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Feature

Waiving intellectual property rights: Boom or bust for medical innovation?

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Proposals to waive intellectual property rights (IPRs) on coronavirus 2019 (COVID-19)-related developments have gained considerable support among politicians, including from US President Biden, academics, nongovernmental organizations (NGOs), the media, and the general public. However, there are surprisingly few reflections about the short- and long-term consequences for medical innovation, particularly the development of new drugs and vaccines. In this feature, I reflect on the consequences for innovative entrepreneurial companies, the incentives to innovate, and consequences for international knowledge flows to low- and middle-income countries. I conclude that waiving IPRs reduces opportunities for entrepreneurial companies to attract sufficient funding for developing medical innovations. Low- and middle-income countries might suffer reduced knowledge inflows in the absence of IPRs that undermine their ability to develop medical innovations.

Keywords: Patent waiver; Intellectual property rights; Incentivizing innovation; COVID-19 vaccines; Knowledge transfer; Low- and middle-income country

Introduction

In early May 2021, US President Joe Biden announced his support for waiving patent protection and other IPRs related to COVID-19 vaccines.[1] A similar proposal had been proposed previously by India and South Africa to the World Trade Organization (WTO). However, this original proposal called for waiving a wider range of IPRs that cover innovations required to support the global response against the COVID-19 pandemic, not only IPRs related to vaccines. As such, the proposed IPR waiver would be extremely broad and could also apply to technologies that are only peripherally related to COVID-19 vaccines or treatments.[2] The proposed IPR waiver would allow all WTO members to not make patents available for product and process inventions and would exempt WTO member countries from granting exclusive rights to patent holders.[3] Implementation of the proposal would allow WTO member countries to break existing patent rights, to not grant new patent rights, and to not pay adequate renumerations for using intellectual property (IP) broadly related to COVID-19. In addition, the original proposal was not restricted to waiving patents but also called for waiving copyrights and eliminating the protection of undisclosed information.[3] The Director-General of the WHO, Dr. Tedros Adhanom Ghebreyesus, supported the IPR waiver proposals and called on governments to waive patents for COVID-19-

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related developments temporarily, with royalties being paid to innovators, to boost global access to effective COVID-19 vaccines, particularly in low- and middle-income countries.[4] Although these proposals have received support from policy makers, academics, NGOs, the media, and the general public around the globe, several (mostly European) governments and industry representatives remain skeptical about whether the proposed actions would be appropriate for improving global access to vaccines and other medications to fight the pandemic.[5] Given these different views and opinions, it is unclear whether IPR waivers would be implemented and accepted among WTO member countries during 2021 or beyond. Moreover, it remains unclear whether broad IPR waivers would be implemented by high- and low-income countries or whether predominantly low-income countries would make use of limited IPR waivers that would extend the existing system of compulsory licenses to copyrights and undisclosed information.

Despite the market approval for several effective vaccines against COVID-19 in many countries, there is little doubt that the first half of 2021 saw a global imbalance in the roll-out of vaccination campaigns.[6] The seemingly limited availability of COVID-19 vaccines in many low- and middle-income countries raises the question of whether the proposed waiver of COVID-19-related patents and other IPRs would increase the availability of effective medication, test kits, or vaccines in low- and middle-income countries. Proponents of waiving COVID-19-related patents and other IPRs argue that this global health crisis creates a (moral) obligation for innovators to share their knowledge. This knowledge should increase the production of vaccines and other medical products and promote domestic production in low- and middle-income countries. This argument is often paired with a more general critique that IPRs, and particularly patent rights, were never designed as a response to global emergencies, that the existing mechanisms for compulsory licensing are insufficient, and that it is the ethical responsibility of seemingly rich pharmaceutical companies to support the higher good of global health by supporting low-income countries.[7–9] This criticism links to the broader debate on IPRs and improved access to new drugs, vaccines, and other medical innovations for populations in low- and middle-income countries.[10] The debate also refers to a moral obligation of (Western) pharmaceutical companies and governments to support the availability and affordability of COVID-19 vaccines in low-income countries. Opponents of waiving IPRs refer to evidence and arguments suggesting that COVID-19 vaccines and other medical products are neither patented nor protected through other mechanisms in most low- and middle income countries; that the relevant knowledge for manufacturing vaccines, particularly those building upon relatively new mRNA technology, is normally not available in these countries; that it is unlikely that actors from low- and middle income countries can replicate production processes and set up specialized supply chains in the near future; and that other global initiatives are more effective in supporting the availability of vaccines and other medical products in low-income countries.[11–13]

