Fractionalized Science: Reforming Patent Infringement for Biotechnology

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FRACTIONALIZED SCIENCE: REFORMING PATENT INFRINGMENT FOR BIOTECHNOLOGY

Student Paper[*]

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ABSTRACT

The ever-innovating field of biotechnology is becoming more and more fractionalized as scientists and researchers continue to develop cutting-edge technologies. Patents for biotechnologies currently on the market are often overreaching, overly broad, and inappropriately create intellectual property rights and inventions that they do not own. These overly broad patents facilitate monopolization with outdated science and prevent new and innovative developments from reaching the people that need them most. This paper proposes reform to patent infringement law so that old and overreaching patents do not suppress innovation. This proposal relieves innovators, or potential infringers, from having to resort to expensive and time-consuming reexamination procedures through the United States Patent and Trademark Office (USPTO) or suffer from extensive damages awarded to prevailing patentees in infringement suits. Overly broad patents in conjunction with current claim-narrowing procedures often create oceans for innovators to cross in order to advance biotechnology. Scholars have argued that changing the process by which patents are obtained could better incentivize researchers to patent their leading technologies. Varying interpretations of 35 U.S.C. § 101, and disagreements with recent Supreme Court precedent have been proposed and, consequently, crowded the scholarship field.

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Simplification of the current patent system seems daunting and likely unsuccessful due to lawmakers' typical lack of knowledge in these highly developed and specialized fields. Though admirable in effort and in volume, I believe that approach has been exhausted. This paper proposes that instead of attempting to change patentable subject matter doctrine or rely on the USPTO reexamination procedures, a statutory defense be added to the patent law that will afford alleged infringers of biotechnology patents the opportunity to escape from infringement liability. By opening up room for new patents to be pursued, the law can work alongside scientists and researchers to get cutting-edge products patented, out on the market, and into application for the betterment of society.

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INTRODUCTION

Patents have been called "the bedrock on which the biotechnology industry is built."[1] Blame the economic incentive that patents provide for their hold on advancement in the science.[2] Generally, without the security of the promise of exclusivity of the market that patents provide, investors will not fund the expensive research that is needed to make the next big biotech breakthrough.[3] Whether patents have rightfully taken control of the industry or not (a discussion reserved for later in this paper), they alone should not dictate when science takes its next big step. The current patent process creates oceans for innovators to cross in order to obtain a patent.[4]

[1] Christopher M. Holman, *Developments in Synthetic Biology Are Altering the IP Imperatives of Biotechnology*, 17 VAND. J. ENT. & TECH. L. 385, 404 (2015).
[2] *See generally*, Yusing Ko, *An Economic Analysis of Biotechnology Patent Protection*, 102 YALE L.J. 777 (1992).
[3] See, Dan L. Burk, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 RUTGERS COMPUTER & TECH. L.J. 1, 16-24 (1991) (discussing the "[b]usiness of [b]iotechnology"). Additionally, a quick internet search for the "importance of patents in biotechnology" revealed a number of articles discussing the critical role of patents in the biotechnology industry not only in the United States, but also abroad.
[4] *Infra*, Part I.

These obstacles suppress innovation in biotechnology at the forefront. On the back end, overly broad patents subject researchers—and the companies that employee them—to harsh infringement liability.[5] The complexity of the patent process is disheartening to innovators, unappealing to investors, and consequently damaging to everyone, everywhere.

When Watson and Crick published their double-helix model for the molecular structure of deoxyribonucleic acid (DNA) in 1953, they opened the door to the wave of modern biotechnology.[6] Modern biotechnology is a very broad discipline that employs biological processes, organisms, cells, or cellular systems to develop tools, products, and technologies.[7] Given its breadth, it is almost hard to avoid biotechnology in everyday life. A reader is likely to have interacted with a biotechnological application even if they had never encountered the term before reading this paper.

There are five commonly recognized branches of the science: animal, environmental, plant, industrial, and medical.[8] These branches of biotechnology are often categorized by color with the most popular being white, green, and red.[9] White includes the industrial processes involving microorganisms in chemical production. White biotechnology is prominent in modern industrial processes because it involves using living cells to create products that require less energy, create less waste, and are easily degradable.[10] Green biotechnology includes processes that improve agriculture. A common example of green biotechnology is a genetically-modified organism, commonly known as GMOs. Red biotechnology includes developments in medicine, health, and diagnostics. The other categories mentioned in the textbook include: blue—marine and aquatic systems; yellow—food and nutrition; grey—environmental biotechnologies and the removal of pollutants; black—biowarfare and bioterrorism; and gold—bioinformatics.[11] This paper's proposal is most directed at innovation in medical biotechnology, and thus will focus on issues and examples within that branch.

[5] *See generally*, Katherine M. Nolan-Stevaux, *Open Source Biology: A Means To Address The Access & Research Gaps?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 271 (2007); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1624-1630, 1676-1683 (2003) (discussing how the patent system has failed to encourage innovation in a variety of patent-dependent industries including biotechnology).
[6] *See generally*, J.D. Watson, F.H.C. Crick*, Molecular Structure of Nucleic Acids*, 171 NATURE 737 (1953).
[7] ULRICH KUCK ET. AL., BIOTECHNOLOGY (Kück, Nicole Frankenberg-Dinkel eds., 2015).
[8] *Id*.
[9] *Id*.
[10] Giovanni Frazzetto, *White biotechnology*, 4 EMBO REPORTS 9 (2003).
[11] J.L.RODRIGUES, FOUNDATIONS OF BIOTECHNOLOGY AND BIOENGINEERING, CURRENT DEVELOPMENTS IN BIOTECHNOLOGY AND BIOENGINEERING, 239-269 (Ashok Pandey and José António Couto Teixeira eds., 2016).

