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RECENT CHALLENGES IN THE SOCIAL REGULATION OF NEW EMERGING TECHNOLOGIES: THE CASE OF SYNTHETIC BIOLOGY

Abstract. *Synthetic biology represents one of the most promising areas of progress in the new emerging technologies. It is a transdisciplinary area of research that combines molecular biology, engineering, biochemistry, computer sciences and other disciplines in new practices of biological design that are diverse in their approaches and full of hope in their promises. In the article, synthetic biology is presented as a good case for understanding the wider ethical, legal and social aspects of recent progress in the new emerging sciences and technologies. More specifically, the precarious issues of risk, commodification and legal protection, which are the central points of discussion in the article, are emerging as salient points not only in this technological "niche", but in practically all modern technologies.*
Keywords: *synthetic biology, governance of technological risk, precautionary principle, proactionary principle, intellectual property right, free access to knowledge*

Introduction

We are living in a time marked by tremendous progress in the new emerging technologies that represent the crucial factor for the progress of modern societies and for humanity as a whole. We are thus faced with the daunting challenge of how to create adequate models for the social regulation of these technologies. Consequently, in the field of social sciences, researchers from different disciplinary, theoretical and methodological backgrounds need to cooperate in order to properly explore all the possible dimensions and social implications of developments in the new emerging technologies. It is becoming increasingly important to integrate different theoretical and methodological perspectives, as the impacts of these technologies on society in the near future will be probably be so extensive that the usefulness of even the most fundamental rationales of contemporary social science approaches will be

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called into question. In this sense, the use of traditional social science explanations is rapidly becoming obsolete. Because of the anticipated radical social changes that will result from the foreseen technological progress, the need to replace existing monodisciplinarily-based explanations with more reflexive and transdisciplinary approaches is growing. Although some critics of the concept of transdisciplinarity are warning that we still know little of how this concept operates in practice, it is nonetheless heuristic useful in explaining many facets of modern technological progress. Namely, never before in the history of technological development have the new technologies been so strongly internally and externally interconnected, and in this regard the reflexive, inter- and transdisciplinary approach can help highlight many issues connected with the social regulation of the new emerging technologies.

In such inter- and transdisciplinary approaches, collaboration between natural and social scientists is becoming both an increasingly important activity and a crucial site of inquiry. Such collaboration is especially important in two respects. First, social scientists are expected to provide natural scientists with a contextual awareness of the interdependencies among science, technology and society, thus allowing broader social perspectives to have a greater influence on the design and conduct of science and technology, and their outcomes. Second, social scientists are expected to learn at least the basic premises of the new emerging technologies and the conditions of their emergence, allowing them to provide more elaborate and better assessments of the social impacts, and to suitably interact with various concerned publics.

Despite some controversial assessments, we can say that we are living in the most exciting historical period of science and technology development, with the new "techno-sciences" strongly interconnected and supporting each others' progress. Cognitive and institutional convergences are further radically transforming the whole configuration of modern science and technology. In the future, basic scientific and technological breakthroughs will even more strongly depend on the ability of researchers (as well as other stakeholders) to cross disciplinary and sectoral boundaries. Synthetic Biology (SB) represents one of the most promising areas in the progress of the new emerging technologies.[1] It is often described as a converging technology in the sense that it brings together different areas of research.[2] Further,

[1] *The current understanding of synthetic biology is mostly the result of a successful framing of the field by three different groups: the Biobricks Foundation/iGEM Community at MIT with Drew Endy, the SynBio group at Berkely with Jay Keasling, and J. Craig Venter and his researchers at the J. Craig Venter Institute (Torgesen et al., 2010).*

[2] *Actually, the concept of converging sciences and technologies was first introduced by the group of experts at the US National Science Foundation in 2002 (Roco and Bainbridge, 2005). At the time, visions of some 100 potential revolutionary breakthrough applications of converging technologies have been formulated, including those pertaining to the creation of artificial life.*

SB is an emerging field that combines molecular biology, engineering, biochemistry, computer sciences and other disciplines into new practices of biological design that are both diverse in their approaches and full of hope in their promises. Its aim is to apply standardized engineering techniques to biology and thereby create organisms or biological systems with novel or specialized functions that could be used to address numerous needs. SB is also characterized as being a key or enabling technoscience, because its advance can lead to progress in virtually all technology-enabled sectors.

