

Big Pharma's Search for a COVID-19 Vaccine: Take It To The Limit!

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Abstract

The 2020 COVID-19 pandemic undermines the world economy, the affordability and accessibility of our health systems. It puts an increasing strain on global production, supply and value chains. The research and development of a set of COVID-19 vaccines is an unprecedented triumph of rapid innovation. The sense of urgency has prompted academic research institutions, big pharmaceuticals and dedicated biotechnology companies to develop vaccines targeting the SARS-CoV-2 coronavirus disease. Simultaneously, it unlocks new value for business, patients and society. Consequently, new business models have come to the forefront.

Keywords: COVID-19, Vaccines, Biopharmaceutical industry, Business Models, Ecosystems.

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1 Context

Already in 1995, Laurie Garrett made a case for “*newly emerging diseases in a world out of balance*”, expressing concern about the appearance of new infectious diseases. In 2015, Bill Gates (gatesfoundation.org) launched a global warning on future disease epidemics, stating that “*the world needs to prepare for the next major health crisis*”.

Since March 2020, the outbreak of the Wuhan Coronavirus disease (SARS-CoV-2) and the COVID-19 pandemic has transformed the world as we know it, disrupting the business models of civil society, (higher) education, world economy, business, governments, policies. We are witnesses of a paradigm shift. It is up to us whether we will influence it or simply allow it to happen. Not only in science-knowledge but also in human interactions and behaviour, basically all aspects of our up-to-now comfortable life.

The 2020 COVID-19 pandemic undermines the world economy and has had an unprecedented impact on health systems around the world. It is recalibrating businesses across sectors, not in the least in healthcare and the biopharmaceutical industry. It unlocks new value for business, customers and society.

The race to find both medicines and vaccines is reshaping the way companies – large and small – collaborate and innovate in life saving projects while maintaining the drive of competition in the long run. It triggered an unprecedented and intense level of global R&D activity and collaboration by research teams in companies and universities across the world. Together with

university research centers and clinical research organizations, the biopharmaceutical companies are actively involved in large-scale clinical and diagnostic testing and development of vaccines, medicines, testing kits and near-patient testing devices. Manufacturing companies outside of the life sciences industry (i.e. pharmaceuticals, biotechnology, medical devices, . . .) are forming partnerships with others to transform some of their manufacturing capacity to assemble much needed critical equipment like ventilators and respiratory appliances (Chesbrough, 2020).

2 Time To Vaccine

The first and most important task today is to defeat the invisible enemy - the virus. Leading pharmaceutical and dedicated biotechnology companies, academic institutions, governments and the broader international scientific community are working together in public private partnerships like never before to produce a treatment and speed up the time to vaccine.

Pharma and biotech companies within many cross-sector collaborations have taken the race to the limit to develop a coronavirus vaccine, simultaneously waking the general public up to an important warning sign: the time of going from concept to marketable product. The pharmaceutical industry hoped to compress the time to market distribution to within 2021 at the earliest, being significantly sooner than the 10 to 15 years the process of getting a new vaccine to market typically takes.

