Unprecedented

The Rapid Innovation Response to COVID-19 and the Role of IP

Executive Summary

Contents

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Executive Summary

The COVID-19 pandemic presented humanity with unprecedented challenges. Researchers and biopharmaceutical companies responded by developing and delivering COVID-19 vaccines and treatments in record time. The innovation response to COVID-19 has been a singular achievement, but we will not be done until every person who needs a vaccine can get one.

Most appreciate the quick development of COVID-19 vaccines and therapeutics, but many overlook the enormous scope of the effort. Many people are unaware of the extensive collaboration among biopharmaceutical companies and other institutions that made it possible to bring these treatments to society with a compressed timeline that was unprecedented. COVID-19 vaccines and treatments are the product of great science, public-private partnerships, and many years of hard work and investments. Underlying all of this was the intellectual property system (IP system), which helped to secure the investments necessary to enable innovation and enabled the trust that supported industry cooperation and collaboration.

This report tells the story of how COVID-19 vaccines and treatments were developed and delivered, focusing on the essential enabling role of intellectual property (IP). One unique contribution of this report is that it relates the views of IP counsel, manufacturing experts, and others in the biopharma industry who played a role in developing treatments. It also documents just how extensive the collaboration and technology transfer has been among biopharma industry companies. Vaccine innovators are sharing proprietary technology with many dozens of partners, on every continent in the world – not despite IP, but rather thanks to the security provided by IP. The research for this report covers the period through August 1, 2021.

This report tells the story of how COVID-19 vaccines and treatments were rapidly developed and delivered to society, focusing on the enabling role of IP.

IP is "the future prospect that reassures investors."

I. The Biopharma Industry and IP

IP protection is essential to the biopharma industry. IP protection:

- Encourages innovation
- Fosters and secures investment; and
- Enables cooperation and coordination among biopharma companies and other institutions.

These three roles of IP help to take a new treatment through every step of developing a drug, from basic research, to applied research, through clinical trials, and onward to developing manufacturing capacity and distribution. Every step of this process is expensive and challenging, and IP provides the security needed to undertake this work.

While great science, hard work, and relentlessly effective execution are at the heart of developing new treatments, they do not happen without the investment secured by IP rights. As Derrick Rossi, the academic founder of Moderna, observed,

> ***"you can be working on the coolest thing, but investors need to know that there is some protection for their investment, plain and simple." IP is "the future prospect that reassures investors."***[1]

Collaboration is also essential to the biopharma industry, as developing and manufacturing a new treatment increasingly requires cooperation among many actors. Collaborations occur in many forms, including:

- *Acquiring Key Technology.* As new technology platforms such as mRNA vaccines are developed, biopharma companies must secure licenses for key technology in that platform developed by research institutions or other companies.
- *Partnerships Between Early Stage and Large Companies.* Earlier stage innovators such as BioNTech often turn to larger, more experienced partners such as Pfizer for expertise in managing clinical trials, securing regulatory approval, ramping up manufacturing, managing complex supply chains, and setting up distribution.
- *Technology Transfer to Manufacturing Partners.* Innovators often work with specialist manufacturers to produce treatments or complete other parts of the production process.

These partnerships and others require the ability to share information without losing control over it. IP rights provide the security necessary to make these partnerships work by ensuring that proprietary technology and information is only used for the purpose intended.

IP rights played all these roles in the development of COVID-19 vaccines and treatments.

When the COVID-19 pandemic arose in 2020, the biopharma industry was able to rise to the occasion by building on previous innovations, innovating new treatments, and manufacturing them at scale, all in record time.

II. Responding to Crisis in Record Time: An Industrial Drama in Three Acts

When the COVID-19 pandemic arose in 2020, the biopharma industry was able to rise to the occasion by building on previous innovations, innovating new treatments, and manufacturing them at scale, all in record time. This remarkable achievement displayed the strengths of an innovation ecosystem that is enabled by IP.

This report tells that story, focusing on developments through the end of July, 2021. We explain the essential role of IP in fostering innovation, securing investment, and supporting cooperation. While many other institutions and factors – government investment, great science, manufacturing expertise, and hard work – were essential, IP played a pervasive and necessary role as a key enabler at every stage.

