


A Double-Edged-Sword Approach to Fighting Pandemics: Patent Waivers and Incentives to Innovate

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Abstract: Although continents recently experienced an apocalyptic pandemic that posed a mortal danger to millions of people, a new, even deadlier pandemic could soon emerge... The paper seeks to address the role played by patent waivers and current contractual arrangements in the pharmaceutical industry in addressing the dangers caused by the current and future pandemics. The process of waiving patents is explored where it is argued that it sadly cannot amount to the knight in shining armour that everyone has been expecting. Due to the lack of coordination, the tremendously long process, and the potential block in innovation arising from pharmaceutical companies having smaller incentives, more attention must be paid to other alternative institutional solutions. Drawing from the economics literature on innovation in the pharmaceutical sector, a conceptual framework is proposed for improved legal intervention in the case of patent waivers in international intellectual property law instruments. In addition, the paper provides a comparative law and economics treatment of current patent waivers in US, EU, and international law instruments.

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1. Introduction

Even though the COVID-19 pandemic might seem less relevant in the light of the successful mitigation policies and Russia's current invasion of Ukraine, thus becoming a non-significant, outdated, and minor topic, virologists are warning that a more deadly pandemic could be coming. Namely, H5N1, known more formally as avian influenza, has long been on the horizon of scientists' fears, with an outbreak of it on a Spanish mink farm having triggered fears of another pandemic. While it is fortunate that this pathogen has thus far not infected many humans when it has, 56% of those known to have contracted it died.¹ Its inability to spread easily, if at all, from one person to another has kept it from leading to a pandemic. However, as the virologist Peacock suggests, this is no longer the case.² Having long caused outbreaks among poultry, the virus is infecting ever more migratory birds, allowing it to spread more widely, even to various mammals, raising the risk that a new variant could spread to and among people.³ At a time when this new pathogen threatens to spread, we lawyers must harness the lessons learned from the COVID outbreak.

The coronavirus disease pandemic created unprecedented demand for a new type of medicine. Pharmaceutical companies worked around the clock to come up with state-of-the-art inventions, gaining a temporary, legal monopoly position in return. Such a position allows a company to charge above its marginal costs, which might limit some states' ability to purchase vaccines. The ensuing system has led to rising inequality in how the vaccines are administered, with low-income countries being particularly affected.

To address the increasing inequality in administering vaccines, Costa Rica for example proposed the creation of a voluntary emergency

¹ Agüero Montserrat et al., "Highly Pathogenic Avian Influenza A(H5N1) Virus Infection in Farmed Minks, Spain, October 2022," *Eurosurveillance* 28, no. 3 (2023), <https://doi.org/10.2807/1560-7917.es.2023.28.3.2300001>.

² Kai Kupferschmidt, "Incredibly Concerning: Bird Flu Outbreak at Spanish Mink Farm Triggers Pandemic Fears," *Science*, January 24, 2023, <https://www.science.org/content/article/incredibly-concerning-bird-flu-outbreak-spanish-mink-farm-triggers-pandemic-fears>.

³ Ibid.

Technology Intellectual Property Pool.⁴ Along this line of reasoning, Rutschman states that less property-like protection could effectively remove some of the most salient transactional obstacles to the development and commercialisation of new and better COVID-19 vaccines.⁵ Further, while examining the market dynamics of infectious disease products Darow, Sinha and Kesselheim claim that the “legislative initiatives launched over the past 15 years to overcome the shortcomings of the patent system have had limited success, in part because they do not adequately address the reasons underlying the disconnect between patents and the antimicrobial market.”⁶ Johnson and Bailey contend the current US patent law acts to limit the free flow of scientific research findings, and suggest a government-funded rewards system as an adjunct to the patent system to incentivise pandemic-relevant research and its rapid publication.⁷ Rimmer notes the constant external and internal pressure on pharmaceutical companies to view the coronavirus pandemic as a profit-making opportunity.⁸ Further, in excess of 140 other organisations and individuals established an initiative calling on the WIPO to ensure that intellectual property (IP) regimes support, namely do not impede, efforts to both fight new coronavirus outbreaks and their consequences.⁹ Roy advocates a waiver of IP rights on COVID-19 vaccines, arguing that market failure and underinvestment in research and development arguments do not hold when granting

⁴ James Love, “President and Minister of Health of Costa Rica Ask Who to Create Global Pool for Rights in COVID-19 Related Technologies,” *Knowledge Ecology International*, March 24, 2020, <https://www.keionline.org/32556>.

⁵ Ana Santos Rutschman, “Property and Intellectual Property in Vaccine Markets,” *Texas A&M Journal of Property Law* 7, no. 1 (2019): 110–32, <https://doi.org/https://doi.org/10.37419/JPL.V7.I1.4>.

⁶ Jonathan J. Darow, Michael S. Sinha, and Aaron S. Kesselheim, “When Markets Fail: Patents and Infectious Disease Products,” *Food & Drug L J* 73, no. 3 (2018): 361. See also: Ana Santos Rutschman, “IP Preparedness for Outbreak Diseases,” *UCLA Law Review* 65 (2018): 1200.

⁷ Eric E. Johnson and Theodore C. Bailey, “Urgent Legal Lessons from a Very Fast Problem: COVID-19,” *Stanford Law Review* 73 (2020), <https://doi.org/https://ssrn.com/abstract=3567412>.

⁸ Matthew Rimmer, “The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines,” *Melbourne Journal of International Law* 5, no. 2 (2004): 335–74.

⁹ Teresa Nobre, “Open Letter to WIPO: Intellectual Property and COVID-19,” COMMUNIA Association, April 16, 2020, <https://communia-association.org/2020/04/03/open-letter-wipo-intellectual-property-covid-19/>.

a patent to COVID vaccines.¹⁰ Thambisetty et al. argue that a waiver under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement is first a necessary and proportionate legal measure for overcoming IP barriers in a direct, consistent and efficient fashion, enabling more companies to freely produce COVID-19 vaccines and other health technologies without fear of infringing another party's IP rights and the attendant threat of litigation. Second, the TRIPS waiver acts as an important political, moral, and economic lever for encouraging solutions aimed at global equitable access to vaccines, which is in the broader interest of the global public.¹¹

Moreover, the World Health Organisation, India, South Africa and 60 other states put forward a "TRIPS waiver" proposal.¹² At a meeting of the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) on 6 May 2022, WTO members additionally discussed the recent document that had emerged from the informal process conducted with the Quad (European Union, India, South Africa, United States) for an IP response to COVID-19 and adopted an oral status report that was to be submitted by the chair of the TRIPS Council.¹³

¹⁰ Gopal Krishna Roy, "An Economic Case for Waiving Intellectual Property Rights on Covid Vaccines," *India Quarterly: A Journal of International Affairs* 78, no. 1 (2022): 143–47, <https://doi.org/10.1177/09749284221078463>. See also: "A Patent Waiver on Covid Vaccines Is Right and Fair," *Nature* 593, no. 7860 (2021): 478, <https://doi.org/https://doi.org/10.1038/d41586-021-01242-1>; Guido Cozzi, "Shall We Fear a Covid-19 Patent Waiver?," *SSRN Electronic Journal*, 2022, <https://doi.org/10.2139/ssrn.4015067>.

¹¹ Siva Thambisetty et al., "The Trips Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to End the Covid-19 Pandemic," *SSRN Electronic Journal*, 2021, <https://doi.org/10.2139/ssrn.3851737>.

¹² In October 2020, India and South Africa led a group of LMICs requesting the WTO to waive certain TRIPS provisions. The request, modified on 25 May 2021, asks for a 3-year waiver of IP protection for products and technologies related to COVID-19 prevention, treatment and containment. Normally, WTO protections for IP last around 20 years.

¹³ The Quad actually adopted a problem-solving approach aimed at identifying practical ways of clarifying, streamlining and simplifying how governments can override patent rights, in certain conditions, to enable diversification of the production of COVID-19 vaccines. However, this also means that the TRIPS Council has not yet completed its consideration of the revised waiver request and will therefore continue its consideration and report back to the General Council as stipulated in Article IX:3 of the Marrakesh Agreement; World Trade Organisation, "TRIPS Council Hears Initial Reactions to Quad's Outcome Document on IP COVID-19 Response," May 6, 2022, https://www.wto.org/english/news_e/news22_e/trip_06may22_e.htm.

Finally, some EU countries have been more reluctant and sceptical of a complete waiver of IP rights and offered an alternative focused on export restrictions, pledges by vaccine developers, and the flexibility of the existing World Trade Organisation rules (i.e., by relying on an existing compulsory licensing instrument).¹⁴ Namely, during the worst phases of the COVID-19 pandemic and even now, several changes were suggested for the policy toolkit, and one of them concerns (temporary and/or partial) waivers and exemptions of relevant medical products (vaccines, diagnostic, therapeutic) from the reach of IP rights, notably the patent rights of the pharmaceutical companies responsible for the corresponding inventions.

