide goods or services (Bull, Holt, and Lilly 1982; Bud 1993). This general notion is open to underlying dynamic changes. The basic structure of biotechnology as a *cross-sectoral technology* encompasses emerging new and existing old areas of science and technology – i.e. it can be applied in various areas such as medicine, agriculture, food processing, environmental protection, energy and raw materials supply.

The function of *innovation* – which is necessary under capitalist conditions – consists of creating new products or more efficient processes. While differences among national innovation systems have become apparent in comparative perspective, the biotechnological innovation regimes are characterised by common features such as new forms of cooperation between universities and industry, intensified technology transfer, entrepreneurial science and academics, venture capital financing of start-ups, small and medium-sized companies as innovation environment for industrial concerns (Kenney 1986; OTA 1990). In addition, the role of regions (i.e. regionally concentrated capacities) and alliances between science, industry, administration, and finance are of significant importance.

In case of attempts to catch up in modernisation, the building of regional capacity is often promoted by government initiatives. Prominent German examples are the establishment of genetics centres in Munich, Heidelberg, Cologne, and Berlin in 1984, or the BioRegio competition concluded in 1996, where – with an eye on Boston/Cambridge and the San Francisco Bay area – regional development plans and alliances between science, state administrations, industry, and banks were promoted by the Federal Ministry for Research and Technology. This Ministry has generally played a central role as initiator in the expansion and coordination of a powerful R&D infrastructure. In Germany, both, a continuity of corporatist patterns (yet superimposed by tendencies towards a "competitive corporatism") and an imitation of elements of the US innovation regime, reflected above all in the creation of a venture capital market and the promotion of start-ups, can be observed (Dolata 2000). The USA continues to be leading in the generation of bioscience and biotechnology as well as in their translation into commercial products. From the beginning, state agencies have played an important role in building an innovation-oriented regulatory framework and, since the mid-1980s, they were engaged in

the promotion of agricultural biotechnology, which had lagged behind biomedicine. On the supra-national level of the EU, biotechnological R&D programmes have been increasingly promoted since the 1980s; however, they have remained modest in comparison with the national programmes. Of great importance is the genome and, above all, the human genome research since this is considered to be the major research project in biology and medicine, relevant to the fundamental understanding of life processes and a wide variety of applications. Together with the project of mapping and sequencing the entire human genome, complex structures of inter-/national cooperation and competition have emerged since the end of the 1980s – i.e. initially national projects have become cooperative international projects while competitive rivalry has continued to exist, at least to some extent (Abels 2000a, 2000b). International organisations have played only a minor role in biotechnological innovation with the exception of the major role played by the OECD in projecting biotechnology as a key technology and in constituting a forum for policy formulation with respect to risk management or patenting. The international regime on biological weapons is a special case (Lederberg 1999) in that it is intended to prevent highly dangerous developments by, at the same time, establishing institutional restrictions and finding possible technological counter-measures.

Generally, the biotechnological innovation regime has been shaped by the world market-oriented technology race and by transnational or transregional competition between regimes.

In liberal societies and states, *risk management* has been institutionalised with the function to regulate existing or potential dangers that result from innovation practices. Risk regulation both enables and restricts innovation. Risk management is crucial with respect to economic efficiency as well as the way a technology is integrated into the environment and society. As characteristic

regime elements, the principles of "the freedom of research" and of "the freedom of the market" are put into relation with "precautionary principles" regarding the protection of health and the environment. From the very start, it has been a main area of conflict; the disputes were generally concerned with the extent to which these principles were applied and were in conflict with each other or not. The central regulatory mechanism for determining and evaluating risks is the "dominant state of science and technology" which sets standards for what is considered to be "scientifically appropriate". Connected to it we find the "precautionary principle" which is justified by a certain level of scientific uncertainty. As a consequence, law, science, and the economy are articulated in a particular manner. Space for political manoeuvre exists also within a liberal framework. However, the ways in which this space is defined and used depends on constitutional traditions and, even more so, on political projects and on balances of power.

On an international level, the USA has acted as a model for the regulation of biotechnology. Both in the USA and in other countries, the different areas of risk management – research and production within closed systems, the deliberate release of genetically modified organisms into the environment, and the introduction of genetically engineered products onto the market – have been built up in a subsequent and uneven way. In international comparison, there have remained or emerged significant peculiarities (Cantley 1995). A specific feature of the German approach to risk management consists, for example, of genetic engineering being regulated by a dedicated law instead of integrating the provisions relevant to genetic engineering into existing regulatory frameworks (such as the regulation of toxic substances). The EU has developed into an increasingly important regulatory framework, a task that has been complicated by the

simultaneous establishment of, both, the EU as a political system (with the need to adjust the different national positions) and of the regulations concerning biotechnology. On the international level, regulations concerning the safety of pharmaceuticals are being supplemented by the Biosafety Protocol as part of the United Nations Convention on Biological Diversity (CBD) and by the Codex Alimentarius of the United Nations Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO), dedicated to the regulation of food standards (Protocol 2000; Codex 2000; Merkle 1994).

In the final analysis, the risk management of genetic engineering can initially be characterised by a historically unique level of regulation when compared, both, with other fields of science and technology and with the state of the art. How can the more cautious approach to genetic engineering be explained? It was motivated, on the one hand, by a high level of scientific and practical uncertainty and, on the other, by experiences with the conflicts around nuclear power. Yet, at some moment, an extended process of deregulation followed (Krimsky 1985; Daele 1997). The relaxation of safety standards can be attributed to increased knowledge and experience as well as to transnational regime competition. It is in this field of conflicting scientific and political positions that the disputes are articulated and shifted, with the assessment of risks related to the deliberate release of genetically modified organisms into the environment being the most difficult and controversial, while the regulation of marketing (an area that is closer to consumer demands) seems to be most susceptible to compromise.

