A REVIEW OF BIOTECHNOLOGY COMMERCIALISATION IN SELECTED COUNTRIES

APPROACHES, CHALLENGES AND STRATEGIES IN ASIA

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Abstract

Biotechnology commercialisation is seen as the economic driver that could trigger extensive national growth while at the same time it provides solutions that will improve the quality of life for human. While the attempts to commercialise various research outputs have been done for many years, the results still vary with many countries experiencing various hurdles and researchers experiencing unexpected difficulties. This article focuses on biotechnology commercialisation in four selected countries namely China, Japan, Singapore and Malaysia. A review was done on the challenges faced by these countries as well as their approaches and strategies to achieve success in biotechnology commercialisation. All four countries face different predicaments and approachs. In conclusion, the main issues that seemed to hamper efforts of biotechnology commercialization were found to be lack of local scientific talent, lack of entrepreneurial skills among the academics and financial assistance from government. These very same issues if tackled strategically will also be the key factors which could ensure commercialisation success of biotechnology processes and products.

Introduction

Biotechnology commercialisation is now viewed as one of the main economic drivers in numerous countries in Asia. Biotechnology commercialisation entails commercialising research and development (R&D) outputs from universities, research institutes and companies into products or processes that have a significant commercial value. However, the commercialisation of life science technologies involves long and bumpy processes, with highly uncertain outcomes and high chances of failure.

The characteristics and the range of issues related to the commercialisation of biotechnology research differ between developing and industrialised countries. In industrialised countries, biotechnology is viewed as an all-pervasive profit-generating technology and a strategic component of industrial competitiveness (Othman, et al., 2014), whereas in developing countries, revenue generation from biotechnology commercialisation is still far from being ideal and rarely meets the expected return from its huge investment. However, despite facing various challenges, several countries in Asia have notably put up the necessary framework which are followed with concrete strategic approaches to harness the benefits of biotechnology commercialisation. China, for example, has shown its commitment and mettle in ensuring that it will be at par with countries like the United States in terms of biotechnology research, innovation and commercialisation of its bioproducts. This paper will review the biotechnology sector of four different countries, namely China, Japan, Singapore and Malaysia in order to understand the current trend and the associated strategic approaches as well as the shortcomings in realising the commercialisation of biotechnology products in Asia.

Tales of four countries

Biotechnology in China

Since 2007, China has collaborated with various main players in the biotechnology industry, particularly from the US and UK. These collaborations resulted in an increase in investments, and joint ventures and alliances with various multinational corporations (MNCs), particularly in the drug producing sectors. Such moves indicated China's intention in pushing towards a bigger and wider strategic approach in biotechnology commercialisation. At that point, the total Chinese biotech market, though still small compared to most Western countries, has attracted the attention of MNCs with its robust growth. It remained focus on the commercialisation of biologics, reagents and new drugs. However, at the end of 2017, President Xi Jinping, while clearly and publicly expressing the Chinese government support for biotechnology research, had also stressed the importance of a more cautious approach towards involving foreign companies especially in the commercialisation of agriculture biotechnology products in China. Foreign investments were to be allowed only in conventional or hybrid seed production, and would be restricted to minority shareholdings in joint ventures with Chinese companies (Global Agriculture Information Network, 2018). China has strategically moved towards becoming its own producer of biotechnology products without relying on foreign investments or foreign technological expertise. The strategy is consistent with *The 13th Five-Year Plan for National Science and Technology Innovation (13th FYP)* issued by the State Council in August 2016, which revealed how China was going to push forward with the commercialisation of key products, including the new generation Bt cotton, Bt corn, and herbicide-tolerant soybeans, and commensurate the central government's pledge to invest heavily in its local biotechnology sector.

The rise of biotechnology research in China could also be observed through the huge number of genetic related patents filed by its scientists. A remarkable 1,599 applications for invention patents on genetic engineering were filed between 1985

and 1999 alone (Huang & Wang, 2003). China has also shown the importance of nurturing and hosting world class scientists through the launch of the *Thousand Talents Plan* in 2008, a scheme that orchestrated the return of leading Chinese life science scientists, academics and entrepreneurs living abroad to China. These returnees have made a huge impact, seen especially in the increased number of new drugs approvals in China. It was estimated that out of 2 million returnees to China over the past 6 years, 250,000 of them worked in the life sciences related sectors (Hepeng, 2018).

