IP Role In COVID Times: Compulsory Licensing, IP Waivers, And Other Initiatives

By Paola Dabbicco[1]

Abstract

This paper analyzes the role of intellectual property rights (IPRs) and, more specifically, of patents during COVID times, with a focus on the pharmaceutical industry and COVID vaccines. In this paper, the author scrutinizes some proposals to quickly obtain access to affordable vaccines, such as the IP waiver and the use of compulsory licensing. This paper shows how IPR protection, and patents in particular, play a pivotal role in the fight against the virus. It also recommends that decision makers, industry, and academia focus on the insufficient R&D investment for the development of new medicines, the lack of production facilities and raw materials supply, and the loss of trust in science among some parts of the population, which might have led to the limited and slow supply of COVID vaccines, and which are not necessarily linked to IPRs. For each of these challenges, the author proposes a different solution.

I. Introduction

The urgency of finding an efficient response to the COVID-19 (hereinafter COVID) crisis has triggered a heated debate about the role of intellectual property rights (IPRs) and, more specifically, of patents in the development and deployment of the needed vaccines. Creating and deploying a drug usually requires massive investment. A recent study on research and development (hereinafter R&D) costs for new therapeutics showed that the estimated average R&D cost per product was USD 985 million, expenditures on failed trials included.[2] Financial resources enable early research, advancing therapies through clinical trials, and the supply of the resulting drug to the patients.[3] By protecting the results of these investments by patents, further investment in R&D is incentivized, potentially resulting in the next vaccine,[4] hence stimulating innovation and economic growth.[5]

As the pandemic rages onward, different IP strategies have been adopted by the leading pharmaceutical companies in relation to COVID vaccines in a bid to avert the crisis. These de-

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1. Paola Dabbicco is currently assisting 4iP Council in research topics. The views expressed herein are those of the author and do not express the opinions of 4iP Council or any of its supporters. All links were last accessed on 19 January 2022.

2. Olivier J. Wouters, Martin McKee, Jeroen Luyten, "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018" (2020) *JAMA* 844, 853 <*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7054832/*>.

3. Adrién Alonso, Marina Espriu, Joan Bigorra, Rafael Vilasanjuan, Gonzalo Fanjul, "COVID-19 and the Reform of the Biomedical R&D System: A Proposal for a Preferred Supplier Model" (2021) *IS-Global*. The article states that: "By October 1st 2020, at least USD 9.18 billion had been invested in R&D aimed at developing COVID-19 innovations. The real figure is most likely higher, due to the lack of transparency of the agreements between the public sector and the private firms which limits the tracking capacity. 91.64% of these funds came from public and academic institutions and 59.36% of the total investment is being used to support vaccine development. Investment in COVID-19 R&D is over four times the annual average investment in R&D for HIV/AIDS, malaria and tuberculosis combined during the period 2007-2018."

4. Deloitte Centre for Health Solutions, "Seeds of Change: Measuring the return from pharmaceutical innovation 2020" (May 2021) <*https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-measuring-the-return-from-pharmaceutical-innovation-2021.pdf#page=8*>. The analysis states that, in 2020, projected returns on investment in research and development (R&D) for a combined cohort of 15 global pharmaceutical companies was 2.5%, 0.9 percentage points higher than in 2019. The average forecast peak sales per pipeline asset—the amount of money a medicine is expected to produce yearly—increased from $357 million in 2019 to $421 million in 2020. Also, until recent years, over half of the late-stage pipelines were sourced through internal innovation, but in the past three years, companies have relied on external sources for more than 50% of their late-stage pipeline. This trend of more innovation coming from external sources is indicative of big pharmaceutical companies seeking to increase their innovation pipeline through acquisitions, collaborations, and scientific partnerships with other players. The analysis also measured the impact of the COVID-19 pandemic on clinical trials to investigate the likely impact on future year returns. The analysis revealed that between March and November 2020, the pandemic affected an estimated 1,210 trials across the industry. The vast majority of these (66%) had delayed starts or completions; and 8% were terminated (permanently stopped) or withdrawn (stopped before enrolling any patients). While all phases of trials were affected, 29% of affected trials were in Phase III, which can impact asset launches and sales.

cisions may be attributed to the demand for transparency in terms of commercialization and distribution of vaccines, as well as the public funding spent towards their development. For instance, Moderna Therapeutics, whose vaccine is the product of heavy investments by the U.S. government,[6] declared that it would not prosecute companies seeking to promote COVID treatments under its patents.[7] By that, Moderna can facilitate a quick adoption of an mRNA vaccine and thus "pave the way to future therapies in the infectious disease space and potentially other mRNA therapies, including the therapeutic candidates that Moderna has steadily developed since 2010."[8] Another company, AstraZeneca, has communicated that it would not profit from vaccine sales to developing countries throughout the pandemic, meaning that vaccines will be licensed to those countries at the cost price.[9] Adopting a similar stance, Johnson & Johnson affirmed that it would sell its vaccine at a not-profit-price[10] throughout the entire pandemic, maintaining its exclusivity rights.[11] However, a different approach has been embraced by Pfizer/BioNTech, stressing the importance of obtaining "marginal profits"[12] from their investment in COVID treatments and being able to enforce their IP rights, if needed.[13]

On the other hand, since the inventions described in the patent cannot be used without the prior authorization of the right holder, *e.g.*, via a license, some have argued that patents are a barrier to the availability and affordability of vaccines during a pandemic.[14] This, they believe, particularly affects low- and middle-income countries. Critics also warn that the "novelty" requirement of patents,[15] which prevents disclosure before a patent application is filed, would prevent scientists from rapidly disclosing research results, thus slowing down innovation.[16] Consequently, some have proposed to grant an IP waiver or a compulsory license under Art. 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter TRIPS Agreement)[17] to address the COVID vaccines access and supply problems, especially for low- and middle-income countries.[18]

Against this background, this paper is structured as

5. European Union Intellectual Property Office (EUIPO), IPR-intensive industries and economic performance in the European Union (Industry-Level Analysis Report, September 2019): "In the period 2014-2016, IPR-intensive industries generated almost 45% of total economic activity (GDP) in the EU, worth €6.6 trillion"; *USPTO*, "Intellectual Property and the U.S. Economy", (2016): "IP-intensive industries accounted for $6.6 trillion in value added in 2014, up more than $1.5 trillion (30 percent) from $5.06 trillion in 2010. Accordingly, the share of total U.S. GDP attributable to IP-intensive industries increased from 34.8 percent in 2010 to 38.2 percent in 2014"; Maureen K. Ohlhausen, "Patent Rights in a Climate of Scepticism" (2016) *Harvard Journal of Law & Technology*, Vol. 30, No.1, Fall 2016.

6. Jacob S. Sherkow, Lisa Larrimore Ouellette, Nicholson Price, Rachel Sachs, "How Does Moderna's COVID-19 Vaccine Work, and Who Is Funding Its Development?" (*Bill of Health*, 27 August 2020) *<https://blog.petrieflom.law.harvard.edu/2020/08/27/moderna-covid19-vaccine-government-funding/>*. In the blog, the authors state that "investments for Moderna vaccine come from two agencies in particular, the National Institute of Health (NIH), Biomedical Advanced Research and Development Authority (BARDA)".

7. Adam Houldsworth, "Your guide to COVID-19 vaccine stakeholders' IP strategies" (19 November 2020) *IAM Magazine <https://www.iam-media.com/coronavirus/your-guide-COVID-19-vaccine-stakeholders-ip-strategies>*.

8. Dan Shores, "Breaking Down Moderna's COVID-19 Patent Pledge: Why Did They Do It?" (11 November 2021) *IP Watchdog <https://www.ipwatchdog.com/2020/11/11/breaking-modernas-COVID-19-patent-pledge/id=127224/>*.