This paper joins in this critical debate by attempting to show that the intertwined static and dynamic efficiency and the *ex ante* vs. *ex post* optimal innovation incentive stream may be a source of additional, insightful guidance for structuring the current discussion on IP rights and potential future pandemics. The paper also seeks to outline ways to ensure the most efficient outcome for all contracting parties in future cases. That is, when a health emergency arises it is crucial to have policy instruments (legal or otherwise) in place that encourage research, development, production, timely distribution, and equal and general access to effective medical tools, for vaccination against and the diagnosis and treatment of pathogens.

This contribution adds to the IP literature and previous work of the authors in several noteworthy respects.¹⁵ First, the best way of tackling contractual bottlenecks in the event of a pandemic or other health emergency is analysed, largely based on the ongoing coronavirus disease outbreak. Ways of striking a balance between incentivising big pharma to make quick and large investments in research and development and making it accessible to

¹⁴ In its recent report, the EU pledges its commitment to the TRIPS Agreement, affirming that the agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to vaccines and medicines for all. In this connection, we reaffirm the right of WTO members to use the provisions of the TRIPS Agreement, which provide flexibility for this purpose, including those relating to compulsory licensing in Articles 31 and 31bis; European Union, "Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property," IP/C/W/680 and IP/C/W/681.

¹⁵ Mitja Kovac and Lana Rakovec, "The COVID-19 Pandemic and Long-term Incentives for Developing Vaccines: Patent Law under Stress," *The Journal of World Intellectual Property* 25, no. 2 (2022): 292–316, <https://doi.org/10.1111/jwip.12223>.

wider society. The analysis considers the question of whether patent waivers are indeed the most efficient way of balancing innovation and the equal distribution of vaccines (or whether other more efficient mechanisms exist); and the most efficient institutional arrangement for dealing with current and future health-related emergencies. Thus, the paper aims to fill the gap in the literature by providing European and international lawmakers with policy recommendations on any future potential health threats.

The analysis in this article is simultaneously positive and normative. The interdisciplinary methodology¹⁶ employed can enrich a theoretical and comparative study of this kind by helping to draft better rules in the day-to-day making of law and policy. However, several caveats are appropriate. First, the situation concerning developing COVID-19-related medicine is unprecedented in human history, meaning that any inferences derived from the recent pandemic may not be accurately extrapolated when it comes to developing future vaccines in non-pandemic times. Second, pharmaceutical firms may instead of patent protection rely on trade secrets and confidential know-how to protect their vaccines and production.¹⁷ Third, potential infringements of, for instance, mRNA vaccines may not be very likely to occur.¹⁸ Fourth, the enforcement of patent rights by pharmaceutical firms for various strategic reasons is not very likely. Although the paper is therefore unable to conclusively identify an appropriate IP law regime, the foundations are laid to better guide the ongoing debate.

This paper is organised as follows. In section 2, the general conceptual framework and current contractual and institutional arrangements are outlined. Section 3 examines the roles of patent waivers and focuses on

¹⁶ Mark Beuker, "Combining Legal and Economic Theory. An Interdisciplinary Approach to Dutch and Polish Family Provisions in Succession Law," *Review of European and Comparative Law* 47, no. 4 (2021): 49–65, <https://doi.org/10.31743/recl.12840>. For a synthesis of law and economics scholarship, see Gerrit De Geest, *Contract Law and Economics – Encyclopaedia of Law and Economics*, vol. 6, 2 ed. (Edward Elgar Cheltenham, 2011). See also: Richard A. Posner, *Economic Analysis of Law*, 8 ed. (Wolters Kluwer Law & Business, 2011).

¹⁷ Hence, there might not be any IP rights issues arising over the most critical parts involved in COVID-19 vaccine manufacturing.

¹⁸ Assuming that patents are filed and granted over a specific COVID-19 vaccine and the manufacturing process thereof, only certain countries with a substantial pharma/generics presence, such as India and Korea, may possess the relevant infrastructure and human expertise to infringe such patents, making such infringement unlikely.

the ways incentives given to firms distort innovation and the fragile balance with the incentives for diffusion. Section 4 provides several, economically-inspired, instrumental insights and a set of recommendations for more sensible EU-wide, supra-national intervention. Section 5 concludes.

2. General Conceptual Framework

Much research in innovation economics is occupied with a basic understanding of the importance of internally generated economic change for the progress of the economy and the weaknesses of static economic analysis in the face of this phenomenon.¹⁹ The first and perhaps most important insight from the economics of innovation is the recognition of the essential dynamism of the innovative process. Knowledge, inventions, and innovations created today build on those created in the past, while the benefits of an innovation are often not felt until it has undergone a dynamic, cumulative learning and diffusion process.²⁰

Hodge et al. show that the COVID-19 pandemic created extreme levels of stress on local health and care systems and describe examples where they have flourished and led to new models of care or new services for rural communities.²¹ Rural organisations are well-accustomed to uncertainty given their often limited and temporary funding, the high turnover of staff, and the shifting priorities of regional and state and/or provincial governments. As such, these organisations have developed a considerable absorptive capacity stemming from the need to adapt to frequent change.²²

Operationally, they identify three key features proven to be paramount for successful innovation and response in rural communities and care systems, captured in their “what” and “how” frameworks.²³ First, a high degree

¹⁹ Bronwyn H. Hall and Nathan Rosenberg, *Handbook of the Economics of Innovation* (Amsterdam: North Holland, 2010).

²⁰ Ibid. See also: Carolina Machado, J. Paulo Davim, and T.T. Benavides, “Social Media and Innovation: Opportunities and Challenges for Organisations,” in *Organisational Innovation in the Digital Age* (Springer, 2022).

²¹ Samuel Petrie et al., “What a Pandemic Has Taught Us about the Potential for Innovation in Rural Health: Commencing an Ethnography in Canada, the United States, Sweden, and Australia,” *Frontiers in Public Health* 9 (2021), <https://doi.org/10.3389/fpubh.2021.768624>.

²² Ibid.

²³ Ibid.

of collaboration and connection must exist. This collaboration is not only internal to the communities themselves, but also with the government on higher levels, private businesses, and social enterprises. Many of these connections already exist in the small places we studied, but our examples of success all included collaboration by numerous stakeholders. Second, a high level of familiarity and knowledge of *local* environments must be present. The axiom that all rural communities are unique appears to hold true, whereby knowing how services are used, who provides them, and who uses which services are essential to a programme's success and adaptation. Third, there must be creativity in how limited resources can be managed and adapted, including with the use of new technologies. The most successful examples we identified responded to a resource shortage with new technologies and an adaptation to the local community context.²⁴

In addition, their investigation shows the potential for innovation in rural communities and rural health and care systems.²⁵ Rural health and care systems can be loci of adaptation and innovation given their appropriate mix of local autonomy, strong service–community connections, high absorptive capacity, and evidence of organisational long-term stability.²⁶

Moreover, in a recent paper, Frankel et al. examine the role of spill-over learning in shaping the value of exploratory vs. incremental R&D.²⁷ Using data from the pharmaceutical industry, they show that novel drug candidates generate more dynamic spill-overs than incremental ones. That is, despite being more likely to fail in the development process, novel drugs are more likely to inspire the development of subsequent successful drugs.²⁸

Motivated by this fact, they develop a model where firms are better able to evaluate the viability of incremental drugs, but where investing in novel drugs helps firms learn about future related projects.²⁹ Their model provides an empirical diagnostic for assessing the relative value of evaluation

²⁴ Ibid.

²⁵ Ibid.

²⁶ Ibid.

²⁷ Alexander Frankel et al., *Evaluation and Learning in R&D Investment*, 2023, <https://doi.org/10.3386/w31290>.

²⁸ Ibid.

²⁹ Ibid.

vs. learning, namely that if firms place greater value on learning, they should then set a lower revenue threshold for investing in novel drugs relative to incremental ones.³⁰ Finally, they provide evidence suggesting that some of these patterns are driven by concerns about the appropriability of any spill-over knowledge.³¹

Patents exist to reward inventors for their new products and services and it is hence no surprise that pharmaceutical industries are highly oriented to profit, as reflected in the agreements they enter into. Inequalities in vaccine distribution were visible at the outset of the pandemic when those wealthier (like the USA, UK, or the EU) entered into advance purchase agreements with the jab developers.³² Agreements with individual vaccine producers guaranteed a number of vaccines to be delivered within a specific timeframe at an already agreed price. The contracting parties agreed to a down payment, which would then partially fund the research and development of the vaccines.

