

The COVID-19 vaccine patent: a right without rationale

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ABSTRACT

Since the approval of COVID-19 vaccines, international efforts have intensified on vaccination schemes perceived as the only light at the end of the tunnel. Governments are working tirelessly to scale up the number of vaccinated people, just as vaccine manufacturers are stretching their facilities to meet the increasing demand for doses. The international community is trying to help the poorest countries in the world by improving vaccine supplies and removing obstacles. In this regard, India and South Africa have applied to World Trade Organisation to waive vaccine-related intellectual property rights. The proposal has sparked off academic debates as to its merit. This article addresses the waiver controversy. Following a critical review of both dimensions of the controversy, the article concentrates on the extent to which the waiver application contradicts the theoretical justification of the patent system. It concludes that the concerns raised over the conflict between the waiver proposal and the patent right philosophy are indefensible.

INTRODUCTION

In October 2020, India and South Africa applied to the World Trade Organisation (WTO) for a waiver from its rules concerning intellectual property rights. The rationale for that application was that, 'an effective response to the COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators as well as vaccines and medicines for the prevention and treatment of patients in dire need', adding that 'as new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns how these will be made available promptly, in sufficient quantities and at affordable prices to meet global demand' (Waiver From Certain Provisions of The TRIPS Agreement for The

Prevention, Containment and Treatment of Covid-19 Communication From India and South Africa 2021). As a result, the proposal demanded 'a waiver from implementation, application and enforcement' of some provisions of the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

Generally speaking, the TRIPS Agreement sets out the legal basis for waivers. Article IX.3 of that instrument states that, 'in exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade Agreements'. Under Article IX.4, 'a decision by the Ministerial Conference granting a waiver shall state the exceptional circumstances justifying the decision, the terms and conditions governing the application of the waiver and the date on which the waiver shall terminate'.

Despite a slow start, the patent waiver proposal later gained traction. In May 2021, the USA shifted from its initial reluctance to eventually support the commencement of talks about patent waiver related to COVID-19 vaccines (Even after US Shift, Opponents Resist COVID-19 Vaccine Patent Waiver—CNA 2021). China and Russia soon followed the US' step towards the tackling of the pandemic. The waiver proposal is now believed to be backed by about 100 countries (It's Time to Consider a Patent Reprieve for COVID Vaccines 2021). Nevertheless, many high-income countries are still reluctant to back the proposal. A similar divergence of views is evident in the academic realm. This article reviews the main arguments of both the proponents and the opponents of the patent waiver application. It concludes that the unease expressed over the potential conflict between the waiver proposal and the patent right philosophy is unwarranted. However, compelling the rationale for patent protection may be, in the face of a global emergency like COVID-19, public health must trump patent right.

THE COVID-19 PATENT WAIVER DEBATES

Advocates of the waiver of COVID-19 patents rely on multiple premises to substantiate their position (figure 1). First,

is that the right of access to vaccines is one of the vital components of the human right to health, which must be prioritised over intellectual property rights. The TRIPS provisions must not be construed or applied in a manner that undermines the right of all peoples to access vaccines in an affordable, fair and equitable way. In this regard, it is worth noting that Article 7 of the TRIPS Agreement provides that the 'protection and enforcement of intellectual property rights' shall be 'in a manner conducive to social and economic welfare'.

Consequently, private profit shall be sacrificed for the sake of public health. In December 2020, the Office of the UN High Commissioner for Human Rights urged companies to be alert to their social responsibility and to engage conscientiously in the fight against the pandemic, calling on them to deem vaccines as public goods (Human rights and access to COVID-19 Vaccines 2020). This call seems reasonable, considering that public spending played a crucial role in supporting the creation of the patented vaccine inventions (Sariola 2021). In the context of the COVID-19 pandemic, it is argued that intellectual property rights tend unjustifiably to protect industry and profit over public health (Sariola 2021).