Patenting constitutes an institutional form to regulate the appropriation of innovations in terms of private property. Its function, which is indispensable to a regime of capitalist production, consists of legally protecting the inventor's innovation for a certain period of time. To speak more precisely, patenting com-

prises a broad range of intellectual property rights such as patents, copyrights or plant variety protection rights. Throughout its evolution, biotechnology has become accessible to patent law only gradually since 1980. Historically speaking, there have been revolutionary breakthroughs in the commodification of nature. The regulatory principles are provided for in patent law, such as novelty, reproducibility, and usefulness; yet, their transfer to the domain of biotechnology causes specific problems. The issue whether the patenting of higher forms of life (or even of parts of humans) is ethically acceptable, defines a problem area, which is ethically over-determined (OTA 1989; Straus 1995).

The USA has also been leading in the area of patenting. The standards set to determine what counts as invention are lower than in Europe, which has the implication that research developments can more easily be blocked by means of key patents. In Germany, patent law related to biotechnology has been developed with a delay. Patenting was first made possible within the framework of the European Patent Convention. At present, the EU Patent Directive is being implemented in national law, allowing certain scopes for discretion despite the aim of European harmonisation. In international comparison, the main differences occur between the major economic blocks, i.e. between the USA, the EU, and Japan. Accordingly, because of the strategic importance of patenting for research, development and industry, efforts to harmonise patent law have been undertaken on an international level. The WTO has become the supreme instance with the Agreement on TRIPs (Trade Related Aspects of Intellectual Property Rights TRIPs 1994) being one of its constitutive agreements.

Patenting is a relatively recent area of regulation, and its development has gone through a long and conflicting, and still ongoing, process. The formulation and revision of patent law is a

consequence of and a precondition for the technology race oriented toward exploitation; it is a field in which the battle between regimes is being fought. While being constitutive for the realm of economy, its form is subject to political negotiation, be it under the European Patent Convention, the EU Patent Directive, or the WTO (or in the relationship between the TRIPs Agreement and the CBD). In general, patent law has undergone a process of politicisation and it has attracted increased public attention especially because of biotechnology. Patenting remains a field of strategic conflict, particularly in the relationship between North and South but also between and within the highly developed industrial nations. As a result of its inclusion in the GATT process and the WTO, patenting marks a strategically disputed field with respect to the globalisation of intellectual property rights.

Biodiversity has become a field of international politics located at the interface between environment and development. Hence it constitutes a subject of strategic negotiations between North and South. It is relevant for the R&D of biotechnology, and it affects the innovation regime on a global scale; another global dimension of biodiversity is related to the increasing extinction of species. The specific constellation of topics and issues that "biodiversity" stands for (as well as the notion "biodiversity" itself) has only been formed since the late 1980s. In international politics, it achieved prominence with the 1992 UN Earth Summit in Rio and the subsequent negotiations within the framework of the CBD. The main issues are: the protection of biological diversity at the level of ecosystems, species, and genes; the access to genetic resources while neither allowing for the previously unlimited access nor imposing a new exclusion from access (by countries of origin based on the ownership claims acknowledged in the CBD); the sustainable use of genetic resources; the sharing of benefits by

way of technology transfer or local capacity building (UNEP 1995; CBD 2000). A set of new orientations and tools (such as legal instruments to protect indigenous knowledge) has been introduced which cannot be classified as private or be attributed to individuals in a way similar to patent law. In addition, certain issues are being subjected to legal regulation for the first time – e.g. in the case of contracts being concluded between the countries of origin of biodiversity or between institutions located in the South and foreign companies from the North (Henne 2000).

In international comparison, certain groups of countries or individual countries hold different positions with respect to the disputed issues under negotiation. Such issues are for example, the global extension of a uniform patent regime or the question how it should be socially shaped so as to allow for exceptions for developing countries. A paradox is constituted by the fact that the USA is not a signatory to the Convention but nevertheless participates in the negotiations with a sizeable delegation. No country assumes an attitude as rigid as the USA (compared for instance with most of the European countries) in fighting for the global recognition of a patent regime similar to its own without allowing for any exception or favourable provisions with respect to countries of the South. Germany is one of the countries that advocate a moderate point of view, although the positions of individual ministries differ in some cases.

The CBD, and the issues and policies associated with it, constitute a central and supportive field of global governance. Correspondingly, as in the case of climate politics, a wide spectrum of "local" actors in the form of NGOs has acquired access to international politics, as have transnationally organised NGOs such as Greenpeace. The participation of industry representatives is also note-worthy. However, the members – and hence the main actors of the CBD – are nation states. Overall, a wide range of

positions has formed within and among the North and the South which are, thus, not uniformly represented by two homogeneous blocks (Flitner, Görg, and Heins 1998).

Bioethics works as an encompassing medium in which moral values and implications of practices are reflected. It regulates – to a greater or lesser extent – the whole range of practices concerning the generation, the implementation, and the use of the new potentials of bioscience and biotechnology. Its structure is correspondingly complex, comprising not only the ethics of medical research, diagnosis, and therapy but also the ethics of agricultural production or the environment; in addition, institutionalised, legally binding or voluntary standards and values at organisational or associational (e.g. as professional ethics), national or international level; finally, the social communication and reception of the moral values of scientific and technical practices. Due to transnational competition, bioethics is subject to international processes, which lead to the upward or downward harmonisation of standards. Hereby, a complete regulation appears neither possible nor desirable. At an international level, ethical rules concerning biotechnology were formulated above all in the Bioethics Convention of the Council of Europe and in the Declaration on the Human Genome and Human Rights of UNESCO (United Nations Educational, Scientific and Cultural Organization) (Braun 1998). In any case, complex structures of the reflection and regulation of biotechnological or biomedical practices have existed or have been emerging corresponding to nationally or institutionally specific traditions and cultures. In individual cases of dispute, convergent or contrary positions result from the specificities of the different contexts. Overall, since the mid-1970s, bioethics has been transformed from a primary instance of criticism to one that legitimises the bioscientific and biotechnological progress. In this process, utilitarian discourses and calculations have gained much

terrain (Brenner 2000; Braun 2000). Nevertheless, bioethics remains an area whose evolution is difficult to predict – and as such it will generate, influenced by the specific social and political cultures, reflections, disputes, and other social responses to the biotechnology development.

