Synthetic biology – pathways to commercialisation

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Abstract: Synthetic biology is transforming the ability to manufacture increasingly needed bio-based products in response to rising market demand. By applying engineering principles to the convolution of recent advances in genomic engineering techniques, information technology and automation, synthetic biology is facilitating the replacement of time-consuming ‘discover and grow’ approaches by more precise and affordable ‘biodesign and biomanufacture’ processes. Meantime, societal awareness of specific health, well-being, and environmental issues is increasing ‘market pull’ that will shape future pathways to commercialisation. Market interests will not only shape targets for product function and cost but also increasingly question their provenance. Sustainability concerns are already driving demand to replace petrochemical-derived by bio-derived products, but many established industries wishing to transition may lack familiarity with bio-manufacturing processes and with the wider issues associated with large-scale bio-feedstock supply chains. Meantime, commercialisation of synthetic biology today is being advanced mostly via start-ups and SMEs. Combining the knowledge and skills required to respond to market interests, as the scale of operations and complexity of issues expands, is likely to stimulate an increasing diversity of collaborative approaches.

1 Introduction

Elements of the synthetic biology ‘toolkit’ such as metabolic engineering and gene editing may be very familiar to establish companies in the life sciences sector, but even for companies that have been working in biosciences for decades, the synthetic biology approach – comprising integrated bio-design and automated optimisation, based upon rapid iteration of the design-build-test-learn (DBTTL) cycle and incorporating multidisciplinary approaches spanning IT and robotics – has the potential to be transformative. However, for many manufacturing businesses spanning the wider bio-economy lacking this background, or to digital innovation in general [1], relevant skillsets may be absent and the approach may well challenge established ways of working. When combined with considerations of sunk capital and lack of familiarity with relevant supply chains, this may generate institutional barriers to uptake, rendering the approach as essentially ‘disruptive’.

Encountering such issues is not specific to synthetic biology, and could potentially apply to any emerging technology. Drawing upon the earlier work of Thomas Kuhn, in his ‘Structure of Scientific Revolutions’ [2], it has been noted that the adoption of a radically new scientific interpretation may require a complete ‘paradigm shift’. In the case of synthetic biology, tens of thousands of students and researchers worldwide have already been introduced to and applied synthetic biology methods during the past decade, collectively sharing the understanding that ‘biology is engineerable’ and contributing towards such a paradigm shift [3].

A consequence of the essentially disruptive nature of the field is that commercialisation today is being driven predominantly via start-ups and SMEs, where many of the required skillsets reside and continue to be formed. A number of established companies possess research groups familiar with synthetic biology, but even so, the commercialisation pathway to date has tended to be via partnerships with specialised SMEs.

Policies to help accelerate manufacturing at scale, therefore, need to reflect the requirements of recently established small companies, which by their nature will have limited resources and track records. The time delay between allocating the costs of early stage publicly funded research and deriving the economic benefits of full-scale manufacture will likely span a decade or more. Economic risk-reward models must assimilate a correspondingly patient approach if the game-changing benefits of a disruptive technology such as synthetic biology are to be fully realised.

2 Progress

The 2012 UK Roadmap [4] mapped out illustrative technological developments and related ‘eco-system’ requirements. The envisioning of a holistic eco-system approach reflected the fact that technological progress cannot be accelerated without the simultaneous consideration of many other factors ranging from governance frameworks and public attitudes to skills, standards, and supply chain infrastructures. Anticipated timescales may be roughly divided into three phases, comprising predominantly research inputs during the first 3-year period 2012–2015, the strengthening of the science-base and development of new applications 2015–2020, and progression to large-scale operations 2020–2030 [5].

Progress across many elements of the roadmap to date has remained broadly on track with expectations, whilst technological progress in particular has been even more rapid than envisaged. For example, CRISPR-Cas9-related gene editing has been developed and had a significant impact since 2012, and advances in the speed, quantity and quality of data generation have enabled machine learning and artificial intelligence approaches to take a more significant role. The development of increasingly effective, affordable, and accessible toolkits is arising from multiple sources of progress across the domain, deriving additional synergistic benefits from simultaneous developments in aspects such as miniaturisation, interoperability, networking, and cloud computing. The adoption of an engineering mindset to the development of synthetic biology has helped drive forward the establishment of relevant operating standards and approaches to metrology, further assisting interoperability and the realisation of such synergies.