From this short explanation, it is easy to see how quickly the list of categories in biotechnology grows very long. From there, the list of subcategories grows even longer. The lists will get even longer as science continues to evolve and more specialized areas develop. In essence, science fractionalizes.[12] If you're a math person, this is simply the real life version of dividing a fraction and getting very large denominator. If you're not a math person, let's conceptualize. Imagine one large square drawn on a piece of paper. This square contains all that is considered biotechnology. Now, two intersecting lines are drawn through this square, creating four sections. Notice: the original square that was drawn didn't get any bigger; nor did it get any smaller. It simply sectioned. Next, two intersecting lines are drawn inside each of the sections. Then, two more in each of the new sections. The hypothetical could last forever. The sections could be unequal in size or shape, or both. One section could keep dividing while the others stop. Instead of drawing a line, someone could draw a circle. The point is that biotechnology (the big square) is defined, but its categories (the sections) are not.

Biotechnology is just one example of how a field of science fractionalizes to deepen its understanding, but it is a very good one. Every advancement, innovation, discovery, or step in biotechnology fractionalizes the field a little more. Fractionalization then, in turn, lends itself to more advancement and innovation. But when an industry of science, whose nature it is to progress, becomes dependent on a patent system, whose nature it is to hold, the scene is set for conflict. Biotechnology patents filed fifteen years ago were at the edge of innovation and their claim language reflects that. But as time passes and new discoveries are made, the things that biotechnology once saw as the most specific are actually quite the category.[13] The problem is that often, when a patent holder wants to enforce his or her rights, the language used at filing to denote a specific material, has become a category of materials.[14] This paper argues that biotechnology innovators should not be held liable for infringement due to a predecessor's inability to accommodate claim language for the chance that science would advance past their own knowledge.

Part A of this article gives an overview of the modern patent process, In doing so, I will address the most relevant issues that are necessary to understand the value of this paper's proposal: patent theories, patentable subject matter doctrine, review and reexamination procedures available through the United States Patent Office (USPTO), licensing issues, and infringement claims. Those previously educated in patent law or familiar with these topics may desire to skip ahead. But this section highlights the issues that specifically affect biotechnology and provides context for other parts of this

[12] This idea is an adaptation of the theory of fractionalization in property law. *See generally*, 58 C.J.S. Mines and Minerals § 223.
[13] *See,* Jorge A. Goldstein, Ph.D., J.D., Sterne Kessler Goldstein & Fox PLLC, *Capturing After-Discovered Embodiments in Biotechnology Patents*, 25 FED. CIRCUIT B.J. 401 (2016).
[14] *See id*. (discussing recent caselaw on the issue of "after-discovered embodiments").

paper. Ultimate reform of the patent process to stop the suppression of innovation in many fields of science may be well overdue and this paper's approach could be applied in other areas to help that cause. This paper, however, will limit the majority of its discussion to reinvigorating and promoting innovation in medical biotechnology. For this reason, it is most likely beneficial even to those that are well versed in the field.

Importantly, Part A discusses a very common proposal by other scholars.[15] Most, if not the vast majority, have argued that the patentable subject matter doctrine analysis should be changed in order to further innovation. In fairness, they are not wrong. The patentable subject matter doctrine is overly complex, often changing, and needs to be simplified in order for patents to serve their most proper purpose. However, as this article will address, this route is exhausted. Scholars have gone to great lengths to try and provide different lenses, ideals, theologies, comparisons, legal frameworks, and scopes to the patentable subject matter doctrine to make this happen. New interpretations of U.S.C. § 101[16], the Constitutional provision permitting patents, Supreme Court decisions, and Patent Office procedural guidelines have all been offered to hopefully spur change in the right direction. In the face of all that has been proposed, nothing has seemed to help.

Part B brings the problem to the front and center in light of the state of affairs as framed in Part A. This section discusses some examples of the problem as well as a hypothetical so that the reader has an opportunity to see the imperative need for a solution. Finally, Part C suggests a new solution: creating room for innovative technologies to be patented by reforming how older, unnecessarily broad patent holders enforce their rights through infringement claims. Instead of changing how we get things done, let's change how we get things undone. This article proposes an amendment to patent law, applicable only to infringement claims concerning patents of material or inventions in biotechnology, to create a new statutory affirmative defense for alleged infringers. This defense would weaken infringement claims initiated by holders of outdated, broad patents in biotechnology without invalidating that patent or impairing any revenue the patent holder may be receiving

[15] *See* Mike Sikora, *Mayo, Myriad, and a Muddled Analysis: Do Recent Changes to the Patentable Subject Matter Doctrine Threaten Patent Protections for Epigenetics-Based Inventions*, 102 MINN. L. REV. 2229 (2018) (discussing the recent change to the patentability analysis and its effect on a specific field of biotechnology—epigenetics); *see also*, Christopher M. Holman, *supra* note 1 (discussing the "unnecessarily expansive language" of recent Supreme Court rulings threatening the "availability of patent protection for some of the most innovative and meritorious application of natural phenomena in the realm of biotechnology . . ."); *see also*, Jerry I-H Hsiao, *Patent Eligibility of Predictive Algorithm in Second Generation Personalized Medicine*, 22 SMU SCI. & TECH. L. REV. 23 (2019) (discussing "the patentability of the predictive algorithm used in Second Generation Personalized Medicine" under the most recent Supreme Court rulings).

[16] 35 U.S.C. § 101 (2012). The foundational federal statute for the patentable subject matter doctrine that establishes a preliminary patenting requirement by identifying patentable subject matter, § 101 has been interpreted by the courts many times over. The resulting caselaw works in conjunction with the statute to provide the modern—and complicated—patentable le subject matter analysis.

therefrom. Weakening patent protection in this area of science will reduce current or potential monopolies that, even if inadvertently, drastically impair further innovation. As this paper explains, current resources or avenues available to researchers and innovators are not providing enough space for advancement. Reforming every aspect of the current patent system would be expensive, time consuming, and, frankly, messy. Providing a statutory safeguard for innovators in this extremely important field of science will allow the expansion of scientific knowledge without completely desecrating a patent holder's exclusivity rights.