For instance, on the EU level it was decided to agree as a whole to ensure “a better hedging of bets, sharing of risks and pooling of investments to achieve economies of scale, scope and speed.”³³ The European Commission approved multiple advance purchase agreements to ensure its adaptiveness to new variant strains and preparedness for potential orders of additional doses in years to come.³⁴ It also called for a possibility to donate or re-direct vaccines to other countries within and outside Europe.³⁵ Nevertheless, the negotiations were not held public and all contracts (except for three

³⁰ Ibid. They in fact find that firms place less value on learning: they are less likely to invest in novel drugs and in turn, novel drugs have higher revenues on approval.

³¹ Ibid.

³² Olga Gurgula and Wen Hwa Lee, “Covid-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?,” *SSRN Electronic Journal* (2021): 61–70, <https://doi.org/10.2139/ssrn.3771935>.

³³ European Commission, “Questions and Answers: Coronavirus and the EU Vaccines Strategy,” September 24, 2020, accessed March 20, 2022, https://ec.europa.eu/commission/presscorner/detail/en/QANDA_20_1662.

³⁴ “Coronavirus: Commission Approves Contract with Valneva to Secure a New Potential Vaccine,” European Commission, September 22, 2020, https://ec.europa.eu/commission/presscorner/detail/en/QANDA_20_1662.

³⁵ Ibid.

since leaked online) are available only in redacted versions, which makes analysing them challenging.³⁶

Consequently, partly due to panic and partly the unprecedented scale of the situation, several privileged countries aimed to hoard the doses available for their citizens, forgetting that during a pandemic no one is safe unless everyone is safe.³⁷ Several academics have sought to explain such phenomena using behavioural science and, while not the focus of this paper, it provides a useful lesson for the future. Sibony underlines the issue of the lack of data surrounding the virus and the time-sensitivity of the issue, which prevented policymakers from conducting a proper cost-benefit analysis.³⁸ This merely added to the conflict between longer-term collective interest and short-term self-interests,³⁹ which many countries opted for – either individually or as part of the European community, separate from the low-income countries.

In addition, regulators must deal with the trade-offs between societal values (like health and privacy) and, simultaneously, pressure from future electoral voters.⁴⁰ The reasons stated above, according to Sibony, contributed to behavioural policymaking not based on evidence.⁴¹

By prioritising the immunisation of more privileged citizens, the chances of fulfilling the WHO goals of global herd immunity have declined significantly.⁴² Even though the agreements did allow for intellectual property

³⁶ The European Consumer Organisation, “Making the Most of EU Advance Purchase of Medicines,” 2021.

³⁷ “A Global Pandemic Requires a World Effort to End It – None of Us Will Be Safe until Everyone Is Safe,” World Health Organisation, September 30, 2020, <https://www.who.int/news-room/commentaries/detail/a-global-pandemic-requires-a-world-effort-to-end-it-none-of-us-will-be-safe-until-everyone-is-safe>.

³⁸ Anne-Lise Sibony, “The UK COVID-19 Response: A Behavioural Irony?,” *European Journal of Risk Regulation* 11, no. 2 (2020): 350–57, <https://doi.org/10.1017/err.2020.22>.

³⁹ Paul A. Van Lange, Jeff Joireman, and Manfred Milinski, “Climate Change: What Psychology Can Offer in Terms of Insights and Solutions,” *Current Directions in Psychological Science* 27, no. 4 (2018): 269–74, <https://doi.org/10.1177/0963721417753945>.

⁴⁰ Ibid.

⁴¹ Ibid.

⁴² “Strategy to Achieve Global Covid-19 Vaccination by Mid-2022,” World Health Organisation, 2021.

sharing,⁴³ they do not specify any other obligations of the pharmaceutical industries in this regard. As explained above, the solutions were, therefore, rushed and lacking in substance.

2.1. Consequences on the Global Level

The situation described above has led to the situation today: 73% of people are vaccinated in the EU or 66% in the USA, compared to only 14.5% of the citizens of low-income countries who have received at least one dose.⁴⁴ Vaccines have been wasted worldwide⁴⁵ and complaints have been made about the lack of transparency on the pricing point.⁴⁶ With headlines like “AstraZeneca did ‘not even try’ to meet Covid vaccine contract,”⁴⁷ one may deduce that the negotiations did not maximise the public’s return on the advance investment.

Danish Member of the Parliament Margrete Auken highlighted “The vaccine development is a success but pre-purchase agreements are not like a gift card for the industry to use without conditions.”⁴⁸ The pharmaceutical companies ultimately managed to shift the negotiations in their favour from liability exemptions for safety incidents to a lack of specific contractual clauses concerning the delivery schedules.⁴⁹ According

⁴³ “Advance Purchase Agreement (‘APA’)1 for the Development, Production, Advance Purchase and Supply of a COVID-19 Vaccine for EU Member States (SANTE/2020/C3/049),” European Commission, Directorate-General for Health and Food Safety, 2020.

⁴⁴ Edouard Mathieu et al., “Coronavirus (COVID-19) Vaccinations,” Our World in Data, March 5, 2020, https://ourworldindata.org/covid-vaccinations?country=OWID_WRL.

⁴⁵ Anne Damiani and Giedre Peseckyte, “EU Countries Are Throwing Away Expired Vaccine Doses,” EURACTIV, July 29, 2021, <https://www.euractiv.com/section/coronavirus/news/eu-countries-are-throwing-away-expired-vaccine-doses/>.

⁴⁶ Salvatore Sciacchitano and Armando Bartolazzi, “Transparency in Negotiation of European Union with Big Pharma on COVID-19 Vaccines,” *Frontiers in Public Health* 9 (2021), <https://doi.org/10.3389/fpubh.2021.647955>.

⁴⁷ Jon Henley, “AstraZeneca Did ‘not Even Try’ to Meet Covid Vaccine Contract, EU Tells Court,” *The Guardian*, May 26, 2021, <https://www.theguardian.com/world/2021/may/26/eu-seeks-court-order-for-astrazeneca-to-supply-vaccine-doses>.

⁴⁸ Giedre Peseckyte, “MEPs vs Commission in Court over Vaccine Contracts,” EURACTIV, October 29, 2021, <https://www.euractiv.com/section/coronavirus/news/meps-vs-commission-in-court-over-vaccine-contracts/>.

⁴⁹ The European Consumer Organisation, “Making the Most of EU Advance Purchase of Medicines,” 2021.

to the BEUC European Consumer Organisation, there is an urgent need for greater transparency of such discussions, with any exceptions being properly justified and assessed independently. There should also be more liability on the companies' shoulders for failing to meet the agreed production and distribution deadlines in the case of disrupted supply chains.⁵⁰

As may be observed, by co-funding the development of medicines and contributing to the extraordinary profit made by pharmaceutical companies, citizens of the world have not received that much in return. Due to inefficiently allocated resources, a lack of precedents, and questionable governmental intervention, we encountered a crisis within a crisis.

3. Patent Waivers and Incentives to Innovate

Notwithstanding that the COVID pandemic is of an unprecedented scale, there were already instances of smaller health emergencies where high-income countries hoarded the available medicines (e.g., the 2009 H1N1 influenza pandemic).⁵¹ As is widely known, we have not learned our lesson, inefficiently balancing the short- and long-term interests.⁵² Such inefficiency of the international health crisis management regime have encouraged ongoing discussions on other possible solutions – for both the current pandemic and future health emergencies. One of the most prominent voices suggested the temporary introduction of a patent waiver under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, initially introduced by South Africa and India in early October 2020.⁵³ TRIPS is probably the most comprehensive international legal agreement on intellectual property rights, applying to World Trade Organisation (WTO) member states. Its main aims are to allocate international transfers, ensure the uniformity

⁵⁰ Ibid.

⁵¹ David Brown, "Vaccine Would Be Spoken for; Rich Nations Have Pre-Existing Contracts," *The Washington Post*, May 7, 2019, <https://www.washingtonpost.com/wp-dyn/content/article/2009/05/06/AR2009050603760.html>.

⁵² Jay J. Bavel et al., "Using Social and Behavioural Science to Support COVID-19 Pandemic Response," *Nature Human Behaviour* 4, no. 5 (2020): 460–71, <https://doi.org/10.1038/s41562-020-0884-z>.