A. Building on Earlier Innovation: Pre-COVID-19 Technologies, Platforms, and Know-how

When the COVID-19 outbreak gained pandemic proportions in March 2020, the global community had no vaccines or treatments available to fight the new virus.[2] Based on historical precedents, medical and public health experts expected that finding a viable treatment could take years.

Fortunately, continuous innovation in the life sciences has built a foundation that allowed researchers and industry to defeat historical expectations. These diverse platforms and other technologies, accompanied by substantial know-how, had been developed through R&D investments and other activities over many years. The existence of these technologies was the product of a well-designed system of innovation that enables collaboration between organizations from the public and private sectors.

As explained by one of the interview subjects for this project, Matthew Pugmire, Assistant General Counsel for Pfizer Inc.,

> ***"The core technologies came together at the right time and were available for the COVID-19 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 the protections afforded by the patent system we have."***[3]

Vaccines are one of the most important tools for fighting any viral outbreak or pandemic. So far, arguably the most effective and helpful have been mRNA vaccines and viral vector vaccines. Both technologies are relatively new, and each is the product of cutting-edge laboratory research translated into clinical applications by the biopharma industry.

Despite the speed with which mRNA vaccines were deployed, they were an overnight success that took decades to achieve. The use of mRNA in vaccines is a novel technology: before the COVID-19 pandemic, none had been fully developed or approved for use.

Although the possibility of using mRNA in personalized medicine or vaccines was speculated about for decades, making the idea a reality required great persistence. mRNA was first discovered in 1961, and the first successful use of in vitro transcribed (IVT) mRNA in animals was published in 1990. However, early efforts to develop mRNA technology were not followed by significant investment in its potential therapeutic uses and many obstacles remained.[4]

Solving these problems required innovative basic science, persistently done over decades. The final breakthrough in basic science – overcoming the body's immune reaction to mRNA – was resolved in 2005 by scientist Katalin Karikó and her collaborator Drew Weissman by creating a kind of "hybrid mRNA" that could evade the body's defenses and stealthily enter its cells.[5]

While the breakthrough by Karikó and Weissman in an academic lab was essential, it took many more years of applied research and billions of dollars of private investment to develop a clinical application. One of the companies that built on Karikó and Weissman's patented research was Moderna. It started when Derrick Rossi, then a postdoctoral fellow at Stanford University, read Karikó and Weissman's 2005 paper and recognized the potential for mRNA-based therapies. As Rossi would later remark,

> ***"It's fun to think about how simply reading a cool paper on pluripotent stem cell science could lead to all of this."***[6]

When he became an assistant professor at Harvard with his own lab in 2007, he decided to pursue his insight. Rossi and his team worked to apply Karikó and Weissman's research. In 2009, they succeeded not only in creating stem cells, but in developing a technology that could program human cells to produce any protein.[7]

Moving Rossi's research from the lab and toward clinical applications required private investment. In 2010, Rossi presented his work to support the launch of Moderna that year. By the time it went public in 2018, it had raised over $2 billion in investments and partnership funding,[8] and another $600 million in a record-setting IPO. As impressive as these large numbers are, they represent only investment in and spending on the development of a technology, rather than a success story. By the time of the pandemic, Moderna had not yet launched a product or turned a profit.

BioNTech's story follows a similar trajectory. By early 2020, BioNTech had been working with mRNA for 25 years, in pursuit of immunology treatments for cancer and a new flu vaccine.[9] The German start-up had raised hundreds of millions and put in over a decade of work to develop its mRNA technology before the COVID-19 pandemic. But it too had yet to launch a product or turn a profit.

What the investment in Moderna and BioNTech and the work they did achieved was to develop a technology that proved to be essential to battling COVID-19. The successful use of this innovative technology to create a COVID-19 vaccine was considered a breakthrough, and one that is expected to lead to more mRNA products becoming available in the future.[10]

Viral vector vaccines were similarly an emerging technology. These vaccines use a different virus from the pathogen – a "safe" virus, the vector – to deliver specific parts (proteins) of the target pathogen that can provoke an immune response from the body. Viral vector vaccines are a well-established technology, as scientists have been creating viral vectors since the 1970s.[11] However, prior to the COVID-19 pandemic, the only approved adenovirus vector vaccine was Johnson & Johnson's Ebola vaccine, which was granted marketing approval by the European Medicines Agency on July 1, 2020.[12]

The technologies underlying the therapies that eventually were developed to combat COVID-19 were built on foundations of previous research. Some were older, such as inactivated virus vaccines.[13] However, key technologies such as viral vector vaccines and mRNA technology were just emerging after undergoing substantial investment and research and development for many years.

