Chapter 4

Changing investment patterns in synthetic biology

Over the last decade or so, there has been a marked increase in public and private investment in synthetic biology. Several countries have been particularly prompt to invest, and the effects are easier to see in the United States. The pattern of investment shows that the technology is also appealing to several key developing nations, and clearly China has strong ambitions. Several countries have also recognised a need to develop international funding mechanisms for student exchange and for reducing wasteful research overlap and duplication. Several key foundational companies have gone through favourable initial public offerings, most of them in the biofuels and bio-based chemicals sectors. However, such companies struggle with the complexities of scale-up to commercial production, especially in transport fuels. There has been a recent shift from biofuels to bio-based chemicals, which have lower production volumes. There may be a case for countries to offer specialised support to small and medium-sized enterprises, such as provision of access to demonstrator plants, testing and certification facilities.

The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law.

"Investment in research and innovation is the only smart and lasting way out of crisis and towards sustainable and socially equitable growth."

European Commissioner Máire Geoghegan-Quinn,
when announcing EUR 6.4 billion for research and innovation
to be allocated by the end of 2011 (Fletcher and Bastin, 2010).

Introduction

For high-technology start-ups, the difficulty of attracting investments has always been one of the largest barriers to success. It may be easier for synthetic biology than for more traditional biotechnologies to attract investments, because of its cross-disciplinary nature and its applicability to health, chemicals, energy and environment. Nevertheless, governments aiming at an industry with a significant synthetic biology platform must prepare for this difficulty. Among the companies currently taking a synthetic biology approach to biofuels or bio-based chemicals production, for example, the big financial issue is not the technology but full-scale production.

Future synthetic biology companies will have various profiles. Many will be industrial-scale gene (and genome) synthesis companies. Already by 2005, there were at least 39 gene synthesis companies located around the world, including in Boston, Hong Kong (China), Moscow, San Francisco, Seattle, Shanghai and Tehran (Bügl, 2007). Once the cost tipping point in gene synthesis is reached (see Chapter 3), small companies offering software-driven services (similar to software design houses) may proliferate. Their investment requirements will be very different (and less of a concern) from those of the formative companies at the current cutting edge of synthetic biology. Today, the challenge is particularly acute for biotechnology entrepreneurs. Many biotechnology firms are years away from any significant revenue stream, have very few tangible assets, usually have significant accounting losses, and require large amounts of capital (Burill and Lee, 1992).

A mature synthetic biology industry sector may have companies ranging from very small software providers and developers to large dedicated and diversified (typically chemical or agricultural) multinational enterprises that act as manufacturers and provide manu-services, and have large customer bases to grow the market for synthetic biology products.

The allure of drug discovery is lessened for venture capitalists by the duration, risks and high costs of clinical trials. The distributed partnering business model described by Roth and Cuatrecasas (2010) may offer a solution. They argue that neither the vertically integrated pharmaceutical company nor the co-partnering biotechnology company is an appropriate model for drug discovery. Under the distributed partnering model, the product definition company would license discoveries from research institutions and raise the money to advance the research to the product development stage. It would then sell the research to pharmaceutical companies, which would complete the development process. Synthetic biology's rational design approach will find a niche in drug discovery and development by decreasing lead times through the efficiencies gained in design. Synthetic biology companies involved in drug discovery may be an intermediate link in the chain between product definition company and large pharmaceutical, potentially invested in by both and also by venture capitalists.