⁵³ Council for TRIPS, "Waiver from Certain Provision of the TRIPS Agreement for the Prevention, Containment, and Treatment of COVID-19 (IP/C/W/669)," World Trade Organisation, 2020.

of intellectual rights regulation, and promote access to medicines for all.⁵⁴ The latter was exactly what India and South Africa aimed to accomplish – in a landmark proposal, they enquired to suspend the IP rights linked to the COVID-19 inventions to balance the vaccine rollouts around the globe. The waiver was to cover all sorts of IP rights related to tackling the pandemic for, at least, the duration of the health crisis. According to both India and South Africa, a patent waiver would aid with the manufacturing, research and development, and distribution of the vaccines, in the end benefitting us all.⁵⁵

What explains why the patent waiver has been so heavily relied on as the best possible solution? Such a technology transfer allows for the sharing of innovative products, processes, and additional, otherwise protected, intellectual property goods. Under TRIPS, on the international level, a waiver would prevent countries from suing other countries over TRIPS non-compliance in instances where they have ceded their IP property rights at the national level.⁵⁶

Yet, it would also affect third parties and the unenforceability of intellectual property rights once implemented in domestic regulations.⁵⁷ COVID-19 would not be the first instance of using patent waivers – among the most popular examples, the United States Department of Energy often enforces patent waivers on products or processes that it has funded.⁵⁸ In the solution proposed by South Africa and India, the patent waiver would work similarly.

The reasoning behind introducing patent waivers in relation to COVID-19 is as follows: due to governments' contribution to developing the vaccine it should be regarded as a common good for the overall wealth of society.⁵⁹ In addition, with transborder issues such as a pandemic, as already mentioned, no one is safe unless everyone is safe. As stated in a key principle of economics, trade can make everyone better off, and at times

⁵⁴ Doha Declaration § (2005).

⁵⁵ Thambisetty et al., “The Trips Intellectual Property Waiver Proposal.”

⁵⁶ Johnson and Bailey, “Urgent Legal Lessons.”

⁵⁷ Ibid.

⁵⁸ 35 U.S. Code § 202.

⁵⁹ “4 Reasons Why Waiving Trips Is the Best Way to Beat COVID-19,” The Left, March 10, 2021, <https://left.eu/4-reasons-why-waiving-trips-is-the-best-way-to-beat-covid-19/>.

of scarce resources like a limited number of vaccines available (especially given their expiry date), the adequate distribution of the resource is crucial.

This means it would only be sensible to make it as accessible as possible, especially for low and middle-income countries otherwise unable to afford their batch of vaccines. As mentioned, the contract between the European Commission and the pharmaceutical companies also gives the latter free will to establish the prices, leaving already disadvantaged countries in a much worse position – a patent waiver is asserted to be able to solve this issue.⁶⁰

Pharmaceutical companies claim that patents are critical for them to make a profit, particularly when huge, rapid investments are needed in the research and development of a new type of medicine.⁶¹ As already outlined previously in this paper, big pharma had the upper hand when negotiating the contracts and managed to secure a very profitable and safe agreement. According to the European Commission, currently, only eight pharmaceutical companies have signed a contract (with not all vaccines yet approved for the general public or still being developed).⁶² This elite, closed group hands these organisations great oligopolistic power over the vaccine market in the European Union. From a Samaritan's point of view, health is not optional – it is a basic right and thus allowing big pharma to benefit from people's suffering is simply inhumane.

Prioritising the private interests of corporations over low- and middle-income countries, notably if the pandemic provides the former with astronomical sums of profit, does not make sense for most. Sadly, it does make sense to those who benefit from the present system and are actually controlling the market. This also largely explains why a patent waiver would not be suitable for fighting the ongoing pandemic as well as any future ones.

3.1. Patents and the Incentive to Innovate

In legal and economic terms, patent protection is an extremely powerful, sophisticated mechanism for providing incentives, and motives for creating

⁶⁰ Ibid.

⁶¹ European Commission, "Pharmaceutical Sector Inquiry Final Report," 2019.

⁶² "EU Vaccine Strategy," accessed March 21, 2022, https://commission.europa.eu/live-work-travel-eu_en.

new ideas, products, inventions, designs, and designs. Analytically speaking, a patent is a monopoly, a grant of exclusive rights in rem over intellectual creations, technical solutions, and inventions.⁶³ According to Douglas North (Nobel Prize winner for Economics), the establishing of these rights (patents) is also one of the most important foundations and reasons for Western civilisation's unparalleled success and prosperity.⁶⁴

Moreover, the adoption of the "Statute of Monopolies of 1623" (1623 c. 3, Regnal. 21 Ja 1) in Britain in 1623⁶⁵ is considered one of the core enablers of the Industrial Revolution and hence the unheard of economic growth, a real explosion of economic activity and the continuous increase in social well-being.⁶⁶ The granting of an exclusive right in rem (a monopoly) permits the creator of an idea to enjoy a large part of its social value.⁶⁷ This right in rem (assuming the strict and objective exercise of such rights) and the ensuing certainty that, if its technical invention is accepted by the market and economically viable, the inventor will be able to recover not only their initial "relation-specific" development costs, and the costs of manufacturing the product or invention, but also that they will be able to reap the benefits (if any) brought by that the product/invention – this ex ante opportunity for cost recovery and participation in potential profits are outstanding motivational mechanisms that act as incentives to potential inventors for their productive behaviour and innovation (which in the long run all increase economic activity, economic growth, and social well-being).

⁶³ Posner, *Economic Analysis of Law*.

⁶⁴ Douglass Cecil North, *Institutions, Institutional Change, and Economic Performance* (Cambridge: Cambridge University Press, 1990). See also: Douglass Cecil North, *Understanding the Process of Economic Change* (Princeton, NJ: Princeton Univ. Press, 2010).

⁶⁵ Harold G. Fox, *Monopolies and Patents: A Study of the History and Future of the Patent Monopoly* (Toronto: University of Toronto Press, 1947).

⁶⁶ Robert Cooter and Hans-Bernd Schäfer, *Solomon's Knot: How Law Can End the Poverty of Nations* (Princeton: Princeton University Press, 2012). See also: Douglass Cecil North, *Institutions, Institutional Change and Economic Performance* (New York: Cambridge University Press, 2017); North, *Understanding the Process of Economic Change*; Mancar Olson, *Power and Prosperity: Outgrowing Communist and Capitalist Dictatorships* (New York: Basic Books, 2000).

⁶⁷ Ejan Mackaay, *Law and Economics for Civil Law Systems* (Cheltenham, UK: Edward Elgar Publishing, 2021).

The granting of patent protection is, analytically speaking, through the grant of a title to a particular invention, in fact the grant of a monopoly over it.⁶⁸ Yet, since according to economic science every monopoly is theoretically and empirically (of course, except for a natural monopoly): extremely harmful, dangerous, a source of inefficiency, destructive of economic and economic activity, inhibitive/inhibits innovation, facilitates the appropriation of unjustified monopoly rents, enables moral hazard, opportunism and nepotism, and thereby directly reduces social well-being,⁶⁹ IP law must strike a balance between fostering innovation and the dissemination of ideas. This trade-off between providing incentives to innovate and preventing monopolies is also the main justification for the strictly limited time of patent protection (up to 20 years) and the evident rise in patent protection maintenance costs.⁷⁰

The legal and economic analysis therefore enables an understanding of the analytical reasons for granting these (otherwise economically damaging) time-limited monopolies since providing incentives for innovative and productive creation is so important that it also outweighs (for a short period of up to 20 years) the negative impacts of such a monopoly (monopoly annuity, reduced use and dissemination of such knowledge, possible opportunism and appropriation of unjustified annuities etc.). Monopolists accordingly enjoy annuities, profits over a normal return on investment, while the monopolies thus granted cause social costs by producing too few monopolised goods at an excessive cost.⁷¹ It also follows that the granting of patents – monopolies for “inventions” that are not true inventions, but merely blueprints of real inventions – is legally and economically unacceptable.

The granting of patents (monopolies) for such blueprints is a direct source of inefficiency, moral hazard and opportunism, transaction costs, and the adverse selection problem and in fact allows the rent-seeking behaviour to remain unjustified. In these cases, this amounts to a complete redistribution, re-distributive behaviour (and not the desirable productive

⁶⁸ Posner, *Economic Analysis of Law*; Cooter Robert and Thomas Ulen, *Law and Economics*, 6 ed. (Harlow: Pearson, 2016).

⁶⁹ Ibid.

⁷⁰ Mackaay, *Law and Economics for Civil Law System*; Cooter and Ulen, *Law and Economics*.

⁷¹ Posner, *Economic Analysis of Law*.

behaviour, like with “real” patents, which are genuinely new technological, innovative, and industrially applicable inventions that enhance social well-being) that directly reduce economic activity and social well-being. The granting of national patents, which are merely a copy, an imitation of some other foreign technical invention (thereby creating small national monopolies for which all incentives for creative, productive behaviour and investment are eliminated), is hence extremely damaging and devastating for the economy and the welfare of a given nation in the long run.

