

Recognising High-Growth Technology Businesses

By Audrey Yap

Growth as spectacular as that of BioNTech, inventor of the Covid-19 vaccine, depends on sequencing a combination of intellectual assets, says Audrey Yap in an article inspired by the EPO and LESI's High-Growth Technology Business Initiative.

It is time to update our definitions of various types of business. We all understand the difference between corner shops and industry giants. We are less clear about what now characterises a high-growth technology business (HTB) or, if you prefer to be more encompassing, a high-growth enterprise (HGE).

Some are happy to take the simple step of adopting the definition of SMEs (small and medium-sized enterprises) for HTBs. Each country has its own interpretation thereof but, in general, they are independent firms that employ less than a given number of employees. European SMEs have been found to generate a 47 percent cumulative increase in gross value added and a 52 percent cumulative increase in employment of the EU's non-financial business sectors.¹ The most frequent upper limit designating an SME is 250 employees, as in the European Union. In Singapore, an SME is officially where the company's annual sales turnover is not more than SGD100 million, or it has no more than 200 employees. This approach to understanding HTBs as a category is limiting and somewhat myopic in this day and age.

A better perspective than a textbook definition is identifying businesses that contribute to significant economic growth. We are talking about high-growth businesses: those where the average annualised growth rate increases by at least 20 percent per annum over a three-year period.²

Regional reports highlight their impact. In May 2019, the European Patent Office and the EU Intellectual Property Office released a study, "High-growth firms and IP rights," profiling high-potential SMEs in

1. EPO and EUIPO (2019), High Growth Firms and IP Rights, a joint project report, p14.

2. Eurostat and OECD (2007) Eurostat-OECD Manual on Business Demography Statistics, chapter 8, p61.

The EPO-EUIPO High Growth Firms and IP Rights study applies the same methodology, using turnover as the indicator of growth.

The European Commission classifies HTBs as enterprises with more than 10 employees and with average employment growth of at least 10 percent over the previous three-year period—European Commission (2018) Annual Report on European SMEs, p76.

Europe. More recently, the Financial Times published a special report, "High-growth enterprises Asia Pacific," taking the line that "businesses with a strong online presence have been turbocharged by pandemic-led digitalisation."

This subset of companies engages in all forms of innovation and lives with risks that their larger counterparts may not or cannot consider. With that intriguing description, how best then to define them? Rather than pigeonhole these businesses as just SMEs, spin-offs, or start-ups (all of which are included), it is better to describe them by their features and characteristics. Regardless of size, these HTBs emphasise:

- Product expertise and focus
- Innovation and ideation in all forms
- Intellectual assets
- Research and development
- Leveraging intellectual property
- Human capital
- Operational excellence
- Experimentation
- International growth
- The ability to adapt fast

HTBs are agents of change. In his book, *Start-up Science*, Masayuki Tadokoro includes other features that fit the idea of HTBs:

- Having disruptive innovation
- Potential for exponential/explosive growth
- Willingness to target entry, even in uncertain markets
- Taking on unknown challenges without competition
- Having a product with a devoted following of customers

Finally, it should be noted that HTBs can also include large enterprises, particularly those that are committed to open innovation and collaborative R&D and/or those who use technologies developed by SMEs and research organisations.

It is therefore critical to debunk the myth that HTBs are only small enterprises that fall within the purview of public support structures offering pro bono legal advice because they are dependent on cost-free support.

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On the contrary, HTBs warrant significant attention in any growing ecosystem because these players are and will continue to be the major engines of economic growth in any region or country.

Surprisingly, company executives and R&D or technical staff in these HTBs are often unaware of the fundamental role that an effective use of the IP system plays in emerging technology sectors. Significant strides are now being made to engage, inform, and train those in and around HTBs. Following the inaugural HTB conference in Dublin in November 2019,³ a task force for high-growth enterprises was established by the EPO and LESI: the HTB Initiative.

A Shot at High Growth

It helps to learn from live case studies of those that have embraced the IP journey effectively. In any iteration or definition, it is always useful to see what success looks like. BioNTech, the German company made famous by its launch of the Covid-19 vaccine, is an inspiring example. This biotechnology company, based in Mainz, develops and manufactures active immunotherapies for patient-specific approaches to the treatment of diseases.

Covid-19 has proven the theory that, while large established companies clearly dominate in mature and stable markets as incumbents, small businesses—more nimble and agile—tend to perform better in a crisis, such as a pandemic, or where there is technology uncertainty (National Academy of Engineering, 1995). The BioNTech story underscores how HTBs are early movers, in particular with respect to recognising and realising industry-specific growth opportunities (Bos and Stam, 2014).

It is almost stating the obvious that the road is long and rocky. Özlem Türeci, Uğur Sahin and Christopher Huber, the core team behind BioNTech, began exploring the use of mRNA more than 25 years ago. The company was then founded in 2008 with seed funding of €150 million. Covid-19 vaccines are the first truly successful application of this technology after 13 years. In other words, their first achievement was surviving.

