3D Printing and Healthcare: Will Laws, Lawyers, and Companies Stand in the Way of Patient Care?

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Abstract
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Keywords
3D printing, healthcare, patents, technology, medicine, law and medicine
3D PRINTING AND HEALTHCARE: WILL LAWS, LAWYERS, AND COMPANIES STAND IN THE WAY OF PATIENT CARE?

Evan R. Youngstrom*

ABSTRACT

Today, our society is on a precipice of significant advancement in healthcare because 3D printing will usher in the next generation of medicine. The next generation will be driven by customization, which will allow doctors to replace limbs and individualize drugs. However, the next generation will be without large pharmaceutical companies and their justifications for strong intellectual property rights.

However, the current patent system (which is underpinned by a social tradeoff made from property incentives) is not flexible enough to cope with 3D printing’s rapid development. Very soon, the social tradeoff will no longer benefit society, so it must be re-evaluated to facilitate the coming of the next generation in medicine.

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* Class of 2015, University of San Diego School of Law. The author would like to dedicate this article to his wife, Daniela, and his mother, Sheri.
INTRODUCTION

Three-dimensional (“3D”) printing is poised to disrupt many industries that rely on protection from intellectual property laws because 3D printing opens the door to a new wave of innovation, known as the Counter Industrial Revolution.\(^1\) The Industrial Revolution was the socio-cultural, socio-economic, and socio-legal shift from small-scale production to large-scale corporate manufacturing. The flip side is the Counter Industrial Revolution, which will be the socio-cultural, socio-economic, and socio-legal shift from large-scale corporate manufacturing to small-scale customizable production.

In essence, 3D printing is the digitization of things, and it will start the engine of change for business models and strategies.\(^2\) Like the invention of the printing press, the assembly line, the Internet, and firearms, 3D printing will disrupt, but ultimately, advance our society. In the end, 3D printing gives the masses the ability to easily create things, which will help accelerate our society to return to its Read-Write\(^3\) origins.\(^4\)

A Read-Write society has a reciprocal relationship between the producer and the consumer.\(^5\) A Read-Only society is when people consume

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2. *Id.* at 1694.
4. *Id.* (explaining the cultural shift from Read-Write to Read-Only in the past century); *Supra* note 1, at 1695 (explaining around 1910, our production oriented society of small entrepreneurs shifted to a consumption-oriented society dominated by corporations).
5. *Supra* note 3.
more or less passively. Currently, we are in a Read-Only society because of the shifts in the doxa that grew out of the Industrial Revolution. Doxa is society’s common belief structure, which transcends generations, shifts over time, and changes between places. The concept of doxa is interconnected with the concept of culture. However, I define “culture” as the accumulation and dissemination of social knowledge. This social knowledge is the engine of our society because it underpins psychology (behavior), economics (needs), art (creativity), law (expectations), and political science (social organization). The power of culture is its force and ability to influence the social domain and the relationships between people, on a small and grand scale. Accordingly, the acceleration of the accumulation and dissemination of social knowledge is known as Cultural Development.

Today, a tension exists between 3D printing and intellectual property laws; specifically, patent law. Patents are intended to accelerate innovation through a social tradeoff, which is made from property incentives. But, fundamentally, patents limit access to information by granting exclusive property rights. This limitation actually decelerates innovation because restricting access to information hinders the development of new inventions that rely on that information to transform into the new invention. Professor Eric Von Hippel, a leading scholar on intellectual property rights and innovation rates, concluded, “patents harm innovation rather than help it.”

3D printing will allow people to rapidly create almost anything themselves, so a person can easily copy a protected thing or process. In other words, 3D printing will allow for mass infringement of patented things and processes, like what Napster did to copyright law. Through the lens of current patent laws and the contemporary doxa, the criminalization of people

6. Id.
7. Supra note 3.
8. Doxa is the combination of both orthodox and heterodox norms and beliefs. It is the presence behind the unstated and taken-for-granted assumptions. Doxa is the common sense behind the distinctions we make. Doxa becomes readily apparent when most people forget the limits that create the unequal divisions in society. Most people adhere to unequal relations of order because the social structure is inseparable from the real world and the thought world. For control, social elites build their power in the thought world to influence the real world. See Pierre Bourdieu, Distinction: A Social Critique of the Judgment of Taste 471 (Harvard University Press 1984).
12. Supra note 1, at 1691.
who use 3D printers seems inevitable. Because patents are based on a social tradeoff that the contemporary doxa says must be made to incentivize innovation, 13 3D printing will test the limits of public policy, especially in healthcare.

3D printing in healthcare has the potential to save lives, but more importantly, 3D printing has the potential to enhance lives. In the near future, doctors will be able to give the soldier, who fought for our country, his leg back, so he can walk his daughter down the aisle. Also, doctors will be able to rapidly test experimental drugs on cancer patients’ 3D printed tissues, so the patients will be spared from suffering through the grueling trials of an ineffective drug. In other words, 3D printing’s benefits in the healthcare industry are profound, and the benefits are too numerous to quantify. Moreover, the benefits should not be quantified because happiness 14 is not measured; it is felt.

3D printing in the healthcare industry is a unique case study because it is a perfect recipe for change. 3D printing has explosive innovation potential because it calls on humans’ innate urge to create. 15 Combine this urge with the desire to save and enhance lives. Mix that with inflexible and strict intellectual property laws, which do not accelerate innovation. 16 Bake at 451 degrees of public policy. Out comes this question and answer; will laws, lawyers, and companies stand in the way of patient care? Yes.

Section II of this article will create a foundation of understanding for 3D printing and its explosive potential in healthcare. Section III will explain what happens when 3D printing clashes with patent law in healthcare’s kitchen, and it will illuminate the people that our current legal system holds liable for patent infringement (the “Criminals”). Section IV will explain why Cultural Development is the secret ingredient for the pursuit of happiness, and it will illuminate the forthcoming trends in the next social tradeoff, in relation to patent law, 3D printing, and healthcare.