9. Peter Beaumont, "Oxford AstraZeneca vaccine to be sold to developing countries at cost price" (23 November 2020) *The Guardian <https://www.theguardian.com/global-development/2020/nov/23/oxford-astrazeneca-results-covid-vaccine-developing-countries>*.

10. Not-profit price means selling the vaccine at its production cost.

11. Houldsworth (n 7).

12. Katherine J. Wu, "Some Vaccine Makers Say They Plan to Profit from Coronavirus Vaccine" (July 2020, updated May 2021) *The New York Times <https://www.nytimes.com/2020/07/21/health/covid-19-vaccine-coronavirus-moderna-pfizer.html>*.

13. Houldsworth (n 7).

14. Peter K. Yu, "Currents and Crosscurrents in the International Intellectual Property Regime" (November 2004) *Loyola of Los Angeles law review 38*; Salla Sariola, "Intellectual property rights need to be subverted to ensure global vaccine access" (2021) *BMJ Global Health*.

15. TRIPS Agreement, Art. 27, Part II, Section 5 on "Patentable Subject Matter." In order to be patentable an invention must be new, inventive, and industrially applicable. To understand what to consider before applying for a European patent, as well as the application process see 'How to apply for a European patent,' *European Patent Office (EPO) < https://www.epo.org/applying/basics.html>*.

16. Eric E. Johnson, Theodore C. Bailey, "Legal lessons from a very fast problem: COVID-19" (December 2020) *Stanford Law Review Online*, Vol. 73.

17. The TRIPS Agreement is an international treaty that came into force on January 1st, 1995, that sets out the minimum legal standards of protection of IP to be provided by each Member state. The aim is to harmonize the IP protection between countries by providing the basis of such protection for all IP rights. In particular, Art. 31 of the TRIPS Agreement allows WTO members to provide for compulsory licenses for patents, including use by the government or third parties authorised by the government. According to national provisions, such licenses can be granted by the relevant authorities.

18. Council for Trade-Related Aspects of Intellectual Property Rights, "Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19" (25 May 2021).

follows: Part II explores the multiple benefits of patents and their contribution in combating the coronavirus. Part III provides a general overview of the role of patents in the pharmaceutical industry, focusing on the importance of R&D investment for medical innovation, in particular, to achieve the remarkable success of the COVID vaccines. Part IV explores the main reasons behind the limited and slow supply of COVID vaccines, and critically analyses some proposed solutions, *i.e.*, the IP waiver and the use of compulsory licensing proposals. Finally, Part V provides a conclusion and highlights the importance of IP rights protection, especially patents, as part of the metaphorical cure to the current challenges brought by the COVID pandemic.

II. Are Critiques Against Patents Justified?

Critics of the patent system tend to ignore its many benefits. Without protection of their inventions, companies would have little incentive to invest in R&D, which could harm innovation. One of the main goals of patents is, consequently, to promote innovation. By disclosing an invention to society, the applicant may obtain a patent for a limited period of time (on average 20 years from the initial filing date). This gives the patent owner the right to exclude third parties from making use of such invention without prior authorization.

The preventive rationale underlying the patent system is particularly important in the pharmaceutical industry, where private companies commonly invest significantly in R&D.[19] Without solid patent protection, this sector could suffer a severe decline, in particular considering that successful medicines are vulnerable to reverse engineering by generic companies at modest costs.[20] The exclusivity right permits the patent holder to gain a financial reward in recognition of its creativity, incentivizing future investments.[21] In addition, the disclosure requirement of the patent system promotes wider dissemination of knowledge and follow-on innovation.[22]

Apart from the foregoing, there are additional reasons why patents represent a valuable asset to organizations. First, they protect inventions against free riders. Second, patents can enhance the reputation of a company. Third, patents can provide leverage in price negotiation, foster cooperation, and encourage joint development and the creation of new companies. Fourth, patents may secure financing from investors by enhancing a company's overall value.[23]

Notwithstanding the benefits presented above, critics seem to have overlooked the likely reason for reduced access to COVID vaccines and their consequent slow roll out: lack of production capacity and limited availability of raw materials.[24] If anything, the COVID crisis has shown the need for a strong IPR system. Thanks to patents, vaccines against the virus have been developed in record time. Normally, it takes up to 10 years and between USD 1 and 2 billion to create a vaccine.[25] Pfizer, however, was able to design a vaccine against COVID in only eight months, applying BioNTech's patented technology, messenger RNA (mRNA),

19. PhRMA, "Profile biopharmaceutical research industry" (September 2021) <*https://www.phrma.org/policy-issues/research-development*>. PhRMA reports that the entire biopharmaceutical industry invested an estimated $102 billion in research and development (R&D) in 2018. The biopharmaceutical industry invests on average six times more in R&D as a percentage of sales than all other manufacturing industries.

20. Ohlhausen (n 5).

21. Bhaven Sampat, Heidi L. Williams, "How Do Patents Affect Follow-On Innovation? Evidence from the Human Genome" (January 2019) *American Economic Review*, Vol. 109, No. 1.

22. WIPO-MOST, Intermediate Training Course on Practical Intellectual Property Issues in Business (Geneva, November 2003) <*https://www.wipo.int/edocs/mdocs/sme/en/wipo_ip_bis_ge_03/wipo_ip_bis_ge_03_2-main1.pdf*>; For an opposing view, see Alberto Galasso, Mark Schankerman, "Patents and Cumulative Innovation: Causal Evidence from the Courts" (2015) *The Quarterly Journal of Economics*, Vol. 130, issue 1, 317, 369: "There is a growing concern that patent rights are themselves becoming an impediment, rather than an incentive, to innovation. The increasing proliferation of patents, and the fragmentation of ownership rights among firms, are believed to raise transaction costs, constrain the freedom of action to conduct R&D without extensive licensing, and expose firms to ex-post holdup through patent litigation. In the extreme case where bargaining failure in patent licensing occurs, follow-on innovation can be blocked entirely. These issues are particularly acute in 'complex technology' industries where innovation is highly cumulative and requires the input of a large number of patented components held by diverse firms."

23. 4iP Council, "4 Reasons to Patent Infographic" (4iP Council-4SMEs, Date of Publication Unknown) <*https://www.4ipcouncil.com/4smes/4-reasons-patent*>.

24. Gabriel Leonardos, "A opinião definitiva contra a quebra de patentes" (17 May 2021) *Mighalas* <*https://www.migalhas.com.br/depeso/345629/a-opiniao-definitiva-contra-a-quebra-de-patentes*>.

25. Jason Millman, "Does it really cost $2.6 billion to develop a new drug?" (18 November 2014) The Washington Post < *https://www.washingtonpost.com/news/wonk/wp/2014/11/18/does-it-really-cost-2-6-billion-to-develop-a-new-drug/*>.

originally developed for flu vaccines.[26] As of September 2021, there were a total number of 331 treatments and 268 vaccines under development.[27]

III. Patents in the Pharmaceutical Industry

a. Public and Private Investments in R&D by Pharmaceutical Companies

Pharmaceutical R&D receives investments from both the public and private sectors. The former generally concentrates more on early-stage research that can provide basic scientific knowledge on the mechanisms of disease, while the latter typically undertakes final-stage research, translating basic research into medical products[28] such as vaccines. As a result, the public sector can influence the innovation cycle by identifying and shaping research priorities as well as by playing an important role in the subsequent stages. For example, governments are usually the main purchasers of health products and often organize their distribution and delivery. It is estimated that government agencies worldwide provided around USD 42 billion in health research funding annually (2011–2014), of which around 60 percent came from the U.S. National Institutes of Health (NIH).[29] Aside from governments, non-profit entities, foundations, and charitable and philanthropic organizations are alternative sources of funding for biomedical research.[30]

On the other side, the private sector is active in all phases of R&D[31] and contributes the most to clinical trials. In 2017, the pharmaceutical industry spent an estimated USD 177 billion on R&D. Two years later, the research-based pharmaceutical industry in Europe invested an estimated EUR 37.5 billion in R&D.[32] From the leading companies (listed in Table 1 below), AstraZeneca invested the most in R&D, with a total of USD 58.955 billion, between 1997 and 2011, resulting in five approved drugs. See Table 1.

