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VULNERABLE SUPPLY CHAINS IN A HEALTH EMERGENCY: AUSTRALIA, LOCAL MANUFACTURING AND 3D PRINTING

Submission to the Productivity Commission Inquiry into Vulnerable Supply Chains

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Executive Summary

The response to the COVID-19 crisis highlighted the weaknesses of the free trade system and failures of the traditional supply chains. Public health preparedness for future pandemics demands nation-states to increase their local production of medical supplies in order to reduce their dependence on third countries. Globally connected local production, enabled by digital fabrication tools, is arguably the best policy response to collaboratively address supply-chain vulnerabilities. 3D printing technology, which is the most prominent manifestation of digital fabrication ecosystems, can play a key role in enhancing the local production capacity in a time- and cost-efficient manner. This submission calls upon the Australian Government to increase its focus on local production of personal protective equipment (PPE) and proposes a more systematic and organized use of onshore 3D printing capabilities to address shortages of critical medical equipment in a health emergency. This submission also addresses intellectual property dimensions of local manufacturing with a key focus on compulsory licensing of patents, Crown use, and the right to repair patent protected devices to address shortages of critically needed medical equipment.

Recommendations

1. The Australian Government needs to work with local industry to enhance localized manufacturing of PPE to reduce its reliance on additional importation of PPE in a health emergency.
2. The Australian Government needs to prioritize onshoring of key strategic industries. The labor costs are higher in Australia but cost-cutting policies can prove costly in a health emergency when human lives are at risk.
3. The Australian Government needs to take proactive legislative measures to improve its legal capacity to efficiently use the compulsory licensing safeguard to override the existing or future patents on COVID-19 related health technologies.
4. The Australian Government needs to legislate a more robust and explicit right to repair as manufacturers' positive obligation to assist consumers in lawfully repairing and servicing the purchased objects. Manufacturers must be obliged 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.

5. The Australian Government needs to support decentralization of manufacturing capabilities and equip hospitals and medical centres with their own in-house 3D printing capabilities to break their dependence on global supply chains.

6. The Australian Government needs to remove regulatory uncertainties regarding the use of 3D printing in the medical sector. A clear regulatory framework should be provided to use the full potential of 3D printing as a life-saving technology in a future pandemic.

7. The Australian Government should provide a specialized mechanism for fast-track safety review and quality validation of PPE designs. Australia may learn from the U.S. government's initiative 'America Makes'.[1]

8. The Australian Government should create its own online repository of approved 3D design blueprints that are shared publicly after officially testing their functionality, reliability, durability, and printability for the specific intended purpose.

9. The Australian Government needs to make concerted efforts for coordinated and organized use of onshore 3D printing capabilities. Australia may learn from the National Institute of Health (NIH) 3D Print Exchange initiative of the U.S. government for open-sourcing/ crowd-sourcing and open sharing of reliable design blueprints.[2]

10. The Australian Government should support education and training in respect of 3D printing and additive manufacturing. As well as including 3D printing in the curriculum at the primary school level, the disciplines should be taught in the engineering curriculum right from the undergraduate level. This capacity-building is important because having a creative mind coupled with the knowledge of digital designing and the basic mechanisms of 3D printing methods and access to 3D printing tools can be a perfect combination for fostering problem-solving innovation in any emergency situation.

[1] See 'America Makes'. This is the nation's leading and collaborative partner in additive manufacturing (AM) and 3D printing (3DP) technology research, discovery, creation, and innovation. <https://www.americamakes.us>.
[2] See the National Institutes of Health (NIH)'s 3D printing program. The NIH Library's 3D Printing Service offers free 3D printing to NIH staff who are creating work- or research-related projects. <https://3dprint.nih.gov>.

Biography

Dr. Muhammad Zaheer Abbas 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. Dr. Abbas served as a Lecturer in Law at Faculty of Law, IIU, and has nearly 10 years of teaching and/ or research experience. He is also an Associate Fellow of the Higher Education Academy UK. He also served as Associate Editor of *'Islamabad Law Review'*, a peer reviewed open access research journal of IIU. He has published 23 peer-reviewed research papers, mostly related to intellectual property protection and the public interest. He has also presented 26 conference papers on related topics.