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13. When the government grants intellectual property rights, it trades off exclusive property (monopoly) rights to the use of a thing in return for: (1) an incentive to create the thing and (2) publication of the thing, rather than the use of secrecy to protect it. See Browyn Hall & Dietmar Harhoff, Recent Research on the Economics of Patents, 4 Annual Review of Economics 541, 541 (2012).
15. Supra note 3, at 28-33.
16. Supra note 9 (explaining the power struggle that underpins the modern intellectual property rights system and synthesizing numerous empirical studies that detest the assertion that strong intellectual property rights lead to an increase in innovation).
I. 3D Printing: A Way Forward in Healthcare and Policy

In the 1980s, Charles Hull invented stereo-lithography ("3D printing"), which he described as the printing of successive layers of material on top of each other to create a thing.\textsuperscript{17} In other words, 3D printing is a manufacturing method where a machine deposits or fuses materials, such as plastics, metals, ceramics, powders, liquids, or living cells, to make a thing.\textsuperscript{18}

Generally speaking, 3D printing will affect two areas: economies of scale and customization. Currently, traditional manufacturing methods are still cheaper for large-scale production, but the cost of 3D printing is becoming competitive for smaller production runs.\textsuperscript{19} For example, NASA now prints certain fuel injectors, which saves taxpayers millions of dollars.\textsuperscript{20} Today, many manufacturing corporations print prototypes to supplement traditional manufacturing methods, such as to aid in the development of molds and models.\textsuperscript{21} Put differently, 3D printing enhances the traditional manufacturing methods because the first thing is inexpensive to create, so it kick-starts traditional manufacturing.\textsuperscript{22} Thus, the cost of the first thing is the same as the last, so the total cost of manufacturing a thing drops.\textsuperscript{23} Further, customization is interrelated with economies of scale, but customization is geared towards personal application.

Now, new companies, such as Helisys, Ultimateker, and Organovo, are applying 3D printing’s potential to the healthcare industry. Specifically, “Organovo designs and creates multi-cellular, dynamic, and functional human tissues for use in drug discovery and medical research.”\textsuperscript{24} But currently, large investments into healthcare related 3D printing are relatively small. It is estimated that “3D printing is currently a $700 million industry, with only $11 million (1.6%) invested in medical applications.”\textsuperscript{25} However, the explosive potential exposed by these companies will attract venture capital like flies to healthcare’s honey. It is projected that “in the next ten

\textsuperscript{17.} U.S. Patent No. 4,575,330 (filed March 1, 1986) (protecting Charles Hull’s apparatus for producing three-dimensional objects by stereolithography).
\textsuperscript{18.} Carl Schubert et al., \textit{Innovations in 3D printing: A 3D Overview from Optics to Organs}, 98 \textit{BRITISH J. OF OPHTHALMOLOGY} 159, 160 (2014).
\textsuperscript{19.} \textit{Id}.
\textsuperscript{20.} \textit{Id}.
\textsuperscript{22.} This is also known as Rapid Prototyping. \textit{See} Matthew B. Hoy, \textit{3D Printing: Making Things at the Library}, 32 \textit{MED. REFERENCE SERVICES Q.} 93, 95 (2013).
\textsuperscript{23.} Schubert, \textit{supra} note 18, at 160.
\textsuperscript{25.} Ventola, \textit{supra} note 21, at 705.
years . . . 3D printing will grow into an $8.9 billion industry, with $1.9 billion (21%) projected to be spent on medical applications.”

In a recent interview about 3D printing in the healthcare industry, Markus Fromherz, Xerox’s chief healthcare innovation officer, stated, “The biggest advantage is that everything is customizable.” However, Fromherz went on to say, “With a regular printer, everyone can create a document, but not everybody will be skilled or knowledgeable enough to create a knee.” Thus, developing these technologies and teaching capable people how to properly use these new tools is essential for rapid innovation. Accordingly, the healthcare industry is starting to prepare for this technological boom. For example, Queensland University of Technology in Brisbane, Australia and three other research universities launched a Master’s program in bioprinting.

Very soon, universities, big businesses, start-ups, “garage inventors, hobbyists, and tinkerers will meet, share ideas, start companies, fail, start again, fail, consolidate, and so on until over time the technology gets better and cheaper.” In healthcare, the results of the innovators’ hard work will generally fall into three categories: scaffolding, tissue, and medical devices. Scaffolding generally includes bones, exoskeletons, prosthetics, and the like. Tissue generally includes anything made from cells. The medical device category is the catch all, which includes everything from pharmaceuticals to eyeglasses.

However, this grouping is not mutually exclusive because 3D printed things are only limited by human imagination and physical constraints. Dr. Edward Tatum, a Nobel Prize winner in medicine, argues for an ambitious new goal for humanity. He argues biology should not only avoid structural and metabolic errors in organisms, but it should also produce better organisms. Professor Andrew Torrance explains synthetic biology aims to

26. Ventola, supra note 21, at 705.
28. Doyle, supra note 27.
30. Desai, supra note 1, at 1696 (alteration to the original).
31. See Doyle, supra note 27.
“shift biological sciences by marrying approaches from engineering and computer science to expand an array of standardized biological parts and sophisticated biological methods.”

Synthetic biology will transform biology into a field in which “it is routine to design and construct custom genes, genomes, proteins, viruses, cells, organs, and whole organisms rapidly, inexpensively, and easily.”

Indeed, 3D printing’s broad applicability is not limited to healthcare, but 3D printing’s potential in healthcare has significantly more social benefits than to simply reduce manufacturing costs or create unique things to sell on etsy.com. Essentially, foreseeable applications of 3D printing in healthcare will save lives, reduce suffering, and enhance abilities, all of which pursue happiness.