Although there appears to be a common goal of ensuring global access to COVID-19 vaccines, personal protective equipment, testing devices, or medications in the short run, there is surprisingly little reflection on the short- and long-term consequences of waiving COVID-19-related IPRs for medical innovation. Here, I contribute to the debate by discussing the role of IPRs, particularly patents, in medical innovation. In doing so, I discuss the role of patents and other IPRs in incentivizing medical innovation, particularly for innovative entrepreneurial companies in the biotechnology and pharmaceutical industry, and the role of patents in knowledge transfer, emphasizing the role of low- and middle-income countries.

Why do we need patents and other IPRs for medical innovation?

The core idea of IPRs, and particularly patents, is that society grants inventors, or more generally originators of ideas, exclusive rights in return for describing their invention. These exclusive rights to use or sell an invention or idea are granted based on the assumption that the incentives to innovate are increased when inventors or originators of ideas are in the position to appropriate the returns that are associated with those inventions or ideas.[14] Patents and other IPRs allow their owners to take legal actions against actors that are infringing their rights in the geographical area for which they hold IPRs. Particularly in the biotechnology and pharmaceutical industries, patents have been an important means to allow innovators to reap the benefits of their innovation efforts. In these industries, innovation is characterized by an expensive and lengthy process that is associated with failures rates as high as 40% or more in several disease areas, even in its later stages, and simultaneously by comparatively low cost of imitation.[15–17] Typically, companies apply for the first patents of their (potential) medical innovations long before their commercial application, such as when new compounds are synthesized. In doing so, they build upon basic research that is conducted in academia, particularly when developing new drugs that have a high degree of scientific novelty.[18]

Although patent owners might voluntarily negotiate licensing contracts with third parties regarding the use of the owner's IP, compulsory licenses force patent owners to share their IP with a third party. Under a compulsory license, a government allows a third party to produce (and sell) a patented product or to use a patented process without the consent of the patent owner. The current WTO treaties allow governments to use compulsory licenses for pharmaceutical products, such as drugs, vaccines, and diagnostics, needed to fight an epidemic.[19] However, compulsory licenses require that negotiations with the patent owner about concluding an ordinary license agreement have not been successful within a reasonable period of time and with reasonable commercial terms and conditions. Several low- and middle-income countries have made use of compulsory licenses for drugs, particularly those being used as treatments for HIV/AIDS.[20]

The rather scarce empirical evidence for the consequences of compulsory licenses for innovation suggests that technologically advanced countries see increasing rates of domestic innovation.[21–22] For technologically less-advanced low- and middle-income countries, the threat of issuing compulsory licenses and the simultaneous existence of a domestic knowledge base that allows for executing these

licenses might force patent holders to make their innovations available in these countries. However, this improvement in access to medical innovations might come at the expense of globally reduced levels of innovation.[23]

In this context, Table 1 relates the use of compulsory licenses in the disease area of HIV/AIDS to the involvement of selected countries in global development activities of pharmaceuticals and medical devices as indicated by clinical trials. Data on compulsory licenses were obtained from The TRIPS Flexibilities Database. Only compulsory licenses in the disease area of HIV/AIDS that were executed were taken into account. Table 1 includes only countries that issued at least two compulsory licenses between 2006 and 2020 in the HIV/AIDS disease area. Data on international clinical trials in the corresponding disease area were obtained from ClinicalTrials.gov, a comprehensive clinical trial registry run by the US Library of Medicine. The number of trials for each country and the growth was calculated based on whether a trial site was located in the country. To put these numbers into perspective, the growth rate was also calculated for unique trials in countries that belong to the same income group.

