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MARIJUANA AND PATENTS: THE COMPLICATED RELATIONSHIP BETWEEN PATENT RIGHTS AND THE FEDERAL CRIMINALIZATION OF MARIJUANA

Reza Roghani Esfahani and Howard Bromberg[*]

I. INTRODUCTION

Difficult questions arise in the context of marijuana-related[1] inventions, patent procurement, and patent enforcement. These questions are a subset of the contradictions in the law of marijuana, where the federal government prohibits marijuana use and yet many of the states legalize, regulate, and tax it. This federal prohibition could discourage research into the health effects of marijuana and makes it difficult for marijuana-related innovations to satisfy statutory patentability requirements. It also renders enforcement of marijuana patents questionable, making marijuana businesses and patent owners vulnerable to non-practicing patent entities, sometimes called "patent trolls."

Under the U.S. Controlled Substances Act ("CSA") of 1970, marijuana is classified as a Schedule I drug, the most restrictive schedule.[2] Accordingly, possession and consumption of marijuana is essentially prohibited under federal law and is subject to harsh penalties.[3] Along with other narcotics—such as heroin, LSD, and ecstasy—the Drug Enforcement Administration ("DEA") classifies marijuana as a Schedule I drug because it has determined that marijuana: (1) has a high potential for abuse; (2) has no accepted medical use; and (3) lacks an accepted safe use for medical treatment.[4] While possession and consumption of marijuana is by and large illegal under federal law, the majority of states have legalized marijuana use in some form or another.[5] For example, thirty-seven states

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1 The term "marijuana" as it relates to the cannabis plant has been criticized for embodying anti-Latino sentiments associating a cultural vice with Mexican immigrants in the early twentieth century. While this criticism is certainly valid, this Article continues to use the term "marijuana," as it is this term (along with "marihuana") that is mostly used in the U.S. Controlled Substances Act and related federal legislation. *See* Robert A. Mikos & Cindy D. Kam, *Has the "M" Word Been Framed? Marijuana, Cannabis, and Public Opinion*, PLOS ONE (Oct. 31, 2019), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0224289 [https://perma.cc/3T36-CF63].

2 *See* Controlled Substances Act, Pub. L. No. 91-513, 84 Stat. 1242 (1970) (codified as amended at 21 U.S.C. §§ 801–971).

3 *See* 21 U.S.C. §§ 841, 844, 863. For example, up to one year imprisonment for first-time possession offense, up to five years imprisonment for first time selling of even the smallest amount of marijuana and up to a life sentence for the maximum amount, and up to three years imprisonment for possession of marijuana paraphernalia. *See* 21 U.S.C. §§ 841, 844, 863.

4 *See* 21 U.S.C. § 812(b)(1).

5 *See State Medical Cannabis Laws*, NAT'L CONF. OF STATE LEGISLATURES (May 27, 2022), https://www.ncsl.org/research/health/state-medical-marijuana-

have legalized marijuana for therapeutic and medical purposes.[6] Nineteen of those states have legalized recreational marijuana as well, making it available for adult use with restrictions relating mostly to quantity possessed.[7] Eleven additional states have legalized low-tetrahydrocannabinol ("THC") cannabidiol ("CBD"), a chemical constituent of marijuana that is non-intoxicating.[8] Indications are that in 2022, some remaining states will further loosen restrictions on medical marijuana, at least as to CBD; and perhaps will legalize adult recreational use of marijuana.[9] While many states have gone beyond merely removing criminal penalties for marijuana possession and consumption and have erected elaborate regimes regulating and licensing marijuana producers and sellers by imposing various taxes and fees,[10] the strict federal prohibition against marijuana use has nevertheless remained relatively unchanged since 1970.[11]

Despite the federal prohibition, marijuana sales in legalizing states are booming. As of 2019, there were approximately 5,000 legal companies and 9,000

laws.aspx#:~:text=A%20total%20of%2037%20states,medical%20use%20by%20qualified%20individuals [https://perma.cc/9SNZ-GYH8]. In 2019, over 30 percent of Americans lived in states that had legalized recreational use of marijuana. *See* Casey Leins et al., *States Where Recreational Marijuana Is Legal*, U.S. NEWS & WORLD REP. (May 27, 2022), https://www.usnews.com/news/best-states/slideshows/where-is-pot-legal.

6 *See State Medical Cannabis Laws*, *supra* note 5.

7 *See id.*; Leins et al., *supra* note 5.