The synergistic contributions of both coordinated projects and also independent market initiatives help accelerate progress. For example, the human genome project (HGP) 1990–2003 provided a critical turning point not only in advancing understanding of the relationship between genetic information and function, but also in stimulating the subsequent rapid development of cost-effective sequencing technologies. Costs dropped more than five orders of magnitude in the decade to 2016 – greatly exceeding the corresponding Moore's law rate associated with integrated circuit
developments during previous decades. It took 10 years and over $2 billion to annotate the first human genome, but today a human genome can be sequenced in a few days for <$1000 [6]. Miniaturisation now enables hand-held sequencers to be taken into the field, and sequencing data are providing the essential starting point for innumerable comparative genomic studies [7]. Analysis can be carried out with ever more microscopically small samples, improving throughout rates whilst decreasing unit reagent costs. Smart, integrated benchtop units such as Cyto-Mine® by Sphere Fluidics [8] provide highly specific functions, whilst other equipment, such as the Bento Lab [9], provide flexible research and learning opportunities. The speed and cost of writing DNA have also fallen, and recent developments [10] indicate the potential for more substantial improvements in the next few years.

DNA Foundries take advantage of recent and ongoing improvements in gene editing, construction, and assembly technologies to automate the entire DBTL cycle, significantly accelerating and reducing the cost of optimising system function, starting from initial in-silico bio-designs. Economies of scale are being achieved via the increasing availability and accessibility of networked services and facilities. Interoperability between critical components such as production and analysis units is being achieved via the adoption of relevant standards and operating software.

Synthetic biology may be viewed as transformative not only in terms of technological developments but also in the manner in which it is being deliberatively shaped and collectively advanced by the practicing community around the world.

Underpinning progress are the many companies focussed on developing tools and techniques, providing services to the field as a whole.

3 Synthetic biology and the bioeconomy

Developments in genomics through the second half of the twentieth century focussed predominantly on healthcare. The OECD have estimated that, when the HGP was published in 2003, only 2% of biotechnology investments were in industrial biotechnology, increasing to just 6% by 2010, compared to 80% in the health sector [11].

The biotechnology market has continued to grow substantially since then. According to a recent report by Grand View Research, Inc [12], the global biotechnology market, worth around USD 370 billion in 2016, is expected to reach USD 727 billion by 2025, representing a growth rate of 7.4% pa. The report highlights key drivers of financial growth being regenerative medicine and genetics in diagnostics (incorporating AI for example to assist patient-specific diagnoses via a deeper understanding of population data).

The same report also identified supportive government (and its allied agencies) policies related to synthetic biology as a major growth impacting driver in this sector, noting that developed economies such as UK and the USA are critically monitoring and funding synthetic biology R&D initiatives. The recent launch of the UK Bioeconomy Strategy reaffirms ongoing UK policy support for this technology [13].

Development of synthetic biology as a distinct approach can be traced back through the 2004 SB 1.0 conference [14], generating a ‘parallel track’ of developments focused not on delivering healthcare per se but on the establishment of an underpinning platform technology based on engineering principles, leading towards the establishment of efficient bio-design to biomanufacturing capabilities with a much broader range of potential applications than the entire bioeconomy. Hundreds of synthetic biology SMEs and start-ups formed since then are currently providing a valuable resource both to explore and develop innovative solutions and also to train skilled workforces for the future.

4 From technology push to market pull

Synthetic biology’s rapid advancement over the past decade and its anticipated future potential represents a strong ‘technology push’. Critical to future commercialisation is also the simultaneous increase in ‘market pull’ for innovative and effective technological solutions, to which synthetic biology may hold the key.

