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**THE RIGHT TO REPAIR MEDICAL EQUIPMENT IN A HEALTH EMERGENCY:  
AUSTRALIA NEEDS TO REFORM ITS PATENT LAW**

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



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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'. This submission reinforces my previous policy submission to the Productivity Commission entitled 'Patent Law and 3D Printing Applications in Repairing Medical Equipment: Australia Needs to Adopt an Explicit Right to Repair Exemption'.

## **Executive Summary**

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 like COVID-19. Time delays in accessing repair information and repair services may result in preventable loss of human lives. 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 optional goodwill and benevolence of profit-driven manufacturing corporations. Corporations are expected to pursue profit-maximising strategies. They do not like competition and look for strategies to extract recurring revenue from their patent-protected products. They like to dominate markets by having exclusive rights and by extending their exclusive rights. It is duty of the Australian government to intervene through policy and legislative measures when the public interest is actually or potentially undermined, especially in times of emergencies.

The COVID-19 crisis exposed vulnerabilities of supply chains and put global healthcare systems under critical strain. It highlighted the importance of 3D printing and the right to repair medical devices. The Australian government's policy and legislative response is required to address the imbalance between the corporate interest and the public interest in the context of the right to repair. There are substantial barriers to repairing medical equipment even during a health emergency. There is a pressing need to think about the existing gaps or imbalances in Australia's patent laws and policies. Patent rights should not be allowed to stand in the way of saving human lives. Australia needs to use the impetus of COVID-19 to reform its patent law. There is a pressing need to legislate a more robust and explicit right to repair and to provide explicit defences or exceptions for the right to repair medical devices in response to the current and future health crisis.

## **Recommendations**

1. To safeguard the public interest, Australia needs to legislate a more robust, explicit, and enforceable right to repair defense. A bright-line test should be provided to distinguish between permissible repair and infringing reconstruction.
2. 3D printing of replacement parts of patent-protected medical devices should be specifically allowed in a health emergency. This exception is critical for making optimal use of unique capabilities of 3D printing to save lives without fear of an actual or potential infringement action. This exception is also important for consistent and predictable application of the Australian patent law.
3. The High Court of Australia endorsed the doctrine of patent 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 by legalising parallel importation.
4. Australia should not merely rely on the High Court decision on patent exhaustion. Australia needs to take stronger actions around patents that go beyond the one policy option of patent exhaustion endorsed by the High Court. There is a need to make a better use of policy space provided under the WTO TRIPS flexibilities to tackle access issues and to safeguard the public interest.
5. Australia needs to learn from the Wyden-style proposals in the U.S. which are really important in providing explicit defences or exceptions for the right to repair medical devices in response to COVID-19. Australia should provide a specific COVID-related right to repair defence or a pandemic-specific exception in its patent law to deal with the current and future health crisis.

## **Biography**

Dr. Muhammad Zaheer Abbas, Member of the Australian Centre for Health Law Research (ACHLR), 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 26 peer-reviewed research papers, mostly related to intellectual property protection and the public interest. He has also presented 33 conference papers on related topics.

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**I. INTRODUCTION**

I am making this submission to reinforce my previous policy submission entitled ‘Patent Law and 3D Printing Applications in Repairing Medical Equipment: Australia Needs to Adopt an Explicit Right to Repair Exemption’ that I made to the Productivity Commission in the beginning of this year. Repair involves several forms of industrial property including copyright, trademarks, designs, patents, and confidential information or trade secrets. Because of its limited scope, the key focus of this submission is only on patent law. Moreover, this submission provides further clarity on the utility of 3D printing in repairing medical devices in a health emergency.

Questions about the right to repair are important in the biomedical context in general and in a public health emergency in particular. 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 in pursuit of profit.<sup>1</sup> Monopolistic ownership of proprietary rights is key concern of commercial manufacturers of medical instruments. Patents, which are considered the strongest form of intellectual property protection, provide the desired tool to manufacturers of medical equipment to dominate the market and derive maximum profits by excluding others.

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. 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. 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

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<sup>1</sup> 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.

exclusive rights.<sup>2</sup> 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 calls for an explicit right to repair exemption in the Australian patent law in response to COVID-19.