Acceptance policy concerns the implementation of new science and technology mainly by way of public communication. It is to serve the improvement of the social and cultural integration of scientific and technological developments as well as of their actors. By trying to shape the public's perceptions and attitudes, it also influences innovation. "Acceptance" has become both a political and a scientific concept linked up with the perception and handling of problems such as resistance to new technologies. Approaches that aim at improving the levels of acceptance prevail; often, they are supported by sociological or psychological research on "public information" and "risk communication". The constellations of non-/acceptance are determined by a variety of factors – about which studies of the "public understanding of science and technology" provide at least some information – and, under certain circumstances, they are subject to greater and even abrupt fluctuations (Plough and Krimsky 1987; Wynne 1995). There is a general difference between the acceptance and the acceptability of technologies that can contribute to explaining, both, the problems of acceptance and aspects of the social significance of certain technologies or products. This can be shown in particular by comparative case studies. The regime form of acceptance policy has been primarily technocratic. However, approaches have emerged that emphasise more seriously the possibility of public participation and conflict moderation (Bora 2000; Fischer 2000). Basically, acceptance policies from the promoters are embroiled in the counter-acceptance policies of opponents, giving rise to social structures of greater or less durability. Their frame of reference is mostly

national – analogous to the extension of the public. At supranational or international levels, initiatives for the coordination of acceptance policy have emerged as well as forums of debate that include influential representatives of organisations that are critical of genetic engineering.

2.3 The distribution of governance capacities among actors

The regime configuration sketched out above can now be interpreted with regard to the governance capacities of the main institutional actors – science, companies, nation states, supranational organisations, international organisations, and NGOs – as given at the national, supranational, and international levels of the various regime areas. This enables us to analyse the distribution of power among the different actors.

Science is important above all as the institutionalised form of research and technology development, and as an organised lobby for its interests. Scientific knowledge and breakthroughs are an essential condition for the possibility of a new biotechnology – with R&D taking place in academic and industrial form. For this reason it is frequently referred to as a new field of a knowledge-based industry. The scientists engaged in a discipline relevant to biotechnology have become subjects of a new entrepreneurship, they have either founded enterprises in parallel to their scientific activity or they have pursued the commercialisation of their research in various other ways – through patent applications, consulting activities for or cooperative projects with industry. Because it plays a leading role in technological progress, scientific expertise is a primary source in the formulation of visions for biotechnology development. Such visions influence the exploration of future paths of technology development, the funding and institutional framing as well as the social perception and enculturation of biotechnology. Scientific expertise is crucial for the evaluation of the

"dominant state of science and technology" that – under a liberal constitution of society – determines the risk management to a large extent. Hereby, the majority opinion that prevails scientifically is the one that counts. Organised science represents the main lobby for scientific interests at the national level and plays at least an advisory function in policy processes. In addition, targeted lobbying activity can be observed particularly at the supranational level where it aims at influencing decisions concerning research funding and regulation according to its own priorities. In heated social controversies, the statements of prominent scientists are especially important as they are considered independent voices in the information of the public.

Companies are the main actors of innovation in biotechnology. They carry out a substantial part of R&D and pursue the marketing of products. Both old and new enterprises are involved, i.e. established companies in traditional sectors and enterprises forming on the basis of the new biotechnology. The innovation processes take place in a variety of forms that are framed, promoted, or funded by the state; they are in part historically new and extend from the regional to the international level. Along with a technological reorganisation in industry, intensive concentration and centralisation between pharmaceutical, chemical, and agro-industrial companies has been taking place. Companies pursue lobbying in the light of their interests in innovation – above all with respect to the funding and institutional support of R&D, the regulatory framework concerning risk management, patenting, biodiversity, and bioethics. Activities of this kind are carried out by lobby organisations at national or supranational levels or by dedicated in-company policy departments. In countries with a strong corporatist tradition such as Germany, companies can be part of a continuous institutionalised arrangement with government and trade unions, hereby revealing a modifying tendency towards "competitive corpora-

tism". In a number of cases, companies also take part in international negotiations such as the CBD. Companies that are exposed to the public, particularly in the pharmaceutical and agro-industrial sectors, pursue a variety of acceptance policy initiatives by disseminating information to specific constituencies, or by participating in organised dialogue and consensus conferences.

Nation states provide the main frame of reference for the regulation and enculturation of biotechnology, as well as for the generation of biotechnology to the extent that this takes place within the framework of national systems of innovation. However, these systems are involved in more – in the case of Germany – or less – in the case of the USA – powerful processes of reorganisation due to global transformations. The capacities for action of the nation state are accentuated both with regard to innovation and regulation, and to some extent they are limited by the fact that they are oriented towards technology race and regime competition. Given the worldwide comparison of R&D and industry locations in the case of transnational technology development, this does not come as a surprise. It is the nation states that promote domestic science and industry according to specific criteria and priorities, that sign international agreements, that set up supra-national organisations and that, as their members, surrender powers to them and to international organisations – above all the WTO – or that negotiate and act within their framework. Such supra-national or international regimes create a level above the nation states, which disempowers these nation states to the extent that their provisions, organisational forms, and sovereignty has become of subordinate importance.

While amongst the *supranational organisations*, NAFTA (North American Free Trade Agreement) merely works as a free trade area the EU constitutes a considerably more advanced project for technological, institutional, and political integration. It has become

increasingly relevant for the development of technologies, and it influences the different biotechnological regime areas in various ways. One of the EU's prime objectives consists of promoting competitiveness and innovation capacities within the EU. Important measures in this regard include pre-competition research funding and the promotion of a coordinate R&D infrastructure across the member states – for instance in order to extend as well as bundle competences, and to avoid duplicate research – and, specifically for biotechnology, to shape the frameworks of risk management, patenting, or public acceptance according to those tasks. Alongside a clear focus on strengthening European science and industry in the global economy, occasionally contradictory or conflicting regulations promote the precautionary principle with respect to health and environmental protection, or the improvement of living standards.