In our article, we will primarily try to show that SB provides an excellent example for understanding some of the wider ethical, legal and political issues and dilemmas connected with the social regulation of new emerging technologies. In the first section, we will attempt to briefly show whether SB is mainly viewed as a linear continuation of genetic engineering or whether it represents a "game changer" in the development of new emerging technologies. Namely, the question of which model of social regulation would be most adequate strongly depends on the definition of SB. In the second section, we will focus on one of the biggest challenges for contemporary social regulation of SB, i.e. the issue of how to simultaneously leverage a promising technology's anticipated benefits while protecting against its potential risks. Finally, in the third section, we will try to point out that the new tools for the modularization of biological structures in the framework of SB are leading to increased processes of commodification in SB. Consequently, the current debate concerning the social regulation of SB is characterized by numerous conflicts between the adherents of open access to knowledge and the advocates of intellectual property rights protection. Namely, the issue of intellectual property rights in SB is very complex and controversial, and further, presents national and transnational stakeholders with many challenges.

The strategy of the double rhetoric: is synthetic biology "everything the new" or "everything the same"?

The social regulation of SB holds many complex and controversial facets, and thus poses a big challenge for modern societies. Looking at the recent progress in SB, we are on the one hand encountering highly visionary assessments that it will lead to the design of "de novo" artificial parts or systems in the biological world. At this time, the potential realization of such visions remains speculative, and the likelihood of creating life from nonliving components ("from scratch") mainly remains in the remote (though foreseeable) future. On the other hand, teams of experts from many of the technologically most progressive countries have already produced roadmaps for many of the main applications of SB expected in next few decades. Such

potential applications include biosensors permanently residing in body, adaptive antibiotics, enzymes that can break down a much wider range of biomass types into useful materials, and biologically engineered substitutes for products that are currently derived from petroleum (for more, see: The Royal Academy of Engineering, 2009).

In such circumstances, practically all concerned social actors are faced with the question of whether and how we can design an adequate model of social regulation that will be able to deliver the predicted outcomes (applications) in a more or less predictable and controllable way, similar to models for the social regulation of technologies that have emerged in the past, for example ICT. Which regime of governance should be used to regulate SB? The answer to this question strongly depends on the basic definition of SB.

If SB is seen as a linear continuation of former, related (genetic) technologies, social actors would be hard pressed to justify demands for completely new models of social regulation for SB. Even when experts do emphasize the innovative character of SB, they still tend to argue that its associated ethical dilemmas and risk issues can be adequately dealt with by existing regulatory regimes, originally established in the framework of "traditional" genetic engineering. In this sense, the latter mostly deals with enhancing existing biological functions or transferring them between organisms based on the modification or transfer of a limited number of genes. According to such views, the old regulatory regime should still be adequate and the development of SB technologies should continue under this framework (Ganguli-Mitra et al., 2009). Summing it up, "we do not need a new bioethics and policy regulations to justify support for research on synthetic biology" (Parnes et al., 2008: 1449). Further, it is interesting that Slovenian experts in SB predominantly hold the view that SB raises no particular (unique) ethical dilemmas and risks by itself. Namely, in the period between December 2013 and April 2014, we have interviewed five Slovenian researchers that work in various areas that fall under SB (Mali and Pustovrh, 2014). Although the small group of interviewees cannot be taken as indicative, the collected opinions of experts can still be seen as a tentative indicator of the views scientists in Slovenia hold of SB. According to this expert view, if any kind of ethical dilemmas do arise, they are mainly related to practical applications (biosafety and biosecurity), not to basic "philosophical" issues.

