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The Medical Right to Repair: Intellectual Property, the Maker Movement, and COVID-19

Matthew Rimmer

Faculty of Business and Law, Queensland University of Technology (QUT), Brisbane, QLD 4000, Australia; matthew.rimmer@qut.edu.au

Abstract: This article considers the strengths and limitations of the use of 3D printing and additive manufacturing for the production of personal protective equipment (PPE) during the COVID-19 public health crisis. It explores the role of the Maker Movement in addressing the shortfall in medical equipment during the public health pandemic. Taking a comparative approach, this article evaluates the responses of both the commercial and amateur sides of the 3D printing community to the COVID-19 public health crisis. In the EU, the Fab Lab Network sought to overcome a breakdown in supply chains. In the US, Dale Dougherty of Make Magazine promoted Plan C, in which volunteers have worked together to produce PPE. In Australia, 3D printing has been used to augment supplies of PPE. In this context, a key issue across jurisdictions has been the tension between intellectual property rights and the right to repair—particularly when 3D printing has been applied to deal with shortages in PPE. Senator Ron Wyden put forward the *Critical Medical Infrastructure Right-to-Repair Act* of 2020 (US) to try to resolve these tensions. Open licensing has proven to be a helpful mechanism to enable open collaboration and sharing of 3D printing designs for the purposes of health care. Nonetheless, it is argued that there should be stronger recognition of the right to repair—particularly in the context of health-care and medical devices. The COVID-19 crisis has highlighted that there needs to be a broader array of intellectual property flexibilities to deal with public health emergencies—including in respect of the right to repair. As such, this article supports a broad vision of a *TRIPS Waiver* which includes the right to repair. The recognition of a right to repair will help promote the realization of the Sustainable Development Goals and a COVID-19 recovery. The topic of the medical right to repair has larger implications for sustainability and the Sustainable Development Goals (SDGs), particularly in respect of responsible production and consumption (SDG 12), as well as good health and well-being (SDG 3), innovation (SDG 9), and partnerships for the goals (SDG 17).

Keywords: intellectual property; 3D printing; the Maker Movement; the right to repair; COVID-19; sustainability; sustainable development goals; pandemics

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1. Introduction

During the COVID-19 crisis, a catch cry of doctors, nurses, and health professionals was 'Get Me PPE' [1]. There was great concern amongst front-line health workers about shortages of personal protective equipment (PPE) (such as face masks, respirators, and other supplies) during the COVID-19 public health emergency.

The World Health Organization (WHO) called for a boost to domestic production of PPE by governments across the world [2]. WHO director-general Dr. Tedros Adhanom Ghebreyesus commented: 'Without secure supply chains, the risk to healthcare workers around the world is real' [2]. He observed: 'Industry and governments must act quickly to boost supply, ease export restrictions and put measures in place to stop speculation and hoarding' [2]. The WHO director-general emphasized: 'We can't stop COVID-19 without protecting health workers first' [2].

In this context, there was much interest in the application of 3D printing and additive manufacturing to address supply shortages—particularly in respect of PPE and other

medical supplies and specialized products [3]. In particular, the Maker Movement has sought to provide help and assistance to public health authorities through 3D printing PPE and medical supplies.

The anthropologist Dr. Sally Applin comments that the Maker Movement's can-do DIY spirit has been helpful in response to the COVID-19 pandemic [4]. She provides an overview of the response of the Maker Movement: 'Right now, all over the world, people are engaging in the construction of critical supplies and [PPE] respirators, and other clinical items, using tools and techniques such as 3D printing, sewing, repurposing factory equipment, and other skills and ways of thinking' [4]. Applin discusses the origin and the evolution of the Maker Movement, and details a number of 3D printing projects in the COVID-19 era. She observed that the education and activity networks of the Maker Movement 'have created a pipeline for information of how to innovate PPEs rapidly across the globe' [4]. She commented: 'It is this history that now critically comes into play with the coronavirus, for the spirit of hacking, making, and co-operative learning going on around the world is based on a straight-out-of-Maker Faire ethos' [4].

Nonetheless, the adoption of 3D printing of PPE and medical supplies raises larger questions about the operation of intellectual property—particularly in respect of the right to repair. Cory Doctorow has contemplated the right to repair in the times of the COVID-19 pandemic [5]. He considered the local 3D printing of replacement parts for ventilators in a hospital in Brescia, Italy, and the ensuing controversy over intellectual property and the right to repair. Doctorow highlighted how the COVID-19 crisis disrupted trade and logistics: 'The global supply-chain shutdown has revealed the fragility of long distance, complex manufacturing systems that are organized around central hubs that represent points of critical failure' [5]. He welcomed the response of the Maker Movement to the COVID-19 crisis: 'The surge in open source hardware designs and parts for medical equipment during the emergency represents a distributed, urgently needed decentralization of our world's critical manufacturing capacity' [5]. Doctorow emphasized: 'The right person to decide whether a field repair should be attempted, and whether the repair is solid enough to rely upon are medical professionals, not the shareholders of med-tech companies or the lawyers who write their terms of service and patent applications' [5]. Doctorow maintained: 'Today, we need those companies to step up by providing repair instructions, specifications, and technical aid to the global volunteer corps of makers and fixers who have given themselves over to helping us all weather this calamity' [5]. Doctorow has expressed broader concerns about the development of Big Tech monopolies through the abuse of intellectual property rights [6].

This article provides an evaluation of intellectual property and the right to repair in light of the public health response to the COVID-19 crisis. It builds upon the literature in respect of several domains. This article contributes to the field of intellectual property and public health—particularly as it concerns access to medicines, and other essential medical technologies during public health emergencies [7–13]. This article makes a contribution to the literature on the right to repair—particularly focusing upon the applications in relation to health-care and medicine [14–17]. This research is also part of a larger body of work on 3D printing regulation—particularly in relation to intellectual property law and policy [18–24]. This scholarship is also part of the emerging and growing field of COVID-19 law and regulation [25–30]. This article also contributes to the growing body of work on intellectual property and sustainable development—focusing, as it does, on the key area of the right to repair, which is designed to promote responsible and sustainable consumption in a circular economy [31–34].

In terms of its methodology, this article is not a traditional piece of black letter legal analysis. There is yet to be clear cut case law on the matters raised in this field. The topic of 3D printing and the COVID-19 crisis demands a mixture of methodologies to make sense of the subject matter. This article provides a history of the community and industry-based 3D printing responses in the COVID-19 crisis. It particularly highlights some of the innovation policies and community responses in respect of 3D printing PPE and medical equipment.

This article also explores the debate over the right to repair, with a particular consideration of medical and health matters during the COVID-19 crisis. It argues that there needs to be further reform of intellectual property laws—particularly in respect to the right to repair and health care. This article also touches upon larger questions around intellectual property and international trade. In particular, the question of a medical right to repair comes within the ambit of the *TRIPS Waiver* [35,36] and the *Ministerial Decision* [37,38]. The topic is part of a larger debate about what intellectual property exceptions should be available during a public health emergency—such as the COVID-19 crisis. It is certainly acknowledged that 3D printing and additive manufacturing of medical supplies during the COVID-19 crisis also raises other policy issues around medical regulation and product liability. However, a full analysis of those adjacent issues is beyond the scope of this particular paper.

This article is a comparative piece of work, looking at intellectual property policy, law, and practice. It compares the legal and political and public health responses of various key jurisdictions—including the European Union (EU), the United States, and Australia. Part 2 focuses on the EU and its approach to intellectual property, 3D printing, and the right to repair during the COVID-19 crisis. It considers the controversy over the 3D printing of replacement valves for ventilators in Italian hospitals during the COVID-19 crisis. Part 3 considers the situation of the US in respect of the right to repair during the COVID-19 emergency. In particular, it examines the *Critical Medical Infrastructure Right-to-Repair Act* of 2020 (US), as well as more general proposals for a right to repair. Part 4 explores the use of 3D printing by Australian universities and industry to provide PPE supplies during the COVID-19 crisis. It considers the Productivity Commission inquiry into the right to repair, and its implications for medicine and healthcare. Part 5 explores the scope for the right to repair in the field of medical matters under international law—particularly the *TRIPS Agreement* 1994. It explores whether the proposed *TRIPS Waiver* and *Ministerial Decision* should have been framed broadly enough to include the right to repair. The conclusion recommends that there should be law reform to provide recognition of the right to repair—with specific reference to the repair of medical supplies during public health emergencies. It maintains that the full recognition of the right to repair will promote the UN Sustainable Development Goals (SDGs)—in particular, promoting responsible production and consumption (SDG 12), as well as good health and well-being (SDG 3), innovation (SDG 9), and partnerships for the goals (SDG 17).

2. The European Union

The European Union (EU) is notable for its strengths in respect of additive manufacturing and industrial 3D printing [39]. In particular, Germany, the Netherlands, and Spain are regarded as leaders in 3D printing. The European Patent Office has undertaken data analysis of the intellectual property landscapes in respect of 3D printing [40]. The field of 3D printing patents is becoming quite crowded, with a thicket of patents. The European Commission has also published a commissioned report on the intellectual property implications of the development of industrial 3D printing in 2020 [41].

In addition to the commercial sector of 3D printing, there is a thriving Maker Movement in the EU. Following the example of the Chaos Computer Club, hackerspaces have a long tradition and standing in the EU [42]. The Fab Lab movement has been particularly popular in the EU. Networks of Fab Labs have collaborated with one another on a range of projects [43,44]. There are also a range of other community-minded makerspaces in the EU. There is also a significant open-source movement in relation to 3D printing in the EU—with open-source companies such as Prusa 3D Printers.