Based on the data, Table 1 suggests that compulsory licensing-issuing low- and middle-income countries are, with the exception of Thailand, involved only to a negligible extent in global development activities in the corresponding disease area. In addition, the growth rates of the number of clinical trials that are at least partially conducted in these countries tend to be lower than the growth rates in all countries in the corresponding income group. In cases, some compulsory licensing-issuing countries show high growth rates in the number of clinical trials; these high growth rates are based on very small absolute numbers of clinical trials that are conducted in these countries. This finding suggests that issuing compulsory licenses is not supportive for embedding low- and middle-income countries in global medical development activities.

IPRS and entrepreneurial companies

It is comparatively small entrepreneurial companies in particular that engage in the development of drugs with a high scientific novelty.[24] Many of these entrepreneurial companies are set up by academic scientists, which makes entrepreneurship an important form of knowledge transfer from academia into industrial applications. Entrepreneurial companies are likely to seek investments from venture capitalists and to seek investors on a stock exchange.[25–26] Normally, entrepreneurial companies do not have an existing portfolio of approved products that generates cash inflows to cover the expenses of developing new drugs. For entrepreneurial companies, patent protection is essential, because it allows them to signal the quality of their innovation efforts to investors who might otherwise not be willing to invest. For investors, patents provide value beyond the patent application itself through search reports, citations, and opposition procedures that are generated by patent offices.[27] In addition, (entrepreneurial) companies might use patents as collateral to access debt financing required to fund innovation and other business processes.[28]

Based on these arguments, waiving patent rights and other IPRs is likely to have considerable negative effects for entrepreneurial companies and, hence, the most innovative companies. When these companies opt for other means of protecting IP, such as trade secrets, they might not be able to adequately signal their quality to investors. In the extreme case of nonexisting or fully waived IPRs, investors will not obtain information produced by patent offices. This information complements the internal information of a company that could be shared with potential investors through other means of communication, but at higher transaction cost. At the same time, the lack of patents that could be used as collateral would make it considerably more difficult to use debt financing as an alternative or complementary source of funding. Given the strong link between the use of IPRs by entrepreneurial companies and the amount venture capital investment,[29] waiving IPRs could lead to lower investments in companies that are developing medical innovations.

IPRS and innovation incentives

Medical innovation is based on complementary public and private investment. The contribution of public investments to medical innovations lies predominantly in basic research and the discovery of new drug candidates, which support follow-on private investments that build upon the corresponding basic scientific knowledge in more applied, clinical research.[30] Given the high cost and high risk of failure during the clinical development of medical innovations, it appears to be neither feasible nor advisable to replace major parts of private investments with public investments. However, this does not imply that governments should not support medical innovation at all. Beyond supporting basic medical research, governmental support is required in disease areas in which the size of the market is too small, despite the existence of IPRs and other forms of market exclusivity, to incentivize private investments in medical innovation.[31–32]

The proponents of waiving COVID-19-related patents might argue that the waiver will be temporarily applied and, hence, that the effects would not severely affect incentives for medical innovation in the short-term. However, given that at least some proposals call for a broad application of IPR waivers, the implications for (dis)incentivizing medical innovation should not be underestimated. Once applied, there will be no return to the market conditions before IPR waivers were introduced, because potential imitators will have acquired knowledge and will keep this knowledge even if IPRs are restored. In the short-term, IPR waivers undermine trust and create uncertainty regarding the potential returns of innovation investments across the globe. Consequently, companies might be hesitant to invest in adapting existing vaccines against new variants of COVID-19 or to invest in the search for effective drugs to treat the disease that are or might be required in the short-term. Investors might shy away from funding these innovation endeavors. Although governments might, depending on political and economic constraints, continue to support medical innovation as they have done during the COVID-19 pandemic, they might also focus on specific types of medical innovation, such as vaccines in the case of COVID-19.[33] Hence, it cannot be taken for granted that governmental supports would ensure medical innovation in its entire breadth.

