Creativity for the Common Good: The Case for Fair Use of Prosthetics Patents

*Roxanneh Mousavi**

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* J.D. Candidate, Seattle University School of Law. The author wishes to thank her family, the Seattle University Law Review, and Professor Steve Tapia for their invaluable assistance and support in writing this Note.

INTRODUCTION

The bonds that children form with their elementary school teachers are among the earliest and most formative of their lives. While these educators are charged with teaching youths about the basics of academic life, they can also instill powerful lessons on the importance of teamwork and compassion. This was certainly the case for Kathy DeBona, a fifth-grade teacher at Western Salisbury Elementary School in Pennsylvania.[1] While using a news site called *Newsela* to improve her students' reading and writing skills, DeBona came across a remarkable story: a five-year-old boy had been given a prosthetic arm that looked just like Iron Man's arm.[2] DeBona's students were inspired by this success story and decided to create their own for another teacher at their elementary school.[3]

Patti Anderson was many of the students' fourth-grade teacher the previous year.[4] Anderson lost one of her hands following a laundry machine accident while in high school.[5] The children wrote letters to the surgeons at Johns Hopkins who had created the Iron Man arm to get a prosthetic for Anderson, as well.[6] The team at Johns Hopkins was so moved that they granted the children's request and created a 3-D printed, zebra-patterned hand for the beloved teacher.[7]

While Patti Anderson's story is a beautiful example of a community rallying around one of its own, this result is unfortunately not the norm. There are many barriers to accessing prosthetic limbs in the United States, including "[g]eographical barriers, gender, age, socioeconomic position, race, education, and cost."[8]

This Note examines how patent law inhibits accessibility to prosthetics, and how a fair use defense for patent infringement will make them more widely accessible. Part I will explain the basics of patent law, including its history, scope, and process of infringement. Part II will discuss the fair use defense against copyright and trademark infringement

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1. *See* Sarah Anderson Goehrke, *Teacher Receives 3D Printed Hand After 5th Grade Students Write Letter to Johns Hopkins*, 3DPRINT.COM (Nov. 26, 2014), https://3dprint.com/26707/students-get-teacher-new-hand/ [https://perma.cc/GNS4-U6KG].

2. *Id.*; *see infra* Section IV(A) (describing how the boy, Griffin Matuszek, got his 3D printed prosthetic arm).

3. *See* Goehrke, *supra* note 1.

4. *Id.*

5. *Id.*

6. *Id.*

7. *Id.*

8. Paul F. Pasquina, Antonio J. Carvalho & Terrence Patrick Sheehan, *Ethics in Rehabilitation: Access to Prosthetics and Quality Care Following Amputation*, 17 AM. MED. ASS'N J. ETHICS 535, 536 (2015).

and explain why this defense should also be enforceable for patent infringement. Part III will provide an overview of 3D printing. Part IV will focus on 3D prosthetics, specifically on the story of two young prosthetic recipients, Griffin Matuszek and Evie Lambert. Finally, Part V will examine the current state of accessibility to prosthetics, common barriers to accessibility, and resources for low-income patients.

I. BASICS OF PATENT LAW

Patents are one of six types of intellectual property.[9] A patent is a limited-term monopoly on the use of an idea via a right of exclusivity granted to the creator of the idea as it is embodied in an invention.[10] This means that creators can prohibit others from selling and making the invention embodying their idea while their patent is valid.[11] In return for the exclusivity right, the creator is required to disclose the idea and how it works in the invention.[12] The purposes of a patent, according to the Supreme Court, are to "foster and reward invention[,] . . . [promote] disclosure of inventions, to stimulate further innovation and to permit the public to practice the invention once the patent expires[,] . . . [and] assure that ideas in the public domain remain there for the free use of the public."[13]

Patents were among the primary things the Constitution outlined for Congress to do in forming the new government of the United States. Specifically, according to Article I of the Constitution, Congress has the power "[t]o 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."[14] Consequently, patents have existed since just after the ratification of the United States Constitution in 1788;[15] Congress passed the Patent Act of 1790 two years later.[16] This Act granted monopoly over a product for fourteen years if the applicant "invented or discovered any useful art, manufacture, [. . .] or device, or

9. *See What Is Intellectual Property?*, WORLD INTELL. PROP. ORG., https://www.wipo.int/about-ip/en/ [https://perma.cc/ZJK2-92QZ] (listing six types of intellectual property: copyright, patents, trademarks, industrial designs, geographical indications, and trade secrets).

10. *See* Sarah Barry & Victor Cardona, *IP and 3-D Printing—Is That Iron Man on That Prosthetic?*, HRFM TODAY (Nov. 11, 2014), https://www.hrfmtoday.com/2014/11/ip-and-3-d-printing-is-that-iron-man-on-that-prosthetic.html [https://perma.cc/46RZ-672R].

11. *Id.*

12. *See* Eldred v. Ashcroft, 537 U.S. 186, 216 (2003).

13. Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979).

14. U.S. CONST. art. I, § 8, cl. 8.

15. *See generally Constitution FAQs*, NAT'L CONST. CTR., https://constitutioncenter.org/learn/educational-resources/constitution-faqs#:~:text=The%20Constitution%20was%20written%20during,signed%20on%20September%2017%2C%201787 [https://perma.cc/G4UP-YJW3].

16. *See* Patent Act of 1790, 1 Stat. 109, 110 (1790).

any improvement therein not before known or used."[17] The product also had to be "sufficiently useful and important" to merit such protection.[18]

Patent law was modified for the first time in 1793 when Thomas Jefferson, acting as then-Secretary of State, clarified the definitions for what could be patented: "any new and useful art, machine, manufacture or composition of matter."[19] Within the next forty years, 10,000 patents had been filed, causing the Patent Office to join the State Department in 1836 to keep up with the sheer volume of new patent applications.[20] In 1849, the Patent Office moved from the State Department to the Department of the Interior and the definition of patentable materials expanded once again to include "all new, useful, and non-obvious works," meaning that "an invention could not be patented if it was a device that was recognized by other professionals within a certain field of study."[21] The final modification of the Patent Act occurred in 1952 and remains the law to this day. This version of the Act "clarified and simplified existing U.S. patent law. It also effected substantive changes, including the codification of the requirement for non-obviousness and the judicial doctrine of contributory infringement."[22]

A. Maintenance and Scope of Patent Protection

In American patent law, most patents are valid for up to twenty years after filing.[23] An exception exists for patents filed before June 8th, 1995, which remain valid for up to seventeen years from the date the patent was granted.[24] In order to keep a patent valid, patent holders must pay maintenance fees every three and a half years.[25]

While there are many types of patents,[26] this Note will focus on utility patents. Utility patents cover the creation of a new or improved

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17. *Id.*

18. *Id.*

19. *See Patent History in the United States*, LAWS, https://patent.laws.com/patent-history/patent-history-in-the-united-states#:~:text=The%20Patent%20Act%20of%201790,be%20used%22%20of%20their%20work [https://perma.cc/72SZ-SKGJ]; *see also infra* Section I(A) (explaining the scope and maintenance of patent protection in the United States).

