

Global Health Technologies are Transforming Intellectual Property and World Trade

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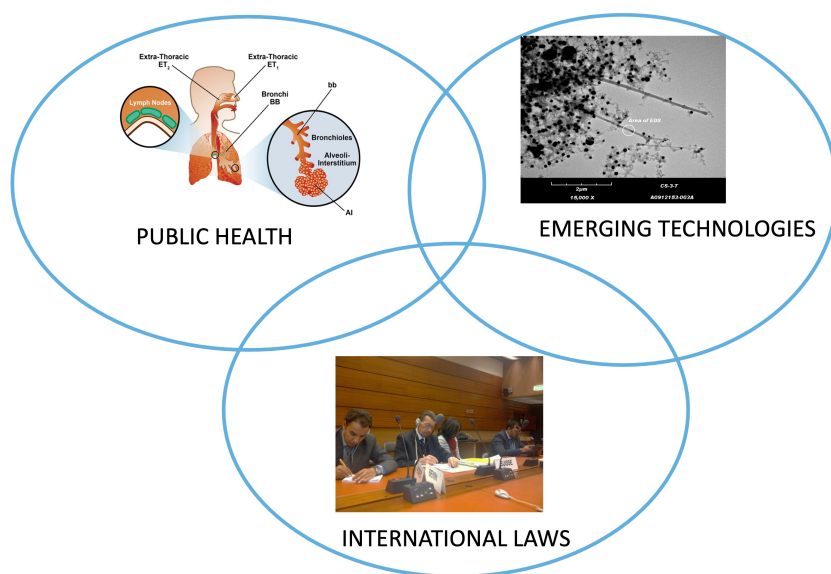
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Abstract

The nano-enabled technology of 3-D printing for medical devices presents a dynamic new avenue for meeting patient needs. 3-D printers can generate food, soaps, cosmetics, body parts, metal devices, or medicines. This technology enables continuity of health care delivery despite disruptive breaks in any supply chain due to war, shortage, or broken distribution lines due to pandemic force majeure.¹ Featuring custom-tailored attributes for each device, economic efficiency by eliminating transport costs during emergencies, avoiding issues of distribution supply chains, and offering biocompatibility, 3-D printed medical devices during the COVID-19 pandemic² provided a very attractive alternative to enduring medical supply shortages worldwide. Beyond the covid-19 pandemic exigencies, 3-D printed medical devices promise custom-tailored meals to meet medical needs that are

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unique for each patient's metabolism and a wide variety of tools for patient care that will change the shape of global commerce.³ 3-D printing offers the alluring promise of biocompatible medical devices, matching any patient's unique anatomy, using a specific patient's imaging data, or using a standard design to make multiple identical copies of the same device, but without delays for transport or shipping and insurance costs. The global health impact of these efforts, from the standpoint of patient safety⁴ and overall deterrence of unnecessary or unsafe medical practices, remains unclear due to the absence of regulation and monitoring. The reality is that commerce can reduce or eliminate transport and storage costs associated with shipping and can change international trade. Yet, 3-D printing simultaneously offers great promise to meet challenges arising from the arcane role of intellectual property rights (IPR)⁵ in shaping the creation and transfer of nanomedicines and nanotechnologies to attain health equity and meet universal needs of health for all. These millennial technological changes may permanently alter how civil society does business for global health.

Purpose and Justification

This article attempts to provide a first overview of the legal issues that arise and the potential regulatory need to address these concerns, using 3-D printing medical devices as an example of new vistas for global health law. It must be emphasized that 3-D printing is only one example of technology that relies on nanotechnology to create new products and new approaches to developing products. These products pose challenges under the law and therefore are described here to illustrate the types of legal issues that may arise as the commercialization of these new techniques becomes commonplace and takes center stage in international trade.

The swift access and reduced downtime for transporting these products make them very attractive. However, this new approach to a manufacturing paradigm evades traditional oversight and enforcement in the regulatory space for medical devices because it uniquely places the manufacturer's activities in the hands of the end user. Left unchecked, these developments run the risk of unfettered harm to public health because the new technologies eschew current working assumptions about regulating the manufacturing space for medical devices and medicinal food under well-established laws. At the same time, 3-D printing used during international public/private collaborations raises a new promise of health equity to overcome the virus and thereby control the pandemic. This promise is embodied in the evolving waiver of World Trade Organization (WTO) agreements regarding the use of the intellectual property across borders concerning the COVID-19 pandemic offer a practical step towards universal health equity. By recognizing the

realities of nano-enabled technologies as a shared endeavor to innovate using discoveries that can protect health for all, the WTO has led the way towards shaping a new global approach to regulation of medical devices that will survive the end of traditional laws such as oversight for regulation and the demise of conventional legal theories about intellectual property. This article concludes that 3-D printed medical devices are one new example of the evolution that expands the WTO waiver process. Both the new waiver precedent and 3-D printing of medical devices under a new construct for global health regulation offer exciting new tools that are important for rebuilding healthcare infrastructure to protect posterity.

