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3D Printing, Intellectual Property Rights and Medical Emergencies: In Search of New Flexibilities

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3D Printing, Intellectual Property Rights and Medical Emergencies: In Search of New Flexibilities

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Abstract

The COVID-19 pandemic has exponentially accelerated the use of 3D printing (3DP) technologies in healthcare. Surprisingly, though, we have seen hardly any public intellectual property right (IPR) disputes concerning the 3D-printed medical equipment produced to cope with this crisis. Yet it can be assumed that a great variety of IPRs could potentially have been enforced against the use of various items of equipment printed out without express consent from IP holders. Many reasons might have motivated IP owners not to enforce their rights during the pandemic, such as the fear of acquiring a bad reputation during a declared situation of national emergency. There is no internationally recognised general exception to IPR enforcement for health emergencies, while several – sometimes ineffective – tools, like compulsory licensing, voluntary licensing arrangements and potential TRIPS waivers, have been considered or used to facilitate access to and the distribution of innovations in critical situations. During the COVID-19 emergency, this has meant that the 3DP community has been operating in a state of relative uncertainty including with regard to the risks of IP infringement. This study contextualises these issues for pandemic-relevant 3DP. Building upon experience gathered during the COVID-19 pandemic, we look to the

future to see what novel mechanisms within the IPR system could provide the additional flexibility required for dealing more smoothly, with the help and support of digital technologies, with situations such as global health emergencies.

Keywords: Pandemics, Supply chain regulation, 3D printing, Intellectual property

Rights, IP exceptions

1. Introduction

Over the past few years, 3D printing (3DP), a process of converting data from digital files into 3D models using a machine that prints layer upon layer of a selected material, has become increasingly important in healthcare space. These developments are driven by some of the main advantages of this technology, such as the fact that it promotes spare parts availability and on-demand production, as the digital element of 3DP reduces both the costs and the struggles related to physical storage and shipping of tangible products and spares^{1,2,3}. Traditionally manufacturing processes remove material from a billet and/or require special tooling to make a part. Those requirements for traditional manufacturing make 3D printing faster for products to market with fewer resources and waste. In addition, starting the manufacturing process via 3D printing is much easier than with any other manufacturing method. Moreover, 3DP is already largely widespread even at homes. That challenges current intellectual property rights (IPR), since manufacturing is easier and more widely available than ever. It is no coincidence that the COVID-19 pandemic has exponentially accelerated the use of 3DP in healthcare, as many schools, universities, organisations and individuals have combined forces to print the equipment needed to protect key workers, as well as private people. The agility of 3DP in terms of delivering and producing products gained momentum especially during the first waves of the pandemic, with the 3D printing community stepping forward by offering their services to ease pressure on governments and broken supply chains. In addition to the COVID-19 case, the story of Dr Tarek Loubani – a Canadian-Palestinian doctor who used 3D printing technology to create a stethoscope to overcome the shortage of medical devices in Gaza – is another: indeed, one of many famous examples to show how 3D printing technology can overcome shortages of essential goods where supply chains have broken down.⁴

Yet all this might not come without legal controversy, notably in relation to IPR in the key technologies and innovations involved. For instance, disputes might arise when the ownership of inventions and creations that are 3D printed is seen to be in conflict with claims to IP rights related to those innovations. Surprisingly, with COVID-19 we have seen almost no public IPR dispute (with few exceptions) on 3D printed medical equipment produced to cope with the

¹ Chekurov and Salmi 2017, p. 23-30

² Chekurov et al. 2021 Journal of Manufacturing Technology Management.

³ Verboeket et al. 2021, p. 25818-25834

⁴ Gander 2015

health crisis.⁵ Yet it is difficult to see how IPR was not relevant for any of the equipment that has been printed out (without express consent) by the 3DP community. The story of an alleged threatened patent infringement litigation by a medical device manufacturer against Italian engineers who reverse-engineered and produced patented valves with 3D printing technology for use in a hospital in North Italy at the beginning of the Covid-19 pandemic showcases the issues well. While such threat was denied by the manufacturer, it yet shows that IPR issues need to be considered and are not only hypothetical.⁶ It appears that in other cases reasons, such as the fear of attracting a bad reputation during a declared situation of national emergency or corporate social responsibility policies) have led IP owners not to enforce their rights during the pandemic. Most aspects of the COVID-19 response via 3D printing, including medical equipment, tracking systems, software, as well as vaccines, diagnostics, and therapeutics, were subject to some form of exclusive IP rights that were at times reproduced without explicit consent

As of today, in fact, there is no internationally recognised general exception to excuse IPR enforcement for health emergencies or pandemics. At the same time, however, while tools such as compulsory licensing, combined with various types of voluntary licensing arrangements, are often referred to as being able to alleviate access to and distribution of innovations in critical situations like the one now considered, most of these tools suffer from multiple shortcomings, for example burdensome, slow and time-consuming administrative processes (e.g. in the case of compulsory licensing), as well as fragmentation and uncertainty (e.g. in the case of most voluntary licensing arrangements). This then raises the interesting legal and policy question whether and to what extent IPR owners *should* be entitled to enforce their rights on critical products or processes in times of medical emergencies such as global pandemics. For instance, in the specific context of 3D printing and COVID-19 related medical products, the non-existence of a general exception for health emergencies or pandemics has meant that the 3D printing community have had to take on the remarkable risk of being sued for IP infringements while printing without express permission. Moreover, one could question whether – even if a general IPR exception or flexibility (or the like) for instance for pandemics or global crises had existed – more players in the digital manufacturing supply chain would have been willing to jump in, thus further increasing supply of critical products and spares.

In view of scientific predictions that quite clearly link the worrisome speed of environmental degradation to the possible increase of global health pandemics, it is not so sci-fi to think that

⁵ Valdes 2020 Journal of Business & Intellectual Property Law

⁶ Mahr and Dickel 2020 Journal of Intellectual Property Law & Practice. The CEO of the the tated that A patent infringement case was never contemplated - <https://www.theverge.com/2020/3/17/21184308/coronavirus-italy-medical-3d-print-valves-treatments>

the next global health crisis is not very far away: what will happen then? Will IP owners still stay calm and quiet as they did with COVID-19? What if the next pandemic comes as soon as COVID-19 is over, for instance: is it realistic even to think that such a laissez-faire attitude by IP owners will continue in the same way? And if this same path is not duplicated but, rather, IP owners aggressively enforce their rights on reproduction of essential medical equipment such as produced via technologies like 3D printing, how will this affect the availability of these as well as the possibility to save lives?

