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A Report on Ten Key Technologies and Their Policy Implications

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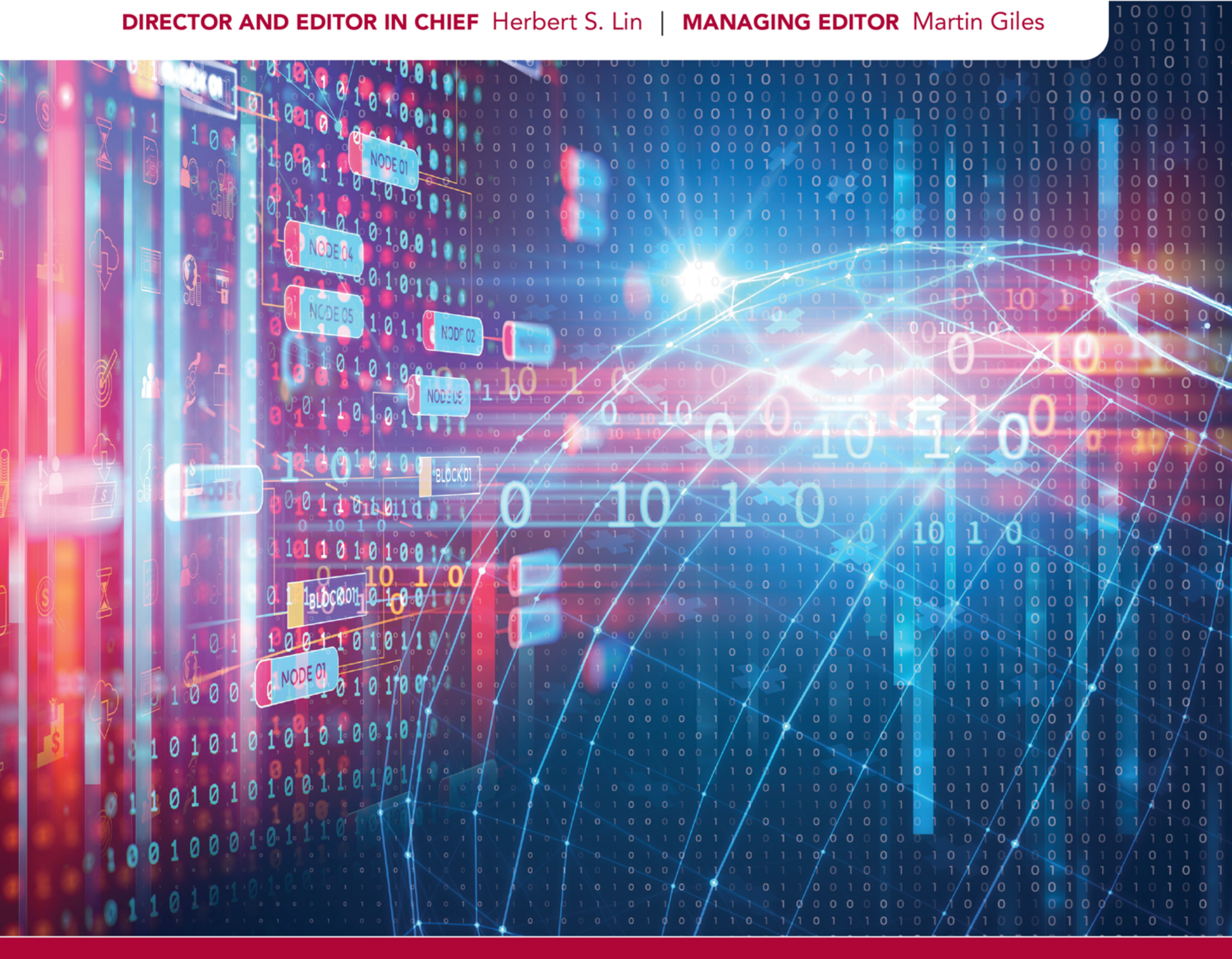


02

BIOTECHNOLOGY AND SYNTHETIC BIOLOGY

KEY TAKEAWAYS

- Biotechnology is poised to emerge as a general-purpose technology by which anything bioengineers learn to encode in DNA can be grown whenever and wherever needed—essentially enabling the production of a wide range of products through biological processes across multiple sectors.
- The US government is still working to grasp the scale of this bio-opportunity and has relied too heavily on private-sector investment to support the foundational technology innovation needed to unlock and sustain progress.
- Biotechnology is one of the most important areas of technological competition between the United States and China, and China is investing considerably more resources. Lacking equivalent efforts domestically, the United States runs the risk of Sputnik-like strategic surprises in biotechnology.