The second argument of the waiver backers is that, although one of the main goals of patent protection is to give patentees a privilege against competitors, in the context of a pandemic like COVID-19, global health and not competition is the priority (It's Time to Consider a Patent Reprieve for COVID Vaccines 2021). Patent right is a reward for the disclosure of inventions. Yet, the disclosure of vaccine patents is asserted to be unsatisfactory. Furthermore, public access to patent applications is justifiably delayed. Moreover, overlapping patent applications with only slight variance tend to create patent thickets that preclude competitors from further research and development, which could otherwise benefit society (Thambisetty et al 2021).

Supporters of the patent waiver proposal also contend that vaccine producers have tried to profit unfairly from the freedom of pricing (Thambisetty et al 2021). According to them, TRIPS paves the way for patent holders to determine prices for their products, which can be kept high and beyond the reach of patients who need them more. For instance, Astra-Zeneca sold its vaccines for US\$2.16 per dose to the EU market, while selling the same for US\$2.25 per dose to South Africa (Sariola 2021). Although another

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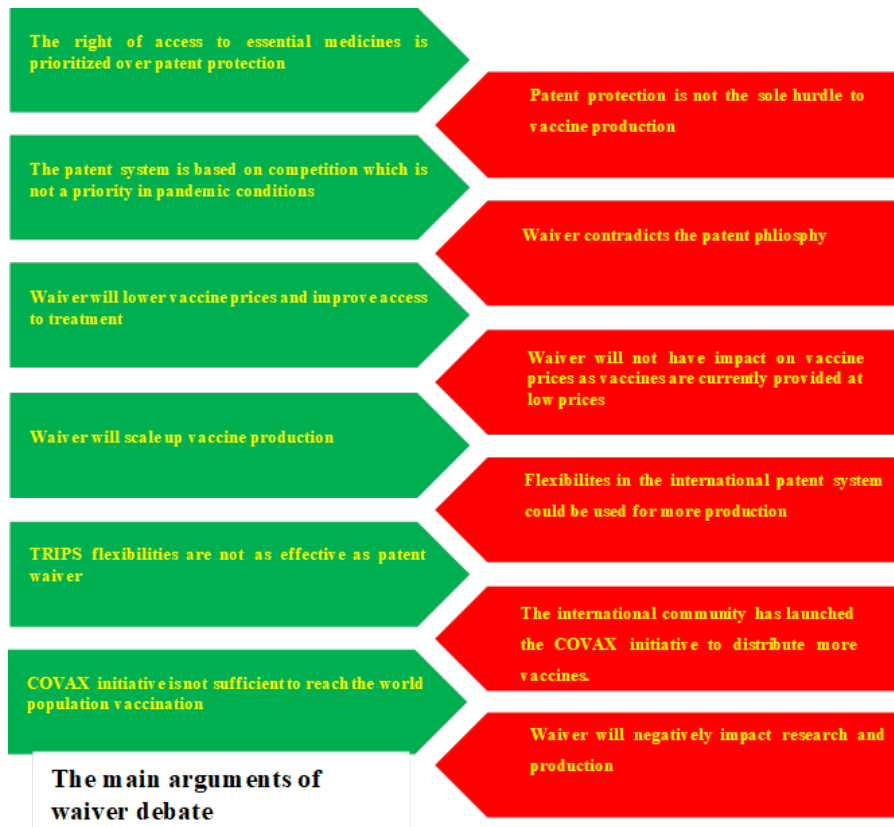


Figure 1 The main arguments of waiver debate.

pharmaceutical giant, Pfizer, promised to provide vaccines at a low price or for free to low-income countries, the contract between that company and the Dominican Republic reflects the opposite (Binagwaho, Mathewos, and Davis 2021). Vaccine producers have, no doubt, made a considerable amount of profit. This is despite the significant public funding received for their research and development that produced the vaccine inventions (It's Time to Consider a Patent Reprieve for COVID Vaccines 2021 (Sariola 2021). Cross et al (2021) reported, for example, that over 97% of the funds employed in the research and development process leading to the invention of the AstraZeneca vaccines was public. It is estimated that public funds amounting to over US\$100 billion were spent on the development of vaccines (Thambisetty et al 2021).

