The Ethics of Synthetic Biology
Contours of an Emerging Discourse

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Synthetic Biology (SB) is the new kid on the block among emerging technosciences that are said to have a revolutionary impact and the potential to pose major ethical challenges. SB aims at designing biological systems for numerous useful purposes, ideally starting from scratch and creating new life forms. The new EU-funded project SYNTH-ETHICS will address a variety of ethical, legal and social aspects (ELSA) of these ongoing and anticipated developments. In the following, we will sketch the contours of the emerging discourse on the ethics of SB and our approach to its analysis.

1 Synthetic Biology

Developments in modern biology have reached a stage in which more radical design approaches than traditional genetic engineering appear to be imminent. At the 1999 annual meeting of the American Association for the Advancement of Science, the famous geneticist Craig Venter, who at that time also headed the privately funded project that competed in the race for complete sequencing of the human genome, already talked about the prospects of creating synthetic life. He outlined the approach to creating a true minimal genome by producing a replicating cell with a minimum gene complement (i.e. a cell which is bereft of all non-essential genes). Venter argued that one would technically need to synthesise a genome "from scratch" and see if it leads to a living organism, but he also added that his team had not done this so far, due to politically motivated ethical and security-related considerations. At the end of the same year, his scientific as well as his discursive strategy became clearer in two publications in the journal Science: A research team from an institute founded by Venter reported the results of an analysis that suggested that 265 to 350 of the 480 protein-coding genes of Mycoplasma genitalium are essential under laboratory growth conditions; this was accompanied by an article on the results of a research project that was conducted on his initiative on the ethics of synthesising a minimal genome (Cho et al. 1999). Venter thus included ethical aspects of SB right from the beginning of his enterprise, planting the seeds of an ethico-political discourse in parallel to the technoscientific endeavours.

Since then, both the research and the ethico-political discourse on SB have gained impetus at an astounding speed. Venter has continued to push forward his specific approach, for instance by way of a complete chemical synthesis of a chromosome. He has also outlined a number of revolutionary implications of future developments in SB, including replacing the oil industry with a new alternative fuel industry based on SB, new insights into the question of how life began on Earth, and the digitalisation of life (for a lively description, see Edge Foundation 2008). Venter argues that life is machinery and now becomes a form of technology as we learn how to engineer and reproduce it: This opens up the prospect of cell design capabilities for a wide variety of very unique utilities. This clearly reminds us, and Venter and others draw this parallel too, of the early expectations raised by nanotechnology, another new technoscience whose emergence was accompanied by a multitude of publicly funded and other research activities into its ELSA.

2 Definitions and contours of the field

While Venter is apparently still the public face of SB (Pauwels, Ifrim 2008), SB is neither a homogeneous field nor is his approach the only research endeavour which is addressed as SB in the mass media and the ethico-political discourse. Accordingly, when discussing the ELSA of the field as well, it is important to make certain distinctions.[1]

The field can very roughly be divided into four sub-communities, each of them using different approaches: first, the minimal genome or top-down approach taken by Venter, his colleagues, and other researchers; second, a biological bottom-up approach which does not take an existing organism as the starting point, but plans to use existing biological parts to create new cells; third, the "protocell" bottom-up approach which has the same goal, but starts with basic chemical compounds; and, fourth, an approach which aims to create new genetic systems based on chemical modifications of nucleic acid bases. Other approaches exist, and it is also possible to organise the field and group the subfields differently (cf. e.g. Benner, Sismour 2005; Boldt et al. 2009; Luisi 2007). A notion often cited in journalistic and other representations of the field is that of creating life "from scratch", which was already used by Venter in 1999. This notion may, however, be more appropriately used only for the bottom-up approaches. In any case, there are overlaps between SB and nanobiotechnology, and SB is also related in some sense to various research activities aiming at the creation of non-carbon-based life (e.g. in the field of "artificial life" [aka "Alife"]).