Overview

Biotechnology involves using living systems and organisms to develop or make products and solve problems. First-generation biotechnology arose over millennia and involved the domestication and selective breeding of plants and animals[1] for agriculture, food production, companionship, and other purposes.[2] Second-generation biotechnology was launched a half century ago with the invention of recombinant DNA[3] and has since encompassed techniques such as genetic engineering, polymerase chain reaction (PCR), high-throughput DNA sequencing, and CRISPR gene-editing technology.[4] Both breeding and editing approaches continue to advance, creating and using ever better tools for sculpting[5] and editing[6] living systems.

Biotechnology products and services realized through breeding and editing are already widely deployed. A 2020 National Academies of Sciences, Engineering, and Medicine report valued the US bioeconomy at around 5 percent of GDP, or more than $950 billion annually.[7] Existing applications involve primarily agriculture, medicines, and industrial materials.[8] A 2020 McKinsey & Company report noted that hundreds of biotechnology projects were under development and estimated that the resulting products could add $2 to $4 trillion in annual economic impact within the next two decades.[9] This projected doubling of the bioeconomy's contribution to worldwide GDP every seven years would match biotechnology's economic track record.[10] The McKinsey report concluded that, ultimately, biomanufacturing could account for around 60 percent of the global economy's physical inputs.[11]

Biology, as a natural manufacturing process, is remarkably distributed and localized. For example, leaves on trees do not come from factories or central facilities; rather, they grow on trees themselves—all over the place. Yet, outside of agriculture, biotechnology has until now been largely practiced and commercialized in a capital-intensive, industrialized, and centralized context.[12] This contrast between biology as a naturally distributed platform and industrialized biomanufacturing processes suggests that biotechnology may be ripe for new modes of practice and products.

Notably, synthetic biology continues to emerge as an important new approach within biotechnology. Synthetic biology combines principles from biology, engineering, and computer science to modify living systems and construct new ones by developing novel biological functions, such as custom metabolic or genetic networks, novel amino acids and proteins, and even entire cells. These new functions are performed through the construction of engineered biological parts that can be reused by humans when appropriate, thereby reducing the need for each project to start from scratch. Synthetic biology thus helps us to create more complex, biologically based systems, including those with functions that do not exist in nature.

In thinking about biotechnology's potential, it is instructive to consider the evolution of information technology over the past several decades. Fifty years ago, computers were mostly industrial, disconnected, and centralized.[13] The emergence of personal computers, packet-switching networks,[14] and programming languages that made computing accessible and fun[15] changed how information science and technologies developed and led to decentralized access to computing and information at unprecedented speed and scale.[16] Biology could experience the same transformation within the next two decades—manufacturing processes could move from being largely invisible to being obvious and apparent to people as they begin to manipulate some of these workflows for themselves.

Key Developments

Distributed Biomanufacturing

The significance of distributed biomanufacturing lies in its flexibility, both in location and timing. Because the apparatus for a fermentation process can be established wherever there is access to sugar and electricity, a production site can be set up almost anywhere. The timing aspect is equally transformative: By removing the need to grow feedstocks, biomanufacturers can swiftly respond to sudden demands, such as a rapid outbreak of disease requiring specific medications. This adaptability not only enhances efficiency but also revolutionizes how we approach manufacturing, making it far more responsive to urgent needs than traditional methods.

In an important demonstration illustrating that distributed biomanufacturing is not a mirage, the synthetic biology company Antheia reported in early 2024 that it had completed validation of a fermentation-based process for brewing thebaine, a key starting material used in treating opioid overdoses with Narcan.[17] The company partnered with Olon, an Italian contract manufacturing organization. Antheia's bioengineered yeast strain was sent to Olon's large-scale fermentation facility in

Italy. Working together, they repeatedly brewed 116,000-liter batches of bioengineered yeast, with each batch making broth containing a metric ton of thebaine—roughly enough for one hundred million Narcan doses.[18] This demonstration highlights the potential for on-demand production of critical pharmaceuticals, potentially revolutionizing drug supply chains and improving access to essential medicines.