What happened next was that companies built on this prior innovation to develop cutting edge treatments for COVID-19.

B. Accelerated Innovation: The Development of COVID-19 Treatments

While earlier innovation created a strong foundation to develop COVID-19 treatments, it was only a start. The biopharma industry faced a tremendous challenge to innovate quickly to address the challenge of COVID-19. The development of COVID-19 treatments is a story of great science, execution, and hard work – but it is also a story of widespread collaboration, big investments, and risk-taking.

Much of the biopharma industry made large investments and took big risks to fight COVID-19. Some of these investments succeeded but many ultimately did not. Risks and failures are intrinsic to developing new treatments. However, a risk that could have undermined everything was the risk of appropriation of otherwise successful work. While the biopharma industry responded to the urgent need, businesses needed the security of IP rights to be able to justify this use of resources to their stakeholders – their employees and the many individuals and institutions that invest in these companies.

One of our interview subjects described the unique use of resources, the need to collaborate to rapidly address the crisis, and the need for the security provided by IP:

> ***"This was not business as usual. This was really an unprecedented situation requiring unusual efforts. Success was certainly dependent on our ability to protect the innovations that were put on the table."***[14]

In this unprecedented effort, collaboration was also essential as innovators quickly established new partnerships, pooling their knowledge and technology. IP was often the precondition to people sitting down at the table to begin collaboration. As Dr. Kathrin Koerner, Head of Patents & Scientific Services at Merck KGaA, explained, "IP enabled the early discussions for COVID-19 collaborations and exchanges. Without it, things could not have been made available to other parties. Because we had already filed for the relevant patents, we were able to provide information to partners about things we had under development."[15]

The account of the creation of COVID-19 vaccines highlights the importance of collaboration and investment, secured by IP rights, in rapidly generating new bio-pharmaceutical technologies during a global health crisis.

After many years and billions of dollars of investment, mRNA vaccines were still only a promising technology that had not yet been fully tested and developed into a treatment. Moderna and the Pfizer/BioNTech partnership were able to take these technologies across the finish line when they were most needed. Both vaccines were produced in record-breaking time. Before these two COVID-19 vaccines, the fastest vaccine development had been that of the MMR vaccine, which took four years. [16]

BioNTech leveraged its existing relationship with Pfizer to help speed up development of its vaccine. Under their March 17, 2020 agreement, BioNTech agreed to disclose its mRNA research to Pfizer.[17] In return, Pfizer contributed manufacturing and regulatory expertise to get the vaccine approved and develop a manufacturing process capable of producing billions of doses.[18]

The BioNTech-Pfizer relationship was only possible with IP protection. As Pfizer's Pugmire observed of the relationship between the two companies,

> ***"IP protection was critical … I can't speak for them, but I cannot imagine they would be comfortable coming and sharing their mRNA construct with a company like Pfizer without IP protection. This is their core technology and the result of all the investments they have made over the years. IP protection gave them the assurance they could share it without losing their investments from over the years."[19]***

In relation to all the vaccines, IP rights made hand-offs work smoothly by defining and securing the rights each party brought to the relationship. The technology used by Johnson & Johnson was based on the company's work in the adenoviral vector field in the last fifteen years. To speed up the identification of COVID-19 vaccine candidates, a collaboration was built on a previous partnership that the company had with Dan Barouch, an immunologist and virologist from Beth Israel Deaconess Medical Centre (BIDMC).[20] Having already worked together with this same technology on other vaccines, such as HIV, Zika, and tuberculosis, the parties were able to quickly come to an agreement to create a COVID-19 vaccine; the agreement was signed on January 31, 2020.[21]

The collaboration between the Oxford University Jenner Institute and AstraZeneca is another example of technology transfer. The Jenner Institute had already been working with the chimpanzee adenovirus vector in relation to other vaccines, and it was able to license this technology to AstraZeneca to enable the development of a COVID-19 vaccine.[22]

C. Innovating, Investing, and Cooperating to Manufacture and Distribute COVID-19 Treatments

Developing vaccines and treatments for COVID-19 was only the first part of the challenge. Manufacturing them at scale and getting them to patients globally has been a vast and ongoing undertaking. Just as with developing treatments, manufacturing and distribution presents novel scientific and innovative challenges, given the cutting-edge nature of many of the technologies. In addition, it presents tremendous logistical and management challenges.