The Patent System

Patent law is complex.[17] This paper's proposal is a simple solution to a complex situation. In order to understand the value of this paper's proposal, it is necessary to grasp the big picture of the patent system and a few relevant proceedings that go along with it. Describing and explaining the patent process naturally lends itself to a discussion of its flaws. It is also helpful in addressing other suggestions for reform. This background section will discuss patent theory, subject matter eligibility, reexamination procedures, and infringement claims.

This section should set the scene for this paper's proposal: a new statutory affirmative defense for alleged infringers of biotechnology patents. In framing the issue, it is helpful to note that this paper does not intend to discuss all of the issues surrounding patents or patent law (of which there are many). For example, this paper is *not* an attempt to argue which patent theory is most accurate. This paper is *not* an attempt to determine the best interpretation of Supreme Court decisions affecting patentable subject matter eligibility. This paper is also *not* an attempt to suggest reform of the review and reexamination procedures. Ultimate reform of the patent process to stop the suppression of innovation in many fields of science may be well overdue, and this approach could be applied in other areas to help that cause. This paper, however, will limit the majority of its discussion to reinvigorating and promoting innovation in biotechnology. Thus, the purpose of this background section is twofold: (1) provide a helpful overview of the patent process and (2) exemplify how complex each step of the process is, especially when patenting biotechnology.

1. Patent Theories

The Constitution permits Congress to grant exclusive rights to authors and inventors to their works for limited times to "promote the progress of science."[18] Congress used this power to create the United States Patent and

[17] Even conducting a "how to get a patent" internet search revealed online articles and blogs referencing the difficulty of the patent process and patent laws. *E.g*. Stephan Kinsella, *The Difficulty and Complexity of Patent Law*, Center For Innovative Freedo (Apr. 2, 2020)(http://c4sif.org/2014/07/the-difficulty-and-complexity-of-patent-law/).

[18] U.S. CONST. ART. I, § 8, cl. 8 ("[Congress shall have the power…t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries").

Trademark Office (USPTO), now a branch of the Department of Commerce, through federal statute.[19] The USPTO grants patents to inventors that are generally effective twenty years from the date the application was filed. There are three common economic theories for the purpose of patents: the incentive-to-invent, the incentive-to-disclose, and the prospect theory.[20]

First, the incentive-to-invent theory holds that the monopolies created by the exclusive rights granted with patents provide an incentive for others to invest in research processes to make new inventions.[21] The exclusive right to make, use, and sell an invention insulates an inventor from any other competition, granting him control of a monopoly on his invention. He can then manipulate that monopoly to recover his investments in research and development.[22] He incentivizes other to make new inventions or else be subject to his control. This theory, however, has been challenged.[23]

Second, the incentive-to-disclose theory holds that the patent process increases the "public storehouse" of scientific knowledge by documenting the inventions made and making them public.[24] General support for this theory lies in the thinking that secrets about new scientific or technological knowledge would deprive the public of a significant benefit and likely lead to duplicative research.[25] Similar to the incentive-to-invent theory though, this has been challenged.[26]

Another popular theory for the purpose of patents is the prospect theory.[27] This theory holds that the granting of exclusive rights to patent holders promotes efficient development. Since patent holders have the right to exploit and improve on their invention, others will refrain from exploiting or improving within that patent's claim (or else be subject to infringement liability, unless arrangements with the patent holder have been made).[28] Similar to the incentive-to-disclose theory, a goal is to avoid duplicative

[19] 35 U.S.C. §1 (establishing the United States Patent Office).
[20] *See* Yusing Ko, *supra* note 2; Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017, 1024-45 (1989). Although, there is a fourth theory discussed by both Ko and Eisenberg called the "incentive-to-innovate theory." *Id.* Attributed to the work of Joseph Schumpeter, this theory suggests that patent monopolies promote technological *innovation*—distinguished from *invention. Id*., at 799. Ko even states that the incentive-to-innovate theory "finds support" in the biotechnology industry. *Id*., at 800. But the Schumpeterian argument provides little insight to reforming infringement law. *Id.*
[21] ROGER SCHECHTER & JOHN THOMAS, PRINCIPLES OF PATENT LAW 1-12 (Concise Hornbook Series 3d. ed., 2019).
[22] Ko, *supra* note 2, at 777; Eisenberg, *supra* note 20, at 1024-26.
[23] *See* Eric E. Johnson, *Intellectual Property and the Incentive Fallacy*, 39 FLA. ST. U. L.REV. 623 (2012)(using behavioral economics, social psychology, and empirical data to argue against the incentive-theory).
[24]Eisenberg, *supra* note 20, at 1020.
[25] *Id*. at 1028.
[26] Ko, *supra* note 2, at 796; Eisengberg, *supra* note 20, at 1028-29.
[27] Ko, *supra* note 2, at 800-802 (citing Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977)).
[28] Ko, *supra* note 2, at 801.

research. But in the prospect theory, focus is not the "public storehouse" of knowledge. Instead, focus is on the role of the patent holder in forcing researchers to share knowledge to create efficient development.[29]

For purposes of this paper, it is sufficient to know that each of these theories do have distinguishing nuances. The differences are significant and do, admittedly, create different perspectives when tackling major issues in the patent system. This paper chooses to focus on furthering innovation in biotechnology specifically and removing the suppressive obstacles in the way of new innovation. The role of patents in the modern biotechnology industry is undeniable. "'Correct' or 'incorrect' application of traditional patent doctrines does not . . . dictate the proper scope of patent protection for biotechnological inventions. The proper scope is that which best promotes technological progress." Now, the imperative is to adapt patent law to permit further innovation without complicating the matter further.