INTRODUCTION

Covid-19 Changed Law and International Trade

As predicted by many nanotechnology⁶ scholars since 2011,⁷ additive manufacturing⁸, including 3-D printing,³ has revolutionized⁹ the business of creating medicines and medical devices. Additive manufacturing,¹⁰ such as 3-D printed medical products that can be downloaded anywhere in the world from any source, and "nanomanufacturing ...will transform manufacturing and the way we produce materials."¹¹ The printing of medical devices during the COVID-19¹² pandemic of 2019-2022 provides a critical example of nanotechnology's "revolution"¹³ for commerce has come to the fore in the daily practice of medicine, medical device production and thus changing the role of intellectual property governing the commerce of global health.¹⁴ 3-D printed products manufactured via remote printing using design patents with established trademarks will become commonplace,¹⁵

according to the US Food and Drug Administration (FDA).¹⁶ The 3-D printing of medical devices used during the COVID-19 pandemic of 2019-2022 provides a critical example of how nanotechnology's revolution for commerce has come to the fore in the daily practice of medicine, perhaps changing the role of intellectual property governing the commerce of global health.¹⁷ Yet, 3-D printed foods, medicines, and relevant medical supplies are innovations that remove or alter dramatically key steps in the traditional legal process mapped out in most laws around the world, possibly rendering parts of the regulatory system inapposite to modern medical device manufacturing, including some intellectual property protections.¹⁸

There was no time to waste when the COVID-19 pandemic created urgent needs for medical devices in saturated healthcare facilities with an unexpected illness raging¹⁹. Because of disrupted supply lines, there was an undisputed need for medical devices due to the exigencies of delivering patient care on a large scale that was not anticipated before the outbreak began. 3-D printed medical devices present an impressive exception to traditional regulatory premarket review requirements and patent and trademark negotiations before distributing a product. During the COVID-19 pandemic, hospitals and medical care providers frequently printed their own devices. The healing opportunities made accessible by these new techniques mean that patient-specific medical devices will be made affordable, faster, and without regard to geography worldwide. Recognizing this impressive new development, the US Federal FDA released a Discussion Paper on December 21, 2021: requesting public comment regarding the future regulation of additive manufacturing and 3-D printing of medical devices at Point of Care (PoC) in Health Care Facilities (HCF), citing supply chain disruptions caused by the COVID-19 pandemic of 2020 force majeure.²⁰ Previously, the USA FDA made extensive efforts to avoid offering Guidance about nanotechnology²¹ but soon realized that 3-D printing was an essential tool for fighting the raging pandemic of COVID-19.²²

The FDA outlined 5 key points of contact where the agency might regulate the production

of 3-D printed medical devices at HCFs.²³ The FDA expressed its concern that manufacturers in these circumstances are end-users and consumers who are untrained while using 3-D printers. 3-D printed medical devices, including (1) Instrumentation (e.g., guides to assist with the proper surgical placement of a device), (2) Implants (e.g., cranial plates or hip joints), and (3) External prostheses (e.g., hands).²⁴ In particular, the USA National Institutes of Health has partnered with the US FDA to create a freely accessible website with standards and methods for 3D printing medical devices for heart, kidney, and biomolecules.²⁵ However, these developments in one nation track developments in parallel worldwide in the fight against the COVID-19 pandemic.

These questions are important both within domestic national regulatory systems and the broader multilateral global health law context. Many innovations are produced by international multicorporate collaborations in partnership with several governments. They build upon pre-existing discoveries to create products the whole world needs. However, globalization means that several influential patent regimes enjoy competing jurisdictions. Failure to register intellectual property rights (IPRs) in a place where the rights may be used excessively risks that the rightsholder will be powerless to prevent infringement because no local laws have been violated without registration. This makes patent and trademark litigation plentiful and expensive. The overarching global burden from these concurrent laws is an obstacle to pandemic recovery. The inability of any regulatory system to respond swiftly to emergencies inevitably questions the value of that same regulatory system. FDA, therefore, has not grappled with key issues regarding how materials and matter act differently at the nanoscale compared to the traditional bulk size but is increasingly pressed to do so, perhaps without notice and comment rulemaking as required by traditional USA administrative and procedural laws.²⁶ Therefore, the occurrence of 3D-printed medical devices during the pandemic raises a problematic question:

How will civil society generate oversight and then allocate responsibility for the quality, Intellectual Property Rights (IPRs), and access to medical devices when time and perhaps

national law does not allow for licensing negotiations?

Today, there is no cohesive, binding international patent law. As a result, nations compete for lucrative business in registration, generating patent rights. Still, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)²⁷ offers a respected benchmark and provides simple rules protecting IPRs, while clarifying the roadmap toward fair use of intellectual property. TRIPS protects these rights but allows governments to temper the monopolistic harm from these practices by allowing companies in their nation to use these rights domestically and sometimes by creating compulsory licensing even if it impacts world trade.²⁸ TRIPS does not entirely solve the problem of equitable allocation of IPRs, among collaborators, but its far-reaching text is widely viewed as designed to influence trade relations regarding the transfer of goods and information in global commerce. TRIPS is intended to²⁹ enable nations to advance commercial interests in trade while at the same time protecting valuable assets in intellectual property. TRIPS is an international governance mechanism with a tribunal that addresses transnational protections for intellectual property, including copyright; trademarks of geographic origins (such as Champagne, Cognac, or Emmental cheese); industrial designs; patents, and trade secrets. TRIPS has 3 goals³⁰:

