Rethinking intellectual property rights and commons-based peer production in times of crisis: The case of COVID-19 and 3D printed medical devices

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At the peak of the coronavirus disease 2019 (COVID-19) pandemic, in March 2020, the Hospital of Chiari (Brescia) was in a state of emergency. The stock of valves needed to operate ventilators was dwindling and the manufacturer was unable to supply them at short notice. Massimo Temporelli, founder of Fablab Milano and one of the 3D printing pioneers in Italy, with the help of the local press, called makers to the rescue. Cristian Fracassi, a young engineer from Brescia, and his colleague Alessandro Romaioli, who works in the world of 3D printing, rose to the challenge. The original manufacturer of the valves was not very cooperative and withheld the design data and blueprints relying on European Union (EU) medical manufacturing regulations. Temporelli, Romaioli and Fracassi were not discouraged and quickly began the process of reverse engineering. The plastic part was re-measured, drawn as a 3D model and finally printed in less than a day with a material cost of less than 1 euro per piece (Fig. 1). Of course, the replica was not certified, but tests were successful, and the devices were subsequently used on more than 10 patients in Italy. Two weeks later, amidst an increasingly serious situation worldwide, in which many supply chains were disrupted, several other maker collectives followed the example of Brescia and supplied hospitals in many parts of the world with spare parts for life support technology. While, under normal circumstances, they would have to fear copyright and patent lawsuits or regulatory intervention, their help is now welcome.

This article traces how, in the case of a global crisis, localized co-productive approaches to solve crisis-induced shortages are gaining increased acceptance and question the structural patterns and mechanisms of late capitalism. In the first section, we disentangle the relationships between the three main practical and symbolic contexts of 3D printing in the early 21st century (maker culture, prototyping and industrial contexts). We devote the second section to reflecting upon 3D printing against the backdrop of a social theoretical understanding of intellectual property (IP) rights. Against this backdrop, we explore, in the third section, how the current global crisis could change our understanding of IP and production methods.

Geek-symbolism, prototyping and additive manufacturing

Since 1974, when the chemist and author David Edward Hugh Jones coined the concept of additive

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This article

- This article explores how, in the case of a global crisis, localized co-productive approaches to solve crisis-induced shortages challenge existing understandings of intellectual property rights.
- It focuses on how the maker community (private individuals with access to 3D printing equipment) engaged in the production of medical devices during the SARS-CoV-2 (the novel coronavirus) crisis of 2020 and how international policymakers and industries reacted to their engagement.
While many AM technologies used in industrial contexts are very expensive and out of reach for private users, the term ‘3D printing’ evokes the image of an inexpensive machine (just like ‘2D printing’) that allows individuals to turn into potential manufacturers. Thus, the narrative of democratizing production through 3D printing has shaped the public discourse on this technology.

Adrian Bowyer, founder of the open-source development project RepRap (Replicating Rapid-Prototyper), positions digital fabrication technologies (like 3D printers) as an innovation that might put the means of production back into the hands of ‘the people’. According to Bowyer, these technologies might ‘allow people to manufacture for themselves many of the things they want, including the machine that does the manufacturing. It is the first technology that we can have that will simultaneously make people more wealthy whilst reducing the need for industrial production’. As such, 3D printing might evolve into a technology that challenges the regime of centralized capitalist production systems whose ownership is restricted to a limited number of people and organizations. ‘[P]eople of modest means […] will be able to make themselves a new flute, a new digital camera, or just a new comb by downloading the designs for them from the Web. Some of the designs will be sold; some will be available free. Industrial production may [only] be needed for the raw materials in considerable quantities.’

The technology journalist and entrepreneur Chris Anderson also views 3D printers as drivers of a ‘next industrial revolution’ in which the role of large-scale factories as traditional sites of innovation and production is eventually replaced by an economy of ‘makers,’ who collaboratively generate new product ideas that can be materialized anywhere. Economic theorist and political activist Jeremy Rifkin picked up on this idea of a new industrial revolution linking it to a decentralized green economy. He suggests that AM may not only be a more sustainable mode of production that reduces waste, but also one that may reduce emissions if truly used as a decentralized manufacturing technology that would diminish the need for the global shipping of goods: ‘[i]f we were to put all the disparate pieces of the 3D printing culture together what we begin to see is a powerful new narrative arising that could change the way civilization is organizing the twenty-first century.’

