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The Medical Liability Exemption: A Path to Affordable Pharmaceuticals

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THE MEDICAL LIABILITY EXEMPTION: A PATH TO AFFORDABLE PHARMACEUTICALS?

CARRIE E. ROSATO¹

ABSTRACT

Patent monopolies are tolerated because we believe they promote progress that benefits society. What should be done when these monopolies actually increase human suffering? Drug prices in America are fifty to eighty percent higher than the rest of the world, meaning many cannot afford drugs that will improve or even save their lives. When striking a balance between the interests of the patent holder and that of the public, it is important to bear in mind that the rewards granted to patentees are secondary to the public benefit derived from their labors. The ideal solution would come from Congress creating a need-based exemption to drug patent infringement, but this is unlikely to occur. An infrequently used statutory exemption, found in Section 287(c) of the Patent Act, precludes liability when a physician infringes a medical process patent. With the advances in 3D printing, doctors will soon be able to print drugs for their patients. The courts could interpret 287(c) to protect physicians from patent liability for printing drugs when provided to patients demonstrating financial hardship. When faced with new technology, the courts have been creative in interpreting the intellectual property statutes in order to reach a just and equitable resolution. The public need for affordable drugs should spur the courts to such creativity when addressing the issue of 3D drug printing.

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I. INTRODUCTION

An unsettlingly high number of people lack access to prescription drugs.² As of 2009, it was estimated that 10 million children die each year from preventable or curable diseases, mainly in developing countries.³ The high cost of drugs limits accessibility in developed

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2. Up to 90 million people in the United States alone. FREDERICK M. ABBOTT & GRAHAM DUKES, GLOBAL PHARMACEUTICAL POLICY: ENSURING MEDICINES FOR TOMORROW'S WORLD 66 (2009).

3. *Id.* at 116; see also Robert C. Bird, *Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effects*,

countries as well, especially in the United States, where medical bills are a leading cause of personal bankruptcy.⁴ While this problem has long been discussed, most proposed solutions have had little impact or have not been implemented.⁵

In the United States, one of the largest impediments to low cost drugs is the patent system. A drug patent grants the drug company a monopoly on that drug for at least twenty years.⁶ With that monopoly a drug company can charge whatever price it chooses.⁷ Normally, competition would push prices to an acceptable level, but the monopoly allows drug companies to keep prices inflated, preventing access to many. This problem is exacerbated by the Medicare Prescription Drug, Improvement, and Modernization Act (“MMA”), which mandates that Medicare pay the manufacturer’s list price for drugs without any negotiation.⁸

In 1996, Congress amended the Patent Act to allow an exemption from damages for infringing medical technique patents, based on the infringer’s status as a physician.⁹ Section 287(c), or the Medical Liability Exemption, barred patent-holders from seeking money damages or injunctions from medical practitioners or related health care entities.¹⁰ The policy rationales given for allowing the exemption are equally applicable to drugs and medical devices,¹¹ and it remains unclear why doctors are precluded from profiting from their process inventions yet drug companies are allowed to use current laws to maximize profits at the expense of human health.

A solution to this issue should come from Congress, such as a compulsory licensing scheme or an amendment to Section 287(c) that

37 J.L. MED. & ETHICS 209, 209 (2009) (noting that tens of millions of adults and children die each year from treatable or preventable illnesses).

4. See Dan Mangan, *Medical Bills Are the Biggest Cause of US Bankruptcies: Study*, CNBC (June 25, 2013, 2:29 PM), <http://www.cnbc.com/id/100840148#>.

5. See Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853 (2003) (studying the grant of six compulsory licenses over drug patents and concluding there was little evidence of a decline in innovation); Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047 (2009) (discussing compulsory licenses as a solution to the high cost of pharmaceuticals and how different countries have approached the issue).

6. 21 U.S.C. § 355 (2012). That monopoly can be extended due to regulatory delays encountered while awaiting FDA approval. 35 U.S.C. § 156 (2012); WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RS21129, PHARMACEUTICAL PATENT TERM EXTENSIONS: A BRIEF EXPLANATION (2002).

7. See Bird, *supra* note 3 (stating that strong patent laws create monopolies that allow drug companies to raise prices in order to maximize profits at the expense of human health).

8. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub L. No. 108-173, § 303, 117 Stat. 2066, 2242 (codified at 42 U.S.C. § 1395w-3a(c)(6)(B) (2012)).

9. 35 U.S.C. § 287(c) (2012).

10. *Id.*

11. Throughout the paper I will refer to drugs as a shortcut, but my arguments apply to both drugs and medical devices.

would limit liability when doctors provide drugs or medical devices to patients that meet certain hardship criteria. However, the pharmaceutical and health products lobby (collectively known as “Big Pharma”) is the largest lobbying group in Washington. Therefore, Congress is unlikely to change the current system to expand the Medical Liability Exception. In the alternative, the rise of 3D printing technology could allow courts to use the Medical Liability Exemption to bar damages from certain “printers” of drugs. When considering how intellectual property statutes should apply to new technology, the Court has imported concepts from other areas of law to facilitate reaching an equitable outcome. This could give the courts some leeway to use the fair use doctrine from copyright law to interpret Section 287(c) in a way that includes 3D printing as a medical process in light of the pressing public health concern. The important public interest in access to affordable pharmaceuticals necessitates that the courts step in and make drugs and devices available to those who cannot afford them.

This Note will propose how the Medical Liability Exemption should be amended and failing such amendment, how the courts could intervene. Part II gives an overview of the patent system and discusses the legislative history of the Medical Liability Exemption and how the exemption should be amended. Part III details why such an amendment is unlikely to occur and how 3D printing of pharmaceuticals and medical devices could be used to prevent the financial hardship many patients face. This Part also discusses Supreme Court precedent applying old statutory language to new technology. Part IV explains the Fair Use Exception found in copyright law and how it could be used to interpret the Medical Liability Exemption. Finally, Part V concludes that the courts should intervene in the interest of human health to minimize liability to physicians that provide patented drugs or medical devices to patients that would go without due to cost.

II. THE CURRENT MEDICAL LIABILITY EXEMPTION AND HOW IT SHOULD BE AMENDED

To better understand the current state of the Medical Liability Exemption and how it should be expanded, a brief overview of the patent system is necessary. It will be helpful to understand what the goals of intellectual property protection are and how those goals are furthered by such an expansion. This Part will also consider the history of the Medical Liability Exemption and how the distinction made between medical processes and drugs is not clear. Finally, an amendment to the exemption will be proposed to extend liability to medical professionals providing drugs to certain low-income patients.

A. *Brief History of the Patent System and
the Medical Liability Exemption*

The Framers placed great importance on promoting the progress of science and the useful arts, granting Congress the power to make laws giving authors and inventors exclusive rights to their writings or discoveries.¹² To acquire a patent, the applicant must meet several requirements, demonstrating the innovation is over patentable subject matter, is properly enabled, and is useful, novel, and non-obvious.¹³ Once these requirements are met, a patent can be issued for a process, machine, manufacture, composition of matter, or an improvement thereof¹⁴ for a twenty-year term.¹⁵

Patents are usually divided into two categories: product or process patents.¹⁶ Process patents have been defined as “a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.”¹⁷ Because Congress intended “anything under the sun that is made by man” to be patentable subject matter,¹⁸ this provision has been construed to grant process patents for medical procedures as long as they satisfy the statutory requirements.¹⁹

It is often thought that the purpose of a patent is to confer benefits on the patent holder. However, the Supreme Court has stated that reward to the owner is a secondary consideration, while the primary object is the general benefits derived by the public of the inventor’s labors.²⁰ Balancing the various interests of inventors and the public is a difficult task that has led Congress to amend the Patent Act repeatedly.²¹

One such amendment, the only limitation on patent liability ever passed, is the so-called Medical Liability Exemption found at 35 U.S.C. 287(c). This provision states:

12. U.S. CONST. art. I, § 8, cl. 8.

13. 35 U.S.C. §§ 101-103.

14. 35 U.S.C. § 101. Section 100(b) defines process as “[a] process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.” §100(b). Of course defining process as a process is quite cyclical.

15. 35 U.S.C. § 154(a)(2).

16. Weldon E. Havins, *Immunizing the Medical Practitioner “Process” Infringer: Greasing the Squeaky Wheel, Good Public Policy, or What?*, 77 U. DET. MERCY L. REV. 51, 60 (1999).

17. *Cochrane v. Deener*, 94 U.S. 780, 788 (1876).

18. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)).

19. Havins, *supra* note 16, at 60-61.

20. *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 429 (1984) (citing C.J. Hughes in the copyright context in *Fox Film Corp. v. Doyal*, 286 U.S. 123, 127 (1932)).

21. *Id.*

(c)(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.²²

(2) For the purposes of this subsection:

(A) the term "medical activity" means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.

. . .

(3) This subsection does not apply to the activities of any person . . . who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office) . . .²³

Essentially, 287(c) creates an exception to patent infringement liability for medical professionals who use a patented method "while performing a medical activity with the goal of treating a human being."²⁴

B. Legislative History of Section 287(c)

As would be expected for such a unique exception to the Patent Act, Section 287(c) has an interesting legislative history. In 1996, a federal district court heard a summary judgment motion in *Pallin v. Singer*.²⁵ The plaintiff was an ophthalmologist who sued several other doctors for using his patented cataract surgical technique without a license.²⁶ The case seems fairly insignificant, especially considering that the court ultimately invalidated all of the contested claims,²⁷ but the case generated significant—mostly negative—attention in the

22. Section 271 details what constitutes patent infringement, while the other provisions describe the remedies available when a patent is infringed, including an injunction, damages, and attorney fees. 35 U.S.C. § 271 (2012).

23. 35 U.S.C. § 287(c).