Finally, in an experimental study Vanneste, Van Hiel, Parisi, and Depoorter show that “anti-commons situations generate greater opportunistic behaviour than an equivalent commons dilemma, and anti-commons dilemmas yield a greater risk for underuse compared to commons dilemmas.”⁷² In other words, their behavioural and empirical study shows that the “tragedy of the anti-commons presents a greater social threat (underuse from blocking the use of resources by posting very high selling prices) than the commons dilemma (overuse of resources).”⁷³ They also argue that the anti-commons might be considered as holding even more serious and problematic consequences than the commons dilemma.⁷⁴

3.2. Patent Waivers as a Solution to Unequal Global Vaccine Distribution

Following the South African and Indian proposal, the G7 countries initially rejected the above approach, quoting several reasons.⁷⁵ The self-labelled “call

⁷² Sven Vanneste et al., “From ‘Tragedy’ to ‘Disaster’: Welfare Effects of Commons and Anti-commons Dilemmas,” *SSRN Electronic Journal*, 2004, <https://doi.org/10.2139/ssrn.548622>. See also: Francesco Parisi, Norbert Schulz, and Ben Depoorter, “Duality in Property: Commons and Anticommons,” *SSRN Electronic Journal*, 2003, <https://doi.org/10.2139/ssrn.224844>.

⁷³ Ibid.

⁷⁴ As they report, these results were obtained with “different methodologies (i.e., lab experiment versus scenario experiment), different research designs (i.e., simultaneous presentation of the two types of dilemma resulting in a within-subjects design versus presentation of different dilemmas in a between-subjects design), and different modalities (e.g., free bidding versus the use of a pay-off scheme), attesting to the stability of these findings and their broad generality”; Vanneste et al., “From ‘Tragedy’ to ‘Disaster’”

⁷⁵ “G7 Leaders Are Failing to Tackle Global Vaccine Access,” Amnesty International, August 8, 2022, <https://www.amnesty.org/en/latest/news/2021/02/g7-leaders-are-shooting-themselves-in-the-foot-by-failing-to-tackle-global-vaccine-access>.

for global solidarity⁷⁶ has faced criticism from the high-income countries, first due to concerns over the potential lack of quality of the new products – with the developer having no to little supervision over the manufacturing, there could be a potential risk of error or deficiencies.⁷⁷

Second, there is no sufficient proof that it is actually the intellectual property rights that have blocked the vaccine distribution – instead, it is more of an issue with other aspects such as politics and management over-doses, particularly those close to their expiry date. Third, and most importantly for the pharmaceutical companies, it would negatively affect innovation and block future life-saving inventions in the future.

To answer the first concern, even with the patent waiver, new manufacturers would still need to adhere to a strict regime and regulations on medical production. The lack of direct supervision by the developer would not mean complete freedom over the manufacturing conditions and not anyone off the street could simply obtain permission to start production.⁷⁸ Nevertheless, the G7 countries might be right when saying that there are more costs to allowing patent waivers than there are benefits. The European Federation of Academies of Sciences and Humanities released a statement pointing out that there are, indeed, other, faster ways of tackling the ongoing crisis. The core of the problem is not who and where owns a patent but the manufacturing capacities of low- and middle-income countries. For instance, even Moderna promised not to sue anyone for any breaches of its patent and there have indeed been developments based on its invention, sadly, with little manufacturing hitherto.⁷⁹ This might indicate that a problem graver than IP agreements is unequal financial and manufacturing capacities.

The above also provides an answer regarding the second criticism. The waste of expired vaccines in high-income countries⁸⁰ indicates although companies like Moderna or BioNTech have the manufacturing capacities

⁷⁶ Thambisetty et al., “The Trips Intellectual Property Waiver Proposal.”

⁷⁷ Santos Rutschman, “Property and Intellectual Property,” 110–32.

⁷⁸ Ibid.

⁷⁹ “Moderna’s Updated Patent Pledge,” Moderna, accessed September 15, 2023, <https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2022/Modernas-Updated-Patent-Pledge/default.aspx>.

⁸⁰ Johnson and Bailey, “Urgent Legal Lessons.”

they lack the support and coordination needed to distribute them to other countries. It has been suggested that what is needed is not an IP law revolution but aid in establishing new plants, ensuring the proper availability of raw materials, and incentivising cooperation between companies and governmental agencies to stimulate even the dispensing of resources.⁸¹ The answer for such supply in low- and middle-income countries is observable in recent decisions by Moderna or BioNTech to build manufacturing plants in Africa.⁸²

Another argument for why waiving patents is no answer is the fact that we actually face an oversupply of doses – as mentioned, a huge number of them have been wasted since the original rollout, even in low- and middle-income countries.⁸³ What we need is not only smoother coordination but also better awareness among citizens to actually accept the medicine. Such hesitancy is also a problem in poorer regions where disinformation prevents people from accessing the resources available.⁸⁴ It has been stated that, instead of changes in TRIPS, public resources would benefit more if invested in public campaigns and information initiatives.⁸⁵

One might also argue that the waiver proposal before the WTO is not well-tailored to the urgent vaccine problem and would require further national legislation to have any effect in practice. A waiver of this nature also raises questions about optimal statutory ex ante design of such a patent waiver.

⁸¹ The ALLEA statement on vaccination bottlenecks in the Global South and a patent waiver for the COVID-19 vaccines, accessed September 14, 2023, https://www.wto.org/english/tratop_e/covid19_e/allea_letter_e.pdf.

⁸² Kyle LaHucik, “BioNTech to Start Building Mrna Vaccine Manufacturing Plant in Africa in Mid-2022,” *Fierce Pharma*, October 26 2021, <https://www.fiercepharma.com/manufacturing/biontech-to-build-mrna-vaccine-manufacturing-plant-africa-mid-2022-plans-finalised>.

⁸³ Edward Mcallister, Libby George and Stephanie Nebehay, “Exclusive: Up to 1 million COVID vaccines expired in Nigeria last month,” *Reuters*, December 8, 2021, <https://www.reuters.com/business/healthcare-pharmaceuticals/exclusive-up-1-million-covid-vaccines-wasted-nigeria-last-month-2021-12-08/>.

⁸⁴ Olivier J. Wouters et al., “Challenges in Ensuring Global Access to COVID-19 Vaccines: Production, Affordability, Allocation, and Deployment,” *The Lancet* 397, no. 10278 (2021): 1023–34, [https://doi.org/10.1016/s0140-6736\(21\)00306-8](https://doi.org/10.1016/s0140-6736(21)00306-8).

⁸⁵ Frankel et al., *Evaluation and Learning in R&D Investment*.

Namely, the current waiver proposal might undermine the predictability and legal certainty of current IP rights. An arbitrary waiver of a patent right (where it is uncertain for which kinds of situations such a waiver might again be invoked) could induce uncertainty to such an extent that it implies a regulatory risk for pharmaceutical companies (direct and indirect costs), which in turn might deter the innovation and research activities of such companies.

3.3. Ongoing Developments

It is important to note that while this paper later analyses potentially more effective alternatives to tackling health emergencies the patent waiver talks are still underway. Just recently, a consensus was reached between the EU, USA, UK, and India on a waiver much more limited than what was originally proposed.⁸⁶ Instead of all innovations, the newest proposal would apply solely to vaccines – which holds the potential to work in the short-term with the COVID-19 pandemic; still, it does not solve any urgent future needs for other health crisis-related medicines.

The sole fact that such an agreement was made (still not officially approved yet) nearly half a year after the first talks about the patent waiver started indicates that the negotiating of patent waivers has not occurred fast enough to keep up with the pandemic. Even though the solution might bring some benefits, it is simply inadequate for dealing with such a fast-paced and urgent problem. The wording also still faces objections from countries with strong pharmaceutical sectors (such as Switzerland and the UK) and many vital elements (like the length of the waiver) have yet to be finalised⁸⁷ – and the clock is ticking. Since WTO proposals require the unanimity of all 164 members, it is likely that we are still a long way from seeing a widely accepted solution.⁸⁸ Even though in theory Article IX(3) of the WTO agreement

⁸⁶ Andrea Shalal and Emma Farge, “U.S., EU, India, S. Africa Reach Compromise on COVID Vaccine IP Waiver Text,” Reuters, March 16, 2022, <https://www.reuters.com/business/healthcare-pharmaceuticals/us-eu-india-s-africa-reach-tentative-pact-covid-vaccine-ip-waiver-sources-2022-03-15/>.

⁸⁷ Ibid.

⁸⁸ Frankel et al., *Evaluation and Learning in R&D Investment*.

permits decisions to be made with a three-quarters majority in exceptional circumstances,⁸⁹ in practice this is unlikely to happen.⁹⁰

4. Towards an Improved Regulatory Regime

As argued, the proposed patent waiver under discussion since 2020 within the World Trade Organisation (WTO) might not resolve these vaccination bottlenecks in the short term. Instead, additional measures should be adopted to accelerate the local manufacturing and distribution of vaccines in low- and middle-income countries, ramp up investment in vaccination campaigns, and facilitate the compulsory licensing of patents and transfer of know-how.

