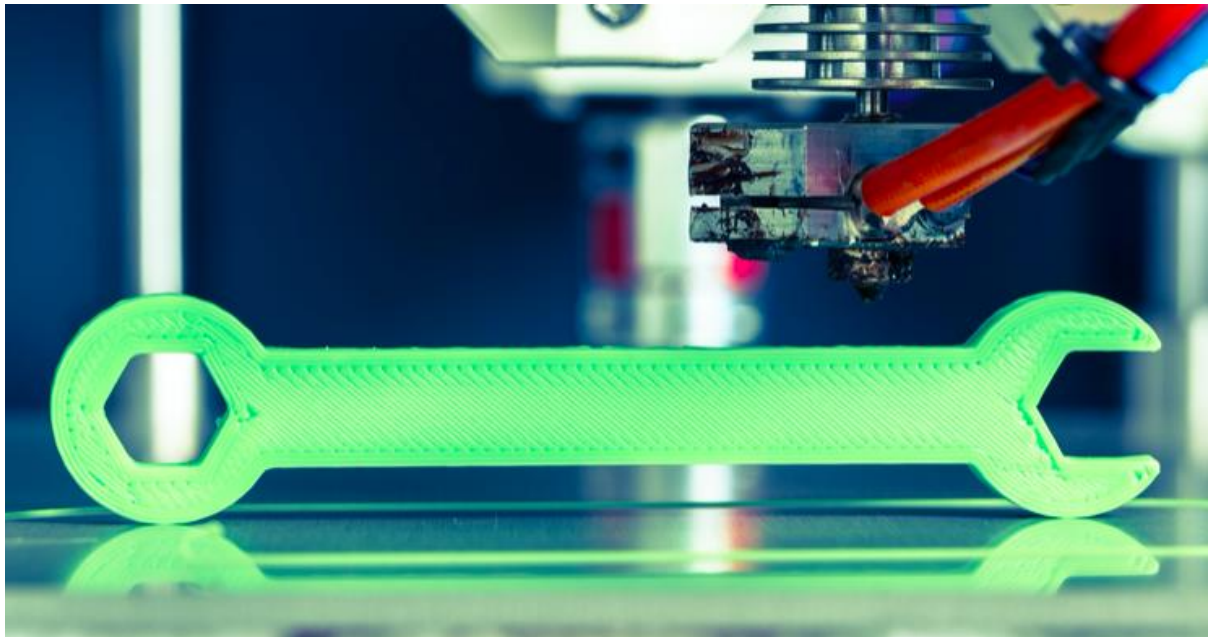


January 2021

**PATENT LAW AND 3D PRINTING APPLICATIONS IN REPAIRING MEDICAL
EQUIPMENT: AUSTRALIA NEEDS TO ADOPT AN EXPLICIT RIGHT TO
REPAIR EXEMPTION**

Submission to the Productivity Commission Inquiry into the Right to Repair in Australia



Source: ifixit.com

Muhammad Zaheer Abbas, PhD*

Postdoctoral Research Fellow

Faculty of Business and Law

Queensland University of
Technology

*muhammadzaheer.abbas@connect.qut.edu.au. A substantial part of this submission is derived from my draft manuscript entitled 'Patent Law and 3D Printing Applications in Response to COVID-19: Exceptions to Inventor Rights'.

Executive Summary

3D printing technology offers promise in relation to much-needed health technologies associated with COVID-19. Additive manufacturing, which allows the rapid conversion of information from digital 3D models into physical objects, is uniquely well-positioned to address the shortage of critical medical devices by enabling the fabrication and repair of medical devices in a timely and cost-effective manner. This submission examines the issue of patent rights being at odds with access to critical 3D printable health technologies during COVID-19 crisis. It undertakes an in-depth analysis of the right to repair and calls for a clearer recognition of the right to repair exemption in Australia. It is important to achieve a balance between the corporate interests of manufacturers and the societal urge for a rapid response to shortages of medical equipment. This submission contributes to the debate over patent law and the scope of 3D printing in response to the current health crisis. This submission will help Australian policymakers by outlining key legislative and policy measures for the adoption and implementation of the right to repair in Australia.

This submission has a three-part structure including the introduction and the conclusion. Part II undertakes an in-depth analysis of the right to repair defence in patent law. It emphasises that the right to repair is not merely a legal concept but is a matter of life or death when it comes to fixing critical medical devices in a health emergency. It considers several issues adversely impacting the Australian repair market and calls for a clearer recognition of the right to repair exemption in Australia. It also highlights the role of 3D printing technology as an enabler of quick and cost-effective repair work. Part III concludes that thinking narrowly about the rights of manufacturers should not be an option during a health emergency like COVID-19. The Productivity Commission should be mindful of the critical need to adopt a more holistic approach which considers the right to repair defence in the light of real-world implications of strictly enforcing the exclusive rights of manufacturers.

Recommendations

1. To safeguard the public interest, Australia needs to legislate a more robust and explicit right to repair. 3D printing of replacement parts of medical devices should be specifically allowed in a health emergency.
2. Manufacturers tend to design and seal products in such a way that prevents attempts of an independent consumer or professional repair. To keep control of the aftermarket repair corporations embed such software programs in products which punitively kick in when an independent repair is detected.¹ There is a need for regulatory intervention to reverse this trend which clearly conflicts with the public interest and consumer welfare.
3. The right to repair should be legislated as manufacturers' positive obligation to assist consumers in lawfully repairing and servicing the purchased objects. Information sharing should not be voluntary or optional. The Australian Government needs to make it mandatory for manufacturers to have viable systems in place to provide consumers and independent repairers with hassle-free and unrestricted access to diagnostic tools, repair manuals and repair information.
4. The High Court of Australia finally endorsed the doctrine of exhaustion in 2020. Australia's current position is still not clear on whether the doctrine of exhaustion applies on a national or international basis. The WTO TRIPS Agreement left exhaustion of rights to the discretion of its Member States. Australia needs to make full use of this flexibility to provide greater certainty by clearly adopting an international exhaustion regime that favours consumers.
5. The Australian Government needs to make administrative arrangements at the national level, through a specialized branch of the Australian Competition and Consumer Commission (ACCC), for enforcement of the right to repair. The ACCC needs to be authorized to impose penalties if manufacturers fail to discharge their positive obligations in relation to providing access to diagnostic tools and repair information.
6. To counter corporations' deceptive policies and false/ misleading representations, which potentially lead to the misbelief that consumers are required under