8 *See State Medical Cannabis Laws*, *supra* note 5; Aleksandra Kicman & Marek Toczek, *The Effects of Cannabidiol, a Non-Intoxicating Compound of Cannabis, on the Cardiovascular System in Health and Disease*, 21 INT'L J. MOLECULAR SCIS., Sept. 2020, at 1, 1.

9 *See* Sean Williams, *3 States Likely to Legalize Marijuana Next*, MOTLEY FOOL (May 9, 2021, 6:36 AM), https://www.fool.com/investing/2021/05/09/3-states-likely-to-legalize-marijuana-next/ [https://perma.cc/P3UH-49UK].

10 *See* MARK K. OSBECK & HOWARD BROMBERG, MARIJUANA LAW IN A NUTSHELL 416–18 (2d ed. 2022).

11 *See id.* at 69, 231–32, 550. The most significant change in the CSA was the 2019 removal of hemp from the CSA definition of marijuana, thereby legalizing derivatives of the marijuana plant with 0.3% or less tetrahydrocannabinol (THC). Although hemp is a variety of the Cannabis sativa plant species, it is an industrial crop and is non-intoxicating. *See also* Agriculture Improvement Act of 2018, Pub. L. No. 115-334, § 12619, 32 Stat. 5018.

growers in the marijuana business.[12] As of 2017, the marijuana business generated an estimated $13 billion in annual revenue and paid an estimated $4.7 billion in federal taxes.[13] Current projections are that national revenue from marijuana businesses will quadruple to some $47.3 billion by 2027.[14] In 2021, states collected more than $3.7 billion in state tax revenue from adult-use cannabis alone.[15] Since 2014, when Colorado became the first state to legalize adult-use marijuana, states have collected a combined total of $11.2 billion in tax revenue from legal, adult-use marijuana sales.[16]

Notwithstanding this explosive growth in marijuana sales, including adult-use marijuana sales, the federal prohibition creates tremendous complications—even contradictions—for state-licensed and registered marijuana businesses. For example, under Section 280E of the federal income tax code, marijuana businesses are denied a deduction for the ordinary expenses of conducting their businesses, making those expenses taxable on their gross

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12 *See* Stephen McBride, *The Reason Pot Stocks Will Never Recover*, FORBES (Aug. 30, 2019, 8:55 AM), https://www.forbes.com/sites/stephenmcbride1/2019/08/30/the-reason-pot-stocks-will-never-recover/#629238687030 [https://perma.cc/4P8J-FJGF].

13 *See* Julie Weed, *Bags of Cash and Stealthy Deliveries: How Pot Start-Ups Pay Taxes*, N.Y. TIMES (May 18, 2018), https://www.nytimes.com/2018/05/18/business/smallbusiness/marijuana-companies-federal-taxes.html [https://perma.cc/LVA4-J9EE].

14 Thomas Pellechia, *Legal Cannabis Industry Poised for Big Growth, in North America and Around the World*, FORBES (Mar. 1, 2018, 8:35 AM). https://www.forbes.com/sites/thomaspellechia/2018/03/01/double-digit-billions-puts-north-america-in-the-worldwide-cannabis-market-lead/#48e4cba65109/ [https://perma.cc/4APF-PR6G] (finding that spending on legal cannabis worldwide expected to grow to $57 billion by 2027).

15 *See* Kyle Jaeger, *States Collected More Than $3.7 Billion in Recreational Marijuana Tax Revenue in 2021, Report Finds*, MARIJUANA MOMENT (Apr. 6, 2022), https://www.marijuanamoment.net/states-collected-more-than-3-7-billion-in-recreational-marijuana-tax-revenue-in-2021-report-finds/ [https://perma.cc/74RL-8T5Q].

16 *Cannabis Tax Revenue in States that Regulate Cannabis for Adult Use*, MARIJUANA POL'Y PROJECT (Apr. 5, 2022), https://www.mpp.org/issues/legalization/cannabis-tax-revenue-states-regulate-cannabis-adult-use/ [https://perma.cc/DC5D-RLGA].

income.[17] Notably, these deductions are ordinarily available even to illegal businesses such as illegal arms sales.[18]

Marijuana businesses also face obstacles in obtaining banking services, as the vast number of banks are federally chartered, insured, and regulated.[19] Given that marijuana businesses are technically engaged in federal crimes, banks that service them risk criminal and civil liability under federal laws targeted at money laundering, bank secrecy, and other strict banking regulations.[20] Likewise, marijuana businesses are frequently denied relief from creditor claims under