This article contextualises these key issues in relation to the role of digital manufacturing technologies like 3D printing in the fight against global health emergencies and crises. We take the COVID-19 pandemic and its implications as a case in point where data on the matter is already available. At the same time, we look to the future to see what adjustments to the IPR system might be possible or even desirable in order to make the best use of these types of decentralised digital technologies that enable local production, building manufacturing capacity and provide considerable advantages for supporting production in situations of broken supply chains. We begin by presenting an overview of how 3D printing technologies have helped in the fight against the COVID-19 pandemic. We then explore the role that IP tools as traditionally used in health emergencies, such as compulsory licensing and some forms of voluntary licensing, have been used during COVID-19 in the 3DP context. This analysis sheds light over the main deficiencies in our current IP system in terms of promoting the use and development of digital manufacturing technologies during periods of emergency. We then build upon this analysis to develop novel mechanisms that could be further explored and tested within the IP system in order to add to the system the flexibilities needed to better and more smoothly overcome global health emergencies and other similar situations through the help and support of digital technologies.

2. Medical 3DP and Pandemics: Past, Present and Future

3D printing can be used to produce various medical devices from patient-specific medical models and implants to instruments and parts for these same devices.⁷ The 3D printing process always requires a 3D model of the object to be manufactured. In medical applications, personal geometry is often based on medical imaging or 3D scanning, but only 3D modelling can also be used.⁸

⁷ Mäkitie et al. 2010

⁸ Salmi 2021, p. 191

At the beginning of the COVID-19 pandemic, different medical supplies were lacking because of both high demand and supply-chain breakdowns due to national and global restrictions and lockdowns.⁹ All this forced nations to look for alternative ways to locally manufacture certain supplies, such as personal protective equipment, ventilators and consumables used in testing for COVID-19. Here, the advantages of 3D printing stepped in: digitalization could help narrow and shorten the supply chain, and local manufacturing would enable manufacturers to reduce waste in time and materials, as well as optimise costs. This could reduce dependency on critical supplies from other countries and increase industrial resilience, as also noted by the European Commission.¹⁰

As a consequence, the development curve of medical 3D printing technologies and applications during COVID-19 has been remarkable, with many solutions having been made available as open-source options. At first, development focused on 3D printing of simple holders for face shields, door openers and other very low-risk, simple parts.¹¹ Then studies demonstrated how different personal protective equipment, such as face masks, or spares for them, could be 3D printed. When COVID-19 diagnostics was ramped up there was a shortage of nasopharyngeal swabs for collecting clinical test samples and 3D printing was able to manufacture those as well.¹² In addition, 3D printing can be used for making prototypes to speed up product development – including products related to the pandemic. At the time of writing, 3D printing is being explored for use in improving devices used to manufacture vaccines,¹³ as well as to print out other forms of personalized medications in both hospitals and in home settings.¹⁴ Clearly such novel applications would not only help to achieve sustainability goals¹⁵ but could become very useful in any future pandemic or other health crisis.

Returning to the present crisis, it is hard to estimate how many medical supplies have been 3D printed during the COVID-19 pandemic. But, for example, tens of millions of swabs have been printed based on the 3D model and the process developed by the University of South

⁹ Bhaskar et al. 2020

¹⁰ Von Der Leyen 2020

¹¹ Novak and Loy 2020

¹² Ford et al. 2020, p. 1-7

¹³ NESSIE (NA)

¹⁴ Beer N et al. 2021

¹⁵ GlobalData Healthcare 2021

Florida.¹⁶ And many similar 3-D printing solutions have been implemented, so the total amount of 3D printed swabs could actually amount to hundreds of millions. The volunteer organization Open Source Medical Supplies alone estimated that they produced 25 million face shields, mostly by 3D printing the frame.¹⁷ Based on open source solutions, the amount of similar devices worldwide is estimated at 4 000 000 nasal swabs, 3 000 000 venturi valves, 700 000 face masks and 1 000 000 face shield holders that could have been 3D printed in a day without taking into account alternative 3D printing devices and materials.¹⁸

The combination of 3D printing technology, an open-source way of thinking and a willingness to share has clearly shown its potential in the COVID-19 pandemic.¹⁹ Overall, 3-D printing has become one of the new key technologies in combating the COVID-19 crisis. That said, it is not entirely clear to what extent such uses would have infringed IPRs, though it can be assumed that many cases could have ended up in litigation if the IP proprietors had chosen to initiate infringement proceedings. Looking ahead, it therefore appears warranted to analyse the flexibilities in IP legislation with regard to new technologies and health emergencies, to ensure that the risk of IP infringement does not slow down or even prevent effective pandemic responses in extraordinary times.

3. Health Emergencies and Flexibilities in European IP Law: the Case of COVID-19 and 3D Printing

3.1. Compulsory Licensing

Compulsory licensing is one of the regulatory mechanisms typically mentioned as offering ways to circumvent the exclusive effects of IP rights. Ordinary licensing is conducted by virtue of a contract between the right holder and the party seeking to use the subject matter covered by the IP right. The conclusion of a licensing agreement grants the licensee the right to use

¹⁶ RSNA 2021

¹⁷ OSMS

¹⁸ Salmi 2020, p. 4004

¹⁹ Because of this rapid development and the crisis situation some countries have used speeded-up and emergency approval processes for producing medical products via 3D printing (see e.g. Manero et al. (2020), p. 4634). In some countries hospitals have used non-approved products, since those were better than no products at all (see Erikainen and Stewart 2020, p. 91). However, in most countries the same approvals and protocols for 3D printing as in 'normal' times have had to be followed (see Cooley LLP 2020)

the invention without infringing it, as use would now be authorized by the right holder. Under compulsory licensing, this authorization is replaced by a decision of a competent authority or court. The mechanism of compulsory licensing is clearly regarded as a last resort, i.e. when negotiation of licensing between the parties is futile or if other factors stipulate non-consensual solutions. As Gordon says: “Although intellectual property has provided mechanisms to facilitate consensual transfers, at times bargaining may be exceedingly expensive or it may be impractical to obtain enforcement against non-purchasers, or other market flaws might preclude achievement of desirable consensual exchanges.”²⁰

Compulsory licensing has been a feature within international IP law for some time now. Most markedly is its introduction in relation to patent law in Article 5.A (2) of the Paris Convention.²¹ The contemporary international framework in the form of the World Trade Organization’s (WTO) Agreement on trade-related Aspects of Intellectual Property Rights (TRIPS) emphasizes the role of compulsory licensing in patent law with its Article 31²² and Article 31 bis, while the Agreement is silent in relation to compulsory licensing of other IP rights.²³ Article 31 TRIPS prescribes the procedural and substantive conditions under which compulsory licensing of patents is possible but they only set minimal standards²⁴ allowing states to devise even more stringent criteria. The conditions set in Article 31 TRIPS include prior attempts to obtain licences on a voluntary basis from the patent holder (which, however, may be waived by member states “in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use”), determination of the scope of the compulsory licence, its non-exclusivity and non-assignability as well as making it subject to adequate remuneration. These conditions stipulate a restrictive application and positioning the provision after Article 30 means that compulsory licensing should be applied in exceptional circumstances while unfettered exercise of the patentee’s right is the rule. This restrictive approach was softened due to the Doha Declaration on TRIPS and Public Health of 2001 and subsequent events, which led to introduction of Article 31bis of the Agreement.²⁵

²⁰ Gordon 2020, p. 1613

²¹ Ricketson 2015, paras 10.40ff

²² The Agreement mentions that Art. 31 relates to “Other Use Without Authorization of the Right Holder” which is understood to refer to compulsory licensing. This is even more clearly the case with the introduction of Art. 31bis, which specifically mentions compulsory licensing.