In 2022, Chinese researcher Chenwang Tang and colleagues noted more generally how synthetic biology allows the rewiring of biological systems to support portable, on-site, and on-demand manufacturing of biomolecules.[19] In 2024, as one of many pioneering examples, Stanford researchers reported on-demand bioproduction of sensors enabling point-of-care health monitoring and detection of environmental hazards aboard the International Space Station.[20] They had already realized many similar demonstrations of distributed biomanufacturing on Earth, ranging from biotechnology educational kits to the production of conjugate vaccines used to stimulate stronger immune responses.[21]

These are just a few examples demonstrating how biotechnology can be used to make valuable products and services locally. Viewed from a traditional perspective, what's happening is a sort of molecular gardening: The energy and material inputs needed to make the biotechnology products are supplied locally, but the process differs from conventional gardening in that the genetic instructions for what the biology should do or make are being programmed by bioengineers. To fully unlock the power of distributed biomanufacturing, it must also become possible to make the physical DNA used to encode the genetic programs locally.

Distributed DNA Reading and Writing

DNA is physical material that encodes biological functions in natural living systems. It is often represented abstractly by its four constituent bases (A, C, T, and G), also known as nucleotides. Unique orderings of these bases encode different biomolecules, which in turn underlie different cellular behaviors and functions.

DNA sequencing (i.e., reading of DNA) and synthesis (i.e., writing of DNA) are two foundational technologies underlying synthetic biology.[22] Sequencers are machines that determine the precise order of nucleotides in a DNA molecule, effectively converting genetic information from a physical to a digital format. Synthesizers generate user-specified digital sequences of A's, C's, T's, and G's, creating physical genetic material from scratch that encodes the user-specified sequence, thus effectively transforming bits into atoms. If DNA reading and writing tools could themselves be distributed, anyone with an internet connection could upload and download application-specific DNA programs that direct distributed biomanufacturing processes powered by locally available energy and supplied by locally available materials.

In the 1990s, public funding for sequencing the human genome jump-started advances in DNA-sequencing tools by creating significant demand for reading DNA.[23] Private capital and entrepreneurs quickly responded.[24] The Human Genome Project (HGP) favored development of DNA sequencers that could read billions of bases of DNA as cheaply as possible, resulting in large-format DNA sequencers that were organized in centralized DNA-sequencing factories.[25] A complementary approach to DNA sequencing has since matured that allows for individual DNA molecules to be sequenced via tiny pores, or nanopores, in ultra-thin membranes.[26] UK-based Oxford Nanopore Technologies has exploited this approach to market small-format, portable DNA sequencers that can be used with laptop computers, allowing DNA sequencing to become a distributed technology (see figure 2.1).[27]

The market for DNA synthesis has developed organically over the past forty-five years.[28] So far, there has been no equivalent to the HGP that has resulted in significant public funding from Western governments for improving the technology of DNA synthesis.[29]

FIGURE 2.1 Portable DNA sequencers enable biotechnology to become more distributed

Source: Oxford Nanopore Technologies, 2024

Improvements in DNA synthesis in Western countries have been sporadic and dependent primarily on private capital.[30] Commercially available gene-length DNA-synthesis services in the United States have improved only modestly in the past six years.[31] Today, most DNA synthesis is carried out via centralized factories.[32] Customers order DNA online and receive it via express shipping; it typically takes these factories from days to weeks to make the DNA molecules themselves.