As new therapies are developed, scientists build an understanding of possible adverse drug effects from the start of the discovery process. There are early toxicological tests in the lab, clinical testing, and the late, pivotal Phase 3 trials. However, the 20 years of data accumulated from researching and developing mRNA foster trust in its long-term safety and confidence in its use.

It should be noted that the R&D required to create the vaccines is incredibly expensive, while employing

top-tier, qualified staff with rare expertise over many years requires significant funding. This calls for endurance, outstanding teams, and expensive laboratories with corresponding biosafety levels and standards, filled with equipment such as bioreactors, centrifuges, cold storage, and very specific devices. IP rights enable ventures like BioNTech to capture the value of their inventions and play a pivotal role in helping secure a return on risky investments because they ensure the exclusive exploitation of protected innovation. The scientific community and companies like BioNTech will struggle to find investment without IP rights.

IP and Complementary Assets

However, IP rights do not stand alone and clearly cannot compensate for weak business management. An in-depth understanding of what advantages IP can offer the HTB in combination with other business assets will allow the company to better exploit its innovation in products and services that create sustainable growth. Powerful combinations include:

- IP and confidential information protected as trade secrets.
- IP and complicated product design.
- IP and speed to market (first-mover advantage).
- IP and other unique, complementary assets, such as regulatory approvals, operational excellence, human capital, and a cultural fit with future partners.

Collaborations and High Growth

All these different combinations can accelerate growth by unlocking the potential for collaborations. The ability to collaborate or be a partner of choice is critical for HTBs that typically have resource constraints. HTBs are innovation-intensive by nature, which requires substantial resource commitment and endurance. Furthermore, in all probability, they lack the ability to fully scale in-house to meet demands, quickly build distribution networks, communicate their strengths, and market their product or services.

BioNTech's team recognised this and one of their main opportunities came in the form of a joint venture with Pfizer. And thus, Comirnaty was born, the mRNA Covid-19 vaccine better known by its collaborators' names, the Pfizer BioNTech vaccine.

What Pfizer brought to BioNTech's table was financial strength, regulatory expertise for approvals, the manufacturing capability to ramp up quickly, and immense channels for distribution. When asked in an interview why Pfizer chose to partner with BioNTech, Brian Zielinski, vice president of Pfizer-BioNTech and its chief IP counsel, gave the following reasons:

- BioNTech was a foundational player in mRNA.
- Although there were other critical players in the

3. Details of the “High-growth technology business conference” (HTBC 2019) at www.epo.org/sme.

space, BioNTech had in-depth knowledge, expertise, and was a leader in the field.

- Pfizer was already collaborating with BioNTech.
- Pfizer saw a strong cultural fit with BioNTech.
- BioNTech had a robust IP portfolio.

Living the Deal

Cultural fit and operational excellence between organisations cannot be underestimated as virtues. In situations where big pharma is looking to partner with smaller specialised biotech companies, an understanding that they have a similar approach to governance, for example, is crucial.

Big pharma is known for its many procedures and rigorous compliance. Finding a partner that shares these values but also has an SME's advantage of speed is a great bonus.

Operational excellence means not only having efficient and effective processes and procedures to get to where you need to be in terms of IP and innovation, it also affects how the merger or collaboration unfolds.

When handling IP once the technology transfer has occurred and best practices shared, how do you ensure that both parties benefit from the deal? Indeed, Pfizer believes it now also has technical expertise in mRNA after collaborating so closely with BioNTech. Were firewalls needed when this was taking place?

Vigilance is essential as contamination of IP is difficult to unravel. Accordingly, from an early stage, processes to facilitate and protect trade secrets and IP in general should include:

- Separating localised R&D related to the mRNA work for the vaccine from other unrelated worldwide research
- Using different teams and separating scientific personnel
- Meticulous mechanisms for storing data and results—technology should be harnessed to allow for this

Finally, given the unique subject matter of vaccines, safety, and safety protocols, diligent reporting and reaction capabilities are a priority. Team experience is vital when responding to adverse events and handling issues in an open way.

Operational excellence will be well and truly tested when growth hits hard and fast: the more complex the network of production, packaging, storage, distribution, and administration of the vaccines, the greater the risks of untoward events.

In this particular instance, Pfizer and BioNTech came together surprisingly quickly because both collaborators had an interest in the scientific venture with the equal intent of harnessing the embedded technology for future applications. In itself, collaboration could

naturally give rise to conflict and competition. However, a win-win mindset allowed them to be first past the post, rewarding their endeavour with supportive clinical data and building the trust and reputation that are critical in a healthcare crisis.