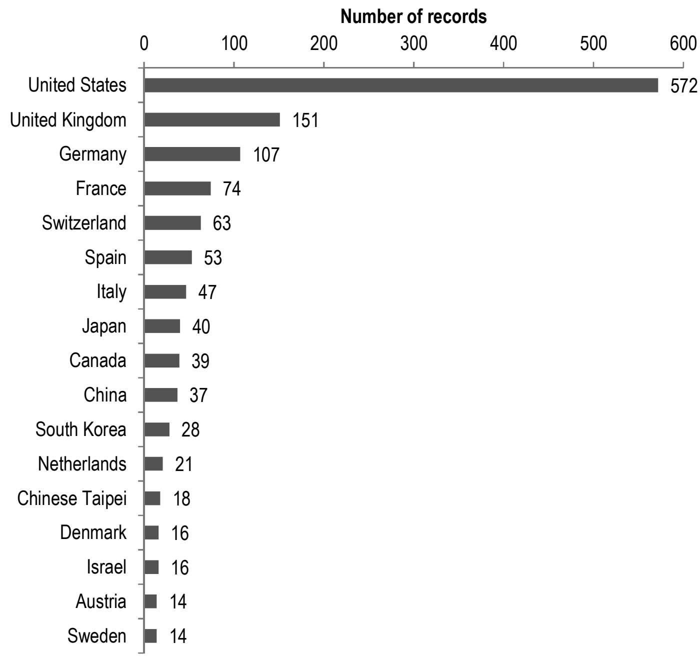
Industrial biotechnology, until the start of the biofuels era, struggled to attract investment, especially from venture capital funds. In 2003 R&D expenditure on industrial biotechnology in OECD countries was 2% of total biotechnology investments, but the OECD expects industrial biotechnology to contribute 39% to gross value added in the biotechnology sector (OECD, 2009). By 2010, the situation was 6% of R&D expenditure on industrial biotechnology compared with over 80% on the health sector. There is a gross mismatch in R&D funding if the OECD's expectations are to be realised.

Public funding

Since 2005, synthetic biology funding has risen significantly in the United States and Europe, roughly coinciding with the growth of the biofuels sector. Driving this increase is the potential to transform world industry in areas such as energy, health and the environment, to produce a new era of wealth generation, and to create large numbers of new jobs (Royal Academy of Engineering, 2009). Among the different emerging trends in biotechnology, synthetic biology may have the most potential to influence, or even transform, economies and society (Cichocka et al., 2011).

There are compelling reasons to believe that synthetic biology will strongly influence the biosciences research agenda in the 21st century and in fact may move biotechnology into the economic mainstream (Newcomb et al., 2007). The discipline arose in the United States, which has established a substantial lead over the rest of the world. Between 2005 and 2010, the US government spent approximately USD 430 million on research related to synthetic biology. The United States has therefore established a favourable intellectual property (IP) position, making it more difficult for the rest of the world to catch up, and will reap commercial rewards. This early lead is apparent from the figures cited in Figure 4.1. Well over half a billion dollars of government funding in the United States and Europe alone has been allocated to synthetic biology research in more than 200 locations.

Figure 4.1. Economies working on synthetic biology, ranked by the number of authors from a country appearing in publications in Web of Science



Source: Adapted from Oldham, P., S. Hall and G. Burton (2012), "Synthetic biology: Mapping the scientific landscape", *PLoS ONE*, Vol. 7.

A diversity of public research funding mechanisms

Different countries have taken different approaches to funding synthetic biology research. Funding mechanisms also differ, and the examples given here are not exhaustive. From 2008, the US Department of Energy has generously funded synthetic biology research on energy applications. The philanthropic Bill and Melinda Gates Foundation awards grants for health and medical applications, especially with a view to supporting health initiatives in developing countries (see Annex A). In the United States, public funding comes from diverse sources, and Europe has also taken various paths to synthetic biology funding. In France and Germany, funding has come from general biotechnology programmes, while Switzerland and the United Kingdom have set up dedicated programmes. Things to be borne in mind when setting up public research funding include the need for multidisciplinarity, for public engagement, for international outreach, and, increasingly, for support to start-up companies.

The dynamics of public funding are likely to be affected by a country's size. Small countries with a single research council may find it easier to monitor their spending. Larger countries with multiple research councils run the risk that, without inter-council co-ordination, overlaps and even duplication of spending may occur. This is especially a risk for synthetic biology, which cuts across biological, physical, environmental and chemical sciences, computing, social sciences and the humanities. Ideally, in times of austerity, co-ordination at international level would avoid the inefficiencies of duplicate spending.