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[17] *See* I.R.C. § 280E ("No deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in controlled substances (within the meaning of schedule I and II of the Controlled Substances Act) which is prohibited by Federal law or the law of any State in which such trade or business is conducted."); Bill Greenberg & Rebecca Greenberg, *26 USC Section 280E: Will the Dragon Now Be Slayed?*, 25 J.L. & POL'Y 549, 568 (2017); Memorandum from W. Thomas McElroy, Jr., Senior Technician Reviewer, to Matthew A. Houtsma, Assoc. Area Couns. 7 (Dec. 10, 2014), https://www.irs.gov/pub/irs-wd/201504011.pdf [https://perma.cc/8GR7-P4T].

[18] *See* Edward Roche Jr., *Federal Income Taxation of Medical Marijuana Businesses*, 66 TAX LAW. 429, 433–34 (2013) (stating that the IRS has allowed illegal arms businesses to deduct typical business expenses, and that courts have sustained such deductions for businesses involving "illegal gambling, [illegal lottery operations], prostitution, racketeering, and general organized crime"). Deductions for the ordinary expenses of conducting a business include employee salaries and wages, rent and utilities, employee health insurance and other employee benefits, taxes, various fees, and licenses, office supplies, equipment depreciation, professional legal and accounting services, transportation, meals and entertainment, and marketing and advertising expenses. *See* I.R.C. § 162.

[19] *See* Julie Andersen Hill, *Banks, Marijuana, and Federalism*, 65 CASE W. RSRV. L. REV. 597, 597, 600, 617 (2015).

[20] *See Biggest Risks Facing Cannabis Businesses*, OG CANNABIS INS.: INS. BLOG (Nov. 25, 2021), https://www.ogcannabisinsurance.com/biggest-risks-facing-cannabis-businesses/ [https://perma.cc/Q2ZU-8EFH]; James J. Black & Marc-Alain Galeazzi, *Cannabis Banking: Proceed with Caution*, AM. BAR ASS'N (Feb. 6, 2020), https://www.americanbar.org/groups/business_law/publications/blt/2020/02/cannabis-banking/ [https://perma.cc/VU4M-GH7E].

federal bankruptcy law.[21] Even companies that transact with marijuana businesses have been denied bankruptcy protection under the doctrine of unclean hands.[22] Marijuana businesses have had difficulty obtaining insurance; and when obtained, they have had difficulties receiving payment on claims, under the doctrine that making such payments would violate public policy.[23] For similar reasons, federal courts, and some state courts, have refused to enforce contracts involving marijuana suppliers.[24]

Additionally, marijuana businesses have faced issues in obtaining legal and accounting services. American Bar Association ("ABA") Model Rule 1.2(d) mandates that it is unethical for a lawyer to assist a client, in conduct that the lawyer knows is criminal fraudulent or a violation of any law.[25] Although every state bar association has a similar rule, many states have made exceptions for lawyers counseling or assisting marijuana businesses, inasmuch as they are in compliance with state law.[26] Tax professionals providing services to marijuana businesses also face state disciplinary rules that could imperil their professional careers, such as those that require "good moral character" of accountants practicing in their state.[27] It has not been decisively resolved whether providing tax and accounting services to a marijuana business demonstrates bad moral character as a violation of federal law.

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21 Blake Marvis, Note, *Reefer Madness in Federal Court: An Overview of How Federal Courts Are Dealing with Cannabis Litigation and Why It Is Necessary to "Dig into the Weeds,"* 23 LEWIS & CLARK L. REV. 967, 979 (2019).

22 Steven Mare, Note, *He Who Comes into Court Must Not Come with Green Hands: The Marijuana Industry's Ongoing Struggle with the Illegality and Unclean Hands Doctrines*, 44 HOFSTRA L. REV. 1351, 1365–66 (2016).

23 *See* Francis J. Mootz III & Jason Horst, Note, *Cannabis and Insurance*, 23 LEWIS & CLARK L. REV. 893, 896 (2019).

24 *See* Todd A. Wells et al., *The Enforcement of Cannabis-Related Contracts & Arbitration Awards*, 1 ITA REV. 3, 8 (2019).

25 MODEL RULES OF PRO. CONDUCT r. 1.2(d) (AM. BAR ASS'N 1983).

26 *See* Dennis A. Rendleman, *Ethical Issues in Representing Clients in the Cannabis Business: "One Toke Over the Line?,"* 26 PRO. LAW. 20, 24 (2019).