Despite the slowing down of biotech commercialisation and start-up in the west due to the global financial crisis, financing for biotechs in China is actually increasing. Chinese venture capitals and private equity funds raised USD45 billion for investments in life sciences in the two and a half years prior to June 2017, according to ChinaBio (Hepeng, 2018). Beside capital investments, various grants are made available to life science scientists in universities in order to aide them in bolstering the accelerating momentum and to further produce scientists with world class aptitude. The strengthening of human capital in life sciences was also complemented by the building of high quality support infrastructure including more than 100 life sciences parks, aiming to push the biotechnology sector pass the 4% of gross domestic products by 2020. These systematic, aggressive and well-timed strategies are set to propel China to be a major biotechnology forerunner in the world, helming the technical and financial aspects of biotechnological commercialisation, without any signs of slowing down. China's deep pocket will continue to enable and sustain the development of its local biotechnology industry without having to rely on foreign investments. Additionally, the homegrown life science scientists will help the country to further explore the vast potential of the biotechnology development and commercialisation well into the future.

Biotechnology in the land of the rising sun

Japan's capability in biotechnology and life science research is outstandingly at par with the US and Europe. The level of commercialisation of the research outcomes is evident in the rising number of biotech start-up companies in Japan as well as the increase in the number of patents being filed. Japan's biotech start-ups involved an enormous capital investment of Japanese Yen (JPY) 445.8 million, with an operating income of JPY47.6 million, and research and development (R&D) expenses totaling up to JPY80.9 million. By 2013, these start-up companies were generating sales of up to JPY668.0 million. As of 2010, Japan's biotechnology industry's worth was estimated to be around JPY2.4 trillion. The Japanese government had earlier introduced the National BT Strategy to ensure that the industry met its full financial prospects. However, the growth of the biotech industry in Japan before 2010 faltered, attributed to the conservative Japanese culture, the country's poor science policy, the massive gap between academic and industry, the abysmal venture capital financing activity, as well as poor public acceptance towards biotechnology products such as GMO (Miyata, 2012). Perhaps the biggest difference between Japan and China is their treatment of foreign investors and partners. China made it clear that foreign involvement was to be limited in terms of shareholding through its tight governance of biotechnology research and commercialisation activities. Japan, on the other hand, welcomes foreign collaborations, which resulted in giant pharmaceutical companies moving their operation from China to Japan. Amidst concerns about China's regulatory efficiency and various impediments faced during bioproducts registration, the acquisition of American pharmaceutical companies such as Althea by Ajinomoto, Plexxikon by Daiichi Sankyo and several others, proved Japan's compelling intention to become a biopharma hub in Asia, and this in turn encouraged foreign companies to work closer with Japan to penetrate Asian markets faster and effectively. Nevertheless, Japan faces a specific and special issue that needs urgent attention in the form of its aging society. The political and socio-economic aspects of Japan's aging population must be taken into account in its quest to develop a sustainable biotechnology sector, the impacts of which cannot be understated. This factor also raises another challenge in the form of a declining labour force, which at the same time also results in rising health demands that need to be addressed. This challenge will inadvertently necessitate efforts for a strong and long term codependency relationship with foreign partners in order to ensure that the biotechnology sector is sustainable in the long run.

Singapore as the new biotechnology hub?

Singapore has indicated its intention to extend biotechnology and innovation as its economic drivers with various strategic moves by the government, which resulted in the increased number of biotech firms in the island state. Between 2015 and 2017 alone, 32 local biotech start-up firms were set up, two times more than the previous 2 years. By the end of 2017, nearly a quarter of the 79 home-grown biotech firms in Singapore were actually spin-offs from the Agency for Science, Technology and Research (A*Star), an agency that was initiated by the government to propel mission-oriented research which then encouraged scientific discoveries and technological innovations. The agency provides a coordinated platform for research, innovation and commercialisation to Singapore's scientists and technologists. The road to a successful biotechnology sector took almost 15 years for the pioneering start-ups and the nation is now enjoying its fruit of labour as the sector is drawing in a steady influx of venture capital financing and producing more biotechnology products which are viable for commercialisation. Singapore's biotech hub largely comprises medical related (medtech) sub industry and by 2016, the medtech industry was reported to be worth about USD3 billion (Hynes, 2017). Singapore's research infrastructure with various world class research facilities, together with the country's foreign investment friendly environment, acted as the main catalyst in attracting local start-ups as well as global multinationals. The government's efforts have resulted in the participation of biotech heavyweights such as GlaxoSmithKline, Sanofi and Novartis; a clear indication of its strategic acumen in ensuring Singapore continues to prosper in leaps and bounds in its biotechnology

innovation and commercialisation activities in the future.