20. *See Patent History in the United States*, *supra* note 19.

21. *Id.*

22. *Patent Act of 1952*, WIKIWAND, https://www.wikiwand.com/en/Patent_Act_of_1952 [https://perma.cc/YVW5-JEMK].

23. *See generally Patent Time Limits: Everything You Need to Know*, UPCOUNSEL, https://www.upcounsel.com/patent-time-limit#how-do-i-apply-for-a-patent [https://perma.cc/6WXA-97ZZ].

24. *Id.*

25. *See id.*

26. This includes plant and design patents. *See Types of Patents*, FINDLAW, https://www.findlaw.com/smallbusiness/intellectual-property/types-of-

invention that meets the threshold criteria of novelty, non-obviousness, and usefulness.[27] There are four categories of things that can be patented as utility patents: (1) processes; (2) machines; (3) articles of manufacture; and (4) compositions of matter.[28] First, a process patent is one that protects "the methods used to perform certain tasks."[29] Examples of such patents include Amazon's One-Click ordering system[30] and Netflix's online system for renting TV shows and films.[31] Second, a patent can be granted to protect a machine, which is defined as "a concrete thing, consisting of parts, or of certain devices and combinations of devices."[32] Examples of patented machines include Apple's iPhone and the Global Positioning System (GPS).[33] Third, an article of manufacture is "a thing made by hand or machine."[34] Examples of articles of manufacture include automobile tires, dinner plates or soup cans. Finally, a composition of matter is "a combination of two or more substances and includes all composite articles."[35] This last patentable category encompasses all such compositions "whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids."[36] Examples of such compositions are prescription drugs and genetically modified organisms (GMOs).[37]

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patents.html#:~:text=There%20are%20three%20types%20of,design%20patents%2C%20and%20plant%20patents [https://perma.cc/CDV5-XWDY].

27. *See generally* Will Kenton, *Utility Patent*, INVESTOPEDIA, https://www.investopedia.com/terms/u/utility-patent.asp [https://perma.cc/SK5V-PZ8A].

28. *See generally Patent Requirements*, BITLAW, https://www.bitlaw.com/patent/requirements.html [https://perma.cc/U9QP-QG8R].

29. *See generally Can You Patent a Process: Everything You Need to Know*, UPCOUNSEL, https://www.upcounsel.com/can-you-patent-a-process#:~:text=One%20example%20of%20the%20importance,business%20process%20patent%20in%202003 [https://perma.cc/NE9Q-RYAD].

30. *Id.*

31. *Id.*

32. *See* Burr v. Duryee, 68 U.S. 531, 570 (1864).

33. *See* Jay Bennett, *15 Patents That Changed the World*, POPULAR MECHS. (Apr. 27, 2018), https://www.popularmechanics.com/technology/design/g20051677/patents-changed-the-world/ [https://perma.cc/RX8D-PNDP].

34. John M. Rogitz, *Supreme Court: Term "Article of Manufacture" Encompasses Both a Product Sold to a Consumer and a Component of That Product*, IP WATCH DOG (Dec. 9, 2016), https://www.ipwatchdog.com/2016/12/09/supreme-court-article-of-manufacture/id=75463/ [https://perma.cc/HQW8-GJ2L].

35. Digitech Image Techs., LLC v. Elecs. for Imaging, Inc., 758 F.3d 1344, 1349 (Fed. Cir. 2014).

36. *See* Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980).

37. *See* Wen Zhou, *The Patent Landscape of Genetically Modified Organisms*, HARV. UNIV. (Aug. 10, 2015), http://sitn.hms.harvard.edu/flash/2015/the-patent-landscape-of-genetically-modified-organisms/ [https://perma.cc/6D9S-YZ2S].

Patent law reflects "a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition."[38] Patents help to avoid monopolies because patents are only available for a certain amount of time and thus the creator's right of exclusion is not indefinite.[39] This balance is important because patents allow inventors to create new and useful products with the ability to recoup their research and development costs while their efforts are protected, while also preventing complete and permanent control of a given market by one person or product.[40]

B. Conditions for Patentability

A patent can be issued for any invention which is "novel," "non-obvious," and is "useful." [41] An invention is considered novel when it is new; that is, the public had no knowledge of the invention before the patent application was filed.[42] In addition, an invention is considered non-obvious when it is "a non-obvious improvement" over prior products or processes.[43] The test to determine non-obviousness evaluates "whether the differences in the new invention would have been obvious to a person having ordinary skill in the type of technology used in the invention."[44] An invention is considered useful if "a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and . . . the utility is specific, substantial, and credible."[45]

C. Patent Infringement Litigation

Individuals can bring infringement actions when they suspect another party is violating their patent. Infringement occurs when a person "(1) without authority (2) makes, uses, offers to sell, sells, or imports (3)

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38. *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989).

39. *See* John Ferrell, *What Are Patents?*, CARR/ FERRELL, LLP, https://www.carrferrell.com/what-are-patents [https://perma.cc/MQD9-PNHK].

40. *See generally* ROBERT MERGES, PETER MENELL & MARK LEMLEY, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 14 (6th ed. 2012) ("[I]ntellectual property laws can be justified by the public goods argument only to the extent that they do on balance encourage enough creation and dissemination of new works to offset those costs . . . . The key to economic efficiency lies in balancing the social benefits of providing economic incentives for creation and the social costs of limiting the diffusion of knowledge.").

41. *See General Information Concerning Patents*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/basics/general-information-patents [https://perma.cc/446B-L8Y4].

42. *See Patent Requirement*, BITLAW, https://www.bitlaw.com/patent/requirements.html#nonobvious [https://perma.cc/SWA5-TEBA] (explaining the novelty (newness) requirement).

43. *See id*. (explaining the nonobviousness requirement).