International organisations are especially relevant for the development of biotechnology as concerns its quality as a transnational technology. The OECD has above all been effective as a forum for discussing the importance of biotechnology as a future key technology and the various requirements that its promotion and implementation imply – such as the appropriate approaches to risk management or patenting. The UN and its various specialised agencies or programmes – above all FAO, WHO, and UNEP (United Nations Environment Programme) – are important for the biotechnology development, particularly with respect to issues concerning developing countries and the relationship between the global North and South. These organisations deal with various and, in part, overlapping aspects. A significant source of conflict is their relationship with the institutions of the liberal world-market order such as the IMF (International Monetary Fund), the World Bank, and the WTO – or the USA to the extent that it questions the legitimacy of the UN as a factor in world politics. In

a way, the WTO acts as the supreme regulatory instance since its far-reaching rules for international trade essentially govern the world trade regime, respectively the articulation of the rights and duties of corporations and nation states. Within this framework, the non-/admissibility of import restrictions and export subsidies, or of social and environmental standards are negotiated. A prominent source of conflict is the harmonisation between WTO and CBD as concerns the agreement on the Biosafety Protocol, or the shape of the biotechnological patent regime. After the failure of the WTO Conference of Ministers in Seattle in late autumn 1999, the current state of market liberalisation as a political project has emerged more clearly: Despite a rhetoric that asserts the necessity to continuously advance liberalisation, the structure of the world market still comprises a variety of protectionist mechanisms that concern particular sectors of industry and trade, or countries. Therefore, the future of market liberalisation will be determined by the further course of political negotiations and by shifts in the balances of power.

NG0s have been important for the development of critical perspectives and positions concerning various aspects of the generation and regulation of biotechnology.[5] In this way they have also exercised considerable influence at early stages of the enculturation of biotechnology. While their criticism has addressed the entire range of issues related to biotechnology, the NGOs do not speak with a single voice and their unity remains abstract: the cognitive and practical focus of the individual organisations can be very selective and the respective goals may also contradict each

5 To some extent, it is misleading to speak of NGOs, since this term was only created in the 1980s reflecting the transformation of the organisational mode of the new social movements; on the other hand, the meaning of NGOs is too narrow since other social organisations (such as trade unions or the churches) have influenced the public debate on biotechnology over a longer period of time, which are better not referred to as NGOs.

other. While certain NGOs have been formed to deal with specific biotechnology issues, others pre-existed biotechnology or earlier have dealt with a broader spectrum of policy issues. In addition, NGOs can be distinguished according to the ways in which they pursue counter-acceptance policies. A historically new process is constituted by the fact that NGOs have become participants in international politics as a consequence of the Rio process (Altvater et al. 1997). This has contributed to the NGOs creating transnational networks between significantly divergent political positions and across power asymmetries.

3. Conclusions and outlook

The analysis has shown that the factors determining the emergence and structure of the biotechnology regime are widely divergent in their nature, they affect varying dimensions and levels of spheres of activity and objects of regulation, they involve political and other institutions and actors in different ways, whereby they give rise to structures of different qualities and potentials for conflict that are subject to more or less dynamic change. Manifold interdependencies exist between the generation and re-/configuration of biotechnology, the biotechnology regime, society, and the global order. The historical and political contexts of biotechnology development to date have pronouncedly structured the general pattern of forces and the positions within it. Against this background, the interactive dynamic between opposing strategies and marked shifts in the constellation of conflicts are more clearly visible. However, it is not yet clear how networks of actors and strategies are formed and become active, how they are extended or become fragmented and reorganised in individual fields. Moreover, events in different countries, with their specific institutional and cultural conditions, are highly varied.

With respect to how biotechnology is shaped in comparative perspective, biotechnology (as based in the fields of molecular biology and genetic engineering) is a trend in scientific and technical development, which is still at a very early stage of its technological and economic life cycles. It has certainly made considerable progress in some areas of development and application (e.g. pharmaceuticals and diagnostics in biomedicine, plant breeding in agriculture, food production and processing, or the production of enzymes and amino acids). It is also expected to make progress in other areas over the next few years (e.g. the regeneration of raw materials and environmental biotechnology), but in other fields its prospects are much more uncertain and speculative (e.g. in bioelectronics and neuroinformatics). Biotechnology, as a series of strategies and methods for studying and exploiting the genetic make-up of organisms and their biological functions, has become an important – even indispensable – factor in the gamut of basic or applied research areas but, as a source of innovative products and production processes, its success has been rather ambivalent. In consequence, biotechnology does not yet constitute a new techno-economic paradigm or technological regime. Since its cross-sectoral character does not qualify biotechnology as a key technology, a complex set of factors determines which of the multiple areas of application are being developed, and how they are being realised. These factors include the scale and the profit margins of the corresponding markets, the R&D and sectoral infrastructures, the ratio between what is already known and what is still to be researched, the variety of potential applications, technological feasibility and social desirability. However, as biotechnology has become a factor in global economic competition, it is being treated as a strategic factor in the struggle for new and existing markets. It is an arena where it will be decided who shall eventually belong to the haves and who to the have-nots of the global economy.

The social configuration of biotechnology governance exhibits a complex structure that extends across national, regional, and local as well as supra- and international levels. Since biotechnology has emerged as a transnational technology, the particular articulation of the different levels of the biotechnology regime respectively the distribution of the capacities among the actors involved determines what the specific quality of the transnational biotechnology governance will be. Yet, the international level is of particular importance with respect to the global governance of biotechnology also in terms of the global governance capacities. The international regimes of particular relevance to biotechnology are above all the regimes of biodiversity, bioethics, patenting, world trade, and risk management. The most complex are the connections between the world trade and the biodiversity regime as represented by the WTO and the CBD. The Biosafety Protocol, which regulates the transnational transfer and use of genetically modified organisms, provides for the first time rules of biotechnological risk management at an international level. The compromise reached in Montreal in January 2000 establishes a multilateral environmental agreement according to which it is to be treated as equal to (and not subordinate to) the WTO regulations. Correspondingly, trade restrictions imposed at national level for reasons of health and environmental protection are generally permitted but depend on a scientific risk assessment (Schomberg 2000). While the structure of conflict between the liberal world trade and restrictive risk policies is global, the policies related to intellectual property rights affect above all conflicts between North and South. In fact, the relationship between the TRIPs and the CBD has been a source of intense controversy, since the principles of the first aim at globally generalised rules of intellectual property rights (although at present allowing countries to implement "sui generis" systems of plant variety rights, for instance),

whereas the principles of the latter aim at provisions favouring countries from the South with respect to the different developmental, environmental, and social tasks of the CBD (Henne 1998; Heins 2000).