²³ The Agreement, however, specifically forbids compulsory licensing of trade marks (Art. 21).

²⁴ TRIPS 1994, Art. 1(1)

²⁵ WTO 2017

Some countries have issued special legislation in relation to compulsory licensing in response to the COVID-19 pandemic. Israel, for instance, has granted a compulsory licence under Article 104 of the Israeli Patent Act in order to import a generic version of AbbVie's Kaletra from India. The provision does not foresee prior consultation with the patent owner, nor does it permit judicial review of the decision.²⁶ Similarly, Germany amended its Act on the Prevention and Control of Infectious Diseases in Humans in early 2020 to address the challenges posed by the Corona pandemic. Part of the amendments delegated special powers to the Federal Minister of Health should an "epidemic situation of national significance" exist (section 5 of the Act), which includes the power to use a patented invention pursuant to Article 13 of the German Patent Act. In comparison to the compulsory licence granted under Article 24 of the German Patent Act, Article 13 does not grant the right to use the patented invention to a particular licensee but rather that the patent holder cannot exercise their right by way of prohibiting acts covered by the order pursuant to section 5(2) n. 5 of the Act on the Prevention and Control of Infectious Diseases in Humans. Such an order can be challenged by the administrative courts though such challenge would not have suspensory effect.²⁷

Applying compulsory licensing as a fall-back solution in medical emergencies has substantial drawbacks which makes it a futile option in the context under discussion. First, the timeframe for overcoming the procedural hurdles to complete the grant of a compulsory licence are not adequate to address a healthcare emergency. The fact that the amendments to Article 31 TRIPS after the Doha Declaration only led to one successful application when Rwanda notified the WTO's TRIPS Council of its intention to obtain generic HIV drugs from the Canadian company Apotex highlights its limited use in a health emergency. There, the whole process was perceived as being cumbersome²⁸ and the drugs destined for Rwanda took 15 months to arrive in the country. Thus, the advantage that 3D printing technologies provide would be lost in a web of procedures and possible litigation by right holders that may wish to oppose the grant of a compulsory licence. As seen, some compulsory licensing procedures can be conducted without notifying the patent holder, as indeed the TRIPS agreement specifically

²⁶ Houldsworth 2020

²⁷ Klopschinski 2020

²⁸ Apotex, the company in Canada producing generic drugs under this particular procedure found it "to be highly inconvenient and commercially unviable" - Dutfield and Suthersanen 2020, p. 410

allows. But this usually requires the involvement of government institutions in some form and does not seem to permit private persons or entities to act unilaterally.

Secondly, compulsory licensing does not cover know-how, and in particular tacit knowledge, surrounding production of IP-protected goods. These may be covered by trade secrets protection and non-disclosure agreements (NDAs). This is particularly relevant in the context of vaccines²⁹ but may also apply to other more complex and sophisticated goods which can be replicated by 3D printing technologies. “Reverse engineering” such knowledge is burdensome and time consuming and would require many trial and error approaches. Thirdly, compulsory licensing is generally available for patented technologies but is not necessarily available in relation to other IP rights which may be relevant for reproduction for medical technologies. For instance, the EU design framework currently does not provide for compulsory licensing while this is not prohibited by the TRIPS Agreement.³⁰ The same applies, with some very minor exceptions, to regulatory data- and market-exclusivities, which might be relevant for some medical devices, products and compounds.³¹ Fourthly, compulsory licensing of an IP right is tethered to the territoriality principle of IP rights.³² This may require applying for multiple compulsory licenses in different jurisdictions which apply different procedures. All in all, compulsory licensing, often proffered as a possible remedy, is rather a “lame duck”.³³

3.1.2. Interim Conclusion

While compulsory licensing is sometimes mentioned as providing access to protected technologies, its drawbacks severely dampen its role as a viable solution for health emergencies in the context under discussion. The speed with which 3D printing could be deployed to address shortages in medical equipment and other tools by leap-frogging supply chains would be eliminated by the burdensome administrative hurdles which potential users need to overcome in order to commence production without the chilling effect of facing potential IP infringement claims by right holders. Furthermore, the fact that compulsory licensing is currently not available for all IP rights which could potentially be affected by 3D printing, the absence of cover of know-how as well as the territoriality issue mentioned above,

²⁹ Gurgula and Hull, p. 1248. See also: Sinha 2021. Forthcoming, Cohen et al. 2022

³⁰ Firth 2009, p. 170. See also Gervais 2012, para 2.345; European Commission 2016, p. 144

³¹ t Hoen 2017, p. 7

³² McMahon 2020, p. 146

³³ Van Zimmeren et al 2022

make compulsory licensing – as a sole solution – a rather clumsy and inept mechanism to deploy in medical emergencies.

3.2. Voluntary Licensing: IP Pools and Pledges

Generally speaking, voluntary licensing is naturally the preferred mechanism for disseminating life-saving technologies. It is built on the main tenets of IP right protection: exclusivity and freedom of contract between the parties. It is also deemed to be the rule because, as previously noted, the TRIPS Agreement prescribes that compulsory licensing can usually only be pursued once voluntary licensing has not successfully been achieved.³⁴ Looking specifically at the COVID-19 pandemic and the way that voluntary licensing has been used in relation to 3D printing, two main tools emerge, namely IP pools and IP pledges.

3.2.1. IP Pools

IP pools – or joint licensing – are agreements between two or more parties to cross-license parts of their current or future IP portfolios related to certain technologies to one another or to third parties.³⁵ Typically, in these structures, licensing occurs via mutual coordination or via a third party administrator. IP pools are especially appealing when dealing with complex and interoperable technologies, where multiple players can join in bringing their own complementary strengths. It is worth mentioning that, although initially viewed with hostility by the regulator due to their potential clash with competition law, IP pools are nowadays quite accepted by competition authorities, if with some reservations.