In the face of the COVID-19 crisis, the 3D printing community in the EU sought to address some of the shortages in medical supplies. Commercial 3D printing companies—particularly those with medical expertise—applied their skills and knowledge in additive manufacturing. A network of Fab Labs collaborated on community projects to help address some of the gaps in health equipment and medical supplies. Such interventions raised some larger questions in respect of intellectual property, innovation policy, and medical

regulation. The EU has been supportive more generally of a right to repair as a means of promoting sustainable development, a circular economy, and a Green New Deal.

2.1. The Italian Dispute

In spite of its modern health care system, Italy was one of the first nations overwhelmed by the COVID-19 crisis [45–47]. In this context, there were issues with shortages of medical suppliers—particularly in respect of medical supplies. In the midst of this public health crisis, volunteers engaged in the 3D printing of replacement valves for ventilators. There were allegations that the original manufacturers had threatened legal action for breach of intellectual property rights for making 3D printed versions of the replacement valves [48–51]. The murky facts of this controversy have been contested. While the media stories suggested that there had been threats of legal action for intellectual property infringement, the original manufacturer has denied making any such calls for litigation. The nature of the controversy has been lost in translation, as the Italian story has been converted into English stories in the popular press. What was left was a Rashomon-style story—with different protagonists providing various accounts of what happened.

Davide Sher provided one of the most thorough accounts of the 3D printing project, discussing the various efforts of the Maker Movement to provide help and assistance to the Italian hospital service [52]. Massimo Temporelli, founder of The FabLab in Milan, was contacted by Nunzia Vallini, editor of the Giornale di Brescia. She explained that the hospital in Brescia urgently needed valves for an intensive care device and that the supplier was unable to provide them in a short time. Temporelli contacted Cristian Fracassi—the founder and CEO of 3D printing company, Isinnova. Isinnova was able to use 3D printing to redesign and produce the missing piece. S.A. Applin highlighted the Italian effort as an example of Maker Culture ingenuity in dealing with the pandemic [4]. *Forbes* provided a profile of the Italian engineers who were 3D printing respirator parts for free [52].

Initially, there were media reports that there had been threats of intellectual property action against the 3D printing project [53]. This story was then amplified by international media [54–56]. Fracassi was reported as saying 'I have lawyers who are evaluating the matter, I am not dealing with it personally because I prefer to devote myself to this [the 3D designs]' [56]. Fracassi was also reported as saying 'In any case, I am holding my hands because in a world where money matters more than someone's health, nothing else can be done' [56]. There seemed to be some ambiguity in the media reports about the story of intellectual property infringement. There was uncertainty as to what regime of intellectual property was involved—it was unclear whether it was a patent matter or a copyright concern or a question of industrial designs. There was also a lack of clarity as to the value of the technology in question.

In an interview with *The Verge*, one of the 3D printing makers Alessandro Romaioli denied that there had been a threat of intellectual property infringement [50]. He observed that the company had refused to release design files, forcing them to reverse-engineer the valve. Romaioli commented: 'I talked to an operator who told me he couldn't give me the files, but after that we didn't receive anything from the original company—so I can assure you we didn't get any threat' [50]. Romaioli observed: 'They said they couldn't give us the file because it's company property, but that's all' [50]. The other 3D printing maker Cristian Fracassi told *Fast Company* over email that 'nobody is causing legal trouble or trying to sue us' for 3D printing these valves [57]. Fracassi also clarified that the original valves did not cost USD 10,000, despite what some outlets had been reporting [57].

The firm Intersurgical denied that the company had ever threatened legal action against the 3D printing of the valves. Managing director Charles Bellm made a statement to *The Verge*, insisting that 'recent reports from Italy are totally incorrect' [50]. Intersurgical have issued further denials of making any threats of intellectual property proceedings on media and social media [58]. The company stressed that 'recent reports from Italy are totally incorrect' [58]. Intersurgical maintained: 'We were contacted at the end of last week for manufacturing details of a valve accessory but could not supply these due to

medical manufacturing regulations' [58]. The company noted: 'We have categorically not threatened to sue anyone involved' [58]. Intersurgical observed that media reports had misrepresented the cost of the technology: 'The valve is an accessory supplied as part of a CPAP Hood system, which alone costs a few euros' [58]. Intersurgical noted: 'Our Italian company has been doing their utmost to supply the hospitals at this time and have been supplying these free of charge in many cases to use with the CPAP Hoods' [58]. The company lamented it had been the victim of false reporting, which had unfairly hurt the company's reputation: 'It's very disappointing that in the current climate this incorrect information is circulating' [58]. Intersurgical insisted: 'Our focus as a company is to be able to supply the hospitals that require these and many other vital products, and we are making every effort to ensure we can do so' [58].

Taking into account the protagonists' comments, fact-checkers have listed the media and social media stories that there was a threat of legal proceedings against the Italian 3D printing project as false [59].

Although the facts about the dispute seem garbled and confused, this controversy has nonetheless sparked a broader debate about intellectual property and the right to repair—particularly in the context of COVID-19.

2.2. 3D Printing and the Right to Repair

In his book, *The Right to Repair*, Professor Aaron Perzanowski comments that there are outstanding issues in respect of patent law and the right to repair ([17], p. 124–132). He specifically raised the risk of 3D-printing users facing patent infringement lawsuits: 'Nothing in patent law would prevent a more mercenary device maker from pursuing such a claim' ([17] p. 132).

Professor Lucas Osborn has focused on how intellectual property doctrine deals with new developments in 3D printing and additive manufacturing [22]. In an op-ed, Osborn commented that the controversy raised larger issues about intellectual property, 3D printing, and medical devices: 'Regardless, this episode represents the first widely publicized instance of 3D printing technology being used to (arguably) infringe a patent on a medical device' [60]. He was particularly interested in questions around patent infringement. Osborn noted that 'anyone who prints the physical valve commits direct infringement for "making" the patented device' [60]. He wondered whether there should be protection for intermediaries in the network for 3D printing. Osborn highlighted the reach of indirect patent infringement: 'A person can be liable for indirect patent infringement for helping or inducing others to commit direct patent infringement' [60]. Osborn commented that the 'creators of 3D printable files, especially those with knowledge of a relevant patent, should be wary of making them available for others on the internet' [60].

Osborn commented, though, that there were reputational costs to patent litigation: 'Even if the patent holder is more interested in making money than saving lives, it may be wise to consider the reputational and other costs associated with denying live saving equipment to hospitals in need' [60]. He noted that patent lawsuits in respect of COVID-19 vaccines had faced a backlash: 'Others, including patent holders relating to vaccine development, have initially threatened patent infringement suits only to backtrack after a storm of public outrage' [60].

Osborn observed that the controversy in Italy raised larger questions about the international framework for intellectual property and public health: 'Although the coronavirus pandemic inflames passions when needed medical equipment is in short supply, it is important to remember that in emergencies Article 31 of [the *TRIPS Agreement* 1994] [61], the key international patent treaty, provides flexibilities for governments to use—and authorize others to use—patents without the consent of patent holders' [60].

Considering the case study, Professor Jorge Contreras noted: 'While the existence of the threat and the patents remains murky, the incident sparked legal commentary regarding the risk that volunteers fabricating parts for lifesaving devices, and the hospitals that use

them, could be liable for patent infringement' [62]. He suggested that the matter raised larger questions of patent exceptions—and the question of the right to repair.

Reflecting upon the Italian controversy, Glyn Moody commented: 'Whatever the details, the episode underlines why the 3D files of these kind of devices should be made available routinely to hospitals' [63]. He observed: 'That would allow them print in cases of urgent need, regardless of any claimed patents, so that this kind of situation doesn't arise at all, and lives are not put at risk' [63]. Moody highlights the need for a better articulation of intellectual property exceptions to deal with public health emergencies in the European Union.

There has also been some discussion as to the operation of compulsory licensing under patent law in Italy [64].

Leading European scholar Professor Rosa Ballardini and her colleagues maintained that there should be further intellectual property flexibilities to deal with 3D printing and medical emergencies [65]. The authors concluded that '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 3D [Printing]' ([65] p. 1168). They observed that there was a need to make the most of the potential of 3D printing and distributed manufacturing: 'Approaches to tackling this and any future crisis may herald a new era of more sustainable digital distribution and trade' ([65] p. 1169).

2.3. Policy Issues

There has been a notable push in the European Union for stronger recognition of the right to repair—particularly to help promote a circular economy and sustainable development [66–68].

The right to repair movement maintained that there was a need for greater policy action on the right to repair during the COVID-19 crisis. Chloé Mikolajczak—a campaigner with Right to Repair Europe—said that the pandemic raised larger questions about the importance of repair [69]. She noted: 'During the pandemic, getting your device or appliance fixed is even more important, at a time when buying a new one might not even be possible, or we might simply not be able to afford it' [69]. She was concerned that 'in several European countries repair has not made the list of "essential activities" that should remain open in these times of crisis' [69]. Mikolajczak was concerned that independent repairers 'increasingly face legal threats' [69]. She argued that 'this criminalisation of independent repair businesses providing essential services needs to stop' [69].

Mikolajczak observed that there was a need for further policy reform post-pandemic: 'We must ensure that the independent repair and reuse sectors are not forgotten in the wider policy conversations about what the post COVID-19 world will look like and how to finance it' [69]. She stressed: 'Not only repair and reuse are essential to reach our climate and sustainability ambitions, both at national and EU levels; they also provide opportunities for jobs and training that will likely be much needed in the next few months and years' [69].

In addition to the Maker Movement, there were a number of European 3D printing companies who contributed towards the public health effort in respect of COVID-19. Materialise NV—based in Belgium—was involved in various initiatives: 'During the COVID-19 pandemic, we drew on the advantages of 3D printing to develop new solutions to support healthcare systems and help individuals stay safe' [70,71]. In particular, Materialise highlighted its contribution to the development of critical medical devices, personal protective equipment, and prevention devices. Materialise emphasized the benefits of distributed manufacturing for hospitals during public health emergencies—such as COVID-19.