¹ Repair Design, 'Does Australia Need The 'Right to Repair'? '(2019) *Repair Design* <<https://repair.design/2019/09/25/does-australia-need-the-right-to-repair/>>. See more a very relevant video clip 'IDIOTS' <<https://www.youtube.com/watch?v=NCwBkNgPZFO>>.

manufacturer's warranty not to use third-party repairers, the ACCC needs to make concerted efforts to assist consumers better understand their rights.

7. Considering the significance of repair work in achieving strong economic, social and environmental outcomes, the Australian Government needs to take measures for the national level proliferation of Repair Cafes. These fixing hubs across the country will not only facilitate the cheaper and convenient availability of repair-oriented services but also create employment opportunities for skilled repairers.
8. To ensure consumer protection, the Australian Government needs to adopt a consistent approach for certification and/ or licensing of repairers in order to meet the minimum standards of professional repair work. The requirements and qualifications for each class of licensing should be prescribed. TAFEs and other relevant technical education institutions should be recommended designing training programs accordingly to prepare human resource capital for a competitive repair industry in Australia.

Biography

Dr. Muhammad Zaheer Abbas, Associate Fellow of the Higher Education Academy UK, is a Postdoctoral Research Fellow at Faculty of Business and Law, Queensland University of Technology (QUT), Brisbane, Australia. In this role, he is working with Professor Matthew Rimmer on his Australian Research Council Discovery Project 'Inventing the Future: Intellectual Property and 3D Printing' (Project ID: DP170100758). In March 2020, he completed PhD in Law at QUT as a recipient of QUT Postgraduate Research Award. Previously, he studied Law at International Islamic University (IIU), Islamabad, Pakistan, and obtained LLB (Hons) with distinction in 2010. He also obtained LLM in International Law, with distinction, from the same university in 2012. He served as a Lecturer in Law at Faculty of Law, IIU, and has nearly 10 years of teaching and/ or research experience. He also served as Associate Editor of '*Islamabad Law Review*', a peer reviewed open access research journal of IIU. He has published 20 peer-reviewed research papers, mostly related to intellectual property protection and the public interest. He has also presented 24 conference papers on related topics.

PATENT LAW AND 3D PRINTING APPLICATIONS IN REPAIRING MEDICAL EQUIPMENT: AUSTRALIA NEEDS TO ADOPT AN EXPLICIT RIGHT TO REPAIR EXEMPTION

Muhammad Zaheer Abbas, PhD

I. INTRODUCTION

The COVID-19 crisis exposed vulnerabilities of traditional supply chains and put global healthcare systems under critical strain. Hospitals and caregivers across the globe were pushed to the brink as there was a significant shortage of materials for medical personnel as well as for patients and regular people.² This high demand exposed the fragility of traditional supply chains as the ramp rate of production further slowed down in COVID-19 emergency because of lockdowns, quarantines, and transport restrictions.³ The stockpiles proved insufficient even in the most resourceful countries.⁴

Overwhelmed with COVID-19 patients, hospitals and medical centres had to seek alternative sources of critically needed medical supplies. 3D printing technology rose to the occasion as a saviour technology and proved its worth in delivering critical components in a timely fashion under extraordinary time-pressure.⁵ The terms 3D printing or additive manufacturing denote ‘any process of creating a physical object through the continual addition of layers of material – in contrast with conventional manufacturing processes in which physical shapes emerge either by removing material, as in machining, or changing the shape of a set volume of material’.⁶ Each of these successive layers of raw material ‘can be seen as a thinly sliced horizontal cross-section of the eventual object’.⁷ Unlike any other manufacturing technology, this advanced fabrication method manufactures three-dimensional tangible products from a

² Dina Amin et al., ‘3D Printing of Face Shields During COVID-19 Pandemic: A Technical Note’ (2020) *Journal of Oral and Maxillofacial Surgery* 1. See more Mostapha Tarfaoui et al., ‘Additive manufacturing in fighting against novel coronavirus COVID-19’ (2020) 110(11) *The International Journal of Advanced Manufacturing Technology* 2915; John Cote et al., ‘COVID-19 and a novel initiative to improve safety by 3D printing personal protective equipment parts from computed tomography’ (2020) 6 (20) *BMC* 1.

³ To curb the spread of COVID-19, more than 7 million flights have been cancelled worldwide. Even several cargo flights were cancelled which adversely impacted the delivery of much-needed medical equipment. See Aamer Nazir et al., ‘The rise of 3D Printing entangled with smart computer aided design during COVID-19 era’ (2020) *Journal of Manufacturing Systems* 1.

⁴ Joshua M. Pearce, ‘Distributed Manufacturing of Open Source Medical Hardware for Pandemics’ (2020) 4(2) *Journal of Manufacturing and Materials Processing*, 1.

⁵ Bankole I. Oladapo et al., ‘Review on 3D printing: Fight against COVID-19’ (2020) *Materials chemistry and physics*, 5.

⁶ Klaus Schwab and Nicholas Davis, *Shaping the Fourth Industrial Revolution* (World Economic Forum, 2018) 142-143.

⁷ Laxitha Mundhra and CIOL Bengaluru, ‘From Face Shields to Ventilators and Nasal Swabs, 3D Printing is changing the Medical Scenario’ (2020) *Athena Information Solutions Pvt. Ltd*, 1.

pre-designed computer-driven two-dimensional blueprint or digital model, called a Computer-Aided Design (CAD) file, of the required shape.⁸ This unique manufacturing method suits time-sensitive innovation, manufacturing, and repair as it does away with the time-consuming and costly tooling and machining requirements.