Conversely, accepting the view that SB actually represents a "game changer" in the context of new emerging technologies (and is not understood only as "old wine in new bottles") would require some radical change in the mechanisms of the social regulation of SB. The view SB poses ethical dilemmas and risks that are beyond those of traditional genetic engineering is really quite widespread (Boldt and Mueller, 2008). Contrary to genetic engineering, SB could represent a radical shift from the manipulation of

nature to the creation of biological systems with features that might never before have arisen as parts of living organisms. In this situation, human beings take on the role of creators, "playing the God" with the science. The phrase "playing God" in SB relates to the idea that scientists now have a responsibility to decide what should or should not be created (or come into existence). Not only philosopher, but researchers in SB as well are inclined to use this rhetoric, which is also popular with the media (Dabrock, 2009). Because of such hype that sometimes surrounds SB, there are also increasing pressures to insert completely new criteria and elements into the relevant regulation regimes. There are many civil society organizations and non-governmental organizations in Europe that call for a radical reshaping of the entire regulatory regime concerning SB, or even – what could be the most unfavorable scenario for its further progress – to impose a moratorium on research and the commercial use of synthetic organism (Koenig et al., 2013; Erickson et al., 2011).

Because of the pressures from some parts of the civil society to slow (or stop) further progress in SB, there is a strong need to establish adequate dialogue between the various social actors. The actors that are involved in the social regulation of SB cannot be restricted only to official policy institutions (legislators, governments, etc), or scientists as experts, but must also include the lay public. Currently we still lack the theoretical frameworks that might comprehensively describe the mechanisms needed to establish participative processes that would include ordinary citizens in discussions of technological progress, but, as we noted in previous analyses (Mali, 2009; Mali et al., 2012), the crucial questions regarding the forms of their inclusion are situated not so much on the theoretical as they are on the practical level. In terms of modern political language, we could say that in practice the various types of deliberative and participatory approaches are lacking (Bogner, 2012; Biegelbauer and Hansen, 2011). This means that organized policy actors (experts, politicians) are still employing the classical models of social regulation of new technologies, that is, the decisionist and the technocratic model. The decisionist model assumed social regulation of technology to be truly and solely the responsibility of the political system, which itself would create the necessary normativity. On the contrary, technocratic approaches to political decision-making tend to emphasize (to varying degrees) the role of experts as informal or even formal decision-makers.[3]

[3] *But, it is also true that expert knowledge must retain an adequate position. Collins and Evans' book "Rethinking Expertise" (Collins and Evans, 2007) is a good case against the uncritical devalorization of expert knowledge. Namely, the epistemological boundary between lay and expert knowledge did not disappear. In the context of growing uncertainty and of ethical dilemmas emerging with the progress of new technologies, the role of expert should be to avoid "over-hyping" the benefits and risks, and to try to keep the debate concerning the progress of SB within reasonable boundaries.*

In such circumstances, it is necessary to try and engage citizens in risk assessment and risk governance of SB still in the early stages of its development. The best possibility for R&D policy actors to avoid the mistakes of the past is not to delay in implementing the process of deliberative science and technology policy engagement. Namely, in the past, R&D policy actors made several wrong steps as far as new technologies are concerned. The typical case is the crisis surrounding the introduction of genetically modified organisms (GMOs) in Europe at the end of the 1990s. Before the GMO crisis, policy decision-makers in many European countries have predominantly employed the technocratic decision-making approach and been totally ignorant as far as relations with the public were concerned (Mali, 2004). Some analysts have described such policy approaches as being "paternalistic, involving reliance exclusively on politics and experts" (Bauer and Gaskell, 2002: 71). The public revolt against GMOs in Europe radically changed the policy approaches used in Brussels as well as in many EU-Member States. One decade later, it seems that the same failure was repeated by R&D policy actors in the case of nanotechnology. Nanotechnology appears to have been strongly affected by the unjustified "nano- phobia" from dystopian doomsday scenarios proliferated by the media, and experts and policy actors did not react adequately against such attacks (for more, see: Barben et al., 2008).