The Dutch-American Company Shapeways also contributed to the COVID-19 relief effort [72]. Shapeways observed: 'Many members of the 3D printing community have set to work producing protective wear for medical personnel, as well as anti-contamination accessories and more' [72]. Shapeways noted that 3D printing was better suited to the production of certain technologies: 'Though not everything can be fully 3D printed due

to FDA regulations and the complexity of medical equipment, 3D printing offers a fast prototyping and production process so that it may step in where traditional manufacturing falls short' [72]. Shapeways, in particular, highlighted the utility of 3D printing in the production of valves and ventilator parts; snorkeling mask ventilators; face shields; test swabs; face masks; door opening accessories; and quarantine booths.

The Czech open-source company Prusa 3D Printing sought to provide open-source designs for 3D printing personal protective equipment [73–75]. Prusa 3D printing emphasized that open licensing would enable 3D printing of personal protective equipment to take place—without any fear of intellectual property reprisals. Prusa 3D Printing also obtained approval for large-scale production of face shields with approval from the Czech Ministry of Health. Josef Prusa commented that the 3D printing community's response to the COVID-19 crisis highlighted the social value of the technology: 'This is a chance for our desktop 3-D community to show as a mature community, not just a bunch of nerds printing toys' [76].

At an industry level, additive manufacturing organizations discussed the importance of 3D printing during the COVID-19 crisis. CECIMO is an umbrella organization that serves the common interests and values of the European machine tool industries and related manufacturing technologies in the EU and at a global level [77]. CECIMO commented: 'The beginning of the COVID-19 crisis posed a challenge to the usual production and distribution channels for medical devices' [77]. CECIMO observed: 'Due to the scale of the demand, the conventional suppliers of this essential equipment were unable to provide immediate solutions to hospitals' [77]. CECIMO highlighted the importance role of additive manufacturing during the COVID-19 crisis: 'Amid this significant disruption in the supply chain, the additive manufacturing (AM) community stepped up and helped cover this surplus demand, providing access to equipment as well as other services' [77].

CECIMO made a number of recommendations to European policy-makers. First, the industry body emphasized that the COVID-19 crisis highlighted 'the need for dedicated AM standards and certification' [77]. The organization observed: 'It is essential to fast-track the development of standards and certification procedures to enable the use of AM in different areas and consequently allow the entire sector to expand' [77]. Second, the industry body noted that the COVID-19 crisis highlighted the 'Importance of rethinking conventional supply chain' [77]. Third, CECIMO commented that 'regulations should focus on unleashing technology's potential' [77]. The organization suggested that the 'EU industry strategy could boost the integration of AM in more sectors, ensuring a more resilient and competitive manufacturing industry in Europe' [77]. Finally, CECIMO noted that the 'lack of skilled workforce can slow-down AM growth' [77]. The industry body noted that 'the quick adoption of AM solutions in hospitals will result in an immediate demand of new specialized workforce' [77]. CECIMO commented that it was 'essential to expand the pool of European workers who are able to work with the full process from design to final parts in different sectors' [77].

3. The United States of America

In spite of being one of the most industrialized nations, the United States was vulnerable to the COVID-19 crisis. It has been reported from 2020 to the beginning of 2023 there were 101,496,168 confirmed cases of COVID-19 with 1,103,936 deaths reported to the WHO [78]. During the first onslaught of COVID-19, the US suffered from shortages in respect of PPE and other medical supplies. There was a significant debate about the ability of the 3D printing community to make and repair medical products in the US.

3.1. The Maker Movement

In March 2020, the US healthcare community experienced profound shortages of PPE and associated accessories, and medical devices to treat COVID-19 patients [79]. There was also a pressing need to fix and repair broken medical equipment, such as ventilators [80].

Founder and editor of *Make Magazine* Dale Dougherty (with Victor Hwang) discussed how 'a grassroots uprising of makers, engineers, and others' are creating a backup plan for the COVID-19 response [81]. They observed: 'In the face of COVID-19, shortages of medical equipment, such as ventilators for patients, and protective gear for personnel in hospitals are becoming a critical problem' [81]. Dougherty and Hwang noted that 'Plan A' involved governments using their powers to produce needed equipment, while Plan B involved private industry stepping up to produce equipment and supplies in their factories [81]. Dougherty and Hwang suggested: 'The Maker Movement might provide a "Plan C" for America and the world' [81]. The authors commented: 'This uprising of action in response to COVID-19 demonstrates the ingenuity and talent that flourishes at the grassroots, alongside the resources of government and the corporate sector' [81]. Dougherty and Hwang hoped that such grassroots innovation by the Maker Movement may be useful for addressing other global development challenges, such as those presented by the UN SDGs.

Dale Dougherty and Representative Tim Ryan (a Democrat from Ohio who was part of the Maker Caucus) called for the Maker Movement to play a key role in the COVID-19 as well [82]. Dougherty and Ryan invoked the historical example of the New Deal program of the Civilian Conservation Corps (CCC) during the Great Depression. Dougherty and Ryan argued: 'It is time for a new version of the CCC, one that coordinates grassroots efforts, provides more training for others to participate, and creates a civic infrastructure that can make our country more resilient in the future' [82]. Dougherty and Ryan suggested: 'Today, we propose launching the Civic Response Corps (CRC), a new program in the spirit of the CCC to coordinate local civic response efforts, train the unemployed, undereducated, and unskilled to participate and create a new civic infrastructure needed not only to respond to the crisis but ramp up the recovery' [82]. They highlighted that 'citizen-makers are rising to the challenge to create the medical supplies needed to address shortages in our local communities' [82]. (Ryan has since left the US Congress in 2023, after his House seat was redistricted, and he made an unsuccessful effort to win a US Senate seat in Ohio).

In addition to community efforts in respect of 3D Printing PPE, industry played an important role with industrial 3D printing. A leading commercial 3D printing company, HP, has been producing critical parts to meet urgent needs—including face shields, masks, personal accessories, and ventilator components [83]. Electronics manufacturing company and open-source hardware design company Adafruit Industries became involved in crisis relief in 2020 after New York City officials put a call out for the local manufacturing businesses to address shortages in personal protective equipment and medical devices [84,85]. A pioneer of the 3D printing industry, Avi Reichental, observed that the crisis had shown the power of open innovation and crowdsourced design: 'One lesson that has been undeniably learned is rooted in the immense power of crowd-sourced design: from homemade cloth masks distributed via online crafting sites to innovative solutions for social distancing, some of the most effective, cost-effective and elegant quick fixes to the staggering challenges created by this pandemic came as a result of decentralized, designers with high creativity and a desire to jump in and help' [86]. Nonetheless, Reichental noted that 'there have also been some hard lessons learned about the need for regulation and oversight, even in an industry like ours which is powered so strongly by the free exchange of ideas' [86].

In the educational sector, there was also some useful applications of 3D printing during the COVID-19 crisis. The University of Miami used 3D printing to develop a reusable N95 mask [87]. Helpfully, New Jersey Institute of Technology (NJIT) joined the Open COVID Pledge [88], making its test swab technology widely available free of licensing fees [89]. Patent pledges and open-source licensing could alleviate some of the concerns about the risks of intellectual property infringement [90].

Professor Joshua Pearce—who has run labs at Michigan Tech and Western University—has advocated a model of open medicine [91]. He has published a roadmap for how open-source medical supplies could be used to address public health pandemics, as well as a possible roadmap for establishing open-source protocols for such lifesaving technology [91].

Pearce has contended: 'Distributed digital manufacturing offers a solution to medical supply and technology shortages during pandemics' [91].

The US Patent and Trademark Office issued an award under its Patents for Humanity scheme to the University of South Florida Health, Northwell Health, Tampa General Hospital, and Formlabs for 3D printed nasal swabs for use during the COVID-19 pandemic [92,93]. There has been a debate, though, whether the Patents for Humanity scheme is only a weak incentive for encouraging humanitarian innovation [94].

The US Food and Drug Administration worked with the National Institutes of Health and Veteran Affairs Department to work together to facilitate regulatory and basic science innovation with 3D printing technologies to respond to COVID-19 [95,96]. Dale Dougherty and Tim Ryan observed that America Makes was organizing community efforts to engage in 3D printing of PPE and medical supplies: 'In Youngstown, Ohio, the national institute for additive manufacturing, America Makes, is coordinating these community-driven efforts to create new, easily-manufactured designs for masks, face shields, ventilator parts, and dozens of other open-source ideas to help protect our front-line medical workers, prevent the spread of infection, and save lives' [82]. America Makes played a critical, key role in coordinating public and private efforts to deploy additive manufacturing in support of the U.S. COVID-19 response [79]. The COVID 3D Trusted Repository for Users and Suppliers through Testing (COVID 3D TRUST) acted as an initiative to gather and test open-source designs for 3D printing PPE and devices [97].

Discussing the situation in the US, Matthew Bultman observed that 'innovators and volunteers are rallying to 3D printing to combat the new coronavirus' but noted that 'with this ingenuity comes concerns about patent infringement and product safety' [98]. He highlighted: 'Owners of patents on certain designs of face shields, masks, and ventilator parts could have infringement claims against printers' [98]. Bultman also noted: 'There is also a risk of lawsuits if supplies are unsafe' [98]. Professor Lucas Osborn commented: 'If there's a patent covering it and you actually 3D print it, then you're clearly infringing' [98]. Attorney Graham Phero commented that 'it's fantastic to have everybody come together' but 'we really do need to respect patent rights and we do need to make sure these products are safe for the end consumers' [98].

3.2. The Medical Right to Repair

In 2020, there was discussion in the US about the need to address the right to repair in light of the public health emergency in respect of COVID-19.