For countries with multiple research councils that award grants in synthetic biology, one way to circumvent inefficiencies is to pool financial resources so that the grants are awarded by more than one research council. This is most likely to be effective for joint biological-physical sciences awards. The biotechnology-computer software interface is particularly important. A panel of representatives of the biological, chemical, physical, social and environmental sciences would have positive effects; a diversity of peer reviewers can stimulate healthy competition/collaboration between and within councils.

Definitions and guidance

The early rush to nanotechnology grant applications led to questions about whether applications truly addressed research at the nano scale or were simply sub-micro. In that case, the simple solution was to define nanotechnology in terms of size. In synthetic biology there is no such clear distinction. Various organisations are presently involved in refining a definition of synthetic biology (see Chapter 1). This is one of the tasks of the European Union's recently formed Scientific Committee on Emerging and Newly Identified Health Risks working group on synthetic biology.[1] Guidance for grant applications could adopt a definition and set boundaries to define qualifying criteria so that applications meet national views of synthetic biology research. This would allow for filtering applications before the lengthy process of peer review, preventing waste of time and resources.

Avoiding institutional bias

Public research funding should be available to all qualified researchers. For strategic purposes it makes sense to have funding ring-fenced or targeted to known centres of excellence. National centres of excellence can be expected to make the large technological breakthroughs, but a discipline is not developing freely until it can be rolled out to institutions with more modest funding. As in any discipline, it is necessary to foster talent by making sure that sufficient funds are available outside these strongholds so as not to stifle the discipline. This is especially important in synthetic biology, which is likely to be attractive to young faculty with undergraduate and postgraduate training in genomics and other -omics technologies who are ready to embrace the open innovation culture.

Centres of excellence

Because synthetic biology is a young discipline that is costly in terms of equipment, people and consumables, the early establishment of national or regional centres of excellence through public funding is a sensible decision. It is in these hubs that success can be bred and rolled out. While the equipment of synthetic biology is not inordinately expensive or fundamentally different from that of routine molecular biology, the crucial link to genomics and other -omics technologies, and their associated computing power requirements, creates a strong imperative to build initial synthetic biology centres of excellence in close proximity to genomics centres. Proteomics, for example, may soon assume a greater role as advances in mass spectrometry bring it to a wider audience. Mass spectrometry has some specific infrastructure requirements and a need for a cadre of specialists who are not readily found in the life sciences.

This clustering of facilities and talent is common in the United States and other developed countries with advanced biotechnology capabilities. Co-location with business facilities, such as business incubators to support start-up companies, as well as the proximity of larger companies, provides an optimum research-to-application environment. Global Bioenergies, one of the few synthetic biology companies in Europe involved in biofuels, is located in Evry, France, close to one of the French synthetic biology strongholds at Genopole. Centres of excellence cost millions of US dollars if created at an existing facility. They would cost much more if built separately. In these early days of synthetic biology, the safer, less expensive solution is to equip existing facilities. Moreover, the companies supplying essential materials, such as oligonucleotides and synthetic genes, are likely to want to be nearby.

Synthetic biology consortium-building workshops

In countries with a highly developed biotechnology community, it may not be easy to identify the academic and industrial stakeholders with an interest in synthetic biology. Industrial stakeholders can come from various sectors, and academics span many disciplines. The public sector can fund workshops to bring interested stakeholders together. Such venues could also be used to discuss legal, ethical and societal issues. Events of this sort can take any number of forms, e.g. delegates could give very short presentations to pitch their expertise, so as to leave time for networking opportunities. It would be important to take such workshops on the road, and not limit them to capital cities or known centres of excellence.

Internet-based knowledge transfer networks

Internet-based networks can rapidly build a community of like-minded professionals, whatever the discipline. The UK Synthetic Biology Special Interest Group (SynBio SIG) is hosted and co-ordinated by the Biosciences Knowledge Transfer Network, in partnership with other relevant knowledge transfer networks (KTNs): HealthTech and Medicine; Nanotechnology; Electronics, Sensors and Photonics; Chemistry Innovation; Environmental Sustainability; Information and Communications Technologies. Building capacity and interest in this manner is relatively inexpensive and puts the synthetic biology community in touch with a wide range of potentially interested stakeholders and *vice versa*. Such KTNs could be open to public interest groups, and may help non-specialists understand other issues at stake, such as biosecurity and biosafety. In the non-digital past, this effort would have meant road shows the length and breadth of a country. It was more expensive and had little chance of capturing the audiences that can be reached with a KTN. In addition, a KTN activity brings in interested parties from other countries.