Statistics on the progress of vaccination were relied on to support the waiver proposal. The world shall vaccinate 70% of its population to ensure a safe return to normalcy (It's Time to Consider a Patent Reprieve for COVID Vaccines 2021). Yet, by March 2022, 50 countries with 20% of the world's population just received 7.7% of vaccines (More Than 11.1 Billion Shots Given: Covid-19 Vaccine Tracker 2022). WHO estimates that just 0.03 went to

low-income countries (Iacobucci 2021). It is believed that the pattern of the current vaccination schemes will leave some poor countries unvaccinated until the end of 2023 (Binagwaho, Mathewos, and Davis 2021). Even more disturbing is that some African countries will only reach the vaccination programme by 2040 (A Patent Waiver on COVID Vaccines is Right and Fair 2021). Patent rights and fears of costly infringement suits have restricted research, manufacture and supply of vaccines needed to tackle the COVID-19 pandemic (Contreras et al 2020). Approval of the patent waiver application would surely help countries that have manufacturing facilities to produce vaccines and export them to needy countries (Ranjan 2021).

Despite the merit of the above arguments and the noble goal that underpins them, other researchers raise opposing voices. The first and most common adversarial argument is that patent protection is not the obstacle to vaccine production. Opponents of the waiver proposal stress that waiver will not quicken the manufacture of vaccines (Ouellette et al 2020). There is a low supply of raw materials and lack of capacity to produce vaccines (Hilty et al 2021). More than just patent waiver, vaccine production requires the availability of vaccine components, training

of people and enactment of suitable legislation, all of which will take some time (It's Time to Consider a Patent Reprieve for COVID Vaccines 2021). Furthermore, vaccine patents are also accompanied by other intellectual property rights, such that the waiver of patent rights alone will not solve the production problem (Bostyn 2021).

More significantly, there is knowhow that should be disclosed, without which patent waiver will be fruitless (Hilty et al 2021). In other words, for waiver to be useful, patent holders must agree to share their knowhow and transfer the relevant technology (Santos Rutschman and Barnes-Weise 2021). In the same vein, vaccine production requires authorisation from health authorities, which is normally based on evidence presented by the manufacturer that the medicine is safe for human use. Producers of COVID-19 vaccines can help local partners to fulfil this requirement only if there is patent protection. Patent waiver will minimise prospects for such cooperation (Hilty et al 2021). Additionally, opponents of patent waiver argue that it is an extreme measure, and should only be a solution of last resort to the lack of vaccine supply (Hilty et al 2021; Mercurio 2021).

Some flexibilities are available to confront health crisis (Ranjan 2021). The TRIPS regime allows compulsory licensing during emergencies. This tool can be used to facilitate vaccine manufacture (A Patent Waiver on COVID Vaccines is Right and Fair 2021). According to one study, between 2001 and 2016, out of 144 cases in which countries applied for TRIPS flexibilities, 100 of them used compulsory licensing (Ranjan 2021). Supporters of patent waiver contend, however, that compulsory licensing is restricted under Article 31 of the TRIPS Agreement. First, it requires negotiation between applicants and patent holders (Sariola 2021). Second, there is an obligation to pay compensation to patent holders, which will exert a heavy burden on low-income and middle-income countries in pandemic situations. Lastly, many other countries in need of treatment, but without production capacity, will not benefit from compulsory licensing as production must be reserved exclusively for the applicant's domestic market (Ranjan 2021). Thus, the compulsory licensing flexibility is a time-consuming and complex process (Thambisetty et al 2021).

A further argument advanced by opponents of patent waiver is that this option will not lower vaccine prices. First, vaccine producers have already indicated

