Patent law and 3D printing applications in response to COVID-19: Exceptions to inventor rights

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Abstract

Three-dimensional (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 paper 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 at the global level. It also evaluates the private and noncommercial use exception and proposes the use of a reasonably broad form of this exception to make it practically significant. It also considers the experimental use exception and calls upon World Trade Organization Member States to provide legislative clarity that a defense of an experimental use extends to repairs. This study is crucial because access to necessary health technologies, in a pandemic context, is a matter of life and death for millions of patients around the globe, especially for underprivileged patients in resource-constrained countries.

KEYWORDS

3D printing, Art. 30 exceptions, COVID-19, medical equipment, patent rights, right to repair
INTRODUCTION

The COVID-19 crisis exposed vulnerabilities of traditional supply chains and put global healthcare systems under critical strain. Hospital 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. 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. The stockpiles proved insufficient even in the most resourceful countries.

Overwhelmed with COVID-19 patients, hospitals and medical centers had to seek alternative sources of critically needed medical supplies. Three-dimensional (3D) printing technology rose to the occasion as a savior technology and proved its worth in delivering critical components in a timely fashion under extraordinary time-pressure. 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.” Each of these successive layers of raw material “can be seen as a thinly sliced horizontal cross-section of the eventual object.” Unlike any other manufacturing technology, this advanced fabrication method manufactures 3D tangible products from a predesigned computer-driven two-dimensional (2D) blueprint or digital model, called a computer-aided design (CAD) file, of the required shape. This unique manufacturing method suits time-sensitive innovation and manufacturing as it does away with the time-consuming and costly tooling and machining requirements.

Although 3D printing technology is well-positioned to deliver critical medical supplies in the COVID-19 health emergency, its key role can be potentially constrained by patent exclusive rights. The current global health crisis put a fresh light on the issue of patent rights and affordable access to innovative health technologies because most of 3D printable medical devices are protected by patents and/or other intellectual property rights. Because of its limited scope, this study focuses only on patent exclusive rights potentially restricting access to 3D printed medical equipment.

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. 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. Given the unprecedented demand for ventilators to treat COVID-19 patients, the stocks started to dwindle quickly because the venturi valve can be utilized for 8 h only without the option of reuse. 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 to inhibit price-reducing competition.

To combat shortages, Massimo Temporelli, founder of Fablab Milano, called 3D makers to the rescue with the help of the local press. 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. Within 3 h of studying the valve, they were able to create a valve prototype. The duo used a desktop 3D printer to fabricate these replacement valves. In less than 24 h, they were able to supply valves for more than 100 ventilators to a local hospital of the town Chiari in the Province of Brescia. These 3D printed valves were dramatically cheaper as compared to the original valves manufactured by the right-holder. 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. 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. Charles Bellm, Managing Director Intersurgical, stated that the company had no intention of making a threat. 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. However, Filip Kober, a GrabCAD user, designed a digital venturi valve model and made it publicly available on the internet. Moreover, to assist the health sector with quick and affordable ventilator repair, iFixit.com has been building a collection of resources and repair information. These developments highlight the increasing importance of repair in responding to the COVID-19 health emergency. This study is timely because the risk of being exposed to legal action is a present and future concern for consumers who engage in repairing activities.

This article examines the issue of patent rights, being at odds with access to critical 3D printable health technologies, from the public interest perspective. 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 article, 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. Patents are private exclusive rights that 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 the development and diffusion of 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. 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.

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 infringing of patentee’s exclusive rights. This article considers three defenses for third parties who engage in repairing patent-protected medical devices without authorization of the right-holders. The scope of this study is confined to those exceptions to patent rights that remove 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. These exceptions remove the patent holder’s entitlement not only to prevent use by third parties but also to receive financial compensation for the use by third parties.

This article has a five-part structure including the introduction and the conclusion. Section 2 undertakes an in-depth analysis of the right to repair defense. It calls for a clearer recognition of the right to repair exemption at the global level. Section 3 evaluates the private and noncommercial use exception. It proposes the use of a reasonably broad form of this exception to make it practically significant. Section 4 considers the experimental use exception. It calls upon World Trade Organization (WTO) Member States to provide legislative clarity that a defense of an experimental use extends to repairs. Section 5 concludes that thinking narrowly about the rights of patent owners should not be an option during a health emergency like COVID-19. There is a critical need to adopt a more holistic
approach that considers exceptions to patent rights in light of real-world implications of strictly enforcing the exclusive rights of patentees. It is important to achieve a balance between the protection of patent rights and the societal urge for a rapid response to shortages of medical equipment. This study will help policymakers at national and international levels by contributing to the debate over patent law and the scope of 3D printing in response to the global health crisis.

2 | RIGHT TO REPAIR EXCEPTION

The right to repair is a consumer’s ability to repair faulty goods, or access repair services, at a competitive price. From patent law perspective, the right to repair is seen as a defense to otherwise infringing conduct. 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.

2.1 | Doctrinal discussion

The notion of the right to repair is not a well-defined free-standing concept in patent law. 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. 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.” In this sense, the repair is not an exception but a permitted activity as it does not conflict with the exclusive patent rights.