24. See Fariba Sirjani & Dariush Keyhani, 35 U.S.C. § 287(C): *Language Slightly Beyond Intent*, 3 BUFF. INTELL. PROP. L.J. 13, 13-14 (2005).

25. *Pallin v. Singer*, Civ. A. No. 2:93-CV-202, 1996 WL 274407 (D. Vt. Mar. 28, 1996).

26. *Pallin v. Singer*, Civ. No. 5:93-202, 1995 WL 608365, at *1 (D. Vt. May 1, 1995). In testimony before Congress, Singer claimed the litigation arose from independent development of the identical cataract procedure. See *Medical Procedures Innovation and Affordability Act and Inventor Protection Act of 1995: Hearing on H.R. 1127 & H.R. 2419 Before the H. Judiciary Subcomm. on Courts and Intell. Prop. of the Comm. on the Judiciary*, 104th Cong. 42-44 (1995) [hereinafter *Hearing*] (statement of Dr. Jack A. Singer) (discussing patent No. 5,080,111).

27. *Pallin*, 1996 WL 274407.

medical community.²⁸ *Pallin* was the first patent infringement suit filed by one doctor against another.²⁹ In a particularly colorful article, one “intraocular lens pioneer” depicted *Pallin* as a “monumental battle,” which could have “devastating and mind-boggling consequences.”³⁰ This description is certainly overstated, but the American Medical Association House of Delegates condemned “this relatively new phenomenon” of patenting medical and surgical procedures and voted to work with Congress to outlaw the practice.³¹ The American Academy of Ophthalmology also lobbied to pass legislation exempting such procedures from patent protection, and this combined lobbying effort would prove successful.³²

The 104th Congress took up the issue, eventually passing Section 287(c) as part of the Omnibus Consolidated Appropriations Act.³³ The first step was a House proposal called H.R. 1127, which would prohibit the issuance of patents on medical and surgical procedures.³⁴ The bill’s sponsors released a statement citing the policy considerations underlying H.R. 1127, noting medical procedures are the product of collaboration and built upon the work of others.³⁵ The Congressmen claimed that medical procedure patents increase healthcare costs and “could deny patients access to the highest quality health care.”³⁶ Some patent experts felt this response was overbroad.³⁷ Others argued that, by redefining what was patentable subject matter under 35 U.S.C. § 101, this bill directly conflicted with the intentions of the Founders who created the patent system.³⁸ H.R.

28. See William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF. SOC’Y 651, 652 (1995) (stating that many physicians consider medical technique patents “an unethical interference with patient care”).

29. Richard P. Burgoon, Jr., *Silk Purses, Sows Ears and Other Nuances Regarding 35 U.S.C. § 287(c)*, 4 U. BALT. INTEL. PROP. L.J. 69, 72 (1996); see also Havins, *supra* note 16, at 53 (claiming that physicians rarely enforced procedure patents, but obtained them to claim credit).

30. Katherine J. Strandburg, *Legal But Unacceptable: Palin v. Singer and Physician Patenting Norms*, in INTELLECTUAL PROPERTY AT THE EDGE: THE CONTESTED CONTOURS OF IP 321, 337 (Rochelle Cooper Dreyfuss & Jane C. Ginsburg eds., 2014) (citing Herve M. Byron, *Is This Déjà Vu?*, OCULAR SURGERY NEWS, June 1, 1994, at 13).

31. Noonan *supra* note 28, at 652 (quoting *AMA Opposes Patents for Medical, Surgical Procedures*, AMA NEWS, July 4, 1994, at 6).

32. *Id.*

33. Omnibus Consolidated Appropriations Act, Pub. L. No. 104-208, § 616, 110 Stat. 3009, 3009-67-3009-69 (1996).

34. *Hearing*, *supra* note 26, at 42-44.

35. See *Patient Access to Medical Procedures Strengthened in Ganske-Wyden Bill*, U.S. Congressional News Release, Mar. 3, 1995.

36. *Id.*

37. See Noonan, *supra* note 28, at 664 (suggesting a compulsory license that would require the patent holder to license for a reasonable royalty).

38. See Burgoon, *supra* note 29, at 74-75; see also Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601, 651 (2000) (stating that 287(c) is problematic because it creates an exception to enforcement based on a person’s status).

1127 would have created a precedent that certain patents are inappropriate when they negatively impact a certain profession, thus creating an exemption based on status.³⁹ Additionally, “because the phrase ‘surgical and medical procedures’ was not defined” in the bill, it was unclear how the Patent and Trademark Office would administer the law.⁴⁰

These concerns, and opposition from the biotechnology industry,⁴¹ sparked an alternative Senate bill one day prior to the H.R. 1127 hearings.⁴² This bill, S. 1334, differed from H.R. 1127 by redefining what constitutes patent infringement under 35 U.S. § 271.⁴³ Essentially, it would have the same effect as H.R. 1127 but would allow patents to issue on medical techniques while preventing a finding of infringement if the infringer was a health care practitioner or associated entity.⁴⁴

Various parties testified before Congress regarding the merits of H.R. 1127, including representatives of the medical community.⁴⁵ A common theme from supporters of the bill was that medical procedure patents would drive up the cost of healthcare, but little data was given in support of this contention.⁴⁶ It was also argued that these patented techniques are the result of years of collaboration and should be shared with the medical community as a whole, especially since such techniques do not usually make significant advances over the prior art.⁴⁷ Representatives Ganske and Wyeth argued such patents run counter to the Hippocratic Oath by limiting patient access, and the United States should join the more than 80 countries that have banned patents on medical procedures.⁴⁸

Those opposed to the bill made a variety of strong arguments. Dr. Pallin, of ophthalmology patent fame, argued patents are a powerful incentive for innovation and this was merely an example of “special interest groups seeking privilege.”⁴⁹ Pallin questioned how H.R. 1127 would be implemented—would a patented veterinary technique that

39. See Burgoon, *supra* note 29, at 75, 77.

40. *Id.* at 75.

41. Emtel, Inc. v. Lipidlabs, Inc., 583 F. Supp. 2d 811, 821 (S.D. Tex. 2008).

42. Burgoon, *supra* note 29, at 76.

43. S. 1334, 104th Cong. § 2 (1995).

44. *Id.* Scholars have raised the concern that this could constitute a taking under the Fifth Amendment. See Leisa Talbert Peschel, *Revisiting the Compromise of 35 U.S.C. § 287(c)*, 16 TEX. INTELL. PROP. L.J. 299, 321 (2008).

45. *Hearing, supra* note 26, at 25-100.

46. *Id.*; Burgoon, *supra* note 29, at 77 n.27 (noting that the new technique saved patients \$17 per operation but not considering how licensing fees would increase the patient cost).

47. See *Hearing, supra* note 26, at 24 (statement of Greg Ganske, Rep. of Iowa).

48. *Id.* at 24-26, 65-66 (prepared statement of William D. Noonan, M.D.) (discussing the ethical problems with medical procedure patents).

49. *Id.* at 39-40 (statement of Dr. Samuel L. Pallin, M.D., F.A.C.S.) (noting several of the Founders who signed the constitution were doctors).

later became applicable to humans be rescinded?⁵⁰ Pallin also doubted the premise that doctors would choose a less effective method to avoid increased cost from licensing a superior patented method, noting that doctors do not buy cheap instruments and similarly will always choose the best methods.⁵¹ His testimony concluded by noting that no one questioned patents on costly new drugs.⁵² This is an important point, as the distinction between methods and drugs does not come from the Constitution or the Patent Office,⁵³ and it seems the policy considerations of innovation, cost, and optimal patient care should apply equally to both.

In his statement to Congress, Dr. William Noonan attempted to elucidate a difference between patents for drugs and medical procedures.⁵⁴ Noonan was in the unique position of being both a physician and a patent attorney.⁵⁵ As such, Noonan felt H.R. 1127 had “the kernel of a good idea” but was overbroad and could eliminate patent protection for new uses of known drugs.⁵⁶ Noonan was concerned that allowing liability for medical process patent infringement would impact a physician’s ability to choose what treatment was best for a patient, however he failed to distinguish this circumstance from a patient’s inability to take the best drug because it was too expensive. This view is logical coming from a doctor, whose primary concern was doctor liability. However, it remains unclear why an exception should be applied to doctors using patented procedures and not patients needing expensive patented drugs or devices.

Others testified to why medical techniques should be treated differently from drugs and devices, with the arguments falling mainly in two categories: economics and ethics. The question remains whether this distinction is persuasive. One of the predominant justifications for the exemption, which at first blush is convincing, is the research and development (“R&D”) cost disparity between techniques

50. *Id.* at 39.

51. *Id.* at 39-40.

52. *Id.* at 40.

53. *Id.*

54. *See id.* at 61-67 (statement of William D. Noonan, M.D.).

55. *Id.* at 61.

56. *Id.* at 61-62.

and drugs.⁵⁷ However, this disparity is not necessarily accurate and the right to a patent does not hinge on the amount spent developing an invention.

A major rationalization of the patent system as a whole, and particularly medical patents, is that patents create an economic incentive to create, especially where R&D costs would be prohibitive otherwise.⁵⁸ Nevertheless, R&D costs are not always as high as manufacturers would have the public believe. Drug companies claim R&D can reach over a billion dollars, but many drugs do not entail a large R&D expenditure.⁵⁹ In a process referred to as “evergreening,” drug patent holders are granted patents for a new delivery system or pharmaceutical mixture in order to extend the life of an expiring patent.⁶⁰ Despite threats that without charging high prices new drugs will not be discovered, half of the new drugs approved between 1998 and 2007 stemmed from research at universities and biotech firms, not big drug companies.⁶¹

Additionally, it is inaccurate to say that all medical procedures are developed with minimal cost.⁶² An often-used example is the Surrogate Embryo Transplant (“SET”) technique for implanting a fertilized

57. See *Hearing*, supra note 26, at 48-49 (statement of Jack A. Singer, M.D.) (responding to a question from Congresswoman Schroeder (D-Colorado), Singer distinguished device R&D costs from techniques, stating there will always be some expenditure for development and marketing for devices, whereas a “pure procedure” comes naturally during practice and lacks similar expense).