Eliminating patents altogether would not solve all the problems that innovations in biotechnology face, but neither will enforcing patents to their maximum exclusivity. A balance of the competing views on the purpose of patents must be achieved. Such a suggestion should not be a surprise. This is a democracy. Not every concern can be met. Not every problem foreseen. But proposing a new solution, coming from a different angle, at a different time, could effectively promote and enable innovation in specialized fields of science while also ensuring patent protection for current patent holders.

2. Patent Eligibility Doctrine

This paper does not propose a solution to overly broad patents in biotechnology by altering the patent eligibility doctrine. But, a brief discussion of the doctrine is helpful to understanding this paper's proposal—reform of patent infringement and invalidation—and why it is the best option. For a big picture of patent eligibility, there are five things to remember: subject matter[30], novelty[31], usefulness[32], non-obviousness[33], and enablement.[34]

In the context of biotechnology inventions and discoveries, the patentable subject matter doctrine receives the most attention. But an invention has to meet all five requirements before being determined as patent eligible. The novelty and non-obviousness requirements mean that an invention cannot be patented if certain public disclosures have been made.[35] The invention has to

[29] *Id.*
[30] *See* 35 U.S.C. § 101.
[31] *See id.* § 102.
[32] *See id.* § 101.
[33] *See id.* § 103.
[34] *See id.* § 112(a) (requiring a "a written description of the invention [that could] enable any person skilled in the art to which it pertains . . . make and use the same").
[35] 35 U.S.C. § 102 governs the novelty requirement. If the claimed invention was (1) patented, described in printed publication, or in public use, on sale, or otherwise available to the public before filing date, or (2) described in standing patent, application for a patent

be new in comparison to "prior art."[36] Usefulness refers to the invention having a useful purpose, which includes the concept of operativeness. The common example for this requirement is that if a machine does not operate to perform its intended purpose, the machine is not useful and will not be granted a patent.[37] To satisfy the enable requirement, an inventor must provide a written description of the invention and that description should "enable any person skilled in the art . . . to make and use the same."[38]

Patentable subject matter is governed by § 101 of the United States Code that allows a patent to be granted to a person that "invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[39] It is generally accepted that this language is broad.[40] The Supreme Court has stated that, "[i]n choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress contemplated that the patent laws should be given wide scope."[41] Together, § 101 of the Patent Act and the current patent subject matter eligibility doctrine form the most challenging patentability requirement for biotechnology inventions on the front side of the patent process.

Before its most recent shift, scholars and inventors alike were well aware of the elusive patentable subject matter doctrine. There was fear that the decisions of the Federal Circuit and the Patent Office, when aligned in the authoritative roles, would create an unprecedented and overwhelming spectrum of eligible patent matter.[42] Jonathon Masur called this the threat of "patent inflation: outward growth in the boundaries of what inventions may be patented."[43] After the Supreme Court sent down impactful rulings covering the patentable subject matter doctrine in *Mayo Collaborative Services v. Prometheus Laboratories, Inc*. and *Association. for Molecular Pathology v. Myriad Genetics, Inc.,*[44] a different author warned that the Court had "opened Pandora's Box" to invalidating a slew of biotechnology patents.[45]

deemed published, that names another inventor and was effectively filed, then a new invention does not meet this requirement. United States Patent and Trademark Office, *General information concerning patents* (Feb. 6 2020)(https://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-5).

[36] 35 U.S.C. §§ 102-103.

[37] United States Patent and Trademark Office, *General information concerning patents* (Mar. 19, 2020)(https://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-5).

[38] 35 U.S.C. § 112(a).

[39] 35 U.S.C. § 101.

[40] Alan L. Durham, *Natural Laws and Inevitable Infringement*, 93 MINN. L. REV. 933, 937 (2009).

[41] Diamond v. Chakrabarty, 447 U.S. 303, 303 (1980).

[42] Jonathan Masur, *Patent Inflation*, 121 YALE L. J. 470, 491 (2011).

[43] *Id.* at 511.

[44] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012); Assn. for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

[45] Sikora, *supra* note 15, at 2230.

In the *Mayo* opinion of 2012, Justice Breyer held that patents effectively claimed the underlying laws of nature, were invalid.[46] The court fashioned a new test to reach its conclusion.[47] The "*Mayo* Test" states that a patent's claimed subject matter must rise to "significantly more than a patent upon the natural [phenomenon or] law itself."[48] Due to its expansive language, the opinion was viewed by some to threaten the availability for patent protection for some of the "most innovative and meritorious applications of natural phenomena."[49] In light of the *Mayo* holding, is important to innovation of scientific fields that patent eligibility is not so tightly restricted that innovators would not be able to patent processes that include underlying natural phenomena, as this would inhibit future discoveries dramatically.[50] Because of the inherent nature of any living organism—its intricacy and complexity—any advancement in biotechnology on the health care or medical front will fundamentally be based on a "natural phenomena" because biotechnology is, in fact, the application of such.[51] In the *Myriad* case of 2013, the Court ruled that "naturally occurring" genome sequences (also known as gDNA) were not a patentable subject matter worthy of patent protection. Yet identical "man-made" complimentary genome sequences (cDNA) were a patentable subject matter and, thus, could receive patent protection.[52] The *Myriad* court distinguished claiming an *invention* of a natural phenomena from claiming the *discovery* of natural phenomena.[53] To do that, the Court defined natural phenomena to be anything, or any characteristic of a thing, that could be discovered in nature.[54]