A. 3D Printing’s Potential in Healthcare

Simply put, with time, money, and knowledge, 3D printing will put the soul in the healthcare recipe. This is evident because of the flood of recent peer-reviewed publications about 3D printing’s current and foreseeable medical applications. Scientists and doctors now know that they can, or will be able to, print customized cells, blood vessels, organs, 3D Bioprinting of Tissues and Organs, 32 NATURE BIOTECHNOLOGY 773 (2014).

33. Torrance, supra note 32, at 629.
34. Torrance, supra note 32, at 665 (alteration to the original).
35. See Kennedy, supra note 14 (defining happiness as “the full use of your powers along lines of excellence”).
36. See generally Schubert, supra note 18, at 160.
37. See e.g., Jordan S. Miller et al., Rapid Casting of Patterned Vascular Networks for Perfusable Engineered Three-Dimensional Tissues, 11 NATURE MATERIALS 768 (2012).
38. Id.
39. See e.g., Sean V. Murphy et al., 3D Bioprinting of Tissues and Organs, 32 NATURE BIOTECHNOLOGY 773 (2014).
bones,\textsuperscript{40} skins,\textsuperscript{41} ears,\textsuperscript{42} eyes,\textsuperscript{43} windpipes,\textsuperscript{44} exoskeletons,\textsuperscript{45} prosthetics,\textsuperscript{46} and drugs\textsuperscript{47} – just to name a few.\textsuperscript{48}

Printed individually these are significant advancements in healthcare, but the explosive potential is released when these applications are combined. In the near future, doctors will be able to replace entire limbs, which is a project the United States Military is already developing.\textsuperscript{49} Dr. James Mah, the Director of the Advanced Education Program at the University of Nevada, is currently negotiating with the United States Military to implement the foundation of this project.\textsuperscript{50} At a conference in Silicon Valley, Dr. Mah explained, “We have soldiers who get injured. They lose limbs and tissues, and it is a challenge to reconstruct them. But, if they are imaged beforehand, we can print the lost limbs and tissues.”\textsuperscript{51} In other words, a digital twin can be made so when injury or disease strikes, doctors can repair the impacted area.

Further, 3D printing will drastically disrupt the pharmaceutical industry because it reduces costs and facilitates customization. Today, 3D printers can print molecules that are combined to make pharmaceutical drugs,
and the U.S. Food and Drug Administration ("FDA") recently approved the first 3D printed drug.\textsuperscript{52} 3D printing’s future promises rapid drug development because it reduces manufacturing costs by increasing efficiency, maximizing resources, and eliminating outdated development procedures. For example, 3D printing will reduce and eventually remove the need for animal testing and the FDA’s costly phase trials.\textsuperscript{53} Also, actual production costs will drop because 3D printing can replace pharmaceutical factories. It is predicted, “in the future, pharmaceutical companies will be replaced by databases of drug compounds which would be emailed to the pharmacy for printing.”\textsuperscript{54} In addition, 3D printed drugs will allow doctors to administer customized “drug dosage forms, release profiles, and dispensing for each patient.”\textsuperscript{55} In sum, doctors and scientists will be able to print tissues and test drugs on that tissue without danger and at very low costs.\textsuperscript{56} The introduction of 3D printing into the healthcare industry will degrade the pharmaceutical giants’ fortified position in our society and their justifications for strong intellectual property rights.

The explicit social benefits of 3D printed tissues and drugs will be uncovered in the fight against cancer. Because costs will fall, customization will rise, and drug testing will be safer, cancer patients will benefit the most. In the near future, cancer patients’ tissues will be printed, and doctors will test customized drugs on those tissues, so the patients will be spared from ineffective and grueling clinical trials.\textsuperscript{57} Also, this technology will accelerate cancer research because large amounts of data will be collected, so doctors can pinpoint specific treatments and, hopefully, find a cure. In sum, 3D printing will remove some misery from the world and possibly lead to significant advancements in oncology.

Today, our society is leaning over a precipice of significant advancement in healthcare. Once we fall, there is no going back. Advancements in 3D printing, progresses in stem cell technology, and changes in the pharmaceutical industry will benefit humanity beyond simple


\textsuperscript{54} Schubert, supra note 18, at 160.

\textsuperscript{55} Ventola, supra note 21, at 706.

\textsuperscript{56} Schubert, supra note 18, at 160.

articulation. Only President Kennedy’s *happiness*\(^{58}\) comes close to explaining 3D printing’s potential in the healthcare industry.

Time will tell, but I predict, because of its explosive potential, 3D printing will be heralded as a game changer in the game of human innovation, like the printing press, the Internet, or any other significant human achievement. In other words, history repeats itself, and it is 3D printing’s turn to play. However, the law is not simply an “umpire calling balls and strikes,”\(^{59}\) it is another active player in this innovation game, and the corporate elites are calling the plays.\(^{60}\)

II. WHEN TOMORROW’S TECHNOLOGY MEETS TODAY’S LAWS

3D printing will bring rapid innovation to the healthcare industry and many others, and the contemporary *doxa* (common belief structure) will drive these early innovators to protect their work via intellectual property laws. Basically, the standard justification for protecting intellectual property rights is utilitarian.\(^{61}\) Copying stifles innovation because “no economic agent exercises productive effort without the certainty of controlling its fruits.”\(^{62}\) We have heard this justification for strong intellectual property rights from politicians, artists, scientists, entrepreneurs, economists, and scholars. Indeed, it is our contemporary *doxa*. However, the adherence to the Origin Myth\(^{63}\) is handcuffing society.

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58. Kennedy, supra note 14 (defining *happiness* as “the full use of your powers along lines of excellence”).


60. See Youngstrom, supra note 9; see LAWRENCE LESSIG, FREE CULTURE 21-26 (2004) (explaining Disney lobbied for stronger and longer copyright laws. Also, Disney’s position is ironic because Disney’s cartoons were ‘borrowed’ from previous works, and the cartoons’ successes were partially based on the previous works’ successes).