58. Beata Gocyk-Farber, Note, *Patenting Medical Procedures: A Search for a Compromise Between Ethics and Economics*, 18 CARDOZO L. REV. 1527, 1541-42 (1997). As of 2009, it was estimated \$160 billion was spent globally on medical R&D, however only 3% went to diseases disproportionately affecting developing countries. See Ann Weilbaecher, *Diseases Endemic in Developing Countries: How to Incentivize Innovation*, 18 ANNALS HEALTH L. 281, 282 (2009).

59. Richard Anderson, *Pharmaceutical industry gets high on fat profits*, BBC NEWS (Nov. 6, 2014), <http://www.bbc.com/news/business-28212223>.

60. See ABBOTT & DUKES, supra note 2, at 3; JAMES BOYLE & JENNIFER JENKINS, INTELLECTUAL PROPERTY: LAW & THE INFORMATION SOCIETY CASES & MATERIALS 631 (2014); Saby Ghoshray, 3(D) *View of India's Patent Law: Social Justice Aspiration Meets Property Rights in Novartis v. Union of India & Others*, 13 J. MARSHALL REV. INTELL. PROP. L. 719, 722 n.2 (2014). But see Jonathan J. Darrow, *Debunking the “Evergreening” Patents Myth*, HARVARD LAW RECORD, 2010, at 6.

61. Robert Kneller, *The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs*, 9 NATURE REVIEWS DRUG DISCOVERY 867, 869 (2010). The present rate of drug innovation is low and large drug companies often leave R&D to universities and smaller biotech firms, therefore the high costs of R&D are not actually felt. See ABBOTT & DUKES, supra note 2, at 51. Subsidies are available for public institutions and small biotech firms that are not usually available to larger drug companies. See Enrico Moretti & Daniel J. Wilson, *Innovation and Incentives: Evidence from Biotech*, FED. RES. BANK OF S.F. (Dec. 8, 2014), <http://www.frbsf.org/economic-research/publications/economic-letter/2014/december/biotechnology-biotech-economic-growth/>.

62. See Ho, supra note 38, at 615-16 (arguing that the distinction in R&D costs between procedures and devices is unsupported and that drug development costs are well documented but similar data on devices is unavailable).

egg into a donor's womb.⁶³ Government funding was denied to the SET developers, who needed \$500,000 to complete R&D.⁶⁴ Private investors, attracted by the potential profit if the procedure was patented, stepped in.⁶⁵ Medical procedures like SET can be just as expensive to develop as drugs or medical devices.

More importantly, it seems the distinction between procedures and drugs based on R&D costs is a red herring. Even if it were true that medical procedures cost less to develop than drugs, this is a distinction without meaning. Nothing in the Constitution or the Patent Act requires a threshold R&D expenditure to procure a patent.⁶⁶ There is a uniform standard for all patent applications—they must be new, useful, and nonobvious; and none of the requirements consider the amount of money spent to create the patented subject matter.⁶⁷ Thus, higher R&D costs do not justify an exemption for medical procedure patents and not patents for drugs or medical devices. Despite these criticisms, the substantive provisions of S. 1334 were included in the Appropriations Act signed by President Clinton in 1996, and the first and only liability exemption to patent infringement based on the infringer's status became law.⁶⁸ The exemption has been rarely used,⁶⁹ providing evidence that there was no crisis to begin with, but it could be utilized in the fight to decrease pharmaceutical costs.

C. Proposed Changes to the Current Exemption

The need for affordable medications is quite apparent in developing countries, but the problem is also prevalent in the United States. Many illnesses require expensive treatment, and cancer treatment is illustrative of the financial impact such an illness can have on a patient and their family. Approximately one in three Americans will receive a cancer diagnosis in their lifetime.⁷⁰ The American Cancer Society estimates more than 1.6 million new cancer cases will be di-

63. Gocyk-Farber, *supra* note 58, at 1542.

64. *Id.*

65. *Id.*

66. See U.S. CONST. art. I, § 8, cl. 8.

67. See 35 U.S.C. § 101 (2012) (stating usefulness requirement); § 102 (stating novelty requirement); § 103 (stating nonobvious requirement).

68. See Burgoon, *supra* note 29, at 69.

69. See *infra* note 144.

70. *60 Minutes: The Cost of Cancer Drugs* (CBS television broadcast Oct. 5, 2014), available at <http://www.cbsnews.com/news/the-cost-of-cancer-drugs/>. While cancer incidence rates are declining in men, are stable in women, and cancer death rates have decreased slightly, cancer deaths in 2014 still averaged 1600 per day. *Cancer Statistics 2014: Death Rates Continue to Drop*, SCI. DAILY (Jan. 7, 2014), <http://www.sciencedaily.com/releases/2014/01/140107102634.htm> (citing two published reports from the American Cancer Society).

agnosed in 2014.⁷¹ Americans have access to some of the best medical care the world has to offer, but a growing number of patients, even those with insurance, cannot afford the drugs their treatment requires.⁷² The term “financial toxicity” has been coined to describe the phenomenon where doctors now need to consider the cost of treatment along with the best treatment methods.⁷³ Patients increasingly must cover drug costs themselves—in 2006 one-quarter of patients reported depleting most of their savings.⁷⁴ Unsurprisingly, a cancer diagnosis is one of the leading causes of personal bankruptcy.⁷⁵

There are some situations “in which the public benefit from . . . [patent] infringement may be so great that it outweighs the patentee’s interest in its exclusive rights.”⁷⁶ The creation of new drugs and medical devices, and the immense benefits they provide to society, are perhaps an area where the stakes for both sides are highest. What could be more beneficial to the public than more affordable medical devices and drugs? If ever a situation existed where the public benefit should outweigh the costs of patent protection, this is it.⁷⁷ Yet Congress could not eliminate patent protection of drugs and medical devices altogether. While the high cost of R&D does not justify the distinction between process and utility patents, eliminating patent protection completely would preclude many innovators from continuing to invent in this field. High R&D costs, coupled with no promise of a monopoly, would likely scare investors away, halting innovation that is incredibly important. How can these competing interests be balanced?

71. AM. CANCER SOC’Y, CANCER FACTS & FIGURES 2014 1 (2014), available at <http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2014/>.

72. *60 Minutes: The Cost of Cancer Drugs*, *supra* note 70.

73. *Id.*; see also Matthew Herper, ‘60 Minutes’ Just Attacked High Drug Prices. Here’s What You Should Know., FORBES (Oct. 5, 2014, 10:31 PM), <http://www.forbes.com/sites/matthewherper/2014/10/05/60-minutes-just-attacked-high-drug-prices-heres-what-you-should-know/>.

74. Bach et al., *In Cancer Care, Cost Matters*, N.Y. TIMES (Oct. 14, 2012), http://www.nytimes.com/2012/10/15/opinion/a-hospital-says-no-to-an-11000-a-month-cancer-drug.html?_r=0.

75. *60 Minutes: The Cost of Cancer Drugs*, *supra* note 70 (one doctor noting, “[h]igh cancer drug prices are harming patients because either you come up with the money, or you die”); see also Peter Ubel, *Beware of Cancer Metastasizing to Your Wallet*, FORBES (Aug. 16, 2013, 10:08 AM), <http://www.forbes.com/sites/peterubel/2013/08/16/beware-of-cancer-metastasizing-to-your-wallet/>; Mangan, *supra* note 4. A 2011 study of 231,799 patients found that after four years, 4805 had filed for bankruptcy. S. D. Ramsey et al., *Cancer Diagnosis as a Risk Factor for Personal Bankruptcy*, 29 J. CLINICAL ONCOLOGY (2011).

76. Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1198 (2000).

77. Access-to-medicines activist Jamie Love, when discussing the social loss associated with monopolies and how certain consumers are priced out of the market said, “In economics . . . we call this ‘dead weight social loss.’ With essential medicines we call it ‘dead people.’” BOYLE & JENKINS, *supra* note 60, at 631-32.

The current language of Section 287(c) makes clear that the exemption is not intended to prevent liability for infringing use of drugs or devices.⁷⁸ However, if the language could be changed to allow such infringement in very limited circumstances, the monopoly incentive to create would not be too disturbed and those who are most in need would be able to receive necessary medical treatment. To accomplish this balance, the language of subsections (2)(A) and (3) should be changed as follows:

(2) For the purposes of this subsection:

(A) the term “medical activity” means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent *unless all of the hardship factors described in subsection (5) are satisfied.*

(3) This subsection does not apply to the activities of any person . . . who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician’s office) . . . *unless all of the hardship factors described in subsection (5) are satisfied.*

(5) *A medical practitioner’s manufacture, use, or distribution of a patented composition of matter shall not be infringing when:*

(A) *the medical practitioner or related health care entity maintains a tax-exempt, nonprofit status as described by the Internal Revenue Service in 26 U.S.C. 501 (3)(c);*

(B) *the patented composition of matter is distributed at no cost to the patient;*

(C) *the patient receiving the patented composition of matter can demonstrate a financial hardship such that payment for the patented composition of matter at the manufacturer’s list price would make financial bankruptcy likely under 11 U.S.C. 1321-1330; and*

(D) *the patented composition of matter is medically necessary to improve or sustain the patient’s life.*⁷⁹

Subsection (3) already clearly states the exemption does not apply to tax exempt organizations that are engaged in *commercial* development, manufacture, *sale*, or distribution of patented compositions

78. 35 U.S.C. § 287 (c)(2)(A), (3) (2012).

