Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance

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ABSTRACT

In June 2020, Gilead agreed to provide the USA with 500 000 doses of remdesivir—an antiviral drug which at that time was percieved to show promise in reducing the recovery time for patients with COVID-19. This quantity represented Gilead's then full production capacity for July and 90% of its capacity for August and September. Similar deals are evident around access to proposed vaccines for COVID-19, and such deals are only likely to increase. These attempts to secure preferential access to medicines and vaccines, so-called vaccine/treatment nationalism, jeopardise supplies of life-saving treatments and vaccines available elsewhere, and jeopardise global equitable distribution of such vaccines/treatments more generally. Much of the focus to date has been on States' role in negotiating such deals. However, such developments also demonstrate the power patent holders have in controlling access to life-saving healthcare, determining who obtains access first and at what price. This article argues that the *extent of control* currently given to patent holders for COVID-19 must be questioned. This article demonstrates that patents have significant implications for healthcare acting as private governance tools over patented inventions. It is only by greater probing of patent holders' role in delivering access to medicines, diagnostics and vaccines for COVID-19 that equitable global equitable access can be achieved.

INTRODUCTION

In June 2020, Gilead agreed to provide the USA with 500 000 doses of remdesivir—an antiviral drug which at that time was percieved as showing promise for patients with COVID-19. Although, recent studies question the effectiveness, if any, of remdesivir for use in the Covid-19 context.[i1] Nonetheless, in June when remdesivir was viewed as a promising potential treatment option for Covid-19, this quantity represented Gilead's then full production capacity for July and 90% of its capacity for August/September.[2 3] Similar deals are evident around access to proposed vaccines for COVID-19,[4] and are only likely to increase as we get closer to securing effective vaccines and treatments for COVID-19.

Although understandable within the national context, these moves to secure preferential access, or so-called vaccine/treatment nationalism,[5] jeopardise supplies of life-saving treatments and vaccines for COVID-19 available in other countries, and more generally, they jeopardise equitable distribution of COVID-19 vaccines and medicines globally. Indeed, prior to the recent WHO recommendation against use of remdesivir for Covid-19 and when it was still perceived of potential benefit for patients, it had been reported that global shortages of remdesivir were, resulting in its rationing in the UK National Health Service context.[6] Much of the focus to date has been on States' role in negotiating such deals. However, such developments are not simply about States prioritising their citizens. They also demonstrate the power patent holders have around key decisions about access to life-saving healthcare, determining who obtains access first and at what price. Patents are generally seen as necessary incentives for the development of health technologies. However, this article argues that the *extent of control* given to patent holders for COVID-19 must be questioned.

The author demonstrates that patent holders' actions can have significant implications for healthcare as patents facilitate patent holders' having a private governance function over patented technologies. It argues that it is only by greater probing of the role that patent holders play within the access to healthcare space for COVID-19 that equitable global access to diagnostics, vaccines and medicines can be achieved. Moreover, while some rightsholders may voluntarily license intellectual property rights (IPRs), including patents on COVID-19 technologies, on a royalty-free basis or at reasonable prices, other rightsholders may not. Thus, a greater awareness and interrogation of existing avenues to intervene with patent holder discretion is needed.

Given the significant practical implications of patent holder decisions for healthcare, it is vital that the global biomedical and bioethics community scrutinise more deeply how patents are operating for COVID-19. As part of this, it is vital that there is a deeper understanding within the bioethics and biomedical community of the avenues to temper patent holder control within patent law and the existing obstacles to these. This article aims to provide an overview of such issues and that this will enable greater critique and advocacy for change of patent law where public health requires it for COVID-19.

In making such arguments, the first part of this article outlines the potential for patent holders' decisions to have significant adverse healthcare implications for COVID-19, and illuminates the

[i]WHO recommends against the use of remdesivir in COVID-19 patients available at https://www.who.int/news-room/feature-stories/detail/who-recommends-against-the-use-of-remdesivir-in-covid-19-patients [accessed 24 November 2020].

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power patent holders have over healthcare access/provision in such contexts. The second and third parts highlight avenues to provide oversight/limits on patent holders' control via compulsory licenses or voluntary licensing initiatives and the key obstacles to using such licensing measures. The fourth part concludes that greater probing of the role of patent holders is urgently needed for COVID-19 to ensure equitable and affordable global access to life-saving vaccines, diagnostics and treatments.

