COPY, PASTE, AND SAVE LIVES: THE EFFECTS OF PATENT INFRINGEMENT ON THE FIGHT AGAINST THE CORONAVIRUS

Joslyeen H. Mitri*

I. Introduction

The COVID-19 pandemic generated uncertainty around the globe, much of which was attributed to the supply-demand war in the healthcare field.[1] As the virus swept across the United States, healthcare professionals painstakingly searched for the most resilient and advanced solutions to save our shrinking population.[2] Three-

* J.D. Candidate, Suffolk University Law School, 2022; B.S. in Corporate Finance and Accounting, Bentley University, 2017. Joslyeen can be reached at joslyeenmitri@gmail.com.

[1] *See* Yu Ying Clarrisa Choong et al., *The global rise of 3D printing during the COVID-19 pandemic*, NATURE REVS. (Aug. 12, 2020), *archived at* https://perma.cc/3A8R-JUKR (emphasizing that the logistical challenges associated with disruptions in manufacturing and transportation, together with pushbacks against globalization and free trade, have constrained supply chains, resulting in critical shortages of essential good). Healthcare systems are fighting a war to increase the capacity of beds, essential supplies, and trained employees. *Id.*

[2] *See* Katrina Quicker et al., *Considerations for 3D Printing of Medical Devices, Accessories, Components and Parts During the COVID-19 Pandemic*, IP INTELLIGENCE (Apr. 13, 2020), *archived at* https://perma.cc/V3DM-BPUQ (detailing that shortages of medical devices including, personal protective equipment (PPE) and ventilators, make 3D printing particularly interesting with regard to fighting COVID-19); *see also* Stephanie Condon, *How the 3D printing industry is stepping up to help the COVID-19 response*, ZDNET (Mar. 24, 2020), *archived at* https://perma.cc/UV7R-YVEQ (stating that the more that the COVID-19 outbreak worsens across the U.S., the urgent need for medical gear has compelled the additive

dimensional ("3D") printing quickly emerged as an effective solution to meet the growing demand.[3] The digital versatility and swift prototyping of 3D printing empowers a rapid response to severe disruptions in supply chain operations.[4] Although 3D printed medical devices could potentially solve the world's supply-demand crisis with

manufacturing industry, including makers of 3D printers like Stratasys and HP, to put their tools to work in completely new ways). *See also* U.S. FOOD & DRUG ADMIN., TECHNICAL CONSIDERATIONS FOR ADDITIVE MANUFACTURED MEDICAL DEVICES: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Dec. 5, 2017) (stating that additive manufacturing (AM) is a process that builds an object by sequentially building 2-dimensional (2D) layers and joining each to the layer below, allowing device manufacturers to rapidly produce alternative designs without the need for retooling and to create complex devices built as a single piece).

[3] *See* David Mills, *Special Issue "3D Printing of Bioactive Medical Device"*, MDPI (Oct. 15, 2020), *archived at* https://perma.cc/Z6DX-KKZ5 (stating that a future where medical treatment becomes on-demand personalized, not "one size fits all," is now being realized). "Recent advances in 3D printing (medical devices, drugs) and bioprinting (microcontact, inkjet, etc.) may enable all on-demand medical treatment and bring us closer to achieving this future." *Id. See also What is 3D Printing?*, 3DPRINTING.COM (2021), *archived at* https://perma.cc/25LB-FEKF (describing the additive process where an object is created by laying down successive layers of material until the object is created). 3D printing covers a wide variety of medical sectors including dental dentures and aligners, hearing aids, hip implants, and the newest sector, bio-printing. *Id. See also* Jeff Kerns, *A Look at the Future of Medical 3D Printing, Part 1*, MACHINE DESIGN (Jan. 4, 2018), *archived at* https://perma.cc/BSS7-A4VQ (explaining that although 3D printing provides exciting medical advances, scientific and regulatory challenges remain, and therefore the most transformative applications for this technology will need time to evolve). *See also* Condon, *supra* note 2 (emphasizing that additive manufacturing was "an essential part" of the pandemic response . . . and employees of Stratasys "are prepared to work around the clock to meet the need for 3D printers, materials, including biocompatible materials, and 3D-printed parts.").

[4] *See* Choong et al., *supra* note 1 (stating that critical parts can be manufactured on-demand by any decentralized 3D printing facility by leveraging designs shared online); *see also* Elizabeth G. Bishop & Simon James Leigh, *Using Large-Scale Additive Manufacturing as a Bridge Manufacturing Process in Response to Shortages in Personal Protective Equipment during the COVID-19 Outbreak*, 6 INT'L J. BIOPRINT 51, 52 (2020), *archived at* https://perma.cc/77G7-VCLV (stating "[w]ith this increased global demand for PPE, governments and organizations have struggled to source enough for millions of regular PPE users, let alone for non-typical users such as pharmacies and general practitioners who are now at increased risk of infection during their daily activities."). *See* Condon, *supra* note 2 (noting that SmileDirectClub, the oral care company known for its teeth straightening kits, is one of the largest 3D printing manufacturers in the United States and has opened its facilities for the production of medical supplies).

just the push of a button, 3D printing also poses an unusual patent infringement dilemma.[5] "Patent infringement issues associated with 3D printing are often a result of the difference between the digital and physical versions of the patented device."[6]

Patent law enables multiple parties to utilize the same invention while protecting the inventors' interests.[7] Patents allow the holder to bring suit for patent infringement against those who violate

[5] *See* Jason Rantanen, *3D Printing, Patent Infringement, and the Coronavirus*, PATENTLY-O (Mar. 19, 2020), *archived at* https://perma.cc/C6AU-8SDJ (detailing that in almost "every case, the patent covers only the tangible object, not the digital version of it."). "[M]erely creating a 3D printable file of the device is not an act of direct infringement." *Id. See also* Niks v. Marinette Paper Co., 11 F.R.D. 384, 385 (N.D.N.Y. 1951) (indicating that blueprints of a physical device alone are not sufficient to find patent infringement). *See also* R. CARL MOY, MOY'S WALKER ON PATENTS § 1:27 (4th ed. 2017) (emphasizing how all laws are a function of underlying policy and that there are two broad justifications for patenting, one that is based on the natural right of the inventor and the other view asserts that patenting is a discretionary act of the sovereign, acting on behalf of the public). *See* U.S. CONST. art. I, § 8, cl. 8 (explaining Congress has the power to protect intellectual property in order "to promote the progress of science and the useful arts"). The intellectual property clause provides Congress with the constitutional power to grant rights to inventors. *Id.*

[6] *See* Rantanen, *supra* note 5 (noting that in the United States, the relevant indirect liability would be inducement under 35 U.S.C. § 271(b), which states simply that, "whoever actively induces infringement of a patent shall be liable as an infringer"). "Although the statute does not say so, liability for inducement requires that the accused have knowledge of the specific patent and that the induced acts constitute patent infringement." *Id.* "Knowledge can be negated by a good faith belief of noninfringement, but it cannot be negated by a good faith belief in the patent's invalidity." *Id. See also* Timothy R. Holbrook & Lucas S. Osborn, *Digital Patent Infringement in an Era of 3D Printing*, 48 U.C. DAVIS L. REV. 1319, 1362 (2015) (recognizing that "[a]s quality 3D printers make their way into the average person's home, the difference between having a CAD file and having the physical object will become increasingly inconsequential.").

[7] *See* 35 U.S.C. § 271 (2010) (detailing that anyone without authority who manufactures, uses, sells, or makes an offer to sell an invention that is protected under a patent is infringing on that patent). *See also* STEPHEN M. MCJOHN, INTELLECTUAL PROPERTY 261 (Examples & Explanations, 7th ed. 2021) (noting that a patent was a way of protecting an invention and allowing others to use it without diminishing its value). A patent allows the owner the right to exclude others from: making, using, selling, offering, or importing the claimed invention and allows the holder to bring a suit for patent infringement against those who violate the patent. *Id.*

the patent.[8] In times of desperation, patent infringement regulations negatively impact society by preventing medical device manufacturers from swiftly producing life-saving patented devices, such as personal protective equipment.[9]

This issue came to the forefront in the past year due to the COVID-19 pandemic, when personal protective equipment was desperately needed, yet unattainable. Medical manufacturers have put their profits above society's welfare during the COVID-19 pandemic by refusing to limit their interest in patents. When facing this devastating challenge of a global pandemic, many countries granted temporary government immunity, protecting manufacturers of medical equipment from patent infringement repercussions. As 3D printing technology becomes more readily available, patent infringement regulation must follow at an equivalent rate in order to effectively integrate the technology into society and provide manufacturers with clear guidelines.

II. History

Ambiguities in relation to patent law and 3D printing have presented multiple issues that have been exacerbated by COVID-19.[10]

---

[8] *See generally* MOY, *supra* note 5, § 1.28 (detailing how patents can be used to protect ideas and allow others to use it without diminishing its value). A patent allows the owner the right to exclude others from a number of activities including making, using, selling, offering, or importing the claimed invention. *Id.* This allows the holder to bring a suit for patent infringement against those who violate the claims of the patent. *Id.*

[9] *See* Holbrook & Osborn, *supra* note 6, at 1324 (stating that "[b]ecause the line between the tangible and intangible is increasingly blurred, the patent system will have to [quickly] react."); *see also* Rantanen, *supra* note 5 (stating that "although the coronavirus pandemic inflames passions when needed medical equipment is in short supply, it is important to remember that in emergencies Article 31 of TRIPS, the key international patent treaty, provides flexibilities for governments to use – and authorize others to use – patents without the consent of patent holders.").

[10] *See* Elsa Malaty & Guilda Rostama, *3D printing and IP law*, WIPO MAGAZINE (Feb. 2017), *archived at* https://perma.cc/34PE-LBKT (noting that "[i]f copies of an original object are 3D printed without authorization, the creator can obtain relief under copyright law."). "Similarly, industrial design rights protect an object's ornamental and aesthetic appearance – its shape and form – while a patent protects its technical function, and a 3D trademark allows creators to distinguish their products from those of their competitors." *Id.* *See also* Davis Doherty,

Patents protect an invention by giving legal rights to its owner to prevent others from manufacturing, using, selling, or importing the claimed invention.[11] Understanding what aspects of 3D printed devices are protected under patent law and to what extent they are protected can be challenging.[12] If a piece of equipment is patented, then making a 3D printed replica of that invention or using it without the patent owner's permission may constitute patent infringement.[13]

DOWNLOADING INFRINGEMENT: PATENT LAW AS A ROADBLOCK TO THE 3D PRINTING REVOLUTION, 26 HARV. J. OF L. & TECH. 353, 354 (2012) (emphasizing that the DIY community is comprised of a collection of people who are engaged in the creation, modification, and repair of objects without the aid of paid professionals). "But if one of these designs happens to infringe on an existing patent, 3D printing also enables widespread patent infringement in the form of digital downloads in much the same manner that the advent of digital music enabled widespread copyright infringement." *Id.*

[11] *See* Angela Wang & Co., *Intellectual Property Issues in 3D Printing*, HG.ORG (Oct. 15, 2020), *archived at* https://perma.cc/QCP2-HQCE (defining the relation between patent law and 3D printed technology). "With increasing availability and wider use of 3D printers, more legal issues would emerge from the use of the technology at both the commercial and consumer levels." *Id. See also* Doherty, *supra* note 10, at 354 (detailing that there are many unanswered questions with respect to intellectual property rights due to the ease of physical objects being rapidly replicated, reproduced, and repaired). *See also* MPEP § 608.01 (9th ed. Rev. 8, Aug. 2017) (explaining the claims define what the patent is and covers). The claims are key in determining if another party has infringed, the courts will look to the claims to determine what the patent covers. *Id.*

[12] *See* Malaty & Rostama, *supra* note 10 (examining that "[m]any commentators believe that a 3D digital file may also be protected under copyright law in the same way that software is."); *see also* Doherty, *supra* note 10, at 355 (stating that the legal regimes that made sense in the traditional manufacturing world are being challenged in their attempted application to the digital manufacturing world).