44. *Id.*

45. MPEP (9th ed. Rev. 10, June 2020) at 2107(2)(A)(3) (examination guidelines for the utility requirement).

the patented invention (4) within the United States, its territories, or its possessions (5) during the term of the patent."[46] Furthermore, "[i]nfringement, whether direct or contributory, is essentially a tort, and implies invasion of some right of the patentee."[47]

The Patent and Trademark Office only issues patents after a lengthy review process (unlike copyright protection which comes into existence without a review process upon a work being fixed in a tangible medium). In light of this lengthy process, patents are presumed to be valid upon their granting.[48] Furthermore, the burden of proof for proving invalidity rests on the person asserting the claim of invalidity.[49] The elements of the prima facie case of patent infringement are: (1) the ownership of (2) a valid patent that (3) without permission or legal justification (4) has been used in the making, sale, or importation of an another invention (5) that embodies all of the claims given protection in the granted patent; and (6) has caused the patent owner damage.[50]

II. FAIR USE AND ITS PLACE IN PATENT INFRINGEMENT

Typically, when an individual brings a lawsuit for patent infringement, Section 282 of the U.S. Code enumerates three defenses against patent infringement: (1) "[n]oninfringement, absence of liability for infringement or unenforceability"; (2) "[i]nvalidity of the patent or any claim in suit . . . [based on lack of] a condition for patentability"; and (3) "[i]nvalidity of the patent or any claim in suit for failure to comply with . . . section 112."[51] In other words, the three established defenses to patent infringement are: (1) the later invention either does not make use of all of the claims of the existing patent or is legally authorized via license or another right; (2) the existing patent does not meet the criteria of patentability (novelty, non-obviousness, and usefulness); and (3) the patent has formal defects (it does not set forth the complete subject matter that the inventor regards as the invention); or the claims do not particularly point out and distinctly define the metes and bounds of the protected invention. Although these defenses to patent infringement are established and available, a fair use defense is not. This Note discusses in later sections fair use and its potential application to patent law.

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46. *See* HERBERT F. SCHWARTZ & ROBERT J. GOLDMAN, PATENT LAW AND PRACTICE 163–64 (6th ed. 2008).

47. *See* Carbice Corp. v. Am. Patents Dev. Corp., 283 U.S. 27, 33 (1931).

48. *See* 35 U.S.C. § 282(a).

49. *Id.*

50. *See generally* 35 U.S.C. § 271 (explaining what does and does not constitute patent infringement).

51. 35 U.S.C. § 282(b)(1)–(3).

A. Fair Use

Fair use is "an affirmative defense that can be raised in response to claims by a copyright owner that a person is infringing a copyright."[52] In copyright, fair use can be invoked as a defense when a copyrighted work is used for policy reasons that Congress and the courts have deemed to justify the use of a copyrighted work without permission "such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research."[53] The four factors of fair use are "the purpose and character of the use"; "the nature of the copyrighted work"; "the amount and substantiality of the portion taken"; and "the effect of the use upon the potential market."[54]

The fair use factors are not a checklist; rather, they enumerate the various considerations that a court needs to examine to justify unauthorized use of a copyrighted work. The first factor looks at whether the use of the copyrighted work is for a purely commercial use (such as using a copyright graphic work on a t-shirt of coffee mug) or for a use like those enumerated in the statute (e.g., criticism, scholarly work, or public commentary).[55] The second factor looks at how creative and expressive the used work is (with highly creative works like books, paintings, and movies being given strong protection while collections of facts with little creative expression get little or light protection).[56] The third factor looks at how much of the infringed work (either in terms of amount or import) is used in the later work.[57] The fourth factor looks at the effect of the later work on the ability of the original work's author to continue to sell or license the original work.[58] A similar concept, "nominative fair use," exists in the world of trademarks.[59] Nominative fair use applies when "a third party can use a mark for the purpose of referring to the mark-owner's product or service and not create any likelihood of consumer confusion."[60]

Unlike the "fair use" concept in copyright and trademark law, patent law does not recognize that certain infringements should be allowed for policy reasons. This approach has been traditionally justified by the notion

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52. *See What Is Fair Use?*, COPYRIGHT ALL., https://copyrightalliance.org/ca_faq_post/what-is-fair-use/ [https://perma.cc/GSX8-562X].

53. 17 U.S.C. § 107.

54. *See Measuring Fair Use: The Four Factors*, STAN. LIBRARIES, https://fairuse.stanford.edu/overview/fair-use/four-factors/ [https://perma.cc/V4ZU-NZS5].

55. *See Fair Use*, COPYRIGHT ADVISORY SERVS, COLUM. UNIV. LIBRARIES, https://copyright.columbia.edu/basics/fair-use.html [https://perma.cc/G766-MBQN].

56. *See id.*

57. *See id.*

58. *See id.*

59. *See* Darian B. Taylor, Annotation, *Nominative Fair Use Defense in Trademark Law*, 84 A.L.R. Fed. 2d 217 (2014).

60. *Id.*§ 1.

that patents promote healthy competition (which can stimulate a nation's economy) and that any use of a patented idea should therefore be a revenue generating event. However, when there is an opportunity for patented materials to serve a public good—like making prosthetic limbs more accessible for people who cannot afford fully patent licensed versions otherwise, thereby enhancing their ability to be productive in the workforce as well as their quality of life—an infringement on these patents should be allowed under a limited fair use doctrine.

B. Why Should Patents Have a Fair Use Defense?

Numerous works of legal scholarship have discussed the importance and benefits of a potential fair use defense in the patent context.[61] Scholars note that such a defense is warranted because of the rise of "open source approaches and user innovation, especially within communities of users."[62] Furthermore, it is possible that patent infringers could continue to innovate if such a defense was available.[63] While this defense may provide these benefits generally, in the context of prosthetics, a fair use defense for patent infringement would alleviate the need for customization and increase accessibility to prosthetics for low-income populations. This idea will be explored further in Part VI of this Note.

III. BASICS OF 3D PRINTING

The first 3D printer was built in the 1980s by Charles W. Hull.[64] Hull worked for a company that used ultraviolet technology to create "tough, durable coatings for tables" when he decided to use the technology to make small prototypes.[65] As opposed to an inkjet printer, which "prints two-dimensional images on a flat surface such as paper, a 3D printer constructs a product in three dimensions, like a sculpture, out of a solid material—typically plastic."[66]

Many industries already use 3D printing to leverage the diverse benefits it can offer. For example, a housing community in the Netherlands

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61. *See, e.g.*, Katherine J. Strandburg, *Patent Fair Use 2.0*, 1 U.C. IRVINE L. REV. 265 (2011); Maureen A. O'Rourke, *Toward A Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000); Joshua I. Miller, *Towards a Doctrine of Fair Use in Some of Patent Law*, 2 AM. U. INTELL. PROP. BRIEF 56 (2011).

62. *See* Strandburg, *supra note* 61, at 281.

63. *Id.* at 281–82.

64. Tony Hoffman, *3D Printing: What You Need to Know*, PCMAG (July 1, 2020), https://www.pcmag.com/news/3d-printing-what-you-need-to-know [https://perma.cc/PE4B-3E7N].