79. *Id.* This provision is intended to draw a line between drugs or medical devices that are treating an illness that impacts a patient’s health versus an elective drug such as Botox or Viagra. *See id.*

of matter. This language implies there is a distinction between infringing use that is intended to make a profit and infringing use with a non-commercial purpose, such as what has been described. A non-profit medical practitioner or health care entity will be precluded from liability when it can demonstrate the patented drug or device was distributed at no cost to a patient who needed the drug or device to sustain life and if forced to pay the manufacturer's list price would likely be pushed into bankruptcy. This would not impair the drug companies' profits because such patients could not have purchased the drug in the first place. Therefore, the delicate balance between public benefit and patent incentive would be maintained.

III. CONGRESSIONAL INACTION MAY NECESSITATE COURT INTERVENTION

The conflicting interests of patent protection and the public benefits to society by medical innovation create an ethical dilemma.⁸⁰ There is a concern that "alleviating human suffering does not belong to the area of economic endeavor or trade and commerce."⁸¹ Several solutions have been suggested to amend the Patent Act in order to better deal with these special situations where the public interest should override the rationales to the patent system. In addition to the proposed amendment detailed above, other suggestions include compulsory licenses or a fair use exception, both concepts found in copyright.⁸² While this Note concedes that these suggestions are probably more logical and efficient ways to deal with the problem, such change would require Congress to amend the Patent Statute. The Legislative and Executive branches of the government are tasked with policy decisions, and weighing the interests between patients and patent holders is clearly a policy matter. Unfortunately, Congress is unlikely to limit profits derived from patented drugs or medical devices.

Illness has a huge financial impact on patients and their families. This impact should move Congress to act, but a discussion of the lob-

80. Chris J. Katopis, *Patients v. Patents?: Policy Implications of Recent Patent Legislation*, 71 ST. JOHN'S L. REV. 329, 352 (1997); see also *Trade, Foreign Policy, Diplomacy and Health*, WORLD HEALTH ORG., <http://www.who.int/trade/glossary/story073/en/> (last visited Apr. 24, 2015) (stating that there is "an inherent conflict of interest between the legitimate business goals of manufacturers and the . . . needs of providers and the public").

81. Katopis, *supra* note 80, at 352 (quoting *Wellcome Found., Ltd. v. Comm'r of Patents*, 1983 N.Z.L.R. 385, 388 (1983)); see also Gregory F. Burch, Note, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139 (1987) (discussing ethical objections raised in the context of patenting medical innovation).

82. See O'Rourke, *supra* note 76; Lorelei Ritchie De Larena, *What Copyright Teaches Patent Law About "Fair Use" and Why Universities Are Ignoring the Lesson*, 84 OR. L. REV. 779 (2005); Katherine J. Strandburg, *Patent Fair Use 2.0*, 1 U.C. IRVINE L. REV. 265, 266 (2011).

bying effects of Big Pharma will demonstrate why this solution is doubtful. The new technology of 3D printing may open a door that would allow the courts to effect change in this area. An analysis of how the courts have dealt with new technology and the precedents that mingle different intellectual property concepts will explain how this can be done.

A. *Illness, a Path to Financial Hardship*

Despite the obvious need for more affordable drug prices, it is unlikely Congress will move to limit the profits of drug manufacturers.⁸³ The need to finance campaigns provides an opportunity for members of Congress to be influenced by lobbying groups. The largest of these groups is the pharmaceutical lobby. According to the Center for Responsive Politics, Big Pharma spent over three billion dollars between 1998 and 2014, the most of any lobbying group.⁸⁴ In 2014 alone, Big Pharma spent more than \$230 million, with a total of 1412 lobbyists serving 350 clients.⁸⁵ Big Pharma does not just lobby Congress directly; it also donates money to non-profits for campaign ads.⁸⁶ Nonprofits, unlike Super PACs, are not required to reveal their donors, and their campaign spending has skyrocketed since the 2010 *Citizens United* decision.⁸⁷ With its money and influence, Big Pharma is a huge roadblock to any limitation on the patent protection of drugs.

The passage of the Medicare Prescription Drug, Improvement, and Modernization Act (“MMA”) elucidates Big Pharma’s influence on Congress.⁸⁸ Signed into law in 2003, the MMA introduced an entitlement benefit for prescription drugs to address the increased role of drugs in patient care and the high cost born by patients.⁸⁹ The MMA

83. See Melissa Ganz, *The Medicare Prescription Drug, Improvement, & Modernization Act of 2003: Are We Playing the Lottery with Healthcare Reform?*, 2004 DUKE L. & TECH. REV. 0011 (2004) (noting that due to “an enormous financial interest in maintaining high prescription drug prices and market exclusivity, pharmaceutical companies have spent millions of dollars to extend patent protection and forestall government regulation of prescription drug prices”).

84. See Ctr. for Responsive Pol., *Top Industries*, OPENSECRETS.ORG, <https://www.opensecrets.org/lobby/top.php?indexType=i&showYear=a> (last visited Apr. 24, 2015).

85. *Id.* A list of top clients includes drug manufactures such as Pfizer, Eli Lilly & Co., Novartis, and Sanofi—maker of Zaltrap. Ctr. for Responsive Pol., *Pharmaceuticals/Health Products*, OPENSECRETS.ORG, <http://www.opensecrets.org/lobby/indusclient.php?id=H04&year=2014> (last visited Apr. 24, 2015). In contrast the oil and gas lobby spent \$141 million in the same time period. Center for Responsive Politics, *supra* note 84.

86. Michael Beckel, *Drug Lobby Gave \$9.4 Million to Nonprofits That Spent Big on 2010 Election*, THE CTR. FOR PUB. INTEGRITY (Feb. 27, 2012, 6:42 PM), <http://www.publicintegrity.org/2012/02/27/8271/drug-lobby-gave-94-million-nonprofits-spent-big-2010-election>.

87. *Id.* See *Citizens United v. FEC*, 558 U.S. 310 (2010) (holding that the government may not suppress political speech on the basis of the speaker’s corporate identity).

88. See Bach et al., *supra* note 74.

89. See, e.g., Ganz, *supra* note 83, at 2, 10-11.

mandates that Medicare must cover every drug approved by the FDA and payments must be at the manufacturer's list price, not including any discounts or rebates.⁹⁰ Additionally, private insurers are held to similar standards by most states,⁹¹ meaning the largest "purchasers" of prescription drugs have no power to negotiate price.⁹² If the purpose behind the act was to address rising drug costs, why forgo an obvious avenue to price reductions through negotiation?

Considering the buying power held by Medicare, such a scheme seems illogical and fiscally unsound,⁹³ especially when legislators often raise concerns over the cost of entitlements.⁹⁴ At the beginning of the millennium, new cancer drugs averaged \$4500 per month, but as of 2012 prices had risen to around \$10,000 per month, with a few costing more than \$35,000 per month.⁹⁵ A perfect example is Gleevec, considered one of the greatest cancer drugs ever invented, which cost \$28,000 per year when introduced in 2001, but as of 2014 had quadrupled in price to \$92,000 per year.⁹⁶ The effect of the law is obvious—the monopoly granted by the patent system, coupled with the legally mandated prohibition on price negotiation, has led to astronomical drug prices that cannot be paid by many who rely on these drugs.⁹⁷

90. Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, § 303, 117 Stat. 2066, 2242 (codified at 42 U.S.C. § 1395w-3a(c)(6)(B) (2012)).

91. Bach et al., *supra* note 59.

92. Theoretically, price negotiation was left to the private insurers, but this has proved ineffective; it is estimated Medicare Part D could save \$116 billion over 10 years if Medicare's low-income beneficiaries were just given the same discount available under Medicaid. Editorial, *Let Medicare Negotiate Drug Prices: Our View*, USATODAY (Apr. 20, 2014, 5:50 PM), <http://www.usatoday.com/story/opinion/2014/04/20/medicare-part-d-prescription-drug-prices-negotiate-editorials-debates/7943745/>.

93. In 2011, only 17% of drug purchases were not covered by insurance or third party payers. Adam J. Fein, *Who Paid for Prescription Drugs in 2011?*, DRUG CHANNELS (Jan. 8, 2013), <http://www.drugchannels.net/2013/01/who-paid-for-prescription-drugs-in-2011.html>. This was a major decline from the 1990s, where in 1990 cash customers made 63% of drug purchases at retail pharmacies. DEPT. OF HEALTH & HUMAN SERVS., PRESCRIPTION DRUG COVERAGE, SPENDING, UTILIZATION, AND PRICES, ch. 3, (2000), available at <http://aspe.hhs.gov/health/reports/drugstudy/index.htm>.

94. In 2013, Medicare accounted for 14% of the federal budget and Medicare payments for prescription drugs totaled more than \$64 billion. *The Facts on Medicare Spending and Financing*, THE HENRY J. KAISER FAMILY FOUND. (July 28, 2014), <http://kff.org/medicare/fact-sheet/medicare-spending-and-financing-fact-sheet/>.

95. See *60 Minutes: The Cost of Cancer Drugs*, *supra* note 70.

96. *Id.*; see also Herper, *supra* note 73. The industry concedes these prices hinder medical treatment. Joe Jimenez, chief executive for Novartis the maker of Gleevec, acknowledged that price will inhibit the ability to stack therapies and that "[t]he whole oncology pricing structure needs to be rethought because it's reached the level that is not going to be sustainable for the long term." *Id.*

97. It should also be noted that some doctors also have an incentive to keep prices high. The "biggest source of income for private practice oncologists is . . . commission . . . from cancer drugs" by buying the drugs wholesale and selling them retail to patients. *60 Minutes: The Cost of Cancer Drugs*, *supra* note 70.