To sum up, the public and private sectors can work in synergy, with the private sector building upon basic research done by the public sector. The continuation of R&D investments by pharma companies has had a positive impact on productivity[33] and the quality of products.[34]

b. Only a Few Medicines Succeed out of Larger R&D Investments

Unfortunately, high investment in R&D does not guarantee success. In particular, a large proportion of projects at any given stage of R&D fails, especially in phases II and III of clinical trials. According to a study by the Tufts Center for the Study of Drug Development analysing 1,442 experimental drugs that were in clinical tests by the end of 2013, the overall chance that a drug entering clinical development will be approved for marketing is under 12 percent.[35] The likelihood of success in each step of drug development has decreased over time. Approximately seven out of eight

26. Albert Bourla, "The CEO of Pfizer on Developing a Vaccine in Record Time" (*Harvard Business Review*, May-June 2021) <*https://hbr.org/2021/05/the-ceo-of-pfizer-on-developing-a-vaccine-in-record-time*>. On that note, the U.S. Chamber of Commerce "highlights IP's vital role in enabling the development of a pipeline of therapeutics and vaccines to combat COVID-19," and pharmaceutical companies underline the need for a "robust IP environment," thanking it for enabling companies to collaborate and deliver fast solutions to the COVID situation. See Thaddeus Swanek, "New Report Reveals Improving Intellectual Property Protections Worldwide" (*U.S. Chamber of Commerce*, 25 March 2021) <*https://www.uschamber.com/series/above-the-fold/new-report-reveals-improving-intellectual-property-protections-worldwide*> and Joint letter (*U.S. Chamber of Commerce*, 29 March 2021) <*https://patentdocs.typepad.com/files/2021-03-29-letter.pdf*>.

27. Milken Institute, "COVID-19 Treatment and Vaccine Tracker" (*Milken Institute*, Date of Publication Unknown) <*https://covid-19tracker.milkeninstitute.org/*>.

28. World Trade Organization (WTO), "Promoting Access to Medical Technologies and Innovation—Intersections Between Public Health, Intellectual Property, and Trade (Second Edition)," (*Publications*, Date of Publication Unknown) <*https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm*>.

29. Roderik F. Viergever, Thom C. Hendriks, "The 10 largest public and philanthropic funders of health research in the world: what they fund and how they distribute their funds" (18 February 2016) *Health Research Policy and Systems* 14.

30. National Center for Biotechnology Information (NCBI), "Strategies to Leverage Research Funding: Guiding DOD's Peer Reviewed Medical Research Programs" (*NCBI*, Date of Publication Unknown) <*https://www.ncbi.nlm.nih.gov/books/NBK215472/*>.

31. World Trade Organization (WTO), "Promoting Access to Medical Technologies and Innovation—Intersections Between Public Health, Intellectual Property, and Trade (Second Edition)," (*Publications*, Date of Publication Unknown) <*https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm*>.

32. European Federation Pharmaceutical Industries and Associations (EFPIA), *The Pharmaceutical Industry in Figures* (2020) <*https://www.efpia.eu/media/554521/efpia_pharmafigures_2020_web.pdf*>.

33. Erik J. Bartelsman, Mark Doms, "Understanding Productivity: Lessons from Longitudinal Microdata" (September 2000) *Journal of Economic Literature*, Vol. 38, no. 3, 569,594.

34. Pier Paolo Saviotti, "R&D and the firm" (2012) *Handbook of the Economics and Theory of the Firm*, 405,423.

35. Thomas Sullivan, "A Tough Road: Cost To Develop One New Drug Is $2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less Than 12%" (*Policy and Medicine*, 21 March 2019) <*https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html*>; Joseph A. Di Masi, Henry G. Gabrowsky, Ronald W. Hansen, "Innovation in the pharmaceutical industry: New estimates of R&D costs" (2016) *Journal of Health Economics* 47, 20,33.

Table 1: Research And Development (R&D) Statistics For Pharmaceutical Companies (1997-2011)

Pharmaceutical Company	Number Of Drugs Approved	Average R&D Spending Per Drug (In $Millions)	Total R&D Spending From 1997-2011 (In $Millions)
AstraZeneca	5	$11,790.93	$58,955
GlaxoSmithKline	10	$8,170.81	$81,708
Sanofi	8	$7,909.26	$63,274
Roche Holding	11	$7,803.77	$85,841
Pfizer	14	$7,727.03	$108,178
Johnson & Johnson	15	$5,885.65	$68,285
Eli Lilly & Co.	11	$4,577.04	$50,347
Abbott Laboratories	6	$4,496.21	$35,970
Merck & Co Inc.	16	$4,209.99	$67,360
Bristol-Meyers Squibb Co.	11	$4,152.26	$45,675
Novartis	21	$3,983.13	$63,646
Amgen Inc.	9	$3,692.14	$33,229

Source: Wikipedia Cost of drug development page, see *https://en.wikipedia.org/wiki/Cost_of_drug_development*

compounds that enter the clinical testing stage will fail in development.[36] Moreover, the total R&D expenditure for the development of new drugs has increased due to increasing specialization and division of innovative labor in recent years.[37]

In light of the above, some commenters have argued that the technological revolution has expanded the gap between investments in new research and their outcomes, lowering R&D productivity in the short term.[38] Furthermore, pharmaceutical innovation is usually a long process since science is constantly improving. Both public and private investors, however, are wary of incremental innovation in already-established therapeutic classes. As a result, R&D investments are shifting toward novel therapeutic classes with high levels of uncertainty and difficulty[39] resulting in a large number of projects failing to develop new medicines.

In the pharmaceutical industry this productivity downturn noted above is a wide-spread phenomenon,[40] due largely to the challenge of generating new pharmaceuticals in an area of high technological uncertainty. Consequently, the interaction of technical progress, drug approval regulations, patent law, and difficulties in finding investment all influence the course of pharmaceutical innovation.

36. Thomas Sullivan, "A Tough Road: Cost To Develop One New Drug Is $2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less Than 12%" (*Policy and Medicine*, 21 March 2019) <*https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html*>.

37. Fabio Pammolli, Laura Magazzini, Massimo Riccaboni, "The productivity crisis in pharmaceutical R&D" (June 2011) *Nature Reviews Drug Discovery 10*, 428,438. In their paper, the authors state that "between 1998 and 2008, the output of new molecular entities (NMEs) has dropped by nearly 50% and attrition rates have increased sharply, especially in the late-phase of clinical trials."

38. *Ibid*.

39. *Ibid*.

40. Following the comparison of *United States (U.S.) v. Europe* (EU) in pharmaceutical R&D, which has been conducted by Pammoli, Riccaboni, and Magazzini in their paper "The productivity crisis in pharmaceutical R&D," it appears that "there is no significant gap between EU and U.S. companies in terms of drug development performances." "By controlling for the portfolio characteristics of the research investments, [we] do not find support for the claim of a R&D productivity differential between U.S. and EU."