Malaysia biotechnology aspiration

Malaysia launched the National Biotechnology Policy (NBP) in 2005, in an attempt to jump start the biotechnology sector. NBP provided a comprehensive framework to guide biotechnology development efforts in the country as well as a more integrated framework for industry development, outlining a comprehensive set of goals, priorities and strategies. This strategy was affirmed in 2006 via the Ninth Malaysia Plan (2006–2010) with a substantial fund allocation of MYR2 billion (USD0.58 billion) for biotechnology-related activities. In support of the strategy, local universities have also been producing more than 4,000 graduates with Bachelor, Masters and PhD degrees since then. The graduates were equipped with a wide spectrum of life sciences and biotechnology based specialisation such as molecular biology, plant biotechnology, bioprocess engineering, bioinformatics and marine biotechnology. The Ninth Malaysia Plan also outlined how the country must focus on implementing the NBP to develop Malaysia's niches in agriculture biotechnology, healthcare-related biotechnology, industrial biotechnology and bioinformatics, intensifying the need to promote local and foreign investments in the sector. However, more than 10 years after the launch of NBP, the intended outcomes have yet to be significantly realised. Stakeholders in the sector cited lack of skilled human capital and industrial bases, and many research products having no commercialisation value (Mokhtar & Mahalingam, 2010) as the main reasons for the underwhelming growth of the biotechnology sector in Malaysia. In 2012, the then government of Malaysia put forward the Bioeconomy Transformation Programme (BTP), aiming to accelerate the industry and maintaining the focus on specific bio-based industries that had been identified as potential key strengths of the nation. Several biotechnology parks were established to act as an economic accelerator for the biotechnology sector. One such park is in the Iskandar Malaysia development area, strategically located in Johor state, just across the causeway from the bustling Singapore. The park is home to several foreign biotechnology companies such Biocon from India, Amore Pacific from South Korea, Hydromission and BioAyzia from Singapore, together occupying about 50% of the park. However, stakeholders in the industry are saying that the development of the biotechnology sector is still not at par with neighbouring countries mainly due to lack of skilled and knowledgeable workers. Despite such setbacks, the government of Malaysia through its government-linked companies and agencies continue to push forward the innovation and commercialisation activities to support biotechnology companies. Based on data from MyIPO, the number of patents issued has steadily increased since 2005 (Figure 1). This goes to show that, while there are still various hurdles to overcome, Malaysia's biotechnology sector is catching up with the rest of the Asian countries.

Key challenges in biotech commercialisation

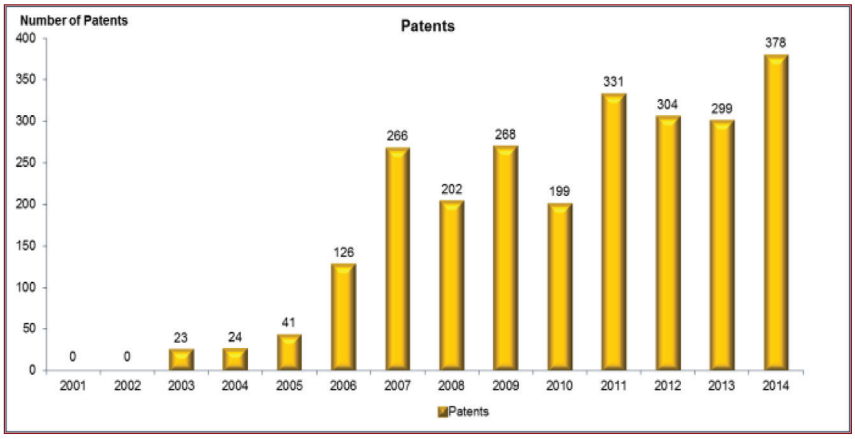
Lack of local talents

In all the countries reviewed above, the main source of knowledge and innovations in biotechnology is the local researchers and the local universities. This pattern shows that it is crucial that Asian countries develop their own biotechnologists and life science scientists in order to propel the growth of the sector. Malaysia's case clearly reflects how a lack of local talents can derail even the most immaculately developed strategy. China's strategy to lure back its life science scientists fortified the importance of having adequate and highly skilled workers to helm the biotechnology industry. The nation honed its own talents while, at the same time, luring foreign scientists with huge R&D funding. Through having a significant number of scientists, China has become the main producer of patents from their research works (Figures 2 and 3). Thus, any countries with a similar aspiration should look into developing a structured academic approach in order to produce highly capable scientists and innovators.