In the medium- and long-term, the negative consequences of waivers for IPRs will not be restricted to COVID-19 or related

TABLE 1

Compulsory licenses and clinical trial involvement of selected countries in HIV/AIDS research.

Country	Period	Number of HIV/AIDS compulsory licenses	World Bank income group	Number of HIV/AIDS clinical trials	Growth rate in number of HIV/AIDS clinical trials (%)	Growth rate in number of HIV/AIDS clinical trials in income group (%)	Difference in growth rates (in %)
Benin	2006–2010	0	Low	2			
	2011–2015	2	income	0	−100.00	61.39	−161.39
	2016–2020	0		0	0.00	11.04	−11.04
Congo	2006–2010	1	Lower	1			
	2011–2015	1	middle	1	0.00	65.25	−65.25
	2016–2020	0	income	0	−100.00	8.72	−108.72
Cote D'Ivoire	2006–2010	2	Lower	3			
	2011–2015	0	middle	9	200.00	65.25	134.75
	2016–2020	0	income	6	−33.33	8.72	−42.05
Cuba	2006–2010	2	Upper	0			
	2011–2015	0	middle	0	0.00	1.43	−1.43
	2016–2020	0	income	0	0.00	−0.35	0.35
Ecuador	2006–2010	1	Upper	2			
	2011–2015	4	middle	0	−100.00	1.43	−101.43
	2016–2020	0	income	2	–	−0.35	–
Gabon	2006–2010	1	Upper	1			
	2011–2015	1	middle	1	0.00	1.43	−1.43
	2016–2020	0	income	1	0.00	−0.35	0.35
Honduras	2006–2010	2	Lower	0			
	2011–2015	0	middle	0	0.00	65.25	−65.25
	2016–2020	0	income	0	0.00	8.72	−8.72
Nepal	2006–2010	2	Low	0			
	2011–2015	0	income	1	–	61.39	–
	2016–2020	0		2	100.00	11.04	88.96
Sierra Leone	2006–2010	2	Low	0			
	2011–2015	0	income	0	0.00	61.39	−61.39
	2016–2020	0		0	0.00	11.04	−11.04
Thailand	2006–2010	3	Upper	94			
	2011–2015	3	middle	80	−14.89	1.43	−16.32
	2016–2020	0	income	47	−41.25	−0.35	−40.90
Togo	2006–2010	2	Low	0			
	2011–2015	0	income	1	–	61.39	–
	2016–2020	0		2	100.00	11.04	88.96

disease areas. Instead, the negative consequences will affect many technologies that are directly or indirectly linked to the development of COVID-19 vaccines or medications. Several developments that provided the basis for COVID-19 vaccines, such as mRNA technology, can be applied to develop new treatment options or vaccines against a variety of diseases.[34] Broad IPR waivers for these technologies could invalidate existing innovation investments and might considerably increase uncertainty of whether and how much of the initial investments can be regained. Empirical evidence suggests that increasing uncertainty is associated with reduced investments in innovation.[35] IPR waivers would allow imitators to develop their own generic versions of a medical innovation, which is likely to cause declining market shares for innovators.[36] These findings raise the question for companies and their investors of whether the risk of developing medical innovations is associated with appropriate returns and whether companies should keep investing in medical innovation if IPR waivers are adopted.

Waiving IPRs during the COVID-19 pandemic would send a strong signal to companies, investors, and other actors that governments could use this policy tool again if there is a perception that the global health situation requires it. Hence, companies and their investors cannot trust that they will be in the position to regain their investments in the future. Consequently, the world might see considerably fewer innovative treatments and diagnostic options for global health problems, such as cancer or antimicrobial resistance.