International funding

Many countries express the need for an international effort to create efficiencies in synthetic biology and bring stakeholders together. Indeed, there is increasing evidence of international co-operation for public funding. Small countries with limited funds, human capital and facilities would benefit from public grants that encourage international collaboration with larger countries with more mature infrastructure. OECD countries with advanced biotechnology infrastructure would also benefit from grants to form ties with developing countries. This would help break down international barriers, ease the development of international regulation, make oversight of biosecurity and biosafety measures more transparent and easier to execute, as well as building capacity in research, human capital and business internationally.

The UK Biotechnology and Biological Sciences Research Council has set up a grant scheme to allow UK research institutions to partner with other countries. For example, it seeks to forge partnerships with Brazil in synthetic biology. Funds can only be used for travel, subsistence and activities such as workshops or exchanges. They cannot cover salary costs, consumables, items of equipment or other research costs or link on-going collaborative projects. The amounts vary from GBP 50 000 for single partner collaborations and up to GBP 100 000 for applications from consortia with several partners from the United Kingdom and Brazil. Additionally, applicants are encouraged to seek additional funding from either the São Paulo Research Foundation[2] or the National Council for Scientific and Technological Development.[3] Under this scheme, partnerships can also be forged with India, China, Japan and the United States.

The European Union Framework Programmes offer the best opportunity for co-operation to prevent duplication of effort in European countries. A new ERA-NET[4] in synthetic biology (ERASynBio) was launched in January 2012. This three-year project is funded by Framework Programme 7 (FP7) and aims to enhance synthetic biology across Europe by co-ordinating national funding, community building, training and by addressing ethical, legal, social and infrastructural needs. As part of the ERA-NET's community-building activities, the ERASynBio Twinning Programme (SynBio TWIN) was launched to provide funding to initiate and develop synthetic biology collaborations between research groups in the ERA-NET partner countries. Other synthetic biology projects funded through the Framework Programmes are listed in Chapter 7.

In September 2012, the US Office of Naval Research advertised a research opportunity entitled "Synthetic Biology Tools for Sensing and Bioprocessing".[5] Research groups in both business and academia outside the United States were invited to apply.

At the "Forum on Synthetic Biology: Challenges and Opportunities for Australia", held in co-operation with the OECD in Sydney, on 13 March 2012, the Australian synthetic biology research community voiced the opinion that Australia suffers from a lack of overseas students and needs to find ways to join the international research community to make synthetic biology grow. This could be addressed by federal international research facilitation funds. In Australia, cultural dynamics exercise a "tyranny of distance" by favouring traditional ties with the United States and United Kingdom over ties with Japan and Korea. In this context, creating a viable biotechnology cluster is an immense challenge, calling for imaginative and finely directed public policy measures (Guilding, 2008). To specialise in synthetic biology, Australia could also look more to the growing Asian genomics and synthetic biology communities, such as the emerging centres of excellence in China (Pei et al., 2011), Japan (Mori and Yoshizawa, 2011) and Korea (Lee et al., 2011).

The route from the laboratory to the market

The value chain

All stages of the value chain are essential for bringing synthetic biology applications from the research laboratory to the market place. Governments are working to develop policies that achieve a balance between the different supports being requested. These include the need for: personnel at all levels (research to testing and assessment to marketing); national and international collaboration and networks; critical mass in R&D; funding (for public- and private-sector research, for development, demonstration and deployment, for infrastructure, for knowledge acquisition and intellectual property management); routes to commercialisation; dissemination and communication with stakeholders; and access to markets, including public acceptance of products. While these needs are not specific to synthetic biology, there are particular challenges for developing the technology and bringing it to the market place. For example, synthetic biology is expected to be applicable in very specific ways in many disciplines and business sectors and an appropriate policy environment needs to be developed.