[13] *See* Wang & Co., *supra* note 11 (observing that in the context of 3D printing, copyright may subsist in the 3D physical objects to be scanned as well as the 3D printed objects, which might be considered as original artistic works). *See also 3D Printing-implications on Intellectual Property Rights ("IP rights")*, WHITE & CASE (Apr. 25, 2014) [hereinafter *IP rights*], *archived at* https://perma.cc/J95U-F5Q7 (maintaining that "[a]lthough many patents are for complex inventions with many components, there are also some simple patented products/inventions which can be produced by 3D printers—for example, certain medical devices such as prostheses and hearing aids."). The plan of a 3D printer is that it may be "downloaded and printed from another person's original design, or a copy can be created from an already existing commercial product." *Id. See also* Doherty, *supra* note 10, at 354 (stressing that "3D printing also enables widespread patent infringement in the form of digital downloads in much the same manner that the advent of digital music enabled widespread copyright infringement.").

An analysis of patent law and the implications associated with 3D printing are critical to understanding the potential direct and indirect forms of infringement.[14] As the growing world of 3D printing blurs the line between digital and physical patents, it has become crucial to develop appropriate regulations and reform existing ones.[15]

A. A Brief Overview of Patent Law and Infringement Lawsuits

1. An Overview of Patent Law

The United States Constitution grants Congress the power to secure, for a limited amount of time, certain rights for inventors to their respective inventions.[16] The purpose of patent protection is to protect

[14] *See IP rights*, *supra* note 13 (describing that "[a]n infringement of patent rights may exist if the infringing product will be kept, used, or offered for sale to potential buyers . . . this does not apply when the products have been produced for private, non-commercial purposes."); *see also* Doherty, *supra* note 10, at 355 (discussing "[t]he modes of infringement made possible by 3D printing technology, identifies the actors most likely to face a risk of litigation, and proposes modifications to the current patent law regime, with an eye toward both preserving the public goods generated by the DIY community and providing patentees with a method for good faith extrajudicial enforcement of their rights.").

[15] *See* Tabrez Y. Ebrahim, *3D Printing: Digital Infringement & Digital Regulation*, 14 N.W. J. TECH. & INTELL. PROP. 37, 40 (2016), *archived at* https://perma.cc/TU6D-TCFH (providing that "technological disruptions of the past, such as with the advent of the printing press, personal computing, and the Internet, the 3D printing revolution will also confront new issues at the intersection of technology, business, and law."). While copyright law and patent law are distinct regimes, patent infringement claims give innovators a better strategic enforcement mechanism. *Id.* at 45. "Moreover, since 3D printing is ultimately about printing physical objects, patent law is the most applicable intellectual property regime." *Id. See also* Holbrook & Osborn, *supra* note 6, at 1364 (indicating that someone printing a patented product with a 3D printer could be liable for direct patent infringement by "making" a replica or for indirect infringement by inducing the infringement of a patent by a direct infringer).

[16] *See* U.S. CONST. art. I, § 8, cl. 8 (conferring upon Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"); *see also Patents*, CORNELL L. SCH. LEGAL INFO. INST. (2020), *archived at* https://perma.cc/34MD-RM2M (detailing the fundamentals of patent law). *See also* MOY, *supra* note 5, §1:1 (describing that the relevant applicant is assumed to hold the rights to a patent and to its utilization). Patent rights can be assigned through contractual arrangements. *Id. See also General information concerning patents*,

the public, accordingly rights are given to the inventor when the public expects to benefit and denied where the public would suffer long-term.[17] Patent law protects the rights of the inventor for a period of time, upon which the invention falls into the public domain.[18] Patent protection provides exclusive rights to the holder of the patent to incentive innovation, which benefits society by providing new and useful technologies.[19] After determining that a patent is the appropriate type of intellectual property protection needed for an invention, the inventor files a patent application with the United States Patent and Trademark Office ("USPTO").[20] With the fast-paced

USPTO (2015), *archived at* https://perma.cc/S8S7-6CXH (noting how this is the only place in the Constitution the Founding Fathers actually used the word "right"). *See also* Gene Quinn, *Patents, Copyrights and the Constitution, Perfect Together*, IPWATCHDOG (Feb. 19, 2018), *archived at* https://perma.cc/P2ME-SLVG (stating that our founding fathers deemed intellectual property rights so vitally important to the success and stability of our new country that these rights were written into the Constitution, a document not generally known for its length and specificity).

[17] *See Patent process overview*, USPTO (2020), *archived at* https://perma.cc/7NPF-J7LX (noting the steps required to receive a patent). If your application is incomplete, you will be notified of the deficiencies by an official letter from the USPTO, known as an Office Action. *Id. See also* 35 U.S.C. § 111 (2021) (detailing the sections required to submit an application). A provisional application, a shorter application which holds a filing date until a later nonprovisional patent application is filed, must include a specification or drawing. *Id.*

[18] *See* MOY, *supra* note 5, §1:27 (describing the broad justifications of patent law). *See also* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974) (noting that patents provide "an incentive to inventors to risk the often-enormous costs . . . [benefiting] society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens").

[19] *See* Quinn, *supra* note 16 (describing the incentive patent laws provide to inventors who spend the time, energy, and capital resources necessary to create useful inventions, which will hopefully have a positive effect on society through the introduction of new products and processes of manufacture into the economy, including lifesaving treatments and cures); *see also* Mazer v. Stein, 347 U.S. 201, 219 (1954) (stating that "the economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in 'Science and Useful Arts.'").

[20] *See Patent process overview*, *supra* note 17 (describing the process and requirements that must be followed to file a patent with the USPTO); *see also General information concerning patents*, *supra* note 16 (stating that "through the preservation, classification, and dissemination of patent information, the Office promotes the industrial and technological progress of the nation and strengthens the economy.").

nature of today's digital era, inventors are struggling to manage the growing number of patent infringers, often with no recourse available due to minimal regulation.[21]

A patent examiner reviews the application to ensure that the patent has not been previously claimed, that it meets the requirements outlined by Congress, and that it fulfills the required patent subject matter inquiry.[22] The patent must meet two criteria to satisfy the subject matter eligibility requirement.[23] The first criteria is that the claimed invention must fall into one of the four statutory categories defined in 35 U.S.C. § 101, including: process, machine, manufacture, or composition of matter.[24] The first of the four statutory categories defines an "action" while the other three categories define "things" or

[21] *See* Dennis Crouch, *Digital Patent Infringement and the ITC*, PATENTLYO (Apr. 30, 2014), *archived at* https://perma.cc/4Y38-NQFN (detailing that "[i]f the physical object is only a click away from being produced by a person's 3D printer, should a court hold that the digital file infringes a patent claim to the physical object, either directly or under the doctrine of equivalents? If not, will claims of indirect infringement be an effective tool against the individuals and websites that host and transmit the CAD files? These questions will be of increasing importance in an era of ubiquitous 3D printing technology."). *Id. See also Refurbishment of Medical Devices: Patent Infringement or Permitted Repair?*, MD&DI (Jan. 1, 1998) [hereinafter *Refurbishment of Medical Devices*] *archived at* https://perma.cc/3CV9-V5EJ (detailing as the use of remanufactured medical devices continues to increase, fueled by market demands for health-care cost containment, so too will the attention that medical device manufacturers must pay to the question of when refurbishing becomes patent infringement).

[22] *See Patent process overview*, *supra* note 17 (explaining the invention must fall under 35 U.S.C. § 101 in order to be patent eligible). *See also* TLI Commc'ns LLC v. AV Auto., LLC, 823 F.3d 607, 613 (Fed. Cir. 2016) (indicating that "[i]t is well-settled that mere recitation of concrete, tangible components is insufficient to confer patent eligibility to an otherwise abstract idea.").

[23] *See* MPEP § 2106.03 (9th ed. Rev. 10, June 2020) (explaining there is a two-step test for determining subject matter eligibility: (a) first, a claimed invention must fall within one of the four statutory categories of invention; and (b) second, a claimed invention must be directed to patent-eligible subject matter and not a judicial exception (unless the claim as a whole includes additional limitations amounting to significantly more than the exception)).

[24] *See* Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 217–18 (2014) (explaining those inventions that as a whole are directed at a judicial exception do not have the appropriate subject matter to be eligible for a patent). *See also* MPEP § 2106.03, *supra* note 23 (outlining the four categories of statutory subject matter: "processes, machines, manufactures and compositions of matter"). *See also* 35 U.S.C. § 101 (describing who may obtain a patent for their inventions of processes, machines, manufacturers, or composition of matters).

"products".[25] The second criteria is that the claimed invention must qualify as patent-eligible subject matter, or the claim must not be directed to a judicial exception unless the claim as a whole includes additional limitations amounting to significantly more than the exception.[26] This criteria is aimed at preventing the monopolization of abstract ideas, laws of nature, and natural phenomenon, which the Supreme Court was concerned would impede innovation rather than promote it.[27]

2. An Overview of the Procedure and Law Surrounding Patent Infringement

By owning a patent, holders may prohibit others from making, using, or selling the protected invention without permission.[28]

---

[25] *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (maintaining that congress intended patentable subject matter "to include anything under the sun that is made by man," indicating the intention to cover a large amount of subject matter limited only by what is man-made). *See also* MPEP § 2106.03, *supra* note 23 (defining "action" as inventions that consist of a series of steps or acts to be performed). Additionally, the categories of subject matter are described as, "the other three categories (machines, manufactures and compositions of matter) define the types of physical or tangible 'things' or 'products' that Congress deemed appropriate to patent." *Id.*

[26] *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71 (2012) (detailing how judicial exceptions include laws of nature, abstract ideas, and natural phenomena). *See also* Thales Visionix Inc. v. United States, 850 F.3d. 1343, 1349 (Fed. Cir. 2017) (noting that "a mathematical equation is required to complete the claimed method and system does not doom the claims to abstraction."). *See also* MPEP § 2106.03, *supra* note 23 (stating that the Court has said that integration of an abstract idea, law of nature, or natural phenomenon into a practical application may be eligible for patent protection).