65. Tuan C. Nguyen, *Who Invented the 3D Printer?*, THOUGHTCO (Mar. 15, 2019), https://www.thoughtco.com/who-invented-3d-printing-4059854 [https://perma.cc/S62U-M2TZ].

66. Bolson Materials Int'l Corp. v. 3D Sys. Corp., 746 F. App'x. 445, 446 (6th Cir. 2018).

was built entirely of 3D printed homes.[67] Furthermore, instead of having to purchase an entirely new door, the U.S. Marines Corps printed a new part of a jet landing door and saved $70,000.[68] Finally, 3D printing has been used extensively to create prosthetic limbs for amputees, which will be discussed in more detail in Part IV of this Note.[69]

The technology of 3D printing has been hailed for its efficiency and cost-effectiveness.[70] Consider, for example, the story of Jose Delgado, Jr.[71] Born with most of his left hand missing, Delgado enlisted help from a company called e-NABLE to 3D print a prosthetic for him.[72] He ended up paying only $50 for his 3D printed prosthetic limb, as opposed to the $42,000 device he had used previously.[73] Moreover, because 3D printed limbs are customizable, Delgado prevented the discomfort and swelling that many amputees face when receiving a new prosthetic.[74]

Despite all the good that can come from its use, 3D printing is not without its critics. John F. Hornick explains how this technology could pose potential problems for law enforcement.[75] First, Hornick states that illegal activity will flourish when individuals can 3D print virtually any object without proper control or regulation.[76] For example, guns or other types of weapons could be covertly created with 3D printing technology.[77] Second, he posits that enforcing the law against these illegal activities will be increasingly "impossible" and "impractical."[78] Third, he argues laws

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67. *See* Veronika Licheva, *Printing 3D Houses in Eindhoven: The Netherlands Is Now Reprinting Homes*, DUTCHREVIEW (May 31, 2018), https://dutchreview.com/news/3d-printing-of-houses-in-eindhoven-the-netherlands-is-now-reprinting-homes/ [https://perma.cc/RJ9H-M9A9].

68. *See* Umair Iftikhar, *U.S. Marines 3D Print F-35 Part to Save $70,000*, 3D PRINTING INDUS. (Aug. 20, 2018), https://3dprintingindustry.com/news/u-s-marines-3d-print-f-35-part-to-save-70000-138484/ [https://perma.cc/PA2P-8973].

69. *See* Dan Perreault, *Open Bionics Introduces Affordable Prosthetic Arm*, NEOMETRIX TECHS., INC. (May 2, 2018), http://3dscanningservices.net/blog/open-bionics-introduces-affordable-prosthetic-arm/ [https://perma.cc/EY58-W77R].

70. *See, e.g.*, James M. Beck & Matthew D. Jacobson, *3D Printing: What Could Happen to Products Liability When Users (and Everyone Else in Between) Become Manufacturers*, 18 MINN. J.L. SCI. & TECH. 143, 150 (2017).

71. *See* Jeremy Simon, *Man Compares His $50 3D Printed Hand to His $42K Prosthesis*, 3D UNIVERSE (Apr. 19, 2014), https://3duniverse.org/2014/04/19/jose-delgado-jr-compares-his-new-3d-printed-hand-to-his-more-expensive-myoelectric-prosthesis/ [https://perma.cc/B57W-FMQ5].

72. *Id.*

73. *Id.*

74. *See* CHRISTOPHER BARNATT, 3D PRINTING 8 (3d ed. 2016).

75. *See* John F. Hornick, *Inside Views: 3D Printing and Public Policy*, INTELL PROP. WATCH (Sept. 7, 2015), https://www.ip-watch.org/2015/07/09/3d-printing-and-public-policy/ [https://perma.cc/2VJT-4TN9].

76. *Id.*

77. *See, e.g.*, Champe Barton & Chip Brownlee, *What Are 3D-Printed Guns, and Why Are They Controversial?*, THE TRACE (Feb. 2, 2021), https://www.thetrace.org/2021/02/3d-printer-ghost-gun-legal-liberator-deterrence-dispensed/ [https://perma.cc/DS94-R9UK].

78. *See* Hornick, *supra* note 75.

that regulate 3D printing will become increasingly impotent because some uses of 3D printers will be progressively difficult to identify and control.[79]

While the concerns that Hornick raises are understandable, the utility of 3D printing technology outweighs its dangers. Users of 3D printing reduce the number of assembly steps while also creating more intricate and personal designs so their limbs can look the way they want them to.[80]

IV. CASE STUDIES

Several companies have utilized 3D printing to make prosthetics accessible to individuals who would face financial barriers.[81]

A. e-NABLE and Griffin Matuszek

e-NABLE is a company that makes "free and low-cost prosthetic upper limb devices for children and adults in need."[82] Individuals who are three years or older,[83] as well as people who are missing arms below the elbow or fingers,[84] are eligible to receive a 3D printed hand. Furthermore, all the designs on e-NABLE's website are open-source, meaning anyone can use them to make their own limbs.[85] Griffin Matuszek is one of the approximately 8,000 people[86] who have benefitted from e-NABLE's work.

In the spring of 2014, Griffin was like any other child; he loved superheroes, played ball, and attended kindergarten with his friends.[87] The one thing that set Griffin apart from his peers was his left hand; he was

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79. *Id.*

80. *See* Paul Hanaphy, *Scientists Create Fully-Automated 3D Printed Prosthetic Production Line*, 3D PRINTING INDUS. (Mar. 9, 2021), https://3dprintingindustry.com/news/scientists-create-fully-automated-3d-printed-prosthetic-production-line-185892/ [https://perma.cc/T3GC-8RP5].

81. *See supra* notes 71–75.

82. *What Is E-Nable?*, ENABLING THE FUTURE, https://enablingthefuture.org/ [https://perma.cc/K28B-ZAC7].

83. *Id.*

84. *Id.*

85. *Id.*; *see also What Is Open Source, and Why Is It Important?,* BIGCOMMERCE, https://www.bigcommerce.com/ecommerce-answers/what-open-source-and-why-it-important/ [https://perma.cc/E6CV-GM97] ("Open source is a type of licensing agreement that allows users to freely modify a work, use said work in new ways, integrate the work into a larger project or derive a new work based on the original."). Open source can be used for product development and designs as well. *See The Open Design Definition v. 0.5.*, GITHUB, https://github.com/OpenDesign-WorkingGroup/Open-Design-Definition/blob/master/open.design_definition/open.design.definition.md [https://perma.cc/YS6Y-MCKS] ("Open Design is a design artifact project whose source documentation is made publicly available so that anyone can study, modify, distribute, make, prototype and sell the artifact based on that design.").