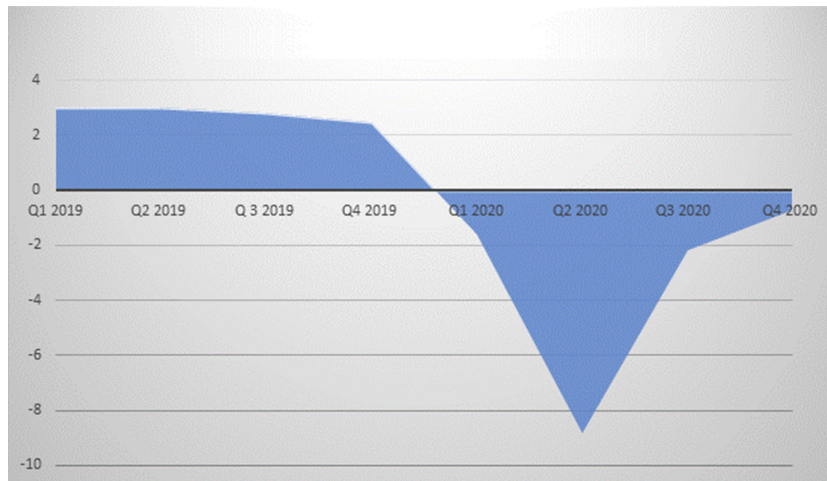


Figure 2 Gross domestic product (GDP) in G20 in 2019–2020.

that they will provide vaccines based on a non-profit approach. Second, vaccine prices are dictated by the cost of intellectual property and by the expensive technologies used in the production process (Hilty et al 2021).

To combat the spread of COVID-19, numerous holders of intellectual property rights voluntarily allowed users worldwide access to such rights without any payment or threat of infringement litigation. Also, vaccine producers and rich countries backed a scheme called COVAX, meant to supply 2 billion doses to vaccinate poor communities in 2021 (COVAX Joint Statement: Call to Action to Equip COVAX to Deliver 2 Billion Doses in 2021). Nonetheless, there were reservations over the capacity of COVAX to reach its target (It's Time to Consider a Patent Reprieve for COVID Vaccines 2021). Eventually, it just administered 900 million doses by the end of 2021 (Akhtar 2022). According to critics, COVAX has been unable to remove the global injustice experienced in respect of access to vaccines (Sariola 2021; Thambisetty et al 2021; Holzer et al 2022).

Perhaps, the main argument put forward by those averse to patent waiver is that it will constitute a hurdle to drug innovation, which is essential to tackle the emergence of COVID-19 variants (Hilty et al 2021; Mercurio 2021). Vaccine producers are adamant that unpermitted copying will endanger public health and increase the risk of the emergence of new viruses (Baachus 2020). The widely deployed justification for patent protection is to compensate inventors for their breakthroughs, as well as encourage them to continue to contribute to economic growth and the diffusion of innovative technology both domestically and globally (Baachus 2020).

Waiver contradicts the justification of the patent system and undermines its goals as it might be exploited by competitors to obtain the expensive technologies that were used in the invention of vaccines (A Patent Waiver on COVID Vaccines is Right and Fair 2021). Rewarding inventors and persuading them to put more funds in underfunded fields is more important than waiver (Santos Rutschman and Barnes-Weise 2021). The European Federation of Pharmaceutical Industries and Associations (EFPIA) raises the concern that waiver will endanger the supply of raw materials by directing it to less-qualified producers. The result will be low-quality vaccines (EFPIA/Vaccines Europe Statement on IP Waiver for COVID-19 Vaccines—Vaccines Europe n.d.).

Finally, it is argued that the USA and other high-income countries will not back a limitless waiver. Time and scope limited waiver could be a solution, but this also takes considerable time as the decision-making procedure in the TRIPS system is cumbersome and time-consuming (Mercurio 2021). Unless there is a consensus among WTO members, to reach an agreement on waiver will involve long-drawn negotiations (Baachus 2020).

THE JUSTIFICATION OF THE PATENT SYSTEM IN THE COVID-19 CONTEXT

One of the main points raised against patent waiver is that it conflicts with the justification of the patent system as a whole. As mentioned earlier, waiver supporters do not deny this fact. Nevertheless, they maintain that patent protection must be reconciled with public health and the right of access to essential vaccines. It seems that, while advocates of patent waiver view it as a temporary expedient

for tackling the COVID-19 pandemic, for some opponents, it amounts to a reformation of the international patent system (Sariola 2021).

Clearly, the COVID-19 crisis has reflected loopholes in the international patent system as a tool for grappling with emergency situations, and has proven its general ineffectiveness (Thambisetty et al 2021). The crisis has fuelled the debate over the inconsistency between the international patent system and the right to health. This reality was reflected in a 2016 UN report, which called for the negotiation of a new code for research and development in the biomedical field and steps to address gaps in innovation related to the medical sector (The United Nations Secretary-General's High-Level Panel on Access to Medicines Report 2016).