Manufacturing mRNA vaccines required a great deal of innovation. Since the Pfizer/BioNTech and Moderna vaccines were the first of their kind to be approved, their makers had not previously manufactured them at an industrial scale. They had to take a process that produced small batches for testing and experimental uses and turn it into an industrial process. One expert summed up the engineering challenges of scaling up mRNA vaccine production from the laboratory to factory by quipping "gee, that 2000-liter reactor with process control and computers hanging off it doesn't look much like a test tube."[23]

Pfizer and BioNTech thus needed to design a new production process. It took several months of working with partners to identify the optimal process for making this mRNA vaccine.[24] They continued to invest in improving the process, eventually halving the production time.[25] Elements of this process are technically challenging. For example, combining mRNA with lipid nanoparticles at industrial scale was difficult.[26] Also, the production process needs to be completed from start to finish inside a hermetically-sealed system.[27]

Another innovation challenge involved creating a new supply chain. The Pfizer/BioNTech vaccine includes 280 materials in total, and about 10-15 of them were novel and had to be created for the mRNA vaccine. In June 2021, Pfizer's Zielinski said that "At this point we have about 86 supplier sites in 19 countries and over 260 manufacturing deals."[28]

Meeting the unprecedented demand for COVID-19 vaccines and treatments required unprecedented investments of time and human resources, as well as unprecedented risk-taking. Companies set aside pre-pandemic priorities, diverted resources, and began large scale production long before they knew they had successful treatments. Two things helped encourage these efforts and mitigate some of the risks they entailed. First, IP protection removed the risk of losing the return on an otherwise successful investment to appropriation and copying. Second, government funding provided resources for scaling production and advance purchase commitments reassured innovators that, in the event of success, they would have a market. Nevertheless, failure was still a risk, and some biopharma companies have indeed incurred the cost of failure when their vaccines and treatments did not make it to market.

Companies first turned inward for resources to meet production demands imposed by pandemic needs. As we describe in detail later, Novartis was a key partner in vaccine production, and it shifted resources quickly towards COVID-19-related projects. Rene Luginbuehl, Novartis' Global Head of Large Molecules, recalled:

"A hundred people had to be mobilized in under three months, and we could do that only by moving people away from other activities."[29] Novartis's Corey Salsberg affirmed that its quick response required "re-assigning highly skilled people from other important projects, diverting resources, and so on. This approach took resources away from other activities. This undoubtedly had a cost for other patients and health needs."[30]

Incurring such opportunity costs to other R&D and manufacturing programs represents a significant investment.

Merck KGaA has said that it was able to quickly pivot its operation to work with Pfizer and BioNTech thanks to existing technologies and IP frameworks. Merck KGaA makes lipid nanoparticles for the Pfizer/BioNTech vaccine.[31] Vivien Tannoch-Magin, Head of Patents, explained that the company

> ***"had planned to make a synthetic cholesterol anyway. When COVID-19 hit, we accelerated that and were able to launch nine months in advance. The condensed timeline required us to move people off other projects and put them on this instead. We tapped into this manpower and historical knowledge, and we had to sacrifice other projects. We focused on this and made it a priority."***

According to Tannoch-Magin, "IP enabled this," by securing the investments that enabled Merck KGaA to develop this technology and divert resources to accelerate its deployment.[32]

Probably the most important thing that companies did to expedite production and distribution was simply to take the risk of producing and stockpiling doses of their vaccines even before they received regulatory approval. Every major vaccine innovator did so.

Scaling up manufacturing while research was still underway was a very unusual step. The development and scaling of manufacturing capacity usually follow the steps in the clinical trial process. Basic, but not optimal, manufacturing processes are normally put in place to produce enough doses for phase 1 trials, while improved, but still not fully scaled, ones are implemented for phase 2 trials. Complete, scalable process are only in place by the time that phase 3 trials are carried out.