A number of civil society groups—including US PIRG, Repair.Org, and iFixit—supported a petition for a right to repair. The petition read as follows: 'U.S. hospitals do not have enough ventilators to meet the spike in cases of respiratory failure that the novel coronavirus is projected to create' [99]. The petition emphasized that 'it will become critical to remove barriers to repairing ventilators' and 'we may need to repair older reserve ventilators so they can be put into service' [99]. As the petition demanded, 'I urge you to immediately release service information—manuals, access to error logs and diagnostic information or other repair resources—for hospital ventilators to help our hospitals combat the coronavirus' [99].

Nathan Proctor, Right to Repair campaign director with U.S. PIRG, said that 'Right now, ventilator repair and maintenance issues are life and death issues' [99]. He contended: 'Manufacturers of ventilators should immediately release service manuals, service keys, schematics and service keys' [99]. Proctor stressed: 'Lives are at stake—This is no time to be proprietary' [99]. Proctor commented: 'From removing barriers to repair to ramping up production, there are steps we must take now to maximize ventilator supply and save lives' [99]. Kevin O'Reilly of PIRG added: 'There is no reason we should tolerate manufacturers putting their own proprietary concerns over patient safety—especially during the pandemic' [100]. He called for Congressional recognition of the right to repair: 'Passing this bill is an easy, common-sense way for the Senate to help hospitals in their time of need, and a terrific first step towards a permanent solution' [100].

Gay Gordon-Byrne of Repair.org commented: 'We've been fighting for our right to repair medical technology since our founding seven years ago' [99]. The executive director argued: 'The coronavirus pandemic has proven that manufacturer restrictions on access to repair information and technicians is a recipe for disaster' [99]. Kyle Wiens, iFixit.com CEO, commented: 'A single hospital might have ventilators made by four different manufacturers and it can be a headache trying to find the right information, so iFixit is trying to help make that easier' [99]. He observed: 'We want to make sure that a technician doesn't have to hunt for these manuals—every second counts right now' [99].

Kathleen Burke of Public Knowledge was concerned about the relationship between intellectual property and the right to repair during the COVID-19 crisis: 'If even hospitals and states during a state-of-emergency face outcry over side-stepping IP barriers to repairing goods that they own, then we have obviously created a system that is broken' [101]. Burke maintained: 'As we rethink how our world is shaped in light of COVID-19, making sure consumers have a meaningful right to repair is one issue space that can help ensure our world is more sustainable' [101]. John Bergmayer, Legal Director at Public Knowledge, supported the call for legislative action: 'Especially during the pandemic, it's important that medical services aren't interrupted by expensive, slow, and unnecessary service requirements' [102].

There have been concerns that intellectual property owners have been hampering repairs in respect of critical medical infrastructure and equipment during the COVID-19 pandemic [103].

Democrats Oregon Senator Ron Wyden and New York Representative Yvette D. Clarke have introduced right to repair legislation in the Senate and the House of Representatives that would make it easier for hospitals to fix medical equipment during the COVID-19 pandemic. Oregon Senator Ron Wyden maintained: 'There is no excuse for leaving hospitals and patients stranded without necessary equipment during the most widespread pandemic to hit the U.S. in 100 years' [100]. He commented: 'It is just common sense to say that qualified technicians should be allowed to make emergency repairs or do preventative maintenance, and not have their hands tied by overly restrictive contracts and copyright laws, until this crisis is over' [100]. New York Representative Yvette D. Clarke observed: 'As America grapples with this lethal pandemic, we are also experiencing unprecedented shortages of medical equipment' [100]. She contended that it was critical to expand access to life-saving devices: 'This narrowly-tailored, common-sense, and time-limited bill will ensure critical medical items like ventilators do not go to waste due to maintenance restrictions that have no nexus to safety' [100].

The United States Congress has been considering the *Critical Medical Infrastructure Right-to-Repair Act* of 2020 (US) [104,105].

The legislation is a bill 'to amend title 17, United States Code, to address circumvention of copyright protection systems with respect to the maintenance or repair of critical medical infrastructure, and for other purposes'. Section 1 provides that the short title of the Act is the *Critical Medical Infrastructure Right-to-Repair Act* of 2020. Section 2 provides definitions in respect of the bill—including in respect to the terms 'commerce', 'covered emergency', 'covered service provider', 'critical medical infrastructure', 'repair', and 'service material', as well as 'critical media infrastructure contract', 'service provider', and 'trade secret'.

Section 3 provides for a new clause in the *Copyright Act* 1976 (US)—section 123, which would provide for a 'Limitation on exclusive rights: incidental copies of service materials made during maintenance or repair of critical medical infrastructure'. Section 3 also provides for an amendment to section 1201 of the *Copyright Law* to allow for the permissible circumvention of a technological protection measure 'to repair or maintain critical medical infrastructure with respect to that covered healthcare provider' as 'part of preparation for, or a response to, the covered emergency'.

This safeguard seems to be a response to copyright litigation over repair manuals during the COVID-19 crisis. In the United States, there have also been copyright threats over repair manuals during the coronavirus public health pandemic [106]. Steris sent a

letter to iFixit asking the repair organization to remove from its website repair information for Steris equipment. iFixit had published the medical device repair information in order to help hospitals and other medical organizations through the COVID-19 pandemic. In response, the Electronic Frontier Foundation responded to Steris on behalf of its client, iFixit [107]. First, the legal advocacy group noted that 'iFixit is protected by Section 512 of the *Digital Millennium Copyright Act*, which allows online platforms to host content contributed by users provided they comply with the Act's requirements, which iFixit does'. Second, the EFF maintained that iFixit was protected under the defense of fair use: 'The fair use doctrine authorizes iFixit and contributors to the Database to share the repair information they are providing' [107]. The EFF considered the various factors involved in a fair use determination, and maintained that such factors favored iFixit. The EFF concluded: 'The Medical Device Repair Database promotes the public interest by improving access to information to help technicians, and the strapped hospitals they work for, do their jobs more effectively' [107]. The EFF commented: 'Given that the market for medical devices is about medical devices, it would be difficult for Steris to plausibly argue that it lacks adequate other incentives to document how to maintain the devices that are its bread and butter' [107]. The EFF concluded: 'The benefit to the public far outweighs any speculative harm to any legitimate interest in restricting their availability via the Database' [107].

It should be noted that there has also been significant copyright litigation against the Internet Archive for making electronic books available in a National Emergency Library during the COVID-19 lockdown [108].

Section 4 of the legislation amends Section 271 of the design patents regime. In the new legislative provision, 'It shall not be an act of infringement with respect to a patent for design obtained under section 171 for a covered healthcare provider to fabricate a part on a non-commercial basis, and as needed, for the repair or maintenance of critical medical infrastructure with respect to that covered healthcare provider, if the repair or maintenance is part of a response to the covered emergency'.

Section 5 deals with contracts. The new provision seeks to prevent the contracting out of the right to repair: 'Notwithstanding any other provision of law or regulation, a provision of a critical medical infrastructure contract is null and void if that provision of the critical medical infrastructure contract prohibits or restricts the ability of a covered healthcare provider that is a party to the contract to, in response to the covered emergency, repair or maintain critical medical infrastructure with respect to the covered healthcare provider'.

Section 6 focuses on manufacturer requirements.

Section 7 asks the Federal Trade Commission, in consultation with the Register of Copyrights and the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, to conduct a study with respect to innovation and anticompetitive practices in the market for critical medical infrastructure.

The House bill has been referred to the House of Representatives Committee on the Judiciary in addition to the Committee on Energy and Commerce. The Senate bill has been referred to the Senate Committee on the Judiciary.

Oregon Senator Ron Wyden wrote an op-ed with the President of the American College of Clinical Engineering, Ilir Kullolli, on the need for the United States Congress to support the bill [109]. They highlighted: 'As the crisis continues, concerns about the maintenance of critical medical equipment, including X-ray machines, dialysis machines, and ventilators, are growing' [109]. Wyden and Kullolli discuss some of the barriers and obstacles to repair of medical equipment during the COVID-19 public health emergency. They despaired: 'Too many hospitals face long waits for authorized technicians to repair life-saving machines' [109]. They lamented: 'A recent study shows that an overwhelming majority of repair technicians have been blocked from making critical repairs as a result of manufacturer restrictions' [109]. Wyden and Kullolli commented: 'This common-sense legislation would allow trained repair technicians to more easily access the information and tools they need to fix and maintain critical medical infrastructure during the

COVID-19 crisis' [109]. Wyden and Kulloli denied that the legislative regime would adversely affect safety standards. Wyden and Kullolli also supported a more general right of repair: 'While this bill is focused on addressing the pandemic-induced emergency facing medical infrastructure, Americans should always have the right to repair the vehicles, tools, and devices they own' [109]. Wyden and Kullolli commented: 'Our hope that this legislation serves as the first step toward establishing a new balance that strikes down unnecessary obstacles to home repair—everything from tractors to electronics—while continuing to allow manufacturers to innovate and thrive' [109].

Various civil society and public interest advocates supported the bill [100]. Alan Morgan, CEO of the National Rural Health Association said: 'As COVID-19 surges across rural America, rural providers must have the rapid ability to maintain effective and operational equipment' [100]. Color Of Change Vice President Arisha Michelle Hatch commented: 'Since the onset of the COVID-19 pandemic in the United States, Color Of Change has pushed ventilator manufacturers to dial-back their dangerous, counterproductive repair restrictions, which have put an unnecessary strain on our medical providers' ability to tackle the virus' [100].The *Critical Medical Infrastructure Right-to-Repair Act* of 2020 (US) has been supported by a spectrum of health care, engineering, and civil society groups. The legislation received endorsements from the American College of Clinical Engineering (ACCE); Association of Medical Service Providers (AMSP); National Rural Health Association (NRHA); National Association of Rural Health Clinics (NARHC); International Association of Medical Equipment Remarketers and Servicers (IAMERS); Alliance for Quality Medical Device Servicing (AQMDS); ISS Solutions Healthcare Technology Management; U.S. Public Interest Research Group (U.S. PIRG); The Repair Association; the Electronic Frontier Foundation (EFF); Color of Change; Public Knowledge; R Street Institute; Re:Create; Lincoln Network; Niskanen Center; Colorado Association of Biomedical Equipment Technicians (CABET); MaineGeneral Medical Center; Pennsylvania Public Interest Research Group (PennPIRG); and Center for Democracy & Technology [110]. R Street supported the bill [111]. According to R Street Distinguished Senior Fellow Mike Godwin, 'This carefully crafted bill allows technical personnel to lawfully repair medical infrastructure and equipment during the COVID-19 pandemic, while also ensuring patent holders control commercial use of their intellectual property per their statutorily defined rights' [111]. The Niskanen Center supported the proposed legislation [112]. Daniel Takash, regulatory policy fellow at the Niskanen Center, was concerned that copyright law and technological protection measures were putting in place unnecessary barriers: 'The consequences of these policies go from excessive to dire if we're talking about medical equipment like ventilators' [112].