Consequently, this makes the reward function of patents even more important as patents spur companies to continue investing in innovation.[41] Patents can also fill a vacuum in legal protection, *i.e.*, it prevents competitors from making use of the invention at no cost or free riding, assuming a lower risk than the creator.[42]

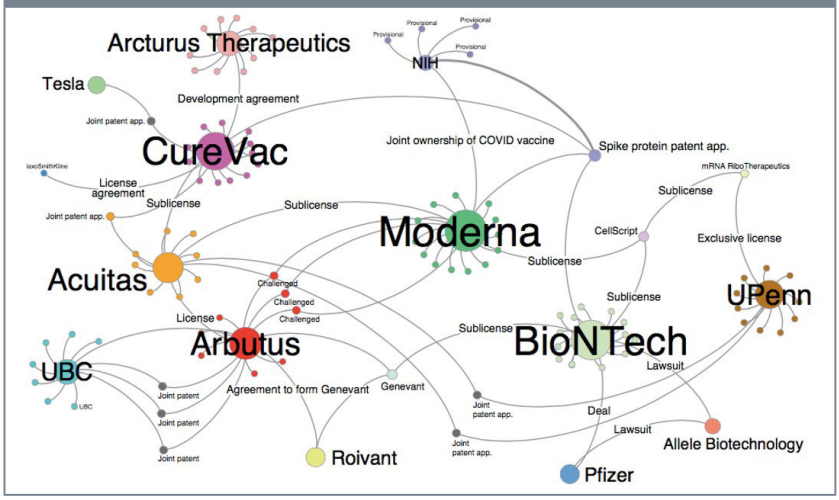
c. The COVID Vaccine: An Unprecedented Success

By disclosing their invention, companies can eliminate duplication and direct their efforts into sectors not previously claimed in published patents, thus maximizing innovative potential. The pandemic has had a significant impact on global health and economy, emphasizing the importance of international cooperation in finding a common solution to a global pandemic.

In fact, since January 2020, scientists have rushed to produce vaccines, treatments, and diagnostics on a global scale. The development of COVID vaccines in such a short time was made possible through intensive collaboration among public and private actors, and thanks to previous studies on the COVID family as well as on the use of existing patented technologies. For instance, in the early 1990s, scientists had studied the use of mRNA as a new therapeutic.[43] In 2005, a group of researchers at the University of Pennsylvania released the results of mRNA technology, regarded essential to the development of mRNA-based therapeutics.[44] The University of Pennsylvania[45] provided a series of sublicenses for mRNA-related patents to both Moderna[46] and BioNTech.[47] In 2019, way before the identification and spread of COVID, Moderna and the U.S. National Institutes of Health (NIH) entered into an agreement to co-develop mRNA coronaviruses vaccines.[48] To date, Moderna, Pfizer and BioNTech, CureVac, and Arcturus have all developed mRNA-based vaccines.[49] This network of patents, licenses, and agreements between various companies (Table 2) shows the complexities of biopharmaceutical research as well as the importance of R&D investments and collaboration among institutions and firms.

The rapid development and clinical success of COVID mRNA vaccines can be credited to the collaboration between inventors and other innovators. As evidenced by the network analysis of COVID vaccine patents,[50] key technological breakthroughs were achieved in academic labs or small biotech companies and then li-

Table 2: Patent Network Analysis Of mRNA-Based Vaccine Candidates For COVID-19



Source: Mario Gaviria and Burcu Kilic, "A network analysis of COVID-19 mRNA vaccine patents" (2021) Nature Biotechnology 39, 546,548*drug_development*

41. Samuel Mark Borowsky, "Preserving Innovation in Face of Compulsory Licensing," (2009) *Florida State University Law Review,* Vol. 36, Issue 2, Article 6.

42. *Ibid*.

43. Mario Gaviria, Burcu Kilic, "A network analysis of COVID-19 mRNA vaccine patents" (May 2021) *Nature Biotechnology* 39, 546,548.

44. Katalin Karikó, Michael Buckstein, Houping Ni, Drew Weissman, "Suppression of RNA Recognition by Toll-like Receptors: The Impact of Nucleoside Modification and the Evolutionary Origin of RNA" (August 2005) *Immunity* Vol. 23, Issue 2, 165,175.

45. The University of Pennsylvania exclusively licensed their patents to mRNA RiboTherapeutics, which then sublicensed them to its affiliate CellScript.

46. CellScript & Moderna, Patent sublicense agreement, EX-10.8, (2017) *<https://www.sec.gov/Archives/edgar/data/1682852/000119312518323562/d577473dex108.htm>*.

47. CellScript & BioNTech, Patent sublicense agreement, EX-10.15, (2017) *<https://www.sec.gov/Archives/edgar/data/1776985/000119312519241112/d635330dex1015.htm>*.

48. Bob Herman, "The NIH claims joint ownership of Moderna's coronavirus vaccine" (*Axios*, 2020) *<https://www.axios.com/moderna-nih-coronavirus-vaccine-ownership-agreements-22051c42-2dee-4b19-938d-099afd71f6a0.html>* ; NHI-Moderna Confidential Agreement *<https://www.documentcloud.org/documents/6935295-NIH-Moderna-Confidential-Agreements.html#document/p105/a568569>*.

49. This vaccine technology platform uses mRNA technology, lipid nanoparticle technology, and delivery system technology to achieve the desired biological response.

50. Borowsky (n 41).

censed to larger companies for product development. The importance of patents for medical innovation is well reflected when some of the most innovative pharma companies *"leveraged their extraordinary R&D capacity to launch the unprecedented development and delivery of diagnostics, medical equipment, treatments, vaccines, digital tools, and information sharing faster than ever before. (…) This would not have been possible absent the United States' robust IP environment, which enables innovators and creators to invest the resources necessary to commercialize new products and services."*[51] External financial support has also been decisive for the success of vaccines.

IV. Supply of COVID Vaccines

1. Challenges

As patents grant an exclusivity right, some argue that patents are a barrier to the availability and affordability of vaccines during a pandemic.[52] The debate around patents has however distracted from the main reasons behind the limited and slow supply of COVID vaccines, which are listed below.

One of the major causes in the delayed deployment of the vaccine and other medicines to treat COVID is related to the export ban on certain medicines imposed by different countries, such as by the UK and the U.S. Giving priority to national use of these medicines is probably the first reason behind the ban in the UK, considering the global shortage in medicines.[53] Nevertheless, these bans are especially detrimental for developing countries that rely on exports to obtain essential medicines and/or material supplies. From the list of 174 medicines banned from export by the British government, around 100 medicines are considered as possible treatments for COVID patients or appropriate to alleviate symptoms of patients in intensive care units.[54]

Moreover, some doctors believe that two of the most recent additions to the list of prohibited exports, *i.e.*, *dabigatran etexilate*, a blood thinner used on some coronavirus patients, and *semaglutide*, could help ease the impact of COVID on patients' hearts.[55] Despite these restrictions on exports, the Association of the British Pharmaceutical Industry released a statement in January 2021, denying they had occurred.[56] Similarly, the U.S. has been accused of an embargo on the export of vaccine raw materials by Adar Poonawalla, owner of the vaccine manufacturer Serum Institute of India (SII).[57] The U.S. is a key supplier of these materials, with reports claiming that the shortages are the result of the Defense Production Act, an emergency statute requiring domestic manufacturers to prioritize federal government purchase orders.[58]

Also to be considered is that, at the beginning of January 2020 when COVID cases were rising in China, the government consequently placed millions of people into quarantine to contain the dire situation, and it took months for the press to disclose a more accurate picture of the situation in China.[59]

In addition to this, some of the world leaders underestimated the threat. For instance, in the UK, Prime Minister Boris Johnson sought to attend a "herd immunity" strategy,[60] way before having the right tools (primarily vaccines) to achieve it. In Brazil, President Bolsonaro encouraged his supporters to disregard

51. Joint letter of AdvaMed, BIO, NAM, NFTC to World Trade Organization, (March 29, 2021).

52. Peter K. Yu, "Currents and Crosscurrents in the International Intellectual Property Regime," November 2004) *Loyola of Los Angeles law review* 38(1).