Drug prices in the United States are fifty to eighty percent higher than anywhere else in the world,⁹⁸ in large part because of the MMA.⁹⁹ The MMA is one of the most expensive bills ever considered by the House, contributing to its rather unusual legislative history. As Representative Jones recalls, the bill—over 1000 pages—was voted on at 3 a.m., the morning after the members received it.¹⁰⁰ Representative John Dingell, Democrat of Michigan, who had been in Congress fifty-two years, said the bill would not have passed without the efforts of the more than 1000 pharmaceutical lobbyists.¹⁰¹ When asked the rationale behind prohibiting negotiation of drug prices, Representative Burton said the drug companies simply did not want it.¹⁰² Solidifying the connection between Congress and Big Pharma, Representative Billy Tauzin, who pushed the bill through the House, became Big Pharma's chief Washington lobbyist.¹⁰³

The MMA is an enlightening example of Big Pharma's influence over the lawmaking process.¹⁰⁴ Coupled with this sway over Congress, there is also evidence that drug companies set prices arbitrarily in an attempt to see what the "market" will bear.¹⁰⁵ Zaltrap, a cancer drug, is one such example. When first released, Zaltrap cost an average of \$11,063 per month, over twice the price of a similarly effective drug.¹⁰⁶ The cost was so high that doctors at Memorial Sloan-

98. *Id.*; see also INT'L FED'N OF HEALTH PLANS, 2013 COMPARATIVE PRICE REPORT: VARIATION IN MEDICAL AND HOSPITAL PRICES BY COUNTRY, available at <http://static.squarespace.com/static/518a3cfee4b0a77d03a62c98/t/534fc9ebe4b05a88e5fbab70/1397737963288/2013%20iFHP%20FINAL%204%2014%2014.pdf>.

99. See *60 Minutes: Under the Influence* (CBS television broadcast Apr. 1, 2007), available at <http://www.cbsnews.com/news/under-the-influence/>. But see Ashutosh Jogalekar, *Why Drugs Are Expensive: It's the Science, Stupid*, SCI. AM. (Jan. 6, 2014), <http://blogs.scientificamerican.com/the-curious-wavefunction/2014/01/06/why-drugs-are-expensive-its-the-science-stupid/> (arguing that greedy pharmaceutical companies are not to blame for high drug costs; instead costs are due to the complex and poorly understood biological systems drugs are intended to work on and the difficult and expensive process of taking drugs from initial discovery to market).

100. *60 Minutes: Under the Influence*, *supra* note 99 (stating in his twenty-two years of politics this was the ugliest night he had ever seen).

101. *Id.* He went on to estimate that of the 1500 bills over the eight years prior to this bill's passing, the drug companies got what they wanted, almost without exception. *Id.*

102. *Id.* (adding that the drug companies want to make as much money as possible and negotiation would inhibit that ability).

103. *Id.*

104. An additional example would be the Drug Price Competition and Patent Term Restoration Act, known as the "Hatch-Waxman" Act, codified in 21 U.S.C. § 355. Passed in 1984, the Act permits limited drug patent extensions to compensate for the time it takes to get a drug approved by the Food and Drug Administration (FDA). See SCHACHT & THOMAS, *supra* note 6, at 2.

105. According to the World Health Organization, the global pharmaceuticals market is worth \$300 billion per year with the 10 largest companies controlling over one third of the market with sales of more than \$10 billion per year and a profit margin of about 30%. *Trade, Foreign Policy, Diplomacy and Health*, *supra* note 80.

106. Bach et al., *supra* note 74; see also Stephen S. Hall, *The Cost of Living*, N.Y. MAG. (Oct. 20, 2013), <http://nymag.com/news/features/cancer-drugs-2013-10/>.

Kettering Cancer Center in New York City decided not to offer the drug to patients, stating that doctors must consider financial strain on their patients alongside the benefits a drug might deliver.¹⁰⁷ Such a decision was surprising from a leading cancer hospital because medical culture usually equates “new” with “better.”¹⁰⁸ It should be noted that Sloan-Kettering was able to make such a decision because there was an available alternative. Regrettably, with many new drugs this is not the case.

After the release of the New York Times article detailing Sloan-Kettering’s decision, Sanofi, the drug’s manufacturer, cut the price in half.¹⁰⁹ At first, Sanofi claimed the drug was priced competitively but eventually conceded that the reduction was due to market resistance.¹¹⁰ As noted by Dr. Peter B. Bach, “Normal markets wouldn’t behave like this. You couldn’t introduce something twice as expensive and no better and still sell it.”¹¹¹ Dr. Bach acknowledged Zaltrap’s price reduction did little to solve the bigger problem of the minimal relation between the prices of drugs and the value they provide.¹¹²

If surgical techniques and other tools of the “healing arts have long been considered a ‘gift from nature to humanity,’ ”¹¹³ why should the same logic not apply to drugs and medical devices?¹¹⁴ Drug companies often manipulate the patent incentive rationale to leverage their monopoly while obscuring the market impact of their predatory pricing.¹¹⁵ The patent system creates the perverse reality that pharmaceutical R&D is driven not by medical need but by profit margins, to the financial detriment of patients.¹¹⁶ Normally society is willing to bear the cost of limited patent monopolies in order to reap the benefits such innovation provides. Nonetheless, in certain circumstances the ability to charge monopoly prices is abused and negatively im-

107. Bach et al., *supra* note 74.

108. *Id.*

109. Andrew Pollack, *Sanofi Halves Price of Cancer Drug Zaltrap After Sloan-Kettering Rejection*, N.Y. TIMES (Nov. 8, 2012), <http://www.nytimes.com/2012/11/09/business/sanofi-halves-price-of-drug-after-sloan-kettering-balks-at-paying-it.html>.

110. *Id.* The article notes that Sanofi offered discounts instead of lowering the price, so that insurance and Medicare reimbursements would remain the same and insurance copays would be based on the higher price. *Id.*

111. *Id.*

112. *Id.*

113. Katopis, *supra* note 80, at 353.

114. See Ho, *supra* note 38, at 631-32 (noting that if restricted access were the driving force behind 287(c), there is an equally compelling argument to apply the exception to patented drugs). An expansion of 287(c) is also an unlikely solution.

115. See Ghoshray, *supra* note 60, at 721-22; see also Greg Martin et al., Editorial, *Balancing Intellectual Monopoly Privileges and the Need for Essential Medicines*, GLOBALIZATION & HEALTH (June 12, 2007), <http://www.globalizationandhealth.com/content/3/1/4>.

116. Greg Martin et al., *supra* note 115; ABBOTT & DUKES, *supra* note 2, at 32 (“Pharmaceutical companies are using patents to their advantage, and to the disadvantage of public health generally.”).

pacts human health. The situation is most dire in the context of rising pharmaceutical prices.

It is implausible that Congress will allow any cutbacks on the benefits to drug patent holders because any legislative efforts would be blocked by Big Pharma. The only other alternative would be a move by the courts to restrict patent infringement liability in certain circumstances. When faced with applying old law to new technology, the Supreme Court has a history of borrowing from other intellectual property disciplines to aid in reaching a just result. The advent of 3D printing technology may allow the courts to create an equitable solution to the drug price disparity based on the fair use doctrine found in Copyright law.

B. *Brief Overview of 3D Printing*

To better understand how courts could use the Medical Liability Exemption to provide drugs to patients who cannot afford them, a general understanding of 3D printing is necessary. 3D printing, also known as additive manufacturing, is the process of “printing” three-dimensional, solid objects using a digital file.¹¹⁷ Thin, successive layers of material are laid down to create the object.¹¹⁸ Essentially, each layer is a horizontal cross-section of the item being created,¹¹⁹ much like a CAT scan of a brain.¹²⁰ A virtual design of the object is created in a Computer Aided Design (CAD) file for use as a blueprint by the 3D modeling program.¹²¹ A printer uses the CAD file to create the object seamlessly, layer by layer, resulting in a three dimensional object.¹²²

The first 3D printer was created in 1984, and in the early days 3D printing was very expensive and not feasible for the general market.¹²³ Initially, plastic was the most common material used, but as costs have gone down and technology improves, 3D printers can use metal, glass, graphite, and other materials.¹²⁴ Would it be possible to break down the materials used into their molecular components, essentially turning 3D printing into a universal chemistry set? Accord-

117. *What Is 3D Printing?*, 3DPRINTING.COM, <http://3dprinting.com/what-is-3d-printing> (last visited Apr. 24, 2015).

118. *Id.*

119. *Id.*

120. See Mayo Clinic Staff, *Definition*, MAYO CLINIC, <http://www.mayoclinic.org/tests-procedures/ct-scan/basics/definition/prc-20014610> (last visited Apr. 24, 2015).

121. *What Is 3D Printing?*, *supra* note 117.

122. *Id.*

123. *The History of 3D Printing*, REDORBIT, http://www.redorbit.com/education/reference_library/general-2/history-of/1112953506/the-history-of-3d-printing/ (last visited Apr. 24, 2015).

124. See *What Materials Are Used in 3D Printing? It's More Than Fantastic Plastic*, LINE/SHAPE/SPACE, <http://lineshapespace.com/what-materials-are-used-in-3d-printing/> (last visited Apr. 24, 2015).

ing to chemist Lee Cronin, who is working on a 3D printer that is able to print molecules, the answer is yes.¹²⁵ Theoretically, 3D printing could then be used to “print” drugs in small batches, at the point of need.

During a Ted Talk filmed in 2012, Cronin discussed the idea as a future possibility, but that possibility is now becoming a reality. Researchers at Louisiana Tech announced a breakthrough in August 2014.¹²⁶ A method has been created, “using affordable, consumer-grade 3D printers and materials,” to make medical implants containing antibacterial and chemotherapeutic compounds used in targeted drug delivery.¹²⁷ 3D printing of drugs has become even more viable with the addition of nanoparticles and other additives to common printing materials that are already biocompatible.¹²⁸ This technology could be used to print drugs on any consumer printer, anywhere in the world.¹²⁹ With new technology generally comes litigation to determine how existing laws should apply to concepts not considered when the applicable laws were created. This is especially true in the context of intellectual property. In such circumstances, the Supreme Court has been flexible in interpreting the intellectual property statutes, importing or creating concepts that allow the Court to reach an equitable outcome.