- (1) Standard setting by defining the elements of intellectual property and attendant rights for a fixed duration and the exceptions, which may be enhanced by national law.
- (2) Enforcement: The system addresses procedures and remedies that enforce IPRs by setting forth general principles applicable to all IPR enforcement procedures, such as national and most-favored-nation treatment, and some general rules to ensure procedural difficulties in acquiring or maintaining IPRs to ensure substantive benefits remain intact.
- (3) Dispute settlement. Disputes between WTO Members about their TRIPS obligations subject are adjudicated at the WTO courts in Geneva, Switzerland³¹

The general goals of the TRIPS Agreement in its Preamble³² include reducing impediments to international trade, effective protection of IPRs, and ensuring that measures and procedures that enforce intellectual property rights do not produce new barriers to legitimate trade by enabling technological innovation and mutually beneficial dissemination of technology. Significantly, Article 8, entitled “Principles,” recognizes the rights of Members to adopt measures for public health and other public interest reasons.³³ Thus, commenters in geopolitics³⁴ and many public health professionals called for a blanket TRIPS waiver to unleash the power of IPRs. by removing rightsholder protections during the exceptionally lethal emergency pandemic of COVID-19.³⁵

Therefore, questions about whether the exigencies of a massive pandemic with millions of deaths in less than 2 years militate in favor of COVID-19 exceptionalism to existing IPR laws while battles about vaccine intellectual property are litigated has been hotly debated at WTO and on social media.³⁶ For this reason, the US Trade representative to WTO surprised many people within the inner circle of the TRIPS agreement enforcement system in the spring of 2022 by proposing a Quadrilateral Agreement³⁷ among the USA, EU, India, and South Africa that distinctly overturned IPR protections, to promote rapid manufacture and development of COVID-19 vaccines and related diagnostics (for testing) and therapeutics for treatment.

This turnabout in the previous US position from the late 1990s and extending into the early 21st century is important not only because of its substance but because of its potential to be a watershed for reducing IPRs in the future. Press releases from the US government heralded this Quadrilateral proposal as a “breakthrough” agreement³⁸ and a keystone to solving the riddle of equitable access to vaccines in nations that are not considered industrialized or rich.³⁹ The waiver does not abandon the pre-existing IPR regime but suspends its applicability to COVID-19 innovations. It creates a fascinating, important precedent for diminishing the barriers that impede global health equity.⁴⁰ Recognizing the need for a multinational waiver to the WTO TRIPS enforcement process to meet the current needs of global health provides one avenue for solving questions

raised by 3-D printed medical devices. The “breakthrough” Agreement brings together old former rivals such as the USA and EU⁴¹. It offers an olive branch across the north-south digital divide to India and South Africa, rejecting the 19th-century patent and trademark protectionism paradigm. In sum, 3-D printed medical devices may present issues in the first case. Still, it will not be the last instance when the law will be required to parse patient safety, patent liability, and liability issues arising when the end user is also the manufacturer. New laws may be needed to protect the integrity of 3-D printed medical products to protect security and public health, but the intellectual property system should not be a barrier to such developments, especially in a global health emergency. Therefore, an uncharted legal landscape concerning the growing use that works in favor of a TRIPS waiver while mindful of competing needs for national or international regulation addressing creations of the human mind otherwise protected as IPRs. Skirmishes about vaccine IPRs traverse only the tip of the iceberg: the change produced by 3-D printing of patentable designs and potential infringement of trademarks are the future battleground of a frozen legal landscape: TRIPS waivers foretell a new paradigm for addressing technologies that transformed fundamental assumptions about innovation. These developments inevitably impact global health care and the future of the intellectual property, shaping medical needs for posterity.⁴²

DISCUSSION:

3-D printing and Nanotechnology's Revolution for Commerce Diminished Global Health Impacts from COVID-19

Classic bioethical questions under law, patient safety concerns, quality controls, and use or misuse of patent, trademark, and design protections remain invisible to PoC production. Figure 1 below demonstrates how knowledge from three seemingly distinct fields of public health, emerging technologies, and international law must be discussed at their intersection to solve important questions raised by 3-D printing. When USFDA released its Discussion Paper requesting public comments⁴³ regarding the future regulation of additive manufacturing and 3-D printing of medical

devices at PoC in HCF US FDA cited supply chain disruptions caused by the COVID-19 pandemic of 2020 as force majeure. Without suggesting that there was a need for conventional administrative notice and comment rulemaking under USA law, FDA proposed to participate in transnational deliberations with the International Medical Device Regulators Forum (IMDRF) to develop standards for Medical Device Printing Systems (MDPS),⁴⁴ including nano-enabled 3-D printers.⁴⁵ Significantly, the FDA appeared to condone the new industrial process without commenting on the potential pitfalls of unfettered use, which bypasses classic inspection points and regulatory oversight in traditional manufacturing. Because these innovations remove or dramatically alter key steps in the traditional process mapped out in most IPR laws and regulatory safety and health frameworks, this use of 3-D printing represents a “game-changer”⁴⁶ that may render existing regulatory systems unable to address instant productivity in MDPSs. Inspection mechanisms and traditional IPR regimes are ill-equipped to capture and monitor on-site production in hospitals, clinics, or other points of care instead of a factory.