63. E.g., Jessica Silbey, The Mythical Beginnings of Intellectual Property, 15 GEO. MASON L. REV. 319, 319-20 (2008) (contending “all of the United States copyright, patent, and trademark regimes are structured around and legitimated by central origin myths - stories that glorify and valorize enchanted moments of creation, discovery, or identity. This article uses a cultural analysis of law, rather than the more familiar economic theory of law.”).
The Origin Myth is the structural foundation for the contemporary doxa, which grew out of the Industrial Revolution. The Origin Myth holds that “all of the United States copyright, patent, and trademark regimes are structured around and legitimized by central Origin Myths, which are stories that glorify and valorize enchanted moments of creation, discovery, identity, and ownership.”64 This foundation allows cultural teachers to “justify intellectual property protection with homage to utilitarianism (maximizing the incentive to create, invent, or produce quality goods) or natural rights (people should own the product of their creative, inventive, or commercial labor).”65 In the end, the teachers force-feed our doxa “creativity without a property right, or at the very least attribution, is the very alienation of one’s self.”66

Historically, especially after the Great Depression, the cultural teachers frightened the public with the puffery, “without intellectual property protection, there will be a market failure in innovation.”67 But, the property rationale creates monopolies on information, which slows, and sometimes stops, innovation.68 The property rationale slows innovation because, “in an environment of cumulative innovation, patents undermine protection for the very inventions they seek to protect.”69

Moreover, the current justifications for patent laws assume that individuals and small businesses lack the capacity - financially and technically - to infringe on a thing or process.70 But, 3D printing directly

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65. Id.
66. See ORLY LOBEL, TALENT WANTS TO BE FREE: WHY WE SHOULD LEARN TO LOVE LEAKS, RAIDS & FREE RIDING 169 (2013).
67. Gregory Mandel, Promoting Environmental Innovation with Intellectual Property Innovation: A New Basis for Patent Rewards, 24 TEMPLE JOURNAL OF SCI. TECH. & ENVTL. LAW 1, 8 (2005); see e.g., Mazer v. Stein, 347 U.S. 201, 219 (1954) (“The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in Science and useful Arts.”).
68. RONALD CASS & KEITH HYLTON, LAWS OF CREATION: PROPERTY RIGHTS IN THE WORLD OF IDEAS 204 (2013).
70. Desai, supra note 1, at 1694.
challenges that assumption. Simply put, 3D printing allows individuals to directly compete with corporate giants. Will we see a Miracle here?

Fortunately, the ability to easily copy a thing or process will disrupt inflexible intellectual property laws and their cultural foundation. Professor Deven Desai explains, “3D printing brings the problems of digitization to patents for the first time, but the technology also extends that issue to copyright and trademark.” However, I will only focus on patents because they are in the crosshairs of 3D printing, whereas copyright and trademark are incidental casualties.

A. The Current Patent System

Patents protect new, useful, and non-obvious inventions from copying, after an application for the patent has been filed and granted by the United States Patent and Trademark Office (“USPTO”). Notwithstanding exceptions, “anything under the sun that is made by man” is patentable; including a man made life form and synthetically created DNA. Once protected by a patent, every unauthorized copy constitutes infringement, even unintentional copying. Put differently, patent infringement is the act of making, using, selling, offering, or importing a patented invention without the owner’s consent. Further, people who actively encourage others to infringe patents may also be liable under agency.

1. The Social Tradeoff

The current social tradeoff is “when the government grants a patent, it trades off exclusive property rights to the use of an invention in return for two things: (1) an incentive to create the invention in the first place and (2) early publication of the invention rather than the use of secrecy to protect its

71.  Id.
72.  Miracle (Disney 2004) (Miracle tells the tale of the 1980 U.S. Olympic hockey team’s victory over the powerhouse Soviet Union team); do you find it ironic that Disney owns most of America’s cultural stories?
73.  Desai, supra note 1, at 1703.
76.  See Diamond, 447 U.S. 303 (holding a human made living organism may be patented).
77.  See Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).
Governments want inventions of the mind to be treated as property because it essentially creates a marketplace for knowledge. They expect this system will birth innovation, but our experience shows the property rationale is not the mother of innovation; necessity is.

a) Property Incentives ≠ Innovation

Innovation will occur regardless of a property based legal regime. However, there is almost no dispute among economists that a well-designed patent system encourages innovation. But, the historical and international evidence suggests that while “weak patent laws may mildly increase innovation with limited side-effects, strong patent laws retard innovation with many negative side-effects.”

The statistical evidence of the current United States’ patent system shows property incentives do not spur innovation because the rate of patent applications is disconnected from the rate of research and development expenditures, which is known as the Patent Paradox. Although patent applications have quadrupled in the last thirty years, research and development expenditures remain comparatively flat. For example, one empirical study from Massachusetts Institute of Technology (“MIT”) focused on the energy industry, and the authors explained “the empirical evidence points to a pronounced increase in patenting in energy technologies over the last decade, despite traditional investment not rising commensurately.”

In 2005, scholars Michele Boldrin and David Levine reviewed twenty-three major studies on the connection between patents and innovation. The studies covered many industries, like software and pharmaceutical, and spanned a combined timeframe from 1850 to 2000. Boldrin and Levine concluded the studies “find weak or no evidence that strong patent regimes increase innovation. It is apparent that the recent explosion of patents in the United States, the European Union, and Japan, has

79. Hall, supra note 13.
81. Id. at 4.
83. Id.
84. See Luis Bettencourt et al., Determinants of the Pace of Global Innovation in Energy Technologies, 8 PLOS One 10 (2013).
86. Id. at 174.
not brought about anything comparable in terms of useful innovations and aggregate productivity.\textsuperscript{87}

Interestingly, a recent study, conducted by professors at Europe’s most prestigious economic schools, concluded that only ten percent (10\%) of the inventions that represented a “technological breakthrough” within the last three decades were patented.\textsuperscript{88} The logical conclusion from this study is “if ninety percent (90\%) of important inventions are never patented in the first place, then patents are not a significant driver of most innovation.”\textsuperscript{89}

Further, a property-based regime is not an element of innovation because people will innovate regardless of property protection for their thoughts. For example, during the Industrial Revolution, countries without patent systems had overall rates of innovation similar to those with a patent system.\textsuperscript{90}

Also, people innovate because of necessity,\textsuperscript{91} not because of property incentives, which first appeared in the Middle Ages.\textsuperscript{92} Back then, political and religious elites created property protections for thoughts, so they could control society by restricting the dissemination of information.\textsuperscript{93} For example, the 1556 establishment of the Stationers’ Company’s printing monopoly in England was largely intended to limit the Protestant Reformation movement’s power and influence.\textsuperscript{94} Finally, humans innovated for millennia before society decided to treat thoughts as property. The idea of a patent system is relatively new on the human timescale.