Nowadays, because of the associated ambiguity (to change or not to change regulatory regimes), SB discussions often employ the strategy of "double rhetoric". In this strategy, there are two discourses, that is, SB is either "everything new" or "everything the same". Actually, such double rhetoric is widely used for several reasons by scientists, ethicists, patent experts and other R&D policy actors. In this way, the view is created that SB is reliable and under control, and that its developmental trajectories are predictable. For example, metaphors and images are often employed, that present new and innovative processes and products by looking at representations and images that are located in older technologies. Let us mention two cases. The first case concerns the strategies of scientists working in SB. They reported that when they tried to avoid eliciting an adverse reaction from the public, they used various types of semantic "gymnastics", i.e. the recasting of the term "living organism" into "self-replicating complex biological entity" (Schmidt et al., 2010). The second case concerns patent policy. At the time when there were big pressures to extend the patentability from mechanical inventions to "biological artifacts", the American Office of Technology Assessment (OTA) published the report "Patenting Life", which stressed the analogy between mechanical (Mousetrap) and biological (Oncomouse) inventions. This analogy was intended to convey that the two inventions presumably share the same character (Tallachini, 2011).

How to leverage the benefits and risks in the context of the social regulation of synthetic biology?

In a situation of such controversial views regarding the progress of SB, the big challenge for the current social regulation of SB is how to simultaneously realize a promising technology's anticipated benefits, while protecting against its potential risks, particularly when the potential risks cannot be suitably understood until the technology itself develops further.

Sociological theorists distinguish between risk and danger, and this distinction has become the main point of departure for almost every discussion of risk. Ulrich Beck (1986) and Anthony Giddens (1990) have proposed a distinction between danger, recognized in traditional societies, and risk, created by reflexive modernization. Whereas in traditional societies, hazards were associated with the past and the loss of faith, risk is linked to modernization and the desire to control the future. Niklas Luhmann treats risk not as an object of "a first-order observation" ("Beobachtung erster Ordnung") (Luhmann, 1991: 23) (which he terms "danger") but as a concept of "a second-order observation." ("Beobachtung zweiter Ordnung") (Luhmann, 1991: 23). Luhmann defines risk not as the contradiction of security, or as a synonym for insecurity, but rather as the way in which the future is contingent on present, current decisions. Thus, risk is a conceptual part of the social system and is inherent in its decisions (for more, see: Mali, 1994). Accordingly, Luhmann draws a distinction between risk and danger, whereas danger is external to the system, and risk is generated by the decisions of the system. In this approach, the key question is not about the quantity of new dangers in the world (more or less severe, calculable or not) but about how the future is conceptualized in the present and contingent on it, and how each decision, or abstention from a decision, concerning the future, determines risk.

Luhmann's sociological category of risk is a good starting point to understand the complexity of the social regulation of new emerging technologies. Today, social actors constantly try to stay ahead of the challenge of how to cope with the multi-dimensional risks of new technologies. Let us take the example of SB. The potential harm of this new technology could affect society in general and manifest itself long after its initial implementation. The creation of several biological hybrids could cause big ecological problems and create completely new uncertainties. Ted Schettler and Carolyn Raffensperger (2004) have formulated an interesting typology of scientific risks, including model, statistical and fundamental risks. According to them, model risk is inherent in scientific systems with multiple variables interacting in complex ways. Contrary to model risk, statistical risk results from not knowing the value of a specific variable at a point in time or space, but

being able to determine the probability distribution of the variable. For this reason, statistical risk is easier to quantify with some precision. The third type of risk is fundamental risk. The latter extends the degree of indeterminacy into ignorance. It represents a lack of valid information concerning the likelihood of specific outcomes in such types of risk. In this case, we do not even know what we do not know. Following the typology of Schettler and Raffensperger, SB certainly encompasses model uncertainty because of its complexity, as SB can be seen as the synthesis of several bodies of knowledge held by diverse scientific fields and research groups.