Nano-enabled 3-D printing for medical devices and vaccines

The nano-enabled technology of 3-D printing for medical devices presents a dynamic new avenue for meeting patient needs. 3-D printing of medical devices offers the promise of helping people despite breaks in any supply chain due to war, shortage, or broken distribution lines due to the pandemic.²¹

Trillions of dollars have been spent on research and development funding the application of nanotechnology in global commerce; nanotechnology represented \$3 trillion in GDP in 2015 and was expected to rise to \$14 trillion by 2022.

Nano-enabled applications empower people to function (whether the public realizes their importance or not) because it is a foundational technology, enabling people to overcome isolation, pandemic illness, and disability and ultimately reduce the global disease burden from COVID-19.

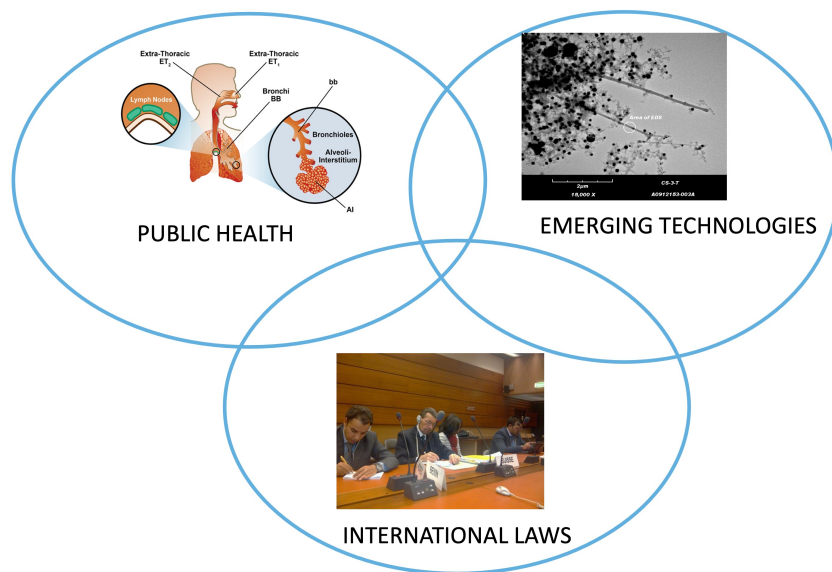


Figure 1. The context for Reviewing Nanotechnology Law and Policies adapted from I L Feitshans, *Global Health Impacts of Nanotechnology Law a Tool for Stakeholder Engagement*, Pan Stanford Publishing, Singapore 2018.

For example, previously frowned upon nano-enabled telehealth communication became a mainstay of psychotherapy and primary care physicians-patient interaction funded under the CARES Act.⁴⁷ Telehealth appointments during the pandemic rapidly became so mainstream that it was advertised on television. Nano-enabled mRNA manipulation is key in creating COVID-19 vaccines, and 3-D printed medical devices offer patients needed supplies.⁴⁸

Covid-19: The Gamechanger for Law and Order

No one was left untouched by COVID-19. The World Health Organization (WHO) designated the ongoing pandemic of COVID-19 a Public Health Emergency of International Concern, and national declarations of a state of emergency followed hours afterward.²⁷ During the spring of 2020, billions of people were under government orders to stay in shelters to prevent the spreading of COVID-19. However, by May 3, 2020, surging COVID-19 cases infected 3 million people and killed 247,838, within a few weeks after patient one, wreaking economic devastation worldwide. One month later, on June 3, 2020, Worldometer.org reported 6.29 million cases and 380,000 deaths. By July 2020, there were over 10 million cases and 500,000 deaths. Two years later:

517,372,784 cases, 6,251,526 deaths, 11,363,105,517 vaccine doses administered.”⁴⁹

Economic Costs of the COVID-19 Pandemic as a Driver in International Trade

One must not understate the impact of the COVID-19 pandemic when evaluating the need for establishing a waiver under TRIPS or IPRs. Civil society stops whenever a pandemic threatens the quality of human life⁵⁰; COVID-19 is no exception to this millennial chain of precedent. Societal problems occurring during the COVID-19 pandemic fit traditional playbooks: key issues during past pandemics include:

1. Underreporting and lack of early recognition,
2. Blaming foreigners while debating responses by the public health infrastructure,
3. Isolation of sick individuals,
4. Closing courts, legislatures, and government offices, and
5. Closing markets and stopping commerce.⁵¹

The pandemic wreaked havoc across economies at macro and micro levels and cost hundreds of trillions of dollars plus opportunity costs from reduced growth in GDPs.⁵² Short-term devastating economic impact on otherwise stable industries forming the backbone of the

21st-century economy, such as airlines, tourism, and food service, added to looming long-term health care costs and remained to be calculated. Internet communication, combined with the societal ability to rapidly close businesses, schools, and public gatherings of all types, from the Olympics⁵³ to weddings, were catastrophically disruptive. Lockdown may work, but it is expensive.