It is worthwhile to note that patent waiver opponents do not use natural right theories as a premise for their arguments. This is probably because natural right-driven rationales are unpopular or because insistence on natural right would be baseless in pandemic conditions. All theories of utilitarianism are based on the belief that patent right is created to encourage inventors to disclose their inventions and boost scientific progress. In return, inventors are rewarded through the grant of exclusive rights, which enable them to prevent others from using their inventions without authorisation.

Multiple rationales have been built on the above system of thinking. For instance, public interest was one of the most popular justifications for the patent system; the idea that the public undoubtedly benefits from the monopoly of patents. Without the patent system and the protection it offers, inventors would not have been persuaded to embark on risky, time-consuming and expensive activities to produce their inventions (Bently and Sherman 2014). The public interest argument has now extended to include the benefit gained through the disclosure of technological information in patent specifications.

Such disclosure is crucial to the development of the state of the art, and the information disclosed would have remained secret, if there had been no patent protection (Machlup and Penrose 2011). The patent system has also been justified in that it encourages inventors to produce more and more inventions to get rewarded by the system (Machlup and Penrose 2011). Lastly is the contract-based rationale, which claims that the patent system guarantees limited time protection for inventors, in return for which they

Table 1 Gross domestic product percentage change in IP5 countries in the four quarters of 2020 compared with the corresponding quarters of the previous year

Country	Q1 2019	Q2 2019	Q 3 2019	Q4 2019	Q1 2020	Q2 2020	Q3 2020	Q4 2020
US	2.3	2	2.1	2.3	0.3	-9	-2.8	-2.4
EU	1.9	1.6	1.7	1.2	-2.7	-13.8	-4	-4.4
China	6.3	6	5.9	5.8	-6.8	3.2	4.9	6.5
Japan	0.1	0.2	1.1	-1.3	-2.2	-10.2	-5.5	-1
S.Korea	2	2.4	2.1	2.6	1.5	-2.7	-1	-1.1
4. Conclusion								

agree to disclose information underpinning their inventions to the public (Bainbridge 2018).

To discuss the rationale of the patent system in the wake of the COVID-19 pandemic, two points should be mentioned. First, the antiwaiver faction seeks to apply the theories of the domestic patent system on the international plane. The debate is not about the enforcement of patent rights at the domestic level. Rather, waiver is being sought on the international scene. The preamble of the TRIPS Agreement starts with the phrase, 'desiring to reduce distortions and impediments to international trade.....' This reflects the main foundation of the international patent system, which is the promotion of international trade. Although technological objectives are also considered, the trade-based justification remains the core rationale for the international patent system.

While the TRIPS Agreement aims to maintain effective protection for intellectual property rights, it also strives to reconcile this with the imperative of ensuring that steps taken to enforce such rights do not constitute obstacles to free and fair trade. No doubt, by granting proprietary rights for new ideas, the patent system encourages innovation. Still, at the international level, the quest for innovation is not a tenable justification for the enforcement of intellectual property rights. The present international patent system differs, in historical origins, from the domestic equivalents.

As international trade has blossomed in recent decades, with unprecedented flows of goods and services across borders, the inadequacies of the patent system in some domestic jurisdictions came into limelight. The legal framework for the protection of intellectual property rights, especially in low-income and middle-income countries, was perceived to be weak or even non-existent. Consequently, inventors from high-income countries considered their investment interests threatened in those countries, with loss of returns caused by violations of their patent rights (Atibasay

2014). They felt that divergences in domestic patent regimes posed a challenge to the effective protection of their patent rights (Chun 2017) as well as international trade (Barton 2004). Weak patent protection was also viewed as inimical to trade across borders through the counterfeiting of goods (Correa 2007).