86. *What Is E-Nable?, supra* note 82.

87. *See 3-D Printed Prosthetic Hand Fit for a Superhero*, JOHNS HOPKINS MED. (2016), https://www.hopkinsmedicine.org/news/stories/3d_griffin.html [https://perma.cc/LB8B-24L8].

born with a tiny left palm and pearl-like fingers.[88] After being advised to find a plastic limb for their son, Griffin's parents procured a beige artificial hand attached to a silicone sleeve that would have to be replaced every two years.[89] This artificial hand came with its downsides: a then four-year-old Griffin thought the arm was "scary" to wear, and such devices cost at least $6,000.[90]

Enter Dr. Albert Chi, "a trauma surgeon whose clinical research is focused on [creating] advanced prosthetics" with the help of open-source design and 3-D printing.[91] He worked with e-NABLE to create an Iron Man prosthetic arm that was better suited for Griffin than the one he had previously.[92] Dr. Chi has dedicated his career to studying advanced prosthetics and biomedical engineering.[93] After a motorcycle accident in college that landed him in the trauma bay of a hospital, Dr. Chi has devoted himself to helping others by providing trauma and critical care as well as volunteering with groups like e-NABLE to make prosthetic limbs more widely available.[94] While it is impossible to calculate exactly how many devices he has helped create, Dr. Chi can point to the definitive effects of prosthetic limbs for children: "With children . . . it makes such a huge impact with how they see themselves, how they interact with the world, and how others see them, as well. . . . It's almost like a cool new toy that they have."[95] In contrast, adult patients focus more on function than aesthetics when choosing prosthetics.[96] Therefore, when designing and creating prosthetics for children, it is important to incorporate their specific priorities to ensure the devices add as much value as possible to the lives of those who wear them.

Apart from creating prosthetic limbs, 3D printing has many other present and prospective uses for the biomedical industry.[97] During the coronavirus pandemic, Dr. Chi has collaborated with other medical professionals and engineers to create a 3D printed ventilator and a 3D printed exoskeleton.[98] Furthermore, he is part of a team that is in the

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

93. *See Biography*, ALBERT CHI, http://albertchi.com/index.html [https://perma.cc/H8KX-J5KW].

94. *Id.*

95. Telephone Interview with Albert Chi, M.D., F.A.C.S. (on file with author).

96. *Id.*

97. *See, e.g.*, Allie Nawrat, *3D Printing in the Medical Field: Four Major Applications Revolutionising the Industry*, MED. DEVICE NETWORK (Aug. 7, 2018), https://www.medicaldevice-network.com/features/3d-printing-in-the-medical-field-applications/ [https://perma.cc/J7E4-UNJQ].

98. Telephone Interview with Albert Chi, *supra* note 95.

process of conducting the first pediatric 3D printed clinical trial.[99] Dr. Chi is hopeful that, in the future, designs for 3D printed prosthetic limbs will be uploaded online for free by banks of engineers, doctors, and scientists who create them.[100] In an ideal outcome, these collaborative teams could scan blood vessels (and other customizable parts of the body), print them, and have them ready for the patient within an hour.[101]

B. Open Bionics and Evie Lambert

There is a parallel effort in the United Kingdom to create prosthetic limbs for children, led by startup Open Bionics.[102] In August 2015, Open Bionics won the James Dyson Award, an international design accolade, for its 3D printed hand prototype.[103] This prototype was well-received because of its low cost, efficient construction, and open-source design—meaning that anyone could download it and print their own prosthetic hand.[104]

Eleven-year-old Evie Lambert was one of the lucky recipients of an Open Bionics arm.[105] Evie was born without her left hand and had negative experiences with other prosthetics because "they didn't allow her enough function."[106] However, an anonymous donor paid for her arm (whose design was based off of the Disney movie Frozen) just in time for Christmas.[107] Evie described it as the best gift she had ever received.[108] As her mother explained:

> It gives her functionality. She's tackling things she wouldn't have done before—little things like brushing her hair, using the hairdryer, opening a lip balm or putting clothes on a hanger. These are things that we take for granted.

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99. *Id.*

100. *Id.*

101. *Id.*

102. *See Open Bionics Is Printing Child-sized Bionic Hands with the Ultimaker 2 Extended*, ADDITIVE (Oct. 6, 2015), https://www.goprint3d.co.uk/blog/open-bionics-printing-child-sized-bionic-hands-ultimaker-2-extended/ [https://perma.cc/KB74-QZT5].

103. *Id.*

104. *Id.*

105. *See* Vanessa Chalmers, *Schoolgirl's Joy as Mystery Donor Pays for Her to Get a Frozen-Themed Bionic Arm Just in Time for Christmas After She Was Born Missing Her Left Hand*, DAILY MAIL (Dec. 19, 2018), https://www.dailymail.co.uk/health/article-6511105/Schoolgirls-joy-mystery-donor-pays-Frozen-themed-bionic-arm-Christmas.html?fbclid=IwAR0dCqS5anbtc7byFxW-0PQk14ewgqimqdXTgF7Tq_lASqjIhEi1NdXMTiI [https://perma.cc/KRH5-RJZ4].

106. *Id.*

107. *Id.*

108. *Id.*

> When she does it her face just lights up. The most amazing thing will be seeing her open her presents on Christmas day.[109]

Griffin and Evie are two examples of how low-cost 3D printed prosthetics can positively impact children's lives. While their stories are heartwarming, the unfortunate reality is that many individuals in need of these devices are unable to obtain them. The following section explores the different barriers to accessing prosthetics and how 3D printing can help overcome those barriers.

V. WHY DOES ACCESS TO PROSTHETICS MATTER?

Prosthetic limbs can drastically improve a person's quality of life.[110] Unfortunately, they are often accessible only to wealthy individuals who can afford these historically expensive devices.[111]

A. Barriers to Accessibility

Financial barriers are the most common obstacles to obtaining prosthetics, given that upper limb devices can cost anywhere between $5,000 and $100,000.[112] Children's rapid rate of physical growth requires regular replacement of their prosthetics to maintain proper fit.[113] Constant replacement places a huge financial burden on families. Other obstacles include "medical availability [and] their perceived durability and complexity of control,"[114] meaning that some individuals may be deterred by prosthetics because they look or feel difficult to use. These hindrances are problematic because a lack of access to these devices can have considerable negative effects on an individual's well-being, as discussed in the section below.