The conclusion that a TRIPS patent waiver is not an efficient solution means there is a need to consider other possibilities for fighting the pandemic. As mentioned, there is an urgent requirement to facilitate better coordination, raise overall awareness, and increase preparedness for coming health crises. The problem at the heart of the current crisis is the uneven concentration of manufacturing and research in high-income countries. The factor common to all of these suggested solutions is collaboration – there are few if any legal documents or agencies coordinating a pandemic on a global scale and everyone is therefore left on their own. This creates further economic inequalities, the uneven distribution of medical supplies, and a lack of fact-checked information. While the COVID-19 pandemic is truly on an unprecedented scale, it has shown us more than ever that it is better to be safe than sorry. Having experienced great losses, it is now the moment to think ahead of time and coordinate global actions in the event of a future global-wide health crisis. Below, the article first discusses potential contractual solutions in future negotiations before moving on to organised collective actions and compulsory licencing.

4.1. Enhanced Contract Negotiations

Especially in the advance purchase agreement between the European Commission and the pharmaceutical companies, there is a need for more concrete

⁸⁹ WTO Analytical Index, WTO Agreement – Article IX(3).

⁹⁰ Simon Lester, Bryan Mercurio, and Arwel Davies, *World Trade Law Text, Materials and Commentary* (Oxford, London, New York, New Delhi, Sydney: Hart Publishing, 2018).

and better-defined contractual obligations. The EU unified the actions of the Member States to do something that should have been done similarly on the global level – to assist poorer countries in the community to access the necessary medications by contracting as a single unity. Nevertheless, partially due to the unparalleled and rapidly developing situation, such agreements were not drafted as well as they should have been. By agreeing to co-fund, the vaccine developments as a pre-payment the European Commission sped up the process by compromising the negotiating power it could have. The agreements only provide very vague terms as to the sharing of spare vaccines, only broadly mentioning “intellectual property sharing”.⁹¹

This allowed the European Commission to make the purchased doses available to the global solidarity effort, yet it imposed no obligations on developers to aid with research and development or licence sharing with others.⁹² Although renegotiating and thus aiding in the current pandemic is highly unlikely now (despite a need to extend the agreements with some companies), regaining the negotiating power in future agreements would be vital. Given the considerable involvement of public funds, society should have the right to benefit from the medicines so funded. In the event of future health emergencies, governmental agencies should ensure that the public interest is satisfied and focus on greater transparency and vaccine sharing already included in the agreement.⁹³

4.2. International Response Mechanisms and Legislation

Several attempts have been made to assist the collaboration during the ongoing crisis and facilitate common information and cash flow. A new COVAX mechanism has been set up to aid with facilitating the export of spare vaccines, albeit donations are too small at the current moment.⁹⁴ This indicates the need for an organised mechanism and not a contribution based on free will. Thus far, two important developments have occurred in this area: the suggestion of a new, international treaty, and the newly

⁹¹ Love, “President and Minister of Health of Costa Rica.”

⁹² Frankel et al., *Evaluation and Learning in R&D Investment*.

⁹³ Ibid.

⁹⁴ The ALLEA statement on vaccination bottlenecks in the Global South and a patent waiver for the COVID-19 vaccines, accessed September 14, 2023, https://www.wto.org/english/tratop_e/covid19_e/allea_letter_e.pdf.

funded European Health Emergency preparedness and Response Authority (HERA). The “pandemic treaty” has been suggested by both the WHO and the European agencies. On the global level, such a treaty would be almost unmatched, with only the WHO’s Framework Convention on Tobacco Control (FCTC) having previously been used in international health cooperation.⁹⁵ The aforementioned document has become one of the widest treaties in the history of multinational collaboration,⁹⁶ possibly indicating the chances of success of a pandemic-oriented document.

According to Moon and Kickbusch, a successful international contractual agreement should have three implications. First, it must meet the self-interest goals of all countries involved.⁹⁷ With a pandemic knowing no borders and holding broad implications for international trade and travel, self-interest becomes the interest of us all. Therefore, such a mutually beneficial agreement has a probability of being respected by a broader community. Second, a treaty should be flexible enough to accommodate various levels of ambitions and willingness to share sovereignty.⁹⁸ The fact that enforcement on the international level can be tricky makes it hard to enforce certain provisions and, indeed, everything depends on a state’s willingness to obey the contractual agreement. It has been suggested that the treaty, instead of regulating the ongoing actions, should concentrate on deep prevention of the pandemic.⁹⁹ Since COVID-19 caused indescribable losses for the global economy, one can hope that countries will be willing to invest in preventing the next health crisis.

Yet, this would depend greatly on the specific wording of the treaty, still in the very early stages of its creation. Finally, a pandemic treaty must address the material conditions able to facilitate adherence, and not rely solely on the normative power of international rules alone.¹⁰⁰ As mentioned,

⁹⁵ Haik Nikogosian and Ilona Kickbusch, “The Case for an International Pandemic Treaty,” *BMJ*, 2021, <https://doi.org/10.1136/bmj.n527>.

⁹⁶ *Ibid.*

⁹⁷ Suerie Moon and Ilona Kickbusch, “A Pandemic Treaty for a Fragmented Global Polity,” *The Lancet Public Health* 6, no. 6 (2021), [https://doi.org/10.1016/s2468-2667\(21\)00103-1](https://doi.org/10.1016/s2468-2667(21)00103-1).

⁹⁸ *Ibid.*

⁹⁹ Jorge Vinales et al., “A Global Pandemic Treaty Should Aim for Deep Prevention,” *The Lancet* 397, no. 10287 (2021): 1791–92, [https://doi.org/10.1016/s0140-6736\(21\)00948-x](https://doi.org/10.1016/s0140-6736(21)00948-x).

¹⁰⁰ Sciacchitano and Bartolazzi, “Transparency in Negotiation of European Union.”

the pharmaceutical companies may have benefited from the panic surrounding the race to obtain the vaccines for citizens. So long as the treaty also includes provisions for quiet times, not only times of crisis, it has prospects of creating effective preventative measures in the future.

One can also consider the logic behind the creation of HERA. Since “no country can effectively prevent or tackle a cross-border public health crisis on its own”¹⁰¹, the European Commission has created a new body aimed at managing health emergencies before they develop and when they are underway. According to Stella Kyriakides, the Commissioner for Health and Food Safety, HERA will be a valuable centrepiece of the European pandemic defence, enabling an organised, joint response to the crisis.¹⁰² With a budget of EUR 5.3 million, the agency will allow for a centralised response from the European Commission. There has been criticism that in fact the Commission already has plenty of agencies that could undertake such a mission.¹⁰³ Indeed, responsibility for the pandemic has thus far been taken over by multiple departments within the Commission; nevertheless, it has not been efficient and has led to organisational disorder.¹⁰⁴ Now, with a dedicated budget and team, more thought can be put into the future contractual negotiations.

4.3. Compulsory Licensing and March-in Rights

A less extreme version of a technology transfer should be considered: compulsory licensing.¹⁰⁵ A compulsory license is granted by a government and allows the use of an invention without the agreement of the patent holder.¹⁰⁶

¹⁰¹ The territorial impact of Covid-19: Managing the crisis across ... – OECD, accessed September 14, 2023, <https://www.oecd.org/coronavirus/policy-responses/the-territorial-impact-of-covid-19-managing-the-crisis-across-levels-of-government-d3e314e1/>.

¹⁰² Sciacchitano and Bartolazzi, “Transparency in Negotiation of European Union.”

¹⁰³ Miriam Reiss, “High Hopes for Europe’s New Health Emergency and Response Authority,” *BMJ*, 2022, <https://doi.org/10.1136/bmj.o127>.

¹⁰⁴ Michael Anderson, Rebecca Forman, and Elias Mossialos, “Navigating the Role of the EU Health Emergency Preparedness and Response Authority (HERA) in Europe and Beyond,” *The Lancet Regional Health – Europe* 9 (2021): 100203, <https://doi.org/10.1016/j.lanepe.2021.100203>.

¹⁰⁵ Kovac and Rakovec, “The COVID-19 Pandemic and Long-term Incentives,” 292–316.

¹⁰⁶ “Medicines Law & Policy Research and Resources on Intellectual Property and Health,” Medicines Law Policy, August 21, 2022, <https://medicineslawandpolicy.org/>.

