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Shifts in technology commercialization strategies: Causes and consequences

In the early 2000's a first commercialization wave within modern industrial biotech started. Back then it still took many years to develop a sufficiently productive and robust microbial production system prior doing any process development downstream or even larger scale piloting. Furthermore, these tasks used to be treated rather distinct from each other. Most projects focused on large markets, e.g. (2G) biofuels or commodity/platform chemicals. In the US the DoE was heavily funding biobased technologies which led to the construction of several dedicated semi-commercial demonstration plants. Despite the significant financial support, the challenges involved in plant design, scale-up and operation as well as the overestimation of a market pull for the products made emerging companies struggling.

In the following years deep transitions were taking place. The rollercoaster oil-prices and the shortage in financing for capital-intensive high-risk ventures demanded new commercialization strategies besides improved methods and technologies. To a greater extend the commercial focus changed to smaller-volume but higher-value products. Partnerships were fostered to connect technology providers, producers and markets. Larger CAPEX projects remained rather exceptions in that phase. As the new products were smaller in volume/scale, technology demonstration started to take place at CRO/CDMO facilities rather than in single-purpose plants. For some ventures this drastically shortened the time from lab to commercial, without compromising on technology de-risking. Simultaneously in Europe an impressive infrastructure of multi-purpose piloting facilities has been established to accelerate validation and commercialization of bioprocesses.

In the very recent years a kind of Cambrian explosion is taking place since the potential of synthetic biology is more accessible. Many partially converging factors are driving this wave:

- Advanced tools and methods for gene-editing and integrated high-throughput screening
- Computational advances and digitalization
- Development of technology platforms (strains, fermentation protocols)
- Steadily increasing market pull arising from customer sustainability awareness
- Increasing venture capital support and also public funding schemes

Subsequently a lot of companies have been founded to deliver (new) products on more sustainable production routes. Beyond that, mature companies are diversifying their portfolio of biobased technologies. Biobased solutions become available in sectors such as agriculture, food/nutrition, cosmetics and many more. Even the low-cost high-volume commodities and bioplastics seem again on the verge to a long await renaissance.

In that light two fundamental forces are going to shape the bioeconomy again (Figure 1): Moore's Law & Murphy's Law.

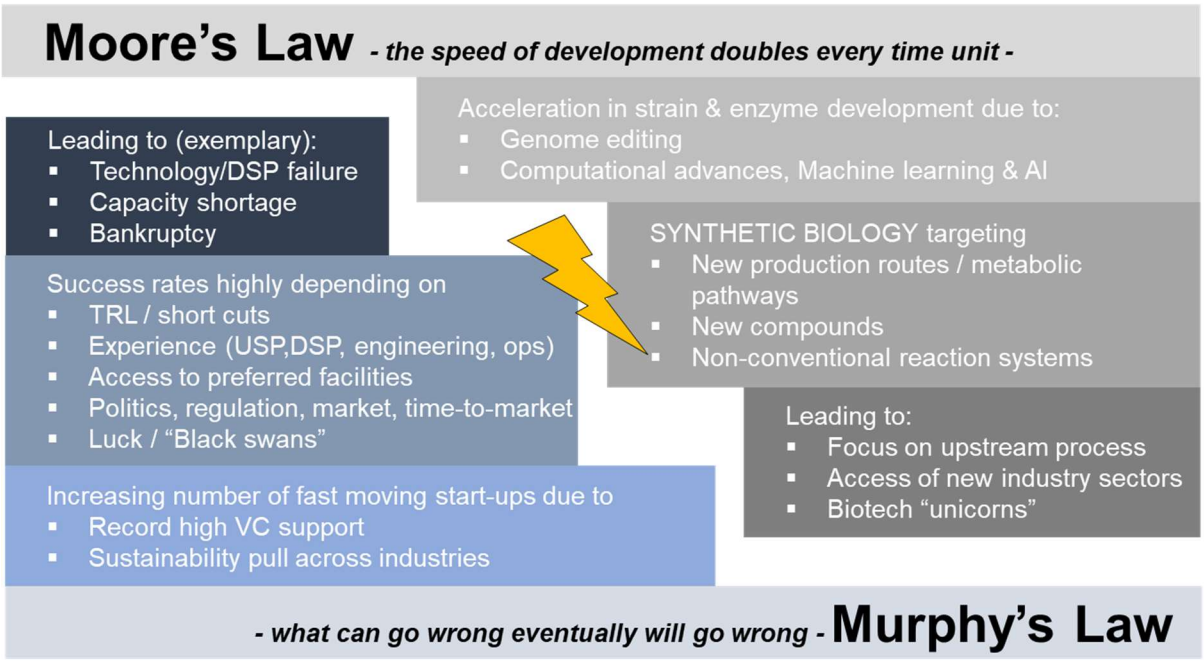

Figure 1: Two forces shape the bioeconomy: Moore's Law & Murphy's Law

Moore's Law is the reason for the tremendous acceleration in biotech developments on a genetic and metabolic level ("Cambrian explosion"). The advances in computation, machine learning and AI are leveraging strain design in the same extent. Countercurrent however are the forces of Moore's Law. Everything that can go wrong eventually will go wrong, especially for companies that are not as prepared as needed, not managing or de-risking properly or if the market conditions are chaotic.

The faster strain and fermentation development targets are achieved nowadays, the more important all other work beyond that point becomes as it also reframes expectations towards other competencies on the route to commercial. This especially puts stress to

- (integrated) DSP development
- Program de-risking (technology, scale-up, commercial approach)
- Managing (external) piloting activities
- Engineering design (in case of CAPEX projects)

Early preparation is key to set the course for the less flexible and more expensive work ahead.

Ventures need to take and be consciously aware of the risks ahead. In parts independent consultants are supporting here already. Interesting however is that CDMOs are rarely regarded as integral part of the solution by both biotech clients and investors in industrial biotechnology, which is different to pharma business. Within industrial biotech their role is typically linked to discrete services, e.g. starting with a fermentation scale-up and ending with the provision of purified product based on customers process description. However past experiences have shown that many commercialization projects would have greatly benefited from a different way of collaboration between them during process development.

About the author

Dr.-Ing. Markus Fritsch is a bioprocess engineer and has been working in the Industrial Biotechnology sector on R&D, engineering, scale-up & biomanufacturing assignments. In particular he enjoyed the last ten years, in which he was managing projects in various positions at the interface of an industrial scale multi-purpose plant that acted as a gateway for commercialization projects.

Markus repeatedly experienced the challenges and dynamics arising out of different perspectives and requirements from customers, technology-, engineering- and service providers, end-users and financial institutes. Now he is providing independent engineering and consulting services for technology ventures, service providers and other stakeholders of the bioeconomy.

Contact us:
Fritsch Bioprocess | Engineering | Consulting
markus@fritsch-bioprocess.com
https://fritsch-bioprocess.com

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