Concerning risk assessment and risk governance of new emerging technologies, various regulation models have already been established. Generally speaking, we can differentiate between cost-benefit, precautionary and proactionary models.[4] The cost-benefit analysis is a simple model which is used by strongly technocratically oriented R&D policy actors. According to the technocratic view, technology risk regulation can only be quantitative, driven by economic cost-benefit reasoning and technocratic in its political implications (Saage, 2007). The evaluation in the context of the cost-benefit analysis is concentrated only on the known consequences. The possible fallibility of acts or policies on a basis other than their consequences is not taken into regard. Such technocratic approaches are not aware that it is relatively straightforward to use cost-benefit models in (rational-choice) economy, but not in the assessment of complex ethical, social and legal implications of the new emerging technologies, with several parameters that cannot easily be quantified.

The main characteristic of models based on the precautionary principle is the use of extreme caution in assessing the risks of new emerging technologies. This governance model affirms that in the case of highly uncertain risks we should be very cautious or even refrain from proceeding until we are completely sure of their status. One premise behind the model based on the precautionary principle is that because there is a social responsibility to protect the public or the environment from plausible and avoidable harms, protections should be relaxed only when science produces evidence that harm is unlikely to result. In some legal systems, such as that of the European Union, the application of the precautionary principle is a statutory requirement (Commission of the European Communities, 2000).

The key characteristic of the model based on the proactionary principle is a strong belief in the intrinsic goodness of progress unless strong,

[4] *Some analysts warn that much of the debate concerning the difference between different models of risk governance has become extremely technical (Ujita et al., 2007). The technical debate pertains to the question of how to adapt risk assessment in such a way that it would be applicable to various regulation regimes. According to our view, it is equally important to investigate the efficient use of the regulation regimes, not solely investigate their technical dimensions.*

compelling arguments to the contrary are presented. Advocates of the proactionary principle voice a strong commitment to intellectual freedom, the autonomy of individual decision making, economic growth, national competitiveness and improved health and well-being. While the above mentioned principles might be seen as allowing science and technology to progress completely unfettered, the proponents of this principle have nonetheless supported some measures of oversight and monitoring (see for example: Parens et al., 2009).

Contemporary philosophers oriented towards a transhumanist line of reasoning usually present the progress of new emerging technologies in a proactionary way. For example, Steve Fuller observes that the progress of human enhancement technologies represents the means to secure and increase the welfare of society. His position is that the freedom to innovate and experiment (the concept of "moral entrepreneurship") needs to be protected, so that new technologies can be allowed to flourish rather than that their potential should be constrained with an overcautious approach. Such a stance is in accordance with the idea of the proactionary principle (Fuller, 2011).

It is interesting that in the case of SB, the use of a new model of social regulation was suggested, i.e. "prudent vigilance". The idea of "prudent vigilance" was originally presented by US Presidential Commission for the Study of Bioethical Issues in 2010 (PCSB, 2010). The US Presidential Commission sees "prudent vigilance" as the best model for the governance of SB, since it fosters the innovation and progress in SB without sacrificing safety, security, and the values of people, environment and society. "Prudent vigilance" also does not demand extreme aversion to all types of risks. While not all safety and security questions can be definitively answered before research begins, but prudent vigilance still calls for an ongoing evaluation of risks of harm along with the benefits. The "prudent vigilance" approach might look like a procedural approach rather than substantive one, not saying what policy actions to take against risks, but how to face them. In this regard, the continuous responsible interaction between all social stakeholders involved in discussions of new technologies is extremely important. In the EU report of President Barroso's Science and Technology Advisory Council "Science for an informed, sustainable and inclusive knowledge society" (EC Report, 2013), there is a similar emphasis on the paradigm of 'responsible research and innovation' which highlights the need to shift the focus from particular risks towards the whole innovation process, and to its governance, which is neither technology-specific, nor solely risk-focused. And again, like in the case of the U.S. Directives, there is an emphasis on a transparent, interactive process in which various stakeholders become mutually responsive to each other concerning the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order