The CBD has worked as an important forum for promoting sustainable development, hereby providing elements of global politics. However, this quality is relatively weak compared to the forces of transnational regime competition on the one hand and to the power of the institutions that promote the liberal world-market order such as the WTO on the other. Nevertheless, as every social order, even the global market is open to change up to a certain extent. An indication for this feature is provided by the disputes on rBST (a recombinant bovine growth hormone) between the USA and the EU within the WTO as well as by the Biosafety Protocol that was agreed upon right after the failure of the Seattle "Millennium Round". In other words, they demonstrate that the shaping and structuring of regimes is dependent on balances of power and political bargaining. Generally, the impacts of markets do not follow universal, uniform patterns, but, instead, develop according to their legal and cultural environments. A crucial question therefore concerns the extent to which potential from democracy and civil society can be mobilised – across the various levels of the regimes – against a dominant, free-market driven globalisation.[6]

The hope invested in biotechnology by its most enthusiastic

6 Against this background, it can be stated with respect to the three perspectives on global governance mentioned briefly that the normativ-emphatic perspective allows us to grip on some aspects of advancement in international politics; however, scepticism is due above all to its largely positive judgements. The political-strategic perspective offers an important perspective of reform; however it must be given more concrete form – especially in the light of appellative attitudes. The empirical-analytic perspective is a precondition for improved political options – as well as what should initially be the main business of social scientists.

promoters, namely that the fundamental growth crisis could be resolved through scientific and industrial conquest of the "new continent of life", has been deceived. The other major promises of biotechnology, that it will contribute to the solution of the great human problems of hunger, disease, and the destruction of the environment, also appear as somewhat double-edged, at the very least. Hunger is first and foremost a social problem of unjust distribution while biotechnology will certainly be able to help increase the productivity of agriculture and food production (Buttel 1995). Biomedicine will be able to make countless contributions to the treatment of disease but many illnesses will remain unexplored and untreated – despite the technical feasibility – because the market or the patients – the clients – are not considered to be of economic interest. Biotechnologies could well contribute to an escalation of environmental problems, yet, it could also lead to their reduction or even solution – although the destruction of the environment can be solved obviously only to a limited extent by way of technological means, and a positive contribution is to be expected rather from a sustainable modification of production and lifestyles (Krimsky and Wrubel 1996).

The idea that the development of science and technology follows an autonomous dynamic is a common misunderstanding. Instead, the processes are linked to certain interests and strategic decisions, socio-technological projects and conditions of use, all of which can be shaped to a greater or lesser extent. Therefore, the evolution of molecular biology or genetic engineering does not follow an inherent logic, as is sometimes suggested by its strongest opponents, but it is the product of a social decision: It is a societal choice to use genetic screening to avoid the employment of potentially susceptible people instead of making the workplace safe; to privatise health risk instead of maintaining or producing systems for social solidarity; to completely dissociate from

developing countries as suppliers of raw materials when these can be biotechnologically reproduced.

In the final analysis, biotechnology provides options that may fit into a framework of neo-liberal or, instead, of sustainable social development. Consequently, the approach to government and policy choices determines how the development and application of biotechnology will proceed, whereby the requirements of how to govern biotechnology do result from science and technology as well.

The more recent debate on governmentality provides an interesting view on the principles that govern the relationships between institutions, discourses, and practices. It denotes the basic "government mentalities" (Miller and Rose 1990; Lemke 1997). In my view, this conceptual idea (that mainly developed in a Foucauldian tradition) can be very useful if functionalist assumptions are avoided. Reflecting the fact that, despite its remarkable speed, biotechnology is still at an early stage of its development, the following conclusion can be drawn: No matter how neo-liberal the regimes of generating (and maybe also of regulating) biotechnology may be, we cannot speak yet of a neo-liberal governmentality as the unifying principle that guides the social appropriation and enculturation of biotechnology, or that characterises the social configuration of biotechnology in general.

Literature

Abels, Gabriele. 2000a. Das globale Genom: Forschung und Forschungspolitik zum menschlichen Genom zwischen Kooperation und Konkurrenz. In *Biotechnologie – Globalisierung – Demokratie. Politische Gestaltung transnationaler Technologieentwicklung*, edited by D. Barben and G. Abels. Berlin: Edition Sigma.

–. 2000b. *Strategische Forschung in den Biowissenschaften*. Berlin: Edition Sigma.

Altvater, Elmar, Achim Brunnengräber, Markus Haake, and Heike Walk, eds. 1997. *Vernetzt und verstrickt. Nicht-Regierungs-Organisationen als gesellschaftliche Produktivkraft*. Münster: Westfälisches Dampfboot.

Altvater, Elmar, and Birgit Mahnkopf. 1996. *Grenzen der Globalisierung. Ökonomie, Ökologie und Politik in der Weltgesellschaft*. Münster: Westfälisches Dampfboot.

Amin, Samir, Giovanni Arrighi, Andre Gunder Frank, and Immanuel Wallerstein. 1982. *Dynamics of Global Crisis*. New York: Monthly Review Press.

Barben, Daniel. 1997a. Ungleichzeitigkeiten und Ungleichmäßigkeiten zwischen wissenschaftlich-technischer, diskursiver und institutioneller Entwicklung der Biotechnologie. Beobachtungen zum Stand der Biotechnologie und Rückschlüsse für ihre sozial- und politikwissenschaftliche Erforschung. In *Politik und Biotechnologie. Die Zumutung der Zukunft*, edited by R. Martinsen. Baden-Baden: Nomos.