These two cases, in addition to others[55], have generated plenty of discussion not only in legal scholarship, but also in the medical field. In an article titled *Was Biotech Patenting Not Complicated Enough?*, the author described the rulings from *Mayo* and *Myriad* as having "shaken up the status quo of biotech patenting."[56] The fear is that relatively unestablished fields of biotechnology will detrimentally suffer from the inconsistent holdings of the Supreme Court as they relate to patentable subject matter and associated patent rights.[57] Which patent theory is the Court trying to push, or promote, with these

[46] *Id*.
[47] The *Mayo* Test, although first applied in 2012, was more clearly articulated in 2014. *See* Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208 (2014).
[48] Sikora, *supra* note 15, at 72-73.
[49] Holman, *supra* note 1, at 901.
[50] *Mayo*, 566 U.S. at 72–73.
[51] Remember that the definition of biotechnology is the employs biological processes, organisms, cells, or cellular systems to develop tools, products, and technologies. *Supra*, note 7.
[52] *Myriad*, 569 U.S. at 580.
[53] Sikora, *supra* note 15, at 2116-2117.
[54] *Id*.
[55] *E.g*. *Alice,* 537 U.S. 208 (2014); Ariosa Diagnostics, Inc. v. Sequonom, Inc., 788 F.3d 1371 (Fed. Cir. 2015).
[56] JENNIFER GORDON, THE IMPACT OF MYRIAD AND MAYO: WILL ADVANCEMENTS IN THE BIOLOGICAL SCIENCES BE SPURRED OR DISINCENTIVIZED? (OR WAS BIOTECH PATENTING NOT COMPLICATED ENOUGH?), 5 Cold Spring Harbor Perspectives In Medicine, 5 (2014).
[57] Sikora, *supra* note 15, at 2232.

decisions? If you can even pick one, are they really accomplishing those goals? For example, de-incentivizing patents may lead to a secret driven industry. Those who do make a breakthrough discovery or invention—that they cannot protect with exclusivity rights—will keep to themselves. Legal scholars continue to suggest that adjusting, again, the patentable subject matter doctrine will relieve the impairment of scientific advancements. Very few scholars suggest reform to infringement or invalidation regimes. Perhaps infringement is not perceived as a solution because the problem has been viewed through the subject matter eligibility lens for so long. Decades worth of legal scholarship focuses on this doctrine because most of the industry-shaking court decisions deal with it.[58] Changes in procedural steps to obtain patents, the patentability analysis for biotechnology, and the interpretation of 35 U.S.C. § 101, have all been suggested.[59]

In his article, *The Mayo Framework Is Bad for Your Health*, Christopher Holman suggests that the Court should "revisit" the issue of the patentable subject-matter doctrine to "re-articulate" the standard of patent eligibility so that it may be "better-suited" to promote both secure patent protection for future innovations.[60] And if this fails, Congress should amend 35 U.S.C. § 101. While the article makes a bold proposal and, frankly, one that should be considered, the likelihood of the doctrine changing to such a degree that it's switch will have the impact innovators and patients, alike, desire is small. Instead, this paper proposes a change to the other end of the patent spectrum—altering the infringement and invalidation procedures so that room for new patent eligible material can be patented without stepping on older, broad patents.

Another author suggested a very radical, novel, and intricate view of the patent system overall and then follow up with his own proposal in this new light. In his article, *Patents, Paradigm Shifts, and Progress in Biomedical Science*, Peter Lee proposes an entirely new type of patent to foster innovation in these specific fields.[61] The "research tool patent" would include a unique experimental use exception, lasting for a short period of time (he suggests five years), during which noncommercial uses of the patented research tool would be allowed. Lee claims this new exception would foster innovation in the biomedical field, when in reality this is nothing new. In fact, Lee expends a great amount of time and paper attempting to apply a view of the evolution of science to the intent and origin of patents—an extremely complicated attempt to end with a very simple solution. Furthermore, Lee focuses his arguments around the notion that the main problem halting innovation in biotechnology

[58] For a more in-depth discussion of the evolution of the patentable subject matter doctrine look to *Patentability Under 35 U.S.C.A. § 101 Which Excludes Laws of Nature, Physical Phenomena, and Abstract Ideas*, 5 A.L.R. FED. 3d Art. 4 (originally published in 2015).
[59] *Id.*
[60] Holman, *supra* note 1, at 902.
[61] Peter Lee, *Patents, Paradigm Shifts, and Progress in Biomedical Science*, 114 YALE L.J. 659 (2004).

and nanotechnology the patenting of only research tools. Lee's paper blends into the mess of articles proposing minor changes at the front of the problem.

It is easy to see how quickly this analysis can get very, very messy. That is likely why so much literature has been produced with numerous proposals to alter, simplify, or change the patent eligibility doctrine. The problem suppressing innovation in biotechnology is seen as eligibility, thus a call for change to that analysis seems appropriate. These options, though commendable—and, some, insightful and creative—have been exhausted. While scholars are going to great length, and confusing ones, to provide new solutions, this paper does not add to that chaos. Instead, this paper proposes a new direction for reform: infringement.

3. Review and Reexamination Processes

Patent reexamination is the statutory process through which issued patents are reviewed by the United States Patent and Trademark Office (USPTO) to determine if the subject matter is still patentable, usually in light of prior art.[62] In 1980 when President Carter signed into law the provisions of the Patent Act that first created reexamination procedures, he declared them "the most significant improvement in our patent laws in more than a century."[63] Since then, the statutes have gone through many changes. The most recent the Leahy-Smith America Invents Act of 2011.[64] Reexamination procedures only come into play after a patent has been issued.[65] Either a patent holder or a third party can file a request for reexamination during the life of a patent.[66] If successful, the filing party can have any of the patent claims invalidated or amended.[67] There are three different types of reexamination procedures: inter partes reexamination (now known as inter partes review)[68], ex parte reexamination[69], and post-grant review.[70]

Post grant review, created by the America Invents Act (AIA), is the newest reexamination procedure.[71] It offers the most comprehensive method of reexamination to potential infringers seeking to dispose of a patent. Only a third party can bring a claim for reexamination in post grant review proceedings, and that party can argue invalidity of the patent on essentially any