Although 3D printing technology is well-positioned to fabricate and repair critical medical equipment in the COVID-19 health emergency, its key role can be potentially constrained by patent exclusive rights. The implications of patent law for access to 3D printable medical devices are not merely a theoretical or hypothetical issue. In March 2020, a case of potential patent litigation in Italy made worldwide headlines. Because of the COVID-19 health emergency, the stock of venturi valves at a local hospital in northern Italy was diminishing.⁹ A venturi valve is one of the key components of a ventilator, which is required to connect the patient's face mask to breathing machines to deliver oxygen at a variable concentration.¹⁰ Given the unprecedented demand for ventilators to treat COVID-19 patients, the stocks started to dwindle quickly.¹¹ The right-holder manufacturing company could not supply valves because of limited manufacturing capacity coupled with supply-chain disruptions. The hospital quickly found itself in a crisis as the right-holder refused its cooperation to scale up production and decided to withhold the design data and blueprints in order to inhibit price-reducing competition.¹²

To combat shortages, Massimo Temporelli, founder of Fablab Milano, called 3D makers to the rescue with the help of the local press.¹³ In response to this call, Cristian Fracassi – CEO of the 3D printing start-up Isinnova - and his colleague Alessandro Romaioli successfully reverse-engineered the ventilator valve.¹⁴ Within 3 hours of studying the valve, they were able to create

⁸ S.K. Bhatia and K.W. Ramadurai, *3D Printing and Bio-Based Materials in Global Health* (Springer Briefs in Materials, 2017) 24. See more Shardha Rajam and Adya Jha, '3D Printing - An Analysis of Liabilities and Potential Benefits within the Indian Legal Framework' (2018) 11 *NUJS Law Review* 362.

⁹ Dana Mahr, and Sascha Dickel, 'Rethinking intellectual property rights and commons-based peer production in times of crisis: The case of COVID-19 and 3D printed medical devices' (2020) 15(9) *Journal of Intellectual Property Law & Practice* 711.

¹⁰ Aamer Nazir et al., 'The rise of 3D Printing entangled with smart computer aided design during COVID-19 era' (2020) *Journal of Manufacturing Systems* 8.

¹¹ *Ibid.*

¹² Dana Mahr, and Sascha Dickel, 'Rethinking intellectual property rights and commons-based peer production in times of crisis: The case of COVID-19 and 3D printed medical devices' (2020) 15(9) *Journal of Intellectual Property Law & Practice* 711.

¹³ *Ibid.*

¹⁴ Aamer Nazir et al., 'The rise of 3D Printing entangled with smart computer aided design during COVID-19 era' (2020) *Journal of Manufacturing Systems* 4.

a valve prototype.¹⁵ The duo used a desktop 3D printer to fabricate these replacement valves.¹⁶ In less than 24 hours, they were able to supply valves for more than 100 ventilators to a local hospital of the town Chiari in the Province of Brescia.¹⁷ These 3D printed valves were dramatically cheaper as compared to the original valves manufactured by the right-holder.¹⁸ Patent rights provide the best explanation for the price difference.

Before proceeding with reverse-engineering, the Italian duo had requested Intersurgical, the right-holder manufacturing company, to release design files but the company refused to share the file stating that the file is company's property.¹⁹ According to media reports, the right-holder purportedly threatened to sue the duo for patent infringement as they had designed and fabricated the valve without prior permission from the patent holder.²⁰ Managing Director Intersurgical stated that the company had no intention of making a threat.²¹ Although it is not clear what happened next, this widely publicized incident sparked serious concerns for 3D Maker communities making goodwill voluntary contributions to address shortages of critical medical equipment. The purpose of voluntarily redesigning and 3D printing these venturi valves was clearly to save lives by bolstering local supplies, and not to make money. Not only 3D makers of potentially infringing medical devices but also hospitals and medical relief organizations requesting and using such devices risk getting caught up in patent infringement lawsuits.

Possibly, because of the threat of potential legal action, the Italian duo did not publicly share the digital design file.²² However, Filip Kober, a GrabCAD user, designed a digital venturi valve model and made it publicly available on the internet.²³ Moreover, to assist the health

¹⁵ Bankole I. Oladapo et al., 'Review on 3D printing: Fight against COVID-19' (2020) *Materials chemistry and physics* 5.

¹⁶ Rance Tino et al., 'COVID-19 and the Role of 3D Printing in Medicine' (2020) 6(1) *3D Printing in Medicine* 1.

¹⁷ Jorge L Contreras, 'Research and Repair: Expanding Exceptions to Patent Infringement in Response to a Pandemic' (2020) 7(1) *Journal of Law and the Biosciences* 1.5.

¹⁸ Rosa Ballardini et al., '3D Printing: How an Emerging Technology May Help Fight a Pandemic' (2020) *IPR Info-IPR University Center*, <<https://iprinfo.fi/artikkeli/3d-printing-how-an-emerging-technology-may-help-fight-a-pandemic/>>. The accuracy of the reported \$10,000 cost of original valves is not well-established. See Jay Peters, 'Volunteers produce 3D-printed valves for life-saving coronavirus treatments' (2020) *The Verge*, <<https://www.theverge.com/2020/3/17/21184308/coronavirus-italy-medical-3d-print-valves-treatments>>.

¹⁹ Ibid.

²⁰ Lucas Osborn, '3D Printing as Indirect Patent Infringement Amid COVID-19' (2020) *Law 360* <<https://www.law360.com/articles/1255547/3d-printing-as-indirect-patent-infringement-amid-covid-19>>.

²¹ Jay Peters, 'Volunteers produce 3D-printed valves for life-saving coronavirus treatments' (2020) *The Verge*, <<https://www.theverge.com/2020/3/17/21184308/coronavirus-italy-medical-3d-print-valves-treatments>>.