Benjamin Louviere has argued: 'The COVID-19 pandemic has cast into sharp relief the already pressing need for Congress to intervene and pass right-to-repair legislation, at the very least with respect to medical devices for hospitals' [113].

In addition to law reform, Professor Jorge Contreras of the University of Utah has called on courts to take a liberal view of the legitimacy of repair in any patent disputes during the pandemic: 'In order to permit needed repairs and parts replacements for critical health-related equipment, courts should take a liberal view of the repair doctrine' [114]. He contended that 'the immunity from suit afforded by the repair right should be extended not only to the owners of patented equipment, but to their suppliers, parts vendors and maintenance organizations' [114]. Contreras has maintained that there is scope for expanding exceptions to patent infringement for research and repair in response to the pandemic [62].

Scholars Ofer Tur-Sinai and Leah Chan Grinvald have contended that 'the need for a right to repair medical equipment is particularly evident during this challenging period' [115]. They added: 'Carving out a safe legal space for repair would serve important policy considerations during "normal" times and increase the preparedness of our legal system' [115].

Shuhan He (of GetUsPPE), Debbie Lai (of CovidActNow), and Jarone Lee endorsed the proposal for a medical right to repair in *The Lancet* [116]. The correspondents supported

Senator Ron Wyden's bill: 'During these extraordinary times, such legislation for the right to repair not only moves the medical field in a more affordable, efficient, and sustainable direction but also enables life-saving services to continue to be available at times of high stress' [116].

The *Critical Medical Infrastructure Right-to-Repair Act* of 2020 (US) H.R. 7956—and its companions—have not progressed through the United States Congress. In the intervening time, there has been organized resistance from medical device makers to the proposal for a medical right to repair. The Advanced Medical Technology Association (AdvaMed) has been a notable opponent of a medical right to repair, arguing that it would undermine health and safety [117]. As well as opposing the Federal bill, AdvaMed has argued that state right to repair laws should not extend to medical technologies and devices [118]. The Medical Imaging & Technology Alliance (MITA) has also been a critic of proposals to extend the right to repair to medical devices [119]. MITA has maintained that a medical right to repair would adversely affect the cost, functionality, and lifetime upkeep of medical technologies and devices [120]. Henry Miller of the Center for Medical Economics and Innovation argued that a medical right to repair would undermine intellectual property and cybersecurity [121]. There are also, more broadly, a variety of technology developers and industry and trade associations who are adamantly opposed to legislative proposals on the right to repair (whatever form they may take).

3.3. Other Right to Repair Proposals

The US policy debate over the right to repair is a longstanding one [122]. The current policy debate over the right to repair has been a dynamic and volatile one. While the Wyden bill for the medical right to repair has languished in the United States Congress, there are a range of other state and Federal proposals on the general right to repair, which have advanced further.

In 2021, Rep. Joseph Morelle put forward a private member's bill, the *Fair Repair Act*, to provide recognition of a right to repair [123]. This legislation would require an original equipment manufacturer (OEM) to make diagnostic, maintenance, and repair equipment available to independent repair providers. Morelle has emphasized that 'For too long, large corporations have hindered the progress of small business owners and everyday Americans by preventing them from the right to repair their own equipment' [124]. As he contended, 'This common-sense legislation will help make technology repairs more accessible and affordable for items from cell phones to laptops to farm equipment, finally giving individuals the autonomy they deserve' [124].

In 2022, House Representatives Mondaire Jones, a Democrat, and Republican Victoria Spartz introduced the *Freedom to Repair Act* to reform copyright law to make it easier for consumers to obtain repairs [125]. Under this legislation, the copyright regime would not prohibit an act of circumvention or trafficking for the purpose of diagnosing, maintaining, or repairing electronic equipment. However, this legislative proposal explicitly excludes the manufacturer or distributor of a medical device.

There is also an *Agricultural Right to Repair Act* sponsored by Senator Jon Tester [126]. There is a bipartisan bill put forward by Republican Congressman Darrell Issa and various Democrat representatives to reduce car repair costs [127]. There are several other bills that have been prepared at a Federal level. There have been proposals for other specialist reforms, such as a right to repair software [128].

In July 2023, the House Judiciary Subcommittee on Courts, Intellectual Property, and the Internet held a hearing on the topic 'Is There a Right to Repair?' The Committee led by Chairman Issa considered a range of stakeholder views on the right to repair [129]. Professor Aaron Perzanowski made the case for a broad recognition of a right to repair, whilst Devlin Hartline of the Hudson Institute argued that the right to repair was a legal fiction. There was also evidence from Scott Benavidez from the Automotive Service Association, Paul Roberts of SecuRepairs, and Kyle Wiens of iFixit. While there was a wide ranging discussion

of the topic of the right to repair, the issue of a medical right to repair was only mentioned in passing.

For its part, the Biden Administration has shown enthusiasm for the recognition of a general right to repair. President Joe Biden has issued an executive order, highlighting that the right to repair is a priority across government [130]. The Federal Trade Commission under Lina Khan has taken a number of enforcement actions in respect of the right to repair (including in the field of health-care) [131]. Moreover, the Federal Trade Commission under Lina Khan has promised further law reform and policy development on the topic of the right to repair [132].

There have been a range of proposals for a right to repair at a state level in the United States. In addition to the Federal *Critical Medical Infrastructure Right-to-Repair Act* of 2020 (US) H.R. 7956, there has also been a specific bill in California focused on a medical right to repair put forward by Democrat Senator Susan Eggman—the *Medical Device Right to Repair Act* (SB 605) [133]. This Californian legislative proposal would require an original manufacturer of powered medical equipment used in the treatment, monitoring, or diagnosis of a patient to provide documentation, parts, service access methods, and tools used to inspect, diagnose, maintain, and repair powered medical equipment to a hospital and an independent service organization engaged by the hospital for the purpose of providing medical equipment maintenance and repair, on fair and reasonable terms, as defined. The bill would subject an original equipment manufacturer who knowingly violates these provisions to specified civil penalties. The bill would exempt any trade secret information from these requirements. The Appropriations Committee failed to pass the California Medical Right to Repair Act [134].

4. Australia

In some respects, Australia had a strong public health response to the COVID-19 crisis, at least initially. According to the WHO, Australia had between 2020 and early 2023 a total of 11,326,032 cases of COVID-19, with 18,190 deaths [135]. Nonetheless, Australia certainly experienced issues in obtaining timely access to essential medicines. Moreover, Australia also had severe shortages of PPE and other medical equipment at the outset of the COVID-19 crisis. During the COVID-19 crisis, the Productivity Commission investigated the question of the right to repair. The Australian Government has begun to implement some of the Productivity Commission's recommendations on the right to repair. However, the topic of the medical right to repair is still in a state of abeyance.

4.1. 3D Printing Response

In 2020, at the beginning of the COVID-19 crisis, the Australian Government sought to map domestic production capability of medical personal protective equipment (PPE) [136]. In particular, the Australian Government sought 'information on domestic production capabilities relevant to a range of medical PPE, including surgical gowns, gloves, goggles, hand sanitisers, clinical waste bags, waste bag closure devices (ties), blood and fluid spill kits, mask fit test kits and thermometers' [136]. In contrast to the focal point of the development of the Canadian Shield in Canada [137], the Australian efforts to provide PPE were somewhat more dispersed and distributed.

In this context, there was activity within the 3D printing community in respect of addressing some of the shortages in respect of PPE. Australian universities and educational institutions were particularly prominent in terms of providing additional capacity for the production of PPE.

The University of Melbourne worked closely with Melbourne hospitals on 3D printing face shields [138]. The Maker Spaces team from the Melbourne School of Design tested designs for face shields. The Melbourne School of Engineering 3D Innovation Centre provided the capacity to print large quantities of 3D printed face masks. Researchers and engineers at the University of Melbourne also worked to develop isolation hoods,

low-cost ventilators, reusable N95 masks, and COVID-19 testing swabs (with the help of 3D printing).

Professor David Grayden commented: 'It's clear that these innovations are something hospitals really need' [138]. He observed that 3D printing enabled open-source collaboration and sharing: 'What COVID-19 is really drawing to the fore is that 3D printing can be used to prototype and rapidly manufacture small batches. If we need it tomorrow, 3D printing is a key way to do that. COVID-19 is showing us that we need to speed up the process between idea and manufacturing' [138].

Dr. Jasamine Coles-Black commented: 'Our vision is to have everyone in the Australian healthcare space linked up, and for no-one to go without PPE' [138]. She was conscious about larger questions in respect of safety, regulation, and intellectual property: 'We don't want to be in a situation where regulatory and administrative roadblocks prevent a validated solution from being effectively delivered to the front lines within an acceptable timeframe' [138]. Coles-Black highlighted larger ethical considerations about access to health care: 'We took an oath to look after our patients and our colleagues' [138].