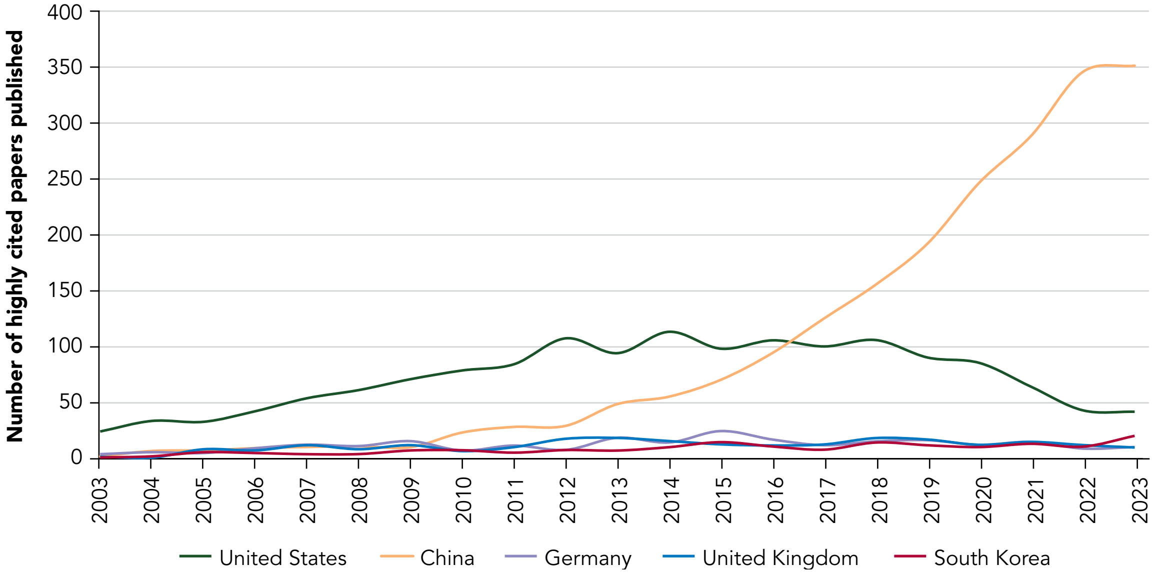
A new generation of companies is pursuing novel approaches to building DNA—most notably enzymatic DNA synthesis, which uses enzymes and simpler chemical inputs to build DNA.[33] These new approaches support hardware and reagent formats that could potentially enable fast, reliable, and distributed DNA synthesis. However, the creation of widely distributed DNA printers is not receiving significant public support, and existing private investments may not be sufficient to make the technology real in a practical sense.

Meanwhile, researchers in China have had the resources to advance gene and genome synthesis. For example, the first synthetic plant chromosome was reported by Chinese researcher Yuling Jiao and colleagues in January 2024.[34] More broadly, researchers in China published nearly 350 papers that ranked among the top 10 percent most-cited papers on synthetic biology in 2023, compared to 41 such papers in the United States (see figure 2.2).

Biology as a General-Purpose Technology

Biotechnology is currently used to make medicines, foods, and a relatively narrow range of sustainable materials. However, as noted earlier, anything whose biosynthesis engineers can learn to encode in DNA could be grown using biology.

FIGURE 2.2 China is outpacing the United States in publishing highly cited research papers on synthetic biology



Source: Adapted from Australian Strategic Policy Institute, Critical Technology Tracker, based on "Appendix 2: Detailed Methodology," in Jennifer Wong-Leung, Stephan Robin, and Danielle Cave, ASPI's Two-Decade Critical Technology Tracker, August 2024

Examples from nature highlight the potential here: Some bacteria are capable of growing arrays of tiny magnets,[35] while select sea sponges grow glass filaments with a refraction index—which determines the speed at which light travels through a medium—similar to that of human-made fiber-optic cables.[36] These bio-made magnets and filaments are created under ambient conditions through naturally sustainable processes and are often more robust than traditionally manufactured alternatives. These and other examples have inspired calls for biology to be recognized as a general-purpose technology that, with appropriate vision and leadership, could become the foundation of a much more resilient manufacturing base.[37]

As an example of the vision that's needed, in 2018, the Semiconductor Research Corporation (SRC) outlined an ambitious twenty-year synthetic biology road map.[38] SRC's first proposed step was to develop DNA as a data storage medium.[39] Such an approach was demonstrated in 2024 when the Hoover Institution Library & Archives partnered with Twist Bioscience to encode a digital copy of the telegram from President Hoover founding his namesake institution within synthetic DNA contained in a tiny ampule (see figure 2.3). Made in this way, the DNA serves as a data storage medium whose digital contents must be recovered via DNA sequencing.

