Unprecedented: Innovation and the COVID-19 Response

Findings

- Our team studied how COVID vaccines and therapies were rapidly brought to society, to identify in particular the enabling role of IP.

- Our sources were media reporting, reports, and relevant academic literature. We also interviewed a dozen senior executives whose companies were involved in the COVID response.

- Our analysis focused on the role of IP in the COVID response, particularly patents and trade secrets.

Our research pointed to a clear conclusion: IP was a crucial enabler of COVID-related innovation.

- IP protection drove the development of the technologies and know-how that were rapidly leveraged by biopharma companies and their partners when the pandemic started;
- IP enabled collaboration for COVID innovation;
- IP supported investments all along the pathways for developing and commercializing new solutions; and
- IP provided a foundation for knowledge and technology-sharing among partners at all stages of development and commercialization, notably manufacturing.

Presentation of our findings

Our research is presented in the report as follows:

- The fundamental role of IP in the bio-pharma industry
- Building on earlier innovations: Pre-existing technologies, platforms, and know-how that existed at the start of the pandemic and that were relevant to the COVID response
- The development of COVID treatments at unprecedented speed
- Collaboration to manufacture and distribute COVID solutions
- Conclusions and insights for policymakers

Key Findings

1. **IP drove the creation of the background technology used to develop COVID solutions.**
2. **IP enabled collaboration, which was crucial to the rapid innovation of vaccines, therapeutics, and diagnostics to fight the pandemic.**
3. **IP enabled important investments in bringing new COVID technologies to society.**
4. **Technology transfer happened rapidly and on a broad scale in response to COVID.**

IP drove the creation of the background technology used to develop COVID solutions.

- When the COVID pandemic began, there was background technology and knowledge that could be applied to address the crisis.

- These provided the foundation to rapidly develop new vaccines and treatments, and to test existing ones for relevance to COVID. They existed thanks to sizeable R&D investments made in the past, enabled by IP protection.

- There were diverse promising technologies to apply to the COVID response. This is because IP systems stimulate efforts to develop different ways to solve the same problem. The diversity of promising compounds and platforms available were used to develop COVID-19 vaccines and treatments in an unprecedented amount of time.

- Innovators drew on existing vaccine platforms, monoclonal antibodies, and manufacturing technologies and related expertise. Some had been developed by public sector researchers.

“The core technologies came together at the right time and were available for the COVID response because we had a strong and robust IP system over the years. You could argue that those technologies would never have been developed without IP.”

IP enabled collaboration, which was crucial to the rapid innovation of COVID vaccines, therapeutics, and diagnostics.

- Time was of the essence and innovators jumped in to address the crisis together with their peers in the biopharma innovation ecosystem. Collaboration was important in order to move quickly.

- IP rights enabled a safe environment for innovators to immediately share proprietary technology and knowledge with partners – including competitors. They did so with the confidence that their IP assets, whether patents or trade secrets, were protected under IP and contract laws. This reduced the risk they would lose the IP and thus competitive advantage.

- They also shared a culture of innovation and respect for IP with their partners. Trust built over time indicated that what they shared would not be misappropriated.

- Stable IP frameworks allowed partnerships to come together rapidly, in some cases even before the details of the working relationship had been worked out

“Pfizer and BioNTech had already been working together to develop a vaccine using the mRNA platform. This is their core technology and the result of all the investments they have made over the years. IP protection gave them the assurance that they could share it without losing all their investments from over the years.”

> *No one party can do everything. No one entity has all the tech to bring to bear to solve a problem like COVID. It has taken a tremendous amount of collaboration. And IP has really facilitated collaboration. It allowed parties to share information freely, knowing there are frameworks to protect that information.*

IP enabled the significant investments that were required to bring new COVID technologies to society.

- Developing drugs is costly and risky at every stage from lab to market.
- IP protection enables investment in R&D ventures – this includes the COVID response. At every step towards bringing COVID vaccines and technologies to society, sizeable investments were needed.
- Companies drew on earnings from past innovation successes to finance COVID R&D and commercialization activities.
- Innovators moved resources away from other projects in order to urgently address COVID. Redirecting manpower and investments to COVID-19 projects was costly and risky.
- IP was crucial to secure investments and collaboration between different actors, including those from the public and private sectors.Bringing a treatment to market requires a division of labor between research institutions, startups, large companies, contract manufacturers, suppliers, and others.
- Innovators invested in developing new solutions, in testing them and securing regulatory approval, in identifying and vetting manufacturing partners, in setting up value chains and distribution networks, and in continuous monitoring and improvement of the COVID solutions themselves.