In the context of COVID-19 patent pools have been developed in general – for example, the recently signed Medicines Patent Pool (MPP) agreement related to the manufacture of a diagnostic kit.³⁶ In the specific context of COVID-19 and related 3D printing applications, the ‘COVID 3D TRUST: Trusted repository for users and suppliers testing’³⁷ created in the USA is

³⁴ TRIPS, Art. 31 (b) This requirement may be waived “in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use”.

³⁵ WIPO 2012

³⁶ WHO news 2021

³⁷ NHI Covid-19 Response 2020; Another example of an IP pool developed in the COVID-19 context is the “C_TAP”, which works through its implementing partners, namely the Medicines Patent Pool, the Open COVID Pledge, and the UN Technology Bank and Unitaid, to facilitate timely, equitable and affordable access to COVID-19 health technologies. WHO 2020

a type of IP pool. The COVID 3D TRUST is hosted under the NIH 3D Print Exchange portal, which is a resource from the National Institute of Allergies and Infectious Diseases (NIAID). The COVID 3D TRUST is a coordinated effort curated by the National Institute of Health (NIH) and NIAID, in collaboration with the US Food and Drug Administration, the Veterans Healthcare Administration, and America Makes. As stated on the website, “This collection is intended to support innovation and informed decision-making during the COVID-19 pandemic, while critical safety and medical equipment are unavailable through traditional supply chains”³⁸. The COVID 3D TRUST pool relies on the same principles and licences as the NIH 3D Print Exchange portal, in that it is an open repository for finding, sharing, and creating (certain types of) 3D-printable models, and uses a variety of licensing options, all of which are open source types of licences.

What is particularly interesting in this example is that the designers are not only sharing their (possibly IP protected) technologies and designs, but they are also responsible for providing “thorough instructions to help others reproduce (them) accurately”³⁹. In other words, this arrangement might – at least partly – overcome one of the main critiques of IP pools, namely that they are venues for only sharing selected IP protected technologies, while know-how is kept outside of the pool. By forcing designers also to share part of their know-how, this might create a better venue for fostering technology transfer, including building capacities. Another interesting point about this type of pool is that it is – again – not a typical ‘closed-doors’ game between selected organizations that have agreed with each other, but is rather an open venue for sharing, where anyone can contribute. Indeed, the choice of relying on open source types of licences enables this more agile and open model of operation. In a way, this type of arrangement is well representative of a large part of the 3D printing and maker community, which relies heavily on concepts of sharing and co-creating. At the same time, however, it is clear that these kinds of arrangements are an impediment for commercialization when open source licences like the GNU licence are used – indeed, this might question and challenge the motivation for sharing from most commercial organizations. In addition, monitoring whether or not the solutions offered in this pool will actually work is highly complex and challenging. The ambition of people also drives similar technical solutions with a slightly modified design, which might lead to too many similar options being offered, while the best ones are lost behind too

³⁸ NHI Essential

³⁹ Ibid

many possible alternatives. Finally, this system carries the risk of people with limited skills and experience manufacturing certain goods which might not even work as expected.

3.2.2. IP Pledges

Another type of voluntary licensing mechanism that has been used during COVID-19 in the 3D printing context is the so-called IP pledge. IP pledges are publicly announced interventions by IP owners “to out-license active patents (or in general IPR), for a certain period of time, free from or bound to certain conditions for a reasonable or no monetary compensation”.⁴⁰ Depending on the conditions, pledges might not necessarily benefit only certain pre-determined groups of actors that have made formal agreements amongst each other, but they can apply to the wider public unconditionally.⁴¹

An example relevant to the COVID-19 pandemic and 3DP, for instance, is the patent pledge announced by University of South Florida Health and Northwell Health for their 3D printed nasal swab.⁴² This pledge concerns access to a protocol and links relevant to making the 3D printed Nasal Swab, a novel invention that was developed by a USF researcher for emergency situations arising out of the COVID-19 public health emergency. This pledge states that: “This 3D print swab design protocol is patent protected. The University of South Florida grants the recipient of design files permission to 3D print and use the swabs for non-commercial purposes until April 15, 2021”. The files, pledge and documents are not available online anymore but possible by request.

Another, larger-scale interesting example is the Open COVID Pledge, an initiative originally launched by “an international group of researchers, scientists, academics and lawyers seeking to accelerate the rapid development and deployment of diagnostics, vaccines, therapeutics, medical equipment, and software solutions in this urgent public health crisis.” The programme is led by the Program on Information Justice and Intellectual Property at American University Washington College of law.⁴³ Anyone can join the pledge, so in a way the Open COVID Pledge provides more like a venue to pledge. So far, many of the largest technology companies – including Amazon, Intel, Microsoft, Hewlett Packard Enterprise and Facebook – have signed

⁴⁰ For a general overview on IP pledges see Contreras and Jacob eds., 2017; Ehrnsperger and Tietze 2019

⁴¹ Contreras et al. 2019. See also Contreras 2020, p. 1146–1149

⁴² Ford et al. 2020

⁴³ Open Covid Pledge

into the pledge. A wide range of licences may apply, as there is not any required form of licence that pledging companies must agree to use. A set of three similar licences was created for the Open COVID Pledge, referred to as an “Open COVID License”. However, there is no standard licence that a licensee can assume controls the licensing. Each licence other than the three versions of the OCL may contain any number of custom terms. In fact, as of today, there are already several other possible licence terms that may apply, which makes it crucial that all licences be reviewed individually. These licences are meant to be effective as of December 1, 2019 and to last until one year after the WHO declares the COVID-19 Pandemic to have ended – and in any event not beyond January 1, 2023, unless otherwise extended by the Pledgor. For the 3D printing side, for instance, the Open COVID Pledge features two examples so far: 1) NASA designs has pledged rights on 3D printed respirators, including relevant instructions, 3D models and initial test data; and 2) the New Jersey Institute of Technology has pledged a 3D Printable forceps swab for COVID-19 testing, designed to reduce infection and contamination risk, including relevant instructions and 3D models.

Indeed, voluntary pledges to make IPR broadly available can overcome administrative and legal hurdles faced by more elaborate legal arrangements such as IP pools, and they can achieve broader applicability and greater acceptance than tools such as governmental compulsory licensing.