Patents, private governance and COVID-19

Patents are IPRs which allow the rightsholder to prohibit others from using the invention for the duration of the patent (generally 20 years). Under international trade law, in all 164 World Trade Organization (WTO) Contracting States, patents must be made available for *all fields of technology* including health-related technologies, such as medicines, vaccines and medical devices.[7]

Patents incentivise technological developments by providing an income stream for the patent holder who can offer licences to third parties for monetary return, and who can choose to exploit the patented invention (eg, medicine) as the sole (monopolistic) supplier for the duration of the patent, thereby potentially increasing costs charged for access to the technology. This income stream can be used to recoup development costs and generate profits and is often put forward as a key incentive for innovation. This article does not question this economic/incentivising function per se, however, as the author has argued elsewhere,[8] patents also bestow on patent holders a significant broader *governance function* which is often overlooked and which warrants investigation in the COVID-19 context if global equitable access to treatments/vaccines is to be achieved.

In terms of a *governance function* the article refers to the fact that once a patent is granted (via a public patent application system), the patent grant means the patent holder effectively steps into a governance role over that patented invention for the duration of patent —as the patent is a private right allowing them to control whether that invention can be used by third parties, if at all, and on what terms. It is conceded that patent holders are limited in this governance function in the sense that any uses of a technology must comply with existing public regulatory frameworks for a technology, for example, medicine regulations. Nonetheless, patent holders play a significant role in shaping the downstream trajectory/uses of patented inventions. Moreover, patent holders can place conditions on use, such as clauses prohibiting use of the invention for particular contexts. They can also limit use by charging high costs for access to the technology, or as noted, they can refuse to license the invention thereby becoming the sole provider. Furthermore, how the patent is licensed can impact other technologies because some technologies require the use of existing patented technologies to operate. Thus, patent holder decisions have the potential to have significant knock-on effects for uses of other technologies, and for research and development within a field of technologies. Arguably, the governance role patent holders play has particularly significant implications for health technologies which are often overlooked.[8]

Such issues are heightened in the COVID-19 context, because it is in all our interests to bring the COVID-19 outbreak under control as quickly as possible, and the best way to do so is to maximise global access to COVID-19 diagnostics, treatments and vaccines for all. Nonetheless, how patents are used can pose obstacles to such access[ii]. For instance, focusing on the example given at the start of this article, if a patent holder such as Gilead refused other companies/States' licences to produce a drug e.g. remdesivir, this would limit who could legally supply the medicine. Depending on the production capacity of Gilead and those to whom it offers licences to produce the medicine, this has knock-on effects on the amount of the drug produced. Within the remdesivir context, at the time when remdesivir was still considered a promising potential treatment for Covid-19 patients, it is conceded that Gilead agreed to provide voluntary licences for remdesivir with manufacturers in Egypt, India and Pakistan to supply low and middle-income countries.[9] If remdesivir had been proven an effective treatment option for Covid-19 such voluntary licenses may have alleviated these issues for remdesivir in such countries. Nonetheless, this would not have alleviated access issues elsewhere including for higher income countries. It is also acknowledged, as noted, that there are now significant questions around the effectiveness of remdesivr in the Covid-19 context,[1 10] however, this example is still important because it demonstrates that even where a treatment is at one point in time percieved as potentially useful/effective if any, in treating Covid-19 that is no guarantee of access to it. Moreover, the key point is that the decision to provide such licences over patented health-technologies to other manufacturers is entirely at the patent holder's discretion, despite the existence of a global pandemic.

Furthermore, as noted, patents also affect the price of the patented technology as patent holders may decide to license or provide that technology for high prices which may far exceed production costs.[11] For example, when it was still perceived as a potentially promising Covid-19 treatment option, the cost of remdesivir in the USA was initially reported as approximately $3200 per 6-day treatment course, whereas the cost of its production was estimated at less than $6 for a 6-day treatment, representing a significant profit margin for the patent holder.[12] Patent holders often argue that prices charged represent a way to recoup development costs and the costs of past failures, however, it is difficult to assess this for several reasons. In particular, such issues are exacerbated by the fact that the prices paid by States to access vaccines/medicines are often not disclosed.[4] Instead, an opaque private governance network operates where the balance of power weighs primarily in favour of patent holders. This is particularly problematic for COVID-19 where timely and affordable access to effective diagnostics, treatments and vaccines is vital to stem daily lives being lost.