27 *See* Jim Arkell & H. Charles Sparks, *It's Illegal! – Marijuana Related Businesses and the Accounting Profession*, 18 J. ACCT. & FIN. 23, 27 (2018) (stating that accountants will not face ethics actions against them as long as the businesses they work with comply with state laws); Alice Guy Azzaro, Designing a Framework for Maintaining Good Moral Character When Providing Accounting Services to the Legal Cannabis Industry 53 (Dec. 2018) (DBA dissertation, Liberty University).

The strict federal prohibition also hampers scientific and medical research into the health effects of marijuana,[28] which has in turn potentially affected the availability of patents. As marijuana is a Schedule I drug, researchers may need DEA approval to conduct tests and trials on marijuana.[29] To obtain this registration, a research plan must pass review by a host of federal agencies including the Food and Drug Administration ("FDA") and the National Institute on Drug Abuse ("NIDA").[30] In addition, marijuana researchers faced other restrictions, some of which have been lifted. For example researchers were required to submit their proposed study for additional approval by the U.S. Public Health Service—a requirement imposed on no other drug.[31] Even if researchers eventually gain DEA registration, they could obtain marijuana for their research from only one supplier—the NIDA Drug Supply Program, which licensed the University of Mississippi as the only grower.[32] This sole source was limited in both quantity and in variety of marijuana strains that scientists proposed researching,

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[28] NAT'L ACADEMIES OF SCI., ENG'G, AND MEDICINE, THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: THE CURRENT STATE OF EVIDENCE AND RECOMMENDATIONS FOR RESEARCH 378 (2017).

[29] *See* 21 C.F.R. § 1301.18 (2021) (stating that notice must be provided to the DEA before conducting research on a Schedule I drug).

[30] *See FDA and Cannabis: Research and Drug Approval Process*, U.S. FOOD & DRUG ADMIN. (last updated Oct. 1, 2020), https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process [https://perma.cc/SHN3-CB4W]; OSBECK & BROMBERG, *supra* note 10, at 108–10 (stating that the DEA places stringent requirements on marijuana research and the NIDA funds scientific marijuana research).

[31] *See* OSBECK & BROMBERG, *supra* note 10, at 92. This restriction was imposed in 1999. *See* Nat'l Inst. Of Health, Announcement of the Department of Health and Human Services' Guidance on Procedures for the Provision of Marijuana for Medical Research (May 21, 1999), https://grants.nih.gov/grants/guide/notice-files/not99-091.html [https://perma.cc/R3RD-XEZH] (requiring HHS approval for marijuana research). This restriction was then removed in 2015. *See* Announcement of Revision to the Department of Health and Human Services Guidance on Procedures for the Provision of Marijuana for Medical Research as Published on May 21, 1999, 80 Fed. Reg. 35,960, 35,960 (June 23, 2015).

[32] *See* OSBECK & BROMBERG, *supra* note 10, at 109 (stating that the DEA determined that the National Center for Natural Products Research at the University of Mississippi was the exclusive source of marijuana research until 2020).

but not necessarily high-grade.[33] And of course, without rigorous scientific studies, marijuana plants and constituents could hardly obtain approval under the federal Food, Drug, and Cosmetic Act ("FDCA").[34]

Of the impediments that trouble businesses and entrepreneurs resulting from the dichotomy between federal and state marijuana laws, those involving intellectual property have received relatively little judicial or scholarly attention in spite of being one of the only rights explicitly protected in the U.S. Constitution. Congress is granted the enumerated 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."[35]

Intellectual property rights have been governed by federal statutes since the first Copyright Act and Patent Act[36] were both enacted in 1790. Because marijuana is illegal under the CSA, federal trademark and patent protections for marijuana businesses have been labeled as "useless."[37] This Article addresses some

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33 NAT'L ACADEMIES OF SCI., ENG'G, AND MEDICINE, *supra* note 28, at 382–83 (stating that there was little variety in the marijuana provided through the NIDA and the marijuana provided was far weaker than what is sold to consumers).

34 Codified as amended at 21 U.S.C. §§ 301–399i. Although perhaps not directly related to the CSA, the procedures of the FDA are also constrictive of the opportunity to patent marijuana plants and strains. Given the complexity of whole-plant drugs, botanical marijuana is unlikely to pass the rigorous trials required by the FDA for drug approval. *See* Rebecca S. Eisenberg & Deborah Leiderman, *Cannabis for Medical Use: FDA and DEA Regulation in the Hall of Mirrors*, 74 FOOD & DRUG L.J. 246, 263 (2019) (explaining that the complexity of marijuana plants leads to more difficulty in obtaining FDA approval). Absent FDA approval, the FDCA also makes the use in food and dietary supplements of a drug or substance undergoing clinical investigation illegal with the exception of several products that are "Generally Recognized as Safe" (GRAS) which generally do not contain active ingredients such as CBD and THC. 21 U.S.C. § 321.