C. Supreme Court Precedent Dealing with New Technology

Many critics have argued that 287(c) was passed in error and should be repealed.¹³⁰ Instead, because of the need to get lifesaving drugs in the hands of those that cannot afford them, the courts could use the Medical Liability Exemption to allow doctors or non-profits to 3D print these drugs under limited circumstances.¹³¹ Courts are loath to legislate from the bench, fearing the moniker of an activist judge, but in certain circumstances, where Congress refuses to address an important public health concern, the court should step in. Scholars and practitioners have pointed out ambiguity in the Medical Liability

125. *Lee Cronin: Print Your Own Medicine*, TED (June 2012), https://www.ted.com/talks/lee_cronin_print_your_own_medicine.

126. Dave Guerin, *Louisiana Tech Researchers Use 3D Printers to Create Custom Medical Implants*, LA. TECH U. (Aug. 20, 2014), <http://news.latech.edu/2014/08/20/louisiana-tech-researchers-use-3d-printers-to-create-custom-medical-implants/>.

127. *Id.*

128. *Id.*

129. *Id.* However, it is likely that materials necessary to print pharmaceuticals will be regulated, and access will likely be limited to only pharmacists and medical professionals.

130. *See* Ho, *supra* note 38, at 609.

131. This solution may seem unlikely, but as discussed above, researchers at Louisiana Tech University have already developed a 3D printer capable of printing drugs. *See* Guerin, *supra* note 126.

Exemption,¹³² which would allow courts room to interpret the language in light of new technology such as 3D printing. When applying old statutory language to new technologies, the courts have imported concepts, such as the staple article of commerce doctrine, from other areas of intellectual property law in order to reach a just result.

One of the goals of Section 287(c) was to harmonize U.S. law with international law.¹³³ International treaties such as the TRIPS Agreement refuse to issue patents for medical treatment procedures or methods,¹³⁴ as do most countries addressing the issue.¹³⁵ A similar bill was proposed but fiercely resisted by lobby groups like Big Pharma.¹³⁶ If the purpose behind 287(c) was to limit enforceability of medical process patents in accordance with foreign laws, then the statute should have been patterned after the straightforward language used in those laws.¹³⁷ This would have given courts tasked with construing Section 287(c) the benefit of ready interpretations used by similar foreign law.¹³⁸ Instead, the language created in response to pressure from lobby groups requires the courts to “guess at the meaning without the aid of any authoritative or persuasive precedent.”¹³⁹

The statute’s language could allow immunity from infringement of any process patent, because unlike the TRIPS agreement and other foreign law, the statute does not limit the subject matter of the infringed patent.¹⁴⁰ Immunity hinges on whether the infringer is a

132. See Sirjani & Keyhani, *supra* note 24, at 16. See generally Joseph A. Grundfest & A.C. Pritchard, *Statutes with Multiple Personality Disorders: The Value of Ambiguity in Statutory Design and Interpretation*, 54 STAN. L. REV. 627 (2002) (noting that statutory language may be intentionally ambiguous as a means of compromise and exploring the dynamics of exploiting the ambiguity).

133. Notice of Hearings and Request for Comments on Issues Relating to Patents Protection for Therapeutic and Diagnostic Methods, 61 Fed. Reg. 10320, 10323 (Mar. 13, 1996) (noting many countries refuse patent protection to therapeutic and diagnostic methods); see also *Hearing*, *supra* note 26, at 56 (prepared statement of Charles D. Kelman, M.D., President, Am. Soc’y of Cataract and Refractive Surgery) (“H.R. 1127 follows the lead of over 80 other countries that have banned medical procedure patents.”).

134. Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS, was signed in 1994. The text of the agreement can be found on the World Trade Organization’s website. *Agreement on Trade-Related Aspects of Intellectual Property Rights*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (last visited Apr. 24, 2015). Today, there are a total of 161 contracting parties. *Other IP Treaties*, WIPO, http://www.wipo.int/wipolex/en/other_treaties/parties.jsp?treaty_id=231&group_id=22 (last visited Apr. 24, 2015).

135. In fact, scholars have noted that the U.S. decision to grant medical method patents but refuse to enforce them might violate the TRIPS Agreement—an international agreement on Trade-Related Aspects of Intellectual Property Rights—which the United States has signed on to, because it requires certain minimum protections of patents. See Ho, *supra* note 38, at 653-73; Peschel, *supra* note 44, at 321.

136. H.R. 1127, 104th Cong. (1995).

137. Sirjani & Keyhani, *supra* note 24, at 15-16.

138. *Id.* at 16.

139. *Id.*

140. *Id.* at 30.

“medical practitioner” and whether the activity that constituted infringement is a protected “medical activity.”¹⁴¹ Section 287(c) does expressly exclude the use of a patented drug, device, or biotechnology system from immunity,¹⁴² but it does not contemplate the possibility of a doctor creating or printing such patented drugs and devices in the process of treating their patients. The statute and its associated conference report are written broadly, and if a court takes a textualist approach, the statute is susceptible to a broad interpretation.¹⁴³ As of this writing, only three cases have referenced Section 287(c), giving little guidance to future courts of how to apply the exemption.¹⁴⁴ If a court were to analyze the Medical Liability Exemption, as applied to the 3D printing of drugs, there is precedent that suggests the court could use the copyright doctrine of fair use to prevent a finding of infringement under certain circumstances. The following cases illustrate how the Supreme Court has incorporated concepts from other areas of intellectual property law when faced with unclear statutory language and a potentially inequitable outcome.

In *Sony Corporation of America v. Universal City Studios, Inc.*, the Court started their analysis by acknowledging that sound policy and history support a “consistent deference to Congress when major technological innovations alter the market.”¹⁴⁵ This is because “Congress has the constitutional authority and the institutional ability to accommodate fully the varied permutations of competing interests that are inevitably implicated by such new technology.”¹⁴⁶ Where Congress has not plainly marked the course, such as where new technology is involved, courts must be guided by these principles when construing the scope of rights created by legislation that did not consider the “calculus of interests” currently before the court.¹⁴⁷ The Court also noted that creative work should be rewarded and encouraged, but the ultimate aim is the benefit conferred on the public by the labors of authors and inventors.¹⁴⁸ “When technological change has rendered

141. *Id.* at 30-32 (noting that it is unclear whether the exception would cover dental or veterinary procedures).

142. 35 U.S.C. 287(c)(2)(A) (2012).

143. Sirjani & Keyhani, *supra* note 24, at 34-35.

144. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 138 (2006) (Breyer, J., dissenting) (dissenting the majority’s dismissal of the writ of certiorari, Justice Breyer argued the Court should decide the case involving §287(c) to aid Congress in determining whether legislation was needed to help medical practitioners better understand their legal obligation); *see Lamson v. United States*, 117 Fed. Cl. 755, 762 (2014) (finding the defense available to the United States as a party); *Emtel, Inc. v. Lipidlabs, Inc.*, 583 F. Supp. 2d 811, 824-25 (S.D. Tex. 2008) (interpreting “related health care entity” to include a diagnostic video conferencing network link provider).

145. 464 U.S. 417, 431 (1984).

146. *Id.*

147. *Id.*

148. *Id.* at 429 (citing *Fox Film Corp. v. Doyal*, 286 U.S. 123, 127 (1932)).

its literal terms ambiguous, the Copyright Act,” and by analogy the Patent Act, “must be construed in light of this basic purpose.”¹⁴⁹

In *Sony*, the new technology to be addressed were VCRs, which allowed the taping of copyrighted television broadcast for later viewing.¹⁵⁰ The copyright holders petitioned the court to find Sony liable of contributory copyright infringement or inducement.¹⁵¹ Both concepts are included in the Patent Act, but were fairly novel in copyright law.¹⁵² Although ultimately finding for Sony, the Court was willing to consider these patent concepts, noting that “[t]he absence of such express language in the copyright statute does not preclude the imposition of liability” where parties have not engaged in direct copyright infringement.¹⁵³ This form of vicarious liability, a concept found in “virtually all areas of the law,” reaches the problem of identifying under what circumstance it is just to hold an individual accountable for another’s actions.¹⁵⁴ It was acceptable to consider incorporating these patent concepts of infringement into copyright because of the “historic kinship” between the two areas of law.¹⁵⁵ Where the infringer was in a position to control others’ use of copyrighted works, and authorized such use without the copyright holder’s permission, the finding of contributory infringement was “manifestly just.”¹⁵⁶

Sony is most notable for applying the staple article of commerce exception in a copyright context. The Court had discovered that as technology advanced contributory and vicarious liability had become too broad, sweeping up parties that equitably should not have been considered infringers.¹⁵⁷ Therefore, the Court was also willing to incorporate an exemption to contributory infringement found in the Patent Act, where precedent did not support infringement liability.¹⁵⁸ This exception, the staple article of commerce doctrine, holds that distribution of a component of a patented device is not infringement when it is suitable for other, noninfringing uses.¹⁵⁹ The concept prevents a patentee from extending a monopoly past the limits of its grant, especially where there is a strong public interest in accessing such an article of commerce.¹⁶⁰ The VCRs in question were analogized

149. *Id.* at 432 (quoting *Twentieth Century Music Corp. v. Aiken*, 422 U.S. 151, 156 (1975)).

150. *Id.* at 417.

151. *Id.* at 434-35.

152. *See id.*

153. *Id.* at 435.

154. *Id.*

155. *Id.* at 439.

156. *Id.* at 437.