Although there are some significant jurisdictional differences, the discussion in this study with limited scope is confined to the right to repair regime in the United States. Under US law, the ownership of a patented article includes the right to repair to preserve the useful life of the original article. For instance, if the battery cover of a remote control is lost, a consumer can lawfully tape the batteries to preserve the useful life of the remote control. More specifically, the US law recognizes the right to repair a patented medical device. The ownership of a patented article, however, does not include the right to reconstruct or reproduce the article. Reconstruction of a device conflicts with the patentee’s exclusive right to make the patented article. Patent law requires the consumer, who wishes to continue using a patented article after it is broken or completely spent, to either purchase a new object or use approved parts to repair the worn-out object.

Courts assess the remaining useful capacity of the patented device in distinguishing between reconstruction and repair. As noted by Jorge L. Contreras, “if the owner of a patented device creates new patented parts to extend the life of the device beyond its anticipated life span, this would likely constitute impermissible reconstruction, whereas if the owner simply fixes a defect in an existing part or replaces it with an unpatented part, during the normal lifetime of the device, this would likely constitute permissible repair.” A consumer may be liable for patent infringement if a patent owner is able to prove that the consumer, instead of repairing an object, reconstructed it.

In the absence of clear guidelines, it is hard to predict the litigation outcomes in suits against consumers who engage in controversial repair activity. Courts rely on subjective assessments of the repairer’s particular activities in analyzing the difference between repair and reconstruction on a case-by-case basis. For instance, in 2001, the Federal Circuit court found that a wide range of repairer’s activities performed in refurbishing cameras are covered under the ambit of permissible repair. The steps of “removing the cardboard cover, cutting open the casing, inserting new film and film container, resetting the film counter, resealing the casing, and placing the device in a
new cardboard cover” as well as replacing the battery in flash cameras and the winding wheel in the cameras that so require are covered under the scope of permissible repair. The court provided a long list of permissible activities without specifically addressing the concepts of repairing or reconditioning patented objects.

Whether or not a consumer infringed upon patent rights by making or reconstructing a protected object is a factual issue which depends not only on patent claims and the nature of patented object but also on the character of the repair work done on it. For instance, if a tennis racket has a patented frame, the consumer does not engage in infringing upon patent rights in the frame if they decide to restring the racket. The same activity may be infringing if both the frame and the strings are protected. The right to repair is, therefore, not a straightforward legal concept. There are so many complexities for consumers in exercising this legitimate option.

Three-dimensional printing further complicates matters and creates new challenges for the repair-reconstruction doctrine. Three-dimensional printing makes consumers less dependent on conventional manufacturers by enabling them to fabricate their own replacement parts. Three-dimensional printing makes it easier and more affordable than before to create replacement parts for complex mechanical devices. 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. Three-dimensional 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 common citizens.

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.” 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. 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. It is important for consumers 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.

Repair through 3D printing has a significant role in saving scarce financial resources by reducing dependence on traditional manufacturers. 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).

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
2.2 | Application to the COVID-19 pandemic

The lack of clarity on the right to repair is highly problematic, especially in a health emergency like COVID-19. In an emergency, 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.

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 derisk users of 3D printed medical devices and replacement parts like hospitals and medical relief organizations.

Civil society organizations can play a key role in advocating for a clearly defined right to repair exemption and greater freedom in choosing independent third-party repair technicians. Such an exemption is particularly important for COVID-related health technologies to use the available healthcare resources to their maximum potential. Community organizations need to press for a change in approach to patent protection. 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.

Civil society organizations should also advocate 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.” 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 to circumvent any technological protection measures on device software. The right to repair should be advocated as manufacturers’ positive obligation to assist consumers in lawfully repairing and servicing the purchased objects.

In their right to repair movement, civil society organizations can draw upon the legal doctrine of exhaustion of rights. Under this doctrine, the right holders’ right to control or restrict further distribution exhausts upon the first sale. 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. This legal doctrine can be used as an effective advocacy tool to prevent patent owners from having control over the property of others.

Community organizations should press 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 World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights. 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.”
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 socioeconomic and technological development." Paragraph 19 of the Doha Ministerial Declaration (2001) reaffirmed that "the TRIPS Council shall be guided by the objectives and principles set out in Arts. 7 and 8 of the TRIPS Agreement." 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 (1995) 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." For a proper balancing of rights and obligations, in light of Arts. 7 and 8 of the TRIPS Agreement, community organizations should press for a binding provision in the TRIPS Agreement (1995) 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 maneuvers which contractually restrict consumers' right to repair. Civil society organizations need to call for a very clear prohibition. Individual consumers lack negotiation power against big corporations who use their economic might to implement favorable terms and conditions through overly restrictive contracts. Consumers in general and repair advocates in particular need to be vigilant and united under the leadership of civil society organizations to protect their right to repair, especially during the pandemic. This is not only desirable but also necessary for the purpose of safeguarding the public interest.

It is important to consider the current real-world law reform efforts to address some of the issues and problems around the right to repair. In Australia, on October 29, 2020, the Treasurer Josh Frydenberg tasked the Productivity Commission of Australia to investigate the right to repair. The Commission will draw on international experience to consider the current legislative arrangements surrounding the ability of Australian consumers to self-repair faulty items or access repair services at competitive prices. The Commission is supposed to produce a final report within 12 months after undertaking broad public consultation on the issue. The inquiry is important because the Competition and Consumer Act 2010 does not comprehensively deal with the right to repair in Australia. This inquiry is a positive sign that Australia is progressing toward a user-friendly repair culture.