35 U.S. CONST. art. I, § 8, cl. 8.

36 *See* Copyright Act of 1790, ch. 15, 1 Stat. 124, 124; Act of Apr. 10, 1790, ch. 7, 1 Stat. 109, § 2 (1790).

37 *See* Sam Kamin & Viva R. Moffat, *Trademark Laundering, Useless Patents, and Other IP Challenges for the Marijuana Industry*, 73 WASH. & LEE L. REV. 218, 259 (2016). Trade secrets are not addressed here for two reasons: (1) they are generally governed by state laws; and (2) they do not require registration with the federal government. *See, e.g.*, MICH. COMP. LAWS §§ 445.1901–445.1910 (1998). For a scathing critique of PTO's requirement of trademark

of the difficult questions relating to marijuana patents, which may be among the most legally complicated and intractable, as they present novel questions that affect businesses, entrepreneurs, scientists, and medical researchers.

The first part of this Article evaluates the difficulties in obtaining or evaluating marijuana patents; particularly, the patentability requirements in view of the CSA and its ramifications. This part finds that because of the illegality of marijuana, satisfying patentability requirements may be more subjective than other fields and that the resulting patents may be inferior in quality. The second part addresses why illegality is likely not an impediment to patentability. The third part of this Article sets forth the challenges associated with enforcement of marijuana-related patents. This section starts by setting forth problems associated with securing counsel. Subsequently, this section examines issues that arise in the pleading stage and considers the shortcomings of discovery in this context. Next, this section assesses the judicial limitations in granting remedies. The last part of this Article suggests that the current approach to patenting illegal substances is bound to raise new patent troll problems.

II. MARIJUANA ILLEGALITY AND THE PATENTABILITY REQUIREMENTS

There is tension at the heart of any discussion of marijuana in the patent context. Marijuana use is illegal under federal law, yet the federal government has issued many patents directed at marijuana use or cultivation in one form or another.[38] Exploration of this tension illustrates important points about both the nature of the federal prohibition for marijuana and patentability requirements. Additionally, with the rapid legalization of marijuana at the state level,[39] the rapid

owners to comply with sundry non-trademark law see Robert A. Mikos, *Unauthorized and Unwise: The Lawful Use Requirement in Trademark Law*, 75 VAND. L. REV. 161, 237 (2022) [hereinafter Mikos, *Unauthorized and Unwise*] (stating that the PTO's requirement to comply with non-trademark laws indicates that the PTO has "lost sight of the statute it is supposed to administer").

[38] *See* Matthew Bultman, *Cannabis Patent Activity Surges Amid Industry Gold Rush*, LAW360 (Oct. 16, 2019, 5:25 PM), https://www.law360.com/ip/articles/1203746/cannabis-patent-activity-surges-amid-industry-gold-rush?nl_pk=c5beb89a-d431-46af-87e7-106bf8075925&utm_source=newsletter&utm_medium=email&utm_campaign=ip [https://perma.cc/7HQD-9VU4] (showing that the USPTO issued more marijuana patents in 2017 and 2018 than it had in the seven years prior).

[39] OSBECK & BROMBERG, *supra* note 10, at 266.

rise of the cannabis industry,[40] and new questions of federalism and industry practice[41], the question of patentability takes on new importance. In fact, "[t]he arms race for cannabis patents has already begun and is likely to intensify as markets and the regulatory landscape mature."[42] Analysts have projected that the cannabis industry will likely grow from an approximate annual revenue of $9.2 billion in 2017 to approximately $47.3 billion in 2027 in North America alone.[43]

The United States Patent and Trademark Office ("USPTO") has issued marijuana-related patents since 1942.[44] Given that federal law classifies marijuana as a Schedule I controlled substance,[45] does the Patent Act conflict with the Controlled Substances Act of 1970?[46] When federal law conflicts with a state law, preemption doctrine dictates the outcome: the federal law is supreme.[47] A more

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40 *See id.* at 416 (showing that the marijuana market is expected to triple from 2019 to 2023).

41 *See id.* at 165.