[27] *See Section 2106 Patent Subject Matter Eligibility*, USPTO (2020), *archived at* https://perma.cc/29VY-X72B (noting how "examiners are reminded that 35 U.S.C. 101 is not the sole tool for determining patentability"). *See also Mayo Collaborative Servs.*, 566 U.S. at 71 (stating that the Court has also emphasized that an invention is not considered to be ineligible for patenting simply because it involves a judicial exception). The Supreme Court in *Mayo* laid out a framework for determining whether an applicant is seeking to patent a judicial exception itself, or a patent-eligible application of the judicial exception. *Id.*

[28] *See* MCJOHN, *supra* note 7, at 261 (defining a patent as a way of protecting an invention and allowing others to use it without diminishing its value). A patent allows the owner the right to exclude others from: making, using, selling, offering, or importing the claimed invention. *Id.* This allows the holder to bring a suit for

Accordingly, if the patent holder discovers that a product is infringing on their patent, they can claim monetary damages and, in some cases, get an injunction to stop the infringing behavior.[29] Under current United States law, patent infringement can be direct or indirect, and these categories are further broken down to active inducement of infringement and contributory infringement.[30]

In order to prove patent infringement in general, the patent holder must first satisfy three criteria.[31] First, the patent owner must prove that they own a valid patent, which is typically proven through a written assignment.[32] Second, the owner must prove that the alleged

patent infringement against those who violate the patent. *Id.* *See also* MOY, *supra* note 5, § 1:27 (detailing how patents can be used to protect ideas).

[29] *See* Michael K. Henry, *PATENT INFRINGEMENT: HOW IT'S PROVEN, AND HOW THIS SHOULD INFLUENCE YOUR PATENT FILINGS*, HENRY PATENT L. FIRM (Jan. 4, 2019), *archived at* https://perma.cc/N4QQ-EN7W (noting that as a patent owner, you have the legal right to exclude others from making, using, selling, or offering to sell the invention); *see also* River Braun, *Navigating Different Types of Patent Infringement*, LEGALZOOM (July 3, 2019), *archived at* https://perma.cc/SP46-L9EH (clarifying that "[u]nlike other statutes of limitation, where the countdown clock starts when the harm occurred, such as the typical one-year statute of limitations following a car accident, the clock in a patent infringement case runs backward from the time the case is filed").

[30] *See* Braun, *supra* note 29 (describing the different types of patent infringement and examples of each); *see also* Rantanen, *supra* note 5 (providing that "[t]he key to appreciating the unique patent infringement issues with 3D printing is to keep in mind the difference between the digital and physical version of the patented device.").

[31] *See* Tulip Mahaseth, *An Overview of Patent Infringement and Defenses Against it*, RED POINTS (Apr. 6, 2019), *archived at* https://perma.cc/2DPP-9Z4H (explaining that in order to successfully sue for patent infringement, "the patent owner must show that each and every element of a patent claim is present literally in the accused product or process, or if the patent owner can show that the accused product or process perform substantially the same function in substantially the same way to obtain the same result as the claimed invention, the accused product or process."). *See also* Henry, *supra* note 29 (reaffirming that "[t]o recover monetary damages from the infringer, you'll also have to prove the value of a reasonable royalty for the invention.").

[32] *See* Mahaseth, *supra* note 31 (detailing the necessary steps "to obtain a utility patent for an invention [that] claimed subject matter including: (1) be a patent-eligible process, machine, manufacture, or composition of matter, (2) be useful, (3) be novel, (4) be non-obvious, and (5) fulfill the written description and enablement requirements, such that person of ordinary skill in the art can understand, make, and use the invention without engaging in undue experimentation."). *See also Patent*

infringer engaged in an act of infringement, often shown through sales data, Securities Exchange Commission ("SEC") filings, or product demonstrations.[33] Third, the owner must prove that the infringing product or process incorporates all of the distinguishing features of at least one independent claim.[34] It is the duty of the patent owner to enforce their patent by keeping a close eye on the market to ensure nobody is using their protected work without permission.[35]

3. Why Patent Infringement is an Issue for 3D Printed Medical Devices

After years of innovation, 3D printing has revolutionized research and development of the medical device world.[36] Comparable

process overview, *supra* note 17 (describing the different ways to receive a certificate of acknowledgement); Henry, *supra* note 29 (noting that "if you enforce a patent, the defendant (the infringer) will be highly motivated to challenge the patent" and "as a rule of thumb, every defendant in every patent infringement lawsuit will find some reason to challenge validity.").

[33] *See* Maria Luisa Palmese, *Patent litigation in the United States*, WESTLAW (July 1, 2018) (reaffirming that patent infringement must be established by a preponderance of the evidence and therefore, there must be a finding that it is more likely than not that what the party is seeking to prove is true); *see also* Henry, *supra* note 29 (stating "[i]n many industries, many different entities collaborate to produce an end product or service, which creates an opportunity for each individual entity to say, I didn't do it.").

[34] *See* Henry, *supra* note 29 (detailing that in order "[t]o meet these standards, you'll need to do a detailed claims analysis that clearly: (1) explains the contents of your patent claims, and (2) compares the claims to the infringing elements of the competitor's product.").

[35] *See* Braun, *supra* note 29 (recommending that "[i]f you encounter someone infringing on your work, contact them and demand that they cease the infringing activities and perhaps . . . offer to negotiate a license.").

[36] *See* Sheila Mortazavi, *Are There Patent Infringement Implications of 3D Printing PPE to Help Health Care Workers in the War Against COVID-19? Yes.*, HUNTON ANDREWS KURTH (Apr. 2, 2020), *archived at* https://perma.cc/2X9E-38LH (stating that many companies have suggested 3D printing as a solution for addressing the medical device shortage, where "companies and even private citizens with 3D printing capability could manufacture PPE, such as surgical masks and face shields and provide that equipment to health care workers"); Michael Weinberg, *IT WILL BE AWESOME IF THEY DON'T SCREW IT UP: 3D Printing, Intellectual Property, and the Fight Over the Next Great Disruptive Technology*, PUB. KNOWLEDGE (Nov. 2010), *archived at* https://perma.cc/S6JY-Y7MC (explaining that the CAD design process eliminates the need to design physical prototypes out of clay or Styrofoam,

to the traditional manufacturing of medical devices, the 3D printing of medical devices requires several different steps.[37] First, the device must be designed and then digitally converted into a file suitable for printing the device.[38] Next, the medical device must be printed and processed further through cleaning, polishing, and sterilization.[39] Then, the device is verified and tested to ensure that it meets all specifications.[40] Lastly, the device specifications are sent to the Food and Drug Administration ("FDA") for review to determine whether the 3D-printed device is safe and effective.[41] So long as those steps can

and that a designer can use a CAD program to create and manipulate a virtual model that is saved to a file).

[37] *See The Limbitless Arm*, ENABLING THE FUTURE (2014), *archived at* http://perma.cc/KP6L-7LU2 (describing that Enabling the Future is an organization that creates 3D printed hands for children throughout the world who were born with missing hand and fingers, and they have created nearly 2,000 3D printed body parts already); Holbrook & Osborn, *supra* note 6, at 1323 (stating that "as quality 3D printers begin to make their way into the average person's home, the difference between having a CAD file and having the physical object, will become increasingly inconsequential.").

[38] *See* Daniel H. Brean, *Asserting Patents to Combat Infringement via 3D Printing: It's No "Use"*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L. J. 771, 781 (2013) (noting that "[f]actories, warehouses, product transportation infrastructure, and storefronts can potentially be replaced with a directory of CAD files and a website in a number of industries.").

[39] *See* Mortazavi, *supra* note 36, at 3 (describing the required steps of the 3D printing of medical devices); *see also* Antonio Gloria, *The Role of 3D Printing in Medical Applications: A State of the Art*, HINDAWI (Mar. 21, 2019), *archived at* https://perma.cc/CPY9-A37Z (demonstrating "a deep research of the 3D printing applications in medical field the usefulness and drawbacks and how powerful technology it is.").

[40] *See* Jamie Bell, *Will hospitals use 3D printing to take greater ownership of supply chains after COVID-19 crisis?*, NS MED. DEVICES (May 29, 2020), *archived at* https://perma.cc/WFK4-R7X6/ (stating that this push of 3D printing pressure has demonstrated the dynamism of the industry and highlights one of 3D printing's biggest benefits, being able to print on-demand).

[41] *See* U.S. FOOD & DRUG ADMIN., 3D PRINTING OF MEDICAL DEVICES (2020) [hereinafter *3D Printing of Medical Devices*], *archived at* https://perma.cc/ZAA9-6X3B (detailing the regulation by the FDA of 3D printed medical implants and other devices used in the medical field); *see also* U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION (2020) [hereinafter *Emergency Use Authorization*], *archived at* https://perma.cc/W2DE-EA34 (explaining section 564 of the Federal Food, Drug, and Cosmetic Act where the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases). *See*

be followed in a timely manner, patent law does not infringe upon the 3D printing of medical devices, however this process was uprooted after COVID-19 swept through the nation.[42]

Prosecuting patent infringement brought on by such a widespread or decentralized production of patent medical devices is exceptionally challenging for patent holders.[43] One of the unique features of 3D printing is the difference between the digital and physical version of a patented device.[44] While an individual who makes a digital version of a medical device may not be a direct infringer, that individual could still be an indirect infringer by distributing the digital version to others who then 3D print the physical device.[45] In other industries, the lack of 3D printing regulation may be overlooked, but for the medical field, the lack of guidance is particularly fatal to the welfare of society.[46]

---

also Xirui Zhang et al., *The Interplay Between the FDA Regulatory Process for Medical Devices and Patent Law – Considerations for 510(k) Submission*, FINNEGAN (Aug. 4, 2020), *archived at* https://perma.cc/AXQ8-H5Y7 (detailing that "after all, by its nature, a 510(k) summary claims substantial equivalence to a legally marketed device, commonly known as a 'predicate device.'").

[42] *See* Ebrahim, *supra* note 15, at 45 (stating "further evaluation of patent infringement in the 3D printing context is needed, especially since the brink of the 3D printing explosion is now occurring.").

[43] *See* Mortazavi, *supra* note 36 (noting that all regulatory gaps apply "not just to 3D printing of PPE but also to any device that may be useful during the COVID-19 pandemic, such as parts used in ventilators or respirators"); *see also* Ebrahim, *supra* note 15, at 48 (stating "[t]he widespread digitization, diffusiveness, and decentralization of CAD files for 3D printing create challenges for protecting patent owners.").

[44] *See* Holbrook & Osborne, *supra* note 6, at 1323 (citing Niks v. Marinette Paper Co., 11 F.R.D. 384, 385 (N.D.N.Y. 1951)) (indicating that "blueprints of a physical device alone are not sufficient to find patent infringement"). There is a unique nature of patent infringement with 3D printing and how it is due to the difference between the digital and physical version of the patented device. *Id.* at 1354.