VULNERABLE SUPPLY CHAINS IN A HEALTH EMERGENCY: AUSTRALIA, LOCAL MANUFACTURING AND 3D PRINTING

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I. INTRODUCTION

The demand for personal protective equipment (PPE) started to rise worldwide with the spread of COVID-19 across continents.[3] In March 2020, front-line health workers in Australia reported shortages of PPE.[4] Lack of PPE in a health emergency like COVID-19 can have dire consequences as 'healthcare workers rely on personal protective equipment to protect themselves and their patients from being infected and infecting others'.[5] Absence of appropriate protection puts healthcare workers at a higher risk in fighting the virus - an enemy that is invisible. It has an adverse effect on the overall functioning of the healthcare system. In Australia, 'the paucity of supplies forced hospitals to stop elective surgeries and left aged care providers with serious threats to their ability to deliver services'.[6]

The COVID-19 crisis greatly exposed the disappearance of key strategic industries from Australia. Before this pandemic, 'only a single Australian factory, Med-Con's Shepparton plant, was producing surgical masks. Similarly, there was only one significant onshore producer of ventilators, a company named Resmed'.[7] Australia imports the majority of its PPE from China.[8] Additional importation from China or other PPE manufacturing countries, in the middle of a pandemic situation, was not very realistic option for the Australian Government given the supply-chain disruptions, export restrictions and nationalistic approaches of countries in dealing with the COVID-19 crisis.

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[3] Fadela Chaib, 'Shortage of Personal Protective Equipment Endangering Health Workers Worldwide' (March 3, 2020) *World Health Organization,* <https://www.who.int/news/item/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide>.

[4] Josh Robertson, 'Health Workers Running out of Coronavirus Masks, Protective Gear as Doctors Call for Urgent Action' (March 25, 2020) *ABC News*, <https://www.abc.net.au/news/2020-03-25/coronavirus-queensland-ppe-mask-shortage-doctors/12086562>.

[5] Fadela Chaib, 'Shortage of Personal Protective Equipment Endangering Health Workers Worldwide' (March 3, 2020) *World Health Organization,* <https://www.who.int/news/item/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide>.

[6] 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>.

[7] Ibid.

[8] Janice Petersen et al., 'As Front-Line Health Workers Report Shortages of Personal Protective Equipment or PPE - Australian Researchers and Scientists Are Mobilizing to Help Increase Supplies through 3-D (2020) *World News Australia,* < https://search.informit.org/doi/10.3316/tvnews.tsm202004020108>.

One solution could be to ramp up local production in Australia through traditional manufacturing methods. As New South Wales Premier Gladys Berejiklian said, the New South Wales Government 'would help manufacturers re-tool in order to produce the PPE'.[9] This approach does not provide a quick solution as it might 'take weeks or months to retool factories to do this work'.[10] This strategy is not well-thought-out and exposes a lack of crisis planning in Australia. The gradual offshoring of PPE production should have been prevented in the first place. As noted by Jennifer Doggett, the chair of the Australian Healthcare Reform Alliance, 'in a wealthy country like Australia, it is unacceptable to risk lives of health professionals because we do not have the facilities to manufacture simple materials such as masks and swabs'.[11]

3D printing of PPE could be an alternate solution to quickly fix the shortages caused by supply-chain failures in response to COVID-19. 3D printing technology has the flexibility to completely revamp the line of production in a matter of days.[12] The Australian government could have mobilized all the existing 3D printing resources in Australia as a stopgap measure to safeguard its health workers. As noted by Andrew Gray, the Director of the Bioquisitive community lab in Melbourne, 'there are hundreds of people in Australia with 3D printers that can each produce at least 36 face shields per day – adding up to tens of thousands'.[13] Michael Larkins, CEO, 3D One Australia, said, 'we currently have 28 printers and the capacity for that is 500 pieces per day'.[14] The Australian Government was not agile enough to respond to the rapid demand for PPE through coordination between individual 3D printer owners, universities, schools, and community groups for optimal utilization of onshore 3D printing capability.[15]

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[9] Josh Robertson, 'Health Workers Running out of Coronavirus Masks, Protective Gear as Doctors Call for Urgent Action' (March 25, 2020) *ABC News*, <https://www.abc.net.au/triplej/programs/hack/coronavirus-covid19-3d-printer-owners-rally-to-produce-ppe/12115626>.