157. Matthew Helton, *Secondary Liability for Copyright Infringement: BitTorrent as a Vehicle for Establishing a New Copyright Definition for Staple Articles of Commerce*, 40 COLUM. J.L. & SOC. PROBS. 1, 8 (2006).

158. *Id.* at 9.

159. *Id.* at 10-11.

160. *Id.*

to other staple articles of commerce such as typewriters, recorders, and photocopy machines in order to find the VCRs noninfringing.¹⁶¹ However, as noted in the dissent, the doctrine was intended to protect those who manufacture components incorporated *into* patented inventions.¹⁶² The majority adapted the doctrine to apply to the machine itself, not just its component parts, in order to reach the desired equitable outcome.

Acknowledging there are “substantial differences between the patent and copyright laws,” the Court found a need to look beyond the statutory language to the purpose of the statute—adequate protection of the monopoly.¹⁶³ A balance must be struck between the interests of the monopoly holder and the public interest.¹⁶⁴ This goal should apply to protecting the public interest as well as the patent or copyright holders. The Court noted that reward to the owner or inventor is a consideration second to the objective of benefitting the public from the labors of these inventors.¹⁶⁵ The monopoly privileges authorized by Congress are not designed to provide a “special private benefit” but are a means to achieve the important public purpose of progress in science and the arts.¹⁶⁶ *Sony* illustrates that when tasked with fitting new technology into old statutory language, the Court is willing to import doctrines used in other areas of law in order to reach the “manifestly just” outcome.

The Supreme Court continued to borrow from patent law in a subsequent case, finding the defendants guilty of inducement.¹⁶⁷ *Grokster* was attempting to capture previous Napster users, after Napster was deemed to infringe music copyright holders, by facilitating digital music downloads.¹⁶⁸ The company had created a system intended to evade the statutory requirements of contributory infringement so that *Grokster* did not have “actual knowledge” of specific instances of infringement and failed to act on that knowledge.¹⁶⁹ Attempting to apply *Sony*, the Ninth Circuit read the case strictly and granted summary judgment in favor of the defendants, *Grokster* and *StreamCast*.¹⁷⁰ In rejecting this finding, the Supreme Court held that

161. *Sony*, 464 U.S. at 426.

162. *Id.* at 491 n.41 (Blackmun, J., dissenting).

163. *Id.* at 442.

164. *Id.*

165. *Id.* at 429.

166. *Id.*

167. *See Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 916 (2005).

168. *Id.*

169. *Id.* at 927.

170. *Id.* at 927-28.

if a device is promoted to infringe, by clear expression or other affirmative steps, then the distributor is liable for infringement under a theory of inducement.¹⁷¹

The outcome of the case could be predicted by the way the Court framed the issue presented as “[t]he tension between the competing values of supporting creativity through copyright protection and promoting technological innovation by limiting infringement liability.”¹⁷² Because of the vast number of infringing downloads and evidence of an intent to evade liability, the argument for imposing indirect liability was powerful.¹⁷³ Even though the Copyright Act does not hold anyone liable for another’s infringement, the Court found that secondary liability doctrines were well established in common law.¹⁷⁴ While limiting liability to “instances of more acute fault . . . leaves breathing room for innovation and a vigorous commerce,”¹⁷⁵ finding liability premised on “purposeful, culpable expression and conduct” did not compromise legitimate commerce or discourage innovation.¹⁷⁶

Faced with new digital music download technology, the Court unanimously decided to incorporate the patent inducement doctrine into copyright law.¹⁷⁷ Just like in *Sony*, emphasis was placed on taking active steps to increase profits by inducing infringement.¹⁷⁸ Unlike *Sony*, where there was no evidence of intent to increase profits, *Grokster* intended to profit from the use of unlicensed copyrighted materials; therefore, a finding of infringement was necessary.¹⁷⁹ Mindful not to impede commerce or discourage development of new technology, the Court found liability under a theory of inducement did not compromise these goals.¹⁸⁰

The back and forth between copyright and patent law can be seen in many contexts. The Supreme Court, relying on dicta from *Grokster*, incorporated the actual knowledge requirement from copyright to find a party had induced infringement of a patent.¹⁸¹ Similarly, the four-factor test used to determine when a permanent injunction should be granted was adopted in a patent case because it was consistent with the approach used under the Copyright Act.¹⁸² As a final example, the Federal Circuit imported an objective recklessness

171. *Id.* at 914.

172. *Id.*

173. *Id.*

174. *Id.*

175. *Id.* at 915, 933.

176. *Id.* at 915.

177. *See id.*

178. *Id.* at 930.

179. *Id.* at 941.

180. *Id.* at 937.

181. *See* *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2067-68 (2011).

182. *See* *Ebay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391-92 (2006).

standard to prove willful patent infringement, as required in copyright law.¹⁸³ There is ample precedent to allow a court to incorporate concepts from copyright law, such as fair use, when interpreting the Medical Liability Exemption of the Patent Act in order to reach an equitable outcome.

IV. A FAIR USE INTERPRETATION OF 287(C)

The public demand for access to affordable drugs can be alleviated with the advances in 3D printing technology. The Medical Liability Exemption could be used as a shield to protect a medical practitioner who provides printed drugs to patients that otherwise could not afford them. This Note makes the novel claim that the Supreme Court's incorporation of concepts from different areas of intellectual property law, such as the staple article of commerce doctrine in *Sony*, should inform courts on how to deal with the fair use exemption and drug patent infringement. When applying the Medical Liability Exemption to physicians, courts should consider interpreting the exemption in light of the fair use doctrine found in copyright law. If the practitioner could demonstrate the drug was medically necessary and given at no cost to a patient meeting certain financial criteria, then the Medical Liability Exemption should provide a complete defense against infringement.

It should be noted that there are major differences between the Copyright Act and the Patent Act. The Copyright Act grants the copyright holder "exclusive" rights in certain qualified ways¹⁸⁴ but also provides for the "fair use" of protected works under certain circumstances.¹⁸⁵ While copyright and patent law concepts are often intertwined, patent protection is basically all or nothing—either you are liable for infringement or you are not.¹⁸⁶ Patents are treated more like real property than any other type of intellectual property, allowing none of the exceptions found in other areas of intellectual property, such as the fair use doctrine. However, it has been argued that this was not the intention of the founders, such as Thomas Jefferson.¹⁸⁷ Mark Lemley criticized this trend, stating that allowing intellectual property owners to capture the "full social surplus" of their inventions goes against "our economic intuitions in every other segment of the economy."¹⁸⁸ Even owners of real property may not "in-

183. See *In re Seagate Tech., L.L.C.*, 497 F.3d 1360, 1371 (Fed. Cir. 2007).

184. See 17 U.S.C. § 106 (2012) (describing the exclusive rights belonging to the copyright holder).

185. *Sony Corp. of Am. v. Universal City Studios*, 464 U.S. 417, 432-33 (1984).

186. See Ritchie de Larena, *supra* note 82, at 779.

187. See Ruth E. Freeburg, *No Safe Harbor and No Experimental Use: Is It Time for Compulsory Licensing of Biotech Tools?*, 53 *BUFF. L. REV.* 351, 391 (2005).

188. Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 *TEX. L. REV.* 1031, 1046 (2005).

ternalize the full positive externalities associated with their property.”¹⁸⁹ A fair use exception could be adopted in a broad patent context; however, this Note argues only for the doctrine to be used when courts consider the Medical Liability Exemption and its applicability to printing drugs in certain contexts.

When 3D printing becomes common and patent holders commence litigation, the Court will again be forced to apply old law to new technology. This Note does not propose a solution for all such printing, but in circumstances relating to the printing of drugs for the underprivileged, a court should use the Medical Liability Exemption to negate any patent infringement. Congress is too beholden to Big Pharma to act on what is an ever-increasing problem, so courts must be creative and limit patent holders’ rights when public policy demands. As discussed above, the rationales for passing the Medical Liability Exemption hold true not just for medical procedures but also for drugs and medical devices. The important concern that doctors will not have access to the best treatment options is just as applicable to drugs and devices. This issue has arisen in medical treatment facilities such as Sloan-Kettering, a hospital that takes seriously the financial impact of expensive drugs on patients.¹⁹⁰

The main difference between procedures and drugs seems to be who feels the impact. Doctors fearing infringement liability have powerful groups to rely on to lobby Congress, such as the American Medical Association. Patients, on the other hand, do not have nearly as powerful a lobby. Additionally, when dealing with a serious illness, a patient or their family is not focused on asking Congress to reform high drug pricing. Once that illness has decimated their finances, that patient or family cannot afford to lobby Congress. Finally, patients who are lucky enough to have the financial ability to pay, or who have insurance that covers most of the cost, do not have an incentive to lobby Congress.

Unfortunately, even if patients were able to lobby, it is doubtful Congress would expand Section 287(c) to cover drugs, nor is a different statutory solution likely. Big Pharma is the largest and most powerful lobbying group, spending more than \$230 million in 2014.¹⁹¹ As they have failed to do so thus far, the members of Congress cannot be relied on to put the public health interest in affordable drugs above their own financial interests.

3D printing will offer many benefits. Drugs can be printed on a small scale and tailored to a particular physician’s practice or patient’s illness. Non-profit groups can be more mobile, taking a small

189. *Id.*

190. See Bach et al., *supra* note 74.

191. Center for Responsive Politics, *supra* note 85.

set-up to the most effected low-income communities, providing the drugs needed at that particular time and place. Doctors that treat illnesses associated with expensive drugs, such as cancer, will be able to help patients that otherwise would have to forgo a more effective line of treatment due to lack of insurance or financial resources. However, if these doctors and non-profits are forced to license each of the needed drugs, the licensing fees will be an insurmountable barrier to providing the needed treatment.