In the United States, 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 in response to COVID-19, to reform the right to repair legislation. 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—to fix short of supply medical technologies on a noncommercial 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." 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. This study, however, calls for international recognition of a more general right to repair that provides a lasting defense beyond the current
COVID-19 crisis. To achieve the United Nation's 2030 Sustainable Development Agenda, it is important for all countries to have a clearer and permanent right to repair exemption across multiple industries.

3 | PRIVATE AND NONCOMMERCIAL USE EXCEPTION

Private and noncommercial use exception is important for public-spirited makers who engage with 3D printing activities without economic benefit considerations. The public policy rationale of this exception is that the patentee's exclusive rights should not be allowed to restrict noncommercial or nonfactory manufacturing activities. As noted 20 years before the TRIPS Agreement came into effect:

The patent laws generally recognize a limitation of the patentee's right with regard to acts constituting non-commercial or non-industrial uses of the patented invention. However, the precise definition of what acts are such may differ in the various countries. Generally use of the patented invention for strictly private or experimental purposes is not to be deemed to be use for industrial and commercial purposes.

Previously, in 1967, Art. 9(2) was introduced into the Berne Convention for the Protection of Literary and Artistic Works of 1886 to provide an exception for the reproduction of protected works "in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author." Later, Art. 13 of the TRIPS Agreement (1995), modeled on Art. 9(2) of the Berne Convention, reiterated that "Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the holder." Both these provisions confine the adoption of exceptions to "certain special cases." Moreover, these provisions only cater for the legitimate interests of the right-holder without any mention of the legitimate interests of third parties.

Art. 30 of the TRIPS Agreement (1995) is the most relevant provision. It stipulates that "Member may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." Art. 26 of the TRIPS Agreement (1995) provides a similar exception related to industrial designs. Arts. 26 and 30 do not confine the adoption of exceptions to "certain special cases." Moreover, these provisions contemplate the balancing of legitimate interests of the right-holder and those of third parties.

Arts. 26 and 30 provided a 3-Step Test which the private and noncommercial use exception is required to satisfy to provide a plausible defense. In March 2000, the WTO Dispute Panel, in the Canada-Generics patent dispute, clarified the following three conditions of the 3-Step Test: First, the exception must be limited; second, it must not "unreasonably conflict with a normal exploitation of the patent"; and third, it must not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legislative interests of third parties."

3.1 | Step 1: Limited exception

This step entails that the exception must be limited. According to the WTO Dispute Panel, the term "limited exception" connotes "a narrow exception—one which makes only a small diminution of the rights in question." The Panel's interpretation of the term "limited exception" is even narrower than the dictionary meaning of this term and has been subjected to criticism. Graeme Dinwoodie and Rochelle Dreyfuss criticized the Panel for applying "an accountant's approach to the issues." Annette Kur noted that "it is definitely inappropriate that the purely
quantitative assessment should become the sole parameter for deciding on the admissibility of an exception. The lack of normative considerations and subjective assessment fails to serve the legitimate purpose of this exception and undermines the public interest.

The Declaration on Patent Protection of the Max Planck Institute for Innovation and Competition proposed that an understanding of "limited exception" should be "reasonably proportionate to its objective and purpose. It must fulfill a legitimate purpose, be adequate to achieve that purpose, and not exceed what is necessary and sufficient to achieve it." The Panel's narrow understanding substantially limits the policy space offered by the TRIPS Agreement to incorporate public interest considerations in national patent laws.

If we apply this condition in the context of the current COVID-19 pandemic, the manufacturers of 3D printed medical equipment satisfy this condition provided that the quantity of production of patent-protected equipment is limited to meeting the urgent demands of the pandemic situation. They can be exempted from liability of patent infringement for reproducing patented products on a limited scale only to help struggling patients and healthcare providers by contributing to relief efforts.

3.2 | Step 2: Normal exploitation is not unreasonably curtailed

This step entails that the exception must not "unreasonably conflict with a normal exploitation of the patent." According to the WTO Dispute Panel, exploitation means "the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patents." The normal practice of exploitation by patentees is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. The panel did not provide any objective or quantitative way to determine the patentee's expected economic returns. Simply put, "normal exploitation of a patent-protected product involves the patentee's ability to recover R&D costs and make a reasonable profit." In Omar Gad's view, "normal exploitation clearly means something less than the full use of an exclusive right." The normal exploitation is not harmed if a limitation does not affect the incentive function. As noted by Lionel Bently, "the welfare costs of patents can be reduced without significantly diminishing incentives to invest in creation." The Panel took a normative policy approach in its assessment of the term "normal exploitation." This lack of quantitative confinement provides more leeway and leaves enough space for national legislators to incorporate public interest considerations.

If we apply this condition in the context of the current COVID-19 pandemic, the noncommercial use of 3D printing technology to fabricate urgently needed parts of medical equipment during the COVID-19 pandemic should not be expected to unreasonably curtail the normal exploitation of patents by the patent holders. It is also important to note here that the patent holders generally struggled in meeting the exceptionally high demand of medical equipment during the current health crisis.