Indeed, we have already seen the significant adverse implications patents could have for health in the COVID-19 context. For example, patents were used in the USA by a patent holder Labrador Diagnostics to challenge another company, BioFire Diagnostics, from providing diagnostic testing for COVID-19 which it initially claimed infringed its patents.[13] Although this challenge was abandoned following public backlash, it highlights the potential for patent holders to limit diagnostic testing available. Moreover, in Italy, at the height of the COVID-19 crisis there, claims arose alleging that a patent holder challenged a group over 3D-printing ventilator parts for use in Italian hospitals to treat patients with COVID-19. These claims were subsequently denied by the individuals involved and refuted by the

[ii]In making this point, the article acknowledges patents or IPRs more generally are not the only obstacles to access, other obstacles include for example, issues around supply chain and manufacturing capacity within States, however, the role patents play is also important and forms the core focus of this article.

patent holder.[14] However, it is entirely legally plausible that a patent holder *could* mount such a challenge.[15] Moreover, fears abound that patents will be used to drive high/unaffordable prices for COVID-19 treatments and vaccines with risks of profiteering by patent holders.[16]

It is conceded that other IPRs and knowledge gaps can also impede downstream access to vaccines. For instance, access to trade secret information, to the basic know-how of how the vaccine is produced and to cell-lines may prove considerable additional obstacles for any generic company in recreating a vaccine.[17] This differentiates vaccines from small-molecule medicines which are often easier to replicate by third parties without having additional knowledge, for example, on the manufacturing process.[17 18] In such contexts, the role of patents should be considered alongside other potential intellectual property (IP) impediments to access,[19] and such issues arguably build a case for considering proposals to mandate rightsholders to disclose information protected by trade secrets,[20] and to general know-how in relation to the inventions working where a compulsory licence over a patent is issued. This is also why the WHO has proposed the COVID-19 Technology Access Pool (C-TAP) which encourages sharing of IPRs, know-how, data and other elements such as cell lines (where needed) under a broader technology transfer to ensure global equitable access for COVID-19 health technologies.

These examples demonstrate the significant control patents give to patent holders by placing patented life-saving treatments, vaccines and diagnostics within private governance frameworks, primarily controlled by large pharmaceutical companies. This article argues that COVID-19 provides a significant catalyst to reconsider the *extent* of patent holders' control in light of the potential impact that patents could have on the global equitable distribution of COVID-19 health-technologies. Avenues exist to limit patent holder control via compulsory licensing or to encourage changes via voluntary licensing mechanisms. However, such avenues are traditionally met with resistance. For these mechanisms to provide an effective counterbalance to patent holder control for COVID-19, greater support for, and critique of, such mechanisms outside patent law is necessary. To achieve this, greater awareness is needed around such licensing measures and their shortcomings within the bioethics/biomedical community so that more critiques of such measures can be mobilised from a global health perspective. The article now considers such licensing initiatives, highlighting key advantages/shortcomings of each in terms of their ability to restrict/modify patent holder behaviour to deliver global equitable access to health technologies for COVID-19.

Prior to delving into such issues, it should also be noted that on the 2nd October 2020, India and South Africa brought a proposal to the World Trade Organisation for a temporary waiver of certain provisions of the international Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement proposing to suspend certain intellectual property obligations (including those related to patents) in relation to the prevention, containment or treatment of Covid-19.[iii] However, this proposed waiver has met with considerable opposition particularly from higher income countries, and discussions on it are ongoing at the time of writing. It remains to be seen whether this temporary waiver will be adopted. However, even if it is adopted, importantly, the waiver relates only to intellectual property rights and thus there is still a strong argument for countries to support voluntary licensing initiatives such as the Covid-19 Technology Access Pool (C-TAP) discussed below which facilitates full technology transfer and sharing of data, cell-lines etc for Covid-19. Furthermore, it is also still important that countries ensure that national compulsory licensing provisions are as effective as possible, as even if the waiver is adopted, it is not clear how long it would last for e.g. until the end of the pandemic or a later date, and compulsory licenses are therefore still very important in the event they are needed at the end of any waiver period. Moreover, even if it is adopted the waiver relates only to Covid-19 and not to other contexts, therefore, having effective national compulsory mechanisms is also vital in the event that these are needed for other public health issues.