[10] Ibid.

[11] 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>.

[12] Ibid.

[13] Josh Robertson, 'Health Workers Running out of Coronavirus Masks, Protective Gear as Doctors Call for Urgent Action' (March 25, 2020) *ABC News*, <https://www.abc.net.au/triplej/programs/hack/coronavirus-covid19-3d-printer-owners-rally-to-produce-ppe/12115626>.

[14] Jessica Hinchliffe, 'Crowdsourcing 3D Printers Set to Create Essential PPE for Australian Hospitals' (April 3, 2020) *ABC Radio Brisbane*, <https://www.abc.net.au/news/2020-04-03/callout-for-3d-printers-to-help-create-medical-supplies/12115074>.

[15] Janice Petersen et al., 'As Front-Line Health Workers Report Shortages of Personal Protective Equipment or PPE - Australian Researchers and Scientists Are Mobilizing to Help Increase Supplies through 3-D (2020) *World News Australia*, <https://search.informit.org/doi/10.3316/tvnews.tsm202004020108>.

In Australia, there is regulatory uncertainty about the use of 3D printing in the medical sector. Despite a spotlight on the potential or actual use of 3D printing as a stopgap measure in response to COVID-19, in Australia, the regulation of 3D printed PPE is still a complicated and murky area.[16] There are potential delays in the Therapeutic Goods Administration's (TGA's) approvals process if there are no clear regulations on standardising designs and quality of 3D printable PPE. This can be frustrating both for hospitals/ healthcare providers and new suppliers of 3D printed PPE, especially in a health emergency. In this context, this submission calls upon the Australian Government to increase its focus on local PPE production and proposes a more systematic and organized use of onshore 3D printing capabilities to address shortages of critical medical equipment in a health emergency.

II. IMPORTANCE OF LOCALIZED SUPPLY CHAINS

Free trade, a policy of minimizing restrictions on imports or exports, lies at the heart of the 21st century global trading system. The World Trade Organization (WTO) came with the promise of rules-based free trade. The key objectives of establishing the WTO include the 'optimal use of the world's resources' and the promotion of multilateral trade liberalization through 'reduction of tariffs and other barriers to trade'.[17] Global cooperation is the essence of multilateralism.

The response to COVID-19 was, however, marked by trade restrictions and protectionism. In many cases, nation-states responded to the crisis individually, not collectively. When demand outstripped the supply of personal protective equipment (PPE) and other medical supplies, countries placed their focus on protecting their own nationals' health without considering the humanitarian needs of other nations.[18] Many countries chose to restrict exports of medical goods - like testing kits, PPE, respirators and ventilators - to secure them for national use.[19] The U.S. purchased all supplies of Remdesivir, a drug that offered hope against COVID-19, making the rest of the world wait for months.[20] Richer countries were reported to have offered

[16] Josh Robertson, 'Health Workers Running out of Coronavirus Masks, Protective Gear as Doctors Call for Urgent Action' (March 25, 2020) *ABC News*, <https://www.abc.net.au/triplej/programs/hack/coronavirus-covid19-3d-printer-owners-rally-to-produce-ppe/12115626>.
[17] World Trade Organization, 'Agreement Establishing the World Trade Organization' *World Trade Organization*.
[18] Christopher Stothers and Alexandra Morgan, 'IP and the Supply of COVID-19-Related Drugs' (2020) 15(8) *Journal of Intellectual Property Law & Practice*, pp. 590-593.
[19] Organization for Economic Co-operation and Development (OECD), 'COVID-19 and International Trade: Issues and Actions' (2020). Available from <https://read.oecd-ilibrary.org/view/?ref=128_128542-3ijg8kfswh&title=COVID-19-and-international-trade-issues-and-actions>.
[20] Thomas J. Bollyky and Chad P. Bown, 'The Tragedy of Vaccine Nationalism: Only Cooperation Can End the Pandemic' (2020) 99(5) *Foreign Affairs*, <https://www.foreignaffairs.com/articles/united-states/2020-07-27/vaccine-nationalism-pandemic?utm_medium=social.>.