53. Anna Isaac, Ashleigh Furlong, "UK restricts COVID medicine exports amid AstraZeneca vaccine fight" (27 January 2021) *POLITICO* <*https://www.politico.eu/article/uk-coronavirus-vaccine-astrazeneca-export-boris-johnson/*>.

54. UK Department of Health & Social Care, List of medicines that cannot be exported from the UK or hoarded (Date of Publication Unknown) <*https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/933527/medicines_that_cannot_be_parallel_exported_from_the_UK.csv/preview*>.

55. Chas Newkey Burden, "UK quietly restricted COVID medicine exports to EU" (January 2021) *The Week* <*https://www.theweek.co.uk/951807/uk-quietly-slapped-restrictions-on-COVID-medicine-to-eu*>.

56. The Association of the British Pharmaceutical Industry, ABPI Comment on medicine export bans (*Press release*, January 2021) <*https://www.abpi.org.uk/media-centre/news/2021/january/abpi-comment-on-medicine-export-bans/*>.

57. Adar Poonawalla Tweet, (April 2021) <*https://twitter.com/adarpoonawalla/status/1382978713302683653?ref_src=twsrc%5Etfw%7Ctwcamp%5Etweetembed%7Ctwterm%5E1382978713302683653%7Ctwgr%5E%7Ctwcon%5Es1_&ref_url=https%3A%2F%2Fwww.aljazeera.com%2Fnews%2F2021%2F4%2F16%2Findias-COVID-vaccine-maker-urges-biden-to-lift-exports-embargo*>.

58. United States Government Accountability Office (GAO), Opportunities Exist to Increase Transparency and Identify Future Actions to Mitigate Medical Supply Chain Issues (*Defense Production Act*, November 2020) <*https://www.gao.gov/assets/gao-21-108.pdf*>; Executive Office of the President of the United States of America, How President Trump uses the Defense Production Act to protect America from the China Virus (*White House Report*, August 2020) <*https://s3.documentcloud.org/documents/7036228/OTMP-DPA-Report-FINAL-8-13-20.pdf*>.

59. Emma Graham Harrison, Lily Kuo, "China's Coronavirus Lockdown Strategy: Brutal but Effective" (19 March 2020) *The Guardian* <*https://www.theguardian.com/world/2020/mar/19/chinas-coronavirus-lockdown-strategy-brutal-but-effective*>.

60. Editorial, "The Guardian View on Herd Immunity: Yes it was 'Part of the Plan'" (29 April 2020) *The Guardian* <*https://www.theguardian.com/commentisfree/2020/apr/29/the-guardian-view-on-herd-immunity-yes-it-was-part-of-the-plan*>.

social distancing measures. After hearing the president's statement against such measures his supporters seemed to underestimate the danger of COVID.[61] Former President Trump as well persistently minimized the COVID outbreak in the very first months of 2020, claiming that he had the situation "completely under control,"[62] while the U.S. was becoming the very global epicentre of the pandemic. The slow response of governments and their reluctance to embrace disruptive and economically painful measures only increased the chaos around a global response that should have been faster and more effective.

Further, when COVID unexpectedly and rapidly spread around the globe there were no large-scale manufacturing facilities in place nor copious raw materials available for use in vaccine supply chains.[63] There are multiple limits in large-scale manufacturing. First the virus must be replicated in large quantities and in bio-safe conditions. Second, there is a need for extensive safety testing. Third, several recombinant proteins may need to be produced simultaneously for use in vaccine production.[64] Consequently and for example, manufacturers in developing countries currently producing vaccines for yellow fever cannot easily retool to produce the high-end mRNA.[65] That said, it is plausible that some additional capacity exists to conduct certain parts of the production process for particular COVID vaccines. But even then, it would be necessary to identify and prepare an inventory of such capacities.

Developing nations typically do not consider IPRs as an attractive solution for promoting the public welfare, particularly when dealing with challenges related to access to essential medicine for their populations. Patents are often perceived by emerging economies as generators of social costs, such as higher prices and royalty payments to foreign patent holders.[66] This, in turn, could prevent access to technological advantages that would otherwise promote their industry and benefit their citizens. In the absence of local competition, consumers might end up relying only on imported goods and usually paying more for them.[67] Given this scenario, a developing country facing a health crisis finds itself in a difficult position. To provide access to medicines that could help to fight the crisis, such a country has three main options: (i) rely on medicine donations from charities and pharmaceutical companies, (ii) be proactive and negotiate bilaterally with such companies, or (iii) issue compulsory licenses[68] or IP waivers.

Due to the scarcity of funds for procurement of these medicines, the third option, *i.e.*, compulsory licensing, is commonly chosen by countries seeking to be proactive.[69] Although bilateral negotiations allow states to negotiate price reductions, the savings generated from these reductions are generally not enough.[70] Thus, some view compulsory licenses as a way to enhance competition amongst suppliers, leading to more significant price reductions.[71]

2.Proposed Solutions

a. IP Waiver and Other Alternatives Impacting IP Protection

Considering the potential cost savings of compulsory licensing, the IP waiver proposal made by India and South Africa at World Trade Organization (WTO) on May 2021—which aims to temporarily suspend several sections of Part II of TRIPS Agreement on IP protection[72]—is now being seen by some countries as a possible tool for access to vaccines, especially for the poorest ones. A few of the arguments made in favor of the IP waiver is that *"no one should be left behind,"* and that *"universal access to immunization,*

61. Aline Burni, Eduardo Takami, "Populist Communication During the COVID-19 Pandemic: Case of Brazil's President Bolsonaro" (2021) Partecipazione e Conflitto.

62. Mike Calia, "Full interview: President Trump Discusses Trade, Impeachment, Boeing and Elon Musk with CNBC in Davos" (22 January 2020) *CNBC <https://www.cnbc.com/2020/01/22/davos-2020-cnbcs-full-interview-with-president-trump.html >*.

63. Holly Ellyatt, "Supply Chain Chaos is Already Hitting Global Growth. And it's About to Get Worse" (18 October 2021) *CNBC <https://www.cnbc.com/2021/10/18/supply-chain-chaos-is-hitting-global-growth-and-could-get-worse.html>*.

64. Neil Wilkof," Vaccine Platforms and Limited Global Production Capacity: What is to be Done?" (*The IPKat blog*, 13 May 2021) *<https://ipkitten.blogspot.com/2021/05/vaccine-platforms-and-limited-global.html>*.

65. Hans Sauer, "Waiving IP Rights During Times of COVID19: a 'False Good Idea'" (19 April 2021) *IP Watchdog <https://www.ipwatchdog.com/2021/04/19/waiving-ip-rights-during-times-of-COVID-a-false-good-idea/id=132399/ >*.

66. Edit Tilton Penrose, "The Economics Of The International Patent System" (1951) *Baltimore: The John Hopkins Press*.

67. Federal Trade Commission, To promote innovation: the proper balance of competition and patent law and policy (Report, October 2003).

68. Henry Grabowski, "Patents, Innovation and Access to New Pharmaceuticals" (December 2002) *Journal of International Economic Law*, Vol. 5, Issue 4.

69. Borowsky (n 41).

70. Grabowski (n 68).

71. Borowsky (n 41).

72. Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement. The TRIPS Agreement is an international treaty, which came into force on January 1, 1995, that sets out the minimum legal standards of protection of IP to be provided by each Member state. The aim is to harmonize the IP protection between countries by providing the basis of such protection for all IP rights.

treatments, testing and other products to control the pandemic should be our priority."[73] Before supporting this strategy, it is important, however, to keep a few things in mind.