From the perspective of MIT professor Neil Gershenfeld, 3D printers are merely a prototype for advanced digital manufacturing (AM) in his New Scientist column Ariadne, the process of AM has not only become a practical reality but also morphed into a cultural icon of 21st-century maker culture, a tool for prototyping in industrial practice. ‘3D printing’ is a colloquial term for additive manufacturing. Today, a large variety of additive manufacturing technologies exist. They share the common feature of using digital data to create three-dimensional objects layer by layer. Guided by computer-controlled devices, the physical material is joined or solidified. Additive manufacturing technologies make it possible to create diverse objects of very different shapes with the same technological infrastructure. During the last decades, additive manufacturing has slowly been integrated into industrial engineering:

‘[w]hen Additive Manufacturing began to be used in the 1990s, it was initially employed for prototyping (primarily in the automotive industry) and subsequently to make casting moulds and tools. Today, it is also used to make end products including small parts, small batches and one-off items for the jewelry or medical and dental technology industries’.2

Figure 1. Tweet by Paola Pisano showing 3D printed valves for emergency ventilators during the COVID-19 crisis in 2020.

1 DEH Jones, ‘Ariadne’ (1974) 64 (917) New Scientist 80.
2 Acatech – National Academy of Science and Engineering, German National Academy of Sciences Leopoldina, Union of the German Academies of Sciences and Humanities (2017). Additive Manufacturing. Munich <https://www.leopoldina.org/en/publications/detailview/publication/additive-fertigung-2016/> accessed 20 April 2020.
3 A Bowyer, ‘Wealth Without Money’ (2004) <http://reprap.org/wiki/Wealth_Without_Money> accessed 21 April 2020.
4 C Anderson, Makers. The New Industrial Revolution (Crown Business 2012).
5 J Rifkin, The Zero Marginal Cost Society. The Internet of Things, the Collaborative Commons, and the Eclipse of Capitalism (Palgrave Macmillan 2014) 98.
fabricators. According to Gershenfeld, anyone with access to such a digital fabricator should be able to make almost anything. In contrast to the typical high-tech visions of modernity, imaginaries of 3D printing do not focus on large-scale technological systems created and used by a distinct techno-scientific elite. Instead, all members of society are portrayed as potential co-creators of a new mode of production in which accessible and affordable devices democratize and decentralize manufacturing.

Tinkering, understood as DIY production, has historically been closely associated with a US identity. Some associate it with countercultural movements since the 1970s as a self-sustaining sensibility that could overcome a reliance on the mainstream consumerist society, while others historicize it and frame it as a genuine part of the frontier spirit that made America great. No matter what political narrative it is associated with, tinkering evokes images of creativity, independence and ingenuity. Its patron saints are, among others, Steve Jobs and Bill Gates. It also evokes an updated version of the American dream: the tinkering geek in his [sic] garage that changes the world or at the very least becomes founder and CEO of a multi-billion-dollar enterprise in Silicon Valley. And very much like the cultural imaginary of its counterpart, tinkering is attracting a wide variety of individuals and associations.

Anyone who has an idea and explores it by technical means can be described as a tinker. The ‘maker’ is a contemporary re-imagining of the tinker and also encapsulates the notion of being part of a 21st-century social movement. Adam Savage, the host of the TV Show ‘Mythbusters’, described ‘making’ at the 2012 Bay Area Maker Faire in the following way:

We are seeing a generational shift back to Making. (...) It would be (...) really great to build your own things, rather than the things that pop culture feeds us. I have built and participated in the building of things from scratch: Robots, theatre sets, furniture, and props, but the love of the objects themselves, this child’s [sic] like desire for the impossible toy seen in a movie, or seen in my head. Wanting to make it, make it something that I have and something I have held. (...) That want of those things, and teaching myself how to make. Things in order to have them is the engine of everything I have achieved in my whole life up till now. It does not matter what you make, and it does not matter why. The importance is that you are making something.

On another occasion he stated: ‘Humans do two things that make us unique from all other animals; we use tools and we tell stories. And when you make something, you’re doing both at once.’ For Savage, this much is clear: to make things by ourselves is both a purpose in itself and an essential marker of the human existence. I make, therefore, I am. Conversely, a complete reliance on industrial mass production might be understood as something contrary to our nature. Such a reliance not only casts mass-production in a bad light but also constructs a social difference between those who ‘make’ and those who don’t. Makers are framed as sovereign actors and not as passive consumers. This distinction is extremely important for the self-perception and identity of the maker scene.

Since 2009, when the startup MakerBot introduced its first affordable open-source model ‘Cupcake’, 3D printers have become an integral part of the identity of those who identify as tinkers or makers. No Makerspace, Hackerspace or FabLab (some of the collaborative places in which modern-day tinkers gather and share their interests) seems to be complete without the ability to 3D print. Smartphone cases, camera gear, tabletop figurines, frames for glasses and superhero masks: all these and far more can be designed and created by using CAD software and desktop 3D printers that can be found in online platforms. Platforms like MakerBot’s ‘Thingiverse’ are actively inviting users to share their own designs with a larger community of other makers. At present, there are over 1.6 million 3D printing blueprints shared on the platform.