3.3 | Step 3: Legitimate interests of the patent owner are not unreasonably prejudiced

This last and important step keeps a balance between the conflicting interests of patent holders and those of third parties. Maintaining such a balance is essential to the proper functioning of the patent system. This step entails that the exception must not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." The Panel noted that the "legitimate interests" of patentees and third parties "must be defined in the way that is often used in legal discourse—as a normative claim calling for the protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms." The "legitimate interests" of patentees should not be seen as the "legal interests" of patentees in the full
enjoyment of exclusive rights for the complete duration of the patent term. The concept of legitimate interests needs to be "broader than legal interests' to make sense of third parties' interests in the Step 3.88

According to the WTO Dispute Panel, "third parties are by definition parties who have no legal right at all in being able to perform the tasks excluded by Article 28 patent rights." The Panel did not provide further clarification as to what constitutes third parties in Step 3. According to the Declaration on Patent Protection of the Max Planck Institute for Innovation and Competition, third parties in Step 3 include: follow-on innovators, competitors and other market actors, scientific and academic researchers, consumers, and the public at large.

If we apply this condition in the context of the current COVID-19 pandemic, both society and users have a legitimate interest if 3D makers are allowed to repair the patent-protected medical equipment to address the life-threatening supply-chain shortages in a public health crisis. Bernard H. Maister noted that the "legitimate interests of third parties might include the right to protect public health."89 Philippe Cullet also supported the use of this exception to meet the legitimate interests of patients in a health emergency.90

The WTO Dispute Panel, in Canada-Generics, assisted in the analysis, but it only interpreted a fraction of Art. 30. The Panel did not address several issues, like what constitutes "unreasonable prejudice" and "unreasonable conflict" with the normal exploitation.91 There is little judicial interpretation of the private and noncommercial use exception as there is hardly any case law specifically related to this exception.92 The national legislators or courts need to normatively assess the undefined terms in the 3-Step Test to provide the necessary ambit for the public health policy considerations. In applying the 3-Step Test, public health and societal welfare should not be considered subordinate to the proprietary rights of patent holders. This approach is in line with Arts. 7 and 8 of the TRIPS Agreement (1995) which are labeled as "Principles" and "Objectives" and emphasize that the goal of the TRIPS regime is not only to promote technological innovation but also to foster social and economic welfare.

Art. 30 is a general and abstract provision. The 3-Step Test is of abstract nature and uses open-ended words which potentially support the adoption of flexible approaches. The abstract nature of the test "provides for enough interpretative leeway for national legislators to accommodate the requirements of the test with their own domestic necessities."93 Most of the WTO Member States included the private and noncommercial use exception in their national patent laws. The formulation and scope of this exception, however, vary from country to country. Some countries have specifically legislated this exception while others implement it through their reading of the patent grant.94

Under European patent law, acts done privately for noncommercial purposes are exempt from patent infringement. Patent holders are protected against infringing acts that are intended to generate profit or achieve commercial goals.95 The primary rationale behind this exception is the view that patent owners are not significantly harmed by private and noncommercial uses of patented inventions.96 As noted by Rosa Maria Ballardini and others:

[It]s not necessary for a patent right to cover private and non-commercial uses of protected inventions in order to achieve the ultimate goal of the patent system—that is, to promote economic and technological development for the benefit of society as a whole. The patent system aims at rewarding inventors for their novel and inventive technological contributions by providing them with temporary exclusive rights to exclude others from exploiting their inventions. To reach this goal, there is no need to extend the exclusive right to the private and non-commercial sphere.97

Although personal activities do not jeopardize the economic interests of patent owners, private and noncommercial use is not a universally available defense. For instance, the United States does not excuse the personal uses of patented inventions. Private users are held liable for patent infringement even if they do not sell the privately made copies of the protected items.98 Such an imbalanced approach prioritizes the corporate interest of right-holders at the cost of undermining the societal interest.

Individual terms and scope of this exception should be clearly defined to facilitate its practical applicability. Personal nonprofessional uses of 3D printing technologies should not be held liable for patent infringement.
Logically, the legal protections should apply only to reproductions of protected items on a commercial scale. The noncommercial repair activities of users do not impair the right-holder's exclusivity in working their inventions. Patentees are not expected to suffer any substantial adverse consequences from the repairs done privately and for noncommercial purposes.

WTO Member States should strongly consider the private and noncommercial use exception to provide a safe harbor to not-for-profit individual and community users of 3D printing tools by insulating them from liability under patent law. The TRIPS Agreement does not define this exception. It rather allows Member States "to develop limited exceptions so long as these comply with certain conditions." WTO Member States should take full benefit of the policy space available under the TRIPS Agreement. As noted by Christopher Garrison:

The narrow form of this exception, i.e. a discrete Private and Non-Commercial Use exception is not likely of great practical use. It will likely shield those from infringement that patent holders wouldn't bother suing anyway. However, the broad form i.e. restricting a patent holder's right to the commercial or industrial sphere could have a more significant utility... it could provide a shied to those carrying on non-commercial activities of non-for-profit entities.