“We had planned to make a synthetic cholesterol before COVID hit. Then we accelerated that and were able to launch nine months in advance. The condensed timeline required us to move people off of other projects, and to put them on this instead. We tapped into manpower and historical knowledge, and we had to sacrifice other projects. We focused on this and made it a priority. IP enabled this.”

“Shifting equipment and people to focus on COVID meant taking them off other things. This is risky and costly. We had to make sure the business would exist on the other side of that.”

Technology transfer happened rapidly and on a broad scale in response to COVID.

- Technology transfer happened at a speed previously unseen, as reported by those with years of industry experience. For example, Pfizer, BioNTech, and Novartis developed a novel manufacturing process for the Pfizer-BioNTech vaccine in roughly four months, even though mRNA vaccines had never been made at commercial scale.

- Technology transfer at the different stages of develpoment and commercialiation was supported by IP protection, as IP assets were rapidly shared and licensed.

- When it came time to manufacture billions of doses, manufacturing partners were rapidly identified and vetted, and global CMO and distribution networks were rapidly established.

- Technology transfer was integral to rapidly bringing many contract manufacturing partners (CMOs) into geographically distributed value chains, in order to rapidly scale production of vaccines. IP enabled technology and knowledge sharing.

- As of August 2021, there are 45 contract manufacturing partnerships (reported publicly) around the world for the Pfizer, J&J, Moderna, and AZ vaccines.

“Reading about manufacturing is the same as playing an instrument by reading a book. You can’t just learn it from a manual. You have to be taught it, then learn it yourself by doing.”

“Ultimately we are sharing the IP in order to show our partners how to safely and effectively make the product. Onboarding manufacturers involves significant technology transfer and you need to be able to share and speak freely.”

Additional challenges: distribution and supply chain management

- Making billions of doses is a significant industrial undertaking. And a health problem affecting the entire world at once is an unusual challenge.
- The manufacturing processes present significant logistical and management challenges. Production must be carried out efficiently, economically, and with high precision and attention to safety.
- The COVID vaccines are complex products requiring a range of materials sourced from many places. Pfizer's mRNA vaccine requires a reported: 86 different suppliers; 280 materials in total; 10-15 unique raw materials; 46 steps to review a batch of vaccine before release.
- When the pandemic began, demand for raw materials and equipment spiked and it became more difficult to source them. This reality has been complicated further in some cases by government policies, notably trade policies.
- Some vaccines need to be stored in ultra-cold freezers, which makes distribution more challenging. Additional innovations – in packaging and labels that stick to frozen vials – were needed in addition to the distribution networks themselves.

Insights for policymakers:

By applying lessons learned, policymakers can support the ongoing COVID response and enhance future pandemic preparedness. IP was an important enabler of the pandemic response.

- Innovators had a range of innovative technologies to apply to the COVID response when the pandemic hit. IP had supported their development.
- Collaboration and knowledge-sharing provided a foundation for rapid innovation in response to the crisis. IP enabled sharing.
- At every stage of development of COVID vaccines and other solutions, significant investments were required. IP protection helped to enable such investments, whether in relation to product innovation, regulatory approval, scaling production, distribution, or other activities.
- Some IP assets relevant to the COVID response were licensed by the public sector research institutes to the private sector, which invested further to transform the research into products. One example is the mRNA platform. This underlines the need for policy frameworks for public-private collaboration.
- Some have called for removing IP on COVID products. This would have slowed the COVID innovation response, by making knowledge and technology sharing unduly risky. It would also have made it more difficult to establish manufacturing networks, which require tech transfer and IP-sharing.

Other types of policies also affected the COVID response, such as government support (productive) and trade restrictions on inputs (counterproductive).

“ *IP is the opposite of a barrier, it’s an accelerator.* ”

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