2. The Criminals

Under our contemporary doxa, it seems inevitable that people who use 3D printers will patent their things and processes, and under the current law, others will infringe those patents. If our doxa and the laws do not change, I predict, once 3D printing’s development reaches its explosive potential, the

\textsuperscript{87} Id. at 170.
\textsuperscript{89} Stephan Kinsella, Study: Most Important Innovations Are Not Patented, Center for the Study of Innovative Freedom (Nov. 30, 2013), c4sif.org/2013/11/study-most-important-innovations-are-not-patented.
\textsuperscript{90} Boldrin, supra note 80, at 7.
\textsuperscript{91} PLATO, THE REPUBLIC, BOOK II (360BCE) (“A true creator is necessity, which is the mother of our invention.”).
\textsuperscript{93} Id.
\textsuperscript{94} Id.
trail of patent applications, litigation, and infringement will mirror the Trail of Tears. In hindsight, the Trail of Tears is undeniably a social tragedy, which was caused by a failure of socio-cultural, socio-economic, and socio-legal policies.

When companies use lawyers to enforce patents, doctors, scientists, and patients will be caught in the crossfire. For context, let's revisit our near future doctors, scientists, and patients related to the soldier example above. For illustration, I will tell you their story.

♦ ♦ ♦

Dr. Mallory Youngstrom, an expert in stem cells, works for a prestigious hospital in San Diego, California. She specializes in applying stem cells directly to patients, and she has a long list of medical achievements since she graduated twenty years ago. When she first started at the hospital, she met Alejandro De La Torre, M.S., who is a mechanical engineer. Together, they modified 3D printers, which already turned stem cells into tissues, bones, and skins. Mallory and Alejandro expressed that their main desire is to save and enhance lives, but would like to make some money from the project. After years of hard work, using personal funds, and irrational dedication to detail, they finally built a 3D printer and developed techniques they believe will be able to print a limb. They mainly used the current technology, but added some personal flavor so they can print skin, bones, and tissues within the same process, which results in the ability to print limbs. They achieved this by copying existing things and processes to learn limitations and potential uses, by combining existing uses to build new applications, and by transforming those applications into a new possibility.

On May 15, 2035, Mallory and Alejandro surgically affixed a 3D printed leg for Kenny Mayfield, a Marine from First Battalion; First Marines; Bravo Company; Weapons Platoon; Assault Section. Kenny lost his leg, from the thigh down, three years ago battling Deash in Syria. Before his deployment, the United States Military, in connection with Dr. James Mah's ongoing program, scanned Kenny's body and DNA.

This was the first surgery of its kind. Essentially, Alejandro used the scans to print the leg, and Mallory then attached it with help from robots. At the time, Mallory and Alejandro anticipated that Kenny would have full motor control of his new leg within a few weeks. Kenny insisted on having the surgery as soon as possible because his daughter was getting married on

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95. In the late 1830s, our nation’s Indian removal policy forced the Cherokee nation to give up its lands east of the Mississippi River and to migrate to present-day Oklahoma.
July 4, 2035. During his struggles, he stated numerous times to his daughter, “I fully intend to walk you down that aisle.”

After ten hours of printing and eight hours of surgery, Kenny rested in the recovery room, surrounded by friends and family. After a few moments, Kenny wiggled his new toes, and everyone felt the happiness.

Soon after, news broke that the surgery was a major success. Accordingly, the Fourth Estate turned its spotlight on Mallory, Alejandro, and Kenny. On June 30, 2035, while Kenny was standing tall for the tailor of his new tuxedo, he received a phone call from a lawyer, who represented a consolidated group of elite biotech companies. The lawyer calmly threatened, “We will recover billions of dollars for infringement from you. Otherwise, we will take back our leg, literally.” Soon after, Mallory, Alejandro, and the hospital received similar calls.

The next day, Mallory, Alejandro, and Kenny consulted with the hospital’s outside counsel, Rick Barton, who explained the situation. Mallory and Alejandro infringed patents that cover the processes that individually protect the 3D printing of tissues, bones, and skins. Although they developed an entirely new application for 3D printing, they unknowingly, but illegally, used the property of others.

Also, Mallory and Alejandro executed indemnification, invention assignment, and confidentiality agreements with the hospital. This means the hospital will defend them, will take ownership of all of their work, and will control what they say. Subsequently, Rick explained that the hospital is also liable under applicable law, and he will provide a legal defense for Mallory, Alejandro, and the hospital. However, Kenny signed numerous contractual waivers and forfeited all rights, so he could receive the experimental treatment. Rick explained to Kenny that he is on his own, and the hospital will be taking an adverse position against him because he insisted, albeit unknowingly, that Mallory and Alejandro infringe those patents.

Rick believed settlement was in everyone’s best interests because Mallory and Alejandro clearly infringed on the patents, and Kenny insisted they do the surgery. Also, Rick believed the settlement might lead to a change in the hospital’s ownership because the financial liability is enormous. At the end of the meeting, Rick remorsefully looked them in the eyes and said, “I am sorry that this feels unjust, but it is our system.”

Now, Mallory and Alejandro need new jobs, are disappointed to find out they do not have any claim to their project, and cannot talk about the situation at all. Across the room, Kenny cannot stop thinking of how he will tell his daughter that they must cancel the wedding.