The University of Wollongong has a strong reputation for its work in bioprinting and medical 3D printing. The University of Wollongong pivoted some of its 3D printing operations to 3D print medical supplies to support healthcare workers during the COVID-19 pandemic [139]. The University of Wollongong Makerspace manager Jessica Grozdanov said the face shield initiative is supported by international open-source collaboration: 'Over the past week, an open source design for a face shield that can be 3D printed has been circulated internationally' [139]. She commented: 'We have 3D printers available at the UOW Makerspace which got us thinking whether our local hospitals could benefit from an initiative like this' [139]. Grozdanov commented: 'Makerspaces and other innovative manufacturing initiatives are increasingly playing an important role in the response to crises, as we can respond quickly to a particular need and can offer innovative, local solutions in high priority scenarios' [139]. In addition, the various centers and facilities focused on bioprinting at the University of Wollongong also provided help and assistance. Professor Gordon Wallace noted: 'We're working towards a common goal and can move quickly, which is critical as face shields are in high demand, there is a great shortage of them and they are needed immediately' [139]. He observed: 'We're here and ready to help' [140].

Researchers at the University of New South Wales also worked on prototyping PPE designs in preparation for the COVID-19 pandemic. As Dr. Blake Cochran explained, 'We have been able to provide some of our early prototypes to our clinicians and to our medical researchers that are working on the virus and we are incorporating their feedback into improving our design' [141]. He reflected: 'So [we are] focusing on things such as making sure that our masks are comfortable, that they can be worn for long periods of time, they don't fog up, and that they are actually suitable moving forward' [141].

The University of Technology Sydney sought to engage in 3D printing of face shields for the benefit of Australia's neighbor, Papua New Guinea [142]. The UTS ProtoSpace encouraged COVID-19 student responders to help produce 300 health shields for medical personnel in Papua New Guinea. ProtoSpace intern Isaac Garcia commented: 'We had a number of channels for people to explore different types of personal protective equipment (PPE) before settling on face shields, as this is an example of the capability of 3D printing and of our capacity to achieve a quick response' [142]. ProtoSpace used an open-sourced design, which was easy to assemble and met Australian health regulations for PPE.

Australian Doctors International Program Officer Mark Newcombe was grateful for supplies: 'We have been able to locate hand sanitisers, face masks, gowns, goggles, gloves—but could not find face shields anywhere, so when Stuart contacted us to consider a donation we were delighted' [142]. He commented: 'We were really impressed with the quality, well designed and well made' [142]. Newcombe noted: 'The face shield obviously delivers protection for the user, but it also extends the life span of face masks, which is important for any equipment in remote and hard to reach areas' [142].

The Australian National University was also involved in 3D printing protective equipment for health workers [143–145]. Dr. John Debs of the ANU MakerSpace commented: 'We see this as a community good from the University to supplement the usual supply chain of hospitals, general practices and other frontline health services' [144]. He observed: 'We had heard buzz around people 3D printing face shields but, after looking at the designs, we knew we could make them faster and more effectively with other tools' [144]. Debs reflected: 'We found some open-source designs from the United States, and we ran with them as a starting point' [144].

The Herston Biofabrication Institute and the public research organization CSIRO were involved in the production of PPE for the assistance of the Queensland state government [146]. Other partners in this endeavor included the Queensland University of Technology (QUT), the University of Queensland, Healthia Group, COVID-SOS, Konica Minolta, and Shapelabs [146].

In the social enterprise field, 3D printing organizations were able to extend their work into new health-related fields. Free 3D Hands is a charity based in Australia, which designs and manufactures 3D printed assistive devices for those with disabilities [147]. The lead engineer Mat Bowtell has relied upon open licensing to make such technologies available and accessible [148]. During the COVID-19 crisis, Free 3D Hands was able to manufacture thousands of face shields for healthcare workers, who were having problems sourcing personal protective equipment during widespread shortages [2]. Mat Bowtell told *The Guardian*: 'With 3D printing, we've been able to go from making hands to making face shields in a matter of, well, days' [2]. He observed: 'To completely revamp our line, that's how agile this technology is and how flexible it is' [2].

In addition, 3D printing companies provided assistance during the COVID-19 crisis. The Sydney-based 3D Printing Studios engaged in the local manufacture of nasal and throat swabs which were used in COVID-19 testing kits [149]. The Melbourne company Seen Technology and Sydney company Composite Images joined a network of 3D printing distributors who were printing PPE [150]. The Australian 3D Manufacturing Association provided support for the community-based efforts of maker societies to engage in the 3D printing of PPE [151].

The 3D printing lab BioFab3D deployed its resources to help make facial shields [141]. Engineer and lab manager Cathal O'Connell commented: 'We are producing about 20 units a day of our face shield design which we supply to some of the clinics at St Vincent's Hospital [Melbourne]' [141]. She commented: 'Our main role being a fabrication lab based within a hospital is that we can try multiple designs with the clinicians themselves, get their approval, and then send out the approved design to the big 3D printing sites who can manufacture them in numbers of hundreds' [141].

There was a larger discussion about how Australia's situation highlighted the risks of offshoring the production of PPE [2].

4.2. The Productivity Commission into the Right to Repair

There has been a longstanding debate in Australia over the right to repair—but it has often been focused on particular sectors, such as automobiles, and agricultural machinery. The COVID-19 crisis raised questions about the right to repair in the context of health-care. The ACT Attorney-General Shane Rattenbury pushed for an inquiry into a right to repair in order to promote consumer rights, competition policy, sustainability, and a circular economy [152]. In the midst of the COVID-19 crisis, the Productivity Commission was asked to investigate the right to repair. The Productivity Commission produced an issues paper [153], a discussion paper [154], and a final report [155].

There were a range of submissions which considered the question of a medical right to repair.

The author of this article made a submission to the Productivity Commission on the right to repair—highlighting amongst other things, the need for a right to repair essential medical equipment, particularly during the COVID-19 crisis [156]. In this submission, it was

noted: 'The draft report by the Productivity Commission briefly discusses in passing some of the impacts of the coronavirus pandemic upon the topic of the right to repair' [156]. As this submission highlighted, 'It would be helpful and useful if the Productivity Commission could devote a chapter or a sub-chapter to the topic of public health and the right to repair (much like it has in respect of intellectual property, consumer rights, competition policy, product design, and e-waste)' [156]. The submission added: 'There has been much discussion of the necessity of law reform during the coronavirus emergency—including in respect of intellectual property and the right to repair' [156].

The author's colleague Dr. Muhammad Zaheer Abbas also made a submission to the Productivity Commission, observing that repair with the help of 3D printing technologies was critically important for medical technologies during the COVID-19 crisis [157]. He later expanded upon the need for patent exceptions for the right to repair to better enable 3D applications in response to the COVID-19 crisis [158].

Medical technology companies, though, have demanded to be exempted from any right to repair regime. For instance, Medtronic Australia argued: 'To ensure the continued safety and effectiveness of health restoring and life-saving medical devices, Medtronic believes medical devices should be excluded from consideration from "Right to Repair"' [159]. As Medtronic Australia maintained, 'Medical devices designed, manufactured, and serviced by the manufacturer are categorically different than consumer and other goods in that they are regulated by the Therapeutic Goods Administration (TGA) throughout their lifecycle to ensure safe and effective operation for an intended use' [159]. Medtronic Australia warned that a '"Right to Repair" could present dangerous unintended consequences for the patient with the key concern that it may compromise patient safety' [159]. Moreover, Medtronic Australia cautioned that a right to repair could compromise cybersecurity [159]. In conclusion, Medtronic Australia recommended that 'the Productivity Commission exclude medical devices and medical technology from the consideration of the "Right to Repair"' [159]. (It should be noted, though, that Medtronic in the United States was willing to pledge intellectual property during the COVID-19 crisis) [90].

In its draft report, the Productivity Commission commented that 'although restrictions on repairs of medical equipment may generate some harm (particularly for any vulnerable or disadvantaged equipment users), this may not be sufficient to justify any policy response, due to elevated safety risks for some types of repair' [154].

In its final report, the Productivity Commission made a number of recommendations about the ways and means of realizing a right to repair in Australia [155]. The Productivity Commission made law reform recommendations in respect of consumer law and competition policy to support the right to repair. The Productivity Commission also made policy reform suggestions in respect of copyright law and the right to repair (but declined to make recommendations about other fields of intellectual property). The Productivity Commission also discussed questions around the right to repair, environmental stewardship, and sustainable development in Australia.

However, the Productivity Commission said that the topic of medical repairs required further investigation ([155] p. 144–146). This is an important and significant qualification to its overall law reform recommendations. The Productivity Commission acknowledged that the issue was a significant one: 'Several inquiry participants said that medical device manufacturers are unnecessarily restricting access to repair information and spare parts' ([155] p. 144). The Productivity Commission was conscious of the economic and health impact of restrictions on medical device repair: 'These repair restrictions can have detrimental impacts for both patients receiving health care (such as by delaying hospital procedures while equipment is awaiting repair) and for device users with a high dependency on their equipment (such as people who use a wheelchair or hearing aids)' ([155] p. 144).

Nonetheless, the Productivity Commission was conscious that there were special considerations in relation to the regulation of medical devices: 'Due to elevated safety risks, the medical device industry is also closely regulated by the *Therapeutic Goods Administration* (TGA), with many medical devices required to demonstrate that they conform with the

"essential principles" in the *Therapeutic Goods (Medical Devices) Regulations* 2002 before they can be supplied in Australia' ([155] p. 145). The Productivity Commission observed that 'it is not apparent that medical device regulations have found the right balance between repair access and device safety, and may be creating strong incentives for manufacturers to restrict repairs, generating harm to patients and device users through medical delays and additional costs' ([155] p. 145). The Productivity Commission held that 'due to the complexity of the medical device market and the wide variety of different devices covered by existing regulations, the Commission did not have sufficient evidence to justify specific policy changes' ([155] p. 145).