The need to prevent patent infringements and maintain undistorted international trade created the desire for the harmonisation of patent systems across the globe to ensure an organised and uniform international patent system (Chun 2012). The result of all this was the adoption of the TRIPs Agreement, which has, for nearly three decades, served as the linchpin of the international patent system, chiefly focusing on the reigning in of counterfeiting and illegitimate trade behaviour (Atibasay 2014).

At the same time, it is relevant to remember that the TRIPS Agreement is part of the Marrakesh Agreements, which established the WTO system relied on by COVID-19 patent waiver applicants. Thus, the key underlying justification of the TRIPs Agreement is the promotion of international trade (Abbott 1998), a point equally acknowledged by Harvey Bale, Director of the International Federation of Pharmaceutical Manufacturers Associations (Bale 1998). As Abbott reflects, strictly speaking, intellectual property protection per se was never the main concern of the WTO (Abbott 1998).

Before the advent of the TRIPs Agreement, several attempts were made to streamline patent laws worldwide within the World Intellectual Property Organisation (WIPO) system (Chun 2017). Those efforts failed as the integration of intellectual property protection into the WIPO system was resisted by low-income and middle-income countries, which also called for a review of the patent rules contained in the Paris Convention for the Protection of Industrial Property of 1883 (Helfer 2003). Amidst that stalemate, the USA concluded that the harmonisation of patent systems was not attainable within WIPO (Braithwaite and Drahos 2000).

Based on this realisation, the USA turned its efforts at the international regulation of patent systems away from WIPO to the WTO (Helfer 2003).

Accordingly, and with the collaboration of European countries, the USA steered the incorporation of intellectual property rights into the international trade arena through the Uruguay Round of discussions on the General Agreement on Tariffs and Trade (GATT), precursor to the WTO, especially during the early phase of the 1990s (Sell 2002). Chun explains that Western countries eventually managed to create a harmonised international patent system through the TRIPS Agreement by successfully linking patent protection and international trade (Chun 2017). Today, according to Adrian Otten, erstwhile Director of the Intellectual Property Division of the WTO, the TRIPS Agreement constitutes a key part of the international trade system (Otten and Wager 1996). Subscription to the TRIPS Agreement is now a prerequisite for accession to and involvement in the WTO system (Ngenda 2005). Oguamanam (2008) observes that the TRIPS Agreement is a turning point in the international regulation and governance of intellectual property. He, like Chun (2017), attributes this to the ideological connection established between intellectual property and the international trade system during the Uruguay Round of GATT negotiations.

All that said, the patent system, as it presently exists, does not command the same level of justification in low-income and middle-income countries as in their developed counterparts. The capacity to generate patent-eligible inventions is limited in low-income and middle-income countries, where most patents are foreign-owned. The immediate concern of these countries is to acquire a fair share of recent technological advances, which continue to be controlled almost exclusively by high-income countries (Oddi 1987).

The COVID-19 patent waiver controversy further highlights the ineffectiveness of TRIPS as a mechanism for the fair and equitable distribution of the fruits

of technological development. Low-income and middle-income countries have persistently nursed reservations about the international trade system, fearing that it is fashioned to serve the parochial interests of some of their developed counterparts (Chun 2017). The genesis of this discord can be traced to the failure of high-income countries to advance acceptable justifications for the harmonisation of the patent system (Chun 2017).

An additional point worth making is that the promotion of innovation tenet, which is much articulated in theories of intellectual property, is not an end in itself, but rather, a means to an end. No matter how construed, the real essence of those theories still revolves around meeting the needs of society, which provides impetus for the generation of ever more inventions. Admittedly, innovation, particularly in the healthcare domain, is vital to the maintenance of product and service quality (Evren Subasi and Subasi 2021; Marika 2021). This claim is consistent with the findings of Marciano and others, who, from their empirical study, also conclude that innovation results in reduction of the cost of services (Marciano et al 2020). As well, Halpaap et al (2020) maintain that innovation helps in enhancing transparency and accountability in the healthcare sector, and its overall durability.