With more and more public and private money flowing into the field, a dispute over "synthetic biology" as a "trademark" may evolve (Benner, Sismour 2005, p. 533), as may endeavours in "boundary work" similar to those in the field of nanotechnology concerning the legacy of Eric Drexler's nanofuturism (cf. e.g. Kaiser 2006). Interestingly, SB can not only in some respects be understood as a technoscience which resembles a broadly defined and highly visionary nanotechnology, but it is actually praised as such, sometimes (cf. e.g. Bedau, Parke 2009) with exact reference to those visions and ideas that have stirred the most spectacular controversies over nanotechnology.[2]

A useful definition of SB is provided by Schmidt (2008). This encompasses the endeavours in the above-mentioned four subfields and closely related research but, in line with EU and other funding schemes, excludes any "alternative biochemistry" approaches (such as Alife): "Synthetic biologists use artificial molecules to reproduce emergent behaviour from natural biology, with the goal of creating artificial life or seek interchangeable biological parts to assemble them into devices and systems that function in a manner not found in nature" (Schmidt 2008, p. 1). With such a definition, highly visionary basic research is included as well as those research directions that are arguably more promising in terms of early application and are, as a rule, more similar to traditional genetic engineering.

In any case, in one way or another, the following two features appear to be distinctive for SB: The first refers to the notion of synthesis and relates to the subject of SB. Its aim thus lies in the design of biological components and entire systems with novel properties and functions which do not occur in nature. This designation makes clear that SB does not merely aim to replicate or slightly modify natural organisms, but to design new ones with specific applications in mind. The second definition focuses more on the method and procedure of SB and, above all, the employment of engineering methods and principles (cf. Endy 2005). Often mentioned here is the fabrication of new biological systems by using standardised and modularised so-called "biobricks". The primary objective of this methodological approach is to conduct genetic engineering in a more rational and systematic way. This second definition also relates to synergies realised through the convergence of genetics with different areas and disciplines such as computational modelling, chemistry, and nanotechnology. There is also a close connection between SB and systems biology, which is sometimes considered the theoretical and analytic framework for SB.

The above-mentioned vision of an alternative fuel industry is only one application of SB that has been proposed by its champions. Since the early days of the emerging discourse, the synthetic production of the malaria drug Artemisinin often plays the role of a "poster child" of SB (ETC Group 2007). It is almost impossible to predict which fields of application will be possible in the medium and long term and, in light of the visions, these appear to be almost unrestricted. Other examples are applications in the manufacturing of new materials (such as biodegradable plastics), the development of biosensors and biocomputers, and artificial bacteria which dismantle environmental pollutants or deliver human tissue.

The prospects of such applications, which promise solutions to major current problems, are sometimes coupled with the proclamation that a new technoscientific and industrial revolution could potentially follow from the rise of SB and its convergence with other disciplines. We here seem to be encountering a dynamics of expectations and promises similar and sometimes directly related to developments in other discourses, such as that on nanotechnology and its convergence with other key technologies (see e.g. Kavli Futures Symposium 2007).

3 The emerging discourse on the ethics of Synthetic Biology

As mentioned above, ethical aspects of SB were taken into consideration very early on when it emerged as a new field of research. Research on ELSA is now receiving significant public funding, and the results of this research are being presented in various forums, e.g. at major conferences held by the SB community, in books (e.g. Bedau, Parkes 2009), and in science journals (e.g. Schmidt 2008). At the European Union level and in some countries (such as Great Britain) at a national level, projects on ELSA are being funded in close connection with SB projects, or the latter are required to include professional ELSA expertise in their work (cf. Calvert, Martin 2009). A range of preliminary studies and policy reports on ELSA of synthetic biology have also been published by a range of actors, such as civil society organisations (ETC Group 2007), policy advisory boards (e.g. Balmer, Martin 2008; Boldt et al. 2009; De Vriend 2006), ethicists (e.g. Wolbring 2007), or researchers active in the field of SB (e.g. Garfinkel et al. 2007). The European Group on Ethics in Science and New Technologies (EGE) is currently preparing an opinion on SB. Several national research institutions and associations have prepared reports on SB, including its ELSA.

As part of the Sixth Framework Programme for Research and Development (FP6) of the European Union, the initiative NEST (*New and Emerging Science and Technology*) was launched to promote activities in emerging or visionary areas, including SB. In the NEST Pathfinder programme, the project SYNBIOSAFE broadly addressed ethics, safety and security issues and other topics related to SB (cf. http://www.synbiosafe.eu). Other relevant work on ELSA was or is done, for example, by the "Human Practices Thrust" of the Synthetic Biology Engineering Research Center (SynBERC) in the U.S., by the Austrian project COSY (*Communicating Synthetic Biology*), and by the FP6 project PACE (*Programmable Artificial Cell Evolution*).