Executive orders during the pandemic changed the law

The pandemic brought turbulent jurisprudential activity across the globe. Worldwide, the COVID-19 response included a plethora of emergency federal, state, regional, and local municipal orders in major cities and small towns when the virus challenged the viability of many well-established institutions in civil society.³⁴ Governments acted swiftly,⁵⁴ taking power to institute anti-COVID-19 programming. Thousands of executive orders at the local, national, regional, and international levels granted the power to address the COVID-19 pandemic law, cresting in exceptionalism that stopped social movements in their tracks and instituted new regimes of law that would be unlikely to pass a legislature but for the global health emergency. Emergency orders were enforced by police in some places; some industries were closed, although frontline workers rendering essential services were allowed to leave home. A systemic shift to remote work changed the landscape of telecommuting, perhaps permanently turning remote work at home into the mainstay of the economy, while schools from crèche to higher level education in universities were closed by executive order with one stroke of the legislative pen. This body of law regarding governance under Executive Orders for the COVID-19 emergency supports the view that law changes for the emergency IPRs are no exception.

Global Governance of Intellectual Property Under WTO TRIPS

WTO's TRIPS agreement balances rightsholder protection against several global equitable needs.³⁵ TRIPS has a unique flexibility feature: its language can be used to uphold a normative intellectual property regime in a Member nation under Articles 25 and 26, or its language can be used to override foreign

intellectual property concerns under Articles 31 and 31 BIS ("The Doha Declaration").⁵⁵ WTO Member nations may provide limited exceptions to the protection of industrial designs under specific conditions. The so-called "Doha Declaration" offers an avenue for nations that lack economic resources to suspend IPRs from abroad within their nation or to require the manufacture and marketing of the protected intellectual property by a third party under a government-backed program of "compulsory licensing." In theory, the only limit is the rather subjective determination of whether the use does not unreasonably conflict with the normal exploitation of protected industrial designs or harm the legitimate interests of the rightsholder: "The owner of a protected industrial design shall have the right to prevent third parties not having the owner's consent from making, selling, or importing articles bearing or embodying a design which is a copy, or substantially a copy, of the protected design..."⁴⁵

This duality between quasi-monopolistic protection and government-imposed permission to disregard the IPRs is driven by geopolitical forces that recognize national sovereign rights both as a source of IPRs under the law and as a reservoir of exceptionalist powers during an emergency. The Doha declaration enables governments to seek voluntary licensing to advance public health, but if the IPR rightsholder refuses, the Member governments nonetheless have the power to require compulsory licensing.

Theoretically, this power under TRIPS can be applied during emergencies without consulting the rightsholder before granting a license. During emergencies, a government theoretically needs only to declare the emergency, and then it can deploy intellectual property from home or abroad that has been registered in its nation. Furthermore, the actual definition of what constitutes an emergency is the subject of extensive legal scholarship. Few scholars agree whether there is a limit on the duration of the powers used during the emergency or if there is no limit at all. Therefore, TRIPS provides a logical and reasonable venue for discussing questions raised by 3-D printed medical devices, requiring society to balance the allure of swiftly

accessible medical devices with vital concerns about patient safety and IPRs.

Permissions required for Non-Rightholders Using Design Patents and Trademarks

Whether to use TRIPS flexibilities to limit patent ownership rights, trademark infringement, and ultimately the affordability of products in different countries has been a perennial question for global health and international trade, now under the spotlight during the pandemic of COVID-19. 3-D printing, due to broken supply and distribution lines, without the time to negotiate permission for use during the pandemic, differs from the typical IPR scenario in the case of medicines, diagnostics, and medical devices, which has been the subject of extensive litigation in the WTO.³⁶ According to a WTO WIPO and WHO report, typically, “application of these procedures must avoid the creation of barriers to legitimate trade and must provide for safeguards against their abuse.”³⁷ For example, printers in a small PoC such as a dental office or clinic can be loaned to third parties for printing medical devices: masks, ventilator parts, or dental implants. This practical reality further confounds conventional discussion of rightsholder entitlements regarding patentable designs or trademark protections. The US FDA does not address IPRs, but does define “medical device.” The Food Drug and Cosmetic Act Medical Device Amendments of 1976 (“MDA”),³⁸ framework in Section 201(h)(1) defines “device” as:

“[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article ... intended for use in the diagnosis of disease or other conditions...”⁵⁶

Similarly, the EU Medical Devices Regulation n.º 2017/745 Annex XVI uses language that is remarkably close to the US FDA counterpart states:

‘Medical device’ means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material ... for one or more of the specific medical purpose(s) of diagnosis, prevention,

monitoring, treatment, or alleviation of disease.”⁵⁷

Volumes have been written about harmonizing these laws, but in practice, there is no clear path to avoid the IPRs problems caused by subtle differences in their terms. Given this overlapping authority found in the concurrent “medical device” definitions, a product that infringes on IPRs. One of these regulatory schemes will also run afoul of the other, doubling the risks and costs. This limit represents an artificial distinction for MDPS because 3-D printed medical devices serve several functions simultaneously. TRIPS, therefore, provides neutral ground to streamline these issues.⁵⁸

TRIPS Section 4: Industrial Designs Article 25: Requirements for Protection

It remains unknown which facets of MDPSs are readily protected under the paradigm outlined in the TRIPS regime because there are so many potential venues for printing an unlimited variety of products.⁴³ TRIPS offers a full panoply of protections following the traditional path of IPR regimes:

“1. Members shall provide for the protection of independently created industrial designs that are new or original. Members may provide that designs are not new or original if they do not significantly differ from known designs or combinations of known design features.”⁴⁴

But such analysis is deceptively simple because the traditional paradigm contemplated by law does not fit 3-D printing. Comparing MDPS with traditional paradigms for applying IPRs reveals that neither control of production nor the distribution lines fit previous patterns, as demonstrated by the WTO’s own report characterizing the value chain for global health use of IPRs in trade shown by Figure 2. “Traditional Distribution and Supply Chains” (WTO, WHO, WIPO Model “Ensuring Access along the value chain of medicines and health products” World Trade Organization ensuring⁵⁹).