Even though the current TRIPS provisions permit such a transfer,¹⁰⁷ the national laws often do not provide a straightforward way of obtaining them.¹⁰⁸ Further, the process has not been very popular as high-income countries like the USA or Japan have not supported the process to protect the interests of their pharmaceutical companies,¹⁰⁹ even though it is something already included in TRIPS and does not impose any additional drafting costs. Moreover, the following system has already been used by Israel, Russia, and Hungary during the ongoing pandemic.¹¹⁰

Nevertheless, to ensure smoother licensing a “Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic” was suggested¹¹¹ to facilitate easier national regulation and incentivise the exchange of knowledge.¹¹² The following could complement the above solutions by enabling a case-by-case analysis of medicines needed on a national level, depending on the current need. It is also important to add that, apart from patents, more attention should be paid to the sharing of trade secrets – there is presently no agreement on compulsory trade secret transfers and the creation of one could allow for better transparency.¹¹³

Still, it has been stated that patent waivers or compulsory licensing are in any case unlikely to help countries lacking manufacturing capacity¹¹⁴ – which is why it is crucial to first and foremost ensure the proper coordination of transfers between countries with better production facilities and

¹⁰⁷ The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) (1994), art. 30, 31 and 31.

¹⁰⁸ Gurgula and Lee, “Covid-19, IP and Access,” 61–70.

¹⁰⁹ “Compulsory Licenses, the Trips Waiver, and Access to Covid-19 Medical Technologies,” Médecins Sans Frontières Access Campaign, accessed September 15, 2023, <https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies>.

¹¹⁰ Ibid.

¹¹¹ P/C/W/680 Council for trade-related aspects of intellectual property, accessed September 14, 2023, <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q/IP/C/W680.pdf&Open=True>.

¹¹² Gurgula and Lee, “Covid-19, IP and Access,” 61–70.

¹¹³ Olga Gurgula and John Hull, “Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer,” *Journal of Intellectual Property Law & Practice* 16, no. 11 (2021): 1242–61, <https://doi.org/10.1093/jiplp/jpab129>.

¹¹⁴ “Interfering with Patent Protection Means Playing with Fire,” Max-Planck-Gesellschaft, March 15, 2021, <https://www.mpg.de/16579491/patent-protection-vaccines-covid-10-reto-hilty>.

those with lesser abilities, on top of aiding the development of manufacturing in low and middle-income countries.

To sum up, there is a need for improved procedures and institutional design should help to streamline the process for the compulsory licensing of pharmaceutical products, including vaccines.

4.4. Trade Secrets, Market Exclusivity, Production Bottlenecks and Competition Law

The ultimate problem actually concerns how to make vaccines more available to non-developed nations around the globe. Namely, how to achieve the allocative efficiency of the COVID-19 vaccines. As argued, the waiver of patent rights might not solve the problem and, due to its adverse effects on innovative activity, actually be counterproductive. That is, what matters for vaccine availability and worldwide production is in fact not the “recipe” for the vaccine but the know-how for using it – that is more expensive and harder to imitate.¹¹⁵ According to Stephane Bancel, Moderna’s chief executive, “There is no mRNA in manufacturing capacity in the world. [...] This is a new technology. You cannot go hire people who know how to make the mRNA. Those people don’t exist”¹¹⁶.

Alongside the issues of manufacturing capacity and scientific know-how, it is notable that it is not easy to make vaccines. Current anecdotal evidence shows that the barriers in terms of knowledge, experience, and money to producing vaccines, even if the recipe is freely available, are much more significant than patent waivers for enabling global vaccine availability. As Tabarrok shows, throughout the world wherever there is the capacity to produce vaccines licenses have been obtained and vaccines are being

¹¹⁵ For example, as far as Moderna is concerned, a patent waiver is irrelevant. Namely, on 8 October 2020 the company announced that “while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic”; Michele Boldrin and David K. Levine, “Should Patents on Covid-19 Vaccines Be Waived?,” *Science, Technology and Innovation*, 2021.

¹¹⁶ Ibid. Duckett also argues that “If you’re point one of a pH unit out, that can be enough to massively disrupt your productivity. Other factors can be cell culture medium, process timing, pH, carbon dioxide concentration, oxygen control, and mixing time to name a few. [...] I worked with one process – if there was a slight overshoot on temperature because the PID loops [proportional–integral–derivative – a feedback control mechanism] weren’t correctly tuned, the cells would stop producing”; Adam Duckett, “What Is Causing AstraZeneca’s Vaccine Production Woes?,” *The Chemical Engineer*, 2021.

produced the problem is not patents but that producing more takes real resources not waving magic patent wands.¹¹⁷

As he shows, the mRNA technology is new and has never been used before to produce at scale. Pfizer and Moderna had to build factories and distribution systems from scratch. There are no mRNA factories idling on the sidelines. If there were, Tabarrok argues, Moderna or Pfizer would be happy to license since they are producing in their factories 24 hours a day, 7 days a week.¹¹⁸ Further, even Moderna and Pfizer do not yet fully understand their production technology, they are learning by doing every single day.¹¹⁹ The patent (recipe) is hence only half the story and the know-how is also crucially important. This would not necessarily be transferred for free, nor is it at all obvious how this could be shared.¹²⁰

In this respect, the EU Commission's argument that the single-most effective way to achieve universal access is to ramp up production, share more vaccines, and make them affordable¹²¹ is in line with the law and economics argumentation. A waiver (in the sense of the co-sponsored proposal at the WTO) of IP protection, including of trade secrets, would never make this know-how publicly accessible, but only remove the possibility of companies enjoying confidentiality protection to sue for trade secret infringement.

¹¹⁷ Alex Tabarrok, "Patents Are Not the Problem!," *Current Affairs, Economics, Law, Medicine*, 2021.

¹¹⁸ *Ibid.*

¹¹⁹ Moderna has said that they won't enforce their patents during the pandemic but no one has stepped up to produce because no one else can; *ibid.*

¹²⁰ As Morgan Stanley analysts detailed in a research note, there is no mechanism "to force management to teach other manufacturers how to make their vaccine, suggesting no change to the status quo"; Carl O'Donnell and Manas Mishra, "Moderna Sees No Impact on COVID-19 Vaccine from Potential Patent Waiver," Reuters, May 6, 2021, <https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-raises-2021-sales-forecast-covid-19-vaccine-192-bln-2021-05-06/>.

¹²¹ EU Commissioner Dombrovskis stated that the EU's plan had three elements: a) export restrictions should be kept to a minimum; b) vaccine producers and developers should also make concrete pledges to increase supply to vulnerable developing countries at production cost; and c) existing WTO rules – compulsory licences – already allow countries to grant licences to manufacturers even without the consent of the patent-holder.

Fixing the supply chain problems, increasing manufacturing capacity, and alleviating bottlenecks might thus prove to be crucial instruments for ensuring global vaccine availability. The problem of production and supply chains is currently a global one and finding solutions to improve the production and distribution (and not the “magic patent waiver”) both in the present crisis and beyond may be one of the most important tasks that international stakeholders face.

The direct or indirect exchange of information between competitors under the EU’s competition rules is a particularly controversial issue, raising one of the most challenging competition law questions.¹²² The biggest change here is the replacement of the centralised notification system with a “legal exemption system”.¹²³ The horizontal effect of the EU’s new legal exemption system upon the provision of stable and optimal incentives (dynamic efficiency) to innovate has largely been left out of the current scholarly debate.

Namely, the legal exemption system and the associated threat of *ex post* punishments may introduce *ex ante* uncertainty and generate negative effects in terms of information production and innovation as concerns the COVID-19 vaccine. The fact that firms can no longer apply for a negative clearance and must self-assess the legality of their cooperation

¹²² Matthew Bennett and Philip Collins, “The Law and Economics of Information Sharing: The Good, the Bad and the Ugly,” *European Competition Journal* 6, no. 2 (2010): 311–37, <https://doi.org/10.5235/174410510792283754>; Antonio Capobianco, “Information Exchange under EC Competition Law,” *Common Market Law Review* 41, no. 5 (2004): 1247–76, <https://doi.org/10.54648/cola2004047>; Information Exchanges Between Competitors under Competition Law, DAF/COMP (2010)26; OECD; Okeoghene Odudu, “Indirect Information Exchange: The Constituent Elements of Hub and Spoke Collusion,” *European Competition Journal* 7, no. 2 (2011): 205–42, <https://doi.org/10.5235/174410511797248324>.

¹²³ Council Regulation no. 1/2003 on the implementation of the rules of competition laid down in Articles 101 and 102 of the TFEU (the ‘Modernisation Regulation’). The new Council Regulation, which came into effect on 1 May 2004, replaces Council Regulation No. 17 which had been in force for over 40 years and been the key to the enforcement of Community competition law (for a synthesis, see Müller, 2004). New Regulation No. 1/2003 thus replaces the centralised notification and authorisation system with an enforcement system based on the direct application of Articles 101 and 102.

introduces the risk that they might refrain from engaging in efficient forms of information exchange.¹²⁴

Further, the block exemptions introduced to categories of research and development indeed reduce the uncertainty for some firms, but not for all given that legal uncertainty remains high as the existing market share threshold and definition of the relevant market are difficult to determine *ex ante*. The present case law on information sharing may itself also increase *ex ante* uncertainty and thus produce a chilling effect on entrepreneurial activity because any information sharing might, in certain circumstances, infringe the EU's competition rules.¹²⁵

Information that is not historical and relates to matters like price, capacity, and cost is commercially sensitive and its exchange is therefore more likely to infringe than other types of information. The exchange of individual data about particular undertakings is more problematic than aggregated data. Another relevant factor is the frequency of any information exchange. A survey of several landmark decisions shows that practically any type of information directly or indirectly capable of being seen as collusive behaviour cannot be exchanged without causing concerns for the EU's competition authorities.