In Finding 4.5, the Productivity Commission found that 'medical device regulations do not consider repair access' ([155] p. 145). The Productivity Commission observed: 'Current regulations of medical devices—such as the "essential principles" in the *Therapeutic Goods (Medical Devices) Regulations* 2002—aim to minimise safety risks to patients and device users, which has the effect of encouraging manufacturers to restrict access to repair.' The Productivity Commission noted in its finding: 'The regulations do not appear to account for the potential harm from reduced access to repair services (such as medical delays and additional costs), or that risks are likely to be low for some devices or for repairs completed by highly-qualified independent repairers' ([155] p. 146). The Productivity Commission was conscious that there could be monopolies in respect of certain specialist medical devices: 'Time-sensitive services and user dependency also mean patients and device users often have limited alternative options, increasing their lock-in' ([155] p. 146).

In Recommendation 4.2, the Productivity Commission called upon the Federal Government to 'review the medical device market and regulations' ([155] p. 146). The Productivity Commission explained: 'The Australian Government should conduct an independent public review of existing medical device regulations to assess whether they strike a balance between repair access and device safety that maximises community wellbeing' ([155] p. 146). The Productivity Commission commented: 'The review should consider whether current regulations create incentives for manufacturers to restrict repair, and examine potential ways to improve repair access for low-risk medical devices or for highly-qualified independent repair technicians' ([155] p. 146).

In a separate inquiry, the Productivity Commission was asked to investigate Australia's vulnerable supply chains in the wake of the COVID-19 crisis. The Productivity Commission reflected that 'Australia's supply chains proved generally resilient in response to the COVID-19 pandemic, unexpected trade restrictions, the devastating 2019–20 bushfires and 2021 floods in Eastern Australia' [160]. However, the Productivity Commission acknowledged that 'these experiences have highlighted potential vulnerabilities in Australia's supply chains', noting that 'the onset of COVID-19 saw immediate impacts on logistics and transport' [160]. The Productivity Commission particularly highlighted issues in respect of access to PPE: 'A global surge in demand and panic buying of some essential goods, notably personal protective equipment, with export restrictions placed on such products by some governments, added a degree of urgency to the unfolding situation' [160]. The Productivity Commission noted: 'Australia was not unique in this respect, with most economies manifesting concerns about how their reliance on imports could jeopardise their ability to meet their population's needs during the COVID-19 pandemic' [160]. The Productivity Commission observed that COVID-19 prompted calls for onshoring—but not everyone agreed.

4.3. The Albanese Government

In 2022 and 2023, the new Albanese Government has provided an initial response to the Productivity Commission inquiry on the right to repair. In 2022, the Assistant Minister for Competition the Hon. Dr. Andrew Leigh MP outlined his initial thoughts about the Productivity Commission report on the right to repair [161]. He recognized that 'Smartphones, watches, fridges, *medical devices*, exercise equipment—our everyday consumer products are increasingly incorporating sophisticated technology' (emphasis added) [161].

Leigh acknowledged: The challenge for consumers globally—not just in Australia—is that technological advances can increase the cost and complexity of repairs' [161]. He argued that the Albanese Government would boost competition in the repair sector 'by ensuring big technology companies cannot create monopolies that allow them to profiteer at the expense of Australians' [161]. Leigh maintained that the Government would protect 'Australians' "right to repair", which gives households and businesses the ability to have their products repaired at a competitive price using a repairer of their choice' [161].

The Albanese Government has thus far focused on the right to repair in motor vehicles [162], and agricultural markets [163]. The Albanese Government has not yet progressed on the spin-off topic of the medical right to repair. As the COVID-19 threat has receded, perhaps the Albanese Government has considered the question of the medical right to repair to be less of a pressing priority. However, it is argued here that the medical right to repair should indeed be a political priority, especially given that a recurrence of the COVID-19 crisis or new pandemics could create similar problems in respect of repairs.

5. The Right to Repair and the TRIPS Waiver

This article has provided national case studies of debates over the right to repair in Italy, the United States, and Australia during the COVID-19 crisis. National law reform initiatives in respect of a medical right to repair also raise larger questions about consistency and conformity with international intellectual property law—most notably, the *TRIPS Agreement* 1994. There is certainly an international dimension to the topic of intellectual property and the right to repair during the COVID-19 crisis. There has been discussion as to whether the proposed *TRIPS Waiver* should extend to the right to repair. Such international debate raises larger questions about the relationship between intellectual property, trade, and the SDGs.

5.1. The TRIPS Agreement 1994

The *TRIPS Agreement* 1994 lays down international standards and norms in respect intellectual property law and policy for WTO members [61].

The right to repair raises questions about the nature and scope of patent law and patent exceptions under the *TRIPS Agreement* 1994. Professor Joshua Sarnoff has explored the international dimensions of patent law and the right to repair during the COVID-19 crisis [164]. He has argued that 'legislative measures to assure the right to repair are fully consistent with the World Trade Organization's [*TRIPS Agreement* 1994]' [164]. Likewise, Muhammad Zaheer Abbas has explored whether a medical right to repair would be consistent with the *TRIPS Agreement* 1994 [158]. He has argued that 'Facilitating increased experimental and repair activity by creating a safe harbor for experimentation with medical devices will better prepare countries to deal with a future pandemic' [158]. Rosa Ballardini and her colleagues have explored what exceptions would be permitted for 3D printing in medical emergencies under the *TRIPS Agreement* 1994 [65].

The right to repair certainly raises issues about the principles and objectives of the *TRIPS Agreement* 1994—as well as provisions on patent rights and patent exceptions. The context of COVID-19 certainly raises further questions about the operation of patent flexibilities during a public health crisis. The *Doha Declaration* 2001 has recognized that nation states are able to make use of intellectual property flexibilities to deal with public health matters [165,166]. The *WTO General Council Decision* 2003 allowed for compulsory licensing to enable the export of pharmaceutical drugs to developing countries, which lacked manufacturing capacity [167].

It is worth noting that the right to repair also raises questions about other domains of intellectual property—including copyright law, designs law, trade mark law, and trade secrets. Sean Flynn and colleagues, for instance, have highlighted that 'Access to copyrighted materials is necessary to create and repair many medical devices needed to treat COVID-19' [168]. Designs law has been invoked in relation to medical designs (including for devices and personal protective equipment). Trade mark law has also raised questions

in respect of the repair of trade marked goods. There has been tension between the right to repair and the protection of confidential information and trade secrets. In the context of COVID-19, the right to repair has raised questions about the use of intellectual property exceptions during a public health crisis. As such, there is a need to contemplate the intellectual property flexibilities permitted by the *TRIPS Agreement* 1994.

5.2. The TRIPS Waiver

The *TRIPS Waiver* featured larger discussions about whether there should be international flexibilities under intellectual property during public health emergencies.

India and South Africa put forward the proposal for a *TRIPS Waiver* [35]. The proposal involved a waiver from certain provisions of the *TRIPS Agreement* 1994 for the prevention, containment, and treatment of COVID-19. The proposal considered access to vaccines, therapeutics, medical products, and health equipment. In its original conception, the *TRIPS Waiver* could have facilitated the right to repair for purposes related to the COVID-19 crisis [35]. India and South Africa emphasized: 'An effective response to COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need' [35]. India and South Africa feared: 'Critical shortages in medical products have also put at grave risk patients suffering from other communicable and non-communicable diseases' [35]. India and South Africa observed: 'To meet the growing supply-demand gap, several countries have initiated domestic production of medical products and/or are modifying existing medical products for the treatment of COVID-19 patients' [35]. India and South Africa commented: 'The rapid scaling up of manufacturing globally is an obvious crucial solution to address the timely availability and affordability of medical products to all countries in need' [35]. India and South Africa were concerned that intellectual property rights were hindering access to medical products: 'There are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients' [35]. So, while in popular discourse the *TRIPS Waiver* has focused on vaccines, the original proposal was broad enough to embrace a right to repair.

At an international level, the United States Government equivocated as to its position on the topic of the *TRIPS Waiver*. The Trump administration was hostile to the adoption of a *TRIPS Waiver*, as promoted by India and South Africa [169]. In an important shift, the Biden administration announced that it would support a *TRIPS Waiver*—although only for vaccines. The United States Trade Representative (USTR) Katharine Tai commented as follows: 'This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures. The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines' [170].

The USTR stressed: 'The Administration's aim is to get as many safe and effective vaccines to as many people as fast as possible' [170]. Katharine Tai promised: 'As our vaccine supply for the American people is secured, the Administration will continue to ramp up its efforts—working with the private sector and all possible partners—to expand vaccine manufacturing and distribution' [170]. Tai also said that the United States Government 'will also work to increase the raw materials needed to produce those vaccines' [170]. The limitation of a *TRIPS Waiver* to vaccines would of course exclude the right to repair for PPE and medical equipment.

The Biden administration was criticized, though, for not being a vocal supporter of the *TRIPS Waiver* during the negotiations.

The Governments of Australia and its neighbor New Zealand largely followed the lead of the United States in the debate over the *TRIPS Waiver*.

After the Biden administration decided to support a *TRIPS Waiver* for vaccines, Australia and New Zealand expressed a willingness to support a *TRIPS Waiver* for vaccines [171,172]. In September 2021, the Coalition Government announced its change in

position [173]. The trade minister Dan Tehan commented: 'When the US came out and said this, the prime minister welcomed that news' [173]. He emphasized: 'We continue to work constructively in Geneva to do everything we can to expand the production of vaccines globally because we need everyone across the globe to get access to a vaccine, ultimately, to be able to be safe' [173]. Tehan maintained: 'We've already expressed that support and we've been working with countries to get a resolution to this issue' [173].