[45] *See* Luten v. Camp, 221 F. 424, 429 (E.D. Pa. 1915) (noting that "[t]he materiality and relevancy of the contract and blueprints is dependent upon the plaintiff establishing (1) that they infringe, and (2) that they were produced by or under the direction of any of the defendants leading up to the contract, or are part of a contract entered into between any of the defendants."); *see also* Holbrook & Osborne, *supra* note 6, at 1371 (recognizing that "[o]f course, because CAD files can be transmitted directly to purchasers for remote printing, the costs of distributing final products be greatly reduced as well.").

[46] *See* Matthew Bultman, *3D Printing Ingenuity During Coronavirus Comes With IP Risks*, BLOOMBERG L. (Apr. 1, 2020), *archived at* https://perma.cc/C678-FU54

A. 3D Printed Medical Devices & the Race Against COVID-19

Companies of all sizes, including Ford and Volkswagen, are fighting the COVID-19 pandemic by placing their usual operations on hold, and using their equipment in never-before-seen ways.[47] "The strengths of 3D printing - be anywhere, print virtually anything, adapt on the fly - make it a capability for helping address shortages of parts related to shields, masks, and ventilators, among other things," said Stratasys CEO, Yoav Zeif.[48] COVID-19 has not changed the FDA's 2017 guidance for the 3D printing of medical devices, although, the FDA has recognized that 3D printing has been useful in combatting medical shortages during the COVID-19 pandemic.[49] Without the proper FDA regulations, several medical device companies are risking the future of their operations by expressly waiving their patent rights

(stressing that "[i]t would be impractical for a patent owner to sue everyone printing supplies on a small scale out of their home or business . . ."); *see also 3D Printing of Medical Devices*, *supra* note 41 (emphasizing that "[d]ue to its versatility, 3D printing has medical applications in: Medical devices regulated by FDA's Center for Devices and Radiological Health (CDRH), Biologics regulated by FDA's Center for Biologics Evaluation and Research, and Drugs regulated by FDA's Center for Drug Evaluation and Research.").

[47] *See* Condon, *supra* note 2 (stating, "[a]s the COVID-19 outbreak worsens . . . makers of 3D printers like Stratasys and HP, as well as their customers – to put their tools to work in completely new ways."); *see also* Doherty, *supra* note 10, at 357 (reporting that "[l]arge-scale industrial manufacturers . . . have demonstrated an interest in exploiting the [3D] printing technology.").

[48] *See* Press Release, Stratistics Market Research Consulting, 3D Printing Medical Devices (Oct. 20, 2016) [hereinafter Press Release], *archived at* https://perma.cc/ZA2L-QNRS (expecting that North America could hold the largest share in the 3D printing global market); *see also* Kerns, *supra* note 3 (highlighting specific achievements that 3D printing has made in the medical field with examples including hearing aids, Invisalign, and prosthetics). *See* Condon, *supra* note 2 (stating that "Stratasys' workforce and partners are prepared to 'work around the clock to meet the need for 3D printers, materials, including biocompatible materials, and 3D-printed parts.'").

[49] *See 3D Printing of Medical Devices*, *supra* note 41 (explaining that "due to the versality of 3D printing, it has medical applications regulated by the FDA's Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, and the Center for Drug Evaluation and Research."); *see also* Press Release, *supra* note 48 (providing that "stringent regulations on medical devices to get approvals and high costs of 3D-printed organs are expected to hinder the market.").

for ventilators, PPE, and other medical devices.[50] On March 17, 2020, the secretary of the Department of Health and Human Services ("HHS") issued a declaration protecting entities that took steps to combat the coronavirus crisis from claims for "any type of loss".[51] In another attempt to remedy the scarcity of materials, former President Donald Trump issued an executive order on March 18, 2020, that categorized "personal protective equipment and ventilators" as "scarce and critical material essential" to the national defense under the Defense Production Act of 1950.[52]

The HHS Declaration and Defense Production Act have been unsuccessful at protecting patent infringement liability of medical device manufacturers.[53] Other governments around the world including those in Germany, the United Kingdom, Canada, and Israel, have all taken measures to completely bypass medical device patents, allowing for the 3D printing of medical devices by any party interested

[50] *See Emergency Use Authorization*, *supra* note 41 (stating that "under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives."); *see also* Condon, *supra* note 2 (detailing that "Protolabs, the Minnesota-based digital manufacturer . . . [has waived] expedite fees for medical companies to get orders out the door as quickly as possible and [additionally, has partnered] with organizations to produce innovative new designs.").

[51] *See 3D Printing of Medical Devices*, *supra* note 41 (emphasizing that the 3D printing of medical applications is regulated by FDA's center for devices and radiological health center).

[52] *See* Exec. Order No. 13,909, 85 Fed. Reg. 16,227 (Mar. 18, 2020) [hereinafter *Executive Order*], *archived at* https://perma.cc/YUG8-UKVN (explaining that former President Donald Trump issued an executive order declaring "personal protective equipment and ventilators" as scarce and critical material essential to the national defense under the Defense Production Act of 1950).

[53] *See* Megan Mahoney, *No Good Deed Goes Unpunished: How 3D Printing Medical Supplies During Global Pandemic Could Lead to Patent Infringement*, FORDHAM I. P. L. J. (Apr. 15, 2020), *archived at* https://perma.cc/F2LH-SV2S (guaranteeing that "patent owners of medical technologies likely have infringement claims against those who 3D print a patented device, as well as those who use the device[s]."). "Patent owners also have a legal claim for indirect infringement, which could create liability for those who [actively induce infringement by] providing 3D printing instructions for patented devices." *Id.*

in doing so.[54] Many medical device companies have taken it upon themselves to waive their patent rights in order to allow collaboration among the medical device manufacturers, permitting the mass production of necessary medical equipment during the COVID-19 pandemic.[55] Although the good faith effort made by large corporations is encouraging, absent any government immunity, patent infringement liability remains a risk to any medical equipment manufacturer, regardless of their lifesaving intention.[56]

III. Facts

A. The Challenges of Patenting 3D Devices

The unique nature of patent infringement associated with 3D printing is due to the difference between the digital and physical version of the patented device.[57] Typically, patents only cover the

[54] *See* Quicker, *supra* note 2 (indicating that "many scientists and lawmakers are urging the World Health Organization to set up a voluntary system for companies to 'pool' their patents and to create compulsory government use licenses that override a company's patent rights.").

[55] *See COVID-19 Supply Chain Response*, NIH 3D PRINT EXCHANGE (Oct. 15, 2020), *archived at* https://perma.cc/9L8N-EQLE (demonstrating that the National Institute of Health (NIH), the FDA, the Veterans Health Administration, and America Makes created an NIH-hosted website that provides a collection of designs for 3D-printed PPE). *See also* Ebrahim, *supra* note 15, at 53 (stating that "the economic interest argument should not drive a determination of infringement under § 271(a) . . . [by] removing the economic motivation and focusing on whether there is economic harm to the patentee would be a better criteria of determining whether a CAD file that can directly print an object would be considered to be an offer for sale.").

[56] *See* Mahoney, *supra* note 53 (postulating that "for many, the risk of liability is not a concern when compared to the benefit of saving lives. Although one can hope that patent owners would not put money above mankind during a pandemic, 3D printing volunteers should be aware of the potential risks."); *see also* Ebrahim, *supra* note 15, at 67 (tracing that "Congress should focus on other ways that limit digital patent infringement liability to prevent the pending litigation between patent owners and 3D printing users and CAD-file sharing websites and '3D printing services' businesses.").

[57] *See* Holbrook & Osborn, *supra* note 6, at 1362 (stating that "[w]hether the device was 'tangible' at the time it was transferred is inconsequential from the view of the patentee's interests."). Furthermore, "[b]ecause the CAD file can be printed with ease in the privacy of a home or business, the patentee does not care whether it was printed before the transfer or after." *Id.* Additionally, ". . . the transfer of the CAD

tangible object, not the digital blueprint of the object.[58] Federal courts have provided helpful rulings to understand what part of an object is entitled to patent protection, demonstrated in *Niks v. Marinette Paper Co.*, the Northern District Court New York held that blueprints of a physical device alone are not sufficient to find patent infringement.[59] Additionally, in *Luten v. Camp*, the Eastern District Court of Pennsylvania clarified the elements that a plaintiff must establish when relying on the materiality and relevancy of blueprints.[60] To prevail on a claim that blueprints are entitled to patent protection, a Plaintiff must prove: first, the manufactures have infringed; and second, that they were produced by or under the direction of any of the defendants leading up to the contract, or are part of a contract entered into between any of the defendants.[61]

file is potentially more harmful to the patentee because that CAD file can be copied and further distributed to many more users." *Id.*

[58] *See* Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contrs. USA, Inc., 617 F.3d 1296, 1312 (5th Cir. 2010) (stating that infringement would hold even if the device was never constructed or was constructed in a modified way to avoid infringement). The court refused to allow subsequent design modification to avoid infringement, stating, "[t]he potentially infringing article is the rig sold in the contract, not the altered rig that Maersk USA delivered to the U.S." *Id.* at 1311.

[59] *See* Niks v. Marinette Paper Co., 11 F.R.D. 384, 385 (N.D.N.Y. 1951) (outlining the facts of the case); Holbrook & Osborn, *supra* note 6, at 1365 (stating "[t]he amount of effort, skill, and resources required to translate the blueprint into the actual invention convinces us that mere blueprints should not constitute infringement for making the claimed invention.").

[60] *See* Luten v. Camp, 221 F. 424, 429 (E.D. Pa. 1915) (explaining that if these blueprints are in the possession of the defendants, the plaintiff is entitled to have an order made for their production and inspection).

> [A]s the blueprints themselves are the best evidence of their contents, the defendants cannot be required in advance of the trial to furnish copies, nor can they be questioned as to their contents unless the originals, being in their possession, are not produced, or unless the originals are shown to have been destroyed or lost, or to be beyond the power of the plaintiff to produce.

Id.

[61] *See id.* (stating that "the question of infringement cannot be determined, except at the trial, it would be impracticable at this time to pass upon the relevancy or materiality of the questions relating to defendants' connection with the blueprints and with the contract.").

1. Direct Infringement

Direct patent infringement arises when someone without authorization makes, uses, sells, offers to sell or imports the patented invention to the United States.[62] Direct infringement typically deals with the physical form of a device, but recently infringement has also begun to include the sale of patented inventions solely based on their blueprint diagrams and schematics.[63] Lines become blurred when digital files, that can be used to directly print operable physical objects, also infringe on the patent claims.[64] Typically, blueprints and molds are not be considered part of the "making" of an invention, and therefore patent owners have been unsuccessful in proving that a digital file is the equivalent of making a patented invention.[65]

---

[62] *See* 35 U.S.C. § 271(a) (2012) (detailing the definition of patent infringement and what it entails); *see also* Timothy R. Holbrook, *Territoriality and Tangibility After Transocean*, 61 EMORY L. J. 1087, 1091 (2012) (clarifying that "it is now possible to find a party liable for infringement even though no sale is ever concluded in the United States, so long as the negotiations contemplate a future sale in the United States."); *see also* Ebrahim, *supra* note 15, at 50 (asserting that "an alternative way to assert direct infringement against the user could be based on use or creation of the digital files themselves.").