Unlike traditional supply chains for distribution⁶⁰, all the steps in MDPS can be performed in one place: without a paper trail of transfer, shipping, and delivery or delays.

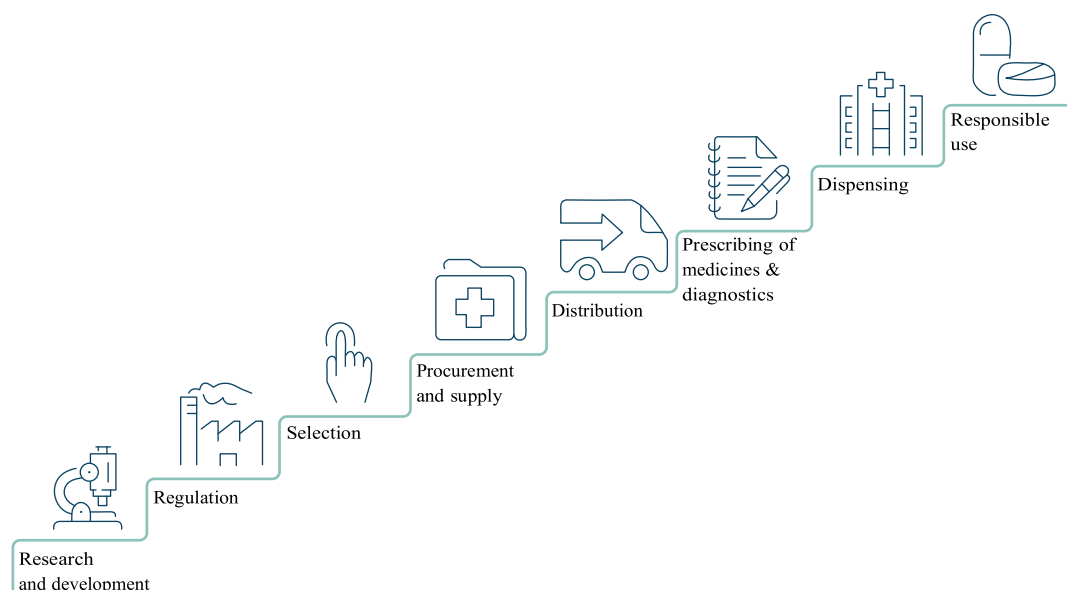


Figure 2: Model for the traditional supply chain intersections between public health, intellectual property, and trade using medical devices as an example. Source WHO WIPO and WTO Collaborative Report: Promoting Access to Medical Technologies and Innovation. The figure demonstrates an example of the traditional supply chain Intersections between public health, intellectual property, and trade (Appearing as “Figure 4.3 “Ensuring Access along the value chain of medicines and health products” World Trade Organization, World Health Organization and World Intellectual Property Organization, 2nd Edition 2020.

Although it is unclear how FDA intends to apply existing inspection and safety laws, controlling MDPS in institutional PoCs is an important first step because it is unlikely that any mistakes or illegal copying of the design can be easily detected. Using the transnational collaboration of governmental partners from the EU and several nations in consultation with private industry that has begun must undergo stakeholder scrutiny to operationalize precautionary principles in an inclusive, equitable, and transparent manner. The enforcement dilemma for oversight of IPRs is equally clear. Without an underlying framework for judging the methods, standards, and penalties upon inspection, accountability will remain poor under the law, and few legal remedies for harm will exist. Therefore, TRIPS waivers can provide practical solutions to IPR entanglements during an emergency. Global trade can work towards equitable health if existing systems are modified to accommodate this technological change. In parallel, compliance activities in safety and health at the national and international levels must also be developed.

TRIPS Flexibilities article and B the “Doha declaration.”

TRIPS flexibilities may provide an antidote to the protection of IPRs. However, that is problematic to discern and thus extremely difficult to enforce during the COVID-19 pandemic. FDA’s Discussion Paper captures the entire process within MDPS,⁶¹ regardless of the printing status, including the manufacture of printing machinery. Still, the question of whether such regulatory activity in tandem with the IMDRF embraces IPRs remains unanswered. Multiple design patent and trademark infringement concerns impact each step of MDPS, while the novelty of each invention and its attribution to one unique rightsholder remains unclear. In addition, design information can come from anywhere and be applied anywhere else to create medical devices with “one-stop shopping.”

This practical reality confounds working assumptions under law, including IPRs. and IMDRF. For example, to what extent are these activities the product of novel creations of the human mind, given the complexity of sophisticated manufacturing that relies on previous knowledge and the collaborative efforts of thousands of researchers worldwide in public and private sectors involve the

Herculean tasks of separating form and function. Similar questions are raised by each additional step in the printing process and teasing apart the role of any potential rightsholders in creating a novel component of these innovations is very complicated without a clear resolution. Therefore, these circumstances are ripe for an IPR waiver exception to meet public health needs.