Having discretion to decide the scope of this exception, WTO Member States should adopt a reasonably broad form noncommercial use exception to make it practically significant. Such an approach is in the interest of public health as it will allow users of medical devices to benefit from the unique capabilities of 3D printing technology in their repair activities with a high degree of confidence that their actions to save lives will not be challenged by the right-holders. This consideration is important to reconcile patent rights with the public interest. The market harm to the patent holder should be weighed against the societal benefit of this exception. Small scale manufacturers and repairers of medical equipment, on noncommercial basis by using 3D printing technologies, should not be expected to negotiate for a licence to use patents. This is unreasonable not only because the economic value such licensing is negligible but also the cost of negotiating such licenses is disproportionately high. Many of these public-spirited manufacturers and repairers might not have the knowledge of patents that can be potentially infringed because of their humanitarian use of 3D printing technology. Noncommercial use exception is an important defense for such innocent manufacturers and repairers as "the knowledge or intention of defendant is not relevant in establishing a patent infringement." More importantly, the potential delays in negotiating licenses to use patents seriously undermine the public interest in a health emergency like the COVID-19 pandemic.

4 | EXPERIMENTAL USE EXCEPTION

One of the key public policy purposes underlying patent law "is to facilitate the dissemination and advancement of technical knowledge." Patent laws generally protect inventors from unlicensed use of their exclusive rights, but some uses of patented inventions can be recognized as noninfringing through an experimental use exception. As noted by the WTO Dispute Panel, in the Canada-Generics patent dispute, an experimental use "exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge" and "both society and the scientist have a legitimate interest in using the patent disclosure to support the advance of science and technology."

It was noted back in 1878 that "Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way. But if there be neither using nor vending of the invention for profit, the mere making for the purposes of experiment, and not for a fraudulent purpose, ought not to be considered within the meaning of the prohibition." Katherine Strandburg explained that "The purpose of an experimental-use exemption should be to protect the patentee's ability to recoup her research and development investment while preventing her from using her exclusive rights to exercise unwarranted control over subsequent innovation." The adoption of an
experimental use exception is important not only for improving upon a patented invention but also for “evaluation of an invention to request a license, or for other legitimate purposes, such as to test whether the invention works, and has been sufficiently disclosed.” In this way, an experimental use exception helps users and competitors to make more informed decisions in opposing patents or challenging the validity of patents.

The experimental use exception in the United States is a judge-made doctrine that was first recognized in Whittemore v. Cutter. Supreme Court Justice Story opined that “it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.” The United States does not allow an experimental use for commercial purpose. The exception is confined to experimental uses that do not lead to a commercial gain for the user and do not harm the patentee’s interest in the patented product. In Cimotti Unharring Co. v. Derboklow, the defendant claimed experimental use of a fur processing machine while the furs used for his experimentation were brought to him by his customers for processing. The court held him liable for patent infringement as he was using the protected machine for commercial gain.

In Madey v. Duke, the US Court of Appeals for the Federal Circuit held that an experimental use defense “is very narrow and strictly limited to actions performed for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” This defense “clearly does not immunize use that is in any way commercial in nature” or “immunize any conduct that is in keeping with the alleged infringer’s legitimate business.” This judgment has “effectively killed off the last vestiges of the U.S. Experimental Use exception.” Such an excessively narrowed approach makes an experimental use defense less significant for inventors and researchers. It adversely impacts the ability of researchers to engage in research and experimentation in the United States.

The scope of an experimental use exception is not defined under any international agreement or standard. The TRIPS Agreement, which offers arrangements to balance the interests of patent owners and the users of patented inventions, left policy space for WTO Member States to provide for an experimental use exception. The 3-Step Test provided under Arts. 26 and 30 of the TRIPS Agreement also applies to the experimental use exception. An appropriately limited experimental use exception is within the scope of Art. 30 of the TRIPS Agreement even if it conflicts with the exclusive rights of patentees. Conceptually, “an exception is a carve-out from the IP right-holder’s right. That is to say, an exception cuts back on the IP right-holder’s right, by removing a part of it.” An exception to avoid infringement is, therefore, expected to conflict with the normal exploitation of a patent under Art. 28 (making, using, offering for sale, selling or importing). If there is no conflict, then there is no need for an exception and Art. 30 becomes redundant.

The interest of third parties in the experimental use of patented inventions, for further improvement of technology, arguably constitute a legitimate interest. The societal interests are undermined if inventors and researchers are constrained in subsequently improving upon existing technologies. WTO Member States should have used the latitude provided under the TRIPS Agreement for the creation of a broader and robust experimental use exception, which is more likely to assist the growth of research and innovation locally. As noted by Susy Frankel, “the TRIPS Agreement requirements do not mandate that the dividing line between experimental use and other infringing use is to be determined by the commercial or non-commercial distinction.” It is unfortunate that not as many WTO Member States made proper use of this flexibility in setting the parameters of an experimental use exception in line with their economic and social policies. As noted by Carlos Correa:

The analysis of the legislation in developing countries and economies in transition indicates that the research/experimentation exception has been widely recognized in patent law both before and after the TRIPS Agreement. Many countries—including the most technologically advanced—have not used, however, the full room for manoeuvre left by the Agreement to legislate on the matter.