[63] *See* Holbrook & Osborn, *supra* note 6, at 1354 (highlighting that historically, direct patent infringement by making, using, or importing the invention was tied to physical inventions, and infringing sales and offers to sell the invention have been based on the economic value of the invention and not the physical embodiment of the invention).

[64] *See* Nicole A. Syzdek, *Five Stages of Patent Grief to Achieve 3D Printing Acceptance*, 49 U.S.F. L. REV. 335 (2015), *archived at* https://perma.cc/D8C4-B9YT (stating that "[a] user's actions fail to trigger direct infringement under § 271(a) unless the physical patented product is, in fact, printed."); *see also* Doherty, *supra* note 10, at 360 (assuming that a user would not be "liable for uploading the CAD file, though she may be liable for any copies of the object that she printed in the process of developing her design").

[65] *See* Holbrook & Osborn, *supra* note 6, at 1367 (suggesting that blueprints and molds did not historically constitute the "making" of a claimed invention; however, the creation of an object from a file is simple and routine, with the interest in the CAD files being the object itself and not the files); *see also* Sam Dillon, *Infringement by Blueprint: Protecting Patent Rights in a World of Low-Cost 3D Printing*, 42 AIPLA Q. J. 425, 443 (2014) (stating "[b]ut direct infringement of a patent covering an object would not occur when someone creates . . . a [CAD file] of that object").

2. Indirect Infringement

In order to further protect patent owners, patent law affords protection against indirect patent infringement, which arises when a third party is held liable for the actions of others who are directly infringing on that patent.[66] United States law provides two forms of indirect infringement: active inducement of infringement and contributory infringement.[67] Active induced infringement is defined as "aiding and abetting another's direct infringement" and requires a showing that the defendant had the specific intent to cause another to infringe upon the patent claims.[68] Contributory infringement may include the sale of a patented machine, manufacture, combination or composition, or the sale of a material or apparatus for use in practicing a patented process.[69] The doctrines of indirect infringement are

[66] *See* Timothy R. Holbrook, *The Intent Element of Induced Infringement*, 22 SANTA CLARA HIGH TECH. L. J. 399, 400–01 (2006), *archived at* https://perma.cc/C5PZ-3EPX (noting that "[a] party is liable as an infringer if she supplies a component of a patented device 'knowing the same to be especially made or especially adapted for use in an infringement of such patent . . .'").

[67] *See* 35 U.S.C. § 271(b)–(c) (2012) (detailing who exactly would be considered a patent infringer and what they must do to be considered one). *See also The Intent Element of Induced Infringement*, *supra* note 66, at 400 (stating that "[l]iability for active inducement of infringement and contributory infringement are variations of third-party liability, where one party is held liable for the directly infringing acts of others."); Charles W. Adams, *A Brief History of Indirect Liability for Patent Infringement*, 22 SANTA CLARA COMPUT. & HIGH TECH. L. J. 369, 370 (2006) (providing that "[e]ven after being codified, the precise extent of the branch of contributory infringement and inducement of infringement remains unclear . . .").

[68] *See* Nat'l Presto Indus., Inc. v. W. Bend Co., 76 F.3d 1185, 1194 (Fed. Cir. 1996) (detailing that the statutory liability for inducement of infringement derives from the common law, wherein acts that the actor knows will lead to the commission of a wrong by another, place shared liability for the wrong on the actor); *see also* Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd., 545 U.S. 913, 931 (2005) (detailing where an article is "good for nothing else" but infringement, there is no legitimate public interest in its unlicensed availability, and there is no injustice in presuming or imputing an intent to infringe).

[69] *See* Patent Act of 1952, ch. 950, 66 Stat. 792-814 (lays out the elements for contributory infringement); *Grokster*, 545 U.S. at 931 (clarifying that the doctrine was devised to identify instances in which it may be presumed from distribution of an article in commerce that the distributor intended the article to be used to infringe another's patent, and so may justly be held liable for that infringement).

stronger than ever and, recently the Supreme Court extended them to cover infringement through the use of file sharing on the Internet.[70]

B. The Patent Infringement Challenges for Medical Device Manufacturers

As the use of 3D printed medical devices continues to surge, the risk of patent infringement liability to medical device manufacturers will follow.[71] Unlike traditional forms of technology, medical devices require clinical studies, peer reviews, and years of research and development while also being subject to FDA regulations which comes at a significant cost to manufacturers before the product can hit the market.[72] Development costs of medical devices are extremely high compared to the low manufacturing costs, often due to

[70] *See* Adams, *supra* note 67, at 396 (stating that the *Sony* Court evidently found that it was unnecessary to address Sony's potential liability for inducing infringement using an analogy to §271(b) because of the conclusion in its footnote that Sony did not intentionally induce its customers to infringe the copyrights on the television programs that the plaintiffs owned); *see also Grokster*, 545 U.S. at 931 (maintaining that with no evidence of stated or indicated intent to promote infringing uses, the only conceivable basis for imposing liability was on a theory of contributory infringement arising from Sony's sale of VCRs to consumers with knowledge that some would use them to infringe).

[71] *See Refurbishment of Medical Devices*, *supra* note 21 (stating that unlike the issues raised by the applicability of FDA's new quality system regulation to remanufacturers, the patent infringement issue is not new, but its importance to the device industry has been growing). *See also* Kristopher Sturgis, *Examining Intellectual Property Concerns In Medical Device Development*, MD&DI (Nov. 18, 2016), *archived at* https://perma.cc/GV4J-GD29 (stating that when it comes to designing and developing new medical device technologies, identifying and protecting intellectual property is often an overlooked step that can have serious consequence).

[72] *See id.* (stating that unlike the high-tech market, where a new product may cost five to ten million to develop, in med tech a high margin product such as an arterial stent, which has relatively low manufacturing costs, may cost upwards of $50 million to develop due to clinical studies and other FDA requirements). Additionally, the patent claims have to be sufficiently broad enough to prevent design-arounds for the same reasons, since claims that are too narrow allow the competition to sell similar products that do not infringe your patent. *Id.* Lastly, is the challenge of defining and then articulating in the patent what makes your product better than existing products or technologies, which is particularly important in areas where there is a lot of prior art (e.g. patents), or so-called crowded art areas. *Id.*

the regulatory requirements of the medical technology industry.[73] Costs associated with patenting devices are also high, as well-thought-out claims must be written such that they are sufficiently broad enough to prevent design-arounds in order to fend off copying and create barriers for competitive products.[74] Additionally, the patent must articulate what makes the product different than existing products or technologies.[75] Finally, patent claims in the medical device industry must take into consideration how that device will interact with the human body.[76]

The FDA requires medical product applicants perhaps the most important element needed to bring the product into the market: assuring the public that a new product is safe and effective.[77] Due to the important physical implications, the medical field is both highly

[73] *See Refurbishment of Medical Devices*, *supra* note 21 (stating that the patent infringement issue is nothing that has not been seen before, but its importance to the device industry has been growing); *see also* Sturgis, *supra* note 71 (stating that patents are absolutely essential to prevent copying and to create barriers to entry for competitive products).

[74] *See* Denise L. Mayfield, *Medical Patents and How New Instruments or Medications Might Be Patented*, MO. MED. (Dec. 2016), *archived at* https://perma.cc/FFQ2-VUHG (noting that medical patents will be defined broadly to include patents that relate to pharmaceuticals; methods of making and using them; medical treatment regimens; surgical procedures; medical devices; health care information technology for hospital; and health care management systems). *See also* Sturgis, *supra* note 71 (claiming that because patent claims can be too narrow, they consequentially allow the competition to sell similar products that do not infringe upon their patent).

[75] *See* Sturgis, *supra* note 71 (maintaining that this is particularly important in areas where there is a lot of prior art (e.g. patents), or so-called crowded art areas); *see also* Alison DeNisco Rayome, *5 common misconceptions businesses have about technology patents*, TECHREPUBLIC (Mar. 29, 2018), *archived at* https://perma.cc/9C3F-3WS2 (stating that the mere fact that a product may have an associated patent application pending, or even an issued patent for that matter, does not mean that the product works better than existing products).

[76] *See* Sturgis, *supra* note 71 (detailing that these claims are accomplished through the use of methods claims, which do not claim the device per se, but rather how the device interacts with the body and/or the result achieved, differentiating the device from all medical devices).

[77] *See* Mayfield, *supra* note 74 (stipulating that the FDA approval process requires compliance with rigorous testing programs (clinical trials) and compliance with a lengthy administrative approval process and is most times very costly); *see also* Julia Kagan, *Biotechnology Intellectual Property Rights*, INVESTOPEDIA (Feb. 11, 2021), *archived at* https://perma.cc/S3S6-PPLW (noting that a patent is a type of intellectual property right and a key driver of value for biotech companies).

regulated and competitive, resulting in new products only holding market shares for a short period of time.[78] Society currently faces substantial concerns regarding the cost of healthcare, where a considerable number of important patent concerns still remain unaddressed.[79] However, new innovations and cost-effective treatments cannot be delayed until a solution can be found.[80] The FDA is currently deficient in enforcing regulatory requirements on new devices, implementing more balanced requirements for market clinical data, and leveraging market forces to reward technology with the greatest value to patients.[81]

C. How the COVID-19 Pandemic Exacerbated the Issue of Patenting Medical Devices

As the COVID-19 outbreak swept the globe, medical manufacturers were unable to keep up with the demand for lifesaving medical equipment.[82] An Italian company held a patent for valves

---

[78] *See Safeguarding Your Medical Patent Portfolio*, MAIER & MAIER PLLC (Nov. 12, 2020), *archived at* https://perma.cc/5HAD-CJ8C (clarifying that it is all the more important to craft an effective and extensive patent protection strategy); *see also* JOSH MAKOWER ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION 8 (Nov. 2010), *archived at* https://perma.cc/FT24-TPL8 (indicating that unpredictable, inefficient, and expensive regulatory processes put the U.S. at risk of losing its global leadership position in med-tech innovation).

[79] *See* MAKOWER, *supra* note 78, at 42 (reaffirming that regulatory processes in Europe have remained relatively constant, making them a valuable comparator for our own regulatory performance in the U.S., it is clear from the data that the European regulatory process is more predictable, reasonable, and transparent, the system also allows companies to make safe and effective new medical products available to patients more quickly, and at a lower cost).

[80] *See* Innovative Therapies, Inc. v. Kinetic Concepts, Inc., 599 F.3d 1377, 1382 (Fed. Cir. 2010) (stating that courts have repeatedly refused to allow FDA 510(k) notification of substantial equivalence as admission of infringement in patent cases); *see also* MAKOWER, *supra* note 78, at 8 (clarifying that the European system also allows companies to make safe and effective new medical products available to patients more quickly, and at a lower cost).

[81] *See* MAKOWER, *supra* note 78, at 42 (observing that only when the FDA imposes reasonable regulatory requirements, will the most effective advances in medical care be developed and delivered promptly to American patients, and only then will the public health and our economy be best served).