Obviously, the application of such wide, all-inclusive, and vague criteria concerning when an exchange of information between undertakings may be regarded as an infringement of Article 101 TFEU may be a source of uncertainty and a needless rise in transaction costs.

The second source of uncertainty, as already stressed, arises from the adoption of the new "self-assessment system", which in reality has exacerbated the problem. This self-assessment system could, as already noted, actually be the most problematic for horizontal entrepreneurial activity because firms face a high level of uncertainty.

One should also mention the overlooked problem of "market exclusivity" under which orphan medicines in addition to the awarded patent

¹²⁴ The horizontal sharing of knowledge (information), and enhancement of information flows between undertakings and cooperation appear to be fundamental for creating the dynamic evolution of markets, improving cost-efficient processes, and enhancing social welfare.

¹²⁵ Mitja Kovac and Patricia Kotnik, "Self-Assessment System: Detrimental Effects upon Entrepreneurial and Innovative Activity," *SSRN Electronic Journal*, 2013, <https://doi.org/10.2139/ssrn.2221811>.

protection benefit also from 10 years of market exclusivity once they receive marketing authorisation in the EU.¹²⁶ This measure is intended to induce the development of medicines for rare diseases by protecting them from competition from similar medicines with comparable indications, which cannot be marketed during the exclusivity period.¹²⁷ Peabody et al. argue that such market exclusivity is the key incentive for orphan drug research, and should be retained.¹²⁸

They also suggest that in the future exceptionally high profits could be limited by a more precise evaluation of disease prevalence, the elasticity of demand, and the other uses of orphan compounds.¹²⁹ The mentioned authors further recommend an expansion of the tax credits and research grants programme and the targeting of “priority” diseases.¹³⁰ They conclude that while market exclusivity has been a valuable legislative initiative, it could be strengthened with some simple extensions of the current incentives that it contains. However, such market exclusivity should never be awarded for medicines (vaccines) developed to tackle outbreaks of pandemics since such diseases are not rare and hence market forces and patent protection provide effective incentives to innovate. In other words, extending such market exclusivity to pandemic-related vaccines will indeed provide an obstacle to such vaccines being generally and rapidly available.

Finally, it is hard to imagine that one policy lever would be sufficient or indeed minimally capable of inducing the desired outcomes. Instead, a combination of instruments in various legal fields (and even

¹²⁶ Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1), last amended by Regulation (EC) No 596/2009 (OJ L 188, 18.07.2009, p. 14). See also: Laura Fregonese et al., “Demonstrating Significant Benefit of Orphan Medicines: Analysis of 15 Years of Experience in Europe,” *Drug Discovery Today* 23, no. 1 (2018): 90–100, <https://doi.org/10.1016/j.drudis.2017.09.010>.

¹²⁷ Todd Gammie, Christine Y. Lu, and Zaheer Ud-Din Babar, “Access to Orphan Drugs: A Comprehensive Review of Legislations, Regulations and Policies in 35 Countries,” *PLOS ONE* 10, no. 10 (2015), <https://doi.org/10.1371/journal.pone.0140002>.

¹²⁸ John W. Peabody, Allen Ruby, and Peter Cannon, “The Economics of Orphan Drug Policy in the US,” *Pharmacoeconomics* 8, no. 5 (1995): 374–84, <https://doi.org/10.2165/00019053-199508050-00002>.

¹²⁹ Ibid.

¹³⁰ Ibid.

non-legal instruments such as direct expenditures to subsidise certain stages in the process) is likely to be a more appealing strategy. Namely, as shown, a patent waiver in isolation is very unlikely to prove effective since a reduction in the price for final buyers (governments, most likely) or even for potential competitors (e.g., generic drug producers with manufacturing capabilities), although helpful, probably will not be enough to provide timely and effective access to relevant medical products.

Perhaps it is even not the most powerful instrument in the short run. One may think of public prizes and subsidies to successful inventors, coupled with risk coverage of potential litigation by the government and with a targeted industrial policy focusing on having capabilities for drug manufacturing at short notice as tools that may bring more powerful effects in the short run.

We accordingly suggest that the pace and reach of vaccines in the COVID-19 pandemic have not been solely influenced – perhaps negatively – by the exclusive rights of patent holders and the current IP law should thus not be seen as an obstacle or cause of the limited availability of relevant medical products.

Other factors may have been equally or even more important in slowing down the vaccination process in many countries, taking as a given the time in which the vaccines were scientifically available such as, for example: a) capacity constraints in the production of dosages; b) costs of coordinating the production processes in various plants; c) costs of coordinating the vaccination campaigns, or opposition to them; d) and the lack of effective redistribution of excess production in certain locations. In the face of a new pandemic disease, in terms of incentives for inventing vaccines and therapies, and having them ready for production and distribution, societies would ideally desire: a) very powerful and quick incentives for obtaining the invention; b) legal mechanisms to circumvent the disincentives to prompt availability arising from concerns with side effects and liability; and e) and legal rules that speed up and facilitate access to the products on a large scale.

5. Conclusion

The COVID-19 pandemic was both unexpected and expected. Although we have faced similar health emergencies in the past, this one was of a truly unprecedented scale and impacted not only the developing countries but also their richer neighbours. Contract law can be a powerful weapon in fighting a pandemic if used wisely, especially given the transborder nature of the issue in question. Citizens can only hope that the contracting governmental agencies have learned from their mistakes and will aim to not only ensure a proper mechanism for the future but also enter into agreements that benefit both sides of the table. Namely, as the world is just beginning to recover from the devastation of COVID-19, the possibility of a pandemic of a far more deadly pathogen is looming.

This paper has examined whether other effects may be associated with the patent waiver, if other problems arise concerning having fast and widespread access to vaccines and therapies unrelated to patent protection, and investigated some alternative or complementary instruments that could be considered to improve outcomes in a health emergency and prepare better for future emergencies. It was suggested that effective procurement contracting by governments, the narrow application of market exclusivity rights, compulsory patent licences, avoidance of bottlenecks in production, and facilitation of information exchange by potential inventors through relaxed antitrust rules on this matter might be effective tools that preserve the dynamic incentives to innovate and secure timely availability and access to relevant medical products. Moreover, patent waivers may not be an effective policy tool for accomplishing the desired goals in the face of pandemics and related emergencies.

Further, the paper has also looked at the current contractual agreements in place and critically assessed them. The findings demonstrate that the intertwined static, dynamic efficiency and the *ex ante* vs. *ex post* optimal incentive stream can contribute to the ongoing discussion surrounding IP rights with regard to current and future outbreaks of dangerous pathogens. Insightfully, it has been suggested in the paper that the patent waiver is sadly not the knight in shining armour that everyone has been expecting. Due to the lack of coordination, the tremendously long process, and the potential block in innovation caused by the smaller incentives to

pharmaceutical companies, more attention should be given to other alternative solutions.

In addition, the biggest challenge facing governmental organisations is the absence of unified resources and power to ensure the smooth transfer of vaccines between those with enough resources to manufacture them and those who cannot afford to do so. Emphasis should also be given to aiding the manufacturing process in such low- and middle-income countries. Solutions like COVAX or HERA are a step forward in tackling future pandemics and other health emergencies. “Pandemic treaties” could also facilitate smoother collaboration and assure that agencies are prepared for future crises. The above could be complemented by compulsory patent and trade secrets licensing, with the former already being put in place via the TRIPS agreement. In the event of transborder issues, greater emphasis should be given to collective, long-term solutions rather than individual short-term gains.

The above nonetheless does not mean that certain exceptional and temporary adjustments of IP laws could not form part of the policy toolbox deployed to achieve health goals. Still, it is clear that changes in IP laws should not be left to ex post adoption once a health emergency is knocking on the door, especially if such adoption requires consensus or faces important administrative costs. Informed lawmakers would prefer instruments that can operate automatically to “reduce” the exclusionary rights of patent holders and lower prices for increasing production to reach populations in need of vaccines and therapies as soon as possible: replacing property-rule protection with liability-rule protection, in the form of compulsory licenses and temporary takings of the IP rights against fair compensation may seem more appropriate.

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