Notwithstanding the possible advantages, however, IP pledges also seem to suffer from limitations. One main concern relates to the fact that conditions to pledge are dependent on the IP owner’s wishes (who pledges), so in a way they are unilateral agreements. Such conditions to pledge vary considerably from one pledge to the other, creating fragmentation and uncertainty, and increasing complexity. For instance, with the Open IP Pledge initiative there is no obligation for the organizations joining in to license an entire patent or copyright portfolio, while each pledging company is free to exclude any of its patents or copyrights.⁴⁴ All this makes it imperative to check the scope of the IP licensed by each pledging company. This might become a heavy burden when several licensing terms and conditions are in use. Another important downside of IP pledges is that they are temporary in duration – as seen in both the 3D printed Nasal Swab and the Open COVID Pledge examples. This might actually lead to a lock-in situation, where organizations that include the IP protected technologies temporarily

⁴⁴ For instance, IBM and Microsoft have pledged to license their entire patent portfolios. Intel has described its intellectual property pledged as its “entire” intellectual property portfolio (subject to a key limitation described in further detail below), which would include software. At the same time, however, the Open COVID Pledge is only for patents and copyright, but e.g. trade secrets and trademarks are excluded. Thus, any statements similar to Intel’s that its “entire” intellectual property portfolio is included in the pledge must be read with this key limitation in mind. See also: Kong S and Warpula C 2020

pledged into their own solutions, might be forced to enter into licensing negotiations when the pledge expires. This is especially so in the case of COVID-19 pledges, where pledges usually apply if the IP is used in relation to COVID-19 (e.g. for developing, diagnosis, prevention or treatment products related to COVID-19). Thus, if the IP is included for example in other products that can be used for other viruses, the risk is that the use will exceed the scope of the licence. It should also not be forgotten that pledges do not obviously include any of the protections that are normally obtained in commercially negotiated licences. Last but not least, IP pledges carry the same general problems as compulsory licensing or IP pools in terms of enabling know-how sharing or local infrastructure development, because it is also true of pledges that what is licensed out is, in most cases, only the IP, while both know-how and training capacities are normally not shared. In sum, even if IP pledges are fast and do not involve heavy administrative tools so that they could allow different actors to develop solutions around some common technological core, they might be too limited when we look at larger multi-technology and multi-purposes innovation ecosystems that are often required in health emergency cases.

3.2.3. Interim Conclusion

All in all, while the advantages of voluntary licensing mechanisms are clear, they also come with several pitfalls. In addition to those mentioned above, which are specific to each type of voluntary licensing tool, voluntary licensing includes more general downsides when placed in the context of global pandemics – especially in relation to 3D printing – that are worth mentioning. First, as IP is territorial, voluntary licensing tends to be limited to a particular territory.⁴⁵ This does not help in the case of a pandemic, where multiple territories are equally hit by a medical emergency.⁴⁶ This gives the originator companies scope to negotiate differentiated terms for different territories. Second, another problem which voluntary licensing is facing specifically in relation to 3D printing is that it may constitute uncharted waters for originator companies. Many might have licensed their IP relevant to creating the technologies to other companies which then manufacture the goods. They might also have assigned their relevant IP rights to other companies. But those companies which largely use conventional manufacturing have not yet been exposed to the possibilities provided by 3D printing technology. This might then lead to uncertainties as to the process of licensing their IP for manufacturing using 3D printing technology, which rights need to be cleared and what royalty

⁴⁵ Eduardo and Ramani 2020, p. 367–384

⁴⁶ This is equally relevant for compulsory licensing where the relevant national procedures for obtaining compulsory licenses need to be adhered to - supra 3.1

rate to ask for. Interestingly, such a development would arguably boost the market in spare parts. Originator companies could add digital inventories to their tangible inventories and add digital distribution of their IP to their business models.

4. Fostering 3D Printing Developments and Uses in Future Health Emergencies and Crises through IPR Flexibility

Our analysis confirms an old known dilemma: IPRs in the health sector are both essential but can be potentially problematic. In particular during health emergencies, reaching a reasonable balance between protection and access to urgently needed innovations is a delicate task. The example of 3DP demonstrates how IPR can at times raise barriers for agile, flexible raising of digital (manufacturing) technologies to provide the rapid and reliable solutions needed during emergency situations. Lengthy and heavily politically influenced negotiations on possible solutions to the 'IP problem', like those surrounding the hotly debated IP Waiver,⁴⁷ demonstrate once again that preparedness and proactivity in IP law needs to be debated proactively – not reactively after a crisis has already emerged. Moreover, what also transpires from the above is the acknowledgement that some of the tools and structures of the current IP system are in need of further development and refinement.

No doubt this is a complex problem with no single bullet-proof solution. Putting all eggs into one basket – as seems to be the hope of some proposed 'solutions' such as the IP Waiver – is most likely not a functional or sustainable way to proceed and has seen much opposition from governments in developed countries. The Decision by the Ministerial Conference of 17th June 2022⁴⁸ thus only provided a significantly watered-down version of the originally proposal by India and South Africa which would have encompassed the suspension of the obligation to enforce certain provisions of the TRIPS Agreement necessary for the prevention, containment and treatment of Covid-19.⁴⁹ The compromise now is limited to the production of Covid-19

⁴⁷ Lawder and Shalal 2022

⁴⁸ Draft Ministerial Decision on the TRIPS Agreement, Ministerial Conference Twelfth Session Geneva, 12-15 June 2022, WT/MIN(22)/W/15/Rev.1, 17 June 2022

⁴⁹ Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19, Communication from India and South Africa, IP/C/W/669, 2 October 2020. Available at:

<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>

vaccines which would not entail 3D printing technologies. After all, existing IPR mechanisms, like those presented in section 3, already have the potential to embed flexibility in the exclusive IP rights framework. This flexibility should not be underestimated or disregarded. The question is instead: Is there a need and sufficient leeway to create even more innovative options for increasing flexibility in IPR to be better prepared for the next health crisis? What could these new tools be in the specific context of 3DP or digital manufacturing technologies? Below we shed light over some prominent suggestions that could be explored in this context.

4.1. New exceptions in IPR

4.1.1. Health Emergency Exceptions

An intuitive legislative tool to swiftly permit time-limited access to and use of protected technology in times of medical emergency is by devising an exception provision that would permit such uses in medical emergencies. Thus, the chilling effect on actors that wish to reproduce or otherwise use protected features by way of 3D printing technologies by the fear of potentially infringing IP could arguably be eliminated or drastically diminished at a time of crisis. They could rely on the exception provision in infringement proceedings brought by the right holder against an alleged infringement where the requirements of the exception provision are laid down. In addition to creating legal certainty linked to a robust definition of what constitutes a medical emergency or “public health emergency”, another benefit of such exceptions is that users would not need to await the right holder’s authorization when reproducing protected features and would not be subject to awaiting the outcome of administrative procedures as required under compulsory licensing.