[62] *See* 35 U.S.C. § 302 (2012).
[63] Nick Messana, *Reexamining Reexamination: Preventing A Second Bite at the Apple in Patent Validity Disputes*, 14 NW. J. TECH. & INTELL. PROP. 217, fn 3 (2016)(citing 3 Pub. Papers 2803 (Dec. 12, 1980)).
[64] 35 U.S.C. §§ 301(a)(1), 302.
[65] Ron Andrew Sassano, *The Rise and Fall of Patent Reexamination Under the America Invents Act: The Burdens and Unconstitutional Aspects of Congress's Latest Attempt at Patent Reform*, 21 J. INTELL. PROP. L. 165, 168 (2013).
[66] "[A]ny time" refers to the 35 U.S.C. § 302.
[67] Douglas Duff, *The Reexamination Power of Patent Infringers and the Forgotten Inventor*, 41 CAP. U. L. REV. 693, 696 (2013).
[68] 35 U.S.C. § 302.
[69] *Id.* § 311.
[70] *Id.* § 321.
[71] *Id.* §§ 321-329.

grounds: lack of eligible patentable subject matter under 35 USC § 101; lack of novelty under 35 USC § 102; or lack of nonobviousness under 35 USC § 103. While granting this much power to potential infringers to invalidate a patent, the AIA tightens the reins some by only allowing post grant review for nine months after the date the patent is issued.[72]

The AIA also had major effects on the process of inter partes reexamination, which it renamed inter partes review. Inter partes review proceedings have a window that begins after the post grant review window closes, or after a post grant review proceeding concludes, and until the patent comes up for renewal. Claimants may only bring invalidity claims of novelty under § 102 or nonobviousness under § 103. Eligible subject matter claims under § 101 are not allowed. Like post grant review, third party requesters participate in the proceedings. The third available avenue, ex parte reexamination, only permits invalidity claims under § 102 and § 103. Different than the either post grant review or inter partes review, the third party requester is not permitted to participate in the proceeding.

Overall, review and reexamination procedures have created more space for new patents. According to the USPTO, of all inter partes reexamination certificates issued only 6% left all claims of a patent confirmed.[73] Yet, these procedures present a number of obstacles to innovators. The first obstacle is that § 101 based actions to amend or invalidate a patent are not permitted during inter partes reexamination. § 101 actions are only allowed during post grant review proceedings.

Second, the post grant review filing period is only nine months from the date that the patent was granted. So, a potential infringer would need to bring his or her § 101 based action against an overly broad patent in a post grant review procedure within nine months of that patent being granted. Rarely, if ever, within nine months, would an advancement in biotechnology occur that could render a freshly-granted patent too broad. This two-fold trap ties researchers hands. When the window to attack the scope of the patent's claims closes, they have two options: wait 20 years until the patent is up for re-issue and quickly file in the post grant review period, or go ahead with their advancement and risk an infringement lawsuit.

Third, review procedures do not assuredly save claimants as much costs in litigation expenses as some claim. Inter partes procedures are touted to save claimants thousands of dollars in costs.[74] In 2018, the USPTO upped the price

[72] United States Patent and Trademark Office, *Inter Partes Review* (last modified May 9, 2017)(Mar. 24, 2020)(https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/inter-partes-review).
[73] United State Patent and Trademark Office, *InterPartes Reexamination Filing Data – September 30, 2017* (https://www.uspto.gov/learning-and resources/statistics/reexamination-information).
[74] Reporting, from 2011 statistics drawn before the America Invents Act went into effect, that the median cost of inter partes reexamination and ex parte reexamination being about

to file inter partes reexamination fees to $15,000.[75] Filing fees for post grant review proceedings can reach between $16,000 or $22,000 per claim.[76]

4. Infringement

Understanding the process by which patents are obtained, and the complex nature of that process, is important to understanding the power of this article's proposal. The sections above explained the front end of the patent process. This section will explain the back end: infringement. The latter is the key to this paper's proposal.

Infringement is defined by federal statute as the unauthorized making, using, offering for sale, or selling a patented invention.[77] Infringement is divided into two basic forms: direct and indirect. Direct infringement focuses on the language of the patent and includes two theories: both a text-based approach, literal infringement, and an equitable approach, the doctrine of equivalents. Indirect infringement includes inducement[78] and contributory infringement.[79] An infringement analysis involves two steps: claim construction (or claim interpretation) and claim comparison.[80] Claim construction is to be determined as a matter of law, with the court focusing on the language of the patent giving the words their "ordinary and accustomed meaning" as understood by persons of "ordinary skill" in the "art."[81] This section will focus on literal infringement and the doctrine of equivalents because this paper's proposal is focused on providing an affirmative defense for alleged infringers of a patent whose language at the time of filing was specific, but at the time of infringement it is broad.[82]

Literal infringement is straightforward: only the patent holder can make, use, sell, or offer to sell the patented invention.[83] Anything else is infringement. Claim construction is a very important step in the analysis because every limitation recited in the claim of the patent must exist in the alleged infringing product in order to succeed on a literal infringement basis.[84]

$30,000 while patent litigation can cost 1 to 5 million dollars. Duff, *supra* note 65, at 700 (citing Andrew L. Schaeffer, *ParallelPatent Reexaminations: The Poor Man's Litigation* 1 PATENT LITIGATION 441, 448 (2011)).

[75] United States Patent and Trademark Office, *USPTO Fee Schedule* (last modified Mar. 1, 2020)(https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule#Patent%20Exam%20Fee).

[76] *Id*.

[77] "[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a) (2012).

[78] *Id*. § 271(b).

[79] *Id.* § 271(c).

[80] Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996).