42 Pauline Pelletier & Deborah Sterling, *What Cannabis Patent Applicants Can Learn From Biopharma*, LAW360 (Jan. 17, 2019), https://www.law360.com/articles/1119184/what-cannabis-patent-applicants-can-learn-from-biopharma [https://perma.cc/72LY-467J].

43 *See* Pellechia, *supra* note 14.

44 Isolation of Cannabidiol, U.S. Patent No. 2,304,669 (issued Dec. 8, 1942).

45 21 U.S.C. § 812(c)(c)(10).

46 *Compare* 35 U.S.C. §§ 1–390, *with* 21 U.S.C. §§ 801–971.

47 Article VI, Paragraph 2 of the U.S. Constitution is commonly referred to as the Supremacy Clause. *Supremacy Clause*, LEGAL INFO. INST., https://www.law.cornell.edu/wex/supremacy_clause#:~:text=Article%20VI%2C%20Paragraph%202%20of,laws%2C%20and%20even%20state%20constitutions [https://perma.cc/LR7U-9UZY]. The jurisprudence of preemption in the context of marijuana law is extensive and controversial. In brief, the Controlled Substances Act—the federal law that prohibits marijuana use by placing it on restricted schedule I—states that:

> No provision of [the subchapter on control and enforcement of United States drug laws] shall be construed as indicating an intent on the part of the Congress to occupy the field . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision . . . and that State law so that the two cannot consistently stand together.

21 U.S.C. § 903. Since 1996, 37 states have legalized medical marijuana; 18 of those states have legalized adult recreational marijuana as well. An additional 11 states have legalized Cannabidiol (CBD), a compound of the marijuana plant, making a total of 48 states that have legalized cannabis in some form, in addition to the District of Columbia and such territorial possessions of the United States as Puerto Rico, Northern Mariana Islands, and Guam. *CBD Legal States 2022*, WORLD POPULATION REV., https://worldpopulationreview.com/state-rankings/cbd-legal-states [https://perma.cc/3ETB-BTGC]. Most courts that have ruled on this issue, have found that these state provisions legalizing marijuana do not represent a "positive conflict" with, and are thus not preempted (invalidated) by, the CSA. *See* Nebraska v. Colorado, 557 U.S. 1211, 1036 (2016); White Mountain Health Ctr., Inc. v. Maricopa Cnty., 386 P.3d 416, 433 (Ariz. Ct. App. 2016); Kirby v. County of Fresno, 195 Cal. Rptr. 3d 815, 940, 963 (Ct. App. 2015); Reed-Kaliher v. Hoggatt, 332 P.3d 587, 591 (Ariz. Ct. App. 2014); State v. Ehrensing, 296 P.3d 1279, 1286 (Or. Ct. App. 2013); Tracy v. USAA Casualty Ins., Co., No. 11-00487, 2012 WL 928186, at *11–13 (D. Haw. Mar. 16, 2012); Ter Beek v. City of Wyoming, 823 N.W.2d 864, 871 (Mich. Ct. App. 2012); Willis v. Winters, 253 P.3d 1058, 1065 (Or. 2011); Qualified Patients Ass'n v. City of Anaheim, 115 Cal. Rptr. 3d 89, 108 (Ct. App. 2010); Cnty. of San Diego v. San Diego NORML, 81 Cal. Rptr. 3d 461, 481 (Ct. App. 2008); City of Garden Grove v. Superior Court of Orange Cnty., 68 Cal. Rptr. 3d 656, 675–78 (Ct. App. 2007); State v. Kama, 39 P.3d 866, 868 (Or. Ct. App. 2002); Erwin Chemerinsky et al., *Cooperative Federalism and Marijuana Regulation*, 62 UCLA L. REV. 74, 113 (2015) (noting the tension between federal and state laws governing marijuana enforcement).

A minority of courts have found state legalization laws preempted, People v. Crouse, 388 P.3d 39, 40–42 (Colo. 2017); Pack v. Superior Court, 132 Cal. Rptr. 3d 633, 649 (Ct. App. 2011); Emerald Steel Fabricators, Inc. v. Bureau of Lab. & Indus., 230 P.3d 518, 528–29 (Or. 2010).