The ultimate goal of SRC's road map is to enable bottom-up construction of microprocessors. To fully realize this goal might cost $100 billion in foundational research investment, smartly managed over twenty years, and as yet there is no such coordinated effort underway. However, the novel notion of growing computers already challenges many framing assumptions and realities underlying contemporary geopolitics.[40] Concerns about computer manufacturing and supply chains presume that making computers is hard. What if making them becomes as easy as growing zucchini?

FIGURE 2.3 DNA is used as a storage medium for a digital copy of Herbert Hoover's telegram founding his namesake institution

A more long-standing example of biology as an increasingly general-purpose technology with potential geopolitical impacts can be found in the 2011 US Navy program, Application of Synthetic Biological Techniques for Energetic Materials.[41] This program began exploring the ability to brew propellants and explosives through a process akin to how Antheia and Olon partnered to brew medicines—an ability that could enable any nation anywhere to create more resilient supply chains for key military materials. A distributed and resilient biomanufacturing network could, for example, help NATO members meet their Article 3 obligations related to supply chain resilience.[42] A bio-based approach to brewing fuels could also help meet climate and sustainability goals.[43]

Pervasive and Embedded Biotechnologies

Most modern biotechnology products and applications are presumed to be destined for deployments carefully contained within steel tanks or constrained by doctors' prescriptions. However, recent developments in consumer access to these products and applications suggest that this will not always remain the case. A US company called Light Bio, for example, now sells petunia plants bioengineered to emit light (see figure 2.4).[44] Light Bio's offering represents one of the first successful launches of a live consumer biologic, enabling anyone in the United States to source and keep a bioengineered organism for personal use.

In 2024, UK-based Norfolk Plant Sciences first made available to US consumers seeds for its purple tomato, a kind of tomato bioengineered to produce high levels of antioxidants thought to help prevent cancer (see figure 2.5).[45] Stanford faculty bought seeds, and soon bioengineered tomatoes were growing in gardens across campus. Indeed, these tomatoes are available for consumer purchase in a number of grocery stores in the American Southeast.[46]

Another category of pervasive and potentially consumer-facing biotechnology involves bioengineering the bacteria that live on our skin and inside our bodies, as well as within the environment around us. For example, in 2023, Stanford researchers pioneered the bioengineering of skin microbes to combat skin cancer.[47] They have since expanded such work to enable the eliciting of more broadly antigen-specific T cells, which target and eliminate cells infected with viruses and bacteria, as well as cancerous cells. T cells also play a role in providing long-term immunological memory.[48] In addition, researchers have identified specific odorants produced by human-skin microbes whose production could be modulated to reduce mosquito bites[49] and have also developed methods for bioengineering microbes to improve gut health.[50]

As these examples suggest, twenty-first-century biotechnologies may increasingly be deployed in, on, and around us—and be made available through established and far-reaching consumer channels.

Biological Large Language Models

In the 2023 edition of *The Stanford Emerging Technology Review*, we discussed how researchers had developed and deployed methods that are based on artificial intelligence (AI) to predict the three-dimensional structures of over 200 million natural proteins,[51] an accomplishment recently recognized via the 2024 Nobel Prize in Chemistry.[52] Anybody with a laptop can now take a DNA sequence encoding a protein and quickly estimate its expected shape. The shape of a protein helps determine its placement and function in a living system. The ability to rapidly generate predicted shapes helps bioengineers modify existing proteins and design new ones from scratch. However, the work of modifying an existing protein sequence and designing a new protein still requires direct human genius and labor.

FIGURE 2.4 Light Bio's petunias are bioengineered to emit light

Source: Light Bio Inc.

FIGURE 2.5 Norfolk Plant Sciences has bioengineered a purple tomato

Source: Norfolk Plant Sciences

Advances in AI may change that. In 2024, new large language models (LLMs) have emerged that are trained on natural DNA, RNA, and protein sequences. For context, ChatGPT and similar LLMs, when trained on sequences of letters and words from composing human languages like English, can generate meaningful new human-readable text. In similar fashion, biological LLMs (bioLLMs), trained on vast datasets of biological sequences, can generate novel sequences with potential biological functions, accelerating the design process in fields like protein engineering and synthetic biology. For example, in early 2024 Stanford researchers reported developing and using a general protein language model to quickly design better virus-neutralizing antibodies targeting Ebola and SARS-CoV-2.[53] Unlike widespread speculative concerns about the destabilizing potential of the use of AI in biotechnology,[54] actual known work in the field seems to instead have directly contributed to public health and biosecurity.