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Here, arguably, current law holds (i) Mallory and Alejandro liable for patent infringement, (ii) the hospital liable under respondeat superior, and (iii) Kenny liable under agency. Foreseeably, if patent laws and our doxa do not change, our system will hold these people as Criminals.

In the near future, will we allow this result? Does this result fit our current experience? Saul Alinsky defines experience as “the integrating of the actions and events of life so that they arrange themselves into meaningful universal patterns.” If our experience is that copying promotes progress, then our laws must reflect that policy.

III. CULTURE AND CULTURAL DEVELOPMENT

Culture is a contested concept with many different interpretations, and culture intertwines with complex ideas about humans, societies, and how they operate. Here, culture is defined as the accumulation and dissemination of social knowledge. This definition is intended to grasp the complex concepts of aggregated human knowledge and its transference. The definition of culture needs to be updated because “all too often, concepts come burdened with the connotations and implications of the past contexts that gave rise to them. Hence a periodic review of our stock of ideas is neither an exercise in [antiquarian] nostalgia nor a ritual occasion for rattling the bones of our ancestors. It should be, rather, a critical evaluation of the ways we pose and answer questions. . .”

Humans’ ability to accumulate and disseminate knowledge is the fundamental source of civilization. Humans cannot build social institutions, governments, or economies without the accumulation and dissemination of social knowledge because culture is the grand social cohesion. Our social knowledge underpins the traditional understanding of humans’ psychology (behavior), economics (needs), art (creativity), law (expectations), and political science (social organization). Simply put, humans teach and learn

96. Oliver Holmes, The Common Law 4 (1881) (“The life of the law has not been logic: it has been experience. The felt necessities of the time, the prevalent moral and political theories, intuitions of public policy, avowed or unconscious, even the prejudices which judges share with their fellow-men, have had a good deal more to do than the syllogism in determining the rules by which men should be governed.”).


from other humans in a social context, and this knowledge transference drives the *doxa*, which transcends generations, shifts over time, and changes between places. Put differently, the power of culture is its force and ability to influence the social domain and the relationships between people, on small and large scales.¹⁰⁰

Social Learning Theory is the centerpiece of an astonishing number of disciplines, such as anthropology, psychology, neuroscience, economics, political science, art, and even artificial intelligence.¹⁰¹ This theory holds learning is a cognitive process that takes place in a social context, and learning occurs through observation, imitation, and modeling, without the need for direct reinforcement.¹⁰² Social Learning Theory’s “social context” is best understood as culture because the surrounding social context is that humans display the social knowledge they learned, and others observe, imitate, and model them. *Monkey see, monkey do.*

Cultural Development is defined as the acceleration of the accumulation and dissemination of social knowledge. Essentially, this term intends to encompass innovation and the related concepts of Social Learning Theory and culture. Simply put, humans learn by copying and innovate by copying, combining, and transforming. Copying is learning: humans cannot create anything new until they have a solid foundation of knowledge and understanding. Learning is combining: humans correlate existing ideas and concepts to form new ones. Combining is transforming: humans use their knowledge and new ideas to make creative and transformative leaps. The acceleration of the accumulation and dissemination of knowledge is the secret ingredient for the recipe of the pursuit of *happiness*. We must feed our *doxa* this, so humans can strive to reach our full potential because we deserve to be *happy*.

### A. The Secret Ingredient

Writer Seth Godin eloquently described our contemporary *doxa*, which grew from the Industrial Revolution, as “[W]hat is not yours is mine.”¹⁰³ Godin’s article explains, “Patents were not developed to protect ideas because ideas cannot be patented. Patents are for the specific execution

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¹⁰³ Seth Godin, *Why I Want You to Steal My Ideas*, TED (February 3, 2015), ideas.ted.com/the-big-mistake-we-all-make-about-ideas/ (alteration to the original); thank you for your ideas Seth.
of useful innovations." But, the reality is companies “use[] the specter of long, drawn-out litigation to extort money from completely innocent [people].” Companies are “selfish, spinning out untruths for personal profit.” Companies “amplify a cultural shift, one that’s left over from the days of Henry Ford and Frank Sinatra. [In the end,] they’d like people to be afraid to steal ideas.” Companies use this strategy because the Counter Industrial Revolution will erode their stranglehold on power and control.

Simply put, corporate elites are winning the innovation game because they manufacture a chilling effect on the doxa. The general misunderstanding of the moral and legal implications of idea theft applies the brakes to Cultural Development.

1. Embrace the Remix

I agree with Godin; “We don’t need to shun those that steal ideas. We need to chastise those that think that this is a problem.” However, this idea is not revolutionary or new. Many great inventors, artists, and economists recognized and embraced the maxim that “everything is a remix.” In 1996, Steve Jobs quoted Pablo Picasso in an interview when he stated, “Good artists copy; great artists steal.” Recently, a member of Apple, Inc.’s executive team clarified what Jobs meant in an interview with CNET, and he said, “I think what Jobs meant by ‘steal’ was you ‘learn’ from past masters, as artists have.” However, Jobs and Picasso were not alone. In 1921, T. S. Eliot wrote, “Immature poets imitate; mature poets steal; bad poets deface what they take, and good poets make it into something better, or at least something different.” Also, Peter Yates claimed he heard the prominent composer

104. Id. (alternation in original).
105. Id. (alternation in original).
106. Id. (alteration in original).
107. Id. (alteration in original).
108. Godin calls this idea the Connection Economy and others have similar names for it. But, Godin and others make the mistake of confining this revolution to one discipline, economics. In fact, it is a combination of socio-cultural, socio-economic, and socio-legal factors.
109. Godin, supra note 103 (emphasis added).
Igor Stravinsky say, “A good composer does not imitate; he steals.” Further, academia’s economists, from UC Berkley and University of Munich, explain, “invention is cumulative, each discovery today builds on discoveries from the past.” In the end, creativity and originality is the skill of concealing the origins.