The cultural imagery associated with 3D printing is even more impressive. For some, it fosters ‘creative literacy’, opens a new perspective on ‘global sustainability’, or leads to more ‘intellectual freedom’. For others, it seems to endanger lives or even ruin whole
industries. However separate these images may seem, they are united by the fact that they attribute a transformative power to 3D printing. It seems that 3D printing has outgrown the actual technology: its possibilities and limitations and have become a ‘boundary object’ for all those who imagine a technologically induced change in our working and living conditions. The sociological concept of boundary object was introduced by Susan Leigh Star and James R. Griesemer (1989). It refers to objects that are used and interpreted in different ways by different communities and acquire different meanings in different social worlds. 3D printers, both as tools and words, are perfect examples of boundary objects. It does not matter whether the images associated with 3D printers have a utopian or dystopian character, or whether they are formulated from the left or the right ends of the ideological spectrum. The discursive power of 3D printing transcends such differences. Like the specimens, maps and field notes in Star’s and Griesemer’s article on the collaboration of amateurs and professionals in building the collections of Berkeley’s Museum of Vertebrate Zoology, the new printing technology as a ‘boundary object’ seems to be both ‘plastic enough to adapt to local needs and the limitations and have become a common identity across constraints of the several parties employing them, [and] robust enough to maintain a common identity across sites’. It yields imaginary and concrete power as a novel technology that inhabits several social worlds and connects them, even if the actors in these worlds interpret and use 3D printers quite differently. Such a communicative function can be observed in both the symbolic and actual use of 3D printing during the present COVID-19 pandemic.

A song of shields, ventilators and IP infringements

Both the AM industry and members of the maker community have been among the first responders to global shortages in crucial medical equipment during the 2020 COVID-19 crisis. The maker community began its response with immediate actions like a viral #NoTouchChallenge to design and produce ‘portable, 3D printable, multi-purpose no touch tools’ or the #DigitalSolidarityChallenge to produce spare parts for emergency ventilators. Meanwhile, industrial actors and lobby groups like the European Association of the Machine Tool Industries and related Manufacturing Technologies (CECIMO) had to first find a way to address and solve an immanent dilemma: first, how to balance the societal urge for a fast response with the protection of IP rights; secondly, how to deal with the public scrutiny and criticism that followed the industry’s reaction to the actions of the Fablab Milano, which cumulated into requests by the European Commission (on 20 March 2020) to loosen copyright during the crisis.

The immediate answer given by Filip Geerts, director general of CECIMO, was the following:

I believe that the additive manufacturing sector could provide immediate solutions to sustain the effort of hospital workers in the middle of this emergency. However, it is in the best interest of all to clarify the regulatory issues in order to move forward quickly and in a way that is not going to delay immediate actions.

Consequently, on 30 March 2020, CECIMO published a call for policymakers to clarify the relationship between 3D printing as a technology, industrial actors and public intensive care requirements. This call included the following six points:

- Use government’s official channels to communicate any requests to print parts, upload a list of essential supplies and provide the necessary files for printing to those companies who request them.
- Temporarily waive the Medical Device and Product Liability Directive requirements that would hamper AM companies’ response to the extraordinary demand of equipment by health care sector.
- Provide temporary authorization to use patents of essential supplies and services without the consent of patent holders.
- Cooperate closely with the customs authorities to accelerate the approval procedures for imports/exports of essential supplies and/or 3D Printing Hardware and ensure free flow of essential supplies and/or 3D Printing Hardware within the EU’s internal market.
- Include the AM sector in the list of the essential value chains that should continue its activities during the lockdown period.

14 EE Petersen, RW Kidd and JM Pearce, ‘Impact of DIY Home Manufacturing with 3D Printing on the Toy and Game Market’ (2017) 5(3) Technologies 45.
15 S Star and JR Griesemer, Ecology, ‘Translations and Boundary Objects: Amateurs and Professionals in Berkeley’s Museum of Vertebrate Zoology, 1907-39’ (1989) 19 (3) Social Studies of Science 393.
16 (Thingiverse, 2020) <https://www.thingiverse.com/> accessed 15 April 2020.
17 ‘CECIMO Press Release: Unleashing the Potential of Additive Manufacturing to Fight COVID-19 – CECIMO Recommendations to Policymakers’ (CECIMO, 2020) <https://www.cecimo.eu/news/unleashing-the-potential-of-additive-manufacturing-to-fight-covid-19-cecimo-recommendations-to-policymakers/> accessed 21 April 2020.
• Enable a quicker and smoother access to the market of new essential medical and protection equipment, by providing temporary access to certification, in response to the coronavirus outbreak. 18