[81] IA Labs CA, LLC v. Nintendo Co., Ltd., 863 F. Supp. 2d 430, 440 (D. Md. 2012), *aff'd,* IA Labs CA, LLC v. Nintendo Co., Ltd., 515 Fed. Appx. 892 (Fed. Cir. 2013)(citing Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005)).

[82] *See generally*, Goldstein, supra note 13.

[83] 35 U.S.C. § 271(a).

[84] Amhil Enterprises Ltd. v. Wawa, Inc., 81 F.3d 1554, 1562 (Fed. Cir. 1996).

For literal infringement, claims are construed as of the time of filing.[85] The doctrine of equivalents is different. The doctrine of equivalents is an equitable doctrine that a patent holder can invoke against an alleged infringer. It generally enforces a patent holder's right of exclusivity, even if an infringer is not literally infringing.[86] The modern formulation of the doctrine applies a three-way test to ask if the accused product (1) performs substantially the same function, (2) in substantially the same manner, and (3) to achieve substantially the same result, as the claimed product.[87] But the reserve is also true. "[W]here a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim" the reserves doctrine of equivalents may be used as defense to defeat a patent holder's action for infringement.[88]

So Why is This a Problem?

Biotechnology is a multi-million dollar, research-driven, patent-dependent industry.[89] The biotech business benefits not only the pot of scientific knowledge and healthcare, but also the nation's economy. Biotechnology innovation creates millions of jobs and billions in revenue.[90] The industry also heavily impacts achievements in "global energy, water, and food security" through genetic and chemical technologies increasing agriculture yields and producing renewable biofuels and other forms of energy.[91] The modern biotechnology sector is perhaps the most patent dependent of scientific developmental sectors.[92]

As discussed previously, the fractionalization of science is the process by which science evolves. To refresh, fractionalization is like one square being cut into sections of different size and shape, over and over. Biotechnology divides into categories when innovations take steps into the future and gather more pieces of scientific knowledge to add to the proverbial bucket. The modern problem is that patents whose claim language was enabling and specific at the time of filing, become broad at the time the patent holder wants to assert their rights of exclusivity. This leaves innovators blocked from furthering scientific advancements. Outdated, broad patents are suppressing the innovation of biotechnology by preventing researchers from obtaining patents on new products. Attempts to reform front end of the patent process

[85] Schering Corp. v. Amgen Inc., 222 F.3d 1347, 55 U.S.P.Q.2d 1650 (Fed. Cir. 2000).
[86] *See* Graver Tank & Mfg., Co. v. Linde Air Prods. Co., 339 U.S. 605, 608, reh'g denied, 340 U.S. 845 (1950)(citing Sanitary Refrigerator Co. v. Winters, 280 U.S. 30 (1929)).
[87] *Grover*, 339 U.S. at 608.
[88] *Id.* at 609.
[89] LARGEST BIOTECHNOLOGY COMPANIES. RANKED BY WORLDWIDE REVENUE IN 2010, 41 Modern Healthcare 31, 33 (2011)(listing the top biotechnology companies based on worldwide revenue and market capitalization).
[90] JOHN RAIDT, PATENTS AND BIOTECHNOLOGY, U.S. Chamber of Commerce Foundation (2014) ("sales of $13.4 billion and revenues of $18.6 billion;" "directly employing 1.42 million Americans in high-quality jobs and indirectly supporting an additional 6.6 million workers").
[91] *Id.*
[92] *Id.*

haven't worked to remove the hurdle and create their own web of traps. An affirmative defense for alleged infringers of biotechnology patents potential infringement claims against them. Overly broad patents, thus, can detrimentally disable innovation in biotechnology just as much as they have in other fields of science.

A simple hypothetical[93] will help to understand and bring the problem to the forefront. BigBiotech is very large and well-funded corporation that specializes in the research and development of biotechnologies that will advance and improve the medical treatment and diagnosis of diseases. In 2010, BigBiotech patented a new drug "formula" that employed "liposomal structures" to more effectively deliver the active ingredients of the drug to the body tissues. BigBiotech's formula consisted of a key ingredient: Lipid O. [94] Lipids are a naturally occurring class of organic compounds that are insoluble in water, but soluble in organic compounds. [95] The Lipid O molecules in BigBiotech's mixture banded together to form a liposome. Liposomes are naturally occurring molecular structures that form when lipid molecules band together in the body. Liposomes have a distinct chemical composition. This unique chemical composition makes them effective for drug delivery. [96] At the time the patent was issued, the "liposomal structures" language in BigBiotech's claim reflected the very latest advancement in the field of biotechnology. BigBiotech's formula delivered and dispersed drugs into body more effectively than any other system on the market. They were the first to patent anything of its kind and the breakthrough became popular news.

SmallSolutions, a privately funded research laboratory, is developing similar systems (as is the rest of the country). In 2015, they produce a drug formula using the same ingredients, but the Lipid O molecules form micelles instead of liposomes. SmallSolutions sees this as a breakthrough because the micelle formations—chemically and structurally distinct from liposomes—actually prevent the other active ingredients in the drug from reacting with each other, which can significantly reduce the effectiveness of the drug. Plus, micelles had only been discovered a few months before. Testing results show that SmallSolutions' mixture is more effective than BigBiotech's has ever been in all aspects. SmallSolutions produces and offers to sell their new drug formula. BigBiotech sues SmallSolutions for patent infringement. So, who wins?