Perhaps the strongest indication that state legalization regimes are not preempted by the CSA is *Nebraska v. Colorado*, 557 U.S. 1211 (2016). In that case, the U.S. Supreme Court declined to hear a challenge by two neighboring states to Colorado's legalization regime as conflicting with the CSA even though the Court had original and exclusive jurisdiction over the case. 28 U.S.C. § 1251(a). By not taking up the case, the Court essentially found Colorado's legalization regime non-preempted. Nevertheless, with the state of the law standing as it is, the question of whether the CSA preempts state legalization regimes adds another layer of uncertainty to marijuana law in the United States.

complicated question, however, arises when there is conflict between two federal statutes. Unlike for federal-state conflicts of laws, the preemption doctrine does not help navigate their nonconformity.[48]

To reconcile legislative enactments, courts often use the implied repeal doctrine—one of the oldest doctrines of statutory interpretation.[49] This doctrine, manifested in the Latin maxim *leges posteriores priores contrarias abrogant*, means "[s]ubsequent laws repeal prior conflicting ones."[50] It has been applied by courts as early as 1614 in Sir Edward Coke's report on *Dr. Foster's Case*.[51] Courts, however, disfavor repeals by implication unless the two laws are in irreconcilable conflict and the intention of the legislature to repeal is clear and manifest.[52]

This question, however significant on first blush, may be easily resolved in this context. The Patent Act and the CSA deal with different areas of the law and are likely not irreconcilable. They have no conflicting legal provisions. It is simply that the CSA, having created an almost unparalleled regime in the United States where federal laws and state laws are in conflict over marijuana legality—presents new questions of patentability.[53] Theoretically, the legality of marijuana

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[48] This is because the preemption doctrine is derived from the Supremacy Clause of Article VI of the Constitution, which applies uniformly among the federal laws. *See* U.S. CONST. art. VI, cl. 2.

[49] *See* ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 327–28 (2012).

[50] *Leges posteriores priores contrarias abrogant*, BLACK'S LAW DICTIONARY (11th ed. 2019).

[51] Dr. Foster's Case (1614) 77 Eng. Rep. 1222, 1231.

[52] Town of Red Rock v. Henry, 106 U.S. 596, 601–02 (1883); *see also* SCALIA & GARNER, *supra* note 49, at 330. The first Congress enacted the Patent Act of 1790 titled "An Act to promote the Progress of Useful Arts" on April 10, 1970. *See* Act of Apr. 10, 1790, ch. 7, 1 Stat. 109 (1790). A series of repeals and amendments, over time, brought about the modern version of the Patent Act— Patent Act of 1952, Pub. L. No. 593, 66 Stat. 792. *See also* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (codified as amended in scattered sections of 35 U.S.C. (2011)). The Controlled Substance Act was enacted as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242. Thus, the Patent Act is nearly two centuries older than the CSA.

[53] A parallel, although concerning an issue of much greater significance, is that of enforcement of the Fugitive Slave Act of 1793 and, in particular, the Fugitive Slave Act of 1850. As with marijuana laws that differ by jurisdiction, the federal government was seeking to enforce a federal slave return law as to an institution that was legal in some states, illegal in others,

under state law should not matter as patents are a federally granted right, yet a recent study found marijuana related patent filings to be growing commensurate to the economic and legislative activity.[54] While there is no irreconcilable conflict between the Patent Act and the CSA, there are major marijuana patentability questions given the seeming conflict (as the law stands now) between federal and state marijuana law.

In the United States, an invention is patentable if it is novel, non-obvious, useful, and directed to eligible subject matter.[55] These, however, are merely some of the patentability requirements. For an invention to be patentable it must meet several other statutory requirements, which include enablement, written description, definiteness, and best mode.[56]

A. NOVELTY

An invention must be novel. To be patentable, what is claimed as an invention must be different from what is disclosed in any other single disclosure.[57]

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and unsettled in federal territories. S*ee, e.g.*, Prigg v. Pennsylvania, 41 U.S. 539, 608–10 (1842). Although the horrific slavery regime was only eliminated by a civil war and constitutional amendment, ante-bellum slavery laws, such as those expounded in *Prigg*, introduced doctrines of federalism and property law that remain relevant to this day.

54 Joseph Wyse & Gilad Luria, *Trends in Intellectual Property Rights Protection for Medical Cannabis and Related Products*, 3 J. CANNABIS RSCH. 1, 8–9 (2021) ("Approximately 570 patent families (2200 patent documents) have been filed in . . . downstream technologies, with the filing rate rising steadily since 2011–2013 . . . . The steep increase in patent filing and grants . . . since 2011–2013 is consistent with the recognition by industry that the number of US states allowing legal medical cannabis was reaching a critical number.").

55 35 U.S.C. §§ 101–103.