Under Art. IX.3 of the Marrakesh Agreement, which established the World Trade Organization (hereinafter WTO Agreement), it is provided that, in "exceptional circumstances," the Ministerial Conference may waive an obligation imposed on a WTO member country.[74] Additionally, Article IX.4 of the WTO Agreement states that the Ministerial Conference, while granting the waiver, shall state the "exceptional circumstances" justifying it and specify the waiver's terms and conditions. Although the term "exceptional circumstances" is not defined in the WTO Agreement, the aim of the waiver appears to be the legalization of non-compliant measures. Indeed, there could be actual situations of urgency in which compliance with WTO rules may not be practicable.[75] It could be argued that the COVID global pandemic falls within these "exceptional circumstances."

According to the IP waiver proposal, WTO members would be relieved of their TRIPS obligations to grant new patents, copyrights, protections for industrial designs, trade secrets, regulatory data, and business confidential information and materials related to COVID innovations.[76] Member states would also be absolved from enforcing pre-existing safeguards in relation to *"diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19"* [77]for a flexible and practical duration that will be assessed by the General Council of the WTO.

The proposed IP waiver would result in the complete suspension of relevant IP rights related to health products and technology. Even if only for a limited period, such waiver would be unprecedented and could be risky for the IP rights ecosystem. In fact, being such a far-reaching proposal, the IP waiver would not only cover patent rights, but also trade secrets. Trade secrets are IP rights that protect *"any confidential business information which provides an enterprise a competitive edge and is unknown to others,"* encompassing both technical and commercial information.[78] In the case of mRNA vaccines, their main value relies on the technical know-how of how to produce them. If disclosed, this would result in a permanent loss of the trade secret as a commercial asset, to the eternal detriment of the companies that have invested very significant resources in the creation of such technologies. Hence, an IP waiver would not be a recommendable approach. Surprisingly, the current U.S. Administration has manifested its support of the IP waiver proposal.[79] In the same direction, some members of the European Parliament proposed negotiations for a temporary waiver of the TRIPS Agreement on patents to improve global access to affordable COVID-related medical products and to address global production constraints and supply shortages.[80] These members of the European Parliament have also called on the European Union (EU) *"to rapidly eliminate export barriers and to replace its own export authorization mechanism with export transparency requirements."*[81]

In June 2021, the European Union submitted a Communication to the WTO General Council,[82] highlighting the value of intellectual property as incentive to follow-on innovation. The EU proposes that WTO members agree on a global trade initiative and consider mainly three components: (i) trade facilitation and disciplines on export restrictions; (ii) expansion of production, including through pledges by vaccine producers and developers; (iii) clarification and facilitation of TRIPS Agreement flexibilities relating to compulsory

73. Third World Network Berhad, "Co-sponsors of TRIPS Waiver Proposal Call for Solidarity at WTO" (*Third World Network*, 19 May 2021) <*https://www.twn.my/title2/wto.info/2021/ti210516.htm*>.

74. The obligation can be both imposed by the WTO Agreement and other multilateral trade agreements, such as the TRIPS Agreement.

75. Isabel Feichtner, "The Waiver Power of the WTO: Opening the WTO for Political Debate on the Reconciliation of Competing Interests" (2009) *European Journal of International Law*, Vol. 20, no. 3.

76. Hans Sauer, "Waiving IP Rights During Times of COVID: a 'False Good Idea'" (19 April 2021) *IP Watchdog* <*https://www.ipwatchdog.com/2021/04/19/waiving-ip-rights-during-times-of-COVID-a-false-good-idea/id=132399/*>.

77. World Trade Organization (WTO), Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of covid-19 (*Revised Decision Text*, 25 May 2021) <*https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True*>.

78. Defined by the World International Property Organization (WIPO).

79. Office of the U.S. Trade Representative, Statement from Ambassador Katherine Tai on the COVID-19 Trips Waiver (*Press release*, 5 May 2021) <*https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-COVID-19-trips-waiver*>.

80. European Parliament, Parliament calls for temporary COVID-19 vaccine patent waiver (*Press release*, 10 June 2021) <*https://www.europarl.europa.eu/news/en/press-room/20210604IPR05514/parliament-calls-for-temporary-COVID-19-vaccine-patent-waiver*>.

81. *Ibid*.

82. European Union, Urgent trade policy responses to the covid-19 crisis: Intellectual property (*Communication to WTO General Council*, 4 June 2021).

licenses.[83] At the same time, the European Commission has repeatedly claimed that IPRs are not a barrier to scaling up the manufacturing of vaccines or other COVID-related products.[84]

Questionable is whether other alternatives to the IP waiver would be better placed to increase the production of vaccines and ensure their quick distribution at affordable prices. Some examples would be (i) the research and experimental use exception (within Art. 30 TRIPS Agreement); and (ii) the compulsory licensing (Art. 31 and 31*bis* TRIPS Agreement).

Under Art. 30 of the TRIPS Agreement, governments can make limited exceptions to patent rights, provided certain conditions are met. The exceptions must neither *"unreasonably conflict with the normal exploitation of the patent"* nor *"unreasonably prejudice the legitimate interests of the patent owner."*[85] One of the most common exceptions in national patent law regimes is the "research and experimental use" of a patented product or method. Under this provision, using a patented product for scientific experimentation without the permission of the patent holder is not considered an infringement. This exception allows researchers to examine patented inventions and, possibly, improve them without worrying about infringing the patent. Although this exception allows for potential advancement in research, the application of Art. 30 of the TRIPS Agreement would not solve the issue of a license for the normal use of the vaccine.

Compulsory licensing falls under Art. 31 of the TRIPS agreement, which provides that *"the law of a Member allows for other use of the subject matter without the authorization of the right holder."* As defined in the Glossary of the WTO, compulsory licensing occurs when *"the authorities license companies or individuals other than the patent owner to use the rights of the patent—to make, use, sell or import a product under patent (i.e., a patented product or a product made by a patented process)—without the permission of the patent owner. Allowed under the WTO's TRIPS (intellectual property) Agreement provided certain procedures and conditions are fulfilled."*[86] "Other use" includes both use of a patent by governments for their own purposes and compulsory licensing.[87] Such licenses may be granted by governments in order to provide access to essential medicines, but they should be used carefully.[88] Nevertheless, compulsory licensing may be far too burdensome for the rapid and large-scale global responses required to curb the deadly pandemic.[89] Primarily, this is due to stringent limits applied to exports of medicines produced under TRIPS compulsory licensing exceptions.

To begin with, Art. 31 requires the use of compulsory licensing to be based on individual merits, suggesting a case-by-case approach.[90] Secondly, except in circumstances of urgency, public non-commercial use, or competition violations, prospective licensees must first attempt to secure a voluntary license on commercially reasonable terms, which can result in time delays.[91] Further, given the circumstances of each case, adequate remuneration is required,[92] and decisions are to be subject to judicial or other independent review.[93] Also, Art. 31(f) provides that products made under compulsory licensing must be used *"predominantly for the supply of the domestic market."* This means that countries would have to justify that the quantity for

83. Point (iii) refers to the objective of the EU Commission of simplifying a procedural aspect of Art.31*bis* of TRIPS Agreement and its Annex, which requires two different notifications by both WTO importing and exporting Members on the products and the grant of license to the TRIPS Council. The goal is to ensure that with a single notification, which will contain the elements required under Article 31*bis* for transparency purposes, the export of vaccines and therapeutics can be supplied directly or through the COVAX Facility.

84. European Commission (EC), Questions and Answers: EU Communications to the WTO—EU proposes a strong multilateral trade response to the COVID-19 pandemic (*Press Corner*, 2 June 2021) *<https://ec.europa.eu/commission/presscorner/detail/bg/qanda_21_2802>*.

85. Art. 30 TRIPS Agreement on "Exceptions to rights conferred" states that "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

86. World Trade Organization (WTO), *WTO Glossary <https://www.wto.org/english/thewto_e/glossary_e/compulsory_licensing_e.htm>*.

