

## The social and ethical regulation of synthetic biology - The views of various stakeholders in Slovenia

By Franc Mali<sup>i</sup>

*Synthetic biology (synbio) is a very young and still unconsolidated new emerging technology, where a variety of scientific disciplines come together in many different ways with the overarching idea of applying an engineering approach to biological systems. So far, neither an authoritative definition nor a wider social consensus exists on how to approach the social, ethical and legal aspects of this most promising of the new emerging technologies. In order to come to better insight in previously mentioned dimensions of synthetic biology in Slovenia we, the partners from University of Ljubljana who participate in the SYNENERGENE project, did an extensive survey among representatives of different stakeholder groups in the first half of 2015.*

We interviewed a total of 17 stakeholders: 7 researchers dealing with synbio at public research institutes, 2 entrepreneurs coming from SMEs, 2 civil servants from R&D policy institutions, 2 science journalists from Slovenian newspapers, 2 philosophers specialized in bioethics and 2 NGO representatives. As there is no such thing as a 'synbio community' in Slovenia -even the scientists involved in synbio research often lack a common background in training and professional experience- we had to settle with a limited list of representatives of various groups of stakeholders. In the case of representatives of business-enterprise sector, we only managed to involve 2 SMEs producing software technologies for DNA sequencing. An attempt to include the representatives of two pharmaceutical companies in Slovenia, which presumably have some synbio elements in their R&D programs, failed.

In our qualitative survey, we focused on the following dimensions which are playing (and which will play also in the future) a very important role in the social governance of synthetic biology in Slovenia: (1) the policy framework, (2) the ethical discourse, and (3) the issues of biosafety and biosecurity.

### The policy framework

Concerning the R&D policy framework, most interviewees refer to the success of Slovenian teams that participated in the international Genetic Engineering Machine (iGEM) competition over a number of years. This competition can be looked at as a basic platform for nurturing young research talents in one of the most promising scientific and technological niches. They think that Slovenia wasted the opportunity



*Slovenia's 2012 iGEM team*

to exploit those successes and failed to translate in further scientific education and scientific careers. R&D policy makers did not recognize the national interest and did not support iGEM students to find a job in high-tech industry after the end of their graduate study. This is quite opposite to actions undertaken by many (big and small) countries that are leading world players in synbio.

Interviewees coming from various stakeholder groups noticed that synbio and new emerging technologies at large in Slovenia are operating within a very rigid R&D and innovation policy framework that does not offer incentives. Both financing for R&D activity in synbio and public venture capital for high tech start-up firms are lacking. On top of that, interviewees identified the lack of priority setting in research as one of the biggest deficiencies in governmental R&D policy. So far, unlike countries such as the United Kingdom, Slovenian R&D policy did not succeed to a roadmap strategy in synthetic biology.



### The broader social-ethical discourse and biopatents

Asking interviewees about the broader social-ethical discourse in current and future development of synthetic biology resulted in a long list of short- and long-range ethical dilemmas. Those with good knowledge of the legal and ethical dilemmas of biopatents (mostly innovators and businessmen) have very pragmatic opinions how to approach to the complex issues of openness in the transfer of synthetic biology information. On the one hand, being aware of rapid progress in synbio research and genetics, they prefer open platforms to bring together all relevant disciplines. For that reason they agree with the statement that it is necessary to prevent concentrated ownership of genetic information. On the other hand, they are also aware that some kind of intellectual property protection (not necessarily the most restrictive) is needed in a market economy. This notion can be understood in the context of memories on rather inefficient approaches to intellectual property rights in the former socialist economy. In any case, they are aware that there is no such thing as 'simple solutions' concerning the ethical dilemmas of biopatents.

### Biosafety: two contradictory views

Concerning the biosafety of synthetic biology, two contradictory views popped up in our survey.

Most of the researchers we interviewed doubt the need for more strict regulatory biosafety regime for synthetic biology. In terms of biosafety they consider synthetic

biology as very similar to 'traditional genetic engineering', so there is no need to introduce new and more restrictive regulatory frameworks.

In contrast to this view, there is a group of mainly non-scientists whose view seems to be fuelled by expected negative consequences of synbio. Most of the NGOs, journalists and bioethicists we interviewed are convinced that the current regulatory framework in European Union does not sufficiently cover the whole spectrum of synthetic biology. Slovenia (and Europe at large) therefore needs to improve the risk assessment and risk governance. Moreover, this group stresses the need to take into account more seriously all ethical dilemmas and potential long-term risks coming with synthetic biology. They insist on developing new approaches that are not included in current regulatory regimes.

### Common ground in flexible regulation

In spite of the fact that our survey did unveil various and even contradictory views among the representatives of Slovenian stakeholder groups, they shared one important common ground: They agreed that safety and security measures should not stifle economic development through legislative over-regulation. This indicates that our interviewees are aware of the importance of finding regulatory regimes with sufficient flexibility. Such flexible regime is not only important for further progress of basic research and use of innovative potential of synbio, but also for the whole processes of democratization in the production of new synthetic biology knowledge.

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