a higher market price to private manufacturers for testing equipment and facial masks. Poorer countries, with already fragile economies and health systems, were given wait times because supplies spanning months of production had been pre-purchased by countries having more purchasing power.[21] This approach seriously undermined trust in the WTO as the global institution failed to assert its leadership role.

Moreover, there can be natural or practical hurdles to free trade 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.[22] Supplies of urgently needed medical equipment can be potentially disrupted by natural disasters like an eruption of volcanos, earthquakes, floods, and hurricanes.[23] It is estimated that about half of the world's face masks are manufactured in China.[24] One can imagine the costs, delivery times, and vulnerabilities of long-distance shipping to far off countries like Australia. Political and diplomatic relations with the exporting countries also potentially impact the accessibility of critically needed health technologies.

COVID-19 is neither the world's first pandemic nor the last. The challenges to free trade will re-emerge whenever demand will outstrip supply in a future health emergency. Public health preparedness for future pandemics demands well-thought-out policy measures. Australia needs to increase its local production of medical supplies in order to reduce its dependence on third countries. There is an urgent need for localization of key lines of production even if those controlling the existing global framework try to maintain the status quo despite obvious failures of the WTO-led multilateral trading system.

IIL. INTELLECTUAL PROPERTY DIMENSIONS OF LOCAL MANUFACTURING

Patent rights pose a significant barrier to local manufacturing in a pandemic situation. There is hardly enough time to engage with patent holders to negotiate voluntary licenses in the fast-

[21] 'Fair and Equitable Access to COVID-19 Treatments and Vaccines' (2020) *Nuffield Council on Bioethics Policy Briefing.*
[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*, <https://doi.org/10.1016/j.jmsy.2020.10.009.>.
[23] Mika Salmi *et al.*, '3D Printing in COVID-19: Productivity Estimation of the Most Promising Open Source Solutions in Emergency Situations' (2020) 10(11) *Applied Sciences*.
[24] Mostapha Tarfaoui *et al.*, '3D Printing to Support the Shortage in Personal Protective Equipment Caused by COVID-19 Pandemic' (2020) *Materials.* Available from <http://www.mdpi.com/journal/materials.>.

paced environment a health emergency. Whilst some corporations may be expected to voluntarily license their exclusive patent rights to avoid reputational damage, many of them may not. Compulsory licensing and crown use/ government use,[25] allowed under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS Agreement),[26] are a critical factor in addressing the situations when local manufacturing is constrained because of non-cooperation of patent holders. A compulsory license is 'an authorization given by a national authority to a person, without or against the consent of the title-holder, for the exploitation of a subject matter protected by a patent or other intellectual property rights'.[27]

Compulsory licensing is a procedurally cumbersome mechanism. As delays seriously undermine the public interest in a health emergency, several countries - including economically advanced countries - adopted compulsory licensing related legislative measures in response to the COVID-19 pandemic. For instance, on March 23, 2020, France enacted Emergency Law No. 2020-290.[28] It introduced a new and wide provision, Art. L3131-15, into the French Public Health Code.[29] On March 24, 2020, Canada amended its Patent Act (Bill C-13) to make it faster for the government to utilize the compulsory licensing option in response to the current pandemic.[30] On March 27, 2020, Germany enacted the 'Prevention and Control of Infectious Diseases in Humans Act'.[31] This legislation empowers the Federal Ministry of Health to compulsorily authorize the use of an invention if there is an 'epidemic situation of national significance'.[32]