As the crisis was worsening during late March 2020 and the public pressure with regard to copyright grew, CECIMO made, as the six points show, temporary concessions on the point of copyright, while simultaneously trying to strengthen the position of industrial actors. Part of this strategic call was to position industrial actors as central contacts for the production of medical parts, to temporarily loosen the regulatory restrictions for new products, and to temporarily stratify market structures. While CECIMO officials stated that ‘many companies from (the) European 3D printing industry (are) already volunteering to aid hospitals and health centers by proposing the use of their machines’, 19 the European maker community was worried with respect to its access to ABS (Acrylonitrile Butadiene Styrene) and PLA (Polyactic Acid) filaments. Makers were worried about their ability to help if the EU would implement such policy measures, given that such a call for re-centralization might (in their interpretation) cost more lives than their decentralized endeavours to assist hospitals during the crisis.20

An even more conservative approach was proposed in the Federal Republic of Germany by the National Academy of Sciences Leopoldina. Its working group ‘Additive Manufacturing’ called for medical devices manufactured with additive technologies to be clinically and legally safe. In the context of the COVID19 pandemic, this can be understood as a moratorium on the inclusion of privately manufactured medical devices in crisis management.21 Outside of Europe, the legal position of tinkerers and makers to help their local emergency wards remained unclear. Neither the US nor China, despite experiencing high rates of infection and large maker communities, adopted the April 2020 policies to clarify the role of makers in responding to the global crisis. While the US Food and Drug Administration did not generally forbid the maker community to act, it warned the public that ‘3D printed masks, for example, might not provide the same level of protection as traditional masks’.22 This led to a public discussion about safety risks and private 3D printed medical goods. While some regarded makers as heroes of first response and ingenuity, others framed them as next-generation quacks. An example of the latter perspective is the MIT researcher Martin Culpepper, who stated that ‘one of the biggest risks with 3D printing for Covid-19 situations is the false sense of hope that we can quickly print PPE (personal protective equipment) to address needs’ and that there are ‘a lot of issues with certain types of 3D printed parts with respect to their use in a clinical setting’, including material compatibility with established sterilizing techniques in hospitals.23 At the other end of the spectrum, the prominent technology YouTube-personality Naomi Wu (SexyCyborg) from Shenzhen (深圳市), China, posted on Twitter that she not only embraced the resourcefulness of the maker and tinker community during the SARS-CoV-2 crisis, but that she encouraged makers and clinicians all over the world to continue their efforts to help their local hospitals by providing spare parts for life-saving equipment (eg respirator elements) and PPEs. She also stated that she would even help ‘reverse engineer’ certain parts ‘and serve as a team’s human shield/patent bullet catcher in China’, because she would have ‘the support of a good Chinese IP lawyer’ (Fig. 2).

The World Intellectual Property Rights Organization (WIPO), which is under normal circumstances the world’s primary source for information, resources and services surrounding questions about global IP rights, has not reacted in its COVID-19 response strategy to the case of decentralized private 3D printing as of 21 May 2020. At the request of the authors of this text, the WIPO’s responsible authorities referred to a white paper from 2015, which, however, does not address action strategies for global emergency situations.24 However, it is possible to extrapolate from older cases where private 3D printing, IP law and social interests collided. We can thus (at least to a certain extend) expand on the first systemic exploration of the problem by Simon Bradshaw, Adrian Bowyer and Patric Haufe.

References

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19 ibid.
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21 Nationale Akademie der Wissenschaften Leopoldina (2020). Stellungnahme. Additive Fertigung – Entwicklungen, Möglichkeiten und Herausforderungen. <https://www.leopoldina.org/uploads/tx_leopublikation/2020_Stellungnahme_Additive_Fertigung_web.pdf> accessed 29 May 2020.
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23 MB Gallagher, ‘3 Questions: The Risks of Using 3D Printing to Make Personal Protective Equipment’ (MIT News, 26 March 2020) <http://news.mit.edu/2020/3q-risks-using-3d-printing-make-personal-protective-equipment-0326> accessed 21 April 2020.
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In their 2010 article, ‘The Intellectual Property Implications of Low-Cost 3D Printing’, they came to the conclusion that ‘personal use of 3D printing technology does not infringe the majority of IP rights’, since ‘[r]egistered design and patent explicitly exempt personal use, trade mark law has been interpreted as doing so, and UDR is only applicable to commercial use’.25 Furthermore, like the format shifting of the music industry (from CD to MP3 and now streaming models like Apple Music and Spotify) would have shown, purely local and personal infringements are impractical to pursue. Nevertheless, Bradshaw and his co-authors also noted that there were (in 2010) indications that in the near future ‘the level of detail and accuracy attainable by personal 3D printed objects [could become] sufficient to seriously impinge upon the market for quality products’.