to allow a proper embedding of scientific and technological advances into our society). It seems that lately the new technology strategies on both sides of the Atlantic – at least at the normative level – are jointly approaching the pluralistic social epistemology that suggests the cooperation of multiple, various stakeholders in coping not only with the intrinsic uncertainty of the progress in new emerging technologies, but in achieving the "right technological impact" (PCSB, 2010: 65).

The "intellectual property rights frame" versus the "free access-to-knowledge frame"

As we have already noted in the introduction, SB represents a new scientific and technological "wave", of which the following revolutionary change is a key characteristic: if we were used to using nonliving building blocks of nature to build sky-scrapers and computers, and to put a man on the moon in the previous century, our engineering ambitions have now expanded into the domain of living nature, ourselves included. Within the paradigm of SB as the engineering of living artifacts, biology is really becoming technology and vice versa, technology is becoming biology (Grunwald, 2012; Bedau et al., 2009).

SB is an example of modern biogenetic science, where the processes of "informatization" and "technization" are leading to new forms of modularization of biological structures. For example, SB as part of "digital biology" (here, the written and unwritten rules from computer sciences and engineering become salient) attempts to create complex living entities from standardized and homogenized biological parts. If such living entities are understood as uniform and homogenous, then they can be more easily treated as commodities which are also subject to intellectual property rights (Calvert, 2010). The large increase of broad patent claims, patent thickets, and the patent gold rush by both the business and enterprise, and the academic sector, go hand in hand with the above mentioned processes of modularization in modern biogenetic sciences. Namely, many inventions long thought un-patentable (everything from gene sequences with unknown functions to one-click purchasing over the internet) are now being claimed as property.

As a consequence, the current debate concerning the social regulation of SB is characterized by many conflicts between the "intellectual property rights frame" and the "free access-to-knowledge frame" (Van Doren et al., 2013; Van den Belt, 2013). On the one hand, the adherents of the intellectual property rights frame claim that exclusive property rights constitute an indispensable incentive for the future progress of SB. The purpose of SB technology should not be to do only pure research with an intention to understand the manner in which human and other living systems are

developing and functioning. The purpose of these new scientific fields is primarily to produce new (marketable) processes and products. In regard to this applicative orientation, great pressures to commodify common scientific resources for private economic benefits are emerging. These processes fit well with the general neoliberal agenda of privatization, globalization and the reduction of the public sector. The recent efforts of the J. Craig Venter Institute to acquire a patent for a new artificial life form represent an extreme model of the intellectual property rights frame. On the other hand, the adherents of the open access-to-knowledge frame represent an opposition against the over-utilization of property rights protection in new technologies. They emphasize the importance of free access to existing knowledge and information as essential inputs for further innovation. They hold that knowledge obtained in the field of SB should never be subject to the protection of property rights (Stemerding and Rerimmassie, 2013; Krikorian and Kapczynski, 2010).

SB is part of "digital biology", where the written and unwritten rules from computer sciences and engineering become apparent. Consequently, the questions arising among experts revolve around whether the frame for the protection of inventions should be derived from biology and the pharmaceutical industry (a practice of heavy patenting is characteristic for this field) or from software development in computer sciences, where a discussion about different forms of protection has emerged[5]. Finally, the idea that inventions in SB are the common heritage of mankind (and that they cannot be patented or directly exploited for commercial benefits) also has strong support. Of course, such general ideas are encountering many problems in practice. Nonetheless, they are part of the recent trends to soften strict intellectual property right regimes and allow – if it is even possible – a free exchange of biogenetic knowledge. For example, the BioBricks Foundation which established the Registry of Standard Biological Parts offers a free exchange of biogenetic information (The BioBricks Foundation, 2013). The BioBricks Foundation is aware that if any single biobrick would be subject to a patent, then a multitude of co-existing patents would be necessary for a single product and it could be very difficult for researchers to obtain materials for their research and studies.

