The importance of R&D alliances to sustain a nano-biotechnology ecosystem

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ABSTRACT

The breakthroughs in nanoelectronics, nanotechnology and biotechnology are resulting in a growing convergence of nano with bio, as they both 'work' at the nanoscale. Nanobiotechnology will push biotech and nanotech R&D centers and companies from all across the spectrum to work more closely together. Consequently, the importance of regional, state, national and global initiatives cannot be overestimated. Regional cluster organizations are well suited to establish this as they are the basic drivers behind local and global ecosystems. This paper highlights international trends and initiatives in developing a nanobio ecosystem, from scientific research down to marketable products. The key issue at stake will be the discrepancy between different business models used in nanotech/nanoelectronics industries versus biotech and pharma industries.
Keywords: nanotechnology, biotechnology, nanobiotechnology, business model, convergence

1 INTRODUCTION

Biotechnology is without doubt poised to become a crucial technology driver in the 21st century. The fundamental knowledge of human – and other - life forms downto its fundamental building blocks, and the functions these building blocks perform with respect to health and comfort, is starting to revolutionize our human evolution more profoundly than ever. Today, bioscience breakthrough after breakthrough are made everywhere in the world. Started as one of the first technologies ever discovered and developed, think e.g. of the brewing process of beer or the fermentation process of cheese, "modern" biotechnology took off with the birth of genetic engineering. The discovery of the double helix structured DNA by Watson and Crick in 1953 marked the beginning of a new era in science and technology. This discovery created a vibrant biotechnology industry, beginning with the birth of the leading biotech company Genentech after the development of the recombinant DNA technique. Many companies have followed since then, often spun out from research institutes and large corporations. Today over 5,000 biotech companies exist worldwide. Their applications range from new biology-based medicines over agriculture to industrial biotech such as biofuels.

At the same time, the increased understanding of matter at the nanometer scale has led to a virtually infinite range of new nanotechnologies that can be applied in a wide range of applications. By manipulating matter at the atomic or molecular level, physical properties of materials can be altered to desired levels, and nano-scaled devices can be manufactured. Although many new nanotechnologies have been developed so far, we are only witnessing the very start of a nanotechnology era.

2 CONVERGENCE

Interestingly, nanotechnologies operate on the same scale as many biotechnologies, since biotech essentially deals with molecular structures which have nano-size building blocks. Consequently, scientists have started to investigate the use of nanotechnologies in biotechnology. As an example, DNA is a long polymer molecule, consisting of millions of repeating units, called nucleotides. One nucleotide is less than 1 nm long and the diameter of DNA is only 2 nm wide. Proteins, the engines in living organisms, measure between 1 and 20 nm in size, arranged in 3 dimensions.

Taking into account that the building blocks of living organisms are in the nano dimensions, it was inevitable that nanotechnology would be applied in biotechnology, hence the birth of "nanobiotechnology". More and more nanotechnology domains, from nanomaterials over nanoparticles and nanodevices to nano-imaging techniques, are being applied to biotechnology to understand biological processes fundamentally. In this way, scientists hope to improve medical diagnosis and disease treatments. Nanobiotechnologies hold the promise to significantly improve the discovery of drugs, to speed up drug development and increase their effectiveness.

3 ECOSYSTEM

The success of a high-tech industry in a country or region depends on many factors. When comparing different technology clusters worldwide, it becomes clear that if more than 2 of these factors are missing, growth will not be above average and will not result in a sustainable industry.

The far most important success factor of technology industries is related to research and development. It has been proven that the presence of R&D centers and excellent university research is a driving factor of new high-tech industrial activities: continuous flow of new know-how into the market through tech transfer and the creation of spin-off companies, and the presence and flow of well-educated and specialized human capital.

Other factors include the existence of a set of government support instruments such as financial incentives, tax support to high-tech industries, the presence of infrastructure, the presence of venture capital and last but not least, the presence of all aspects of the tech value chain, networking as much as possible.