Given the compressed timetable of the COVID-19 pandemic, however, this incremental process, which would normally take years, had to be condensed into a matter of months. Companies such as AstraZeneca, Johnson & Johnson, and Pfizer front-loaded the scaling of manufacturing, building out production capacity and optimizing processes while clinical trials were still underway. According to one person close to these activities:

> ***"We were building the plane as we were flying it. We were making manufacturing steps as we went, making cell lines, cooling cell lines, doing it all to expedite things and get things to clinical trials."***[33]

Companies maintained open dialogue with regulatory agencies, to dialogue in real time about relying on new, expedited methods for production and testing without compromising on quality or patient safety.

> ***"No one party can do everything. No one entity has all the technology 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 so it's properly used."***

– Matthew Pugmire, Pfizer

One of the least-heralded but most essential aspects of the biopharma industry's response to COVID-19 has been collaboration among companies to manufacture vaccines and other treatments. One contribution of this report is to provide an overview of manufacturing collaboration and assess the implications. Collaboration and technology transfer in COVID-19 vaccine manufacturing has been widespread, and IP rights facilitated that cooperation.

The existence of that collaboration and the role of IP in supporting it appears to be widely overlooked and misunderstood. There is currently a proposal to suspend the IP treaty obligations of World Trade Organization members regarding COVID-19 treatments. It is often referred to as the "TRIPS waiver", since it would temporarily set aside WTO Members' obligations under the TRIPS Agreement. One motivation for that proposal is the contention that innovators are slowing vaccine manufacturing by refusing to grant manufacturing rights or share relevant know-how. One prominent critic asserts that

> ***"the knowledge that can help end the pandemic should not be a secret."***[34]

The reality is that innovators have been widely sharing knowledge and technology with manufacturing partners, which in some cases include their competitors. The experts we interviewed emphasized that innovators have worked hard to increase manufacturing capacity, searching widely and thoroughly for partners with the necessary equipment and skills to make effective use of technology transfer, then sharing the necessary information with partners once they are found.

This account was confirmed by a recent Wall Street Journal report about Pfizer's efforts to find manufacturing partners for the mRNA vaccine and transfer the necessary technology to them.[35] Pfizer has a small team of experts who are "among a relatively small number of professionals with the rare skill set to enable other companies to produce the shots."[36] They scout for companies with the capabilities to effectively receive and implement mRNA vaccine manufacture technology transfer.[37] The Wall Street Journal report further recounted that once Pfizer finds a potential partner, getting them ready to manufacture is a many months-long process of working hand-in-hand, which included sharing "more than 500 top-secret files – at least 5,000 pages of documents on making the vaccine – over secure computer servers."[38]

As of the time we did our research, we were able to identify numerous partnerships using public sources. We note that new partnerships are being added and disclosed frequently. As of August 1, 2021, among five leading vaccine innovators – AstraZeneca, Johnson & Johnson, Moderna, Novavax, and Pfizer/BioNTech – we found:

- Over 40 manufacturing partnerships to produce the main components of the vaccine,
- 27 "fill and finish" partnerships, to place the vaccine in vials, label, and prepare for distribution, and
- 6 distribution partnerships to provide regional capabilities
- Partnerships in at least 25 countries.

Pfizer and BioNTech's primary partnership, which is assisted by a further network of partners, is an example of the collaboration needed to manufacture and distribute COVID-19 vaccines. The partnership began with urgency and a willingness to collaborate when Pfizer and BioNTech signed a Material Transfer and Collaboration Agreement on March 17, 2020. This allowed them to begin working together immediately and finalize the details of their partnership at a later date. BioNTech developed the vaccine, and the parties agreed that BioNTech would retain the IP rights to the vaccine and its earlier technology. Meanwhile, Pfizer contributed significant abilities in the areas of R&D, regulatory compliance, extensive capabilities in production and distribution. Pfizer has also helped BioNTech to expand its manufacturing capacity substantially. The two companies manufacture at sites[39] in Europe and the United States, which include facilities owned by the two companies themselves and those of contract manufacturers.[40] Biovac in South Africa has more recently become part of the manufacturing network. Furthermore, according to Pfizer, many of its suppliers depend on it (Pfizer) for significant amounts of technical or financial assistance that Pfizer transfers backwards along the supply chain.[41]

Pfizer/BioNTech partnered with many others to develop the necessary capabilities to deliver their vaccine. A notable partner was Novartis, a company that might otherwise be viewed as a competitor. Novartis was engaged to help develop the manufacturing process and to carry out the fill-and-finish phase of production. Novartis was able to bring skilled personnel, quality systems and regulatory expertise, and logistical competencies, as well as process optimization techniques, such as increased automation.