From a policy perspective, exceptions also have advantages over other legislative mechanisms, such as excluding certain subject matter from IP protection. Such exclusions – for instance, those available for methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body⁵⁰ or for discoveries, aesthetic creations or computer programs as such⁵¹ in patent law – exclude this subject matter

⁵⁰ E.g. Art. 53 c EPC 2000

⁵¹ E.g. Art. 52 (2)(3) EPC 2000

from being protected by an IP right.⁵² Consequently, the relevant features would remain in the public domain, unencumbered by exclusive rights and free for anyone to use and reproduce. This may, however, negatively affect research and development in these areas as the incentive mechanism of IP would not apply here.⁵³ This may in turn motivate developers to keep their developments secret,⁵⁴ which would make reproduction of such features by 3D printing more tedious.⁵⁵ Exceptions nevertheless enjoy the advantage that they do not fully take the incentive mechanism away that the IP right seeks to confer on right holders.⁵⁶ Another disadvantage of exclusions is their nature as an *ex-ante* mechanism. Legislators must decide *ex ante* what subject matter ought to be excluded, and under what conditions, such as a health emergency. But how could legislators ascertain *ex ante* which technologies would be required to remain in the public domain in order to use the required technologies for medical emergencies? Exclusions may also be required horizontally in relation not only to patents but probably in relation to other IP rights. But even where an exclusion could be drafted more narrowly by, for instance, excluding medical products from patent protection, this would arguably be in violation of the TRIPS Agreement and its non-discrimination principle found within Article 27 (1).⁵⁷

The attractive option of legislating a general exception provision, however, needs to overcome a steep hurdle. The so-called three-Step Test⁵⁸ that can be found in relation to all IP rights within the TRIPS Agreement poses a significant barrier for legislators in WTO member states for introducing such an exception.⁵⁹ In order to be applicable to the health emergencies stipulated in this paper, such as the Covid pandemic, an exception provision would need to be

⁵² Other examples which can be mentioned here are the functionality exclusions in EU trade mark and design law, Art. 7 Nr. 1 (e) (ii) Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark, *OJ L 154*, 16.6.2017, p. 1–99; Art. 8 (1) Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs. Official Journal L 003, 05/01/2002 P. 0001 - 0024

⁵³ Bently et al. 2010, p. 64

⁵⁴ In relation to patents see: Machlup 1958, p 21

⁵⁵ This, of course, depends on the complexity of the object to be 3D printed and how easy this would be to reverse engineer by those seeking to 3D print it.

⁵⁶ Bently 2011, pp. 331-332

⁵⁷ Bently and Sherman 2015, p. 326

⁵⁸ A two-step test in relation to trade marks, see Art. 17 TRIPS.

⁵⁹ Art. 13 TRIPS in relation to copyright; Art. 17 TRIPS in relation to trade marks, Art. 26 (2) in relation to designs and Art. 30 TRIPS in relation to patents. The terminology between these provisions is largely the same while there are important differences that could lead to diverging interpretations.

broadly drafted to be workable in a medical crisis by being flexible enough to encompass a plethora of permitted uses in relation to a plethora of possible technologies and devices.⁶⁰ An exception provision in relation to patented inventions could, for instance, be drafted so that “the rights conferred by a patent shall not extend to any of the following: (a) acts done to address a health care emergency.”⁶¹ This may seal the fate of such provisions since its broad nature would arguably conflict with the first step of all these three-step tests which all mandate that an exception must be limited. In the *Canada - EC* decision of 2000,⁶² the Panel held that the term ‘limited’ has a narrow meaning.⁶³ This provides a qualification of the term ‘exception’, suggesting a ‘limited derogation’ of the patent right, i.e. “one which makes only a small diminution of the rights in question”.⁶⁴ Applying this rationale to the health case emergency exception example given here, such a provision would most likely not comply with the reasoning of the Panel in the *Canada - EC* decision. As the test fails where one of the requirements of one step is not met, the entire exception provision would fail.⁶⁵ The option of drafting a tighter and narrower exception provision that would limit permitted uses to such conduct as uses digital manufacturing by 3D printing would arguably also fail at step 1. As such an exception would not provide for any quantitative limitations of how many products would be produced under the exception, it will most likely meet the same fate as the Canadian Stockpiling exception which was under scrutiny in the *Canada-EC* decision. This approach, coupled with the way the test is interpreted, may hinder legislators from providing exceptions provisions which could be TRIPS-compliant for our purposes since the real life economic impact on the rights holder⁶⁶ and the relevant policy considerations⁶⁷ behind the exceptions are not considered at all unless this interpretation is dropped.⁶⁸

⁶⁰ Kur 2008, p. 9

⁶¹ This text is modelled upon the exception provisions as found within the Agreement on a Unified Patent Court, Art. 27.

⁶² WTO 2020 WT/DS114/R

⁶³ Ibid, p. 155, 7.30

⁶⁴ Ibid, p. 155, 7.30

⁶⁵ Ibid, p. 152, 7.20. See also: WTO 2020 WT/DS160/R, p. 30, 6.97

⁶⁶ Correa 2020, p. 299

⁶⁷ Dinwoodie and Dreyfuss 2012, p. 62; Kur 2008, p. 24

⁶⁸ Correa points out that future panels are not bound by this interpretation and suggest that exceptions may be deemed limited based on the acts involved, the purpose of use, the outcome of use of the invention, the persons invoking the extraction or its duration - Correa 2020, p. 299

4.1.2. Private use

Another option could be to try to enhance flexibilities in IPR via better promoting the role of an Open Source (OS) vision and related activities. As previously mentioned, for instance, during the COVID-19 pandemic OS communities played a key role in the context of use of 3DP technology. In particular, two types of actors from the OS community emerged in this context:

1. Those who produced essential equipment (e.g. face shields) based on someone else's instructions and donated them to e.g. hospitals and health care organizations.
2. Those who developed new innovations relying on 3DP technology to help with the pandemic crisis (e.g. in the case of 3D printed ventilators) and licensed them out via open source licences.

While point 2 poses, in principle, little concern, point 1 is a matter for concern. The activities carried out by the actors in point 1 raise several possible infringement concerns when the items – or parts of them – or the methods they include, are protected by IPR. As previously mentioned, this seems highly likely.