Australia had already made changes to its compulsory licensing regime shortly before the onset of the current pandemic. In February 2020, Australia amended its compulsory licensing

[25] A compulsory license is issued upon a motion submitted by any interested party in cases of abuses of monopoly by a patentee while government use or crown use is invoked on grounds of national security or for the maintenance of essential supplies and services. See Bassam Peter Wu, Xiaoping; Khazin, 'Patent-Related Actions Taken in WTO Members in Response to the COVID-19 Pandemic' (2020) *World Trade Organization (WTO), Geneva* 19.
[26] *TRIPS Agreement*, Art. 31.
[27] Aswathy Asok, 'Compulsory Licensing for Public Health and Usa's Special 301 Pressure: An Indian Experience' (2019) 24(5–6) *Journal of Intellectual Property Rights* 125.
[28] Wu, Xiaoping; Khazin (n 25) 18.
[29] Martina Dani, 'Public Health Comes First' (2020) 15(11) *Journal of Intellectual Property Law & Practice* 871.
[30] Ed Silverman, 'A Canadian bill would make it easier to issue compulsory licenses for Covid-19 products' (2020) *Pharmalot*, https://www.statnews.com/pharmalot/2020/03/25/canada-compulsory-license-coronavirus-covid19/.
[31] Nirmalya Syam, 'Intellectual Property , Innovation and Access to Health Products for COVID-19 : A Review of Measures Taken' (2020) (80) *South Centre-Policy Brief* 3.
[32] Wu, Xiaoping; Khazin (n 25) 17.

provisions[33] to provide a more certain framework under which these provisions can be used.[34] A compulsory license will now be granted if it satisfies the 'public interest' test.[35] The new test has replaced the previous 'reasonable requirement of the public' test.[36] The new test has a more efficient and simplified approach in determining the use of compulsory licensing safeguard. Grant of a compulsory license to meet the unmet demand for patented health technologies in a pandemic clearly passes the 'public interest' test.

Australia also amended its Crown use provisions[37] to provide more clarity on what constitutes a Crown use purpose. Crown use 'permits a government department or authority to exploit an invention for the services of the Crown'.[38] The amended provision clarified that the Crown use purpose includes exploitation of the underlying invention for the 'services of a relevant authority'. The provision of healthcare - one of the services in which the government authorities have the primary responsibility for providing or funding - falls within the ambit of the amended Crown use purpose. The previous Crown use provisions lacked clarity and 'failed to sufficiently provide for transparency and accountability'.[39]

The changes to compulsory licensing and Crown use provisions were not triggered by the current pandemic. These changes were underway, well before the start of the COVID-19 pandemic, following reviews and observations by bodies including the Productivity Commission[40] and the Australian Law Reform Commission.[41] Australia needs to use the impetus of COVID-19 to further review its ability to grant compulsory licenses in a time-efficient manner. In addition to strengthening its enabling legislation, Australia should also pass a resolution to declare that the current health crisis justifies the use of compulsory

[33] *Patents Act 1990* (Australia), ss.133 and 136D (Chapter 12).
[34] Suzy Madar and Kim O'Connell, 'Patent rights during COVID-19 – can the Government step in?' (03 April 2020) *King & Wood Mallesons* https://www.kwm.com/en/au/knowledge/insights/patent-rights-during-covid-19-can-the-government-step-in-20200403
[35] James Neil and Richard Hoad, 'The race for the COVID-19 vaccine and patents: Do we need a temporary lockdown?' (20 June 2020) *Clayton Utz* https://www.claytonutz.com/knowledge/2020/june/the-race-for-the-covid-19-vaccine-and-patents-do-we-need-a-temporary-lockdown
[36] Herbert Smith Freehills, 'Australian Patent Update: three key changes underway' (15 August 2019) *Lexology* https://www.lexology.com/library/detail.aspx?g=e9151698-cb34-4b33-bf45-8d5759329c65
[37] *Patents Act 1990* (Australia), ss. 163 and 163A (Chapter 17).
[38] Jesse Strafford, 'Covid-19 and the patent path forward' (June 2020) *Henry Hughes Intellectual Property Australia & New Zealand* https://www.henryhughes.com/Site/news/covid-19-and-the-patent-path-forward.aspx
[39] Herbert Smith Freehills, 'Australian Patent Update: three key changes underway' (15 August 2019) *Lexology* https://www.lexology.com/library/detail.aspx?g=e9151698-cb34-4b33-bf45-8d5759329c65
[40] See Compulsory Licensing of Patents, Public inquiry, *Australian Productivity Commission* https://www.pc.gov.au/inquiries/completed/patents
[41] Suzy Madar and Kim O'Connell, 'Patent rights during COVID-19 – can the Government step in?' (03 April 2020) *King & Wood Mallesons* https://www.kwm.com/en/au/knowledge/insights/patent-rights-during-covid-19-can-the-government-step-in-20200403