During emergencies, governments may suspend enforcement of these rights to preserve public health. Articles 31 and 31 BIS of the Doha Declaration affirm “the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility” to protect public health.⁴⁶ A decision implementing paragraph 6 of the Doha Declaration (2003 Decision) affirmed: the “rights, obligations, and flexibilities that Members have under the provisions of the TRIPS Agreement.”⁴⁷ This language and subsequent WTO enforcement decisions suggest TRIPS language allowing compulsory licensing for any reason might be adequate to answer this need, but the Doha Declaration is a soft law consensus document, lacking the teeth of hard law. Therefore, it is possible that 3-D printing of medical devices could violate TRIPS protections even in times of emergency unless those rights are subject to a waiver.

For this reason, India and South Africa called for a general waiver of IPRs protected by TRIPS early in the Covid-19 pandemic, asserting that such a waiver would enable their governments to establish factories to manufacture vaccines, diagnostics, and therapeutic products. At first, this request was resisted as an unreasonable demand. As the pandemic progressed, however, a great international effort was launched with governments and the private sector working together to create a viable vaccine, produce it and distribute it across the entire population at risk from COVID-19. This unprecedented global effort across nations and across economic sectors proved important. As a result, the US reversed its traditional opposition to the weakening of TRIPS protections less than one year later, taking the lead for the Quadrilateral Agreement described below.⁶²

US-EU India and South Africa Quadrilateral Agreement for a TRIPS Waiver

Responding to health disparities revealed during the pandemic, and the emerging picture of systemic inequity in global health care and delivery, India and South Africa called for a TRIPS waiver for vaccines and medical devices.⁶³ Their arguments before the TRIPS Council became the forerunner for the “Quadrilateral Agreement” between the US, EU, and their nations. However, neither document has been discussed for consensus at WTO meetings, but the sheer influence of these four players combined with the exceptional context of the COVID-19 pandemic suggests referent power to become viable soft law. The Quadrilateral Agreement reflects a departure from long-standing US foreign policy at the WTO that favored dogmatic IPR protection.⁴⁹ Regardless of whether the authors’ intent is a genuine “breakthrough” in response to COVID-19 (as the Agreement has been presented by the US President’s administration), the text clearly reflects the underlying technological revolution.⁵⁰ Using words that are short and powerful, not limited to vaccines (despite brouhaha about its narrowness). Point 6 states:

“Members will decide on its extension to cover the production and distribution of COVID-19 diagnostics and therapeutics.”⁵¹

The Agreement vests WTO Member governments with the ability to address the potential trademark infringement or unauthorized use of design patents rife throughout MDPS. This language is neither vague nor unintended.⁶⁴ This one nano-enabled sentence unleashes the power of States to erase IPR obligations in a variety of circumstances, armed with many tools that do not require rightsholder consent. Consistent with the large corpus of executive orders and emergency legislation declared during the COVID-19 pandemic, the terms of the Agreement paint with sweeping brush clear permission for compulsory licensing across technologies throughout MDPS:

1. “[A]n eligible Member may authorize the use of patented subject matter under Article 31 without the right holder’s consent through any instrument available in the law

of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place...of 'law of a Member' referred to in Article 31 is not limited to legislative acts such as those laying down rules on compulsory licensing, but it also includes other acts, such as executive orders, emergency decrees..”.

2. “(a) *An eligible Member may issue a single authorization to use the subject matter of multiple patents necessary for the production or supply of a COVID-19 vaccine. The authorization shall list all patents covered. In the determination of the relevant patents, an eligible Member may be assisted by WIPO’s patent landscaping work, including on underlying technologies...to include other patents.*

“(b)... *need not require the proposed user of the patented subject matter to make efforts to obtain authorization from the right holder for the purposes of Article 31(b).*”⁵² (emphasis in text)

Thus, the Quadrilateral Agreement unpacks traditional IPRs in exchange for a waiver of TRIPS provisions to fight the COVID-19 pandemic. In sum, this broad mandate makes it difficult to argue that design patents and trademarks for MDPS have not been waived.

TRIPS Waivers for All: Ministerial Decision on The TRIPS Agreement Adopted June 2022

Following merely weeks later, the WTO Ministry issued a Ministerial Decision on the TRIPS Agreement Embracing the Quadrilateral Agreement Across All Member Nations announced: The *Ministerial Conference, having regard to* paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization; *Noting* the exceptional circumstances of the COVID-19 pandemic; *Decides* as follows:

“*Notwithstanding the provision of patent rights under its domestic legislation, an eligible Member¹ may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter “the Agreement”) by authorizing the use of the subject matter of a patent² required for the production and supply of*

COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic, in accordance with the provisions of Article 31 of the Agreement....”⁶⁵

Contrary to traditional TRIPS protections, these uses may be authorized by a WTO member government “without the right holder’s consent” using a wide variety of legislative mechanisms and executive orders, including but not limited to “any instrument available in the law of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a member has a compulsory license regime in place.”