The collaboration with Novartis necessitated significant – and swift – technology transfer. To begin this knowledge transfer as quickly as possible while still maintaining an environment of trust, the two companies put in place a confidential disclosure agreement in a period of just a few days. This allowed them to begin technology transfer while still negotiating the final terms of their arrangement, and, as a result, to mobilize a hundred Novartis employees for the project in a period of just three months and to have batches rolling off of Novartis' production line in four months. As Novartis' Global Head of Large Molecules, Rene Luginbuehl, recounted, this cooperative relationship among competitors simply made sense for all of the parties involved since "We all had a common purpose which was to come together to address the pandemic."[42]

Pfizer's Zielinski observed that

> ***"IP facilitated these relationships. The same way that BioNTech was able to work with Pfizer due to IP protection, we were able to work with partners on manufacturing deals. Patents provided security, in addition to know-how and trade secret protections."***[43]

The following is a list of Pfizer/BioNTech COVID-19 manufacturing facilities and partnerships, based on public sources, as of August 2021:[44]

Company/Contractor	Location	Manufacturing Role
Baxter	Halle, Germany	Fill-and finish, main production.
BioNTech	Mainz, Germany	Main production
BioNTech	Idar-Oberstein, Germany	Main production
BioNTech	Marburg, Germany	Main production
Biovac Institute Ltd.	Cape Town, South Africa	Fill-and-Finish
Delpharm	France	Fill-and-Finish
Dermapharm	Brehna, Germany	Fill-and-Finish
Dura-Fibre	United States	Vaccine Distribution
Eurofarma	Brazil	Fill-and-Finish
Novartis[45]	Stein, Switzerland	Fill-and-Finish
Pfizer	Puurs, Belgium	Main production, Fill-and-finish
Rentschler Biopharma	Germany	Vaccine Distribution
Sanofi	Frankfurt, Germany	Fill-and-finish
Siegfried	Hameln, Germany	Main production
Thermo Fisher	Italy	Fill-and-Finish

The other innovators discussed in this report also relied on partnerships and technology transfer to manufacture and distribute COVID-19 vaccines and treatments. Like Pfizer and BioNTech, other companies have followed a strategy of establishing geographically distributed manufacturing and distributing networks. We identify these partnerships in the Report and its Annex.

Global cooperation has been the key to fulfilling the determined ambition to end the pandemic. Typical of that ambition and spirit of collaboration is the partnership between Johnson & Johnson and Merck & Co. to manufacture vaccines, which they characterized as a "wartime pact."[46] The COVAX partnership further typifies the importance and spirt of cooperation. At present, many countries have signed and agreed to be part of this effort to distribute the vaccines to the world's low and middle income countries, with over 2 billion vaccine doses being administered in more than 190 countries as of June 2021, with the hopes for this number to increase.[47]

At the G20 Summit in May 2021, the President of the European Commission, Ursula von der Leyen, stated some key principles that would be needed to help end the pandemic. These include "no export bans, keeping global supply chains open, and working to extend capacity everywhere."[48] This reflects the substance and spirit of cooperation that will be needed to reach the target goal of delivering 11 billion doses.

III. Conclusions and Lessons Learned

The effort to develop and distribute COVID-19 vaccines and treatments is likely to be seen by history as one of the most remarkable achievements of the IP-enabled biopharma industry. Since the need is so urgent and vast, there is still much work to be done and many improvements to make. Nevertheless, we can already begin to draw lessons from the successes and challenges about the biopharma industry, about IP, and about public health policy.

A. Takeaways from the COVID-19 pandemic about IP and Biopharma Innovation

1. **IP-enabled innovation created the necessary background technology and knowledge to develop vaccines and treatments on an accelerated timeline.** When the pandemic started, the global research community and the biopharma industry were able to draw on a diverse set of technologies and know-how that had already been developed. Many of these technologies owed their existence to an IP system that had incentivized investments in R&D.