–. 1997b. Genese, Enkulturation und Antizipation des Neuen. Über Schwierigkeiten und Nutzen, Leitbilder der Biotechnologie zu re-konstruieren. In *Technikgenese. Befunde aus einem Forschungsprogramm*, edited by M. Dierkes. Berlin: Edition Sigma.

–. 1997c. Neoliberale Formierung der Biotechnologie? Zur Hegemoniegewinnung einer flexiblen Strategie. *Das Argument 220* 39 (3):383-395.

–. 1998a. Genese und Wirkungen biotechnologischer Regime. Elemente einer erweiterten Regimeanalyse. *Österreichische Zeitschrift für Politikwissenschaft* 27 (1):47-61.

–. 1998b. The Political Economy of Genetic Engineering. The Neoliberal Formation of the Bio-technology Industry. *Organization & Environment* 11 (4):406-420.

–. 1999a. Ein "neuer Kontinent des Lebens"? Regime der Ent- und Begrenzung biotechnologischer Industrialisierung. In *Grenzenlose Gesellschaft? Verhandlungen des 29. Kongresses der Deutschen Gesellschaft für Soziologie, des 16. Kongresses der Österreichischen Gesellschaft für Soziologie, des 11. Kongresses der Schweizerischen Gesellschaft für Soziologie in Freiburg i.Br. 1998*. Teil 2, edited by C. Honegger, S. Hradil and F. Traxler. Opladen: Leske + Budrich.

–. 1999b. Leitbildforschung. In *Handbuch Technikfolgenabschätzung*, edited by S. Bröchler, G. Simonis and K. Sundermann. Berlin: Edition Sigma.

–. 1999c. Social Studies of Contested Technologies. The Case of Biotechnology and Genetic Engineering. *Swiss Journal of Sociology/Schweizerische Zeitschrift für Soziologie* 25 (3):449-458.

Barben, Daniel, and Gabriele Abels, eds. 2000. *Biotechnologie – Globalisierung – Demokratie. Politische Gestaltung transnationaler Technologieentwicklung*. Berlin: Edition Sigma.

Barben, Daniel, and Maria Behrens. 2001. Internationale Regime und Technologiepolitik. In *Politik und Technik. Analysen zum Verhältnis von technologischem, politischem und staatlichem Wandel am Anfang des 21. Jahrhunderts. PVS-Sonderheft 31*, edited by G. Simonis, R. Martinsen and T. Saretzki. Wiesbaden: Westdeutscher Verlag.

Bora, Alfons. 2000. Verhandeln und Streiten im Erörterungstermin: Zur Bürgerbeteiligung in gentechnikrechtlichen Genehmigungsverfahren. In *Biotechnologie – Globalisierung – Demokratie*, edited by D. Barben and G. Abels. Berlin: Edition Sigma.

Brand, Ulrich, Achim Brunnengräber, Lutz Schrader, Christian Stock, and Peter Wahl. 2000. *Global Governance: Alternative zur neoliberalen Globalisierung?* Münster: Westfälisches Dampfboot.

Braun, Kathrin. 1998. Zivilisation oder Dehumanisierung? Menschenrechtsschutz und internationales Bioethik-Regime. *Österreichische Zeitschrift für Politikwissenschaft* 27 (1):63-77.

–. 2000. Grenzen des Diskurses: Biomedizin, Bioethik und demokratischer Diskurs. In *Biotechnologie – Globalisierung – Demokratie*, edited by D. Barben and G. Abels. Berlin: Edition Sigma.

Brenner, Andreas. 2000. Den Rubikon überschreiten: Konsequentialistische Tendenzen in der Bioethik am Beispiel der Embryonenforschung. In *Biotechnologie – Globalisierung – Demokratie. Politische Gestaltung transnationaler Technologieentwicklung*, edited by D. Barben and G. Abels. Berlin: Edition Sigma.

Brunnengräber, Achim, and Christian Stock. 1999. Global Governance: ein neues Jahrhundertprojekt? *Prokla 116* 29 (3): 445-468.

Bud, Robert. 1993. *The Uses of Life. A History of Biotechnology*. Cambridge: Cambridge University Press.

Bull, Alan T., Geoffrey Holt, and Malcolm D. Lilly. 1982. *Biotechnology: International Trends and Perspectives.* Paris: OECD.

Buttel, Fred H. 1995. The Global Impacts of Agricultural Biotechnology: A Post-Green-Revolution Perspective. In *Issues in Agricultural Bioethics*, edited by B. Mepham, G. Tucker and J. Wiseman. Nottingham: Nottingham University Press.

Cantley, Mark. 1995. The Regulation of Modern Biotechnology: A historical and European Perspective. In *Biotechnology. Legal Economic and Ethical Dimensions*, edited by H.-J. Rehm and G. Reed. Weinheim: VCH.

CBD. 2000. *Convention on Biological Diversity: Official CBD Documents*. Montreal: United Nations, Secretariat of the Convention on Biological Diversity. http://www.biodiv.org/conv/cbd_documents.html

Codex. 2000. *Codex Alimentarius: FAO/WHO Food Standards*. Rom: United Nations, Food and Agriculture Organization, World Health Organization. http://www.fao.org/WAICENT/faoinfo/economic/ESN/codex/Default.htm

Cox, Robert W. 1987. *Production, Power and World Order. Social Forces in the Making of History*. New York: Columbia University Press.

–, ed. 1997. *The new realism: perspectives on multilateralism and world order*. Tokyo, New York: United Nations University Press, St. Martin's Press.

Crouch, Colin, and Wolfgang Streeck, eds. 1997. *Political Economy of Modern Capitalism: Mapping Convergence and Diversity*. London: Sage.

Daele, Wolfgang van den. 1997. Deregulierung: Die schrittweise "Freisetzung" der Gentechnik. In *Zukunft der Gentechnik*, edited by P. Brandt. Basel, Boston, Berlin: Birkhäuser.

Demirovic, Alex, Hans-Peter Krebs, and Thomas Sablowski, eds. 1992. *Hegemonie und Staat*. Münster: Westfälisches Dampfboot.