Currently research on the ethics of SB is also being funded by the FP7 programme "Science in Society". The project SYNTH-ETHICS (*Ethical and regulatory issues raised by synthetic biology*), which runs until August 2011, will analyse a broad range of ethical, legal and social implications of SB and make recommendations on the political and social shaping of the new field. The Institute for Technology Assessment and Systems Analysis (ITAS) at the Research Centre Karlsruhe is one of the main partners in the project, which is coordinated by the Technical University of Delft and also involves the Dutch research institute TNO, the University of Padua and the Australian National University. The SYNTH-ETHICS partners will closely cooperate with SYBHEL (*Synthetic Biology for Human Health: Ethical and Legal Issues*), another project in the "Science and Society" programme, which will focus on ethical and legal aspects of medical applications of synthetic biology.

What are the main topics in exploring ELSA of SB? Very roughly, two major strands of concern and controversy can be discerned,[3] both of them connected with the claim by synthetic biologists of applying an engineering approach to biology – and neither of them is completely unknown from previous (and ongoing) discussions on genetic engineering and other fields such as nanobiotechnology.

On the one hand there is the "risk issue", well-known under the two headings of "biosafety" and "biosecurity" (or "dual use") from related areas such as nanotechnology or genetics. Is there a risk of artificial organisms getting out of hand and developing unintentional and unexpected properties that make them detrimental to human health and the biosphere? And is there a potential for deliberate misuse of SB methods, for example for the creation of bacteria or viruses for military or terrorist purposes? While the revolutionary character of the field is often emphasised by many promoters of SB, they tend to argue that these issues have been dealt with sufficiently in relation to genetic engineering and that there are no new arguments to be added with regard to SB. Especially on the issue of biosecurity, it is regularly stressed that, given the high expenditures and the complexity of SB, deliberate misuse is unlikely to appear. However, the ambition of

SB to assemble an organism with new properties by using standardised biological modules that are publicly available feeds concerns about a new quality of "biosafety" and "biosecurity" problems. If the visions of SB become reality, then no further big investments and only little specific expertise might be needed to produce an organism with new properties.

The second strand of debate is linked to the long-standing philosophical question that relates to the epistemological fundaments of biology, the notion and definition of life. What would "artificial life" actually mean? Will impacts of SB extend beyond the manipulation of nature performed already by genetic engineering or traditional breeding? In what way might our attitude towards the living be altered, if life in the future can be produced artificially? How could everyday and scientific distinctions between the "natural" and the "artificial" change and our appraisal of the "natural" life be affected? Are we, as the technofuturist physicist Freeman Dyson (2007) argues, "moving rapidly into the post-Darwinian era, when species other than our own will no longer exist, and the rules of Open Source sharing will be extended from the exchange of software to the exchange of genes" and when biotechnology could "move into the mainstream of economic development, to help us solve some of our urgent social problems and ameliorate the human condition all over the earth"? And, if so, does the emergence of SB "compel us to give a new twist to Freud's title *Unbehagen in der Kultur* (i.e. *Civilization and Its Discontents*), taking into account that now the discontent may shift "from culture to nature itself", leading to a situation where nature is no longer the "reliable 'dense' background of our lives", but appears "as a fragile mechanism which, at any point, can explode in a catastrophic direction" (Zizek 2008)? Is there any solid basis for our future expectations? Whatever the appropriate perspectives and concepts of life and nature may be, the jargon used by synthetic biologists (such as "living machines") and the far-ranging visions might find their way into public awareness. Some of the emergent fears are associated with the artificial creation of higher life forms – an idea that is far beyond the horizon. There is also the question as to the effect the creation of life could have on the self-image of mankind (e.g. from *homo faber* to *homo creator*; cf. Boldt et al. 2009). But even if these fears and concerns have only little in common with the current state of the art in SB, one would be ill-advised to simply push these fears aside. In particular from a political perspective and with regard to the goal of a public dialogue, it is important to investigate the "unease" with SB, such as mistrust towards scientists who appear to be "tampering with Nature" or "playing God".

As the new kid on the block, SB knows more about the social environment it "moves to" than its predecessors did; it has had the chance to learn lessons from earlier debates. However, the conclusions drawn from these lessons appear to differ, with some important players in the field apparently seeing no need to refrain from using even far-flung visions for its promotion. Obviously, the discourse on SB is another example of the strategic use of relatively far-reaching visions of how to apply the results of emerging research areas in the future. However, those who are active in the accompanying research on emerging technologies appear to have learned their lessons too. More and more approaches and studies take such issues into account as the sociology of expectations, the pitfalls of a speculative ethics of technology, the danger of a vicious circle of inflated promises in research policy, and other intricacies that one can encounter in ethico-political discourses on emerging technologies.[4] In addition, investors are advised on what they can learn from earlier hype-driven discourses such as those on nanotechnology or the Internet (Lux Research 2009).