[82] *See* Ebrahim, *supra* note 15, at 48 (reasoning that the combination of advancements in printing technology, the prevalence of more powerful computers,

used in respirator machines, which were critical to the survival of patients suffering from coronavirus.[83] Due to surging demands during the pandemic, the company was unable to fill all orders, but refused to share the design file with engineers seeking to help.[84] Two engineers from Northern Italy were able to create a digital version of the valve, producing over one hundred valves and saving hundreds of lives.[85] In almost every case, the patent covers only the tangible object and not the digital version and therefore, by merely creating a 3D printable file of the valves, the Italian engineers did not engage in an act of direct infringement.[86] "The patients were people in danger of death, and we acted. Period," claimed the Italian engineers.[87]

Contrary to the success of these Italian engineers, COVID-19 exposed the hypocrisy of patent laws in the United States, that sought to limit accessibility to patented devices while increasing corporate profits during a public health emergency.[88] Those who hold patents

and the growing market demand for 3D printed objects has caused a recent explosion of 3D printing technology into the mainstream consumer market).

[83] *See* Rantanen, *supra* note 5 (clarifying that an Italian company had a PR disaster when they held a patent on a valve used in breathing machines critical for coronavirus patients and could not meet the surging demands for its valves, refusing to allow other manufacturers to use their patent).

[84] *See* Jay Peters, *Volunteers produce 3D-printed valves for life-saving coronavirus treatments*, THE VERGE (Mar. 17, 2020), *archived at* https://perma.cc/5LXJ-XAGC (reporting that a group of Italian volunteers distributed 3D-printed versions of a vital medical device, although it does not appear that the original manufacturer threatened a legal crackdown).

[85] *See* Rantanen, *supra* note 5 (stating, "[i]n a remarkable testament to the speed and flexibility of 3D printing technology, on the same day the engineers learned about the shortage of valves, they were able to create a digital version of the valve and 3D print working valves.").

[86] *See id.* (maintaining that "[c]reators of 3D printable files, especially those with knowledge of a relevant patent, should be wary in making them available for others on the internet.").

[87] *See* Peters, *supra* note 84 (noting that the Italian engineers had no intention of profiting off of this situation, they were simply using the designs or products beyond the strict need for them to act, with no intention of spreading the drawing or blueprints to other manufacturers).

[88] *See* Enrico Bonadio & Andrea Baldini, *COVID-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health*, NCBI (Apr. 11, 2020), *archived at* https://perma.cc/3QMK-J995 (observing that "[w]hile IP laws are certainly crucial as they incentivize the development of (often) vital drugs, they are far from perfect, and may very well require further adjustment or reform to meet overarching public interests. The solution is not to erode the mutual trust required to make international public health cooperation work.").

on technologies critical to COVID-19 responses could easily take economic advantage by creating a monopoly.[89] For more than a century, the law has allowed the government to appropriate any invention necessary or required for natural defense, without previous arrangements or negotiation with the owner.[90] Federal leaders must be prepared to use all tools available to overcome patents that interfere with the response to the pandemic .[91]

Actions that contest pharmaceutical monopolies, rather than encourage them, are necessary to protect public health.[92] The Trump administration previously filed a lawsuit alleging that Gilead Sciences, Inc. has profited from research funded by hundreds of millions of taxpayer dollars by selling HIV drugs back to the American public at

[89] *See* Christopher Morten & Charles Duan, *The tension between public health and patents in the era of COVID-19*, STATNEWS (Apr. 14, 2020), *archived at* https://perma.cc/DS9B-WJ72 (explaining that "patents can block others from using these inventions, even when those other uses may be the key to stopping infections and saving human lives."). Technologies include vaccines, diagnostic tests, computer models, ventilators, and more. *Id.*

[90] *See* Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH. 275, 299 (2017) (noting that "[t]he House Committee on Patents' Report accompanying the bill reveals that the law was clearly understood not only to excuse inadvertent infringement, but also to permit the government to intentionally infringe patents to secure benefits for the public[.]"); *see also* Christopher J. Morten & Amy Kapczynski, *United States v. Gilead: Can a Lawsuit Yield Better Access To PrEP?*, HEALTHAFFAIRS (Nov. 18, 2019), *archived at* https://perma.cc/DG3S-88XR (explaining that "the U.S. government very rarely goes to court to enforce its patents, and the suit marks the boldest step the government has ever taken to recoup some portion of the enormous profits a pharmaceutical company has earned after privatizing publicly funded research.").

[91] *See, e.g.*, 56 CONG. REC. 8780 (1910) (statement of Rep. Dalzell) (stating that no one will contend that the Government ought to be prohibited from appropriating to its use any patent that it deems to be necessary, in the interest of the public service).

[92] *See* Alex Moss & Elliot Harmon, *The Feds Can Stop Patent Trolls from Endangering COVID-19 Testing and Treatment*, EFF (Mar. 25, 2020), *archived at* https://perma.cc/TJ6Q-MK3L (providing that "[n]onprofit researchers have developed low-cost tests for COVID-19—truly life-saving innovation—that companies like Labrador could block by asserting their patents and thus invoking their right to exclude. Fortunately, the U.S. government can do something about it. 28 U.S.C 1498 allows the government to use or authorize others to use any invention 'described in and covered by a patent of the United States.'").

very high prices.[93] Although the federal government plays a vital role in policing the use of patents, State regulation is equally as important.[94] Courts have interpreted the states' reserved powers under the Tenth Amendment to include police powers, such as the authority to take action in response to a public health emergency.[95] States that were hit the hardest by COVID-19, or best positioned to combat price gouging or shortages, have the advantage of sovereign immunity or manufacturing their own materials, especially if the federal government is unwilling or gridlocked.[96] As Americans have learned in the past and are remembering now, protecting the people of our country requires a firm government, willing to stand up to powerful patent interests and prioritizing the health of their citizens.[97]

---

[93] *See* Morten & Kapczynski, *supra* note 90 (detailing that "HHS's press release observes that 'Gilead has profited from research funded by hundreds of millions of taxpayer dollars and reaped billions from PrEP through the sale of Truvada® and Descovy®.' HHS's lawsuit suggests that we are in a new political era: the long-running status quo in which Americans pay twice for prescription drugs—first as their tax dollars fund research into new medicines and again as they pay for those medicines— may no longer be stable.").

[94] *See* Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 636 (1999) (stating that "Congress may not abrogate state sovereign immunity pursuant to its Article I powers; hence the Patent Remedy Act cannot be sustained under either the Commerce Clause or the Patent Clause"); Morten & Duan, *supra* note 89 (noting that "[u]nder constitutional principles of federalism and sovereign immunity, states may not be liable for patent infringement as long as they offer adequate compensation for doing so.").

[95] *See* Morten & Duan, *supra* note 89 (emphasizing that "[u]nder constitutional principles of federalism and sovereign immunity, states may not be held liable for patent infringement as long as they offer adequate compensation for doing so."). States should explore options under sovereign immunity during the COVID-19 pandemic, especially if the federal government is leaving them no other options, as happened during the anthrax crisis. *Id.*

[96] *See Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. at 661 (noting that "the Patent Remedy Act, however, was passed to prevent future violations of due process, based on the substantiated fear that States would be unable or unwilling to provide adequate remedies for their own violations of patent-holders' rights.").

[97] *See* Morten & Duan, *supra* note 89 (explaining that "[r]ather than helping the COVID-19 crisis, history shows that these changes would raise prices, reduce access to medicines and diagnostic tests, inhibit scientific research, and delay innovation."). Furthermore, it only takes one patent to throw a wrench into the public health machine. *Id.*

IV. Analysis

A. The Necessity of Additional FDA Regulations for 3D Printed Medical Technology

As innovative medical technology and the possibilities surrounding 3D printing skyrocket, their pioneering potential is weighed down by the lack of necessary regulations and protections.[98] After providing general recommendations in December 2017, the FDA failed to expand further regulations on the 3D printing industry during the COVID-19 pandemic when medical devices became crucial and PPE equipment became scarce.[99] The specific requirements enacted by the FDA for 3D printing are dependent on the classification of the medical device – Class I, II, or III – with increasing regulatory requirement as the class increases.[100] Comparable to the traditional manufacturing of medical devices, the 3D printing of medical devices involves multiple steps including design, digital conversion,

[98] *See* Quicker, *supra* note 2 (stating that "COVID-19 has not changed the FDA's general recommendations for 3D printing of medical devices from those found in the 2017 guidance."). According to the FDA, "[a]dditive manufacturing is a process that builds an object by sequentially building 2-dimensional layers and joining each to the layer below, allowing device manufacturers to rapidly produce alternative designs without the need for retooling and to create complex devices built as a single piece." *Id.*

[99] *See id.* (noting that an example that the 3D printing industry assists during COVID-19 is by producing PPE to provide a physical barrier, but challenges still remain for the FDA to establish the regulations around a fluid barrier or air filtration of the PPE). Additionally, in the guidance, the FDA discusses design and manufacturing process considerations, device testing considerations, and labeling for the emerging technology of 3D printing medical devices. *Id.*

[100] *See id.* (explaining the three steps associated with the patenting a medical device).

> First, the device must be designed. Then, the device design must be digitally converted into a buildable file and sent to a printer. Third, the appropriate materials must be selected and loaded into the printer. Next, the medical device must be printed. Some devices are then processed further to clean, cool, drill, cut, polish or sterilize them. After the device is finished, most devices must be validated and verified. That is, certain functions may be tested to ensure they meet specifications. Alternatively, process validation ensures that a manufacturing process will produce product that is within defined specifications, as long as specified processing parameters are monitored and controlled.

Id.

appropriate materials, and verification.[101] The last step includes device test results being sent to the FDA for review, in order to determine whether the 3D printed device fulfills the criteria of the FDA as safe and effective for distribution.[102] These extensive regulations slow down the process, causing a hinderance on the efficient eradication of a public health emergency.[103]

The FDA acknowledges that 3D printing provides a benefit in the fight against COVID-19, but with emergency approved technology, the FDA is tasked with the challenge of ensuring patient safety with the use of 3D printed medical devices.[104] As acknowledged by the FDA, 3D printing could be used to combat COVID-19 specifically by producing items such as tubing connectors for multiplexing ventilator use, which are the topic of emergency use authorization for ventilators, ventilator tubing connectors, and ventilator accessories.[105] During the pandemic, medical device

[101] *See Emergency Use Authorization*, *supra* note 41 (explaining section 564 of the Federal Food, Drug, and Cosmetic Act where the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases).

[102] *See* Mayfield, *supra* note 74 (noting that "[t]he FDA approval process requires compliance with rigorous testing programs (clinical trials) and compliance with a lengthy administrative approval process and is most times very costly."); *see also* Kagan, *supra* note 77 (detailing that a patent is a type of intellectual property right and a key driver of value for biotech companies).

[103] *See* Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 627 (1999) (explaining that states are obligated to take a stance and use the power given to them by the Tenth Amendment to stop the spread of the virus and take advantage of the medical technology industry in order to produce required amounts of equipment).