## II. THE RIGHT TO REPAIR IN THE AUSTRALIAN PATENT LAW

The right to repair is not an established or a well-defined free-standing concept under the Australian patent law. Schedule 1 of the Patents Act does not include the right to repair a patented product.<sup>3</sup> The Product Stewardship Act 2011 is another relevant national-level legislation which does not include the right to repair.<sup>4</sup> 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. In the absence of a bright-line test, courts and tribunals evaluate subjectively what constitutes the right to repair in Australia. 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. 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.<sup>5</sup>

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. The current distinction between repair and

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<sup>2</sup> Standing Committee on the Law of Patents, *Exceptions And Limitations To Patent Rights: Private And/Or Non-Commercial Use*.

<sup>3</sup> *Patents Act 1990* (Australia), Schedule 1.

<sup>4</sup> *Product Stewardship Act 2011* (Australia) No. 76, 2011.

<sup>5</sup> World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)*, Art. 28(1)(a).

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.

The legal doctrine of exhaustion of patent rights 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.<sup>6</sup> Purchasers, who lawfully acquired patented products, cannot be prohibited from engaging in repairing activities if patent owners have already 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.

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*.<sup>7</sup> In 2019, the Full Federal Court confirmed in *Calidad Pty v. Seiko Epson Corporation* that there was no doctrine of patent exhaustion in Australia.<sup>8</sup> In 2020, the High Court of Australia overturned the Full Federal Court's decision and endorsed the exhaustion principle.<sup>9</sup> 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'.<sup>10</sup> Australia needs to make full use of this flexibility to provide greater certainty by clearly adopting an international exhaustion regime that favours consumers by legalising parallel importation (**See Annexure I**)

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

<sup>7</sup> *National Phonograph Co of Australia Ltd v. Menck* (1911) 12 CLR 15.

<sup>8</sup> *Calidad Pty Ltd v. Seiko Epson Corporation* (2019) FCAFC 115.

<sup>9</sup> *Calidad Pty Ltd & Ors v. Seiko Epson Corporation & Anor* (2020) HCA 41.

<sup>10</sup> *TRIPS Agreement*, Art. 6.

which is another cost-reducing and access-enhancing policy option provided under the WTO TRIPS Agreement.

More importantly, Australia should not merely rely on the High Court decision on patent exhaustion. Australia needs to take stronger actions around patents that go beyond the one policy option of patent exhaustion endorsed by the High Court. There is a need to make a better use of policy space provided under the WTO TRIPS Agreement to tackle access issues and to safeguard the public interest. Australia should provide a well-defined, clear and enforceable right to repair defense in its patent law to stop any actual or potential infringement actions in a health emergency. Restrictions on independent or third-party repair should not be allowed to cause any outages and delays in times of a health emergency. There are shortages of medical equipment in emergency situations because of supply-chain disruptions. Unnecessary or unreasonable restrictions on independently refurbishing medical equipment worsen the already worrisome situation for hospitals and healthcare providers.

### **III. UTILITY OF 3D PRINTING IN REPAIRING MEDICAL DEVICES**

3D printing, which allows the rapid conversion of information from digital 3D models into physical objects, is a very useful tool for instant and affordable repair of medical devices in a health emergency. 3D printing makes it easier, quicker, and more affordable than before to create replacement parts for medical devices. 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. For instance, during the COVID-19 health emergency, there was critical shortage of ventilator valves in Italy. Within 3 hours of studying the valve, two gentlemen Cristian and Allesandro were able to create a valve prototype. The duo used a desktop 3D printer to fabricate these replacement valves. In less than 24 hours, they were able to supply valves for more than 100 ventilators to a local hospital in Italy. One can imagine the amount of time traditional manufacturers would have taken to make these valves available.