The Layers of IP

It is an understatement to say that IP should be robust in this field. Any biological application has layers and layers of IP in a variety of forms, even more so for vaccines during a pandemic. The most obvious are patents, as they protect the core inventions that are fundamental to the entire product development. Nonetheless, there are also trade secrets and expertise in the key processes and procedures, as well as the reputation embedded in a company's brand and trademarks, crucial to building trust for the urgent roll-out of global vaccination programmes.

In the deal with BioNTech, IP issues were clarified at an early stage. Arguments about IP for core technology, improvements, and patentability issues would have been counterproductive, distracting attention from work on the vaccine itself and getting it to where it is most needed. A useful checklist of aspects to resolve in such collaborations is shown below.

- **IP Inventory:** it is advisable to draw up an IP inventory as to who owns what and what is brought to the table. Differentiating between the background IP (what has been developed, identified, and owned) versus foreground IP (what will and continue to be developed) is critical.
- **Dealing With Joint IP:** keep a record of how it occurs and who owns what rights at the end of the collaboration, if a timeline can be anticipated.
- **Defining the Entities Involved:** which companies and what cultures are we referring to? Where are they based? Will that continue and will new entities be involved?
- **Exclusive and Non-Exclusive Licences:** clarify and specify what IP will be licensed exclusively and non-exclusively, with a clear understanding of its relationship to future and background IP. Again, deciding how these licences will be handled at a termination event will be key.

The challenge is keeping all these issues straightforward and preventing them from becoming obstacles to progress. Experience and specialists can help strike the right balance. Apart from IP expertise, the depth of the team's transactional abilities is what gets the deal through.

IP and Ramping Up Production

Understanding what works and quickly embracing it allows for an even faster ramp-up geographically. On the strength of its robust IP protection, Singapore was

selected as BioNTech's fully integrated mRNA manufacturing facility and its first regional headquarters for Southeast Asia. When it opens in early 2023, the facility is expected to have highly automated, end-to-end mRNA production capabilities. A similar plan is in the pipeline for South Africa's Biovac Institute to manufacture for the African Union. A great IP portfolio welcomes and allows for regional growth that translates effectively across borders.

Innovation Continues After Take-Off

It is a fallacy that innovation only takes place at the beginning of the journey, when candidates are identified, targets selected, and delivery platforms defined. The truth is that, once technology takes off and an enterprise ramps up for the next level, there is an explosion of innovation—and it continues. The Covid-19 vaccine development illustrates this entire experience perfectly, despite being compressed and accelerated at breakneck speed.

Innovation is required at every level and every stage, from the focus on which variants to use to the challenges of rapid scale. It naturally follows that although, quite correctly, the initial vaccine research prioritised safety and efficacy, escalating demand required that production timelines be cut back. Innovation decreased the initial 110 days for manufacturing one vial of vaccine to 60, while efforts to reduce this period still further are ongoing. Transportation difficulties in sub-zero conditions similarly spurred the search for new formulations that are equally stable at higher temperatures and for specialised storage equipment.

Sudden worldwide demand meant that transportation and logistics also had to be considered. New, unique containers were designed that could fit and maximise delivery in cold storage trucks. Tracking where and how the vaccines were delivered (to ensure optimal conditions were maintained) involved using new methods such as probes combined with GPS. Innovation was also needed to cut costs, whether in production or distribution, to ensure that more of the global population could benefit.

BioNTech clearly believes in continual investment here, as its R&D spending in the first six months of 2021 was €417.3 million, compared to €160.3 million for the same period in 2020. It is interesting to note reports that the increase was due to development expenses for BioNTech's BNT-162 programme as purchased services, initially incurred by Pfizer and subsequently charged to BioNTech under the collaboration agreement. Being able to defer expenses with support from big pharma allows ventures such as BioNTech to focus on their core tasks, confident that the necessary financial resources are available. As such, BioNTech was able to report significant progress across its various programmes, mainly those that target the Delta variant of Covid-19, as well as in its other work in oncology, influenza, and malaria, creating a virtuous cycle of new growth and products.

Conclusion

BioNTech estimates the revenue generated by its Covid-19 vaccine at €15.9 billion for the 2021 financial year, on delivery of its targeted supply under contracts of about 2.2 billion doses by July. This underscores that IP is not just pie in the sky but has a real impact on the value and financial strength of HTBs.

BioNTech's story emphasises that having a robust IP portfolio and including an IP strategy in the overall business strategy are key success factors. IP rights (and patents in particular) are instrumental in overcoming barriers in value-creation transactions. In the case of the collaboration between Pfizer and BioNTech, they created a virtuous and positive cycle of greater and better innovations that were complementary and built on the core technology. For future HTBs, it maps out a clear path to follow from start-up to SME and to a partner of choice as one of the major players. ■

Available at Social Science Research Network (SSRN): <https://ssrn.com/abstract=4099671>

For further details of the High-Growth Technology Business Initiative, see www.epo.org/high-technology-businesses. To stay updated, follow the high-growth technology business community on www.linkedin.com/company/htbcommunity.