[104] *See* Condon, *supra* note 2 (stating that the more that "the COVID-19 outbreak worsens across the U.S., the urgent need for medical gear has compelled the additive manufacturing industry, including makers of 3D printers like Stratasys and HP . . . to put their tools to work in completely new ways."); *see also* Quicker et al., *supra* note 2 (emphasizing that as "the FDA realizes that 3D printing may increase availability of medical devices, the FDA is willing to discuss potential applications and concerns of 3D printing with manufacturers and facilities.").

[105] *See COVID-19 Supply Chain Response*, *supra* note 55 (demonstrating that the National Institute of Health (NIH), the FDA, the Veterans Health Administration, and America Makes created an NIH-hosted website that provides a collection of designs for 3D-printed PPE). *See also* Ebrahim, *supra* note 15, at 53 (stating that "[t]he economic interest argument should not drive a determination of infringement under § 271(a) . . . [and] should remove the economic motivation and focus on

manufacturers began expressly waiving their patent rights to ventilators and PPE, and even the FDA provided a collection of patented 3D printed designs for PPE to be manufactured, but none of it was enough.[106]

One of the distinguishing challenges of the 3D printing industry is the contrast between the digital and physical version of a patented device.[107] Although individuals are not a direct infringer when making the digital version of the medical device, they could still be an indirect infringer by distributing the digital version to others who then 3D print the physical device.[108] In any other industry, the lack of infringement regulation around 3D printing may be overlooked, but for the medical field, lack of FDA guidance is not an option when it comes to saving human lives.[109] Although the FDA acknowledges the vital impact that 3D printing technology could have on the pandemic, it failed to give 3D printing manufacturers any guidance or immunity

whether there is economic harm to the patentee, which would be a better criteria of determining whether a CAD file be considered to be an offer for sale.").

[106] *See* Quicker et al., *supra* note 2 (noting that "even the National Institute of Health (NIH), the FDA, the Veterans Health Administration, and America Makes created an NIH-hosted website that provides a collection of designs for 3D-printed PPE."). "Nevertheless, at this time there is no immunity from patent infringement liability for individuals and manufacturers that make medical equipment to help with the ongoing pandemic." *Id.*

[107] *See* Niks v. Marinette Paper Co., 11 F.R.D. 384, 385 (N.D.N.Y. 1951) (indicating that blueprints of a physical device alone are not sufficient to find patent infringement); s*ee also* Holbrook & Osborne, *supra* note 6, at 1323 (noting the unique nature of patent infringement with 3D printing and how it is due to the difference between the digital and physical version of the patented device).

[108] *See* Luten v. Camp, 221 F. 424, 429 (E.D. Pa. 1915) (detailing that the relevancy of a contract "is dependent upon the plaintiff establishing (1) that they were infringed upon, and (2) that they were produced by or under the direction of any of the defendants leading up to the contract, or are part of a contract entered into between any of the defendants."); *see also* Holbrook & Osborne, *supra* note 6, at 1371 (noting that "because CAD files can be transmitted directly to purchasers for remote printing, the costs of distributing final products can be greatly reduced.").

[109] *See* Bultman, *supra* note 46 (detailing that "it would be impractical for a patent owner to sue everyone printing supplies on a small scale out of their home or business"). *See also 3D Printing of Medical Devices*, *supra* note 41 (clarifying that due to its versatility, 3D printing has medical applications in "[m]edical devices regulated by FDA's Center for Devices and Radiological Health (CDRH), Biologics regulated by FDA's Center for Biologics Evaluation and Research, and Drugs regulated by FDA's Center for Drug Evaluation and Research").

from patent infringement liability while assisting in the ongoing pandemic.[110]

Without the FDA creating a path for 3D printing in the medical world, the advantages of being able to mass produce medical equipment locally by utilizing 3D printing technology becomes worthless due to the risk of patent infringement.[111] If a 3D printed product is determined to be defective, it will be difficult to determine whether the flaw occurred in the original design, the printing process, or elsewhere.[112] Moreover, there is no guarantee that 3D printed face shields will provide the same level of protection, or that 3D printed ventilators valves can withstand daily use.[113] In order to ensure the quality of 3D printed medical devices, mitigate the risk for the manufacturers, and utilize 3D printing to its full capacity, the FDA must enact regulations related to the 3D printing of medical devices, and provide immunity to those providing equipment in times of global scarcity.[114]

---

[110] *See* Mahoney, *supra* note 53 (highlighting that for many, the risk of liability is not a concern when compared to the benefit of saving lives). "Although one can hope that patent owners would not put money above mankind during a pandemic, 3D printing volunteers should be aware of the potential risks." *Id. See also* Quicker et al., *supra* note 2 (clarifying that "currently there is no immunity from patent infringement liability for individuals and manufacturers that make medical equipment to help with the ongoing pandemic.").

[111] *See* Ebrahim, *supra* note 15, at 48 (noting that "[t]he combination of advancements in printing technology, the prevalence of more powerful computers, and the growing market demand for 3D printed objects has caused a recent explosion of 3D printing technology into the mainstream consumer market.").

[112] *See* Bultman, *supra* note 46 (explaining how using "a defective 3D printed product and pinpointing its origin, whether the flaw was in the original design, the printing process, or somewhere else, could lead to finger-pointing."). "'The goal is not to tell these universities and entities not to do this . . . it's to make sure they understand there are potential gaps in the law and potential liabilities they could incur later if one of these products are found defective or causes an injury to someone.'" *Id.*

[113] *See id.* (stating that the Food and Drug Administration has said it is possible to use 3D printing to make certain parts in short supply but that some complex products might not be easily produced). "It has warned that 3D printed masks, for example, might not provide the same level of protection as traditional masks. Safety risks can arise when organizations or individuals move forward even though they are unaccustomed to making medical supplies and lack quality-control measures." *Id.*

[114] *See* Sturgis, *supra* note 71 (stating that, "[u]nlike the high-tech market, where a new product may cost five to ten million to develop, in med tech a high margin

B. Requirement of Government Immunity During Times of Global Crisis

1. The Role of the Federal Government

While the regulations set forth by the FDA are crucial to the expansion and capabilities of the 3D printing industry, measures taken by the government are equally as important to its potential impact.[115] Notwithstanding an attempt to limit liability for claims of antitrust, the HHS Declaration and Defense Production Act have not successfully protected manufacturers of medical devices from patent infringement liability suits.[116] Although the Trump administration asked companies to retool production lines to produce ventilators and PPE, no affirmative steps have been taken to protect companies from patent infringement lawsuits.[117] If the federal government is unwilling or

product such as an arterial stent, which has relatively low manufacturing costs, may cost upwards of $50 million to develop due to clinical studies and other FDA requirements.").

[115] *See* Quicker et al., *supra* note 2 (clarifying that although the "HHS declaration and the DPA expressly limit liability for certain claims such as product liability, antitrust and breach of contract, neither expressly absolves a manufacturer from patent infringement liability. And though Trump publicly has asked companies to retool production lines to start producing ventilators and PPE, his administration has yet to take affirmative steps that would protect companies from patent infringement lawsuits."). "[O]n March 27, Trump issued another executive order, 'Delegating Additional Authority Under the DPA with Respect to Health and Medical Resources to Respond to the Spread of COVID-19,' which tasks the HHS secretary with increasing the 'domestic industrial base capabilities to produce' health and medical resources." *Id. See also* Executive Order, *supra* note 52 (explaining that Trump issued an executive order declaring "personal protective equipment and ventilators" as scarce and critical material essential to the national defense under the Defense Production Act of 1950).

[116] *See* Mahoney, *supra* note 53 (maintaining that "[p]atent owners of medical technologies likely have infringement claims against those who 3D-print a patented device, as well as those who use the device."). "Patent owners also have a legal claim for indirect infringement, which could create liability for those who "actively induce infringement" by providing 3D printing instructions for patented devices." *Id.*

[117] *See* Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 651 (1999) (Stevens, J., dissenting) (noting that the HHS declaration and the DPA expressly limit liability for certain claims like product liability, antitrust, and

gridlocked, states that were hit hardest by COVID-19 are best positioned to combat price gouging or shortages, and therefore these states are responsible for exploring their options under sovereign immunity or the local manufacturing of medical equipment.[118]

Contrary to other governments around the world that have taken measures to bypass medical device patents entirely, the United States has failed to make an equivalent effort.[119] The United States should implement similar methods as those of the German government that has limited the patent rights of medical devices in view of the global pandemic.[120] Actions taken by Germany, Israel, and other countries to use compulsory licenses as a tool to limit intellectual property in the event of a public health emergency, could also prove to be beneficial to the United States.[121] The United States needs to be protected by a secure government, willing to accommodate the law and put measures in place to mitigate infringement repercussions, in order to enhance the success rate of the fight against COVID-19.[122]

---

breach of contract, never expressly absolving a manufacturer of patent infringement liability, the main issue present).

[118] *See id.* at 662 (Stevens, J., dissenting) (observing that "[t]he Patent Remedy Act, however, was passed to prevent future violations of due process, based on the substantiated fear that States would be unable or unwilling to provide adequate remedies for their own violations of patent-holders' rights.").

[119] *See* Quicker et al., *supra* note 2 (stating that "many scientists and lawmakers are urging the World Health Organization to set up a voluntary system for companies to 'pool' patents and to create compulsory government use licenses that override a company's patent rights.").

[120] *See* Bonadio & Baldini, *supra* note 88 (detailing that in addition to Germany's attempt to limit patent laws, "the Chilean parliament and Ecuador's National Assembly have adopted resolutions that would pave the way for the issuance of compulsory licenses to tackle the coronavirus outbreak.").

[121] *See id.* (expanding on Israel's strategies, by stating that "in the wake of the coronavirus crisis, in March 2020, Israel issued a compulsory license in relation to Kaletra, an HIV medicine that is currently being tested for effectiveness in the treatment of COVID-19.").

[122] *See* Morten & Duan, *supra* note 89 (explaining that "rather than helping the COVID-19 crisis, history shows that these changes would raise prices, reduce access to medicines and diagnostic tests, inhibit scientific research, and delay innovation . . . [i]t only takes one patent to throw a wrench into the public health machine.").

2. The Strategic Outlay to Combat a Medical Device Monopoly

Companies that hold patents on technologies critical to the fight against COVID-19, including vaccines, diagnostic tests, computer models, ventilators and more, could easily take economic advantage against companies attempting to manufacture similar lifesaving equipment.[123] Federal leaders are elected to protect and serve United States citizens, and are obligated to use all tools available to protect medical manufacturers from law suits that interfere with critical pandemic responses.[124] Federal leaders should enact these four strategies to successfully combat pandemic challenges: first, utilize the law to interfere with the pandemic response; second, avoid pro-patent positions; third, encourage states to utilize state sovereignty; and fourth, be wary of a potential patent monopolies on medical devices.[125]

Under the first strategy, federal leaders must use all tools available to interfere with the pandemic response such as, utilizing the

---

[123] *See id.* (noting that "patents can block others from using these inventions, even when those other uses may be the key to stopping infections and saving human lives.").

> Already, Labrador Diagnostics has used a patent lawsuit (since dropped) to try to block a COVID-19 testing firm, and another patent holder may have threatened an Italian hospital trying to repair ventilators. If the United States is attempting to finally put a stop to this pandemic as quickly as possible, it needs to brace itself against profit-motivated patent assertion that could harm public health.