3D printing technology has the flexibility to completely revamp the line of production in a matter of days.<sup>11</sup> More importantly, there are no issues of shipping of parts as the required parts can be fabricated closer to the point of use by using 3D printing technology (**See Annexure II**). This is important because there can be natural or practical hurdles to shipping of parts

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<sup>11</sup> Christopher Knaus, 'Manufacturing Face Shields within Days: How Australian Industry is Pivoting to Fight Coronavirus' (April 5, 2020) *The Guardian*, <<https://www.theguardian.com/world/2020/apr/05/manufacturing-face-shields-mat-bowtell-3d-printing-australia-fight-coronavirus>>.



during an emergency. Even when the needed resources are available overseas, they may not be delivered on time – especially to geographically remote countries like Australia - because of closed borders and transport restrictions. To curb the spread of COVID-19, more than 7 million flights were cancelled worldwide. Even several cargo flights were cancelled which adversely impacted the delivery of much-needed medical equipment.<sup>12</sup> 3D printing technology is less affected by the ground realities of an emergency as it allows virtual data shipping instead of physical part shipping.<sup>13</sup> Digital files can be swiftly and economically shared over the Internet. Low-cost 3D printers, which serve as mini-factories in a box, make it possible to convert these electronic files into ready-to-use physical goods.

From a legal perspective, 3D printing further complicates matters and creates new challenges for the repair-reconstruction doctrine by expanding the scope of possibilities. With its unique capabilities, 3D printing empowers ‘consumers [] to create many parts by simply downloading, scanning, or creating the CAD file and printing it in plastic, metal, or other materials’.<sup>14</sup> 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. 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.<sup>15</sup> 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.

Consumers need to be certain about the legality of their actions to confidently embrace the disruptive 3D printing technology. 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

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<sup>12</sup> Aamer Nazir *et al.*, 'The Rise of 3D Printing Entangled with Smart Computer Aided Design during COVID-19 Era' (2020) *Journal of Manufacturing Systems*, <<https://doi.org/10.1016/j.jmsy.2020.10.009>>.

<sup>13</sup> Nari Lee, 'Intellectual Property and Open Innovation in 3D Printing: A Different Form of Exclusivity' in *The Innovation Society and Intellectual Property*, Josef Drexler, Anselm Kamperman Sanders, eds. (Edward Elgar Publishing, 2019).

<sup>14</sup> New Car Retailing Industry A market study by the ACCC (2017) *Australian Competition and Consumer Commission*, 1157.

<sup>15</sup> *Ibid*, 1166.

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.

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’.<sup>16</sup> Art. 8 further illustrates public policy objectives of enforcing intellectual property rights. It allows WTO Member States to ‘adopt measures 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’.<sup>17</sup> 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’.<sup>18</sup> 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.

Australia should 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,<sup>19</sup> in response to COVID-19, to reform the right to repair legislation.<sup>20</sup> The bill provides COVID specific right to repair to temporarily suspend restrictions that may block needed repairs. The specific purpose of the Bill is to stop infringement actions in order to fix short of supply medical technologies on a non-commercial basis during the current pandemic.

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<sup>16</sup> World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)*, Art. 7.

<sup>17</sup> *Ibid*, Art. 8.

<sup>18</sup> *Doha Ministerial Declaration on TRIPS Agreement and Public Health*, 20 November 2001, Para 19.

<sup>19</sup> 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.

<sup>20</sup> ‘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->>.

The Wyden and Clarke narrowly tailored 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’.<sup>21</sup> Australia needs to learn from the Wyden-style proposals in the U.S. which are really important in providing explicit defences or exceptions for the right to repair medical devices in response to COVID-19. Australia should provide a specific COVID-related right to repair defence or a pandemic-specific exception in its patent law in order to deal with the current and future health crisis.

### III. CONCLUDING COMMENTS

The current patent law regime in Australia privileges patent-holders over repairers. Patent law is an important area when it comes to affordable access to medical technologies. It is critically important to reform patent laws to address any actual or potential concerns about timely and affordable repair of life-saving medical devices in a time-sensitive situation like a pandemic. There is scope and pressing need for balancing of rights and obligations. Companies, hospitals, and capable independent repairers should be allowed to make independent or third-party repairs to medical devices without the fear or risk of facing an IP action or a potential lawsuit.

The High Court decision on patent exhaustion is a positive development, but the Australian government needs to take stronger actions around patents to tackle access issues, especially during a health emergency like the COVID-19 pandemic. Just relying upon the High Court decision on patent exhaustion may not be a well-thought-out policy option for Australia. Australia needs to do more in terms of making a better use of policy space provided under the WTO TRIPS Agreement.

The right to repair defence is not a well-defined free-standing concept in the Australian patent law. 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 Australian patent law.

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<sup>21</sup> 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/>>.