As expressed in the 2012 UK Synthetic Biology Roadmap [4] (‘the Roadmap’), the ongoing increase in human population upon our finite planet will have significant consequences both for the future quality of life and for the environment upon which we depend. Needs arising to which synthetic biology could potentially offer solutions were summarised in the Roadmap under the broad headings of ‘well-being (predict/prevent diseases, personalised healthcare, employment)’, ‘security (food, water, energy)’ and ‘sustainability (manage natural resources, reduced dependence on non-renewable sources, climate change mitigation)’.

It can be observed that synthetic biology applications are indeed being developed within scope of all three main categories of need as originally identified. However, due to the rate and scale of climate change and human population increase alongside constrained or even diminishing primary resource availabilities, the associated global challenges seem likely to continue increasing, with associated negative consequences, unless substantial ground-breaking technologies can not only be identified and demonstrated but also deployed at scale.

Not only has the technology driving synthetic biology advanced even more rapidly than might have been envisaged at the time of the ‘Roadmap’, but ‘market pull’ has intensified. Sustainability challenges continue to be clarified and recognised internationally, relevant examples including the 2015 Paris Climate Agreement [15] (with ongoing updates leading to COP24 [16]), the UN’s 17 Sustainable Development Goals [17], mounting publicity of the role of plastics on ocean pollution [18] leading to a raft of political responses to curb the use of plastics [19], and so on. Such challenges are stimulating the commercialisation of an increasing range of applications via synthetic biology.

The NSF report ‘Industrialisation of Biology’, published in 2015 [20] illustrated 20 classes of biomaterial being developed by industrial biotechnology and synthetic biology companies. It also noted an OECD analysis that, ‘whilst there are more than $4 trillion of products made by chemical transformation globally, only about 5% of these potentially ‘addressable markets’ have been addressed biologically’ [21].

Potential blockers to such developments include the inertia associated with massive sunk investments in conventional infrastructures and supply chains, not least in the entire oil, gas, and associated petrochemical industries, together with the predominance of thermo-chemical processes and expertise which favour large-scale operations. Such economies of scale also make it difficult to compete with fossil fuels and bulk chemicals exclusively on economic grounds. However, the market demand for greater sustainability is becoming an increasingly important driver even at this very high volume end of the manufacturing scale.

Climate change mitigation requires a reduction in the use of fossil fuels, and the use of biofuels has been increasing steadily over the past 15 years. In response to the 2015 Paris Agreement [15] (to restrict any future climate change related global average temperature to well below 2°C above pre-industrial levels and to pursue efforts to limit further the temperature increase to 1.5°C), Shell recently applied its well-established scenario planning approach to map out how meeting such goals in practice could be envisaged [22]. These scenarios are not framed as predictions, but nevertheless provide valuable insights due to the breadth, depth, and rigorous internal consistency applied to generate viable world models.

‘Sky’, the resulting new scenario, was published in March 2018. In this scenario, electric vehicles will come to dominate the passenger vehicle fleet by 2070, whilst advanced biofuels will grow rapidly to displace fossil oil for applications where the energy density of liquid fuels remains a critical factor. The biosphere takes on an increasingly important role in stabilising the climate through the twenty-first century, both from its carbon storage potential and from its role in providing a renewable feedstock option for chemicals and materials. Photosynthesis not only provides a mechanism to capture solar energy in molecular form but also...
generates molecular building blocks for future bio-manufacturing industries.

Infrastructural inertia not only applies to the processes that make and distribute liquid transport fuels but also to the persistence in the market of the engines that are designed to use them. Biology does not naturally provide components that can fully substitute the grades of fuel required by modern engines [23]. Ethanol is the most common biofuel blending component due to familiarity with and prevalence of the fermentation process, but it is restricted to use at relatively low concentrations in the gasoline mix by typical engine tolerances. Finding alternatives to ethanol as a gasoline component, or to transesterified vegetable oils as diesel-blending components, whilst maintaining good overall energy balance, scaleability, and infrastructure compatibility remain a challenge. Matching biologically expedient metabolic pathways from lignocellulose with the essential requirements of a finished fuel reveals alternative pathways – such as via levulinic acid [24] – and illustrates just one of a number of ways that could extend the range of future advanced biofuel options.