B. Effects of Inaccessibility

Inaccessibility to prosthetic limbs can have significant effects regardless of the recipient's age. Studies have shown that "[a]ccess to a device can have a significant impact on a child's psychosocial

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109. *Id.*

110. *See infra* notes 116–26 (explaining that prosthetic limbs can add a sense of normalcy to patients' lives, allow them to engage more fully in daily activities, and improve their social and emotional health).

111. *See How Much Does a Prosthetic Arm Cost?*, COSTHELPER , https://health.costhelper.com/prosthetic-arms.html [https://perma.cc/F2UB-89NX].

112. *See id.*

113. *See generally* Albert Manero, Peter Smith, John Sparkman, Matt Dombrowski, Dominique Courbin, Anna Kester, Isaac Womack & Albert Chi, *Implementation of 3D Printing Technology in the Field of Prosthetics: Past, Present, and Future*, 16 INT'L J. ENV'T RES. & PUB. HEALTH 1641 (2019) [hereinafter *Implementation of 3D Printing*].

114. *Id.* at 1641.

development."[115] Adults with limb differences can have "depression, anxiety, [and] low self-esteem" and an overall negative perception of their body image.[116]

Conversely, accessible prostheses can have positive impacts on their recipients. A 2002 study conducted by the University of Southampton demonstrated the significant positive difference a prosthesis can make in the daily lives of amputees.[117] This study gathered a group of amputees who were being fitted for prosthetics with silicone covers at an Independent Limb Centre.[118] The group answered two scaled questionnaires once a month for six months.[119] The first questionnaire, "Engagement in Everyday Activities involving Revealing the Body" (EEARB), used a ten-item scale that measured the number of times respondents had participated in events which involved revealing their bodies over the past three months.[120] The second questionnaire, "Discomfort related to Engaging in Everyday Activities involving Revealing the Body" (Discomfort-EEARB), was an eleven-item scale that asked respondents to rate their level of comfort when imagining themselves in situations described in the EEARB.[121] The responses were then compared to a sample group of able-bodied students from the University of Southampton.[122] The table below[123] shows the percentage of respondents who felt comfortable participating in these activities before receiving the prosthesis ("Time 1") and 12 weeks after receipt ("Time 2"). The right two columns are the values for able-bodied male and female university students. As the table shows, receiving a prosthesis had a positive impact on every activity the study focused on.

115. *Id.*

116. *See* M.K. Donovan-Hall, L. Yardley & R.J. Watts, *Engagement in Activities Revealing the Body and Psychosocial Adjustment in Adults with a Trans-Tibial Prosthesis*, 26 PROSTHETICS & ORTHOTICS INT'L 15, 15 (2002).

117. *Id.* at 18.

118. *Id.* at 17.

119. *Id.*

120. *Id.* at 17.

121. *Id.*

122. *Id.* at 18.

123. This table is a recreation of Table 3 in the study. *See id.*

Activity	Proportion of sample who had engaged in that activity during the past three months			
	Amputees Time 1 (n=11)	Amputees Time 2 (n=10)	Able-bodied females Time 1 (n=59)	Able-bodied males Time 1 (n=42)
Taken a shower in a public place	9.1%	30.0%	47.5%	54.8%
Taken a shower/bath in front of partner	36.4%	55.6%	86.4%	85.7%
Undressed in a public place	9.1%	20.0%	64.4%	57.1%
Undressed in front of partner	81.8%	77.8%	94.9%	92.9%
Used public swimming pool	27.3%	40.0%	61.0%	50.0%
Used public gym/sports centre	18.2%	50.0%	69.5%	59.5%
Worn tight trousers/leggings	36.4%	60.0%	83.1%	45.2%
Worn short skirt/shorts	9.1%	70.0%	83.1%	88.1%
Worn open toe sandals	27.3%	60.0%	89.8%	38.1%
Walked about with bare legs/tights	18.2%	80.0%	91.5%	88.1%

Many respondents reported that having a prosthesis was a vital part in restoring a feeling of normalcy to their lives.[124] The study noted that:

> Following receipt of the cosmesis there was a very marked increase in engagement by amputees in activities involving revealing the body, to levels only a little lower than in the able-bodied sample[.] Paired t-tests confirmed that amputees' EEARB and Discomfort-EEARB scores increased significantly. . . . Amputees' scores were reduced on the self-esteem, anxiety and depression scales at Time 2, although this decrease did not reach significance.[125]

124. *Id.* at 20.
125. *Id.*

Furthermore,

> [twelve] weeks after taking delivery of a prosthesis with a silicone cover, there were significant increases in amputees' reported frequency of engaging in activities which involved revealing the body. Amputees' perceptions of how comfortable they thought they would feel when engaging in activities which involved revealing the body also significantly increased. These changes in behaviour [sic] and confidence provide some preliminary evidence that receiving a silicone cosmesis may enhance the psychological adjustment of some amputees.[126]

Other studies about the positive effects of prostheses on individuals' social and emotional health have reached the same conclusions.[127]

C. The Current State of Access to Prosthetics

Although technological innovation is lowering the cost of prosthetics,[128] cost remains a significant bar to access for many patients. According to Glenn Garrison, Director of Prosthetics and Orthotics at the Hospital for Special Surgery in New York, "[Prosthetic limbs are] probably in line with a cost of a car. It can be a pricey thing to work with."[129] However, the recent rise of organizations like e-NABLE have led to an increase in "open-source customizable designs and new 3D printers used in schools, libraries, and even residences."[130] This kind of collaboration is important for technological innovations in the medical industry and beyond, as it allows for creators to build on each other's work, fine-tuning processes and designs. University researchers have also become increasingly involved; some institutions are attempting to establish best-practices backed by data-driven analytics to help streamline the process of prosthetic production.[131] For example, Professor Jorge M.

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126. *Id.* at 21.

127. *See* Craig D. Murray, *The Social Meanings of Prosthesis Use*, 10 J. HEALTH PSYCHOL. 425, 439 (2005) (explaining how patients used prosthetics to conceal their limb differences, to facilitate social integration, and to reduce emotional problems surrounding their physical differences).

128. *See, e.g.*, Ian Birrell, *3D-Printed Prosthetic Limbs: The Next Revolution in Medicine*, THE GUARDIAN (Feb. 19, 2017), https://www.theguardian.com/technology/2017/feb/19/3d-printed-prosthetic-limbs-revolution-in-medicine [https://perma.cc/Z4S8-ZFJV]; Cliff Brown, *Reducing the Costs of Prosthetic Manufacturing*, DIGIT. PATTERNING (Oct. 30, 2019), https://www.digitalpatterning.net/dpblog/reducing-the-costs-of-prosthetic-manufacturing [https://perma.cc/V9AB-ZACB].