As a second example, researchers at Stanford released a genomic foundation model named Evo that performs prediction and generation tasks across DNA, RNA, and proteins.[55] (Foundation models are discussed in chapter 1 on artificial intelligence.) They then used Evo to help design synthetic gene-editing systems. DNA, RNA, protein, gene, and genome language models will continue to emerge and develop throughout the 2020s. The greatest bottleneck will likely be the limited capacity available to build and test the biological sequences generated by the models. Any adult English speaker can quickly read a passage of LLM-generated English text and evaluate its purpose and quality. For now, only living systems themselves can ultimately interpret and establish whether the function and performance of a bioLLM-generated design actually works as expected. The ability to operate platforms that scale high-throughput testing of bioLLM designs is a significant advantage in inventing, improving, and offering world-leading foundation models in biology and biotechnology.

Over the Horizon

Routinization of Cellular-Scale Engineering

There is no natural cell on Earth that is fully understood. Even for well-studied model organisms like *E. coli*, there remain genes with unknown or incompletely understood functions, highlighting the complexity of cellular systems. The microbes that have been subject to the most intense study still require more than seventy genes whose functions no researcher understands.[56] Each gene encodes some unknown life-essential mechanism. Our collective ignorance means that all bioengineering workflows remain Edisonian at the cellular scale—we are tinkering and testing. Bioengineering students are taught the mantra “design, build, test, learn,”[57] where the test portion implies a very large amount of empirical lab work to understand basic phenomenology. By contrast, the routinization of bioengineering workflows at the cellular scale sufficient to realize “design, build, work” workflows—a hallmark of all other modern technologies that implies doing a relatively small amount of empirical work primarily to validate the analysis underlying the construction of a biological artifact—remains

> **The ability to construct life for the first time, without being restricted to any terrestrial lineage, is akin to launching to orbit the first artificial satellite.**

fringe foundational research. Consequently, such bioengineering workflows remain in their earliest stages.[58]

Nevertheless, because cells are the fundamental unit of life, researchers[59] and start-ups[60] across the United States, Europe, Japan, and China are scrambling to learn how to build fully understandable cells from scratch. The ability to construct life for the first time, without being restricted to any terrestrial lineage, is akin to launching to orbit the first artificial satellite. Just as rockets allow us to ascend Earth's gravity well, giving us access to the privilege, perspective, and power of space, the ability to transcend the constraints of Earth's existing life-forms[61]—organisms constrained by lineage and the requirements of reproduction and evolvability—will unlock the next level of biotechnologies, providing a powerful perch from which to access everything that biology can become.

A first organized and professional attempt to construct life from scratch will likely cost $100 million. The Institute of Synthetic Biology (ISB) at the Shenzhen Institute of Advanced Technology in China is one organization where such an effort could now be carried out rapidly. The ISB hosted a global summit on coordination of synthetic-cell building in October 2024.[62] Lacking equivalent efforts domestically, the United States is risking a Sputnik-like biotechnology surprise.[63]

Electrobiosynthesis

Carbon is central to life. Currently, we rely on photosynthesis for production of organic carbon molecules. Recent thinking, however, suggests that electricity could be used to fix carbon directly from the air to create organic molecules that could be fed to microbes—a process that may come to be known as electrobiosynthesis or, more simply, "eBio"—and that doing so could be an order of magnitude more efficient from a land-use perspective than traditional agriculture.[64]

In other words, the idea is to engineer a parallel carbon cycle that starts with air and electricity, perhaps generated via solar panels, to create organic molecules that can power bioproduction processes. For example, in August 2024, Stanford researchers reported the creation of a system that combines electrochemistry with biological processes that do not use cells to transform simple carbon compounds into a key organic molecule called acetyl-CoA, which is present in all living things and acts as a building block for other molecules within cells.[65]

Although eBio is still a very immature technology, its potential significance and impacts are hard to overstate. For example, surplus power from large-scale renewable energy generation could be used to directly produce biomolecules such as proteins and cellulose without requiring massive conventional battery banks to store energy that cannot be used immediately. The development of eBio could also enable bioproduction in places where soils are poor, water is scarce, or climate and weather are too uncertain. And it could raise the ceiling on how much humanity could make in partnership with biology. We would be constrained only by how much energy we can generate for such purposes. This approach could significantly reduce the land and water requirements for biomass production, potentially alleviating pressure on agricultural resources and offering a more sustainable path for biomanufacturing.