The only way to give effect to exceptions is by way of national law. Making use of an experimental use exception, WTO Member States should reform their national laws to expand the scope of permissible activities
within the parameters of TRIPS compliance. They need to adopt clear and unambiguous statutory provisions to allow users to engage in a larger range of experimental activities. WTO Member States may consider a model provision drafted by Carlos Correa which reads as:

The patent shall have no effect with respect to any act including testing, using, or making the invention solely for purposes reasonably related to the development and submission of information required under any law of (country) or of another country that regulates the manufacture, construction, use or sale of any product.119

In Carlos Correa's view, third parties' legitimate interests could include those of follow-on inventors, competitors, and users, as well as the interests of society at large, for instance, in addressing a public health crisis or in ensuring the advancement of science and technology.120

If we consider the experimental use exception in the context of the current COVID-19 pandemic, an experimental and repair activity by using 3D printing technology during the current public health crisis clearly falls in the ambit of third parties' legitimate interests. Such activity should be expressly immunized from patent infringement liability. WTO Member States need to provide legislative clarity that a defense of an experimental use extends to repairs. Facilitating increased experimental and repair activity by creating a safe harbor for experimentation with medical devices will better prepare countries to deal with a future pandemic. It will be a legitimate way to address the competing interests of fostering innovation and promoting equitable access by balancing the private interests of patentees and the public interest. The policy approach of clarifying and broadening the scope of the experimental use exception, by making full use of the policy space provided under the TRIPS Agreement, is in line with public health needs in a pandemic and in support of the objectives and principles set out in Arts. 7 and 8 of the TRIPS Agreement (1995).

5 | CONCLUSION

The use of patent rights is generally justified to foster innovation in technically complex scientific areas. Over-reliance on 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 patent owners should not be an option during a health emergency like COVID-19. There is a critical need to adopt a more holistic approach that considers real-world implications of strictly enforcing exclusive patent rights.

The right to repair defense is not a well-defined free-standing concept in patent law. There are murky distinctions drawn between permissible and impermissible repair. 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 derisk users of 3D printed medical devices and replacement parts like hospitals and medical relief organizations.

Private and noncommercial use exception is important for consumers and public-spirited makers who engage with 3D printing activities without economic benefit considerations. WTO Member States should adopt a reasonably broad form of this exception to make it practically significant. Such an approach will allow users of medical devices to benefit from the unique capabilities of 3D printing technology in their repair activities with a high degree of confidence that their actions to save lives will not be challenged by the right-holders. This consideration is
important to reconcile patent rights with the public interest. The market harm to the patent holder should be weighed against the societal benefit of this exception.

An experimental use exception is important for improving upon a patented invention. The scope of this exception is not defined under any international agreement or standard. The TRIPS Agreement left policy space for Member States to provide for an experimental use exception. The only way to give effect to experimental use exception is by way of national law. Making use of the TRIPS flexibility, Member States should reform their national laws to expand the scope of permissible activities within the parameters of TRIPS compliance. They need to adopt clear and unambiguous statutory provisions to allow users to engage in a larger range of experimental activities. WTO Member States need to provide legislative clarity that a defense of an experimental use extends to repairs. Facilitating increased experimental and repair activity by creating a safe harbor for experimentation with medical devices will better prepare countries to deal with a future pandemic.

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The author declares no conflicts of interest.

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ENDNOTES
1 Muhammad Z. Abbas, ‘Access to Medical Equipment in a Pandemic Situation: Importance of Localized Supply Chains and 3D Printing’ (2021) 213 Southview 1–2. See more Muhammad Z. Abbas, ‘COVID-19 and The Global Public Health: Tiered Pricing of Pharmaceutical Drugs As a Price-Reducing Policy Tool’ (2020) JGM, doi/10.1177/1741134320963146; Muhammad Z. Abbas, ‘Parallel Importation as a Policy Option to Reduce Price of Patented Health Technologies’ (2021) JGM, doi/10.1177/1741134321999418
2 Dina Amin and Others, ‘3D Printing of Face Shields During COVID-19 Pandemic: A Technical Note’ (2020) JOMS 1. See more Mostapha Tarfaoui and Others, ‘Additive Manufacturing in Fighting Against Novel Coronavirus COVID-19’ (2020) 110(11) IJAMT 2915; John Cote and Others, ‘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 canceled worldwide. Even several cargo flights were canceled which adversely impacted the delivery of much-needed medical equipment. See Aamer Nazir and Others, ‘The Rise of 3D Printing Entangled With Smart Computer Aided Design During COVID-19 Era’ (2020) JMS 1.
4 Joshua M. Pearce, ‘Distributed Manufacturing of Open Source Medical Hardware for Pandemics’ (2020) 4(2) JMMP 1.
5 Bankole I. Oladapo and Others, ‘Review on 3D Printing: Fight Against COVID-19’ (2020) MCP 5.
6 Klaus Schwab and Nicholas Davis, Shaping the Fourth Industrial Revolution (World Economic Forum, 2018) 142. See more Abb (n 1) Southview 2.
7 Lakitha 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.
Sujata K. Bhatia and Krish 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 NLR 362.

