The Biotechisation of Pharma

The ‘biotechisation’ of pharma companies and other current experimental approaches of Big Pharma to increase R&D productivity and innovativeness will have major influences on the nature of pharma-biotech collaborations.

It is widely recognised that those within the pharmaceutical industry, particularly the larger companies, are in a crisis – both regarding their R&D productivity and their R&D development. Numerous articles have pointed out the fact that despite increasing investments in R&D and clinical development over the last decades, both the number and innovativeness of new products coming onto the market have not increased and, in many cases, have even decreased (1). Considering the imminent patent expirations of many top-selling drugs, the rising cost pressures and regulatory requirements from payors and government, the pharmaceutical industry has maneuvered itself into a quite precarious situation.

It is evident that the traditional, productivity-led pharma business model – characterised by tight management, goal-setting, cost focus and controlling – cannot deliver a sufficient competitive advantage anymore. In the past, Big Pharma has more and more focused on developing drugs with blockbuster-potential (annual sales of more than $1 billion) and on decreasing R&D costs by primarily engaging in low-risk projects. However, this has only led to incremental innovations with limited blockbuster-potential and many ‘me-too’ products, contributing little value to the overall drug market.

In response to this situation, several business model experiments have been initiated by large pharmaceutical players within the last decade, which are oriented towards more creativity-led approaches and traditionally pursued by most biotech companies or even academia. The creativity-led model is characterised by a focus on scientific excellence and a certain degree of freedom that will ultimately lead to the development of highly innovative products (breakthrough innovation) (2). Other biotech characteristics such as small size, autonomy, flexibility, direct accountability, greater willingness to take risks, and quick decision-making are seen as conducive for achieving a higher and more innovative R&D output as they enable a creative working atmosphere and provide strong incentives for performing well.

Following this rationale, several large pharma companies have begun to re-design their R&D model. Among the examples of biotechisation experiments of Big Pharma discernable to date, two dimensions can be distinguished: biotechisation of organisational structure, and biotechisation of R&D strategy.

Biotechisation of organisational structure relates to re-organisation of R&D or business units in an effort to make them more biotech-like in terms of size, accountability and incentives. This also includes resource allocation processes which are similar to VC-funded biotechs, where the budget is allocated in triennial cycles and is tied to output milestones, which are reviewed on a regular basis. Also, grouping a small team at one location who are working towards the same goal is a characteristic of the biotech sector, which is conducive for achieving better communication and motivation of the staff.

Biotechisation of R&D strategy, on the other hand, refers to the company’s mentality towards R&D and its logic in selecting focus areas or projects. This includes being more open for high-risk and innovative approaches, limiting the commercial influence in early R&D, for example by not making high peak-sales a top priority and selecting diseases as initial proof-of-concept indications that have traditionally been avoided by Big Pharma.

**Biotechising Pharma**

It is important to note that depending on the overall company strategy, focus and culture, many variations of this biotechisation approach exist. In order to provide a better picture of the current biotechisation efforts of Big Pharma and their differences and similarities, selected examples from GSK, Sanofi, AstraZeneca, Pfizer and Novartis will be briefly discussed below (see Figure 1).

GSK’s DPU’s Mimic Biotech Environment in Early Development

GSK’s R&D structure is composed of eight therapeutic area-focused Centers of Excellence for Drug Discovery (CEDDs) which have been re-termed ‘Therapy Area Units’ (TAUs). These in turn are divided into approximately 36 Drug Performance Units (DPUs) to foster innovative output by enabling accountability and creativity (3).

Biotechisation in the sense described above is achieved through small unit size (varying from six to 80 scientists), autonomy, as well as three-year funding cycles allocated by a Discovery Investment Board, which sets objectives in terms of deliverables and spending. If the DPU does not meet the agreed upon objectives then funding can be cut, in the worst case leading to the closing of the respective DPU.

The next step in GSK’s R&D re-organising process still anticipated in 2011 is the
integration of DPUs and the later-stage Medicines Development Centers for certain therapeutic areas in order to streamline processes, communication and collaboration between early and late-stage development. Some DPUs are already fully integrated, for example rare diseases, oncology and dermatology.

**Sanofi Engages in Two Different Biotechisation Experiments in Parallel**

In 2009, Sanofi took an integrative approach to restructuring its R&D-processes. Two models can be distinguished. First, they established two fully integrated business units for diabetes and oncology that are aligned across research through clinical development and registration. Second, Sanofi also established five early-stage units – called Therapeutic Strategy Units – consisting of immuno-inflammatory disorders; infectious disease; fibrosis and wound repair; the physiology of ageing; and an Asia-Pacific region focused unit, which are integrated from discovery through Phase 2b proof-of-concept in patients. The final late-stage clinical trials and commercialisation is then taken over by the global development group (4).

Through this integration of functions across a wide part of the discovery process, communication and interaction between the several functions can be increased. This leads to a more streamlined and manageable discovery and development process that is meant to favour innovative and successful product creation.

**AstraZeneca Intends to Foster Intrapreneurship**

AstraZeneca has taken a similar approach to Sanofi by establishing nine Innovative Medicines Units (iMeds) which span the discovery and early development process, after which the resulting drug candidates are handed over to the ‘Global Medicines Development’ for late-stage development and commercialisation. iMeds are grouped in the following way:

1. Small molecule iMeds (oncology, infection, respiratory and inflammation)
2. Aligned small molecule and biologics iMeds (cardiovascular, gastrointestinal and neuroscience)
3. Biologics iMeds (oncology, infection, respiratory and inflammation)
4. New opportunities iMed focus on identifying external opportunities

The smaller size of these units is intended to enhance the entrepreneurial character in order to foster innovation during the early development stage and to enable better connection and streamlining for early clinical studies research (5).