²² Aamer Nazir et al., 'The rise of 3D Printing entangled with smart computer aided design during COVID-19 era' (2020) *Journal of Manufacturing Systems* 8.

²³ Ibid.

sector with quick and affordable ventilator repair, iFixit.com has been building a collection of resources and repair information.²⁴ These developments highlight the increasing importance of repair in responding to the COVID-19 health emergency. This submission is timely because the risk of being exposed to legal action is a present and future concern for consumers who engage in repairing activities.

There can be two broad types of patent protection claims in respect to 3D printing. First, patent protection of the 3D printing technologies themselves can be asserted. Second, there may be patent protection claims related to objects that are fabricated by using 3D printing technologies. The discussion in this submission, in the context of 3D printing applications in response to the COVID-19 health crisis, is confined to the second issue only. Patent protection potentially conflicts with reverse-engineering and 3D printing of medical parts, if such activities are carried out without the right holder's consent.

Most of the modern medical equipment is protected under patents as medical equipment industry relies on a closed innovation model and grants relatively higher importance to patents.²⁵ Patents are private exclusive rights which allow patent holders to control whether or not, and on what terms, the protected items can be used by third parties. In the case of an emergency, when there is a sudden surge in demand, patent exclusive rights and restrictive licensing practices pose a serious barrier in development and diffusion of the urgently needed medical devices. The demand outstrips the supply if patent owners or their authorized suppliers do not meet the extraordinary demand because of their limited manufacturing and delivery capabilities.²⁶ Right-holder companies, despite their limitations to scale-up production and supply, tend to aggressively protect their patent exclusive rights. Exclusive controls on manufacturing and distribution can lead to chaos as any reserves deplete rapidly in a crisis and it is extremely difficult to secure enough new supplies. People die because of lack of access to critical medical equipment.²⁷

²⁴ Anthony D Rosborough, 'Unscrewing the Future : The Right to Repair and the Circumvention of Software TPMs in the EU' (2020) 11 26. *JIPITEC* 26 para 1, 31.

²⁵ Michele Boldrin and David K. Levine, *Against Intellectual Monopoly* (Cambridge University Press, 2008) 62-63. See more Ugo Pagano, 'The Crisis of Intellectual Monopoly Capitalism' (2014) 38(6) *Cambridge Journal of Economics* 1409-1429.

²⁶ According to WHO prediction, to protect themselves and others from COVID-19, frontline healthcare workers around the world need an estimated 89 million masks, 76 million gloves, 30 million gowns, 1.59 million goggles, and 2.9 million liters of hand sanitizers every month. See World Health Organization, 'Disease Outbreak News' (2020) <<https://www.who.int/csr/don/en/>>. See more Mostapha Tarfaoui et al., '3D Printing to Support the Shortage in Personal Protective Equipment Caused by COVID-19 Pandemic' (2020) 13(15) *Materials* 3.

²⁷ Soufiane Belhouideg, 'Impact of 3D Printed Medical Equipment on the Management of the Covid19 Pandemic' (April) 1014.1015.

Patents and other forms of protection pose a serious barrier to universal and affordable access to medical products. There are certain exemptions and limitations to the patent holder's exclusive rights. Exceptions to patent rights create safe harbors for users to use a protected product in ways that are otherwise considered an infringement of patentee's exclusive rights.²⁸ The right to repair is one of the plausible defenses available to third parties who engage in repairing patent-protected medical devices without authorization of the right-holders. This submission undertakes an in-depth analysis of the right to repair defence and calls for a clearer recognition of the right to repair exemption in Australia.

II. RIGHT TO REPAIR EXCEPTION IN PATENT LAW

The right to repair is a consumer's ability to repair faulty goods, or access repair services, at a competitive price.²⁹ From patent law perspective, the right to repair is seen as a defence to otherwise infringing conduct. This defence or exception removes liability for patent infringement without requiring permission from the patent holder or the government and without entailing payment of compensation or royalty to the patent holder. This doctrine has been receiving renewed attention because of extra-ordinarily high demand for ventilators and other medical devices in the wake of the COVID-19 health emergency. It is very timely to consider how patent law interacts with repairs.

The notion of the right to repair is not a well-defined free-standing concept in patent law.³⁰ This lack of clarity is highly problematic, especially in a health emergency like COVID-19. There is no clearly defined standard or test to assess whether or not a repairer of a patented product engaged in infringing conduct. The broad test is that the repairer's activities do not deprive the patentee of their exclusive rights. The right to make a patented article is one of the exclusive rights of the patentee.³¹ In Lord Hoffmann's view, repairing and making are two mutually exclusive activities. Right to repair is 'a residual right, forming part of the right to do whatever does not amount to making the product'.³² In this sense, the repair is not an exception but a permitted activity as it does not conflict with the exclusive patent rights.

²⁸ Standing Committee on the Law of Patents, *Exceptions And Limitations To Patent Rights: Private And/Or Non-Commercial Use*.

²⁹ Equil, Productivity Commission Inquiry into Repair (2020) *Equil*, <<https://equil.com.au/2020/10/29/pc-inquiry-into-repair/>>.

³⁰ The term 'Repair' is not used even once in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

³¹ World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)*, Art. 28(1)(a).

³² Brian Whitehead and Richard Kempner, 'Manufacture or repair?' (2011) 6(1) *Journal of Intellectual Property Law & Practice* 10.

Right to Repair in Australia

In Australia, the repair does not have a glossy history. As noted by Tom Lee and others, ‘We don’t have universities or TAFEs offering degrees in repair, churning out increasingly large numbers of repairers. Repair exists in the shadow of design, in unfashionable, unofficial pockets’.³³ Although there are some notable repair initiatives like the Bower Reuse and Repair Centre in Sydney and the Victorian Repair Café, there is no specialized legislation on the right to repair.³⁴ The right to repair is not an established concept under the Australian patent laws. Schedule 1 of the Patents Act does not include the right to repair a patented product.³⁵ The Product Stewardship Act 2011 is another relevant national-level legislation which does not include the right to repair.³⁶ The Australian Consumer Law entitles consumers to a repair or a replacement if a product is faulty.³⁷ Manufacturers, however, try to control the aftermarket for repair by using different strategies, which can be in breach of the Australian Consumer Guarantees provided in the Australian Consumer Law.