Joshua D. Sarnoff, ‘The Right To Repair in A Pandemic’ (2020) NULR 2.

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) JIPLP 711.

Najir and Others (n 3) 8.

Ibid.

Abbas (n 1) Southview 3.

Mahr and Dickel (n 11).

Ibid Mahir and Dickel (n 11).

Najir and Others (n 3) 4.

Oladapo and Others (n 5) 5.

Rance Tino and Others, ‘COVID-19 and the Role of 3D Printing in Medicine’ (2020) 6(1) 3D PM 1.

Jorge L. Contreras, ‘Research and Repair: Expanding Exceptions to Patent Infringement in Response to a Pandemic’ (2020) 7(1) JLB 1.5.

Rosa Ballardini and Others, *3D Printing: How an Emerging Technology May Help Fight a Pandemic* (IPR Info-IPR University Center, 2020) <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 Peters, Jay ‘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>

Ibid Ballardini.

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>.

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>

Najir and Others (n 3) 8.

Ibid 8.

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

Michele Boldrin and David K. Levine, *Against Intellectual Monopoly* (Cambridge University Press, 2008) 62. See more Ugo Pagano, ‘The Crisis of Intellectual Monopoly Capitalism’ (2014) 38(6) CJE 1409.

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 and Others, ‘3D Printing to Support the Shortage in Personal Protective Equipment Caused by COVID-19 Pandemic’ (2020) 13(15) Materials 3.

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

Standing Committee on the Law of Patents, *Exceptions and Limitations To Patent Rights: Private And/Or Noncommercial Use*.

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

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

World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights 1995* (TRIPS Agreement), Art. 28(1)(a).

Brian Whitehead and Richard Kempner, ‘Manufacture or Repair?’ (2011) 6(1) JIPLP 10.

The right to repair has been recognized in the U.S. since 1850. In *Wilson v. Simpson* 50 U.S. (9 How.) 109 (1850), the US Supreme Court distinguished the right of a purchaser of a patented planning machine to replace the machine’s cutting-
knives when they became dull or broken, from the patentee's sole right to make or renew the entire machine. In Aro Manufacturing Co. v. Convertible Top Replacement Co., 377 U.S. 476 (1964), the Court drew a distinction between permissible repair and impermissible reconstruction of a patented article.

36 Jazz Photo Corp. v. International Trade Commission, 264F.3d 1094, 1102 (Fed. Cir. 2001).

37 Kelsey B. Wilbanks, 'The Challenges of 3D Printing to the Repair-Reconstruction Doctrine in Patent Law' (2013) 20(4) GMLR 1148.

38 Kendall Co. v. Progressive Medical Tech. Inc., 85F.3d 1570 (Fed. Cir. 1996).

39 Sandvik Aktiebolag v. E.J. Company, 121F.3d 669 (Fed. Cir. 1997); Lummus Indus, Inc. v. D.M.E. Corp., 862F.2d 267 (Fed. Cir. 1988). See more Contreras (n 17).5.

40 Aro Manufacturing Co. v. Convertible Top Replacement Co., 365 U.S. 336 (1961).

41 Wilson v. Simpson 50 U.S. (9 How.) 109 (1850).

42 Jazz Photo Corp. v. International Trade Commission, 264 F.3d 1094, 1102 (Fed. Cir. 2001).

43 Ibid.

44 Ibid.

45 Ibid.

46 David Vaver, Intellectual Property Law: Copyright, Patents, Trade-Marks (Irwin Law, 1997) 405.

47 Ibid.

48 Wilbanks (n 37) 1148.

49 Ibid 1150.

50 Ibid 1157.

51 Ibid 1166.

52 Rosborough (n 26) 31.

53 Duckett, Chris, ‘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/>.

54 World Trade Organization (n 33), Art. 6.

55 Ibid, Art. 7.

56 Ibid, Art. 8.

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

58 World Trade Organization (n 33), Art. 30.

59 Chris Duckett, ‘Australian Productivity Commission to Look into Right to Repair’ (2020) CISCO Intersight <https://www.zdnet.com/article/australian-productivity-commission-to-look-into-right-to-repair/>.

60 For details see Australian Government Productivity Commission website current Inquiries, Right to Repair <https://www.pc.gov.au/inquiries/current/repair>.

61 Previously, 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 penalized 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 customers that they were not entitled to a remedy for their faulty devices if they had used a third-party repairer. Customers are legally entitled to a repair or a replacement under the Australian Consumer Law if a product is faulty. 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/>.

62 Previously, in 2012, the first right to repair legislation was introduced in Massachusetts. Another 20 States in the US 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. 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/>.

63 '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-barrers-to-fixing-critical-medical-equipment-during-the-pandemic>.
64 TechNation Development Team, ‘Proposed Bill Ends Barriers to Fixing Critical Medical Equipment During Pandemic’, TechNation <https://1technation.com/proposed-bill-ends-barriers-to-fixing-critical-medical-equipment-during-pandemic/>

65 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>

66 Christopher Garrison, ‘Exceptions To Patent Rights in Developing Countries’ [2006] (17) ICTSD.

67 Stephen P Ladas, Patents, Trademarks, and Related Rights: National and International Protection (Harvard University Press, 1975) 413.