3 Surfacing Business Models - The Biomolecular Platform Business Model

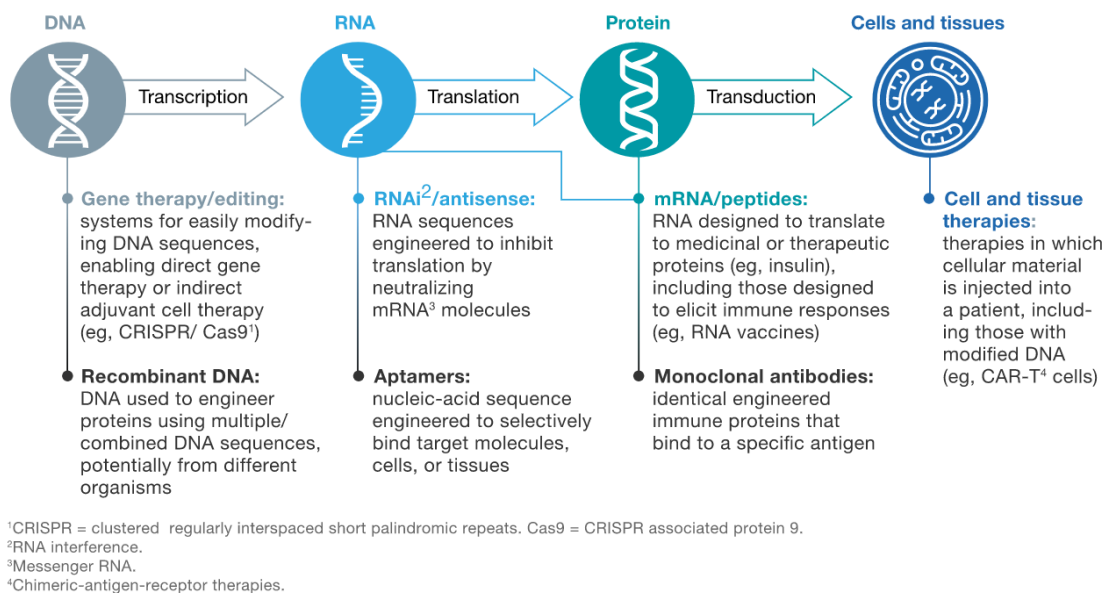
COVID-19 is transforming old and creating new business models of both cooperation, competition and elements of open innovation. Coopetition describes a the phenomenon where companies both compete and cooperate in a so-called cooperative competition. The following two “*COVID-19 induced*” business models have proven to be the most important since the outbreak of the coronavirus disease.

Biomedical platforms have yielded new treatments – spanning various DNA-, RNA- and cell-based therapies – with broad potential applications (Leclerc and Smith, 2018). Digital health is a key part of the genetic information-driven business model of biomolecular platform companies. The viability of a biomolecular platform as a therapeutic modality itself is the source of value creation, e.g. whether the platform can be used to deliver vaccines. This approach is being applied across a range of biomolecular platforms, from DNA-based gene therapies to CAR-T therapies to emerging microbiome platforms. mRNA has only recently come into the focus as a potentially powerful drug class able to deliver genetic information and to develop vaccines against infectious diseases (Sahin, U., Karikó, K., Türeci, Ö, 2014), such as the coronavirus disease (COVID-19).

Currently, we are witnessing the successful widespread rollout of the Pfizer-BioNTech and Moderna vaccines, next to the Janssen (Johnson & Johnson) and the more troublesome AstraZeneca vaccine. GSK - the leading manufacturer of vaccines globally - partnered up with Sanofi. In the partnership, Sanofi provides its recombinant antigen and GSK contributes its pandemic adjuvant. GSK is also working together with CureVac for next generation mRNA vaccines.

3.2 The Public Private Partnership Business Model

Government funding and financing of translational research performed at universities and research powerhouses have become increasingly important for the development of new vaccines. This created a new momentum for the public private partnership business model, which is increasingly deployed for the financing of clinical studies and to speed up production capacity worldwide. The public part (government side) of the business model is about creating medical



Source: Leclerc and Smith (2018) – McKinsey

Figure 1. Genetic-information-driven technologies

and societal impact – speeding up the worldwide available supply of vaccines and equitable access of COVID-19 solutions. The private part (business side) relates to economic and regulatory issues, investor financial returns and value co-creation.