Many consumers in Australia mistakenly believe that the manufacturer’s warranty requires them to get their products fixed by an authorized repairer.³⁸ There is a common perception that authorized repair is mandatory under the manufacturer’s warranty and independent repair would void the warranty.³⁹ Corporations tend to exploit this mistaken belief by further contributing direct and implied representations in their ‘service manuals to the effect that authorized dealers must carry out services or repairs’.⁴⁰ In June 2018, Apple was fined \$9 million by the Federal Court when the Australian Competition and Consumer Commission (ACCC) won a legal claim against the leading Tech company. Apple unfairly penalised 257 customers by making their iPhones and iPads inoperable as they had downloaded software from an unauthorized third-party repairer. Apple made false or misleading representations to

³³ Tom Lee et al., ‘Design and repair must work together to undo our legacy of waste’ (2019) *The Conversation*, <https://theconversation.com/design-and-repair-must-work-together-to-undo-our-legacy-of-waste-119932>

³⁴ Leanne Wiseman and Kanchana Kariyawasam, ‘US and EU laws show Australia’s Right to Repair moment is well overdue’ (2020) *The Conversation* <<https://theconversation.com/us-and-eu-laws-show-australias-right-to-repair-moment-is-well-overdue-127323>>.

³⁵ *Patents Act 1990* (Australia), Schedule 1.

³⁶ *Product Stewardship Act 2011* (Australia) No. 76, 2011.

³⁷ *Competition and Consumer Act 2010* (Australia), s. 58.

³⁸ While consumers in Australia are free to choose a repairer for the purchased products, a vast majority of them prefers to opt authorized repairers when the product is under warranty. See David Spicer ‘Consumer experiences of buying, servicing and repairing new cars’ (2017) *The Australian Competition and Consumer Commission*, 46.

³⁹ *Ibid*, vi.

⁴⁰ New Car Retailing Industry A market study by the ACCC (2017) *Australian Competition and Consumer Commission*, 6.

customers that they were not entitled to a remedy for their faulty devices if they had used a third-party repairer.⁴¹

It is not clear what constitutes permissible repair in the Australian context. There is a lack of clarity regarding the distinction between infringing remanufacturing and permissible repair. Courts and tribunals evaluate subjectively what constitutes the right to repair in Australia. The Australian Taxation Office (ATO) shed light on the meaning of the word ‘repairs’. According to the ATO ruling, the word repairs ‘means the remedying or making good of defects in, damage to, or deterioration of, property to be repaired ... and contemplates the continued existence of the property ... A repair merely replaces a part of something or corrects something that is already there and has become worn out or dilapidated’.⁴² The ATO, however, noted that ‘a minor and incidental degree of improvement, addition or alteration may be done to property and still be a repair’.⁴³ In the absence of a bright-line test, courts and tribunals rely on subjective assessments of the repairer’s particular activities in analyzing the difference between repair and reconstruction on a case-by-case basis.

A consumer may be liable for infringement if a manufacturer is able to prove that the consumer, instead of repairing an object, reconstructed it. Consumers have to carefully consider whether their repair activities potentially infringe the rights of manufacturers. In the absence of clear guidelines, it is hard to predict the litigation outcomes in suits against consumers who engage in controversial repair activity. The right to repair is, therefore, not a straightforward legal concept. There are so many complexities for consumers in exercising this legitimate option. Australia needs to provide a clear distinction between permissible repair and infringing reconstruction so that consumers have more certainty about the legality of their actions while deciding the extent and character of repair work.

This submission draws upon the legal doctrine of exhaustion of rights, which offers support to the right to repair. Under this doctrine, the right holders’ right to control or restrict further distribution exhausts upon the first sale.⁴⁴ Purchasers, who lawfully acquired patented products, cannot be prohibited from engaging in repairing activities if patent owners have already

⁴¹ See Guido Verbist, ‘Right to Repair: Establish a Consumer Right to Repair & Enshrine It in Legislation - The Bower’ <<https://bower.org.au/2020/08/28/right-to-repair-establish-a-consumer-right-to-repair-enshine-it-in-legislation/>>.

⁴² Australian Taxation Office, Taxation Ruling Income tax: deductions for repairs TR 97/23, *Australian Taxation Office*, Para 13 and 14.

⁴³ *Ibid*, Para 16.

⁴⁴ World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)*, Art. 6.

exhausted their rights upon the first sale. Patent owners, once they have received their full profit from the first sale, should not be allowed to control the aftermarket or secondary market for repair and service. This legal doctrine can be used as an effective advocacy tool to prevent patent owners from having control over the property of others. As noted by Professor Aaron Perzanowski, ‘by denying consumers the ability to repair their goods, manufacturers of smart goods are challenging, and even undermining, the very notion of physical ownership’.⁴⁵

Until very recently, the doctrine of exhaustion was not applicable in Australia. The principle of not applying this doctrine in Australia arose from *National Phonograph Co of Australia Ltd v. Menck*.⁴⁶ In 2019, the Full Federal Court confirmed in *Calidad Pty v. Seiko Epson Corporation* that there was no doctrine of patent exhaustion in Australia.⁴⁷ In 2020, the High Court of Australia overturned the Full Federal Court’s decision and endorsed the exhaustion principle.⁴⁸ This landmark ruling brings Australia’s position in line with the approach taken in the U.S. and EU. It is a positive development in Australia considering the importance of this doctrine in protecting the public interest and enhancing consumer welfare.