[iii]For a full discussion see: https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm

Compulsory licensing and COVID-19

A compulsory licence allows a third party to produce a patented technology without the patent holder's permission. Article 31 of the TRIPS Agreement allows all WTO States to issue compulsory licences subject to certain criteria.[19] First, all cases are considered on their individual merits. Thus, a blanket compulsory licence for certain technologies, for example, medicines, is not possible. Second, prior attempts to negotiate a licence for the invention on reasonable terms with the patent holder must be evident. This requirement can be waived in 'a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use' which would likely apply for COVID-19. Third, the scope/duration of the licence must be for the limited purpose it was authorised for. Fourth, the licence is non-exclusive so the patent holder can still enter into licensing agreements with others. Fifth, use of the licence is generally permitted predominantly for the supply of the domestic market of the State where the compulsory licence is granted. Finally, the patent holder must be paid 'adequate renumeration' for the compulsory licence.

In 2001, due to concerns around the impacts of patents within the access to medicines context during the HIV/AIDS crisis, the Doha Declaration on the TRIPS Agreement and Public Health was adopted.[21] This Declaration affirmed that 'the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health'. It also clarified several TRIPS provisions as they pertain to compulsory licensing including confirming that it is up to States to determine what constitutes a 'national emergency'. Subsequently, Article 31*bis* of the TRIPS Agreement was introduced, which allows States to import patented inventions made under a compulsory licence elsewhere under certain circumstances.[22]

Compulsory licences could act as a check on or safeguard against patent holder decision-making which is contrary to delivering equitable global access for COVID-19. However, several obstacles exist to effective uses of compulsory licensing agreements for COVID-19.

First, while the international WTO framework sets down the minimum criteria for compulsory licences to be compatible with international trade law, compulsory licences are granted at the national State level because patents are territorial in nature. There is no 'global' patent instead, patents are national rights. Thus, national laws will generally set out how compulsory licences can be granted within each State. The legal avenues to obtain compulsory licenses at the national level may be heavily bureaucratic or unclear, placing burdens on their effective utilisation. Moreover, national laws may add further requirements for the grant of compulsory licences, which can place additional obstacles on their grant. For example, in Ireland, compulsory licences on a*ny grounds* can only be granted 3 years after patent

grant.[iv] Ordinarily, this is not a significant practical limitation to the use of compulsory licences given that it generally takes much longer than 3 years for medicines or vaccines to gain regulatory approval for use. However, there are moves within the COVID-19 context to seek faster regulatory approval, and if this materialises, the lack of availability of compulsory licences within 3 years of patent grant could plausibly limit their effectiveness for such new vaccines/treatments.

Moreover, alongside general compulsory licensing provisions some countries, including Ireland and the UK, have Crown/government use provisions, these are akin to compulsory licensing provisions, in that they allow use of a patented invention without the patent holder's permission. However, such provisions are directed at use by the government/Crown within a State to ensure services/availability of a patented invention often in a time of crisis.[v] Crown or government-use licenses have rarely been issued in practice in many high-income States, although arguably they are useful negotiation tools to secure reasonable terms within licenses, nonetheless to be more effective in many cases such provisions may warrant clearer guidance on the criteria applicable.

States should be encouraged to ensure national laws provide effective and clear avenues to obtain compulsory licences (and licences for service of State/Crown where applicable) where needed for COVID-19. Since March 2020 some countries have adopted legal measures to achieve this. For example, Canada passed laws facilitating quicker grant of compulsory licences.[23] Moreover, Germany passed the *Prevention and Control of Infectious Diseases in Humans Act* amending existing laws on compulsory licensing by giving the Federal Ministry for Health competence to issue compulsory licences under Section 13 of the Patents Act in the event of the declaration of a national epidemic.[24] In many cases, the threat of a compulsory licence will encourage patent holders to negotiate a more reasonable price/offer. Hence, it is in all States' interests to clarify national provisions on compulsory licensing and remove obstacles to their use as soon as possible.