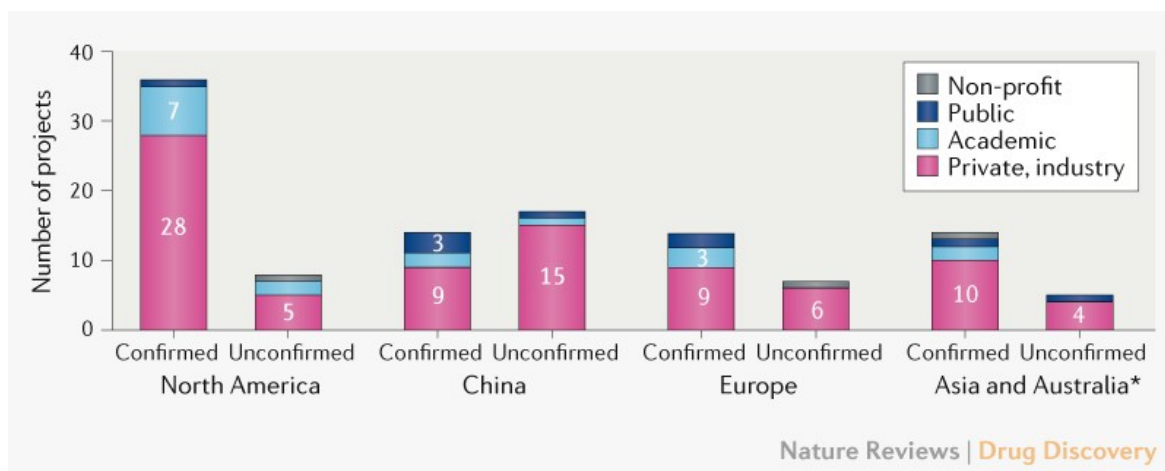
In a first wave of research and development, leading (bio)pharmaceutical companies and governments are working together in public private partnerships (PPP) like never before to produce life-saving coronavirus vaccines (Segers and Gaile-Sarkane, 2020). According to Thanh Le et al. (2020), it will be important to ensure coordination of vaccine manufacturing and supply capability and capacity to meet demand. Pfizer-BioNTech, Moderna Therapeutics, Janssen (Johnson & Johnson) and the alliance of Oxford University Hospitals, Oxford Biomedica and AstraZeneca have made tremendous progress since the outbreak of the pandemic (see World Health Organization, 2021 (who.int)¹).

In the second wave, the focus has shifted from speedy research and development of new vaccines to leveraging the global production capacity. Companies are increasingly sharing infrastructure and investing in leveraging joint production capacity.

A growing number of global Public Private Partnerships have been deployed to tackle the COVID-19 crisis. They are explained in short below:

1. **CEPI**, the Coalition for Epidemic Preparedness Innovations, unites the network of governments, pharmaceutical industry, regulators, academia, philanthropies, civil society and health organizations into a global health ecosystem (Debruyne, 2021). It is dedicated to finance independent research projects to develop vaccines against emerging infectious diseases;
2. CEPI, GAVI (Global Vaccine Alliance) and the World Health Organization are co-leading **COVAX** (COVID-19 Vaccines Global Access) to ensure equitable access to the vaccines. COVAX is the vaccines pillar of the ACT-Accelerator; the **ACT Accelerator** (Access to COVID-19 Tools) is a ground-breaking global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines;

1. https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_18May2021.pdf



Source: Thanh Le et al. (2020)

Figure 2. Profile of COVID-19 vaccine developers

3. The Innovative Medicines Initiative (**IMI**) is the world's biggest public-private partnership in the life sciences. It is a joint technology initiative between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The key goal of IMI is speeding up the development of innovative medicines. The focus is currently on the development of and access to therapeutics and diagnostics to tackle current and future coronavirus outbreaks (drug development and repurposing);
4. **HERA-Incubator** - the European bio-defence preparedness plan – is a public private partnership similar to BARDA (US Biomedical Advanced Research and Development Authority);
5. **Operation Warp Speed** in the United States, a national program with BARDA to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics;
6. COVID-19 Technology Access Pool (**C-TAP**) is a call to action to voluntarily share knowledge, intellectual property and data;
7. The Accelerating COVID-19 Therapeutic Interventions and Vaccines (**ACTIV**) partnership, i.e. a public-private partnership to speed COVID-19 vaccine and treatment options by the National Institutes of Health in the United States. It brings together more than a dozen leading biopharmaceutical companies, the FDA (Food and Drug Administration) and the EMA (European Medicines Agency) to develop an international strategy for a coordinated research response to the COVID-19 pandemic;
8. **Open government** approaches to tackling COVID-19 (Mention, 2020), building trust between government and citizens, digital platforms or apps.