licensing if patent holders do not cooperate through voluntary licensing or unilaterally suspending their rights. Australia has issued only three compulsory licenses since 1903.[42] Such a resolution will send a clear signal to patent holders that the Australian Government will not put up with delays in locally manufacturing COVID-19 related health technologies. This pro-public health gesture will act as a safeguard against patent holders' irresponsible decision making.

Moreover, the right to repair has a pivotal role in addressing shortages of medical equipment through prompt and cost-effective repair of broken devices. 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.[43] The Product Stewardship Act 2011 is another relevant national-level legislation which does not include the right to repair.[44] The Australian Consumer Law entitles consumers to a repair or a replacement if a product is faulty.[45] It is, however, 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.

Australia needs to legislate a more robust and explicit right to repair in order to safeguard the public interest, especially in a health emergency. 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. The Australian Competition and Consumer Commission (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.

IV. POTENTIAL ROLE OF 3D PRINTING

3D printing technology brings new possibilities to promote agility in dealing with health emergencies. This unique manufacturing method allows the rapid conversion of information from digital 3D models into physical objects. 3D Printing technology is perfect for localized manufacturing and problem-solving innovation in a crisis situation. Joel Cutcher-Gershenfeld

[42] Ibid.
[43] *Patents Act 1990* (Australia), Schedule 1.
[44] *Product Stewardship Act 2011* (Australia) No. 76, 2011.
[45] *Competition and Consumer Act 2010* (Australia), s. 58.

and others rightly noted, 'at a time when global supply chains and large-scale manufacturing are being revealed as fragile and vulnerable, the role played by digital fabrication technologies and local ecosystems gives us a glimpse into a future in which new forms of self-sufficient production can empower communities all across the world'.[46]

This disruptive technology is less affected by the ground realities of an emergency as it allows virtual data shipping instead of physical part shipping.[47] 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. The Australian Government needs to support decentralization of manufacturing capabilities and equip hospitals and medical centres with their own in-house 3D printing capabilities to break their dependence on global supply chains and to de-risk shortages of materials in a health emergency.

3D printing makes it possible to produce medical equipment on the spot or closer to the point of use.[48] This disruptive technology enables 'products designed, customized, and produced by the individuals and communities for themselves instead of mass-produced and mass-distributed products'.[49] For instance, in March 2020, because of the COVID-19 health emergency, the stock of venturi valves[50] at a local hospital in northern Italy was diminishing quickly given the unprecedented demand for ventilators to treat COVID-19 patients.[51] The manufacturing company could not supply valves because of limited manufacturing capacity coupled with supply-chain disruptions. Two public-spirited inventors, Cristian Fracassi and Alessandro Romaioli, tried to reverse-engineer the ventilator valve in order to combat critical shortages. Within 3 hours of studying the valve, they were able to create a valve prototype.[52] The duo used a desktop 3D printer to fabricate these replacement valves.[53] In less than 24 hours, they

