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Creative Disruption in Life Science Industries

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SUSTAINABILITY OF LIFE SCIENCE INNOVATION MODELS

For more than ten years, analysts have been claiming that, despite a series of life science-based innovations, the overall drug discovery and development model of the pharmaceutical industry sector is fundamentally unsustainable. Explanations have included failure of innovative capacity, too great a focus on incremental rather than radical innovation, excessive regulation, and lack of venture capital investment.

However, from an alternative perspective, one could say that the innovation model that has evolved in the life science industry sector has been remarkably robust compared, for example, to those in information and communication technologies. Despite difficulties in markets, the emergence of a series of potentially disruptive innovations, the steady build-up of an onerous regulatory system, development costs approaching $1 billion per product and a product development life span of up to 12 years, the underlying business model of the industry sector has remained remarkably constant, and indeed has been reinforced, over the past fifty years. The dominance of the multinational corporations (MNCs) and their prevailing block-buster drug model of innovation has until now been unassailable.

The life science innovation model has been remarkably robust compared to the IT sector

Some of the innovative ideas that have emerged from life sciences have been 'incremental', presenting few serious challenges to the prevailing innovation model and easily accommodated within it. Others are potentially 'disruptive', stepping outside existing paradigms, leading to discontinuities in innovation pathways, to major shifts in product types and their place in the market, and even to the creation of new industry sectors or radical re-structuring of existing sectors.

Incremental and disruptive innovation

Underlying at least some of the public and commercial investment in life sciences has been the assumption that the technology in question might be the 'next big thing', the innovation that will lead a company to become a multinational in its own right, with a winning strategy that is different from incumbent multinationals. More realistic investors assume that they will support a new biotechnology firm (NBF) only until it becomes large enough or successful enough to be taken over by, or to license its technology to, a multinational.

This paper tries to explain this remarkable robustness in the life science innovation model, but also recognises that disruptive change is becoming increasingly inevitable. It focuses on the combinations of circumstances likely to lead to radical disruption and points to the need for such change to be carefully managed to ensure that life science research continues to deliver both public and commercial benefits.

Disruptive change is becoming increasingly inevitable

BARRIERS TO ENTRY

Regulators impose very significant constraints on life science innovation through the lengthy, expensive and complex set of requirements needed to bring a product to the market. This forms a barrier to entry for any new firm and is one of the most important factors giving multinational companies their dominant role in the sector. A symbiotic relationship has built up between the sectoral innovation system and regulatory bodies since the 1950s, with each change in the regulatory environment being incorporated into the innovation system in a way that reinforced the dominant position of the multinational companies.

Regulation is the key, controlling influence on the long term resilience of the 'big pharma' innovation model

Many analyses acknowledge a role for regulation as one factor among many in influencing sectoral innovation systems in life sciences. However, we would give it *the key, controlling* role in explaining the long-term resilience of the current innovation model of the multinationals. By acting as such an effective barrier to entry to the sector it has ensured that, with a few early exceptions, no NBF has been able to develop an innovation strategy which challenges or would compete with those of the multinational companies.

The market context is also an important, but lesser, barrier to entry to the sector. Unlike most markets, products are not sold directly to the public. Despite the increasing volume of internet sales, they are still delivered mainly through highly specialist health care networks, publicly or privately funded. As with regulation, it is very difficult for a new entrant to break through this barrier and to market its products independently.

PROBLEMS OF MATURITY – A SECTOR THAT IS RIPE FOR DISRUPTION

Another factor to be taken into account in charting the future of the life science sector is its maturity, in the sense that products have been developed for all the easy targets and these compounds are now off-patent commodity products no longer attracting high profit margins. It has become increasingly difficult to find new products that are effective enough to compete with existing product ranges, safe enough to pass the regulatory systems, and cheap enough to manufacture. These factors, and not complacency or a failure of innovative capacity, are the main reason for the drying up of product pipelines. These problems of maturity became urgent for both agrochemical and pharmaceutical companies in the late 1980s. They are an indication of a sector that is ripe for a period of creative destruction where new companies with a range of different innovation models challenge the status quo.

Rather than failing to fill up pipelines, biotechnology may have enabled companies ride out their maturity problems for another ten years

Biotechnology was expected to provide this challenge but most industry-watchers point to its failure to rejuvenate product pipelines. However, there is an alternative explanation. Biotechnology may have succeeded in enabling pharmaceutical companies to ride out their maturity problems for at least another ten years, contributing to preventing major disruption of their innovation model and a slide to become mere producers of commodity chemicals.