Challenges of Innovation and Implementation

Many first-generation synthetic biology companies continue to struggle.[66] Billions of dollars of private capital have been lost in biotechnology investments made with the best of intentions in the United States alone over the past two decades. One perspective is that these early big bets were simply too early.[67] The hope is that smaller and scrappy next-generation efforts will find their way to success. However, an immediate short-term issue is that many sources of private capital funding to support these next-generation commercial efforts are now shut off for synthetic biology, adding headwinds to the general challenges of obtaining capital that young, innovative businesses face.

Another perspective is that America has relied too heavily on the private sector to invent, advance, and deploy emerging biotechnologies. The biotech equivalent of the publicly funded tooling and infrastructure development in the early days of US strategic computing and networking programs is today pursued only via private investment and commercial platforms. Because private investors expect these foundational tools and platforms to quickly generate and sustain revenue growth to justify further funding, businesses developing them often fail repeatedly.

Breaking this cycle will require smart and sustained public investments in foundational bioengineering research, from tools for measuring, modeling, and making biology to public-benefit research platforms. The National Science Foundation's August 2024 investment in five academic biofoundries may be one small step forward in this respect.[68]

Policy, Legal, and Regulatory Issues

Safety and national security concerns New organisms not found in nature raise concerns about how they will interact with natural and human environments. For instance, bioengineered organisms that escape into the environment and possibly disrupt local food chains or natural species have long been a concern. Moreover, as the science and technology of synthetic biology becomes increasingly available to state and nonstate entities, there are legitimate concerns that malicious actors will create organisms harmful to people and the environment.[69]

Ethical considerations Different religious traditions may have different stances toward life and whether the engineering of new life-forms violates any of their basic precepts. Often classified as potential nonphysical impacts, the effects on biotechnology when considering these religious concerns are sometimes difficult to predict in advance. In the words of a Wilson Center report on this topic, such concerns involve "the possibility of harm to deeply held (if sometimes hard to articulate) views about what is right or good, including . . . the appropriate relationship of humans to themselves and the natural world."[70]

The United States and other nations are working hard to develop, advance, and refine strategies for biotechnology, biomanufacturing innovation, biosecurity, and the bioeconomy overall. For example, the United States' National Security Commission on Emerging Biotechnology continues its work.[71] The congressionally mandated Department of Defense Task Force on Emerging Biotechnologies and National Security is also underway.[72] Both efforts are expected to produce substantial reports and products throughout 2025, complementing activities ongoing within the executive office of the president, including work as ordered by Executive Order 14081 on biotechnology and by Executive Order 14110 on artificial intelligence. Internationally, the Organisation for Economic Co-operation and Development's Global Forum on Technology selected synthetic biology as one of three key initial technologies to focus on, with work now well underway.[73] The World Economic Forum has also renewed its Global Futures Council on Synthetic Biology, which continues its work.[74]

One overall challenge for policymakers—and the biotechnology community—is to preserve and advance the very significant public benefits of research into biosciences and biotechnology while minimizing the real and perceived risks associated with potential misuse of the resulting knowledge and capacities. For example, in response to the concern about the escape of harmful bioengineered organisms into the environment, synthetic biology itself offers the possibility of bioengineering organisms from scratch that are incapable of escaping or evolving.[75] But it is a matter of policy to ensure that necessary safeguards are included in projects intended to create new organisms.

In short, policymakers will have to be aware of—and able to navigate—issues and aspects of emerging biotechnologies, such as the ones included in this section, if they are to help guide the development of the field and the increasing diversity of the biotechnologies that emerge from it.

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