Australia’s current position is still not clear on whether the doctrine of exhaustion applies on a national or international basis. Australia is yet to make optimal use of the policy space provided under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS Agreement). The TRIPS Agreement left exhaustion of rights to the discretion of its Member States. The footnote to Art. 28(1)(a) of the TRIPS Agreement clearly indicates that the patent holder’s right to control import is subject to Art. 6 of the TRIPS. Art. 6 mentions ‘exhaustion’ but leaves it unregulated: ‘nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights’.⁴⁹ Australia needs to make full use of this flexibility to provide greater certainty by clearly adopting an international exhaustion regime that favours consumers.

3D Printing and Repair Work

Hospitals in advanced countries are increasingly acquiring consumer versions of 3D printers for on-spot fabrication and repair of medical devices. Many hospitals in advanced countries leveraged their internal 3D printing capabilities to address imbalances in supply and demand

⁴⁵ Leanne Wiseman and Kanchana Kariyawasam, 'Is Australia ready for a 'Right to Repair'?(2020) *Law Future Centre, Griffith University* <<https://news.griffith.edu.au/2020/02/03/is-australia-ready-for-a-right-to-repair/>>.

⁴⁶ *National Phonograph Co of Australia Ltd v. Menck* (1911) 12 CLR 15.

⁴⁷ *Calidad Pty Ltd v. Seiko Epson Corporation* (2019) FCAFC 115.

⁴⁸ *Calidad Pty Ltd & Ors v. Seiko Epson Corporation & Anor* (2020) HCA 41.

⁴⁹ *TRIPS Agreement*, Art. 6.

for medical equipment.⁵⁰ 3D printing makes consumers less dependent on conventional manufacturers by enabling them to fabricate their own replacement parts. 3D printing makes it easier and more affordable than before to create replacement parts for complex mechanical devices.⁵¹ It reduces the need to replace faulty devices with new purchases from specialized manufacturers. As noted by Kelsey B. Wilbanks, consumers may use 3D printing to replace several parts of an object simultaneously or make multiple repairs sequentially throughout the life of the object to preserve its utility.⁵² 3D printing even enables consumers to engage in the reconstruction of patented products by reducing costs and infrastructural needs for creation processes and by making these processes simple to carry out without specialized knowledge and skills. These processes were once cost-prohibitive and technically too cumbersome to be carried out by consumers.

Repair work enabled by 3D printing has a role in producing sustainable outcomes by contributing to the durability and environmental longevity of products through cost-efficient and convenient repair activities.⁵³ Consumers' ability to repair household objects can be crucial in achieving the United Nation's 2030 Agenda for Sustainable Development. Goal No. 12 the 2030 Agenda is focused on achieving responsible consumption and production patterns.⁵⁴ It is important to prevent the premature transfer of consumer products into waste. The excessive cost of repair leads to untimely dumping of products which can otherwise be worthy of further use. On average, each year Australians generate around 23.6 kilograms of e-waste per capita.⁵⁵ As noted by Julie Owens, Member of the Australian House of Representatives, 'We have all found times when we have thrown something out because it was too costly to repair it or could not get it repaired and it has gone into landfill when it probably had years of life yet'.⁵⁶ Affordable repair of consumer goods, especially electronics, can save the planet by extending

⁵⁰ Maria Castellucci, 'Hospitals, Systems Leverage 3D Printing Capabilities during Pandemic' (2020) 50(15) *Modern Healthcare* 1-3.

⁵¹ Kelsey B. Wilbanks, 'The Challenges of 3D Printing to the Repair-Reconstruction Doctrine in Patent Law' (2013) 20(4) *George Mason Law Review* 1148.

⁵² *Ibid*, 1150.

⁵³ In Europe, the *EU EcoDesign Directive*, coming into force in 2021, is partly motivated by the Right to Repair movement for environmental longevity of consumer goods. This *Directive* requires manufacturers to provide spare parts for up to ten years. See Leanne Wiseman and Kanchana Kariyawasam, 'Is Australia ready for a 'Right to Repair'?' (2020) *Law Future Centre, Griffith University* <<https://news.griffith.edu.au/2020/02/03/is-australia-ready-for-a-right-to-repair/>>.

⁵⁴ United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development', UN Doc. No. A/Res/70/1 (October 21, 2015), Goal No. 12.

⁵⁵ Jesse Adams Stein, 'Does Australia Need the 'Right to Repair'?' (2019) *E Waste Watch* <<https://ewastewatch.com.au/2019/09/30/right-to-repair-uts/>>. See more 'Australia: Can we fix it? Yes we can! ACT secures national agreement on a right to repair' (2019) *MENA Report*, 1.

⁵⁶ Leanne Wiseman and Kanchana Kariyawasam, 'Is Australia ready for a 'Right to Repair'?' (2020) *Law Future Centre, Griffith University* <<https://news.griffith.edu.au/2020/02/03/is-australia-ready-for-a-right-to-repair/>>.

product life and reducing dangerous e-waste.⁵⁷ Repair is a much better option than recycling in terms of achieving the goal of responsible consumption and production.

Repair work through 3D printing has a significant role in saving scarce financial resources by reducing dependence on traditional manufacturers. Consumers have more choices when buying new products, but their choices are constrained if manufacturers impede competition in repair and compel them to get products repaired by authorized repairers only. Consumers can save money by 3D printing replacement parts for household objects. They do not need to go for expensive repairs or even more expensive replacement objects. Another way the ability of consumers to repair and service products is economically beneficial to society is by creating a secondary market for repair and service. The repair can, therefore, play a role in reducing unemployment (Sustainable Development Goal No. 8) and poverty (Sustainable Development Goal No. 1). According to the Australian Competition and Consumer Commission (ACCC) ‘consumers [also] benefit from competitive aftermarkets’.⁵⁸

From a legal perspective, 3D printing further complicates matters and creates new challenges for the repair-reconstruction doctrine. With its unique capabilities, 3D printing empowers ‘consumers with broken objects around the house to create many parts by simply downloading, scanning, or creating the CAD file and printing it in plastic, metal, or other materials’.⁵⁹ Patent holders may be frustrated by the loss of revenue if a trend of convenient and extended repair through 3D printing develops and continues to grow. Patent owners may view 3D printing of replacement parts as theft or piracy.⁶⁰ This conflict of interest will lead to foreseeable tensions between consumers, who will strive to maintain their right to repair, and patent owners, who will strive to restrict the consumers’ activity of 3D printing replacement parts.