For jet-fuel, ‘drop-in’ pure hydrocarbon quality is an essential requirement. Aviation fuel regulations specify not only the final component, but the processing pathways. In response to sustainability challenges, these regulations continue to evolve to facilitate the inclusion of bio-derived components. For example, in April 2018, ASTM International approved the use of jet fuel blending components (blendable in concentrations up to 50%) produced from ethanol as an intermediate [25]. This regulatory development now permits commercial pathways to biojet via ethanol to be considered, such as using Lanzatech’s gas fermentation to ethanol process [26].

The importance of using renewable feedstocks is being increasingly recognised within the chemical industry. A survey carried out for ICIS by Genomatica, published in Nov 2017 [27], determined that over two-thirds of respondents believed that renewables-based chemicals will be in common use in 5 years’ time. Producers reported that 65% of their customers are interested in sustainably produced chemicals (compared to just 34% in a similar survey carried out in 2014). 63% reported a higher, or much higher, level of interest from their customers than 3 years before.

Early examples of chemical companies shifting production pathways from fossil to bio feedstock routes are provided by DuPont and BASF. DuPont teamed up with Genencor as early 1997 to apply metabolic engineering to convert glucose to 1,3-propanediol (PDO), and later formed a joint venture with Tate and Lyle to scale up the industrial fermentation process thereby succeeding in producing bio-derived 1,3-PDO – a key intermediary for many products including carpets – at commercial scale in late 2006. Using corn-sugar as feedstock, this approach currently claims to use 30% less energy and to achieve 70% GHG reduction relative to the equivalent fossil-oil-based pathway [28]. In 2013, BASF partnered with Genomatica for access to their GENO BDO™ patented single-step fermentation process to produce bio-based 1,4-butanediol (‘bio-BDO’), (an intermediate used in a wide range of products including plastics, solvents and fibres). Following successful production of commercial volumes, they plan to build a world-scale plant (75,000 ton/year) [29].

However, these examples also highlight the considerable development times required by early pioneers – nearly a decade in the Genencor/DuPont example and a development period of 5–8 years reported by Genomatica prior to their partnership with BASF [20].

Continuing advances in the synthetic biology toolkit plus accumulating experience is helping reduce commercial development times and costs, permitting full-value chains to be established by start-ups. Start-ups such as Amyris [30] and Green Biologics [31] have succeeded in developing and demonstrating commercial scale without the need to join resources with a more established industry partner, by retaining the flexibility to pivot business models in response to market needs. Amyris has shifted its commercial focus from a potential fuel component, farnasene, towards a range of higher value consumer products, including cosmetics, flavours, and fragrances and zero-calorie sweeteners. Likewise, the Green Biologics pathway to n-butanol, although a potential fuel blending component, is reaching markets as a solvent or additive, and as a feedstock for higher value chemicals used in fragrances and cosmetics. Further to its partnership with BASF for bio-1,4-BDO, Genomatica also established a partnership with Versalis in 2013 to co-develop a process to produce bio-based 1,3-BDE (‘bio-butadiene’), reaching pilot-scale production of biopolybutadiene, a ‘bio-rubber’ with potential applications in the tyre industry [32].

In addition to the demand for greater sustainability of current product lines, the continuing need for new and advanced chemicals and materials is providing another form of ‘market pull’. The DARPA-funded ‘Living Foundries 1000 Molecules’ project [33] deliberately set out to discover radically different chemistries, using synthetic biology to introduce new options and pathways to access molecules that are critical, high-value but also prohibitively high cost using current technologies. With similar objectives, a synthetic biology roadmap to new advanced materials, setting out a number of potential pathways, was published by the University of Manchester in 2018 [34].

Meantime, entirely new market interests and applications are already emerging, such as the use of synthetic biology to generate DNA for data archiving [35].