[46] Joel Cutcher-Gershenfeld *et al.*, 'The Promise of Self-Sufficient Production' (2021) 62(2) *MIT Sloan Management Review*.
[47] Nari Lee, 'Intellectual Property and Open Innovation in 3D Printing: A Different Form of Exclusivity' in *The Innovation Society and Intellectual Property*, Josef Drexl, Anselm Kamperman Sanders, eds. (Edward Elgar Publishing, 2019).
[48] Jim Romeo, '3D Printing Emerges as Valuable Technology to Produce Face Masks in Time of COVID-19 Pandemic' (2020) *GrabCAD Blog.*
[49] Cutcher-Gershenfeld *et al.*, 'The Promise of Self-Sufficient Production', p. 70.
[50] 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. See Aamer Nazir *et al*., 'The Rise of 3D Printing Entangled with Smart Computer Aided Design During COVID-19 Era'.
[51] 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 pp. 711-717.
[52] Bankole I. Oladapo *et al*., 'Review on 3D Printing: Fight Against COVID-19' (2021) 258 *Materials Chemistry and Physics.*
[53] Rance Tino *et al.*, 'COVID-19 and the Role of 3D Printing in Medicine' (2020) 6(11) *3D Printing in Medicine*.

were able to supply valves for more than 100 ventilators to a local hospital of the town Chiari in the Province of Brescia.[54]

3D printing has a unique role in expanding the scale of production and scope of inventive activity by empowering the participation of common citizens. Fabrication using 3D printing requires the user to understand the basic details of digital designing and the basic mechanisms of 3D printing methods, 3D printers and printing materials.[55] Without needing the specialized skills, prior knowledge, or equipment traditionally needed to create professional designs, anyone familiar with 3D modelling can create digital designs from the comfort of their desktop. As noted by a commentator, the 3D printing 'maker movement is remarkable not because these things didn't previously exist, but because these things are now accessible to 'average people' who didn't go to art school, or trade schools, or engineering schools. The 'democratizing' component here is that previously most people needed to go through one of these channels to have access to and training on tools and technology'.[56]

3D printing makes it possible for the concerned community members to make practical contributions on humanitarian grounds. For instance, in Canada, a 12-year-old Boy Scout, named Quinn Callander, came up with the idea of 3D printed tension relief mask adjusters or ear guards to make face masks more comfortable to wear.[57] This is a simple but valuable contribution because wearing one-size-fits-all face masks for longer periods can cause chafing and even bruises.[58] Quinn 3D printed hundreds of mask adjusters and donated them to various hospitals.[59] The digital design of the mask adjuster is available in the public domain so that anyone with a 3D printer can feel free to print the design.[60]

3D printing offers the promise of delivering lifesaving products through globally connected local production. In Australia, professional 3D print services are available in almost all major

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[54] Jorge L Contreras, 'Research and Repair: Expanding Exceptions to Patent Infringement in Response to a Pandemic (2020) 7(11) *Journal of Law and the Biosciences*.
[55] Megha Trivedi *et al.*, 'Additive Manufacturing of Pharmaceuticals for Precision Medicine Applications: A Review of the Promises and Perils in Implementation' (2018) 23 *Additive Manufacturing*, pp. 319-328. Available from <https://doi.org/10.1016/j.addma.2018.07.004.>.
[56] Esther Fuldauer, 'Makerspaces for Economic Development and Social Cohesion' (26 February 2019) *Tomorrow City*, Available from <https://tomorrow.city/a/makerspaces-for-economic-development-and-social-cohesion-2>.
[57] Jonny Evans, '3D Printing Signs up to Fight COVID-19' (April 9, 2020) *Computerworld.*
[58] 'Ricoh 3D Producing 40,000 Face Shields a Week as Part of COVID-19 Response' (May 21, 2020) *The Prince's Responsible Business Network,* <https://www.bitc.org.uk/case-study/ricoh-3d-producing-40000-face-shields-a-week-as-part-of-covid-19-response/>.
[59] Quinn Wilson, 'Local Manufacturer Uses 3D Printing to Provide 'Relief' for Medical Workers' (April 28, 2020) *The Recorder*.
[60] *Ibid.*

cities as well as some regional centres.[61] Monash University in Melbourne, University of New South Wales (UNSW) in Sydney, and some other universities provide 3D printing and scanning services at their shared facilities.[62] Australians are generally known as early adopters of emerging technologies, but Australia's uptake of this disruptive technology has been slower as compared to the U.S. and quite a lot of the European countries.[63] Arguably, only a small percentage of Australians, especially those living in far off regional areas of Australia, are familiar with 3D printing or have adequate personal access to digital fabrication tools.