As 3D printing is rapidly growing, it is increasingly becoming important to define clearer standards to distinguish permissible repair of a patented article from the impermissible reconstruction. There is a need for a bright-line test to determine whether a consumer infringed upon patent rights, for instance, when they replace several parts on one occasion. With a high probability of such repair activity in the future, because of the enabling role of 3D printing, such clarity is critical to provide consistent and predictable applications of the law. Consumers

⁵⁷ E-waste is the fastest growing waste stream in the world. Only 15-20% of e-waste is recycled. See <<https://repair.eu>>.

⁵⁸ New Car Retailing Industry A market study by the ACCC (2017) *Australian Competition and Consumer Commission*, 3.

⁵⁹ *Ibid*, 1157.

⁶⁰ *Ibid*, 1166.

need to be certain about the legality of their actions to confidently embrace the disruptive 3D printing technology. There is an urgent need for a well-defined standard or set of standards so that consumers can anticipate when their repairing activity is too extensive to constitute infringing recreation or reconstruction. The current distinction between repair and reconstruction is too ambiguous to provide legal certainty to potential infringers of patent rights. This murkiness negatively impacts their ability to predetermine the validity of their conduct, their freedom to operate, and their ability to make more informed legal decisions.

Need for a Robust Right to Repair

A more robust and explicit right to repair exemption needs to be incorporated in patent law in response to the COVID-19 health emergency. To safeguard the public interest, 3D printing of replacement parts - like venturi valves - should be specifically permitted. Saving lives is more important than considering whether a patented device is used past the end of its normal product life span. The repair is savior in a health emergency if it extends the use of a medical device after it is completely worn out and spent. This clear exemption is important so that consumers of medical devices and 3D maker communities can confidently engage in humanitarian efforts to repair critical life-saving medical equipment without risking patent infringement. An explicit right to repair exemption will also de-risk users of 3D printed medical devices and replacement parts like hospitals and medical relief organizations.

This submission advocates for a clearly defined right to repair exemption and greater freedom in choosing independent third-party repair technicians, who are not authorized by or affiliated with the patent holder manufacturers. Consumers benefit from having a choice of providers to fix their broken products. Such an exemption is particularly important for COVID-related health technologies in order to use the available healthcare resources to their maximum potential. The current health emergency highlights the need to consider the societal and public welfare objectives related to the right to repair, which has a pivotal role in respect of health, sustainable development, and saving scarce resources. There is no reason to prioritize proprietary concerns of manufacturers over the public interest.

This submission also advocates for greater access to diagnostic tools and repair manuals. Demand for mandatory sharing of repair information is important as in many cases ‘consumers or third parties are prevented from being able to repair the products due to a lack of access to

necessary tools, parts or diagnostic software'.⁶¹ Most manufacturers in Australia refrain from providing consumers and independent repairers with 'equivalent access to the technical information provided to their authorized dealers and preferred repair networks'.⁶² By withholding technical information, manufacturers can steer repair work to their authorized or preferred repairers. Such an approach is profitable for manufacturers, but undermines consumer welfare by increasing costs of repair and causing delays and inconvenience.

Manufacturers of medical devices tend to be possessive with their repair manuals, which can be dangerous in a health emergency. Some devices may be subject to certain software technological protection measures. Manufacturers should also be required to release necessary information to enable repairers circumvent any technological protection measures on device software. Consumers will have more choices available to them if manufacturers are obligated to share information to support competitive market for repair. This submission supports the right to repair as manufacturers' positive obligation to assist consumers in lawfully repairing and servicing the purchased objects.

Over-reliance on technological hegemony of traditional manufacturers or a relationship of complete dependence is not socially beneficial for consumers. Repair allows active interaction with technology which fosters consumers' creativity, problem-solving skills, and understanding of the world around them. As noted by Anthony D. Rosborough, 'by becoming agents and masters of our own stuff, we become not merely those who consume, but also those who create, invent, use, participate and find solutions for the benefit of others'.⁶³ This submission presses for a clear right to repair exemption to achieve the social benefits of sharing knowledge, information, expertise, and tools for solving technical problems.

The proposed exemption is in line with the object and purpose of the WTO TRIPS Agreement. Art. 7 of the TRIPS Agreement is a balancing provision which states that intellectual property rights should be protected and enforced 'to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.⁶⁴ Art. 8 further illustrates public policy objectives of enforcing intellectual property rights. It allows WTO Member States to 'adopt measures

⁶¹ Chris Duckett, 'Australian Productivity Commission to look into right to repair' (2020) *ZDNet* <<https://www.zdnet.com/article/australian-productivity-commission-to-look-into-right-to-repair/>>.

⁶² New Car Retailing Industry A market study by the ACCC (2017) *Australian Competition and Consumer Commission*, 10.

⁶³ Rosborough (n 24).46.

⁶⁴ World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)*, Art. 7.

necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development'.⁶⁵ Paragraph 19 of the Doha Ministerial Declaration reaffirmed that 'the TRIPS Council shall be guided by the objectives and principles set out in Arts. 7 and 8 of the TRIPS Agreement'.⁶⁶ The proposed right to repair exemption mirrors the objectives and principles enshrined in Arts. 7 and 8 for a balance between the private interests of right-holders and the collective interests of society.