However, in spite of this shift in position of the US and its allies, there remained opposition to a *TRIPS Waiver* for vaccines, or more broadly, from the EU and some of its member states, the United Kingdom, and Switzerland. As a result, the World Trade Organization was unable to reach consensus amongst member states on such a formula for a *TRIPS Waiver*.

5.3. Ministerial Decision

At an international level, it should be observed that the EU opposed the relaxation of intellectual property rights under the *TRIPS Agreement* 1994 during the COVID-19 crisis. The European Union was opposed to a broad *TRIPS Waiver*—much to the despair of the public health community [174,175]. Instead, the EU promoted their own counter-proposal focused on voluntary licensing [176,177].

The EU also promulgated the Quad Proposal [178,179]. The Quad Proposal formed the foundation of what was to become the *Ministerial Decision on the TRIPS Agreement and Public Health* 2022 [37]. The Ministerial Decision was limited in its scope to vaccines. There has been discussion as to whether the Ministerial Decision should be extended to diagnostics and therapeutics [180]. It would seem, though, that the Ministerial Decision would not include the right to repair.

In the end, the World Trade Organization agreed to a much more limited Ministerial Decision [37]. The scope of this declaration is very narrowly limited to compulsory licensing for export of vaccines. USTR Katharine Tai was upbeat about the disappointing decision, saying 'The text-based negotiations with other WTO Members that we called for have produced accommodations to the intellectual property rules for COVID-19 vaccines that can facilitate a global health recovery' [181]. She commented: 'Through difficult and protracted discussions, Members were able to bridge differences and achieve a concrete and meaningful outcome to get more safe and effective vaccines to those who need it most' [181]. As Tai noted, 'This agreement shows that we can work together to make the WTO more relevant to the needs of regular people' [181]. She stressed: 'During a global pandemic, under difficult circumstances, the WTO moved quickly to address a major global challenge and respond to the strong desire of our African partners to produce a meaningful outcome' [181]. Tai promised: 'Going forward, the Biden Administration will continue work with WTO Members, the private sector, and other partners to expand vaccine manufacturing and distribution to facilitate the global health recovery needed for a robust global economic recovery' [181].

There has been some debate as to whether the clause should also be extended to diagnostics and therapeutics [182]. The United States International Trade Commission is holding hearings to investigate COVID-19 diagnostics and therapeutics and flexibilities under the *TRIPS Agreement* 1994 [183].

In any case, the scope of the Ministerial Decision is far too narrow to deal with the right to repair of medical equipment and 3D printing PPE and other similar supplies. Arguably, there is a disjuncture between the Biden Administration's support for a right to repair at a domestic level and its failure to support a right to repair during the discussions over the *TRIPS Waiver*.

The new Australian Labor Party Government led by Anthony Albanese welcomed the Ministerial Conference decision [184]. The Minister for Trade and Tourism Senator Don Farrell commented: 'In the first Ministerial Conference since the COVID-19 pandemic, WTO Members decided on a waiver of certain intellectual property rules to promote access to COVID-19 vaccines—sending a powerful signal of global solidarity in fighting COVID-19

and reaffirming the role the WTO can play in responding to urgent global issues' [184]. He observed that the decision will 'support equitable access to vaccines for developing countries, including across the Indo-Pacific region' [184]. However, this statement really failed to contemplate the very limited circumstances under which the Ministerial Decision could be invoked.

Moreover, the Ministerial Decision has no application to the circumstances covered in the scenario of 3D printing PPE and other medical equipment. There is a lack of international consideration of intellectual property and the right to repair in circumstances of public health emergencies. It has been argued in this article that should be recognition of a medical right to repair, not only in national laws and policies, but at an international level. Such a recognition would help bolster a COVID-19 recovery and future pandemic responses—especially in light of the UN SDGs.

6. Conclusions

To recap, this article has explored a number of themes, including the utility of 3D printing and additive manufacturing in the delivery of PPE and medical supplies; the role of the Maker Movement in responding to public health emergencies; the role of open licensing; intellectual property reform, particularly relating to the right to repair; and the geopolitical debate about whether there should be a *TRIPS Waiver*, and, if so, what its scope should be. It has argued that the recognition of a right to repair (including a medical right to repair) will promote public health, innovation, and sustainable development.

This article has highlighted the deployment of 3D printing and additive manufacturing during the COVID-19 crisis to address shortages in PPE and medical equipment. It has documented how 3D printing and additive manufacturing was used during the public health emergency in several jurisdictions, such as the European Union, the United States, and Australia. This work has highlighted the utility and flexibility of 3D printing and additive manufacturing in respect of healthcare and medicine, public health emergencies, and humanitarian aid. An article in *Nature Reviews Materials* observed: 'In the heat of the COVID-19 pandemic, 3D printing has stepped up to become a vital technology to support improved healthcare and our general response to the emergency' [185]. The piece observed: 'The digital versatility and quick prototyping of 3D printing empowers a swift mobilization of the technology and hence a rapid response to emergencies' [185]. The review suggested that 3D printing could be useful in the future in dealing with SDGs and challenges: 'The crisis has highlighted how 3D printing can be at the base of a greener and more environmentally friendly future' [185].

There has been a strong connection between the right to repair and the UN SDGs—especially responsible production and consumption (SDG 12), but also good health and well-being (SDG 3), innovation (SDG 9), and partnerships for the goals (SDG 17). The United Nations Development Programme has sought to make greater use of 3D printing and additive manufacturing in its accelerator labs to boost the UN SDGs [186]. As a technology, 3D printing could certainly enable the achievement of the UN SDGs—in particular, the goal relating to sustainable production and consumption; the goal associated with innovation; the goal focused upon public health; and the goal focused on partnerships [187].

This article has highlighted how the Maker Movement's use of 3D printing during the COVID-19 crisis was facilitated by patent pledges and open licensing. In the European Union, open licensing could have averted some of the concerns about intellectual property infringement. In the United States, a number of 3D printing initiatives during the COVID-19 crisis took up the Open COVID Pledge [90]. In Australia, there was adoption of open-licensing models in terms of developing PPE. Likewise, South Africa made use of open-licensed designs for PPE and medical equipment. Professor Joshua Pearce observed that there is a need to provide better protection of open-source developers: 'Lawyers can help as well as technologists by developing Good-Samaritan laws to protect makers, designers, and users of open medical hardware, as well as to compel those with knowledge that will save lives to share it' [91]. Pearce concluded: 'Requiring all citizen-funded research to be

released with free and open source licenses in the future will prevent such artificial scarcity from needlessly allowing people to die' [91]. At an international level, UNESCO and others have promoted open science models to foster collaboration during the COVID-19 crisis [188,189]. The COVID-19 crisis has underlined the need for better governance of the medical commons [190].

This article has also highlighted that intellectual property can provide barriers and obstacles to the rapid manufacture of PPE and other medical equipment. There have been a number of controversies during the COVID-19 crisis, in which there have been concerns about intellectual property imposing restrictions on repair. Professor Joshua Pearce has been concerned that a key inhibitor to the rapid manufacture of ventilators, other medical equipment, and goods in general has been intellectual property [191]. This article has called for law reform on intellectual property and the right to repair at a national level—particularly in light of the COVID-19 crisis. There have been various law reform proposals in the key jurisdictions studied in this article, but they have not yet necessarily come to full fruition. There have been concerns as well that such proposals have been too narrowly framed and circumscribed. In the European Union, there has been policy movement towards a stronger recognition towards a right to repair—although from the perspective of environmental stewardship and sustainable development. In the United States, there was a concrete proposal for the *Critical Medical Infrastructure Right-to-Repair Act* of 2020 (US) put forward by Senator Ron Wyden. While this was a comprehensive proposal, it has not yet been taken up by the United States Congress. In Australia, the Productivity Commission has made a number of recommendations to better recognize the right to repair in Australia. However, the law reform body has hesitated about a medical right to repair—calling for a new, separate inquiry on that particular topic. As part of their flexibilities under the *TRIPS Agreement* 1994, national governments do need to implement broad-based defenses in respect to the right to repair—across the various regimes of intellectual property.

This article has also highlighted the need for a rethink of international trade law in its approach to intellectual property and public health. A broad-based *TRIPS Waiver*—as envisaged by the Governments of India and South Africa—would have helped provide protection for the right to repair during the COVID-19 crisis [35]. A narrower *TRIPS Waiver* limited to vaccines or vaccines, treatments, and diagnostics would not have included the right to repair [170]. The *Ministerial Decision on the TRIPS Agreement* 2022 certainly does not embrace the right to repair [37]. The Ministerial Decision does not deal adequately with the problem of access to affordable medical equipment and supplies—which has been a major issue during the COVID-19 crisis.

In addition to matters of intellectual property and the right to repair, there has also been questions of medical regulation of 3D printing and additive manufacturing during public health emergencies [192]. This article has touched upon some of those public policy issues, but they have not been the central focus of the piece. There has certainly been significant discussion of regulation of health-related 3D printing, medical 3D printing, and bioprinting [193]. There have also been some special protocols in relation to the use of such technology during the COVID-19 crisis [194–196]. Professor Joshua Pearce contends: 'Policies are needed to protect the productivity of laboratories, makerspaces, and fabrication facilities during a pandemic to enable such products to be fabricated when the need arises' [91]. Pearce acknowledges: 'These products need to be safe, but there is also a need for streamlining the regulatory process' [91]. This topic is beyond the scope of this paper, but it deserves further research and examination. Likewise, there have been issues arising in respect of product liability in respect of the use of 3D printing and additive manufacturing generally [197–199]. There are perhaps special considerations of product liability of 3D printing and additive manufacturing during public health emergencies [98,200–202]. More generally, there has been a discussion about product liability and medical indemnity issues in respect of other medical products, such as vaccines, treatments, and diagnostics during the COVID-19 crisis [30]. Such matters of 3D printing, medical regulation, and product

liability during a public health emergency certainly deserve further consideration and analysis in the future.

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