Co-operation between the public and private sectors

Co-operation between the public and private sectors can take the form of shared projects, technology transfer and public-private partnerships (PPPs). For the outputs of publicly funded research to reach the market place, some form of technology transfer is required. Technology transfer mechanisms can provide academic researchers and those in public research organisations the means to do so through licences and patents). Industry can benefit from technology transfer to renew its processes and products. For synthetic biology, there are technology transfer issues related to the novelty of the discipline, its multidisciplinary nature and the wide range of sectors in which it may prove to be applicable.

Partnerships are another area of co-operation between the public and private sectors. PPPs are one way to fund the large investments needed for the application of synthetic biology to industrial biotechnology (for example, for the construction of demonstrator plants or larger biorefineries). In 2007, the Energy Biosciences Institute,[6] the largest PPP of its kind in the world, was formed, at a cost of USD 500 million, to use advanced biological knowledge to develop bioenergy. The partner institutions are: the University of California, Berkeley; the University of Illinois at Urbana-Champaign; the Department of Energy's Lawrence Berkeley National Laboratory; and the international energy company BP.

PPPs in Europe include BE-Basic[7] in the Netherlands, which develops industrial bio-based solutions for a sustainable society. It has an R&D budget of more than EUR 120 million, half of it from the Dutch Ministry of Economic Affairs, Agriculture and Innovation. BE-Basic was founded early in 2010, and puts its international focus into practice through strategic partnerships in Brazil, Malaysia, the United States and Viet Nam.

Company creation and development

Like start-ups in other areas of the life sciences, synthetic biology start-up companies are likely to be years from their first products and revenue streams. Their only tangible assets may be some intellectual property and their personnel. During periods of economic austerity these companies are financially vulnerable because they need the high early-stage investments characteristic of life sciences research. They are likely to be dependent on genomics services and to require large numbers of consumables, especially the (as yet) relatively expensive synthetic genes. They also may require access to computing facilities beyond their means.

Access to public funding

When small companies seek funding from governments or from the European Union via the European Commission, they often lack the staff and expertise to deal with the bureaucratic hurdles. This is a long-standing problem and also affects synthetic biology companies, but is increasingly being addressed, for example in the upcoming Horizon 2020 Framework Programme for Research and Technological Development.[8]

Other opportunities for synthetic biology companies to access public funding include, in some countries, programmes for academic-industrial collaboration. However, within such programmes, the sums available are often quite small and the eligible costs are limited. They are also generally project-related.

Venture capital funding

Company growth requires injections of funding at various stages. In many countries, the venture capital (VC) route is not well developed, particularly for companies for which the rewards are long-term such as those in synthetic biology. Some countries have tried to develop policies to support this type of investment, particularly as financial support to companies from public sources, such as that mentioned above, is likely to be limited by state aid rules, for example. Nevertheless, direct support mechanisms are becoming more diverse.

The clearest evidence of a growing industry based on synthetic biology is found in the United States. A number of US companies have been founded from VC investments in synthetic biology platform technologies. They are mostly involved in bioenergy and bio-based materials production and target the boom in bioenergy in the United States from around 2005. Several of these companies have had initial public offerings (IPOs) (Table 3.2), and some have raised over USD 100 million.

Table 4.1. IPOs of some recent synthetic biology-based companies in the United States

Company	IPO (USD millions)	Product description
Codexis	78	Evolved biocatalysts
Amyris	84	Isoprenoids
Gevo	107	Isobutanol
Solazyme	227	Plant-based oils
KiOR	138	Crude oil from wood chips and switchgrass
Myriant	150	Succinic acid
Elevance	100	Specialty chemicals from biomass-based oils
BioAmber	150	Succinic acid

Source: Various sources.