The discussion of risks in the COVID-19 pandemic has been complemented by a discussion of decentralized aid strategies for hospitals experiencing supply problems in the face of an unforeseen crisis. As early responders to this situation, regulators in Canada released, in mid-April 2020, guidelines for the production of PPE by private individuals, maker collectives and small manufacturers with access to 3D printers. Based on an interim order from 18 March 2020, these actors were urged to use a number of standards and IPs for Face shields (ANSI/ISEA Z.87.1 (2015), CSA Z94.3 (2020), CSA Z94.3.1 (2016)) and Face masks (ISO 22609 (2004), ASZM F2100 (2019), ASTM F2101 (2019), ASTM F1862/F186M (2017), ASTM (F2299 (2003 R2017) in their attempt to reduce shortages within the medical system, regardless of possible claims by the actual right holders.26 However, the prerequisite for this was either a registration under the Interim Order Act or the possession of a valid Medical Device Establishment License (MDEL). Both were intended to keep the situation controllable, on the one hand, and to ensure compliance with safety standards, on the other. However, Class II medical products, such as spare parts for medical ventilators were excluded from the scheme. A release of these for private 3D printing should only be granted if the situation deteriorates dramatically in the coming months. The experiences from Lombardy in Northern Italy should be evaluated for this purpose.

A ‘global hackathon’

Even without immediate reactions from global authorities like WIPO, it seems that the COVID-19 crisis could become a catalyst for a major shift in how we understand IP rights and the ways we distribute and produce things in the future. Beyond current discussions between industrial actors, politicians and makers, many front-line medical experts started (despite possible risks) using locally and privately 3D printed supplies. Some examples are the ventilator valves and PPE produced by Cristian Fracassi and the Fablab in Milan discussed above.27 While COVID-19 mercilessly exposed the weaknesses of our globalized industrial supply chains, 3D printing might give new meaning to local solutions. The current real-time experiment of decentralized and private production can be seen as a kind of socio-technical prototype in itself. Amidst all the challenges of the COVID-19 epidemic, 3D printing appears as a unifying object that connects different stakeholder communities in new ways. The ‘global hackathon’ of 2020

25 S Bradshaw, A Bowyer and P Haufe, ‘The Intellectual Property Implications of Low-Cost 3D Printing’, (2010) 7 (1) SCRIPTed: A Journal of Law, Technology and Society 5.
26 Government of Canada, ‘3D Printing and Other Manufacturing of Personal Protective Equipment in Response to COVID-19’ <https://www.canada.ca/en/health-canada/services/drugs-health-products/medi-devices/covid-19-unconventional-manufacturing-personal-protective-equipment.html> accessed 12 June 2020.
27 O Solon and A Glaser, ‘A Worldwide Hackathon: Hospitals Turn to Crowdsourcing and 3D Printing Amid Equipment Shortages’ (NBCNEWS, 21 March 2020) <https://www.nbcnews.com/tech/innovation/worldwide-hackathon-hospitals-turn-crowdsourcing-3d-printing-amid-equipment-shortages-n1165026> accessed 21 April 2020.
tested the possibilities and limitations of a comprehensive maker production in a publicly visible and performative way. The example of Naomi Wu is paradigmatic for this. It shows that the ethos of commons-based peer production and open science surrounding the maker community aligns quite well with systems and policies of industrial production that do not respect IP rights and have lower standards with respect to consumer protection.28

New production methods and questions about IP rights in times of an unprecedented pandemic present a new challenge for the IP rights community. In what way can additive and decentralized manufacturing be reconciled with quality, safety and IP rights? One possibility would be the formation of a joint commission for future crises. This could bring together regulators, ethicists, lawyers and members of the industry community to develop guidelines for global crisis scenarios. An example of this is the cooperation between the FBI in the USA and the DIY biology community to identify and solve security risks and copyright problems in the biochemical sector. They have established a forum for exchange in which educational workshops are held on a new way of participating in technology, in which security issues are explored and in which mutual role expectations are discussed.29 Perhaps, a similar model could address the issues raised above, for the benefit of everyone involved.

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29 H Wolinsky, ‘The FBI and Biohackers: An Unusual Relationship’, (2016) 17 (6) EMBO Rep 793