The situations presented in point 2 are likely not to be caught by the private and non-commercial use exception, as it is currently interpreted because both conditions must be present for the exception to be applicable. In this regard, what could be considered is whether it would be possible to develop a stream of interpretation of, for example, the private and non-commercial use exception that could also apply to consumer-engaging technologies like 3DP during health emergency situations where conditions of both private and commercial use are not met. Mendis et al.,⁶⁹ for instance, suggest that to encourage follow-on innovators to step in quickly in situations such as a pandemic could be to create a carve-out which would apply to private or non-commercial uses of technologies (like 3D printing), when needed during public (health) crises. This carve-out could become applicable upon declaration of an emergency by local or national authorities. This would enable possibilities for making copies of life-saving medical equipment, as this would be exempted from liability for the duration of the crisis. To avoid abuse of the exception post-crisis, follow-on innovators would be forbidden from releasing the digital files containing the instructions for 3D printing the required medical equipment or drugs, amongst others.⁷⁰ Similar solutions would also need to be taken into

⁶⁹ Mendis et al. 2020

⁷⁰ Technical solutions for this purpose are already available in the market. See e.g. <https://secured3d.com/> that offers secured cloud storage and streaming 3D designs with monitoring, managing, and tracking IP, as design files are printed inside and outside the company.

consideration in case other technologies are considered. This would continue to encourage innovation and promote access to inventions and maximise the use of 3D printing as well as intellectual property rights for the greater public good at a time of health crisis.

However, the clear challenge with this proposal is lack of compensation for technology developers, especially if we consider inventions and patents. Moreover, the private and non-commercial use exception in patent law in the context of 3DP has already raised the eyebrows of many. Historically, the private and non-commercial use exception in patent law has been quite uncontroversial, as use by private persons for non-commercial purposes (excluding research and experimental purposes) has been rare for both technological and economic reasons.⁷¹ Similarly, hobbyists' and DIYers' activities have traditionally attracted little attention from patent holders because these types of use of patented inventions are normally a one-time use only and, as such, do not fall within the targeted market of patent owners in the value chain. 3DP as a technology already challenges the rationale and acceptability of this exception, as it offers novel possibilities to reproduce inventions relying on the private and non-commercial use exception. With that in mind it might be difficult to try to even further relax an already controversial exception in the context of 3DP; thus, this solution – although interesting – might be quite difficult to gain acceptance.

4.2. New Mechanisms to Foster Resilience during Pandemics

To reduce the negative impact of pandemics in general, including the effects on governments, companies as well as individuals, important considerations might include other mechanisms that try to optimize mitigation of both monetary and health-related losses through fostering cooperation amongst stakeholders towards enhancing knowledge sharing and capacity-building. With intelligent cooperation, it would be possible to find win-win types of collaboration, instead of having IPR, skills and capacity all held individually by different partners.

In this context, one option could be to take a similar approach as, for example, the mobile networks industry has taken in relation to standard essential patents. When facing the increasing problem of interoperability between various devices globally, companies did not opt for making different basic network technologies between different manufacturers, but instead they standardized and used essential patents to create network compatibility through a

⁷¹ Ballardini and Lee 2017

mechanism of royalty compensation under ‘fair, reasonable and non-discriminatory’ (FRAND) licensing terms and conditions for the developer of a technology solution.⁷²

As far as pandemics are concerned, the same approach and logic could, for example, imply the following: If national governments predict shortages of specific IP-protected equipment that is declared ‘essential’ to fight an emergency (for example as in the case of ventilators or PPE with COVID-19), those organizations holding IP rights on these products or methods would assign their rights to, for instance, specific collective management organizations under FRAND licensing conditions to enable manufacturing to be ramped up globally. In this regard two options could be considered: one could be to expand the scope of existing collective management organizations to include management of licences on IPR other than copyright, for example during exceptional circumstances, as when national health emergency situations are declared. Another option could be the creation of an ad-hoc collective management organization for health emergencies. Perhaps the former option could be more manageable as it would rely on an already well established institution, thus reducing the transaction costs of creating a new body. Regardless, it is clear that investment in further developing the structure and model of how such a stream of licensing management should work once a state of emergency is declared should start immediately – not only after an emergency situation has arisen. Organizations that are working on innovations that have a high likelihood of being needed in health emergency situations could also already start entering into negotiation agreements with these organizations, so that the licensing management mechanisms could be operative immediately once a state of emergency occurs.

This proposed model might be more complex to design and manage than the currently existing similar systems for e.g. in Europe. For instance, one complexity comes from the likely higher heterogeneity of the actors from where these organizations would have to acquire the rights to license the IPR protected innovations. Indeed, this would depend from the type of specific IP-protected equipment is declared ‘essential’ to fight the emergency at stake, but for e.g. in the case of 3DP, it could encompass equipment and material manufacturers, as well as possibly several prosumers of the technology, like do-it-yourselfers, etc... Moreover, as previously mentioned, these new organizations would have to operate with different types of (often overlapping) IPR (not just copyright), and also different types of uses of the IP protected innovation. In addition, these new organizations would have to deal with a wide variety of industries, while for example most existing right management organizations tend to focus on

⁷² Pila 2020, p. 533

one specific industry field at a time, like the music sector. All this, might make it more difficult to agree on royalties – especially as such royalty shall be based on FRAND principles, rather than on market influence and demand for the the innovation (as in the case of the models used by most existing rights management organizations). Partly, also national legislation might need to be adapted to integrate this model. Therefore, designing and testing the system proactively and well before any pandemic begins is utterly important, as multiple trials and reiteration might be needed in order to achieve a satisfactory result.

As to the nature of these types of licensing agreements, it would seem difficult to arrange these licences on a compulsory basis – if anything, they would be caught by the compulsory licensing legal provisions (with all the administrative burdens they entail). On the other hand, as we know, a voluntary tool carries the challenge of needing key players in the market to commit themselves. Indeed, public pressure and brand values could be powerful tools in pushing organizations to join the effort. In addition, it could also be considered, from a company or corporate law perspective, that a requirement at the level of corporate social responsibility could be contemplated, for example by adding a strong recommendation for companies to join in these types of efforts.

These types of semi-automatic mechanisms to gain the required permissions for using certain innovations central to tackling a health emergency would be highly beneficial for the 3DP community, as it would make it easier to allocate from whom to obtain licences and it would also ensure that licences are affordable. Yet licensing IPR – especially in terms of patents and technologies – might not be enough. As we see with the current ongoing pandemic, for example, it is not enough to free, for instance, vaccines from patents to enable developing countries to reproduce the innovations involved. There is a need also to share valuable relevant trade secrets and know-know, as well as to develop tools to foster capacity building. As to the latter point, digital manufacturing technologies like 3DP actually hold considerable potential because of their flexibility. They do not require part-specific tooling, data can be sent through the internet and different parts can be made in the same production run. This gives us even more reason to frame the legal system in order to promote developments and uses of these technologies. As to the former point, however, the fact that sharing IPR is just not enough is very much true also with 3DP, the reason being that IP does not give 3D files, a print constellation and an actual 'recipe' for how products should be made.