[5] *The problem is that the software employed in SB fits neither into the copyright model nor into the patent model. In general, copyright law covers original works of expression and excludes works that are functional, while patent law covers inventions that are functional, i.e. useful, novel and non-obvious (though algorithms are excluded from patentability). Software (in SB, computer sciences, etc.) is in the middle: it is too functional for copyrights and too close to algorithm to be a patent. Only after several years software came to be recognized as covered both by copyright and patent. Within the software regime, it appears that the two models of protection have now been generally elaborated: a proprietary one and open-source one (for more, see: Koenig et al., 2013; EGE, 2009; Calvert, 2008).*

In the case of SB, the question of intellectual property rights can be the subject of discussion not only from an economic perspective, but from an ethical perspective as well. Increasing processes of commercialization in SB biology are giving rise to the same dilemmas that arose in the previous stages of development in the biosciences. The endeavors to patent biological organisms, particularly human genes and other human parts triggered many ethical controversies right from the start. Even then it was not clear what exactly can be considered "natural" and what can be seen as "artificial" (Mali, 2009). It seems that with the development of SB, there are even greater ethical dilemmas and tensions concerning the borderline between the natural and the artificial. The same could be said for ethical controversies surrounding inventions that should be not patentable contrary to morality or the public order (Van Doren et al., 2013; Kinderlerer and Milius, 2009). Namely, many synthetic biologists use the idea of the "unnaturalness" of synthetic organisms as part of arguments that patenting in this area is justified. Some synthetic biologists even purposefully emphasize the unnaturalness of their creations. Their "play" with the distinction between the natural and the artificial is part of a strategy to increase the strength of patent claims in the recent processes of commodification in academic science (Oye and Wellhausen, 2010; Calvert, 2008).

Here, we will not go any deeper into the investigation of the numerous ethical controversies surrounding intellectual property rights in the biosciences. In general, without exploring this precarious past and future issue in more detailed, we would like to note that such controversies in SB will probably continue to increase, as a balance between private and public interests will be difficult to achieve. Thus it is unlikely to expect that this scientific field will soon achieve – if we use the terminology of Nico Stehr – a "konsensfaehige etische Platform"[6] (Stehr, 2003: 202). And such a situation will only serve to further complicate the social regulation of SB.

Conclusion

Recently, the social regulation of SB has come to represent a growing challenge for modern societies. SB is one of the latest "niches" in the progress of new emerging technologies that strives to collect the best from various kind of knowledge in order to create new organisms (hybrids) with novel or specialized functions that could address numerous societal needs. Advances in SB will bring many social and economic benefits. On the other hand, the uncontrolled development of SB could significantly challenge many ethical norms that have been established for individual and communal

[6] *An ethics platform that is capable of achieving a consensus.*

interactions. Namely, the tremendous progress of SB is opening many new questions, since it problematizes various dimensions of natural and social life: biorisks, biosafety, the meaning of personal identity and human dignity (the issue of borders between natural and artificial life), etc. Although many of the dilemmas mentioned are not yet apparent or at least not yet at a critical stage today, we are nonetheless at a point when we have to design suitable models of social regulation in order to avoid the numerous possible negative implications. In the article, we have attempted to show the importance of an adequate model for the social regulation of SB. Here, we can learn a number of important lessons from the development of previous new emerging technologies such as ICT, nanotechnology, etc., including the fact that it is essential to timely address possible benefits and risks in order to ensure a balanced progress of SB in society.

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