Malaysia's biotechnology sector evidently suffers from lack of talents as capable researchers remain the most important part of biotechnology commercialisation, regardless of demographic, social and cultural aspects. High quality life science scientists are the core element which ensure continuous production of novel ideas, innovations and bioproducts. The lack of such important element has severely impeded Malaysia biotechnology research and the subsequent commercialisation efforts compared to Singapore.

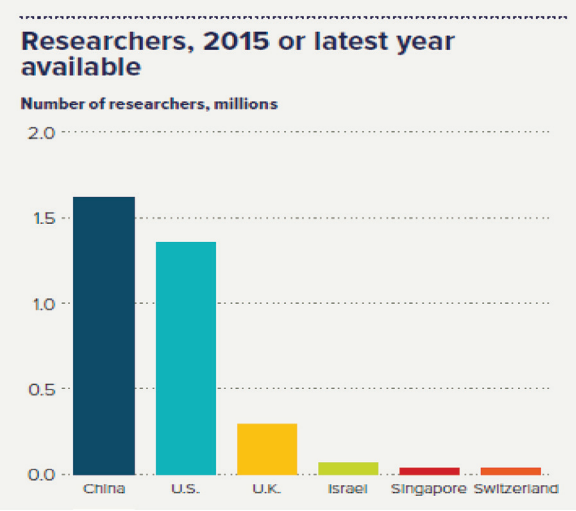
Entrepreneurial acumen

Commercialisation of any type of innovations, especially involving academics, is not for the weak-hearted. Multi-dimensional aspects of commercialisation include such elements as business acumen, critical soft



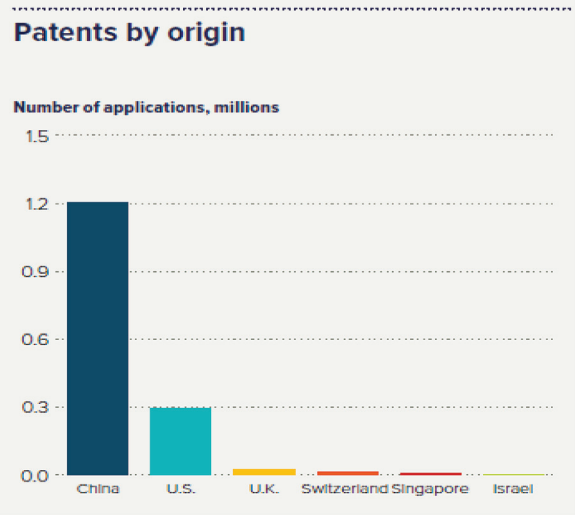
Source: Bibliometric Study 2015, MASTIC

Figure 1: Number of patents filed in Malaysia from 2001-2014



Source: World Intellectual Property : The Global World Innovation Index 2018

Figure 2: Number of researchers (in millions) by countries



Source: World Intellectual Property: The Global World Innovation Index 2018

Figure 3: Number of patents applications (in millions) by countries

skills; e.g. in negotiation, legal aspects of licensing and many other business related dexterities, which are not exactly the forte of most academics. Biotechnology commercialisation focuses on revenue generation by bringing the products to the market. However, for this to be successfully done, there are various pre-market processes that the scientists as the owner of the technology must undergo. Such activities include filing for patents, the technology licensing procedure, assessing the potential of establishing spin-off companies, determining the amount of royalty payments, as well as deciding on the most suitable business plan. All these could be very overwhelming to academicians, especially when they have not been exposed to any business knowhow before undertaking the commercialisation related activities. To some researchers, especially the newly minted entrepreneurs, they might be reluctant to leave behind their role as a scientist and may experience hesitancy in delving wholeheartedly into becoming a full time entrepreneur. Having to perform a dual role, both as a researcher as well as an entrepreneur, may prove to be burdensome, especially when there is a serious lack in commercialisation knowledge and business knowhow. Therefore, it is crucial for support agencies, either the university itself or the commercialisation agency, to understand this problem and provide adequate training and support to the scientist-turned-entrepreneur in order to ensure the commercialisation process is successful and start-ups are sustained.