The project SYNTH-ETHICS will first distinguish relevant ethical issues related to SB in close collaboration with the SB community and by means of a literature review. This will be followed by an in-depth analysis of selected ethical issues. In parallel, the public discourse on SB will be analysed from an international perspective. This analysis will be conducted by ITAS alone and aims to increase existing knowledge (cf. Pauwels, Ifrim 2008) of the public image of SB in terms of the extent and general characteristics of its coverage in the mass media. A selection of articles will be analysed in-depth, and particularities and dynamics in the emergence of the public discourse will be sought. Moreover, the project aims (congruently with the goals of the Directorate "Science, Economy and Society" of the EU Research Directorate-General) to identify civil society organisations for whom the issue of SB and its ELSA is of specific interest. This relates to the tasks of the project to include a wide variety of stakeholders in the discourse and to prepare for a rational and informed public deliberation on the ELSA of SB. Another goal of SYNTH-ETHICS is to analyse relevant normative frameworks and their adequacy for the challenges raised by SB. The concept of a normative framework (Gorp, Grunwald 2009) includes all relevant norms and principles for an existing research field, including legal and other social regulations as well as codes of conduct. In a final step, SYNTH-ETHICS will develop recommendations targeted at European policy makers, the relevant research communities, and civil society, based *inter alia* on the results of a larger stakeholder meeting, which will take place in Karlsruhe in the winter of 2010/2011. Both the meeting and events to promote public dialogue that will be organised by the Technical University of Delft also intend to stimulate public discussion and broaden the public discourse on SB.

Notes

1) For an excellent overview and ethical analysis, see Boldt et al. 2009.
2) Examples for the most spectacular controversies over nanotechnology are the visions of Drexler and the notion of "converging technologies" that was advanced in the U.S. in 2001; cf. e.g. Coenen 2009.
3) For a detailed overview cf. e.g. Boldt et al. 2009.
4) For a recent comment, see Nordmann, Rip 2009.

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World Wide Views on Global Warming
Weltweite Bürgerbeteiligung zu einem globalen Problem

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Der Klimawandel stellt aufgrund seiner globalen Dimension eine Herausforderung dar, die über die Ebene der Nationalstaaten hinausgeht. Folglich sind bei der Erarbeitung von Strategien zur Anpassung und von Maßnahmen zur Abmilderung der Klimaerwärmung neuartige globale Ansätze nötig. Das Danish Board of Technology (DBT) hat anlässlich der UN-Klimakonferenz im Dezember 2009 in Kopenhagen ein Projekt initiiert, das eine globale öffentliche Plattform zur Bürgerbeteiligung schaffen soll. Partizipative Verfahren werden im regionalen Maßstab bereits erfolgreich in umweltpolitischen Prozessen eingesetzt, um die Akzeptanz für so getroffene Entscheidungen zu erhöhen. Im Vorfeld der Weltklimakonferenz werden im Rahmen des Projekts „World Wide Views on Global Warming" (WWViews) unter Koordination des DBT weltweit Bürgerkonferenzen stattfinden, auf denen Bürger ihre Meinungen zur Klimapolitik äußern können. Das Projekt kann als Experiment angesehen werden: Gelingt der Versuch, in einer globalisierten Welt auch Bürgerbeteiligung weltweit zu begreifen?[1]

1 Klimawandel als globale Herausforderung für die Klimapolitik

Die von Klimaforschern seit geraumer Zeit prognostizierte signifikant fortschreitende Erhöhung der globalen Durchschnittstemperaturen ist mittlerweile deutlich messbar und auch von anfangs skeptischen Vertretern der Wissenschaft nicht mehr zu leugnen. Obwohl die globalen Temperaturen sich erst um einen Bruchteil der vorhergesagten Spanne erhöht haben, werden bereits jetzt Umweltveränderungen in vielen Bereichen deutlich, die eindeutig mit dem Klimawandel in Zusammenhang gebracht werden können. Für die kommenden Jahrzehnte ist bei einem Fortschreiten des Temperaturanstiegs mit einer Verstärkung dieser Klimafolgen und daraus resultierenden