4 R&D COOPERATION

The development of new applications based on emerging technologies such as nanotechnology, are increasingly research intensive and necessitate heavy and time-consuming investments. Many industries based on nanotechnologies and nanoelectronics such as computers and cell phones are faced with ever shorter product life cycles and shrinking time-to-market. In order to be able to bring their new products timely to market with enough return on investment, companies increasingly need to set up partnerships with other companies and research organizations to develop the needed technologies, in time and cost efficiently.

Take e.g. the semiconductor industry. The semiconductor industry started some 50 years ago with the discovery of the transistor. Since then, this industry has succeeded to develop new generations of so-called integrated circuits (IC) with a cycle of 2-3 years, following the so-called Moore's Law, named after co-founder Gordon Moore who predicted this evolution more than 40 years ago.

Today, semiconductor technology has dived well into the nanometer scale, bringing integrated circuits to market in which the transistors exhibit feature sizes of a few nanometer long. They constitute wat is called top-down nanotechnology, meaning that nano-sized dimensions are made starting from macroscopic dimensions in which deposition and lithographic techniques are so advanced they can make these tiny structures.

For these semiconductor technologies to be developed timely and cost efficient, industry has been forced to cooperate, not only in manufacturing, but more and more so in development and even research. This industry is used to work with research cooperation schemes, within the sequence of a value chain as well as between competitors. Within the value chain, more and more alliances have been created between supplier and customer, e.g. equipment supplier and IC manufacturer. More remarkable has been the cooperation between competitors. The key to success in this kind of cooperation scheme is the degree to which technology is distant from the market, i.e. the technology to be investigated should be pre-competitive and as generic as possible (but not fundamental research, since that has no commercial end point, and hence is of no commercial interest to companies). To put it differently, the technology is a basic technology that every player needs for their subsequent product development, but it does not constitute a characteristic that differentiates one player from its competitor.

This pre-competitive R&D cooperation scheme has proven its value, and is fairly common amongst semiconductor organizations. The most well-known example of such R&D alliance is IMEC. IMEC, an independent R&D center based in Leuven, Belgium, has managed to group the world's largest industry research partnership in semiconductor technology research, with members such as Intel, Texas Instruments, Samsung, Panasonic, and many more. Their business model [1], once unique, is now copied more and more throughout the world. It is based on co-ownership without accounting to one another. This means that all partners will co-own the intellectual property of the results of the research program, and can use it for their own commercialization purposes. The program also allows for some results to be exclusively owned by a certain partner, typically more partner-specific outcome.

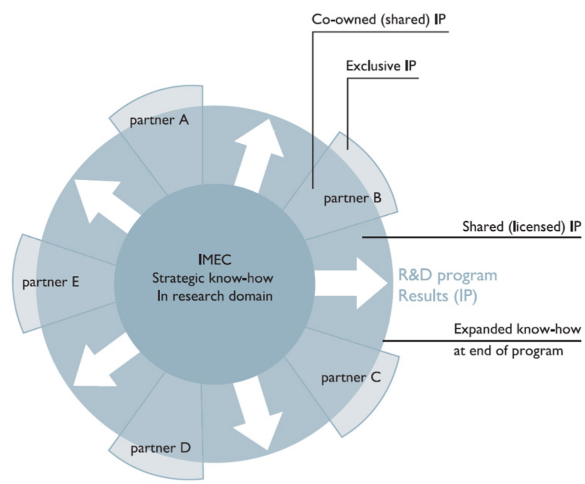

Figure 1 : R&D cooperation model of IMEC's industry partnership (source: IMEC).

The advantages of such joint R&D programs are manyfold: sharing of cost, sharing of infrastructure such as labs, sharing of expertise and sharing of risk. Since the results are pre-competitive, they do not constitute a risk of diluting the intellectual property rights of the product development that follows the research program, as this product development typically is carried out in-house and results in exclusive intellectual property rights.