With the advent of 3D printing technology, the courts will have the ability to effect real change in the area of high drug prices. The absence of the staple article of commerce exception in copyright law did not prevent the Supreme Court from applying the exception in *Sony*, and it should not prevent importing fair use into patent law in this limited context. Balancing the interests of promoting innovation in new drugs and saving lives, the Court could construe the Medical Liability Exemption in light of its basic purpose—to protect doctors and allow them to choose the treatment that is best for their patients. The process of printing a drug is not outside the definition of a process patent.¹⁹² In light of this growing public health concern, drug printing could thus be considered a medical process exempted from liability under Section 287(c). The copyright doctrine of fair use could be the vehicle that would allow courts to reach this justifiable outcome.

In copyright, if the fair use exception applies, then the user has not infringed the copyright.¹⁹³ The exception was originally a judge-made doctrine that was codified in Section 107 of the 1976 Copyright Act, using language mostly derived from an 1841 opinion by Justice Joseph Story.¹⁹⁴ The legislative history details efforts to remove fair use from the Act, based on the concern that codifying it would alter or “freeze” the common law form of the doctrine and judicial discretion along with it.¹⁹⁵ One reason for the heated negotiations was the controversy surrounding the emerging technology of photocopying.¹⁹⁶ The process of codifying the fair use exception demonstrates

192. See *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876). Process patents have been defined as “a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.” *Id.* at 788.

193. See 17 U.S.C. § 107 (2012).

194. See Barton Beebe, *An Empirical Study of U.S. Copyright Fair Use Opinions, 1978-2005*, 156 U. PA. L. REV. 549, 559-60 (2008).

195. *Id.* at 558-59.

196. *Id.* at 559-60.

that even when Congress is aware of emerging technologies at the time of drafting, determining a solution is a difficult process that does not always end with a perfect solution.

As the law currently stands, there are four factors to consider when determining whether the fair use exception precludes a finding of infringement:

1. The purpose and character of the use, including whether the use is commercial in nature.
2. The nature of the copyrighted work.
3. The amount and substantiality of the portion of the use in relation to the copyrighted work as a whole.
4. The effect of the use on the potential market for or value of the copyrighted work.¹⁹⁷

Courts have used different approaches regarding the weight to be given each factor, but in a recent decision the Eleventh Circuit stated that the factors should not be given equal weight.¹⁹⁸ This mirrors the opinions of other circuits, which have emphasized that the factors should not be applied formulaically and the test is not “an algorithm that enables decisions to be ground out mechanically.”¹⁹⁹ Instead, based on the circumstances of the case, certain factors will weigh more heavily.²⁰⁰

When considering the applicability of fair use to 3D printing of pharmaceuticals, courts should place more emphasis on the first and fourth factors. When considering the first factor, courts generally determine whether the use is transformative or noncommercial.²⁰¹ This analysis generally ties in with the fourth factor’s market consideration, since a noncommercial use is less likely to adversely affect the market for the work at issue.²⁰² If a doctor can show a drug was provided at no cost, in limited quantities, to patients that cannot afford the market price, then the use is non-commercial and would not

197. *Id.* at 557-58.

198. *See* *Cambridge Univ. Press v. Patton*, 769 F.3d 1232 (11th Cir. 2014).

199. *Chicago Bd. of Educ. v. Substance, Inc.*, 354 F.3d 624, 629 (7th Cir. 2003) (Posner, J.); *see also* *Fin. Info., Inc. v. Moody’s Investors Serv., Inc.*, 751 F.2d 501, 508 (2d Cir. 1984) (“The four factors . . . are equitable considerations to be assessed and weighed by the court; they are not simply hurdles over which an accused infringer may leap to safety from liability. Rather than a sequence of four rigid tests, the fair use analysis consists of a ‘sensitive balancing of interests.’” (quoting *Sony Corp. of Am. v. Universal City Studios*, 464 U.S. 417, 455 n.40 (1984))); *Beebe, supra* note 194, at 561.

200. *Cambridge Univ. Press*, 769 F.3d at 1260 (citing *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 588 (1985) (Brennan, J., dissenting)); *Wright v. Warner Books, Inc.*, 953 F.2d 731, 740 (2d Cir. 1991); *see also* *Beebe, supra* note 194, at 582 (noting that different courts give more weight to different factors, but it is generally assumed that the ultimate determination of fair use hinges on the fourth factor).

201. *Beebe, supra* note 194, at 583.

202. *Id.*

harm the market for that drug.²⁰³ As previously discussed, there should be minimal impact on a manufacturer's profits because the patient would not have been financially capable of purchasing the drug. To prohibit 3D printing of drugs, the drug manufacturer should have to prove that even when the printing is done for non-commercial purposes there is a likelihood of meaningful future harm to the potential market for the drug.

The non-commercial nature of a work is "not conclusive" and only one factor to consider.²⁰⁴ While often regarded by courts and commentators as peripheral to the outcome of a fair use analysis, factors two and three must also be considered.²⁰⁵ Factor two, the nature of the work, draws on the "value of the materials used."²⁰⁶ Whether a work is sufficiently close to the core value to be protected is often determined by distinctions between fictional and factual works or whether the work is published or unpublished,²⁰⁷ but this distinction does not apply in the patent context. However, under this factor courts could consider what type of drug was at issue and whether it was medically necessary. Elective drugs such as Botox or Viagra should not be covered by the exemption.

Factor three, the amount and substantiality of the use in relation to the work as a whole, is often disregarded like factor two. It is clear that when applied to patent infringement this factor will favor plaintiffs because the infringer would have used the entire patent. While factors two and three cannot be entirely ignored, determining that they favor the plaintiff is not fatal to a defendant's ability to use a fair use defense. The strength of factors one and four coupled with the great public health need should tip the scale in favor of finding that the Medical Liability Exemption applies to 3D printing of drugs in light of the fair use doctrine.

Cases like *Sony* and *Grokster* illustrate the Court's willingness to find solutions outside of the applicable statute in order to reach a result that is "manifestly just." New technologies have been consistently difficult to deal with in intellectual property cases. Congress often does not act quickly enough, and the courts are left to apply existing

203. However, the commercial or nonprofit purpose is only one element in the enquiry into the purpose and character of the infringement. *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 584 (1994).

204. *Id.* at 585.

205. Beebe, *supra* note 194, at 583.

206. *Campbell*, 510 U.S. at 586 (calling "for recognition that some works are closer to the core of intended copyright protection than others, with the consequence that fair use is more difficult to establish when the former works are copied").

207. Beebe, *supra* note 194, at 611-15. *See, e.g.*, *Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 348-51 (1990) (contrasting creative works with bare factual compilations); *Stewart v. Abend*, 495 U.S. 207, 237-38 (1990) (contrasting a fictional short story with factual works); *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 455 n.40 (1984) (contrasting motion pictures with news broadcasts).

law, despite potentially inequitable outcomes. In the past the Supreme Court has balanced the interests of the innovators and the public to reach a determination of what seems “fair.” Where the current law did not prescribe what was “fair,” the Court borrowed concepts such as inducement from the Patent Act and applied them to copyright cases. The same could be done in patent law by importing concepts like the fair use doctrine.

The *Sony* court stated that the Constitution assigned to Congress the task of defining the scope of protection granted to inventors “in order to give the public appropriate access to their work product.”²⁰⁸ This task involves balancing the interests of inventors in controlling and exploiting their discoveries with society’s competing interests, and the various intellectual property acts have been amended to accommodate this balancing.²⁰⁹ Congress did just such a balancing when creating the Medical Liability Exemption. Congress had not clearly marked the course in dealing with the new VCR technology, so the Court was guided by “[t]he *limited scope* of the copyright holder’s statutory monopoly.”²¹⁰ Likewise, Congress could not have anticipated that a great public need could be cured by allowing patent infringement so long as it is tailored to a limited use, like 3D printing would allow. This gives the Court some leeway to construe Section 287(c) to cover 3D printing as a medical process, in light of public health concerns.

Allowing such printing will have a huge impact on improving health in low-income communities and treating illnesses that have high treatment costs. It might even incentivize drug companies to lower drugs costs in an attempt to recapture some of those lost customers. It could also spur Congress into action, creating a statutory exception in certain circumstances.²¹¹ The public need for affordable drugs outweighs the need to incentivize drug companies; therefore the courts should be willing to consider certain printing of drugs exempt from infringement under Section 287(c).

V. CONCLUSION

The skyrocketing cost of drugs in the United States should be at the top of Congress’s priority list. Drugs cost more in America than anywhere else in the world, and medical bills are one of the main reasons individuals file for bankruptcy. The amendment to the Medi-

208. *Sony*, 464 U.S. at 429.

209. *Id.*

210. *Id.* at 431 (emphasis added) (citing *Twentieth Century Music Corp. v. Aiken*, 422 U.S. 151, 156 (1975)).

211. Although, realistically, intervention from the courts could also spur Congress to forbid the printing altogether.

cal Liability Exemption proposed in this Note would shield medical practitioners from liability when meeting certain criteria. Unfortunately, Big Pharma is the largest lobbyist of Congress and the largest campaign contributor for state and local elections. There is little hope that Congress will amend the Patent Act to limit infringement liability of drug patents. The plight falls to the courts to work with current laws to find a solution.

With the advent of 3D printing, small scale printing of drugs is not just plausible but very likely. The Medical Liability Exception could be used to insulate doctors and non-profit organizations from patent infringement liability when they provide drugs based on need. The courts have taken innovative approaches to analyzing intellectual property statutes when applied to new technology. The great public health concern over skyrocketing pharmaceutical costs should spur courts to apply the Medical Liability Exemption to 3D drug printing when doctors can demonstrate the patient's financial hardship. The fair use doctrine found in the Copyright Act could be incorporated into the patent analysis to determine when physicians should be immune from liability. The rarely used Medical Liability Exemption could be expanded to have a real impact on suffering patients who cannot afford the drugs that could improve or even save their lives.