Financial assistance

Funding is deemed critical for the enrichment of biotechnology research (grants to universities and third party research companies) as well as to support the commercialisation process itself (seed money, start-up grants etc.). It might be a surprise to many that even Apple Inc. was once the receiver of US government funding (Mazzucato, 2013). China's deep pocket has proven to be its strength as, funded heavily by the central government, China's biotechnology sector boasts of world class research and commercialisation infrastructures and enormous financial support that do not only lure its citizens, but are able to entice even the Western researchers. Free of financial worries, these researchers are able to focus solely on conducting high quality research that eventually lead to equally high quality bioproducts. Financial assistance not only will ensure more uptake of life sciences related research, but will also provide a sense of security for researchers-turned-entrepreneurs into embarking into the uncertain world of commerce. Apart from that, strong support from the government is also perceived as the country's commitment in ensuring continuous promotion of the biotechnology sector, just as Singapore is being perceived by foreign investors from the US and UK. Biotechnology related investment is deemed as high risk with high uncertainty, thus a compounded effort by the host country can be the deal breaker to attract foreign investors and collaborators into to the local biotechnology scene.

Conclusion

Biotechnology commercialisation could become the new significant source of

national income for various developing countries in Asia as it is in the developed nations. However, it is important that each element of the commercialisation process be strongly supported in order for the products to successfully reach the market. The commercialisation process, starting from the laboratory until the end consumers, needs to be within a tested framework that can be regulated. At the same time, the implementation and execution of the commercialisation process involving technology transfers needs to be carried out effectively in order to mitigate any risks of failure. Government support, strategically through proper commercialisation system and human capital development, and financially through various funding of commercialisation activities, is the main catalyst in ensuring that the commercialisation process of biotechnology in Asia will achieve its desired outcomes.

References

- ✓ Global Agriculture Information Network (2018)
- ✓ Hepeng Jia (2018, January). Retrieved from https://www.nature.com. *Nature* 553, S8 (2018)
- ✓ Huang, J., & Wang, Q. (2003). Agricultural biotechnology development and policy in China.
- ✓ Hynes, C (2017, Nov) Singapore Wants To Add Biotech Hub To Its List Of Accomplishments. Retrieved from https://www.forbes.com.
- ✓ Mazzucato, M. (2013). The entrepreneurial state: Debunking the public vs. private myth in risk and innovation.pp106-119. Anthem, London.
- ✓ Miyata, Mitsuru (2012). The next challenges of biotechnology of Japan. Global forum on Biotechnology, OECD, Nov 12, 2012.
- ✓ Mokhtar, K. S., & Mahalingam, R. (2010). The current biotechnology outlook in Malaysia. *Economia: Seria Management*, 13(1), 11-26.
- ✓ Othman, S. N., Yaacob, N. A., Yamin, F. M., & Ismail, R. M. (2014). Innovation culture among academicians in biotechnology R&D in Malaysian Research University. Journal of Technology Management and Business, 1(1).

Guide to tackling issues in access & benefit-sharing agreements

The World Intellectual Property Organization (WIPO) and ABS Capacity Development Initiative have jointly published "A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements". The guide, which is complementary and mutually supportive of the WIPO database of biodiversity-related access and benefit-sharing agreements, covers the conceptual and practical aspects of dealing with intellectual property in the context of access and benefit-sharing agreements.

Genetic resources are subject to access and benefit-sharing regulations, in particular within the international legal and policy framework defined by the Convention on Biological Diversity and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, the International Treaty on Plant Genetic Resources for Food and Agriculture of the United Nations Food and Agriculture Organization and the Pandemic Influenza Preparedness Framework of the World Health Organization. Intellectual property issues are one of the elements of the broader framework on access and equitable benefit-sharing. The strategic management of intellectual property issues in an access and benefit-sharing agreement can influence the degree to which providers and users of genetic resources and associated traditional knowledge can achieve their goals and serve their mutual interests.

The Guide's objective is to support providers and users of genetic resources and associated traditional knowledge when managing intellectual property issues in access and benefit-sharing agreements. It does so by explaining how intellectual property clauses may influence the approach and results of the utilization of genetic resources and associated traditional knowledge, providing an overview of the types of intellectual property related issues that providers and users of genetic resources and associated traditional knowledge are likely to face when negotiating an agreement, and outlining the options available in managing those issues, thereby enhancing the information available to stakeholders. The guide draws on a number of practical experiences across a range of economic sectors, including pharmaceuticals, industrial biotechnology, agriculture, cosmetics, and food and beverages, and describes issues that have arisen in practice in those sectors and the various approaches taken to resolving them.

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