129. Gillian Mohney, *Health Care Costs for Boston Marathon Amputees Add Up Over Time*, ABC NEWS (Apr. 24, 2013), https://abcnews.go.com/Health/health-care-costs-boston-marathon-amputees-add-time/story?id=19035114 [https://perma.cc/S59X-AG4T]

130. *See Implementation of 3D Printing, supra* note 113, at 1641.

131. *Id.*

Zuniga of the University of Nebraska Omaha[132] designed the Cyborg Beast Hand, a wrist-powered design that "built on the prior work[,] improved integration and assembly challenges, [and] has seen significant implementation for children with limb differences . . . ."[133]

After the prosthetics are designed, produced, and placed onto people's bodies, the next step is physical therapy.[134] Patients must often attend physical therapy for weeks or months, depending on which limb the prosthetic is replacing.[135] Furthermore, the cost can vary greatly based on which limb is the focus of the therapy.[136] While some patients can walk on their own as early as four weeks after receiving the prosthetic, Garrison says most will have to get a second limb a year later because of the ways the body changes in that time.[137]

In addition, Medicare Part B covers up to 80% of the cost of prosthetic limbs that are "needed to replace a body part or function when a Medicare-enrolled doctor or other health care provider orders them."[138] However, patients must visit a Medicare-enrolled supplier in order for the program to pay for the service.[139] Disturbingly, suppliers who are enrolled in Medicare but not "participating" can refuse to accept assignment of the costs; in this case, there is no limit on how much they can charge patients.[140] Fortunately for patients, there are nonprofits around the country dedicated to providing resources to low-income amputees, ranging from medical equipment and running prosthetics to assistance with out-of-pocket costs.[141]

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132. As of March 2022, Professor Zuniga works at the University of Nebraska Omaha. *See Jorge Zuniga, PhD*, UNIV. OF NEB. OMAHA, https://www.unomaha.edu/college-of-education-health-and-human-sciences/biomechanics-core-facility/about-us/directory/jorge-zuniga.php [https://perma.cc/KYJ2-9EEP]. However, when the Cyborg Beast Hand was designed and produced, he was conducting his work at the University of Creighton. *See The Cyborg Beast*, ENABLING THE FUTURE, https://enablingthefuture.org/upper-limb-prosthetics/cyborg-beast/ [https://perma.cc/B52W-SK32].

133. *See Implementation of 3D Printing, supra* note 113, at 1641.

134. *See* Mohney, *supra* note 129.

135. *See id.*

136. *Id.*

137. *Id.*

138. *See Your Medicare Coverage: Prosthetic Devices?*, MEDICARE.GOV, https://www.medicare.gov/coverage/prosthetic-devices [https://perma.cc/L8YQ-GEJL].

139. *Id.*

140. *See What Coverage Does Medicare Offer for People with Limb Loss?*, AMPUTEE COALITION (Sept. 2021), https://www.amputee-coalition.org/resources/medicare-for-people-with-limb-loss/ [https://perma.cc/34DN-THKT].

141. Amputee Coalition lists many of these organizations on their website. *See Financial Assistance for Prosthetic Services, Durable Medical Equipment, and Other Assistive Devices*, AMPUTEE COALITION (Sept. 2019), https://www.amputee-coalition.org/resources/financial-assistance-for-prosthetic-services/ [https://perma.cc/VF7X-LLFM]. For example, Amputee Blade Runners provides free running prosthetics for amputees; Ability Found helps amputees get medical

D. Federal Regulation of Prosthetic Limbs

In the United States, the Federal Food and Drug Administration (FDA) regulates medical devices, including prosthetic limbs.[142] Medical devices fall into one of three categories: Class I, Class II, and Class III.[143] Prosthetics are considered Class I devices, which "are subject to the full set of general controls, including that they be 'manufactured under a quality assurance program, be suitable for the intended use, be adequately packaged and properly labeled, and have establishment registration and device listing forms on file with the FDA.'"[144] However, custom-made parts are not federally regulated,[145] nor are "parts [which have been customized] after distribution by a registered establishment."[146]

While the FDA seeks to encourage innovation and accessibility to 3D printed prosthetics, individual states can put up their own barriers to these products. For example, in 2001, Ohio prosthetic developers who sought a license from Ohio's Occupational Therapy, Physical Therapy, and Athletic Trainers Board were required to complete an undergraduate degree and a residency program, work for at least eight months under the supervision of a licensed prosthetist, pass an exam, and pay a fee—all of which could take up to six years to complete.[147] However, Ohio enacted a new law in 2019 specifically to allow companies and charities to make and distribute 3D printed prosthetics on their own.[148]

In contrast, European regulations vary on 3D printed medical devices.[149] For example, a hospital in Brescia, Italy used a 3D printer to make one hundred respirator valves after they had run out of such devices.[150] The hospital had 250 coronavirus patients in their intensive

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equipment at little to no cost; and Help Hope Live provides financial assistance for out-of-pocket costs such as medication and wheelchair modifications. *Id.*

142. *See generally Federal (US) Regulation of Prostheses*, OPEN PROSTHETICS, https://www.openprosthetics.org/wiki/federal-us-regulation-prostheses [https://perma.cc/RBU7-2XSV].

143. *Id.*

144. *Id.*

145. This statement is true as of May 2022. *See Product Classification,*, U.S. DEP'T OF HEALTH & HUMAN SERVS., https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm

146. *Federal (US) Regulation of Prostheses, supra* note 142.

147. *See* Erin Kidd, *3D-Printed Prosthetics: Addressing Regulations to Accept an Artistic and Accessible Alternative*, RICH. J. OF TECH. (Oct. 11, 2019), https://jolt.richmond.edu/2019/10/11/3d-printed-prosthetics-addressing-regulations-to-accept-an-artistic-and-accessible-alternative/ [https://perma.cc/V5E2-6EE4].

148. *Id.*

149. *See* Mikahila L.*, Is the EU Lagging Behind in 3D-Printed Medical Device Regulation?*, 3DNATIVES (Oct. 6, 2021) https://www.3dnatives.com/en/3d-printed-medical-device-regulation-061020216/#! [https://perma.cc/HM6M-QXR4].

150. *See* Anas Essop, *Hospital in Italy Turns to 3D Printing to Save Lives of Coronavirus Patients*, 3D PRINTING INDUS. (Mar. 18, 2020), https://3dprintingindustry.com/news/hospital-in-italy-turns-to-3d-printing-to-save-lives-of-coronavirus-patients-169136/ [https://perma.cc/PMG8-CENZ].

care unit who relied on respirators.[151] The original supplier could not supply the necessary valves in time to save lives.[152] Seven printers were used, and each valve cost €1 (about $1.22) and one hour to produce.[153] Despite the efficiency and the potentially lifesaving results of the 3D printing process, people who have access to these machines often must balance altruism with wariness of legal repercussions.