Dierkes, Meinolf, and Ute Hoffmann, eds. 1992. *New Technology at the Outset: Social Forces in the Shaping of Technological Innovations*. Frankfurt/M.: Campus.

Dolata, Ulrich. 2000. Hot House – Konkurrenz, Kooperation und Netzwerke in der Biotechnologie. In *Biotechnologie – Globalisierung – Demokratie. Politische Gestaltung transnationaler Technologieentwicklung*, edited by D. Barben and G. Abels. Berlin: Edition Sigma.

Dosi, Giovanni. 1982. Technological paradigms and technological trajectories. *Research Policy* (11):147-162.

Dosi, Giovanni, and Luigi Orsenigo. 1988. Coordination and transformation: an overview of structures, behaviours and change in evolutionary environments. In *Technical Change and Economic Therory*, edited by G. Dosi, C. Freeman, R. Nelson, G. Silverberg and L. Soete. London: Pinter Publishers.

Fischer, Frank. 2000. Citizens and Experts in Biotechnology Policy: The Consensus Conference as Alternative Model. In *Biotechnologie – Globalisierung – Demokratie. Politische Gestaltung transnationaler Technologieentwicklung*, edited

by D. Barben and G. Abels. Berlin: Edition Sigma.

Flitner, Michael, Christoph Görg, and Volker Heins, eds. 1998. *Konfliktfeld Natur. Biologische Ressourcen und globale Politik*. Opladen: Leske + Budrich.

Freeman, Chris, and Luc Soete. 1997. *The Economics of Industrial Innovation*. 3 ed. Cambridge/Mass.: MIT Press.

Freeman, Christopher. 1993. Technical Change and Technological Regimes. In *The Elgar Companion to Institutional and Evolutionary Economics*, edited by G. M. Hodgson, W. J. Samuels and M. R. Tool. Aldershot: Edward Elgar.

Gill, Stephen, ed. 1997. *Globalization, Democratization and Multilateralism, International Political Economy Series: Multilateralism and the UN System*. New York: St. Martin's Press.

Gill, Stephen, and James H. Mittelman, eds. 1997. *Innovation and Transformation in International Studies*. Cambridge/UK, New York, Melbourne: Cambridge University Press.

Global Governance, Commission on. 1995. *Our global neighborhood: the report of the Commission on Global Governance*. Oxford, New York: Oxford University Press.

Heins, Volker. 2000. Modernisierung als Kolonialisierung? Interkulturelle Konflikte um die Patentierung von "Leben". In *Biotechnologie – Globalisierung – Demokratie. Politische Gestaltung transnationaler Technologieentwicklung*, edited by D. Barben and G. Abels. Berlin: Edition Sigma.

Heintz, Bettina. 1998. Die soziale Welt der Wissenschaft. Entwicklungen, Ansätze und Ergebnisse der Wissenschaftsforschung. In *Wissenschafts- und Technikforschung in der Schweiz. Sondierungen einer neuen Disziplin*, edited by B. Heintz and B. Nievergelt. Zürich: Seismo.

Henne, Gudrun. 1998. *Genetische Vielfalt als Ressource. Die Regelung ihrer Nutzung*. Baden-Baden: Nomos.

–. 2000. Bioprospektierung: Auf dem Weg zu einem neuen Nord-Süd-Verhältnis. In *Biotechnologie – Globalisierung – Demokratie. Politische Gestaltung transnationaler Technologieentwicklung*, edited by D. Barben and G. Abels. Berlin: Edition Sigma.

Hirsch, Joachim. 1998. *Vom Sicherheitsstaat zum nationalen Wettbewerbsstaat*. Berlin: ID Verlag.

Hübner, Kurt. 1989. *Theorie der Regulation. Eine kritische Rekonstruktion eines neuen Ansatzes der Politischen Ökonomie*. Berlin: Edition Sigma.

Jasanoff, Sheila, Gerald E. Markle, James C. Petersen, and Trevor Pinch, eds. 1995. *Handbook of Science and Technology Studies*. Thousand Oaks, London, New Delhi: Sage.

Jessop, Bob. 1995. The regulation approach, governance and post-Fordism: alternative perspectives on economic and political change. *Economy and Society* 24 (3):307-333.

Keeley, James F. 1990. Toward a Foucauldian analysis of international regimes. *International Organization* 44 (1):83-105.

Kenney, Martin. 1986. *Biotechnology: The University-Industrial Complex*. New Haven, London: Yale University Press.

Keohane, Robert O., and Joseph S. Nye. 1989. *Power and Interdependence*. 2 ed. New York: Harper Collins Publishers.

Kohler-Koch, Beate, ed. 1986. *Technik und internationale Politik*. Baden-Baden: Nomos.

Kohler-Koch, Beate, and Thomas Schaber. 1994. Regimeanalyse. In *Lexikon der Politik. Politikwissenschaftliche Methoden*, edited by J. Kriz, D. Nohlen and R.-O. Schulze. München: Beck.

Krasner, Stephen D., ed. 1983. *International Regimes*. Ithaca, London: Cornell University Press.

Krimsky, Sheldon. 1985. *Genetic Alchemy: The Social History of the Recombinant DNA Controversy*. Cambridge/Mass.: MIT Press.

Krimsky, Sheldon, and Roger Wrubel. 1996. *Agricultural Biotechnology and Environment*. 1 ed. Urbana and Chicago: University of Illinois Press.

Latour, Bruno, and Steve Woolgar. 1986. *Laboratoy Life: The Construction of Scientific Facts*. Princeton: Princeton University Press.

Lederberg, Joshua, ed. 1999. *Biological Weapons: Limiting the Threat, Basic Studies in International Security*. Cambridge/Mass.: MIT Press.

Lemke, Thomas. 1997. *Eine Kritik der politischen Vernunft. Foucaults Analyse der modernen Gouvernementalität*. Hamburg: Argument.

Lenoir, Timothy. 1997. *Instituting Science: The Cultural Production of Scientific Disciplines*. Stanford: Stanford University Press.