Concurrently, when patent rights are granted as reward for innovation, they are expected to contribute to the achievement of a robust and competitive economy in the country granting them (Evren Subasi and Subasi 2021). They should facilitate optimal resource allocation by reducing costs associated with disease treatment (Zozaya, Alcalá, and Galindo 2019). New drugs invention should play a role in curbing hospital visits, admission and related treatments (Zozaya, Alcalá, and Galindo 2019). Proksch et al (2019) contend that medicare innovation boosts national productivity, as new drugs production support human health, vitality and productivity (Schiener et al. 2021). As WHO notes, an unhealthy population translates to a unhealthy workforce, which, in turn, results in shortage of critical manpower and a shrinking national reserve (Who Guide to Identifying The Economic Consequences of Disease and Injury 2009).

A plethora of studies clearly demonstrate a nexus between sound health and productivity, at both the levels of individuals and firms (Thomas and Strauss 1997; Mushkin 1962; Bloom, Canning, and Sevilla 2004; Arora 2002). In Germany, Schiener et al. (2021) investigated the socioeconomic

effects of migraine and found that this disease caused the country a productivity loss of €112 billion. Significantly, the authors also found that this loss could have been reduced to about €85.5 billion, if the Aimovig drug was used for migraine treatment. With regard to vaccine inventions, these have also spared the healthcare system of substantial sums. The smallpox vaccine is reported, for example, to have resulted in annual savings of US\$2000 million (Ehreth 2003). Similarly, the US economy recorded substantial economic gains from the polio vaccine, which are worth more than six times its actual cost (Thompson and Tebbens 2006). In the same vein, the use of vaccines for influenza and pneumonia led to a reduction in cases of hospital admission by about 39% (Nichol, Wuorenma, and von Sternberg 1998). The CNN reports that COVID-19 vaccination could similarly have produced savings of US\$21 752–US\$49 441 in the cost of hospitalisation for a single patient, which got as high as 150–300 times the cost of vaccination (Murez 2021). Needless to mention, the emergence of the COVID-19 pandemic adversely impacted domestic productivity across the globe. As shown in figure 2,¹ gross domestic product (GDP) in the G20 member countries during the four quarters of 2020 declined dramatically, when compared with the corresponding quarters of the previous year. The GDP growth was 3%, 3%, 2.8% and 2.5%, respectively in the first, second, third and fourth quarters of 2019, compared with those for 2018. By contrast, the spread of the COVID-19 pandemic and the resulting lockdowns caused the GDP to fall in the first, second, third and fourth quarters of 2020 respectively by 1.6%, 8.8%, 2.2% and 0.7%.

Table 1² shows the change in GDP in the IP5 countries, which are the leaders in global innovation, and with economies that rely very much on intellectual property rights. Hence, the innovation-based justification is well-established in their patent systems. Notwithstanding, it can be asserted that, overall, the economic impact of the COVID-19 pandemic takes away the economic justification from patent protection as it slows down vaccination, which is the solely available pathway to the recovery of humanity.

CONCLUSION

Opponents of the patent waiver proposal raise many questions over its merit. One of the most significant arguments is that waiver contradicts the philosophy that underlies patent protection. The patent

system is designed to encourage inventors to make painstaking efforts to create new ideas that promote the economy and the overall welfare of society. On this account, opponents fear that waiver will serve as a tool for competitors to free-ride on the findings of inventors, without affording them any reward. Thus, waiver will not be a solution to the COVID-19 pandemic, but rather an obstacle to the fight against it.

This study makes two main arguments. First, the antiwaiver faction wrongly applies the philosophy of the domestic patent system to the international arena whose foundation is different from that of the former. The international patent system is mainly designed to remove obstacles to international trade, which is undeniably damaged by the COVID-19 pandemic. Second, innovation is, at the end of the day, a mere tool for economic growth. Current statistics show that the pandemic has negatively affected the production of goods and services worldwide. Ultimately then, vaccination should be prioritised over the protection of innovation, important as it may be.

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NOTES

1. The data have been derived from the Organisation for Economic Co-operation and Development (OECD) website: <https://www.oecd.org/sdd/na/g20-gdp-growth-Q1-2021.pdf> Last access on 27 July 2021.
2. The data have been derived from the OECD website: <https://www.oecd.org/sdd/na/g20-gdp-growth-Q1-2021.pdf> Last access on 27 July 2021.

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