Overall, this proposed solution could enable companies and organizations to receive fair and reasonable royalties. Moreover, it could reduce the duration of lockdowns, leading to considerable reduction in both economic and wellbeing-related losses as people could be treated and protected. It would also guarantee that companies are able to fully rely on IPR

during emergencies, securing revenues. In addition, since the medical business is quite traditional and the majority of the market is held by large corporations, this could allow smaller, innovative and agile companies a way to enter the market and resolve some market needs caused by pandemics.

Another example to permit commercial-scale use of patented technology without consent is government or crown use, which is for instance provided within UK patent legislation. This feature was developed initially by case law regarding the Crown's privileges against patentees to use an invention without the consent of the patentee and without compensation.⁷³ The Patents, Designs and Trade Marks Act 1883, which is the basis of the modern provision, placed Crown use within statutory law, though compensation to the patentee now needed to be paid.⁷⁴ Currently, crown use of patented inventions is regulated within Sections 55 - 59 UK Patents Act 1977 and permits "any government department and any person authorised in writing by a government department" acts listed within subsection 1 of Section 55, namely making and using a patented invention without the consent of the right holder. Section 59 extends these powers even "during any period of emergency" where an emergency has been declared. The necessary authorisation in writing which third parties require in order to be able to conduct the uses specified in subsection 1 can be arranged before or after the patent is granted and also be provided before or after the authorised acts have been executed.⁷⁵ While crown use specifically covers "the production or supply of specified drugs and medicines", the general term "for the services of the Crown" is not exhaustively defined⁷⁶ and thus able to cover, for instance, PPE.⁷⁷

The Court of Appeal has recently ruled that the authorisation given by government must not be general in its wording but rather "must be an authorisation to do acts in relation to a patented invention, not merely an authorisation to do acts".⁷⁸ Thus, the CIPA commentary notes that the decision may require contractors to "be advised to identify any need to use such inventions in advance wherever possible, and to secure an express authorisation from the

⁷³ Yang 2015, p. 399; Johnson 2020, p. 594

⁷⁴ *IPCOM GmbH & Co Kg v Vodafone Group Plc & ors* [2021] EWCA Civ 205[130].

⁷⁵ Sec 55(6) UK Patents Act 1977. The general compatibility of retrospective authorisation with the TRIPS Agreement beyond cases of "national emergency or other circumstances of extreme urgency" and "public non-commercial use" as provided in Art.31(b) TRIPS was questioned the Court of Appeal recently - *IPCOM GmbH & Co Kg v Vodafone Group Plc & ors* [2021] EWCA Civ 205 [150].

⁷⁶ Sec 55 (1) (a)(ii) UK Patents Act 1977; see also: *IPCOM GmbH & Co Kg v Vodafone Group Plc & Ors* [2020] EWHC 132 (Pat) [188].

⁷⁷ Lawder and Shalal 2022, p. 256

⁷⁸ *IPCOM GmbH & Co Kg v Vodafone Group Plc & ors* [2021] EWCA Civ 205 [150].

relevant government department where necessary, noting that such departments are likely to encourage their contractors to pursue commercial licensing solutions in preference to the exercise of Crown user rights wherever possible.⁷⁹ Liddicoat and Parish, however, suggest that this requirement would be rather straightforward to fulfil in the scenario they investigate, which is the Covid 19 pandemic.⁸⁰ However, an element which might deter crown use is that the royalty is negotiated after use, which may lead to hesitancy in employing this tool.⁸¹ To conclude, in assessing the viability of such provisions for this study, it is quite telling that the United Kingdom has not used this tool during the Covid 19 crisis.

5. Conclusion

At the time of writing this article (summer 2022), there seems to be no full agreement yet on the proposed WTO vaccine patent waiver compromise.⁸² At the same time it is clear that the debated Covid IP waiver alone will not be a “silver bullet” which would automatically restore the balance between the necessary protection to incentivise innovation and fair global access. But it is our hope that the current focus on the role of IP will trigger more nuanced debates that will ultimately enable us to improve pandemic preparedness, as well as to develop more innovative and sustainable pandemic responses for many sectors, including 3DP printing.⁸³

More broadly, our analysis might very well find applications also outside the 3DP and medical pandemic context, as these are rather fundamental issues related to the oft-discussed critical question how to find a balance between IPR protection and access. As a provocative example, one could ask: what if the next pandemic or crisis is local, e.g. affecting only developed countries like the EU or the USA, instead of global? Let us also assume that this local Western crisis will lead to a shortfall of critical innovations that are for some reason mostly owned outside the EU/USA, such as China: Would Chinese companies freely allow the EU/USA to reproduce and use their protected innovations to face the crisis? These thoughts are not so futuristic after all. Access to a large part of raw materials supply is insecure in Europe, as clearly demonstrated also by recent developments affecting the political stability of Ukraine and Russia. Not only over 80% of these CRMs are located outside the EU and the USA, but

⁷⁹ CIPA 2020, Supplement, Commentary on Section 55

⁸⁰ Liddicoat and Parish 2021, p. 255

⁸¹ Walsh et al. 2021, p. 404

⁸² Lawder and Shalal 2022

⁸³ Cf. on the preceding debates: Matthews and Minssen 2021 (Debating IP waivers...); see also: Matthews and Minssen 2021 (US COVID IP waiver...)

also most technologies to recycle and recover such CRMs are actually being developed (and protected) by non-European/American players. All this indeed drives us to better think about the magnitude of the problem, with the importance of further developments in this area becoming even more palpable.⁸⁴

More generally, in the midst of every crisis, such as the Covid-19 pandemic, lies opportunity. 3D printing technologies have been able to show some of their incredible potential at a time of emergency. This article has sought to identify means of unleashing the potential benefits of this technology while affording legal certainty to users and fair consideration of the property rights of right holders. Thus, cautious legislative changes are warranted and have been suggested here and elsewhere. However, the Covid crisis might also showcase the potential for right holders to consider 3D printing and its related technologies as a new form of distribution. The breakdown of traditional manufacturing and supply chains during the Covid 19 pandemic has shown how fragile these traditional forms of trade can be.⁸⁵ In contrast, digital trading platforms could at least supplement the way right holders commercialize their products and provide an additional income stream. This, however, raises other legal (i.e. the legal nature of CAD files), regulatory (i.e. product liability) and commercial questions, which fall outside the scope of this paper. Approaches to tackling this and future crises may bring a new era of more sustainable digital distribution and trade.

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⁸⁴ See e.g. Bhaskar et al. 2020

⁸⁵ Ibid

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