Id.

[124] *See, e.g.*, 56 CONG. REC. 8780 (1910) (statement of Rep. Dalzell) (stating that "[n]ow, I assume no one will contend that the Government ought to be prohibited from appropriating to its use any patent that it deems to be necessary, in the interest of the public service.").

[125] *See* Bonadio & Baldini, *supra* note 88 (emphasizing the importance of managing IP protection and patent regimes with great care, and the willingness to occasionally set aside financial considerations in favor of ethical or moral concerns, especially in times of global health emergencies like the COVID-19 pandemic).

> While IP laws are certainly crucial as they incentivize the development of (often) vital drugs, they are far from perfect, and may very well require further adjustment or reform to meet overarching public interests. The solution is not to erode the mutual trust required to make international public health cooperation work.

Id.

law that has allowed the government to employ any invention necessary during a global health emergency, without previous arrangement or negotiation with the owner.[126] Second, federal leaders must avoid pro-patent positions, that could possibly limit the ability to respond swiftly to times of crisis.[127] An example of this impressive effort was made by the Trump Administration, when they filed a lawsuit claiming that Gilead has profited hundreds of millions of dollars by selling HIV drugs to the American public at obscenely high prices, bringing attention to the issue of monopolization in the medical field.[128]

Third, individual states play a vital role in policing the use of patents by utilizing the constitutional principles of sovereign immunity and providing adequate compensation to companies who have waived their medical device patents to assist during the pandemic.[129] Lastly,

---

[126] *See* Brennan, *supra* note 90 (stipulating that the House Committee on Patents' Report accompanying the bill reveals that the law was clearly understood not only to excuse inadvertent infringement, but also "to permit the government to intentionally infringe patents to secure benefits for the public"); *see also* Morten & Kapzynski, *supra* note 90 (summarizing that "the U.S. government very rarely goes to court to enforce its patents, and the suit marks the boldest step the government has ever taken to recoup some portion of the enormous profits a pharmaceutical company has earned after privatizing publicly funded research.").

> The Trump administration should exercise this power promptly if the makers of patented tests, treatments, vaccines, or devices (such as ventilators) overcharge for these products, or cannot keep up with demand, and to thwart patent trolls who assert patents to frustrate a public health response. We agree with the editors of the Financial Times, who wrote: "Trade rules allow compulsory licensing. If necessary, it must be used."

Morten & Duan, *supra* note 89.

[127] *See id.* (emphasizing the importance of denouncing powers that allow a medial monopoly like those that occurred in the AIDS treatments). This specifically occurred in the "Bayer's patent presented by the Bush Administration because the Administration had previously denounced powers like section 1498 in trade negotiations over AIDS treatments." *Id.*

[128] *See id.* ("maintaining that Gilead has 'profited from research funded by hundreds of millions of taxpayer dollars and reaped billions' by selling HIV drugs based on that research back to the American public, at very high prices. Actions that challenge pharmaceutical monopolies, rather than entrench them, are necessary to protect public health").

[129] *See* Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 636 (1999) (noting that "Congress may not abrogate state sovereign immunity pursuant to its Article I powers; hence the Patent Remedy Act cannot be sustained under either the Commerce Clause or the Patent Clause.").

the President and Congress should be wary of patent owners who seek to use the pandemic to expand upon bulletproof patent protections, in search of benefiting by raising prices, reducing access to medication, and inhibiting scientific research.[130] Without a good faith effort made by the United States government and FDA, the threat of patent infringement liability will be an uphill battle along the longstanding fight against COVID-19.[131]

C. Proposal of a 3D Printing Technology FDA Organization

One of the few silver linings provided by the COVID-19 pandemic was the awareness brought to the healthcare industry of the potential that additive manufacturing can bring to the medical industry.[132] However, the transition of incorporating additive manufacturing into the medical world will likely contain several

[130] *See* Morten & Duan, *supra* note 89 (explaining that "[s]ome experts who represent biotech and pharmaceutical companies have called for broadening patents on diagnostic testing; other experts seek to increase the patent term for vaccines (already often as long as 25 years), and the pharmaceutical industry wasted no time inserting favorable patent language into a [COVID-19] spending bill."). "Rather than helping the COVID-19 crisis, history [has proven] that these changes would raise prices, reduce access to medicines and diagnostic tests, inhibit scientific research, and delay innovation." *Id.*

[131] *See* MAKOWER, *supra* note 78, at 42 (guaranteeing that only when the FDA imposes reasonable regulatory requirements, will the most effective advances in medical care be developed and delivered promptly to American patients, and only then will the public health and our economy be best served); *see also* Ebrahim, *supra* note 15, at 48 (highlighting that the combination of advancements in printing technology, the prevalence of more powerful computers, and the growing market demand for 3D printed objects has caused a recent explosion of 3D printing technology into the mainstream consumer market); *see* Rantanen, *supra* note 5 (noting that an Italian company had a PR disaster when they held a patent on a valve used in breathing machines critical for coronavirus patients and could not meet the surging demands for its valves, refusing to allow other manufacturers to use their patent).

[132] *See* Bell, *supra* note 40 (indicating "[i]n late March[,] when the number of global [COVID-19] cases was still in the hundreds of thousands, rather than millions[,] Jos Burger, the CEO of Dutch 3D printing firm Ultimaker, told NS Medical Devices the wider use of additive manufacturing after the crisis was 'unavoidable'"). If the world was under normal circumstances, "in a [non-COVID] world, devices produced using additive manufacturing would undergo similar regulatory assessments to medical equipment made in any other way." *Id.*

barriers including the regulatory environment and immense costs associated with owning or maintaining 3D printing machines.[133] Many companies have begun and will continue to 3D print medical devices during the COVID-19 pandemic, and will need to employ engineers of the proper level of expertise to operate and maintain them.[134] Without guidance by the proper authorities or universal regulations by government agencies, redundant bottlenecks will continue to clog the industry and prevent 3D printing from assisting the healthcare industry to its full capacity.[135]

Under current FDA regulation, fewer medical device start-ups are being launched in the United States and medical device companies are relocating to other countries.[136] Currently, medical devices are regulated through the FDA's Center for Devices and Radiological Health ("CDRH"), but they are lacking a specific sector to address the expansive regulations necessary to regulate 3D printed technology.[137]

---

[133] *See id.* (clarifying that because "3D printing is a relatively new, yet rapidly evolving, technology, there is limited awareness of — or at least exposure to — additive manufacturing and the workflow requirements associated with it which could also be an issue.").

[134] *See id.* (stating that what is happening now is that people are seeing additive manufacturing being used for reasonably useful products).

> As a manufacturing tool it is definitely emerging, but it will not be the be-all and end-all. It will be a tool in the toolbox that should be used appropriately; and it's not really until people start designing their products to be suitable for additive manufacturing, to take advantage of additive manufacturing, that you will get a significant benefit.

Id.

[135] *See id.* (explaining that when an innovator went "to the aid of a Brescian hospital in March, the company not only saved lives, but also demonstrated the potential 3D printing has when used in a context that suits its particular strengths."). "[Today], it would be up to those within the healthcare sector to identify where more of these specific settings lie in a [non-COVID] world and deploy additive manufacturing in the areas it is needed most." Bell, *supra* note 40.

[136] *See* MAKOWER, *supra* note 78, at 8 (indicating that "to truly promote the public health, the FDA must impose reasonable regulatory requirements on new innovations, implement more balanced requirements for premarket and post market clinical data, and go back to leveraging market forces to reward technology that presents the greatest value to patients"). "Only then will the most effective advances in medical care be developed and provided promptly to American patients; and only then will the public health and our economy be best served." *Id.*

[137] *See id.* at 12 (detailing that "[t]hrough the combined efforts of both small and large MedTech companies alike, R&D investment in the industry more than doubled

3D printed devices are supervised using premarket approval pathway ("PMA") to evaluate high risk technologies, and employing the FDA statute of 510(k) process for low to medium risk devices.[138] The lengthy process for regulating innovative medical devices in the United States has led us to a device lag, not because the FDA is attempting to protect patient health, but because they are simply unprepared to provide regulations for these innovative technologies.[139] By implementing an additional sector of the FDA focused on innovative medical technologies, the United States will ultimately have the regulatory efficiency to give patients the best possible care by utilizing the latest and greatest 3D printing technology.[140]

V. Conclusion

As 3D printing technology becomes an integral part of society, patent infringement regulation must follow at an equivalent rate to effectively integrate the technology into society and provide producers with clear guidelines. Without the FDA creating a path the incredible advantages of being able to mass produce medical equipment through 3D printing becomes valueless, due to the risk of patent infringement. While the regulations set forth by the FDA are crucial to the development and abilities of the 3D printing industry related to medical devices, measures taken by the government are equally as important to its potential impact. If the federal government is

during the 1990s, and it continues to outpace the R&D investment of companies in other U.S. manufacturing industries by an average of twice as much.").

[138] *See* Zhang et al., *supra* note 41 *(*detailing that "after all, by its nature, a 510(k) summary claims substantial equivalence to a legally marketed device, commonly known as a predicate device. The predicate device may become potential prior art if all or some elements of the claims of the patent exist in the predicate device.").

[139] *See* MAKOWER, *supra* note 78, at 34 (noting that the lengthy process for innovative medical devices in the United States has led us to a device lag, where medical technologies are becoming available to United States patients an average of two years later than patients in Europe); *see also* Mayfield, *supra* note 74 (stipulating that "the FDA approval process requires compliance with rigorous testing programs (clinical trials) and compliance with a lengthy administrative approval process, and is most times very costly.").

[140] *See* MAKOWER, *supra* note 78, at 34 (detailing that "[w]ith no available evidence to suggest that the safety of these devices is being substantially improved . . . it is reasonable to question whether the lengthy and expensive FDA process is truly protecting patient health, or more simply delaying patient access to new therapies that are available years earlier in other geographies.").

unwilling to assist states or gridlocked, then states that were hit hardest by COVID-19 are best positioned to combat price gouging and therefore are obligated to explore their options under sovereign immunity or by manufacturing medical equipment locally.

By following the plan of other governments around the world including Germany, the United Kingdom, or Canada, the United States may also be able to bypass medical device patents entirely. Federal leaders should enact these four strategies to successfully combat pandemic challenges, including (1) law implementation to interfere with the pandemic response; (2) avoidance of pro-patent positions; (3) encouraging states to utilize state sovereignty; and (4) wariness of a potential patent monopoly on medical devices. Furthermore, assistance from the government or state sovereignty would be greatly beneficial, however, companies still require guidance by the proper regulatory agencies. The implementation of an additional sector into the FDA primarily focused on innovative medical technologies, would empower the United States with regulatory efficiency and provide patients the best possible care through the latest and greatest 3D printing technology. By applying measures of state sovereignty, creating FDA regulations devoted to 3D printing, and preventing a medical manufacturing monopoly, the United States may eradicate the world's COVID-19 supply-demand crisis of 3D printing, and avert patent liability ramifications in the process.