The pandemic is stimulating innovation in regulatory and IPR (intellectual property rights) issues (Chesbrough, 2020). A number of countries and international organizations argue for removing IP protections (open IP) on COVID-19 vaccines, medical tools and technologies during the duration of the pandemic. They support a temporary global waiver of the Trade Related Intellectual Property Rights (TRIPs – World Trade Organization) agreement. The TRIPs agreement introduced global minimum standards for protecting and enforcing nearly all forms of intellectual property rights, including those for patents. Scaling up mass vaccine and therapeutic production at lower prices is key to achieving vaccine equity for developing countries, for global health security and preparedness for future pandemics.

An international coalition (Geneva Network, 2021) released a joint declaration on continued

international collaboration between governments, private sector and other stakeholders, stating that “IPRs are crucial to sustainable vaccine manufacturing scale-up and that an IP waiver would have no effect on vaccine production without forced tech transfer, which would be extremely slow, beset by legal difficulties and economically damaging”. Others argue that rapidly scaling of production of vaccines implies enforced licensing deals with big pharma. According to Vanhaverbeke (2021), the focus of governments should switch from waiving patent protection to different types of licensing agreements with other pharma companies and generic drugmakers.

4 Exemplary Country Case: Belgium

The biopharmaceutical industry within biotech clusters around the world are more than ever considered as strategic industries in many countries. The vibrant biotechnology and pharmaceutical industry is one of the driving forces of the Belgian economy. According to the OECD reports, Belgium is among the leading countries for performance in innovation and industry development as measured by R&D-intensity, patent applications, the number of drugs in the pipeline, venture capital invested in biotechnology and the number of new biotechnology firms.

The Belgian pharmaceutical industry is highly R&D-intensive, which explains the bioRegions of Flanders and Wallonia hosting a number of global players in medical research and development (Segers, 2017a; 2017b). Belgium plays a central role in the European Union for clinical trials and translational vaccines research and production, given the historical presence of global pharmaceutical companies and headquarters such as Pfizer, Janssen Pharmaceuticals (Johnson & Johnson) research campus including JLABS, GlaxoSmithKline (GSK), Sanofi and many others. In addition, dedicated new biotechnology firms like Ziphius Therapeutics – together with Univercells/Exothera/Quantoom Biosciences – and eTheRNA are investing heavily in mRNA-based immunotherapies to create the next generation of vaccines.

The Belgian biopharmaceutical industry rises to the occasion in three key areas: research & development, manufacturing & production and logistics & distribution. In the combined regional ecosystems of both Flanders and Wallonia (Segers, 2017a), the interplay between various players and stakeholders (governments – high technology industries and industry-specific umbrella organizations – academia and research institutions) provide a momentum towards the urgently needed efficacious vaccines to contain the ongoing coronavirus disease. The ecosystems cover every aspect of the biopharmaceutical value chain (Pharma.be, 2020):

- research and development and clinical trials;
- production (intermediary products, active pharmaceutical ingredients, raw materials, diagnostic tools);
- a global logistics hub for medicines and vaccines and exports.

5 Conclusion

The COVID-19 pandemic undermines the world economy and our health systems. The joint battle against the coronavirus led by governments and the global biopharmaceutical industry creates new business models, leverages public private partnerships and enhances voluntary collaboration between firms. The emergence of new platforms, treatments and therapies has been accompanied by massive public and private investments in the search for efficacious COVID-19 vaccines. The sense of urgency was translated in an unprecedented level of global R&D activity, collaboration by research teams in companies and academia across the world. Questions and concerns remain with respect to the urgently needed scaling up of vaccine manufacturing capacity and supply and the

ongoing discussion about intellectual property rights and patents. Take it to the limit !

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Biographies



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