Thus, our corporately manufactured doxa is preventing Cultural Development. Public policy must shift our doxa to accept socio-cultural, socio-economic, and socio-legal policies that promote Cultural Development.

2. Leaders of Cultural Development

Today, there are leaders of Cultural Development that are pushing our doxa forward, so it reflects our experience and the realities of the Counter Industrial Revolution. These leaders understand Cultural Development is more important than strong individual property rights. Elon Musk, the entrepreneur behind Tesla and SpaceX, demonstrated that alternative policy choices promote Cultural Development. Also, Lawrence Lessig, a co-founder of Creative Commons, is now the poster boy for re-inventing the public domain. These two leaders understand that the modern intellectual property right regime needs to be reformed, so the law reflects our experience because experience is the soul of the law.

a) Elon Musk

In June 2014, Elon Musk tore down the justification for patents when he opened Tesla’s patents to the world. Musk stated in Tesla’s press release, “Maybe patents were good long ago, but too often these days they serve merely to stifle progress, entrench the positions of giant corporations, and enrich those in the legal profession, rather than the actual inventors.”

115. Hall, supra note 13.
116. See Cyril Joad, LIBERTY TODAY 27 (1933); that is to say, ninety-nine percent (99%) of innovation is robbery.
117. Holmes, supra note 96 (“The life of the law has not been logic: it has been experience. The felt necessities of the time, the prevalent moral and political theories, intuitions of public policy, avowed or unconscious, even the prejudices which judges share with their fellow-men, have had a good deal more to do than the syllogism in determining the rules by which men should be governed.”).
119. Id.
Musk also recognized that Cultural Development promotes social welfare rather than individual property rights, when he stated, “We believe that Tesla, other companies making electric cars, and the world would all benefit from a common, rapidly-evolving technology platform.” Further, Musk embodies the philosophy that a “rising tide lifts all boats.” This is demonstrated in the final sentence of his press release; “We believe that applying the open source philosophy to our patents will strengthen rather than diminish Tesla’s position.”

Musk’s actions should make society seriously rethink the intellectual property system. Rapidly developing technologies are not benefited by long protection terms because ideas and things evolve too fast. Essentially, a good idea yesterday is outdated by a better idea today. By restricting access to the older idea, the development of newer ideas is significantly slowed down. But, lengthy protection terms benefit companies who use patents to shake down genuine innovators and control the dissemination of knowledge.

b) Lawrence Lessig

Professor Lessig is a founding member of Creative Commons, which is an organization whose goal is to support a larger public domain. Creative Commons “develops, supports, and stewards legal and technical infrastructure that maximizes digital creativity, sharing, and innovation.” Essentially, Creative Commons advocates for “Some Rights Reserved” as opposed to “All Rights Reserved.” A Creative Common license allows access to information, so others can copy, combine, and transform.

Lessig believes intellectual property rights are essential to promote Cultural Development. Lessig’s goal is to reform, not revolutionize, copyright law. Lessig supports the idea of Free Culture, which is a socio-cultural, socio-economic, and socio-legal philosophy. A Free Culture

120. Id.
122. Tesla, supra note 117.
124. Id.
125. Id.
126. CREATIVE COMMONS, creativecommons.org (last visited Oct. 11, 2014).
supports and protects creators and innovators by granting limited rights, so to
guarantee that follow-on creators and innovators can copy, combine, and
transform freely. However, a Free Culture is not a culture without property.
Like a free market, regulations are needed to provide stability. But, strict
financial regulations, like strong intellectual property rights, “create subsidies
for certain players, skew the incentives of some actors to undermine
compliance, encourage regulatory arbitrage, promote herding, and provide
pro-cyclical incentives.”

In sum, to allow for fair competition to exist, an intricate system of
rules and regulations are needed, but the problem is the current laws
facilitate unfair competition, oppression, and rent extraction. Lessig’s
Creative Commons is just one example of a different policy that intends to
increase innovation (i.e., Cultural Development), which can be reasonably
elaborated to apply to patent law today.

Society is better off cooking a different recipe for healthcare and
patent law. That recipe needs to be made from negotiations between public
interests to find the right balance. But, new seeds must be planted in culture
to facilitate the coming of the next generation of medicine.

B. The Next Social Tradeoff

The doxa shifts around the turn of the Twentieth Century steered the
direction of the rest of that century, and now, the doxa shifts around the
turn of the Twenty-First Century will steer the direction of the rest of this
century. Simply put, the doxa’s acceptance of the Counter Industrial
Revolution will reduce the value of intellectual property and erode entities’
power over our democratic process. However, shifting the doxa is not easy,
and resistance is strong because the bourgeoisie dug their roots deep,
infiltrating culture. Put differently, modern bourgeoisie’s means of
production is intellectual property.

128. Id. at xiv.
129. Id.
130. Frank Partnoy, Financial systems, Crises, and Regulation, 10-11, Oxford
131. Id. (quoting Ronald Coase).
132. See Desai, supra note 1, at 1695.
133. Id.
134. See Youngstrom, supra note 9.
135. Bourgeoisie is defined as the capitalist class who own most of society’s wealth
and means of production. In this Article, I also refer to the Bourgeoisie as cultural teachers
and corporate elites.
But, we must start somewhere. That is why 3D printing and healthcare is the perfect recipe for change. In the kitchen, healthcare and rapid innovation clash with inflexible patent laws, under the heat of public policy. Especially here, happiness outweighs the current justifications for patent law because humanity’s potential to save and enhance lives should not be limited by words on paper that invisibly grant property to a single person or entity.

The next social tradeoff for healthcare and patents should be based on open competition, limited by some regulation to solidify expectations about fair play. The incentives for profits should be derived from services, not property because numerous options in an open market will promote competition, innovation, and investment, as we see in the fashion industry.\(^\text{136}\) In other words, sharing knowledge and large profits are not mutually exclusive. At the core, necessity is the mother of innovation,\(^\text{137}\) and we have plenty of needs in healthcare.