87. World Trade Organization (WTO), Obligations and exceptions - Under TRIPS, what are member governments' obligations on pharmaceutical patents? (*Facts sheet*, September 2006) *<https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm>*.

88. Madeline Kleyn, Enrique Longton, "Patent Waiver in the Time of COVID19" (July 2021) *Les Nouvelles <https://www.lesi.org/publications/les-nouvelles/les-nouvelles-article-of-the-month/les-nouvelles-article-of-the-month-archives/les-nouvelles-article-of-the-month---july-2021>*.

89. Kerry Cullinan, "Is European Union on Collision Course with European Parliament on COVID IP Waiver?" (2021) *Health Policy Watch <https://healthpolicy-watch.news/eu-may-be-at-odds-with-european-parliament-over-trips-waiver/>*.

90. Art. 31 (a) TRIPS Agreement on Other Use without the authorization of the right-holder.

91. Art. 31 (b) TRIPS Agreement on Other Use without the authorization of the right-holder.

92. Art. 31 (h) TRIPS Agreement on Other Use without the authorization of the right-holder.

93. Art. 31 (i) TRIPS Agreement on Other Use without the authorization of the right-holder.

export is a limited percentage relative to domestic supply. In a pandemic where large-scale and rapid assistance is required, this provision could be problematic. However, even before the COVID pandemic, Canada issued a compulsory license in 2007 in favor of Apotex to manufacture and export the HIV-drug TriAvir to Rwanda.[94] In the early stages of the pandemic, Canada aspired to enable quicker and easier procedures for the grant of compulsory licenses in order to overcome possible IP barriers to uptake of COVID technologies.[95] As a result, Canada amended its Patent Act allowing the *"Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to the public health emergency described in the application."*[96] In the meantime Biolyse Pharma, a pharmaceutical company based in Canada, has expressed its intention to seek a compulsory license under the amended Canadian Patent Act to obtain a license from Johnson & Johnson, of which Biolyse could manufacture and export a generic version.[97] It is though unclear whether the requirements for granting a compulsory license would be fulfilled in this case. The European Commission has also emphasised that compulsory licenses should be applied *"as a means of last resort and a safety net, when all other efforts to make IP available have failed."*[98]

As highlighted above, in the last few months the EU has stressed the use of compulsory licenses "as a last resort" while opposing the proposal for a temporary IP waiver.[99] Others suggest, as an alternative approach, harmonizing the rules on compulsory licensing at the EU level in order to avoid the so-called *"vaccination tourism."*[100] Others have proposed to create a central body with administrative power to decide when to trigger compulsory licensing.[101]

Emerging economies face challenges of a lack of or insufficient manufacturing capacity, which prevents them from using the compulsory license mechanism. For such reasons, the Doha Ministerial Declaration of 14 November 2001 introduced Art. 31*bis*, permitting a country which requires a drug but cannot manufacture itself, to import it under a compulsory license. In the Doha Declaration, WTO Members wanted to stress the importance to interpreting the TRIPS Agreement in a way that supports public health, by promoting both access to existing medicines and the creation of new medicines.[102]

b. Different Approach to the Same Problem: Israel and the European Union

In different parts of the world, several initiatives have been developed to promote the effectiveness of the IP system in order to encourage access to innovative remedies in the health system in a bid to curtail the harm inflicted by COVID.

In Israel, for example, various factors contributed to a successful vaccination campaign:[103] from the high percentage of the young population to the health-care community-based system. Israel chose a collaborative approach with the pharmaceutical companies. The law related to vaccines was amended to give protection to the pharmaceutical companies, so that anyone facing unexpected side-effects by the vaccines would be compensated. The country succeeded in the supply of the vaccine mainly because of the short period it required until it signed the agreement with Pfizer. Accordingly, the government agreed to share aggregated data on the vaccination campaign and to overbuy vaccines in advance. In exchange, the pharmaceutical company allocated sufficient stocks of vaccines in the country advance.[104]

On the other hand, the EU countries jointly negotiated the purchasing of vaccines with the pharmaceuti-

94. Holger P. Hestermeyer, "Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines" (10 December 2007) *American Society of International Law,* Vol. 11, Issue 28 <*https://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and#_edn1*>.

95. World Trade Organization (WTO), Response to questions on intellectual-property challenges experienced by members in relation to COVID-19 (*Communication to Council for Trade-related aspects of Intellectual Property Rights*, 15 January 2021) <*https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W673.pdf&Open=True*>.

96. Art 19.4 (1) Patent Act.

97. Arianna Schouten, "Canada based Biolyse Pharma Seeks to Manufacture COVID-19 Vaccines for Low-Income Countries, may test Canada's compulsory licensing for export law," (12 March 2021) *Knowledge Ecology International* <*https://www.keionline.org/35587*>.

98. In the IP action plan published in November 2020.

99. *Ibid*.

100. BBC, "Covid vaccines: Tourists head to the U.S. to get vaccinated" *BBC News* (29 July 2021) <*https://www.bbc.com/news/av/world-us-canada-58004253*>; FIDE, TIPSA, "The Role of IP in a Post Crisis World" (2021) *First Global Digital Encounter Report*, Vol. 1.

101. FIDE, TIPSA (n 100).

102. World Trade Organization (WTO), The separate Doha Declaration explained (*TRIPS and Public Health*, Date of Publication Unknown) <*https://www.wto.org/english/tratop_e/trips_e/healthdeclexpln_e.htm*>.

103. Bruce Rosen, Ruth Waitzberg, Avi Israeli, "Israel's Rapid Rollout of Vaccinations for COVID-19," (26 January 2021), *Israel Journal of Health Policy Research 10*, Article no. 6. The article states that "as of the end of 2020, Israel, with a population of 9.3 million, had administered more COVID-19 vaccine doses than all countries aside from China, the US, and the UK. Moreover, Israel had administered almost 11.0 doses per 100 populations, while the next highest rates were 3.5 (in Bahrain) and 1.4 (in the United Kingdom). All other countries had administered less than 1 dose per 100 populations."

104. FIDE, TIPSA (n 100).

cal companies and distributed them through EU's own mechanisms among the members.[105] The EU Vaccines Strategy[106] presented different objectives such as the swift access to vaccines for Member States and their populations and an equitable access to affordable vaccines as quickly as possible.[107] As of 14 December 2021, the EU donated about 317 million doses to low- and middle-income countries through COVAX, a global partnership that facilitates the purchase and delivery of COVID vaccines.[108] However, there is a drop in doses along the production line when looking at the figures: only 218 million doses of the total amount have been ordered from vaccine manufacturers, of which 159 million have been released for shipment and 127 million are in transit or have arrived at their destination.[109] Donations and deliveries are, in fact, two different things: the availability, allocation, acceptance, approvals, and arrival of doses represent different steps of the production chain, each of which requires the engagement of multiple parties. In the European scenario, many challenges still remain, from the recipient countries rejecting doses with a short shelf life, to bureaucracy limits that make deliveries difficult to accept, and a lack of capacity to absorb the doses in the different health systems.

V. Conclusions

The development of COVID vaccines has experienced an unprecedented success. This can be attributed to the efforts of numerous researchers, public institutions, and private actors, all of whom have shared capital and resources to fight the escalation of the pandemic.[110]

In this context, IP has often been perceived as part of the solution, as IP encourages the rapid establishment of collaboration and innovation synergies among different actors. In particular, patents represent a reward system that induces high-cost R&D which otherwise would be vulnerable to free riders and appropriation. Moreover, studies have shown that strong IPRs correlate with economic growth and R&D.[111] In consequence, a strong and efficient patent system has the potential to lead to more innovation. Furthermore, the commercialization of inventions often requires significant investments: patents motivate businesses to invest money in order to turn the abstract technology claimed in a patent into an actual product.[112] Patents might not often be the primary driver of inventions, but they can help to accelerate innovation.