IPRS and knowledge transfer

Proponents of IPR waivers argue that this is an appropriate means to ensure access to COVID-19-related vaccines and therapeutics for low- and middle-income countries.[37] However, waiving COVID-19-related IPRs is not unambiguously positive for actors in low- and middle-income countries. Although some actors might gain access to cutting-edge technologies, such as mRNA vaccines, others would see their innovation investments and knowledge invalidated, including investments linked to several vaccines and vaccine candidates that have been developed in countries such as India and China.[38] In addition, waiving IPRs is likely to have a negative effect on international knowledge transfer to actors in low- and middle-income countries. Much literature has suggested that there is a positive relationship between the strength of IP protection, particularly patent rights, and knowledge transfer to other organizations.[39–40] Foreign patents are an impor-

tant source of knowledge transfer from technologically more advanced economies to low- and middle-income countries that have a sufficiently developed domestic knowledge base to make use of these knowledge inflows.[41–42] This literature suggests that waiving IPRs would deter knowledge transfer to low- and middle-income countries. Countries such as India and China have a sufficiently developed knowledge base to make use of knowledge inflows from licensed IP. However, even innovators in these countries depend on the transfer of undisclosed knowledge that is equally important as knowledge disclosed in patent documents for producing COVID-19 vaccines and other medical innovations.[43] IPR waivers are likely to deter the important transfer of knowledge that is not disclosed in patents or other documents because the incentives for IPR owners to engage in knowledge transfer are reduced. In addition, IPR waivers could reduce the ability of low- and middle-income countries to produce their own versions of COVID-19 vaccines and other medical products in the medium- and long-term. In the longer term, the negative impact on knowledge transfer to the Global South is likely to negatively impact the recent success of low- and middle-income countries in becoming part of global science and research networks as well as in increasing their participation in global clinical trials (i.e., studies testing the safety and efficacy of new medications or medical devices).[44–45]

Concluding remarks

The arguments presented herein raise considerable concerns about whether waiving IPRs, particularly patent rights, is a strategy that leads to short-term or long-term benefits in responding to the COVID-19 pandemic or other global health challenges. In the short-term, few actors in low- and middle-income countries might benefit from obtaining access to technologies and knowledge that would otherwise not be available to them. In case these actors are successful in translating this knowledge into safely produced vaccines and other medical products, the global supply might be increased. However, this benefit comes at the expense of invalidating investments into vaccine candidates and other medical innovations made by public and private actors across the globe, reducing their incentives for further investments (e.g., for adapting vaccines to new variants of COVID-19), and reducing their ability to acquire funding for these innovation endeavors. These negative consequences not only affect actors from high-income countries, but also apply to many actors from low- and middle-income countries. In the medium- and long-term, broad IPR waivers are a threat to medical innovation, because the incentives to innovate and the opportunities to attract investments that enable medical innovation are considerably reduced. This applies particularly to the most innovative, entrepreneurial companies. Consequently, waiving IPRs might reduce medical innovation across a variety of disease areas well beyond COVID-19 or other infectious diseases. Waiving IPRs is also likely to reduce knowledge flows to low- and middle-income countries. As a consequence, the proposed waiver for IPRs is unlikely to be an enabler of medical innovation in these countries but is rather likely to reduce the ability of actors from low- and middle-income countries to respond to global and local health challenges. However, strengthening the capacity of domestic actors to respond to local and global health challenges is important both within and beyond the pandemic. Innovation originating in high-income countries tends to be expensive and might not correspond to the local health infrastructure and local health needs.

Instead of waiving COVID-19-related IPRs, a greater engagement of high-income countries to ensure global access to COVID-19 vaccines, personal protective equipment, testing devices, or medication through donations or support of WHO initiatives appears to be the more effective policy in the short-term. In the long-term, there is a need to strengthen the national innovative capacity of low- and middle-income countries (i.e., the long-term ability to produce commercially relevant innovations[46]to increase their ability to respond to new and existing local and global health challenges. Instead of reducing knowledge transfer through waiving IPRs, the WHO and governments of high-income countries could support the development of national innovative capacities of low- and middle-income countries by supporting knowledge transfer. This knowledge transfer should not only enable licensing agreements that allow for the domestic production of medical innovations, but also provide support for effective technology transfer and for effect domestic competency development. The Medicines Patent Pool is a promising example of supporting licensing of essential medicine to actors that would sell generic versions to low-income countries while simultaneously providing assistance with the technology transfer activities from patent holders to generic manufacturers.[47]

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