2. **IP secured big investments at every step of developing and delivering treatments to society.** During the pandemic, innovators invested in developing new technologies, establishing and upgrading facilities and networks for manufacturing, identifying new approaches to securing regulatory approval, testing existing compounds for relevance to the pandemic, and setting up new global distribution networks. They worked with partners and carried out significant technology transfer to rapidly move COVID-19 treatments from the lab to patients. At every step, IP helped to secure these investments from the risk that they might be lost to a competitor copying the technology or know-how without agreement.

3. **IP enabled collaboration to develop COVID-19 treatments.** Every COVID-19 solution required partnerships along the pathways of R&D, commercialization, and distribution. Even solutions developed in-house, such as the Moderna vaccine, required contract manufacturing to achieve commercial scale. Technology transfer was a crucial part of these relationships. IP rights removed some of the risk for innovators that collaborating on COVID-19 treatments would give away other valuable opportunities.

4. **IP enabled collaboration with contract manufacturers across supply chains.** Both contract manufacturing and supply relationships were made possible by sound IP rights. No one party had the necessary manufacturing capacity to meet global needs in house. IP contributed to this disaggregated manufacturing, as it took much of the risk out of the huge amounts of technology transfer – through the licensing of patents and trade secrets – that were necessary in contract manufacturing relationships.

B. What would happen if COVID-19 innovations were deprived of IP protections?

Without IP rights, innovators would still come forward to help with the pandemic response, but it is likely that they would opt to work differently. In the absence of IP protection, they would undoubtedly share less, slowing the development of new solutions. Innovators would work with fewer partners – or with no partners at all, keeping everything in house. Working with competitors would become particularly treacherous, so trade secrets would need to be kept strictly under wraps. Perhaps fewer patents would be filed, so as to not disclose early on the discoveries that could ultimately become the new solutions. In relation to COVID, this type of approach would have stalled the response significantly.

For instance, it would have made it impossible to rapidly manufacture the number of vaccines needed for the global population.

C. Insights for Policymakers

Innovation during the COVID-19 pandemic was accelerated by certain enabling policies and actions. By applying lessons learned, policymakers can support the ongoing COVID-19 response and enhance future pandemic preparedness.

IP was an important enabler of the COVID-19 pandemic response. Alongside patent protection, trade secrets protection has been crucial. Systems for IP protection support efforts by innovators to develop and move new vaccines and drugs to society – especially during a crisis.

- Innovators had a range of pre-existing innovative tools and technologies to apply to the COVID-19 response when the pandemic started. IP had supported their development in the past. IP systems stimulate the development of a variety of possible solutions to the same challenges, given the need to design around others' IP.
- Collaboration and knowledge sharing provided a foundation for rapid innovation in response to the crisis. IP enabled the sharing of valuable technology and know-how without innovators losing their competitive edge.
- At every stage of development of COVID-19 vaccines and other solutions, significant investments were required. IP protection helped to enable investments, whether in relation to product innovation, regulatory approval, scaling production, or distribution.
- Some IP assets relevant to the COVID-19 response were licensed by the public sector research institutes to the private sector, which further invested to transform them 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 protection for COVID-19 solutions. This would have made it very difficult if not impossible in the case of COVID-19 to innovate so quickly, by making knowledge and technology sharing unduly risky. It would also have made it more difficult to establish distributed manufacturing networks, which require tech transfer. Without IP, innovators would be less likely to work with partners, setting back innovation to address health crises.
- Other types of policies also affected the COVID-19 response. Government support, whether financial support or cooperation with innovators to expedite regulatory approval without compromising safety and quality, accelerated the response. In contrast, some policies, such as export restrictions and other counterproductive trade policies, interfered with the operation of efficient value chains.

The COVID-19 response can be considered to have been the IP system's finest moment, allowing different types of innovators to immediately share knowledge, technology, and resources in order to develop and manufacture new life-saving solutions at unprecedented speed. Their efforts resulted in a competitive marketplace of vaccines and treatments that includes technologies that had never before made it to market. The role of IP in supporting investments to develop and commercialize new health technologies is well known. What the COVID-19 experience underscores, in addition, is the crucial role of IP in enabling the collaboration and knowledge transfer necessary to solve global health challenges.

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