COMPARING CASES – DEGREES OF DISRUPTION

This analysis compared three case studies, the impact of GM crops on the agrochemical industry and of pharmacogenetics and stem cells on the pharmaceutical sector, to identify why some innovations fail to have the predicted disruptive impacts, while others are more disruptive than expected. We claim that an innovation that challenges a sector's internal R&D model and at the same time its regulatory and market environments is much more likely to be seriously disruptive of the sector than one which only affects one of these areas.

GM crops proved to be highly disruptive of the innovation model of the agrochemical industry because of their simultaneous impacts on company R&D (requiring a shift from chemical to biology-based development and production systems), on markets (selling

seeds is a very different business from selling pesticides), and on regulatory systems (the European Union deemed it necessary to develop a new regulatory system from scratch to deal with this new product type). There are some important lessons to be learned by the pharmaceutical sector from the earlier experience of the agrochemical industry with GM crops.

With pharmacogenetics, companies have been able to exert more control over the way the innovation is being incorporated into the innovation system. They are attempting to guide market expectations and at the same time focusing on applications which will avoid potential market disruption, and they are also influencing the plans and expectations of regulators as they consider modifications to regulatory systems. Pharmacogenetics therefore seems unlikely to be disruptive for the pharmaceutical industry.

Pharmacogenetics seems unlikely to be disruptive for the pharmaceutical industry

On the other hand, stem cells, as with GM crops, could have major simultaneous impacts on innovation systems, markets and regulatory systems, in a manner that is much less controllable by the multinational companies than is pharmacogenetics. An important difference from GM crops is that so far pharmaceutical companies are only planning to use the technology in an incremental manner, as a tool to develop new and better drugs, and not to develop products based on stem cells themselves.

REGULATORY – TECHNOLOGY INTERACTIONS

GM crops were almost totally disruptive of agrochemical innovation systems but they would have been a much less disruptive innovation for seed companies of any size. However, once the agrochemical industry had decided to focus its future innovation system on GM crops, these other players were either bought out by agro-biotechnology companies or left the field, as for example did Unilever. One could speculate that, if GM crops had been developed by seed companies, European regulators would have been less likely to erect such an onerous regulatory system.

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A similar situation arises for stem cells. They would be highly disruptive of pharmaceutical R&D systems, markets and possibly also regulatory systems, but largely an incremental innovation, for example for a small tissue engineering company. Whether the multinationals or the tissue engineering companies take the lead in developing stem cells as products will depend mainly on the still-evolving regulatory systems. If this becomes so onerous that it is impossible for small companies to continue to operate independently, then stem cells will be an incremental rather than a disruptive innovation for pharmaceutical companies. On the other hand, if NBFs are able to develop the technology independently, then it may become externally subversive of pharmaceutical innovation systems rather than internally disruptive.

If NBFs are able to develop stem cell technology independently this may become externally subversive of 'big pharma' innovation systems rather than internally disruptive

The research community and the industry have so far paid little attention to the role of regulatory systems in determining the kinds of company that are able to develop innovative technology and the nature of, and markets for, the products themselves.

THE FUTURE OF 'BIG PHARMA'

The agro-biotechnology sector has already seen major change and radical re-structuring of its profit models, at least partly as a result of its incorporation of GM crops within its product range. Companies in this sector are now no longer divisions of joint companies with pharmaceutical companies. They are less varied, less powerful and less able to withstand disruptive shocks than they were previously.

It is conceivable that pharmaceutical multinationals could continue to survive in their present form despite the alleged unsustainability of their innovation models. However, this model is being undermined, not only from within through the problems of maturity, but also through regulatory and market challenges, with demands for cheaper drugs, regulatory changes encouraging drugs to be developed for small niche markets and an increasingly negative public image of the sector. These factors were also part of the environment that contributed to the disruption of the agro-biotechnology sector.

The balance of power is slowly shifting

The pharmaceutical innovation sector is now becoming more diversified – it is still dominated by the pharmaceutical MNCs but the balance of power is slowly shifting and impacts from regulatory systems and market structures are the primary influences likely to speed up the rate of change.

The key to managed change is through the regulatory system

If, as we propose, disruptive change in pharmaceutical innovation systems is increasingly inevitable, it will be important for the delivery of medical benefits to the public that this change is balanced and carefully managed. The key to achieving this is through evolution of the regulatory system – regulatory change needs to be accompanied by a good understanding of the subtlety and complexity of the interactions between regulation and innovation in life sciences. Among other things this will require a more detailed analysis of the nature of the regulatory systems themselves which will be the subject of a further paper.

NOTES

This research briefing is based on Tait, J. (2007), "Systemic Interactions in Life Science Innovation", *Technology Analysis and Strategic Management*, 19/3:257-277.

EGN research ranges across the whole field of genomics, covering areas as diverse as plant and animal genetics, embryonic stem cell research, and associated health applications.

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