The second obstacle for effective utilisation of compulsory licensing for COVID-19 is the *(un)willingness of States* to use such compulsory licensing measures. Traditionally, the use of compulsory licensing provisions has been rare in high-income countries although more common in lower income countries for the procurement of medicines.[25 26] Furthermore, some States who sought to use compulsory licensing provisions in the past faced litigation and trade sanctions.[27 28] Moreover, certain high-income countries have a strong pharmaceutical industry, which provides key economic benefits within that State, and governments may fear industry backlash from using compulsory licensing. However, COVID-19 is sparking change and some countries have already issued compulsory licences for COVID-19. For example, on 18 March 2020, Israel allowed a compulsory licence for the import of AbbVie's Kaletra from India for COVID-19.[24] This move had knock-on effects as AbbVie subsequently announced it would not enforce its patents on Kaletra anywhere in the world, resulting in the possibility of producing generic versions of Kaletra globally without fear of patent infringement challenges. There is strength in numbers in this context—arguably, the greater number of States that show willingness to use compulsory licensing for COVID-19, the stronger the ability of States to use such measures without backlash and the more powerful a deterrent compulsory licensing can provide against potential uses of patents by patent holders for profiteering in the pandemic. Thus, greater work is needed to normalise the use of compulsory licensing at the national level, so States show greater willingness to use such measures where public health requires it.

Third, there can be regulatory obstacles to effective uses of compulsory licensing for health technologies. For instance, in Europe, marketing and data exclusivity periods around medicines present significant obstacles to effective uses of compulsory licensing for health technologies. There is an 8-year data exclusivity protection under European Union (EU) law which means that a generic producer cannot use the original testing data on the patented medicine to support the approval of a generic medicine during this time. Additionally, generic medicines cannot be marketed until 10 years after the original medicine obtained authorisation. Such regulatory protections mean that it may not be possible to obtain generic approval within a timely manner. These protections deterred Romania's use of a compulsory licence in 2016 for sofosbuvir to treat hepatitis C.[29] Accordingly, such obstacles need to be addressed within the EU to make the system more effective, and similar regulatory obstacles must be considered and addressed elsewhere.

Fourth, under a compulsory licence the patent holder must be provided with '*adequate renumeration*'. The national State issuing the compulsory licence must determine how this amount should be set based on the circumstances of each case. There are WHO guidelines on setting renumeration for non-voluntary uses of a patent.[30] However, the question of how renumeration is set in each case can be a contested issue with questions arising over how rates should be set. A lack of clarity on renumeration could deter States from using compulsory licensing as failure to set an appropriate renumeration could render States liable to challenge.

Fifth, and relatedly, legal protections for patent holders may apply under investment treaty law, depending on the agreements applicable and whether exceptions are found to apply for compulsory licences.[31] This could render States open to litigation if renumeration provided under a compulsory licence was deemed insufficient and further clarity on this aspect is needed to ensure it does not deter States issuing compulsory licences.

Sixth, some States have adopted bilateral treaties with clauses limiting the use of compulsory licensing or placing additional restrictions on their use. This may prove problematic if such States wish to use compulsory licensing to tackle COVID-19.

Seventh, compulsory licensing provisions under Article 31(f) of the TRIPS Agreement state that compulsory licences must be used 'predominantly for the supply of the domestic market of the Member authorizing such use'. This means that States with limited manufacturing capacity may be unable to effectively use compulsory licensing measures to produce patented medicines, diagnostics or vaccines. To address this, as noted, Article 31*bis* of the TRIPS Agreement was introduced which incorporated avenues for countries to import medicines made abroad under a compulsory licence in specific circumstances.[22] However, there are arguably insufficient incentives for third parties to assist such a State and produce medicines for export to them. Moreover, some higher income countries/regions opted out of Article 31*bis* as importing members. This includes the EU, which means that EU States currently cannot avail of Article 31*bis* as importing

[iv] Article 5(A)(4) of the Paris Convention 1883, as amended, imposes this 3-year requirement but only in the context of compulsory licences granted on the grounds of 'failure to work or insufficient working'.

