Science Business: The Promise, the Reality and the Future of Biotech

Gary P. Pisano

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In the book, Pisano mainly argues that in the past 30 years, the biotech industry did not play well either in generating profit or the productivity of drug research and development (R&D). He describes that the enthusiastic belief in biotech industry in the past 30 years was mainly driven by the rapid knowledge growth in life sciences (as in Chapter 1, p. 4): 'since the invention of genetic engineering technology in the early 1970s, we have been living amid one of the greatest scientific revolutions in human history. By almost any measure - rates of publication, growth of biological databases, increases in patenting ... there has been a veritable explosion of basic biomedical know-how'. But the question is how efficiently the biotech industry have transformed the 'knowledge growth' into a 'profit growth' ever since the sector was created 30 years ago. He presents a figure (Figure 1-1 in Chapter 1, p. 5) to show that all publicly held biotechnology companies (in aggregate as one) had profits consistently at or below zero from 1975 to 2004, while their revenues were growing steadily. This fact leads him to a basic conclusion: 'the vast scientific success (of biotechnology) has yet to translate into financial success or improved R&D productivity' (Chapter 1, p. 6).

Pisano's book came around the time when big pharmaceutical (Big Pharma) companies are facing enormous pressure externally and internally for reforming their infrastructures to improve their R&D productivity to support a sustainable growth in next 5-10 years. While many people believe the biotech industry can be the light, his analysis and warning raises appropriate concerns. The recent decline of Amgen's stock price and the increasing competition from the biological 'me-too' seem to be quite supportive of his perspective, which alerts people to revisit the business models and the governance philosophy of biotech companies.

One may argue that the future of the biotech sector will look better because drug development takes a long time, for example, 8–12 years, to generate returns to the investment. Pisano defends his opinion by showing that, if the most profitable biotech giant – Amgen had been singled out, the performances for all other companies in the field would have been even worse with profit levels below zero from 1987 to 2004 (Figure 6-2 in Chapter 6, p. 115). In addition, from 1976, when the first modern biotech company – Genentech was established, to present, the length of time (~30 years) is enough for running 2–3 cycles of new product development in the biotech field, so time should not be the 'excuse' for a later pay back to the long-term investment. Furthermore, he states that the technical aspect of the biotech industry is also depressing. The biotech companies have not done better than the so-called 'traditional' Big Pharma companies in terms of the R&D productivity. Quite a lot of biotech companies 'burn money' for more than 10 years without getting any profitable products.

Although the book points out a number of problems with the biotech industry, its purpose is more likely to attract people's attention to resolve these problems rather than simply 'complain and criticise', from my perspective. In the last chapter: 'The path ahead', he prescribes several options for both academic institutions and industry: for the issue of R&D productivity, he emphasises the importance of translational research that needs more close collaboration between academic researchers and industrial entrepreneurs; for business models he recommends the 'quasi-public corporation' that has the majority of their stock held by a single entity who has a long-term investment and strategic interest. A successful example he gives is Genentech, as 60 per cent of its equity is owned by Roche. The two companies had established a set of guiding principles for their relationship since the deal was made. Genentech, however, still keeps its independence and has maintained a separate board of directors, which not only makes the Genentech R&D among the most productive in the field but also makes the company itself the most successful one so far.

Overall, Pisano's book provides good guidance for people who want to know more about the biotech business and the monetisation process of intellectual properties. But as nothing is perfect, one thing the book does not give enough attention to is the interplay between the 'traditional' pharmaceutical companies and the biotech industry nowadays. The biotech industry has never been staying far away from its counterpart, the major drug makers, in its 30-year history. Without the partnership and the cash flow from Big Pharma, many of the biotech giants today would have died as infants. Meanwhile, the Big Pharma companies also have quickly caught up with the revolutionary progress in the life science field, for instance, structure-based drug esign and high-throughput screening. Although Pisano tries to define 'biotechnology' as broadly as possible (Chapter 1, p. 16), it is not convincing that these technologies belong to the biotech field alone.

Moreover, while the technology part progresses a lot, the basic concepts and procedures of drug R&D established by major drug makers have never been altered significantly in the past 30 years, whether it is for biological or small drugs. At the same time, Big Pharma companies are developing their own biological product lines. They have established quite strong R&D pipelines in biologicals through either their own endeavours or merge and acquisition, such as Novartis's purchase of Chiron and Merck KGaA's acquisition of Serono in recent years.

On the other hand, similar to information technology-based companies, the biotech companies, with numerous small start-ups as the majority, have been characterised as one high-tech engine for innovation. If we, however, examine them more closely, we can see more and more start-ups armed with specialised small-drug technology or proprietary lead compounds are emerging as new partners with Big Pharma companies. These small molecule-based companies have quite similar business models to the existing biologicalbased companies except that their drug substance is in different category. Besides, those established biotech companies have also shown keen interest in the small molecules. For example, Gilead Sciences actually have a prominent product pipeline in small molecules, such as Truvada[®], Viread[®] and Tamiflu[®], so the company does not look like a typical biotech company in the biotech field. To sum up, the boundary between the biotech and

pharmaceutical sector will eventually be smeared during their bidirectional fusion. An interesting fact is that the US Food and Drug Administration (FDA) transferred the product oversight responsibilities for most of the recombinant protein and monoclonal antibody products from the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER) in 2003.¹ Is this a sign that the industry regulator would like to follow the trend in the biotech and pharmaceutical industry?

Weijun Li

Bayer HealthCare Pharmaceuticals, Berkeley, CA, USA E-mail: liweijun@gmail.com

Reference

1. http://www.fda.gov/cder/biologics/default.htm.