68 Berne Convention for the Protection of Literary and Artistic Works 1886, Art. 9(2).

69 World Trade Organization (n 33), Art. 13; Ibid Art. 9(2).

70 World Trade Organization (n 33), Art. 30.

71 World Trade Organization (n 33), Art. 26.

72 Noncompliance may attract a WTO Dispute Settlement Procedure which can potentially result in trade sanctions. See Marc Dominic and Marc D. Mimler, The Public Interest and the Construction of Exceptions to Patentee’s Rights—A Comparative Study of UK and German Law (Queen Mary, University of London, 2015).

73 World Trade Organization, Canada—Patent Protection of Pharmaceutical Products (January 2000) 56.

74 World Trade Organization, ‘Canada—Patent Protection of Pharmaceutical Products’ (January 2000) 56.

76 Frederick M. Abbott, ‘Bob Hudec as Chair of the Canada – Generic Pharmaceuticals Panel – The WTO Gets Something Right’ (2003) JIEL 733.

77 Graeme B. Dinwoodie and Rochelle C. Dreyfuss, A Neofederalist Vision of TRIPS—Resilience of the International Intellectual Property Regime (Oxford University Press, 2012) 69.

78 Annette Kur, ‘Of Oceans, Islands, and Inland Water—How Much Room for Exceptions and Limitations under the Three Step-Test?’ (2008) RJGLB 340.

79 Matthias Lamping and Others, ‘Declaration on Patent Protection—Regulatory Sovereignty under TRIPS’ (2014) 45 IIC - IRIPCL 679.

80 World Trade Organization (n 33).

81 World Trade Organization, ‘Canada—Patent Protection of Pharmaceutical Products’ (January 2000) 56.

82 Ibid.

83 Altinay Urazbaeva and Others, The Functional Field of Food Law (Wageningen Academic Publishers, 2019) 138.

84 Carlos M. Correa and Abdulqawi A. Yusuf (Eds.), Intellectual Property and International Trade: The TRIPS Agreement (Kluwer Law International, 2008) 371.

85 L. Bently, ‘Exclusions from Patentability and Exceptions to Patentees’ Rights: Taking Exceptions Seriously’ (2011) 64(1) CLP 315.

88 World Trade Organization (n 33).

89 World Trade Organization (n 33).

86 World Trade Organization, Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules (Edward Elgar, 2010) 250.

90 Urazbaeva and Others (n 83).

91 Garrison (n 66).

92 Urazbaeva and Others (n 83).

93 Dominic and Mimler (n 72).

94 Urazbaeva and Others (n 83).

95 De Clercq Advocaten Notarissen, ‘The Legal Aspects Of 3D Printing’ (2015) De Clercq Advocaten Notarissen 6.

96 Timothy R. Holbrook and Lucas S. Osborn, ‘Digital Patent Infringement in an Era of 3D Printing’ (2014) 48 UCDL Rev. 86.
97 Ibid.
98 Lucas S. Osborn, 3D Printing and Intellectual Property (Cambridge University Press, 2019) 49.
99 Carlos M. Correa and Reto M. Hilty, Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law (Springer, 2022).
100 Garrison (n 66).
101 Hao-Yun Chen, A Maker or an Infringer? 3D Printing Technology and Patent Infringing Liability: Taiwan Perspectives (National Taiwan University Law Review, 2017) 2(12).
102 Urazbaeva and Others (n 83).
103 Gregory Pate, ‘Analysis of the Experimental Use Exception’ (2002) 3(2) NCJLT 270.
104 World Trade Organization, ‘Canada—Patent Protection of Pharmaceutical Products’ (January 2000) 56.
105 Jessel M.R. in Frearson v. Loe (1878) 9 Ch. D. 48.
106 Katherine Strandburg, ‘What Does the Public Get? Experimental Use and the Patent Bargain’ (2004) WLR 100.
107 Carlos M. Correa, ‘Patents’ in Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (2nd Edition) (2016) 30.
108 Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).
109 Cimotti Unharring Co. v. Derboklow 87 F. 997 (C.C.E.D.N.Y. 1898).
110 Madey v. Duke 307 F.3d 1362 (2002).
111 Madey v. Duke 307 F.3d 1362 (2002).
112 Garrison (n 66).
113 Susy Frankel, ‘An Experimental Use Exception from Patent Infringement for New Zealand’ (2009) 12(5) JWIP 456.
114 Andrew Christie, ‘Maximizing Permissible Exceptions to Intellectual Property Rights’ [2011] (553) MLSRP 4.
115 Frankel (n 113).
116 Frankel (n 113).
117 Carlos Correa, ‘The international dimension of the research exception’ SIPPI Project, AAAS, Washington DC (2005).
118 Christie, ‘Andrew, Maximising Permissible Exceptions to Intellectual Property Rights’ [2011] (553) MLSRP 4.
119 Carlos M. Correa, Integrating Public Health Concerns into Patent Legislation in Developing Countries (South Centre, 2000) 71.
120 Carlos M. Correa, Trade Related Aspects of Intellectual Property Rights—A Commentary on the TRIPS Agreement (Oxford University Press, 2007) 311.

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