Despite their many benefits, some have raised concerns on the impact that patents could have on the availability and affordability of COVID vaccines. As a result, some have called for a suspension of patents and other IPRs, to achieve low prices for the vaccine and foster the transfer of know-how and technology, thus increasing global industrial capacity.[113]

As this paper has demonstrated, IP in general, and patents in particular, have little to do with the problem of inaccessibility of the COVID vaccine. The challenges seem rather to be the insufficient R&D investment for the development of new medicines, the lack of production facilities and raw materials supply, the loss of trust in science among some parts of the population, and the high costs of medicines.

To address these above-mentioned problems some proposals are detailed in the following:

1. To efficiently combat the COVID crisis, increased R&D investment is required. Governments have been some of the largest investors in the health response since January 2020,[114] along with the

105. Ashleigh Furlong, Sarah-Taïssir Bencharif, Giovanna Coi, "Tens of millions of Europe's donated vaccines haven't arrived. Who's to blame?" (16 December 2021) *POLITICO*: "For EU countries to donate vaccines, trilateral agreements were drawn up between COVAX, donor countries and vaccine manufacturers. To avoid having 27 agreements for each vaccine, donations were channelled via three agreements: Sweden for Oxford/AstraZeneca vaccines; Belgium for Johnson & Johnson; and France for BioNTech/Pfizer."

106. European Commission (EC), EU Strategy for COVID-19 vaccines (*Communication*, 17 June 2020) < *https://ec.europa.eu/info/sites/default/files/communication-eu-strategy-vaccines-covid19_en.pdf*>.

107. European Commission (EC), Coronavirus: Commission unveils EU vaccines strategy (*Press release*, 17 June 2020), < *https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1103*>.

108. United Nation Children's Fund (UNICEF), COVID-19 Market Dashboard (*UNICEF*, Date of Publication Unknown) <*https://www.unicef.org/supply/covid-19-vaccine-market-dashboard*>.

109. Ashleigh Furlong, Sarah-Taïssir Bencharif, Giovanna Coi, "Tens of millions of Europe's donated vaccines haven't arrived. Who's to blame?" (16 December 2021) *POLITICO* <*https://www.politico.eu/article/millions-europe-donated-coronavirus-vaccines-arrival-blame/?utm_source=POLITICO.EU&utm_campaign=bfa5dae9fc-EMAIL_CAMPAIGN_2021_12_17_04_54&utm_medium=email&utm_term=0_10959edeb5-bfa5dae9fc-189896773*>.

110. Examples of collaborations between the private sector and research centres are: the COVID-19 Therapeutics Accelerator, <*https://www.therapeuticsaccelerator.org/*>; the EU-backed Swift Coronavirus Therapeutics Response, <*https://cordis.europa.eu/project/id/101003627*> and Corona Accelerated R&D in Europe (CARE), <*https://cordis.europa.eu/project/id/101005077*>.

111. Correlation does not imply causation.

112. Ohlhausen (n 5).

113. Human Rights Watch, "Urgently Waive Intellectual Property rules for vaccine" (10 December 2020) <*https://www.hrw.org/news/2020/12/10/urgently-waive-intellectual-property-rules-vaccine*>.

European Union, the International Monetary Fund, and other development banks and philanthropic organizations.[115] However, more could be done. Other actors, such as pharma companies, have invested massively in R&D but they will only continue doing so if they can rely on a strong IPR system. Moreover, an increase in R&D investments will make it possible to develop medicines and vaccines at competitive prices, thereby reducing the high costs of the same.

2. Identifying possible production facilities around the world is probably one of the most efficient ways to scale up COVID vaccine rollout, followed by building materials supply lines. As suggested by some companies,[116] the outcomes of the Quad leaders' summit[117] have the potential to address the supply chain bottlenecks and strengthen health systems in developing countries.[118] At the summit, the "Quad Vaccine Partnership"[119] has been established in order to enhance an equitable access to vaccines in the Indo-Pacific region. Since March 2021, the Quad leaders have taken actions to expand safe and effective COVID vaccine manufacturing capacity such as the global donation of vaccines[120] and the cooperation between Quad leaders to assist the Indo-Pacific region in responding to the pandemic.[121] This kind of partnership can also broaden efforts to identify and eliminate related barriers to global vaccination. Also, through bilateral and multilateral negotiations with private actors, governments can achieve low and accessible prices for vaccination of their citizens.
3. Another important factor is the role of politicians in the perception of the pandemic. In general, those countries led by populists have struggled the most with managing the COVID outbreak. Typically, populists lack transparency in their communication and are sceptical towards science. Their strategies rely on denying the seriousness of the health crisis and shifting the blame to the media, foreign governments, and local authorities.[122] For a successful vaccination campaign, it is very important to rely more on scientific studies and to promote science among the population, with awareness-raising campaigns supported by data and facts. The more people get vaccinated, the faster it will be to overcome this crisis.
4. A unified and rapid response is needed to win the race against the virus. The main obstacles to worldwide vaccination access are not connected to intellectual property matters. IP waivers or similar tools that weaken IP may seem an appealing option at first glance, but mid-term would only be deleterious, mostly for R&D investments, which are essential for developing new medicines and stimulating innovation, especially in view of new COVID variants and future viruses that the world will face in the coming years. ■

Available at Social Science Research Network (SSRN): *https://ssrn.com/abstract=4179533.*

114. Devex, "Funding the Response to COVID19," (*Analysis of funding opportunities*, 1 January 2020 – 27 June 2021) *<https://public.tableau.com/app/profile/devexdevdata/viz/COVIDFundingvisualisation/COVID-19funding>*.

115. World Health Organization (WTO), "COVID19 Vaccination Financing and Budgeting Q&A" (*WTO News*, 27 April 2021) *<https://www.who.int/news/item/27-04-2021-COVID-19-vaccination-financing-and-budgeting-q-a>*. The article states that there are three main sources of funding for COVID vaccines: domestic revenue, external funding (for low and lower-middle income countries, funding can take the form of grants or highly concessional loans) and alternative financing (*i.e.* immunization trust funds, social impact bonds).

116. Joint letter of AdvaMed, BIO, NAM, NFTC to World Trade Organization (WTO) (March 29, 2021).

117. On September 24, 2021, Prime Minister Scott Morrison of Australia, Prime Minister Narendra Modi of India, and Prime Minister Yoshihide Suga of Japan have met for the first time ever in person at the White House, during a meeting hosted by President Joe Biden.

118. The White House, Fact Sheet: Quad Summit (*Press release*, 12 March 2021) *<https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/12/fact-sheet-quad-summit/>*.

119. The White House, Fact Sheet: Quad Leaders' Summit (Statements and releases, 24 September 2021) *<https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/24/fact-sheet-quad-leaders-summit/>*.

120. In their statements, Quad leaders have committed to donate more than 1.2 billion vaccine doses globally, in addition to the doses financed through the COVAX program.

121. From the Quad Leaders statements: "Australia will deliver $212 million in grant aid to purchase vaccines for Southeast Asia and the Pacific. In addition, Australia will allocate $219 million to support last-mile vaccine rollouts; through $3.3 billion in the COVID-19 Crisis Response Emergency Support Loan program, Japan will continue to help regional countries to procure safe, effective, and quality-assured vaccines."

122. The idea behind populist statements is that "the people" are essentially good and those part of "the elite" are essentially bad. The elite is composed by political elites (parties, government, and ministers), but also the media, the state (administration, civil service), intellectuals (universities, writers, and professors), or economic powers (multinationals, employers, trade unions, and capitalists). Aline Burni, Eduardo Takami (n 61).