Lipietz, Alain. 1985. Akkumulation, Krisen und Auswege aus der Krise. Einige methodologische Anmerkungen zum Begriff der "Regulation". *Prokla* 58:109-137.

–. 1993. *Berlin, Bagdad, Rio: das 21. Jahrhundert hat begonnen*. Münster: Westfälisches Dampfboot.

–. 1998. *Grün. Die Zukunft der Politischen Ökologie*. Wien: Promedia.

Martinsen, Renate, and Georg Simonis, eds. 1995. *Paradigmenwechsel in der Technologiepolitik*. Opladen: Leske + Budrich.

Mayntz, Renate. 1995. Akteurzentrierter Institutionalismus in der Technikforschung. Fragestellungen und Erklärungsansätze. In *Jahrbuch Technik und Gesellschaft, Band 8: Theoriebausteine der Techniksoziologie*, edited by J. Halfmann, G. Bechmann and W. Rammert. Frankfurt/M.: Campus.

Mayntz, Renate, and Fritz W. Scharpf. 1995. Der Ansatz des akteurzentrierten Institutionalismus. In *Gesellschaftliche Selbstregelung und politische Steuerung*, edited by R. Mayntz and F. W. Scharpf. Frankfurt/M.: Campus.

Merkle, Rüdiger. 1994. *Der Codex Alimentarius der FAO und WHO. Die Entwicklung von Codex Standards und deren Auswirkungen auf das Europäische Gemeinschaftsrecht und die nationalen Lebensmittelrechte*. Bayreuth: PCO.

Messner, Dirk, and Franz Nuscheler, eds. 1996. *Weltkonferenzen und Weltberichte. Ein Wegweiser durch die internationale Diskussion*. Bonn: Dietz.

Miller, Peter, and Nikolas Rose. 1990. Governing economic life. *Economy and Society* 19 (1):1-31.

Mürle, Holger. 1998. *Global Governance. Literaturbericht und Forschungsfragen. INEF-Report, Heft 32*. Duisburg.

Nelson, Richard R., ed. 1993. *National Systems of Innovation*. Oxford, New York: Oxford University Press.

Nelson, Richard R., and Sidney G. Winter. 1977. In Search of a Useful Theory of Innovation. *Research Policy* 6 (1):36-77.

OTA. 1989. New Developments in Biotechnology: Patenting Life. Special Report. Washington, D.C.: U.S. Congress, Office of Technology Assessment.

–. 1990. Biotechnology in a Global Economy. Washington, D.C.: U.S. Congress, Office of Technology Assessment.

Perez, Carlota. 1983. Structural Change and the Assimilation of New Technologies in the Social System. *Futures* 15 (5):357-375.

Pickering, Andrew, ed. 1992. *Science as Practice and Culture*. Chicago: University of Chicago Press.

Plough, Alonzo, and Sheldon Krimsky. 1987. The Emergence of Risk Commu-

nication Studies: Social and Political Context. *Science, Technology, & Human Values* 12 (3/4):4-10.

Protocol. 2000. *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*. Montreal. http://www.biodiv.org/biosafe/Protocol/Index.html

Rammert, Werner. 1993. T*echnik aus soziologischer Perspektive*. Opladen: Westdeutscher.

–. 1994. Die Technik in der Gesellschaft: Forschungsfelder und theoretische Leitdifferenzen im Deutschland der 90er Jahre. In *Mitteilungen Heft 13*, edited by Verbund Sozialwissenschaftliche Technikforschung. Köln: Max-Planck-Institut.

Rittberger, Volker, ed. 1990. *Theorien der Internationalen Beziehungen. Bestandsaufnahme und Forschungsperspektiven. PVS Sonderheft 21*. Opladen: Westdeutscher.

Rosenau, James N. 1992. Governance, order, and change in world politics. In *Governance without Government: Order and Challenge in World Politics*, edited by J. N. Rosenau and E.-O. Czempiel. Cambridge, New York, Melbourne: Cambridge University Press.

Sakamoto, Yoshikazu. 1994. A perspective on the changing world order: A conceptual prelude. In *Global transformation. Challenges to the state system*. Tokyo, New York, Paris: United Nations University Press.

Scharpf, Fritz W. 1988. Verhandlungssysteme, Verteilungskonflikte und Pathologien der politischen Steuerung. In *Staatstätigkeit*, edited by M. G. Schmidt. Opladen: Westdeutscher.

–. 1996. Föderalismus und Demokratie in der transnationalen Ökonomie. In *Politische Theorien in der Ära der Transformation*, edited by K. Beyme and C. Offe. Opladen: Westdeutscher.

Schomberg, René von. 2000. Agricultural Biotechnology in the Trade-Environment Interface: Counterbalancing Adverse Effects of Globalization. In *Biotechnologie – Globalisierung – Demokratie. Politische Gestaltung transnationaler Technologieentwicklung*, edited by D. Barben and G. Abels. Berlin: Edition Sigma.

Straus, Joseph. 1995. Biotechnology and Intellectual Property. In *Biotechnology: Legal, Economic and Ethical Dimensions*, edited by H.-J. Rehm and G. Reed. Weinheim: VCH.

TRIPs. 1994. Agreement on Trade-Related Aspects of Intellectual Property Rights. Genf: World Trade Organization. http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

UNEP. 1995. *Global Biodiversity Assessment*. Cambridge/UK, New York, Melbourne: Cambridge University Press.

Weingart, Peter, ed. 1989. *Technik als sozialer Prozeß*. Frankfurt/M.: Suhrkamp.

Winner, Langdon. 1977. *Autonomous Technology. Technics-out-of-Control as a Theme in Political Thought*. Cambridge/Mass., London: MIT Press.

Woolgar, Steve. 1988. *Science: The very idea*. Chichester, London, New York: Ellis Horwood, Tavistock.

Wynne, Brian. 1995. Public Understanding of Science. In *Handbook of Science and Technology Studies*, edited by S. Jasanoff, G. E. Markle, J. C. Petersen and T. Pinch. Thousand Oaks, London, New Delhi: Sage.