**Pfizer Focuses on Late Development and Commercialisation**

While the above mentioned companies have set their focus on the biotechisation of the early R&D stages, streamlining them with the later development stages, Pfizer has taken a different approach, applying the biotechisation-principle only to the later development stages.

The company underwent significant structural change in its R&D operations in 2008 in order to establish development/commercial business units in the areas of oncology, primary care, specialty medicine and emerging markets. These business units take over molecules at clinical proof-of-concept delivered by Pfizer’s ‘Global R&D’ or ‘Biotherapeutics and Bioinnovation Center’ units. Each business unit has its own profit and loss meant to endow them with more responsibility and autonomy (6).

**Novartis Pioneering Biotechisation of R&D Strategy**

Whereas the aforementioned companies have started with the biotechisation of their organisational structure,
Novartis has chosen to engage in the biotechisation of their strategy. As one of the first, Novartis introduced this new research concept in 2006 and focused on intensive contact with academia and biotech, while deliberately distancing itself from the ‘traditional’ Big Pharma approach of aiming at achieving blockbuster sales with the least risky path available.

In Novartis’ eyes the ‘traditional’ low-risk path does not lead to the kind of breakthrough innovations required to significantly impact and refill the currently empty development pipelines. As a consequence, Novartis is pursuing higher-risk targets and approaches similar to that of biotech companies. They are supporting their research strategy through investing strongly in infrastructure and personnel at a time when most other Big Pharmas are downsizing their R&D operations and staff. In addition, they are heavily recruiting R&D managers from the academic and biotech sectors, which recently made up about two thirds of the new hires within their research organisation.

In order to mitigate the risk of failure associated with their new R&D projects, they follow a proof-of-concept strategy based on niche disease indications that are phenotypically related to other broader indication areas. If the drug candidate proves to be successful the chance of success is broader indications related to the niche disease rises. With this logic Novartis is striving to decrease attrition rates while still being able to engage in highly innovative R&D projects.

**Points to Consider**

Even though we are still at a point where the outcome of the biotechisation-experiments is highly uncertain, a few basic rules or caveats have to be considered if these experiments are to work at all. To begin with, the internally allocated time span has to be long enough in order to properly evaluate and exploit the full potential of the chosen biotechisation strategy. Due to the inherent timelines of the drug development process, taking 10 to 15 years from lead identification until commercialisation, the impact of certain measures will only be discernible in the long run. However, managerial attention span has become a problem due to the high turnover rate of CEOs whose average tenure is now approximately four years or less. In addition, major M&A events often lead to repositioning of the company and changes to the structure and strategy. These and similar breaks in continuity are not conducive to fully exploit the potential of such biotechisation approaches.

Furthermore, the nature of creativity in a scientific environment has to be considered if the chosen biotechisation approach is to deliver the intended breakthrough innovation. There is a limit to the application of the managerial principle. To achieve innovation, there is still the requirement of unregulated spaces to facilitate creativity and personal initiative. Top-down only implementation risks the killing of personal initiative and engagement, which are invaluable ingredients in a science-driven environment. Thus, a balance between bottom-up ‘unplannable’ initiative and top-down direction setting has to be found in terms of biotechisation.

A very decisive element for the success of biotechisation and its wider implementation as a business model is whether Big Pharma will be able to maintain its present advantage of economies of scope over smaller companies. Cross-fertilisation by making use of the high variety of expertise present in a large company is key to remaining competitive by devising creative approaches and decreasing uncertainty during drug development. If cross-fertilisation cannot be upheld with the new structure of business units, this will severely impact the potential for innovation in the respective company, counteracting the purpose of engaging in biotechisation in the first place.

Despite these caveats, biotechisation of Big Pharma provides compelling rationales to improve the current situation and tackle the productivity and innovation gap at its core. Nonetheless, it remains to be seen whether these experiment rationales prove to work and address the current problems effectively; or, in an even more cynical scenario, whether initiatives are not just a cover-up for simple cost-cutting procedures. Yet, in any case experiments are better than inertia or throwing more money at things that have already proven to not work.

**What Does it Mean for Biotech?**

The biotechisation trend of Big Pharma has two major implications for the biotech industry. On the one hand, Big Pharma and biotech will become more alike in terms of culture and approaches taken, which should facilitate interactions and communication between the two sides. On the other hand, interactions with the other side could also become far more complex, as the biotechisation approach will have a large impact on partnering and business development (BD) processes of biotech companies. Whereas in the past, Big Pharma consisted of largely monolithic structures with more or less centralised contact persons/departments for early stage BD, in the future contacts to larger companies will entail far more complex interactions and decision processes as the individual business units will each have partnering discussion of their own. This new situation requires adaptations from the biotech side but is not expected to represent a major barrier for biotech-Big Pharma interactions in the future.

Another conceivable implication of this trend for the biotech industry is that during a merger and acquisition, integration processes will be much ‘softer’ than in the past, meaning that the culture and processes of the acquired biotech will be left more or less intact. This could make the option of getting acquired more attractive from the biotech side.

**Conclusion**

All in all, the observed biotechisation of Big Pharma represents a change in business model thinking that, if successful, will in one way or another affect all components of the densely interwoven
biopharmaceutical industry. In any case it will be exciting to see how these experiments turn out and who, in case of success, will be able to benefit the most.

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