This permission “is not limited to legislative acts such as those laying down rules on compulsory licensing, but it also includes other acts, such as executive orders, emergency decrees, and judicial or administrative orders” whose “subject matter of a patent” includes ingredients and processes necessary for the manufacture of the COVID-19 vaccine. Furthermore, Members need not require the proposed user of the subject matter of a patent to make efforts to obtain authorization from the rightsholder as set out in Article 31(b). They may waive such rights without triggering a procedure that would challenge the trade practice under the terms of the TRIPS agreement in order “to supply its domestic market and may allow any proportion of the products manufactured under the authorization following this Decision to be exported to eligible Members, including through international or regional initiatives that aim to ensure the equitable access of eligible Members to the COVID-19 vaccine covered by the authorization.

Although re-exportation involving products manufactured by compulsory licensing or under the purview of the waiver is not expressly approved, it is only limited by “reasonable efforts to prevent the re-exportation of the products.” The overarching goal is “Recognizing the importance of the timely availability of and access to COVID-19 vaccines, it is understood that Article 39.3 of the Agreement does not prevent an eligible Member from enabling the rapid approval for the use of a COVID-19 vaccine produced under this Decision.”⁶⁶

Significantly for 3-D printing, “No later than six months from this decision date, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics.” At the time of this writing, therefore, an expansive view of the TRIPS waiver to address emergencies looms on the horizon.

In summary: A TRIPS Waiver Allowing 3-D Printing Advances Global Health Equity

Can a TRIPS waiver solve MDPS problems concerning 3-D printing to meet patient needs and intellectual property concerns impacting public health? Clearly, TRIPS waiver proposals under the Quadrilateral Agreement can be applied regardless of whether vaccines or medical supplies are produced. Thus, the

extensive debate about patent rights for the COVID-19 vaccine masks a bigger issue: specifically, a waiver may be better suited to the dilemma posited by medical devices because even though billions of vaccine doses have been administered, medical devices are much more prevalent and represent a larger part of GDP for long-term health and pandemic recovery. If so, the need for shared information that cannot be traced to one specific rightsholder or owner and cannot enjoy a monopoly of exclusive use to stop an urgent situation suggests a diminishing role for the protection of intellectual property in the future. Additionally, the rarely used text of WTO Article 8 concerning the role of governments in protecting public health opens the door for further scrutiny of the long-term implications for products that impact global trade and health.

Conclusion

In conclusion, it is possible and even likely that the unprecedented international effort to find a vaccine also produced a new understanding of the revolutionary character of changes in technology, heralding a new IPR paradigm for an essential social good. Health care using medical devices touches every species on earth. Therefore, medical devices are commonly subject to extensive regulation nationally, internationally, across trade agreements, and under some religious laws. Nanotechnology is a key component of the social forces shaping this discourse about new approaches to governance and the regulatory state, moving away from unidimensional, monopolistic control of each phase of production and distribution. These traditional IPR paradigms have changed because of nano-enabled 3-D printing as part of MDPS to diminish the global disease burden of COVID-19. In so doing, however, these changes call into question traditional oversight systems for protecting patient safety, product safety, allocating liability in the event of harm, and intellectual property.

What do these changes suggest for the future of intellectual property, especially for industrial design and trademarks that are otherwise protected under TRIPS?

Exceptionalism During Exigency: The Future of Intellectual Property Law

COVID-19 and the sweeping legal changes it has wrought in response demonstrate that during force majeure, geopolitical and legal implications of manufacturing and distribution must be redefined. Accordingly, COVID-19 worked in favor of suspending IPR, at least temporarily. This shift means rethinking IPR and recognizing that industrial ideas are not possessed by one entity. This means moving towards a more realistic modern development: from greening pre-existing patents to make them last longer or fit unconventional uses to a waiver-based view of IPRs.

Although the 20th-century law was about balancing diversity by maintaining cultural differences without prejudice, 21st-century laws have overcome many of those challenges and instead stare down the crossroads of science influencing social policy, including intellectual property rights. Shaping new laws for implementation and compliance will engage governments in a complex set of deliberations that requires balancing the allure of swiftly accessible medical devices with patient safety concerns and rightsholder concerns within a whole new paradigm for global business as exemplified by 3-D printed medical devices during the pandemic emergencies created by COVID-19.

Conflict of interest

The author has no relevant financial or non-financial interests to disclose. For a signed statement contact the journal office editor@precisionnanomedicine.com.

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¹ *Force majeure* events are usually defined as certain acts, events or circumstances beyond the control of the parties, for example, natural disasters or the outbreak of hostilities. A *force majeure* clause typically excuses one or both parties from performance of the contract in some way following the occurrence of such events. Its underlying principle is that on the occurrence of certain events which are outside a party's control, which excuses them from the contract.

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¹⁵ Jasper L. Tran The Law and 3D-printing 31 J. Marshall J. Info. Tech. & Privacy L. 505 Spring, 2015 “3D printers print by setting raw ingredients into two-dimensional patterns on a platform and gradually raising to stack one layer on top of another until completion. ... 3D printers need to follow an electronic blueprint to print, called a Computer-Aided Design file (“CAD file”). Users can create CAD files by designing from scratch or scanning an object, then edit and share CAD files with others through the Internet. Soon, the 3D printer will be just another home appliance”.

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