5 BIO AND PHARMA

In life sciences, up till today, the situation has been much different. Biotechnology is a relatively young player in this field when compared to pharmaceutical companies. For many years, pharma's success has been based on the commercialization of so-called 'blockbuster' drugs, drugs that are used by a large population to treat a chronic condition, and have sales exceeding 1 billion USD. Many people do not realize this, but blockbuster drugs are really not that effective: they might be efficacious in only 40% of the general population. This also means that the development of such drugs has a long road to go as a sufficiently large number of clinical trials have to be carried out to show clear efficacy. As a result, development costs are extremely high, amounting up to 802 million USD in 2000, according to the Tufts Center for the Study of Drug Development. Nearly half of the total costs in drug development are due to the time value of money: it takes between 8 to 12 years for an experimental drug to get to the market. This, combined with the fact that a mere 10% of all drug candidates ever reaches the market, leads to the high risk, high cost picture of the pharma business [2]. No wonder that this market is dominated by a few large and well-established players, forming an effective barrier to new entrants.

With the emergence of biotechnology, the search for the right drug has changed. Thanks to molecular sciences and nanobiotechnology, industry is starting to be able to define diseases much more accurately, how they function at the molecular level and as a part of the biological system. The biological approach is based on a fundamental understanding of disease and is derived from human proteins or antibodies, in contrast with the typically used mice and other animals.

But there is a drawback. The insight in biological processes at the genomic and proteomic level requires understanding our genes and proteins, and this is quite a challenge. It is estimated that the human body contains over 500,000 different proteins, more than 10 times the number of genes. And it gets worse. Many diseases are related to more than one gene, and knowing how they work together is essential. It is like a geographical map. We have mapped the entire human genome, so we have the map, but we still do not know well how to read it. And a map is static, we do not see the functioning of all parts in the map.

What does this mean for R&D? Research will have to make radical changes to be able to cope with these new domains to turn these advances into targeted drugs. Thanks to genomics, researchers are starting to find out to predict which drugs would work best on which patients. This segmentation has significant consequences for the pharma business. Instead of deploying a blockbuster drug for a large population, these new targeted drugs will fragment the market based on probable responses for segmented patient groups. On the other hand, genomics and proteomics will enable pharma to define diseases much more accurately and develop much more efficacious drugs for smaller patient populations. It will increase market opportunities also in other ways. Patients will be served with comprehensive drug therapies that really work for them, starting from diagnostics, molecular markers for defining the disease state from which they suffer, monitoring mechanisms and targeted treatment using these new drugs.

6 CONVERGING BUSINESS MODEL?

As these markets become more fragmented, pharma companies will need to decide which disease family they want to concentrate their research on. This means that they will first build disease knowledge, which is generic in nature and should be allowed to be used by others too. Alternatively, it would mean that it would allow research partnerships based on pre-competitive molecular science to be set up. This industry should start to cooperate in research and development, much as the semiconductor industry has done in the last 2 decades. It will need to cope with the increasing complexity associated with many disease areas and product types to work in.

The resulting disease knowledge should lead to target knowledge, ending in a therapeutic molecule, new biomarkers and molecular diagnostics tools and methods. Most of the disease research will be carried out at or in collaboration with academia and research centers. As soon as it becomes clear how the disease works and what business can be made out of it in terms of diagnostics, targeted treatment and monitoring, pharma companies will take the lead. These companies will need to communicate with regulators much earlier as they will need to deploy proof of concept studies of treatments earlier in the development process.

With the emergence of nanobiotechnology, the challenge of cooperation is even higher. While the nanotechnology industry, and the semiconductor industry in particular, is used to work in true R&D cooperation schemes, biotech and life sciences still aren't. Typically, the development of new drugs, be it chemical or biological, is still a matter of exclusive intellectual ownerships. In essence, any cooperation between these 2 worlds, nanotech and biotech, would result in a clash of business models, and hence, inhibit the growing convergence on the fundamental scientific level.We believe it will not be a clash as the evolution of new drugs into the biotech scene, based on a more fundamental understanding of diseases, will indeed allow for more R&D partnerships to be formed within the life sciences domain as well as in nanobio, since new developments will need a combination of generic pre-competitive technology to be developed together with proprietary research for drug and therapeutic developments. Increased interaction to learn from each other's world is crucial in order to ripe the true benefits of nanobiotechnology. Those regions who will be able to join these different worlds together, will be the next technology pioneers in the world.

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