5 Supply pipeline

The quest for greater sustainability is generating a market pull for the substitution of fossil fuels and petrochemicals by bio-derived equivalents, but the suitability of the resulting solutions must take into consideration not only issues of renewability and potential reduction in net carbon emissions to the atmosphere, but also other environmental and societal factors associated with the entire supply chain. These may be associated with the source of the bio-feedstock, such as competing uses for land, water, smallholder livelihoods, and the conservation of biodiversity, or conversely associated with clear additional benefits of using residues and wastes in the context of establishing a more circular economy. To address such complex issues, modifying human behaviours through societal endeavours or political initiatives will inevitably play a critical role, but it is recognised that access to new technologies are also vital to help provide solutions.

Pollution and diseases, droughts, increasing salinity and soil degradation pose significant threats to agricultural production, but current solutions, such as the extensive use of pesticides, can introduce other consequences for the environment. Conventional plant breeding can help confer important traits, but is not always sufficient or rapid enough to address all the challenges and demands. Advances in technology such as gene editing of plants to confer resistance to pests or diseases may become critical in generating potential solutions and to helping balance the many competing requirements facing future production.

Water quality is also becoming increasingly recognised as a critical factor. Pollution of watercourses by toxic chemicals, plastics, and other materials is a significant issue for human health directly and for the aquatic species upon which livelihoods and ecosystems may depend. Synthetic biology has, for example, been applied to develop affordable technologies to detect pollutants such as arsenic in drinking water, and the start-up Customem [36] has applied synthetic biology to develop a method to remove persistent hazardous chemicals from wastewater.

The need to reduce plastic waste exists alongside the need to make whatever plastics continue to be required – for example to reduce food spoilage – to be biodegradable or at very least recyclable, and for alternative packaging solutions to be developed. These and related issues are generating ‘market pull’ from sectors already associated with such supply chains. For example, the fashion industry, which for many years has been making significant efforts to improve working conditions in the textile supply chain, is now also recognising the contribution of textile dyeing to water pollution and worker health. The $3 trillion textile industry is world’s second largest polluter of water. Using synthetic biology, Colorifix [37] has engineered a microorganism that carries synthesised colour molecules that can be attached very efficiently to a broad range of textile materials, generating a product that is not looks like a natural fibre but is otherwise fully biodegradable.
only less toxic to the workers but can also reduce water use by 90%, energy by at least 20% (potentially much more), and deliver a 99% reduction in dyes released to the environment.

Consumer products and lifestyle choices are starting to generate additional forms of ‘market pull’. Of 27 start-ups identified by Synbiobeta as having received private funding in the first quarter of 2018, eight companies were developing applications in food and agriculture and another eight in pharma. Several more food-product related start-ups, such as impossible foods [38], received significant private funding in the second quarter of 2018 [39]. Such investment patterns reflect an increasing recognition of shifting societal attitudes – in this particular case, ones that are steadily increasing the market pull for more sophisticated plant-based ‘meat’ substitutes [40].

Other synthetic biology companies are addressing the increasing market demand for alternatives to other animal-derived materials such as lab-grown leather (e.g. by Modern Meadow [41]) or silk (e.g. by Bolt Threads [42]) as recently highlighted in London’s V&A Museum exhibition ‘Fashioned from Nature’ [43].

6 Summary

The ability to tackle increasingly challenging bio-design issues and to develop pathways to bio-manufacturing continues to advance rapidly as synergies are being realised between the many technological elements (both hardware and software) that are collectively progressing the frontiers of synthetic biology.

Many different pathways to commercialisation exist, depending whether the main objective is to produce an established product more cheaply or sustainably, to generate a product conferred with new technical functionality, or to confer a product with new attributes dictated by evolving societal and market expectations.

Applications currently being developed commercially are now leading to products relating to all the main classes of market need initially identified under the broad headings of ‘well-being’ and ‘environmental’ in the 2012 UK Roadmap. Just as technology itself continues to advance and introduce new options, so ‘market pull’ also continues to evolve in response to mounting societal and political awareness of the global challenges and associated demand for innovative solutions. ‘Business-as-usual’ will no longer provide a good model for the future.

Combining the knowledge and skills required to respond as the scale of operations and complexity of issues expands is invoking the need to adopt more holistic approaches and to draw upon an increasing range of collaborative approaches.

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