[v] For a list of such measures and their use in the COVID-19 context to date, see ref [36].

members. This could be highly problematic for COVID-19 if national manufacturing capacity or supply chains are affected by the pandemic. States which have opted out of Article 31*bis* as importing States should urgently reconsider this opt-out.[32 33]

Finally, a compulsory licence must be obtained for each State individually and on a case-by-case basis for each patented invention, for example, for each medicine or vaccine. There is no international avenue to obtain a compulsory licence applicable in more than one State. Thus, there is no possibility to use such measures as a blanket overarching solution for access to COVID-19 technologies in a region or globally. Hence, such processes are likely to be slow and cumbersome. A global health pandemic requires responsive action to deliver access to proven vaccines and medicines as quickly as possible. Therefore, even with the changes suggested, arguably compulsory licensing *alone* cannot provide the timely global approach needed to ensure patents do not obstruct access for COVID-19. Such changes should nevertheless be adopted because compulsory licences, despite not being the panacea, form one part of a broader toolkit used to rebalance patent holder power, and to deter uses of patents in a manner which is contrary to public health needs for COVID-19 and more generally.[19]

Voluntary licensing agreements and global equitable access

Aside from compulsory licensing mechanisms access issues can be alleviated by encouraging voluntary licensing of patents on reasonable terms for COVID-19. Arguably, compulsory and voluntary licensing exist in a symbiotic relationship, as other than in an emergency context, prior to issuing a compulsory licence there must be an attempt to negotiate a voluntary licence with the patent holder and failing to reach such an agreement can result in a compulsory licence. Thus, often a threat (or perceived threat) of a compulsory licence leads patent holders to agree to a voluntary licence on more favourable terms. This is not to dismiss the fact that some patent holders may be independently motivated by broader social/ethical responsibilities or reputational concerns to offer voluntary licences to alleviate access issues within a particular crisis, for example, such as within a global pandemic. Nonetheless, as much depends on patent holder discretion, thus the threat of a compulsory licence is a useful tool in encouraging patent holder participation in voluntary agreements, and/or in encouraging patent holders to voluntarily pledge/share their IP to broader IP initiatives or IP pools set up in a time of crisis.

Two different examples of voluntary licensing initiatives for COVID-19 include pledges and pools such as: the Open Covid Pledge, and the World Health Organisation's (WHO) Covid Technology Access Pool (C-TAP). The Open Covid Pledge was launched in April 2020 as a platform to facilitate IP holders to voluntarily share/license technologies related to COVID-19 on a temporary royalty-free basis, and acts akin to a 'joint initiative of multiple organizations to share their IPR on similar terms'.[vi]

In May 2020, the WHO launched C-TAP which aims to share IPRs, data, knowledge, know-how technology and other components necessary to develop and provide equitable global access to COVID-19 health technologies as safely and quickly as possible. It encourages IPRs holders to voluntary license IPRs to the Medicines Patent Pool. The C-TAP initiative was launched by the WHO under a global solidarity call for action to tackle COVID-19. Despite WHO backing, at the time of writing,[vii] C-TAP has only 40 endorsements from States,[34] and the USA and the UK initially were reported to have opposed the C-TAP initiative.[35] Arguably, the greater the numbers of State endorsements for C-TAP, the stronger the pressure on patent holders to sign up to C-TAP. More States should endorse C-TAP and other voluntary licensing initiatives for COVID-19. Indeed, the 73rd World Health Assembly passed a resolution in May 2020 entitled 'COVID-19 Response' which includes a commitment to developing existing voluntary licensing of patents for COVID-19.

One element of the WHO's Solidarity Call to Action for COVID-19 encourages stakeholders, including national governments and other funders, who provide significant public money towards the development of COVID-19 health technologies, to include clauses in funding agreements with third parties to ensure the accessibility/affordability of such technologies, such as by including clauses within funding agreements providing global non-exclusive licences to resulting COVID-19 health technologies. It remains to be seen to what extent such clauses will be used in practice by States and other funders, but arguably funders have significant leverage in such contexts, and initiatives like C-TAP and the 'Solidarity Call to Action' could be used to foster such moves within the pandemic and more broadly.

Notably, voluntary licensing agreements have several advantages over compulsory licensing agreements for COVID-19. First, unlike compulsory licensing, voluntary licensing pools/initiatives can be set up at an international level. They can act as broader global/regional mechanisms to encourage sharing of IPRs over health-related technologies for COVID-19. Nonetheless, as noted, this does not discount the role of compulsory licensing, because if patent holders sense governments are willing to issue compulsory licences, and there is a threat (or perceived threat) of a compulsory licence within a particular context, this can act as a catalyst encouraging patent holders to license to such pools/initiatives.