There is scope for further balancing of rights and obligations. Art. 30 of the TRIPS Agreement states that 'Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner'.⁶⁷ For a proper balancing of rights and obligations, in the light of Arts. 7 and 8 of the TRIPS Agreement, community organizations should press for a binding provision in the TRIPS Agreement in relation to the right to repair. Such a reciprocal provision can be drafted as follows: 'Patent holders shall exercise the exclusive rights conferred by a patent, provided that such exercise does not unreasonably conflict with the consumer's right to repair and does not unreasonably prejudice the legitimate interests of the consumer and public at large'.

Patent law is not the only barrier to the right to repair. Manufacturing companies tend to contractually enforce repair prohibitions - for instance, through restrictive service agreements - so that consumers may be forced to buy more products instead of repairing the existing ones. It is important to prohibit any such manoeuvres which contractually restrict consumers' right to repair. This submission calls for a very clear prohibition on contractual restrictions on the right to repair. Individual consumers lack negotiation power against big corporations who use their economic might to implement favourable terms and conditions through overly restrictive contracts. Protection of consumers' right to repair, especially during the pandemic, is not only desirable but also necessary for the purpose of safeguarding the public interest. In a health emergency, like COVID-19, hospitals cannot wait for days or even weeks for an authorized technician because patients cannot be made to wait if a ventilator or defibrillator goes down. In such a situation, healthcare providers, facing life-threatening logistical problems, cannot and should not rely on goodwill and benevolence of profit-driven manufacturing corporations.

⁶⁵ Ibid.

⁶⁶ *Doha Ministerial Declaration on TRIPS Agreement and Public Health*, 20 November 2001, Para 19.

⁶⁷ World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)*, Art. 30.

Australia may learn from law reform efforts in key international jurisdictions. For instance, in the U.S., Senator Ron Wyden and Representative Yvette Clarke put forward a new bill (The Critical Medical Infrastructure Right-to-Repair Act of 2020) at the federal level,⁶⁸ in response to COVID-19, to reform the right to repair legislation.⁶⁹ The bill nullifies any contract provision that restricts the ability of the owner or licensee of critical medical infrastructure to repair or maintain such infrastructure in response to the emergency.⁷⁰ This bill provides COVID specific right to repair to temporarily suspend restrictions, such as restrictive service agreements, that may block needed repairs. The specific purpose of the Bill is to stop infringement actions - related to copyright, technological protection measures, and designs – in order to fix short of supply medical technologies on a non-commercial basis during the current pandemic.

The Wyden and Clarke bill is a timely law reform effort motivated by noble considerations. As noted by Christopher Nowak, Senior Director, Information Services, Healthcare Technology Management at Universal Health Services, ‘This legislation will provide a safer environment and experience for patients. Devices will have more availability and uptime for patient and caregiver needs through this legislation’.⁷¹ This narrowly tailored and time-limited bill enjoys the support of public-interest organizations, like the Electronic Frontier Foundation, and high-profile politicians, like Senator Elizabeth Warren and Senator Bernie Sanders.⁷² This submission, however, calls for international recognition of a more general right to repair that provides a lasting defense beyond the current COVID-19 crisis. In order to achieve the United Nation’s 2030 Sustainable Development Agenda, it is important for Australia to have a clearer and permanent right to repair exemption across multiple industries.

III. CONCLUDING COMMENTS

The use of patent rights is generally justified to foster innovation in technically complex scientific areas. The Productivity Commission should carefully consider that over-reliance on

⁶⁸ Previously, in 2012, the first right to repair legislation was introduced in Massachusetts. Another 20 States in the U.S. have tried to introduce right to repair legislation in the following years. Corporations like John Deere, Apple, Microsoft, and Dyson have consistently opposed such legislative efforts.

⁶⁹ ‘Wyden and Clarke Introduce Bill to Eliminate Barriers to Fixing Critical Medical Equipment During the Pandemic | U.S. Senator Ron Wyden of Oregon’ <<https://www.wyden.senate.gov/news/press-releases/wyden-and-clarke-introduce-bill-to-eliminate-barriers-to-fixing-critical-medical-equipment-during-the-pandemic>>.

⁷⁰ *Critical Medical Infrastructure Right-to-Repair Act of 2020*, H.R.7956, 116th Congress (2019-2020) <<https://www.congress.gov/bill/116th-congress/house-bill/7956>>.

⁷¹ TechNation Development Team, ‘Proposed Bill Ends Barriers to Fixing Critical Medical Equipment During Pandemic,’ *TechNation* <<https://technation.com/proposed-bill-ends-barriers-to-fixing-critical-medical-equipment-during-pandemic/>>.

⁷² Matthew Gault and Jason Koebler, ‘Congress Will Consider National Right-to-Repair Legislation for Medical Equipment’ <<https://www.vice.com/en/article/akzyy5/congress-will-consider-national-right-to-repair-legislation-for-medical-equipment>>.

patent rights for promoting R&D investments in relatively simpler forms of life-saving technologies, like ventilators, is in conflict with the public interest and societal values. There is a serious and urgent need to strike a proper balance between patent protection and affordable universal access. Patent rights should not be allowed to stand in the way of saving human lives. Thinking narrowly about the rights of manufacturers should not be an option during a health emergency like COVID-19. In its legislative and policy response, Australia needs to adopt a more holistic approach which considers real-world implications of strictly enforcing the exclusive rights of manufacturers.

The right to repair defence is not a well-defined free-standing concept in the Australian legal framework. There are no clear distinctions between permissible repair and impermissible reconstruction. In the absence of clear guidelines, it is hard to predict the litigation outcomes in suits against consumers who engage in controversial repair activity. There is a need for more clarity for consistent and predictable application of the law. This is particularly important in the context of COVID-19, as the right to repair medical equipment is a matter of life and death. Consumers need to be certain about the legality of their actions to confidently embrace the disruptive 3D printing technology. An explicit right to repair exemption will also de-risk hospitals and medical relief organizations as users of 3D printed medical devices and replacement parts. The regulatory and policy response in Australia should aim at harnessing the full potential of 3D printing as an enabler of repair activities.