Lack of access to basic digital infrastructure is a global issue. It has been estimated that 4.2 billion people lack regular access to the Internet.[64] People at the lower end of the economic order are disadvantaged as 'there are substantial disparities in the quality and reliability of computing and Internet access, with billions of people having mobile-only access, inconsistent connectivity, or tiered access, with the faster tiers being out of financial reach'.[65] Billions of people in the world are excluded from digital fabrication because access to computing and the Internet is a basic requirement to connect with the 3D printing community. There is a need to bridge the digital divide if the world wants to be better prepared for a future pandemic. Digital literacy and digital infrastructure building, with a key focus on capacity-building for 3D printing, should be a priority for the Australian Government. Concerted policy efforts are needed to empower Australians through access to modern digital fabrication technologies.

V. CONCLUSION

The COVID-19 crisis highlighted free trade setbacks and significance of domestic self-sufficiency. When logistical constraints in a health emergency required increased coordination and cooperation amongst governments to tackle COVID-19, several responsible governments preferred nationalistic approaches over global collaboration and trade facilitation. The underlying values and principles of the WTO were overlooked. There is a need to improve transparency and certainty about policy actions related to medical supplies in order to restore

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[61] 3D Printing in Australia, <https://www.choice.com.au/electronics-and-technology/gadgets/3d-printers/articles/3d-printing-update-and-makerspaces>. See more 3D Print Australia <https://3dprint-au.com>; Core Electronics, Services (Manufacturing) <https://core-electronics.com.au/services.html>.

[62] 3D Printing in Australia, <https://www.choice.com.au/electronics-and-technology/gadgets/3d-printers/articles/3d-printing-update-and-makerspaces>.

[63] Create Digital, 'Will 3D Printing Ever be the King of Australian Manufacturing?' (October 17, 2017) *Create Digital*, <https://createdigital.org.au/3d-printing-australian-manufacturing/>.

[64] Amy Nordrum, '3 Ways To Bridge The Digital Divide' (April 14, 2016) *IEEE Spectrum,* <https://spectrum.ieee.org/tech-talk/computing/networks/3-ways-to-bridge-the-digital-divide.>.

[65] Neil Gershenfeld, Alan Gershenfeld and Joel Cutcher-Gershenfeld, *Designing Reality: How to Survive and Thrive in the Third Digital Revolution* (Basic Books, 2017).

confidence in the multilateral trading system. Global trade and cross-country collaborations are essential as some countries lack the capacity to produce their own medical supplies.

It is equally important to look for alternative options to address the failures of global markets. The Australian Government needs to make policy decisions and budget allocations to boost domestic production capacity to support localized supply chains of strategic goods. Government intervention in this sector is a matter of public interest, not an exceptional case of private sector risk management. The Australian government should not view vulnerable supply chains as a residual risk. Global markets can be anticipated to fail every time in a pandemic situation to risk human lives. Reliance on global markets for strategic goods is a huge risk which should be mitigated on a priority basis. Australia also needs to address the intellectual property dimensions of local manufacturing in order to be better prepared for a future emergency.

3D printing technology is best suited to reduce the infrastructural cost of developing a viable local production capacity. Public policy decisions around 3D printing in the coming years should be aimed at making this technology available for public use. Local manufacturing, empowered by 3D printing, should be allowed to co-evolve to complement traditional supply chains in a crisis situation. There is a need to enhance access to modern digital fabrication tools to fully leverage their unique capabilities as enablers of problem-solving innovation and democratized manufacturing. Policy decisions should also be made to support education and training in respect of 3D printing and additive manufacturing at schools and colleges.