Cristian Fracassi, whose product development company, Isinnova, helped to create the prototypes and final products for the hospital's 3D printed valves, says that "he does not plan to release the design publicly, despite additional hospitals requesting more valves."[154] This is due in part to the threat of being sued for copyright infringement because the original manufacturers did not authorize reproduction of their product and will not share the blueprints for reproduction.[155] Despite the lifesaving potential, Fracassi also raised concerns about the valves being difficult to print, as well as the potential for contamination to occur outside of clinical environments.[156]

As countries all over the world are producing 3D printed prosthetics, they face difficult decisions amid rapidly changing and disruptive technology:

> To begin with, they need to decide whether bioprinting should be regulated under new or existing frameworks, and if the latter, which ones. For instance, should they apply regulations for biologics, a class of complex pharmaceuticals that includes treatments for cancer and rheumatoid arthritis, because biologic materials are involved, as is the case with 3D-printed vaccines? Or should there be a regulatory framework for medical devices better suited to the task of customizing 3D-printed products like splints for newborns suffering from life-threatening medical conditions?[157]

Nebulous regulations, which are unable to keep up with rapidly changing technology, prevent innovations in 3D printing technology and block access to prosthetics for high-need patients.

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151. *Id.*
152. *Id.*
153. *Id.*
154. *Id.*
155. *Id.*
156. *Id.*
157. *See generally* Dinusha Mendis & Ana Santos Rutschman, *3D Printing of Body Parts Is Coming Fast—But Regulations Are Not Ready*, THE CONVERSATION (Jan. 10, 2020), https://theconversation.com/3d-printing-of-body-parts-is-coming-fast-but-regulations-are-not-ready-128691 [https://perma.cc/SP8S-ZMTZ].

VI. PROPOSED SOLUTIONS

A. Fair Use Defense for Patent Infringement

While the greatest barrier for low-income individuals to overcome to obtain prosthetic limbs is a financial one, intellectual property laws also play a significant part in preventing access to these devices. If a fair use defense for patent infringement existed as it does for copyright and trademark infringement, prosthetic manufacturers could use and improve upon patented designs while utilizing 3D printing technology to manufacture prosthetics at scale, reduce costs, and provide greater access to prosthetics.

Some companies have already taken the initiative to open their patents to the public. For example, Tesla released its patents in 2014 and pledged not to "initiate patent lawsuits against anyone who, in good faith, wants to use its technology."[158] The purpose of this policy was to "encourage the advancement of [electronic car development,] a common, rapidly-evolving platform[.]"[159] Similarly, the purpose of the open-source designs for 3D printers, such as those used by e-NABLE and Open Bionics, is to promote the advancement and improvement of a new, collaborative, and rapidly changing platform. Tesla and other corporations have seen the value of prioritizing scientific advancement over intellectual property rights, and prosthetic companies should adopt this approach as well.

Opponents of the patent fair use defense are likely to suggest that allowing such a defense would discourage patentees from creating their works for fear that anyone could come in and take them for their own commercial benefit. However, the importance of public health, in the context of 3D printed prosthetic limbs, trumps profitability and must be put aside as society values the common good over one company making massive additional profits.

B. Changing the United States' Regulatory Scheme

The United States would benefit by following Europe's lead in allowing hospitals to become manufacturers of 3D printed devices and have printers on-site for situations such as those described in this Note. Having 3D printers in hospitals would allow doctors to treat their patients more efficiently. In the medical field, mere minutes can be the difference between life and death. With 3D printers on premises, medical

158. *Patent Pledge*, TESLA, https://www.tesla.com/about/legal#patent-pledge [https://perma.cc/E9FK-MWWE].

159. *Id.*

professionals would be able to make life-saving materials, like the valves in the Italian hospital, in as little as an hour.[160] Other biomedical materials, like 3D printed prosthetic limbs, could also be produced at a much faster rate at a lower cost.[161]

Critics of this approach are likely to mention that medical practitioners will have to be trained in how to operate the printers, as well as how to design the specific body parts that patients need. However, medicine and other scientific fields rely on innovation to sustain and improve them. It is imperative that practitioners adapt to—and take advantage of—new technologies, even if it means they must spend additional time training to use new equipment.

There may also be the fear of opening hospitals up to liability if they become manufacturers of these products themselves. Nevertheless, 3D printing technology has already been used in various contexts, all of which carry some risk of harm or defect.[162] While there is always a chance that a patient's body does not respond well to the prosthetic, the collaborative nature of making 3D printed limbs—involving doctors, engineers, and designers—will lower this risk as much as possible.

CONCLUSION

The pillars of intellectual property law are the beliefs that products of human intellect should be protected and that such protections will incentivize further innovation and creative thought.[163] However, when there is a compelling public interest in overturning these protections, they should be set aside in limited circumstances. One such circumstance is patient access to prosthetic limbs as discussed in this Note. Prosthetics can significantly improve patients' confidence and self-esteem, bring a sense of normalcy to their lives, and ease physical and emotional navigation of the world. Access to devices that have such potential for invoking positive change in patients' lives should not be barred because of design patents or

160. *See* Essop, *supra* note 150.

161. *See* Heidi Reidel, *The Successes and Failures of 3D Printed Prosthetics*, PRESCOUTER (July 2017), https://www.prescouter.com/2017/07/3d-printed-prosthetics/#:~:text=3D%20printed%20prosthetics%20can%20also,fit%20their%20wants%20and%20needs. [https://perma.cc/9P97-FMLX] ("According to a statement made by the American Orthotics and Prosthetics Association, the average prosthetic costs between $1,500 to $8,000. This expense is often paid out of pocket rather than covered by insurance. By contrast, a 3D printed prosthetic costs as little as $50! 3D printed prosthetics can also be made much quicker; a limb can be made in a day.").

162. *Id.* (explaining that 3D printed limbs break "far more often than traditional prosthetics" due to improper handling or temperature regulation during assembly); *see also* Juliet Childers, *How Close Are We to 3D Printing Bodies?*, EDGY (Mar. 14, 2018), https://edgy.app/how-close-3d-printing-bodies [https://perma.cc/PYA2-QPCQ] (explaining that rejection of prosthetic limbs is a serious concern).

163. *Intellectual Property*, LEGAL INFO. INST., https://www.law.cornell.edu/wex/intellectual_property [https://perma.cc/C77E-6FM2].

lack of financial resources. By utilizing 3D printing technology and allowing open-source designs to continue, more people can have access to these important products regardless of their financial status.