[93] Loosely based on *Roche Palo Alto LLC v. Apotex, Inc.*, cited by Dr. Jorge A. Goldstein. Jorge A. Goldstein, Ph.D., J.D., Sterne Kessler Goldstein & Fox PLLC, *Capturing After-Discovered Embodiments in Biotechnology Patents*, 25 FED. CIRCUIT B.J. 401 (2016) (citing Roche Palo Alto LLC v. Apotex, Inc., 31 F.3d 1372 (Fed. Cir. 2008)).
[94] In *Roche*, the ingredient was a phenolic lipid called "O_{40}."
[95] FAHY, EOIN ET AL., LIPID CLASSIFICATION, STRUCTURES AND TOOLS, 1811 Biochimica et biophysica acta 11 (2011).
[96] LAUREN FINNEY, ADVANCES IN LIPOSOMES RESEARCH 8 (Nova Science Publishers, Inc., 2014).

Courts will engage in a lengthy analysis most likely to include literal infringement, the doctrine of equivalents, the doctrine of reverse equivalents, embodiment, and enablement issues.[97] Courts are inconsistent in their rulings with doctrines like these.[98] Instead of continuing to tweek patent law one case at a time in hopes that the next slight adjustment suddenly supports innovation in biotechnology, let's take action. This story of legal solutions to the impairment of scientific advancement is choppy. The Supreme Court's alterations to the patentable subject matter doctrine are often quick, strong, and difficult to keep up with. What if alleged infringers could affirmatively defend themselves from an infringement liability by demonstrate in good faith and with factual support that (1) a patent's subject matter is biotechnology, (2) a patent is outdated in light of recent scientific developments, and (3) the language of the older patent is overly broad in light of those recent developments?

A New Angle: Creating Space for Innovation

Patents have become so integrated with the biotechnology industry that in order to promote and encourage innovation and growth in the scientific research, patent law needs to change. This article proposes an amendment to patent law. A statutory affirmative defense applicable only to infringement claims concerning patents of material or inventions in biotechnology. An affirmative defense will speed infringement suits. The defense would weaken infringement claims without invalidating patents. An affirmative defense will make litigation of biotechnology patents, at least in the realm of infringement, easier.

The affirmative defense should only be applicable only to infringement claims concerning patents of material or inventions in biotechnology.[99] The statute would state that if an alleged infringer can demonstrate in good faith and with factual support that (1) the patent's subject matter is biotechnology, (2) the patent is dated in light of recent scientific developments, and (3) the language of the older patent is overly broad in light of those recent developments, there has been no infringement.

This paper spent a great deal of time discussing the flaws of the current patent process. Reforming the entire patent system would take an incredible amount of time, money, and effort. The value of this paper's proposal is its simplicity. First, a defense like this would significantly speed infringement suits. Even if an alleged infringer failed to plead facts to support a dismissal of the case on grounds of affirmative defense, an infringement suit is still viable.

[97] *See generally*, Goldstien, supra note 13.
[98] *Id*. (analyzing multiple court decisions in cases where a "claim term that has gone from specific at filing to categorical at infringement" to suggest the best strategy for inventors facing infringement suits to escape liability).
[99] This paper is focused on furthering innovation in biotechnology through the lens of patent law. While maybe a good idea in other patentable areas of science, this paper's scope is limited. As such, so it its proposal.

Caselaw, other pleadings, and other defenses are all left untouched. Second, a defense like this would weaken patent rights without destroying them. Plus, the defense is only applicable to biotechnology patent infringement claims. Weakening patent protection in biotechnology will relieve the suppression of innovation in this field, without impairing patent rights overall. And third, it will make biotechnology patent litigation easier. A checklist of things to accomplish before getting to court, with the chance to avoid court altogether.

Modern biotechnology has been defined multiple times. Often, as discussed above, scientific knowledge in the field expands quickly. Courts should consider evidence presented by both parties in determining whether a subject matter falls within the definition of biotechnology. Biotechnology should include any technological application that uses or employs any biological living organism, systems, processes, cells, cellular systems, or derivatives thereof, to make or modify products or processes for a specific use.[100] Although the definition seems broad, it is appropriate to encompass the breadth of field of biotechnology.

Permitting an alleged infringer to defend themselves by producing recent scientific developments to show that an older patent is dated puts patents like these in their appropriate place of power. An alleged infringer would need to produce enough evidence of scientific development or advancement to show that the subject of the older patent is outdated. For example, SmallSolutions from the hypothetical in Part B could produce scientific work from other peer-reviewed authors in the field showing that micelles are separate and distinct from liposomes. The amount of evidence will depend on the science in dispute.

This kind of statutory framework would require courts to put priority on the determining the scope of the claim of an older patent during its claim construction for infringement suits earlier and in from a more educated position. Specifically, courts would be able to compare the scientific evidence and knowledge used to develop the older patented invention to that used to develop the new invention. Having the two sets of data to compare against one another will enable an administrative patent judge likely untrained in the biotechnology-specific area of the patent to more fairly judge the situation. Innovators will be able to show that although a new method may seem identical to the patentee holder's, the steps that have been made in that area of science are significant.

CONCLUSION

Biotechnology is a specialized science, but an ever-fractionalizing field. Once cutting-edge specialties are sliding back from the forefront as the wealth of scientific knowledge accumulates. Scientists and researchers continue to

[100] SRIVASTAVA, SHILPI, AND ATUL BHARGAVA. BIOTECHNOLOGY : NEW IDEAS, NEW DEVELOPMENTS: A TEXTBOOK OF MODERN TECHNOLOGY 1 (Nova Science Publishers, Inc., 2012).

innovate, develop, and apply their discoveries. Most seek to patent their inventions. Overly broad patents stand in their way and in the way of scientific advancement. This paper's proposal is novel and simple. A statutory defense for alleged infringers of biotechnology patents. It attempts to support innovation in biotechnology and limits its proposal for that purpose. Reforming every aspect of the current patent system would be expensive, time consuming, and, frankly, messy. This proposal is clean. Providing a statutory safeguard for innovators in this extremely important field of science will allow the expansion of scientific knowledge without completely desecrating a patent holder's exclusivity rights, changing modern infringement doctrine, or causing a ripple effect in every other patent-driven industry.