Extensive VC investment in the life sciences, including synthetic biology, is much less common in other countries. Only a small number of European companies have been able to raise significant VC investment in the life sciences. While some support may be available in the early stages for some synthetic biology companies, later-stage investment generally requires much higher sums and is less attractive to investors. In addition, VC is not tailored to the innovation cycle of agro-industrial biotechnology companies, for example, since the return period is too long (7-13 years) and the risks too high. Some governments are taking measures to stimulate VC investments, using existing resources to leverage private funding.

Other financing mechanisms

Indirect mechanisms to support industry R&D include tax incentives such as tax credits. Unlike grants, they are generally available to all companies and are therefore neutral in terms of region and industry. The number of countries using R&D tax incentives is increasing, often with generous terms and conditions. Over 20 OECD countries use this indirect mechanism.[9] Consideration should be given to using these financing mechanisms for synthetic biology.

One example of such financing is France's young innovative companies (YIC) scheme (*Jeune Enterprise Innovante*),[10] which provides incentives for eligible companies by reducing social costs (social security, unemployment and pensions) and tax burdens and also provides incentives for investors. In France, more than 2 000 companies now benefit from this scheme. They are, by definition, research-intensive, and some 20% are active in the life sciences (EuropaBio, 2007). Detailed information about the benefits available through the scheme can be found at the French Ministry of Higher Education and Research website.[11]

Uruguay has very recently approved strong tax incentives for biotechnology companies.[12] The new law is a milestone in the implementation of the national strategic plan for the rapidly growing biotechnology industry, which has been officially declared strategic to the country's future industrial development. Under the new law, biotechnology start-ups can benefit from tax breaks of 50-90% of corporate tax until 2021.

Another example is the R&D tax incentive introduced in Australia (July 2011), which aims to encourage companies to invest in R&D. It provides small and medium-sized enterprises (SMEs) with an aggregate turnover of less than AUD 20 million a year with a 45% refundable tax offset. This reduces the cost and risk of undertaking R&D, and can improve cash flow for firms in a tax loss situation. As of early 2013, almost AUD 2 billion of innovative R&D had been registered by businesses since the incentive began.[13]

Joint ventures are being used by some synthetic biology companies (for example, certain companies developing biofuels and bio-based products) to overcome the challenge of large-scale production, which requires high levels of investment. For example, in Italy a 50/50 joint venture between Polimeri Europa/ENI and Novamont is converting a former ENI chemical plant into a third-generation biorefinery for the production of bioplastics and other bio-based products.

A specialised support infrastructure for SMEs across regions is a public measure worthy of consideration. It could advise interested stakeholders on the strategic use of instruments (e.g. standards, labels, certificates) and provide access to demonstration, testing and certification facilities. A region-wide approach bringing together suppliers and potential users downstream in the value chain would increase the probability of avoiding market failures and earn societal benefits earlier, contributing to a lead market advantage.

Conclusion

The linking of synthetic biology to a future manufacturing base clearly changes the dynamics of investment. Compared to basic research, taking biotechnology from the laboratory to the market increases the need for investment many-fold. The earliest synthetic biology investments at the company level have been mostly related to biofuels applications, and as a result many of the tools for high-throughput strain construction are being developed this way. Countries that are making public investments in synthetic biology are devising a variety of ways to do so. One aspect that arises frequently is the need for international funding to build lasting partnerships. It is hoped that this will make for more efficient public spending by cutting down on duplication. It is also a way to bring different countries with different problems together and could be especially important for bringing developed and developing countries into alignment.

Notes

1. http://ec.europa.eu/health/scientific_committees/consultations/calls_experts/scenihr_exp_07_en.htm.
2. www.fapesp.br/en/.
3. www.cnpq.br/.
4. The objective of the ERA-NET scheme is to step up co-operation and the co-ordination of research activities carried out at national or regional level in member and associated states through networking of research activities conducted at national or regional level and mutual opening of national and regional research programmes.
5. www.fbo.gov/index?s=opportunityandmode=formandid=4d0a0d102395ed78014629e71aa58468 andtab=coreand_cview=1.
6. www.energybiosciencesinstitute.org/.
7. www.be-basic.org/.
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