Second, while compulsory licensing needs to be considered for each new medicine/vaccine on a case-by-case basis, voluntary licensing initiatives can be established to cover a suite of treatments/vaccines or for a specific issue, for example, COVID-19. Such voluntary licensing agreements can also be designed to incorporate clauses requiring the broader transfer of technology, sharing of data etc whereas compulsory licenses are confined to the use of the patent rights. This more expansive and malleable nature of voluntary licensing initiatives makes them a broader, and therefore likely more efficient tool to achieve regional/global impact.

Third, while compulsory licensing is open to costly challenge and dispute, which can potentially delay the impact/effect of such mechanisms and deter States from using them, voluntary licences are premised on patent holder consent/buy-in. Thus, they are often not susceptible to the same level of delays/challenges and offer a timelier solution, ideally suited for COVID-19.

However, relatedly, the main disadvantage and potentially the Achilles' heel of voluntary licensing arrangements is that they are entirely dependent on patent holder buy-in. Nonetheless, if sufficient pressure is placed on patent holders to join forces in a commitment to global solidarity to tackling COVID-19, then it is highly plausible such patent holder buy-in will be achieved. Already, patent holders have shown willingness to ensure patented inventions are licensed reasonably for COVID-19, and such voluntary licensing should be encouraged at the State and international level. The greater the number of patent holders that sign up to such initiatives, and the more States and international bodies support them, the greater the likelihood of reputational fall-out for patent holders who refuse to opt in.

[vi] For a discussion on the distinction between pools/pledges see ref [37].

[vii] 9 October 2020.

Reputational fall-out could lead to public backlash against patent holders with attendant financial implications. This can likely be a strong motivator for patent holders to act, and to encourage buy-in to voluntary licensing schemes for COVID-19.

Mobilising public knowledge of the potential impacts of patents on healthcare access/delivery can also be a powerful tool. In the COVID-19 context, in many cases when restrictive uses of patents are reported within the media, patent holders have changed practices, arguably likely fearing reputational damage. Hence, voluntary licensing initiatives have considerable potential to be leveraged to alleviate access issues posed by patents for COVID-19 but they need greater State support and public understanding to maximise patent holder buy-in.

Concluding thoughts

Patents allow patent holders to dictate who uses the invention for the duration of patent grant, and on what terms, with (generally) limited external State intervention. When the invention is a health technology such as an essential medicine, vaccine or diagnostic, how the patent holder licenses that patented technology can have significant implications for healthcare. Yet, despite the health-related implications of patents, historically legal tools that exist to limit patent holders' discretion have often been exceptionalised—seen as devices of last resort. Such issues are brought into stark focus by COVID-19, which has shone a spotlight on patents' implications for healthcare and the level of control patent holders have over access to patented medicines, vaccines and diagnostics. In a global pandemic, which threatens health and lives globally, and which has attendant consequences for the functioning of our society and economies, the level of control which patent holders have over essential health technologies needs to be reconsidered.

For any sense of global normality to return, everyone globally must have affordable access to future effective COVID-19 vaccines, medicines and diagnostics as soon as possible. This is in all our interests. Yet, current patent practice could plausibly be used to obstruct or delay this. Furthermore, even though many patent holders have adopted commendable practices to ensure fair and reasonable access for COVID-19 technologies, others may not, and risks of profiteering are highly plausible.

Despite measures for State intervention with patent holder discretion via compulsory licensing, shortcomings remain. Such shortcomings should be addressed as a matter of urgency to ensure greater pressure and oversight can be leveraged over patent holders should public health require it for COVID-19. Additionally, support is needed for voluntary licensing initiatives, which offer useful global/regional mechanisms to address access issues around COVID-19 health technologies. However, without greater public and State awareness and support of voluntary licensing initiatives they will lack the strength required to encourage patent holder buy-in.

Crucially, it is only by starting a deeper conversation around the role of patent holders within the health context for COVID-19 and of the role of the public interest within patent law more generally that we can address and pre-empt some of the current obstacles posed by patents to equitable global access to healthcare. Given the significant health implications at stake it is vital that this conversation is informed by a global health and bioethics perspective.

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