Game theory teaches us that if each person acts in his own self-interest, the sum of the aggregated action is disastrous for the group.\(^\text{138}\) Accordingly, cooperation is the preferred strategy to maximize results for each individual and the group.\(^\text{139}\) Thus, the proper strategy here is for the doxa to embody mutual cooperation balanced over self-interest by not treating thoughts as property.

Essentially, the human race will benefit the most if innovation in healthcare comes from the top down (big corporations) and from the bottom up (small inventors). An open, creative, and competitive space will connect everyone, which will push the technology forward. This new space will democratize innovation in healthcare, which will bring equilibrium to some current social disparities.\(^\text{140}\) The byproducts of this new tradeoff will be lower costs for, and higher access to, quality medical care, while preserving incentives for the pursuit of profits in the form of services.

The cultural shifts towards community, the disconnect between intellectual property laws and public policy, and the public’s rapidly growing awareness to this innovation problem demonstrates that the oven of change

\(^\text{136}\) See e.g., Kal Raustiala & Christopher Sprigman, The Piracy Paradox: Innovation and Intellectual Property in Fashion Design, 92 Va. L. Rev. 1687, 1689 (2006); the fashion industry is generally not protected by copyright law, but that does not stop rapid innovation or limit profits. Copying runs rampant, but profits still increase.

\(^\text{137}\) Plato, supra note 91 (“A true creator is necessity, which is the mother of our invention.”); the healthcare industry obviously is full of necessity, so it is prime for this new tradeoff.


\(^\text{139}\) Id.

\(^\text{140}\) See Eric Von Hippel, Democratizing Innovation 2 (The MIT Press 2005) (explaining open source theory “appears to increase social welfare”).
is heating up. I believe the cultural shifts towards community\textsuperscript{141} will help propel our society towards accepting a different understanding of inventions of the mind, especially in healthcare.

Also, empirical studies show there is a strong disconnect between modern day intellectual property laws and the public’s perception of sound policy in intellectual property law (what the law should be).\textsuperscript{142} Boiled down, the studies indicate that most people believe intellectual property laws are too strong and too broad.\textsuperscript{143} Professor Gregory Mandel concluded from the studies, “the intellectual property system will remain hard-pressed to achieve its objectives given the widespread disconnect between the public psychology of intellectual property and the reality of intellectual property law.”\textsuperscript{144} Moreover, the public’s awareness to this innovation problem is growing rapidly,\textsuperscript{145} which is essential for a successful grassroots movement.

In sum, by properly grasping policies that promote Cultural Development, there will be a socio-cultural, socio-economic, and socio-legal shift to the pursuit of happiness in the healthcare industry. The creation of an open, creative, and competitive space will increase innovation in healthcare, which will propel humanity into the next generation of medicine. But first, we must re-invent the idea of the public domain before we can save it.\textsuperscript{146}

“Systems should exist to serve society. Right now, our system is not serving society; it is serving shareholders. And we cannot run around

\textsuperscript{141} For example, in 2012, Delaware amended its code to create a new corporate entity, known as a Public Benefit Corporation (“PBC”). Under Delaware law, the purpose of a PBC is to operate in a responsible and sustainable manner. The statutory directive provided by Delaware law requires the balancing of “(1) the pecuniary interests of the stockholders, (2) the best interests of those materially affected by the corporation’s conduct, and (3) the specific public benefit or public benefits identified in its certificate of incorporation.” 8 Del. Code §365; arguably, PBCs are not subject to Revlon duties because PBCs are not bounded by law to maximize results for shareholders.


\textsuperscript{143} Id.

\textsuperscript{144} Id. at 308.

\textsuperscript{145} Gaëlle Krikorian & Amy Kapczynski, Access to Knowledge in the Age of Intellectual Property 17 (The MIT Press 2010) (explaining “criticisms of the existing state of intellectual property law have gone viral”).

\textsuperscript{146} See James Boyle, The Second Enclosure Movement and the Construction of the Public Domain, 66 Law & Contemp. Probs. 33, 74 (2003) (explaining the public domain must be re-invented before it can be saved).
expecting different outcomes until we change the rules of the game”\textsuperscript{147} and the social recipe.

**CONCLUSION**

3D printing is concocting a secret recipe for change in healthcare’s kitchen that will directly challenge the kitchen’s investors’ position at the top. Obviously, the investors do not want you to taste the secret ingredient because that will erode their position in our society. However, we have the ability to taste the recipe at any time because, in the end, it is our choice.

Today, we are taught that inventions of the mind are property that can be bought and sold. However, this is partially based on the false assumption that a person does not learn from past masters. But, our experience is that everything is a remix because inventions are cumulative.

One of the investors’ enforcement arms is patent law, and this arm will try to reach into healthcare’s kitchen to slap away our spoon. In healthcare, rapid development of 3D printing will benefit humanity beyond simple articulation because 3D printing will help humanity pursue happiness. However, the investors will do almost anything to stop the flavors from touching our tongue because once it does, we will want more and more.

So, to answer the question, will laws, lawyers, and companies stand in the way of patient care? Yes, at first, but I predict that our doxa will embrace the remix, and society will adopt a new social tradeoff. *I believe the root cause for our current problem (the answer “yes”) is viewing inventions of the mind as property.* The way foreword is to promote Cultural Development, which will push our doxa to accept the Counter Industrial Revolution.

The shift towards a more socially responsible doxa is now clear. With the help from stronger winds, we will witness our doxa shift. The hours of the corporately manufactured doxa are limited, and the Counter Industrial Revolution and the socially responsible doxa are nearing their sunrise.

\textsuperscript{147} TEDx Talks, *TEDxPhilly - Jay Coen Gilbert - On Better Businesses*, YouTube, at 10:06-10:18 (Dec. 1, 2010), http://www.youtube.com/watch?v=mGnz-w9p5FU.