56 35 U.S.C. § 112. While these statutory requirements also present interesting questions in the context of marijuana-related patents, this Article focuses on the four requirements of novelty, non-obviousness, usefulness, and subject matter eligibility.

57 35 U.S.C. § 102 ("A person shall be entitled to a patent unless (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or (2) the claimed invention was described in a patent issued . . . or in an application for patent published or deemed published . . . [that] names another inventor and was effectively filed before the effective filing date of the claimed invention.").

Simply put, what is claimed as an invention cannot be shown, discussed, taught, or otherwise disclosed in any single previous patent, publication, or anything that is in public use or on sale.[58] If what is claimed by the patent applicant already publicly exists, such an applicant is not entitled to a monopoly.[59] There is one caveat, though. To reject a patent claim for lack of novelty, what is claimed as an invention must be entirely present within the four corners of a single patent, publication, or anything that is in public use or on sale.[60]

In the case of marijuana-related inventions, like any other field, it is easy to imagine that some permutation of compositions using active ingredients derived from cannabis, or method of extracting such compounds, or even method of preparing, processing, and cultivating cannabis could be novel and meet the definition set forth in § 102.[61] Due to the illegality of marijuana, however, the USPTO, the agency responsible for evaluating patent eligibility, may face several challenges in finding and evaluating prior art.[62] Prior art is a term commonly used in patent law which encompasses all information published or unpublished available to the public before an applicant's priority date. [63] These challenges are

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58 *Id.*

59 Bonito Boats v. Thunder Craft Coats, 489 U.S. 141, 148 (1989) (stating that § 102 bars a person from patenting what is already in the public domain as this section "express[s] a congressional determination that the creation of a monopoly in such information would not only serve no socially useful purpose, but would in fact injure the public by removing existing knowledge from public use"). In consideration for the full disclosure and public dedications of a new and useful invention, a patentee is granted limited monopoly. *See* United States v. Dubilier Condenser Corp., 289 U.S. 178, 186 (1933).

60 Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in claim is found, either expressly or inherently described, in a single prior art reference.").

61 *See, e.g.*, Methods of Growing Cannabaceae Plants Using Artificial Lighting, U.S. Patent No. 9,844,518 (filed Sept. 30, 2015) (issued Dec. 19, 2017); 35 U.S.C. § 102.

62 *About Us*, USPTO, https://www.uspto.gov/about-us [https://perma.cc/6VJG-V6YH].

63 *See* John DiGiacomo, *The Difference Between a Patent Filing Date and a Priority Date*, REVISION LEGAL (July 26, 2021), https://revisionlegal.com/patent/the-difference-between-a-patent-filing-date-and-priority-date/ [https://perma.cc/R2TU-L7CC]. Priority date is a date that reflects the cut-off date for defining the universe of prior art. DONALD CHISUM, CHISUM ON

further discussed below. Moreover, it is at least questionable whether an interested person or entity, who already practices the "newly-claimed" invention, would contest the patentability of an application—possibly risking self-incrimination—based on the grounds that such invention is in public use or on sale.[64] Despite these challenges, it does not seem that the novelty requirement is a particularly unique barrier to patenting marijuana-related inventions. In other words, while it may affect the quality of the patents granted, as far as acquiring patent rights is concerned, it is of no special consequence.

B. NON-OBVIOUSNESS

The non-obviousness requirement does not present unique hurdles for patent applicants either. Simply put, the non-obviousness requirement is whether a person of ordinary skill in the art would find the claimed invention obvious either on its face or by combination of two or more previous patents, publications, or anything that is in public use or on sale.[65] Section 103 of the Patent Act disallows patents if "the differences between the claimed invention and the prior art are such that the claimed invention"—*i.e.*, the invention sought to be patented, "would have been obvious" before the priority date of the application "to a person having ordinary skill in the art to which the claimed invention pertains."[66] For marijuana innovations, like any other field, various claims as to compositions using cannabis-derived active ingredients, methods of preparation of such compositions, or processes of extracting, preparing, and cultivating cannabis could fit within the statutory requirements of this section.

However, the lack of substantial, relevant, and accessible prior art, noted above and discussed below, may be more troublesome in evaluating non-obviousness of a claimed invention.[67] This is because, unlike the novelty

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PATENTS, § 10.03 Priority Rules (1978). Art that pre-dates the priority date may be used to show that an application is not eligible for patenting because it lacks novelty or is obvious. *Id.*

64 *See* 35 U.S.C. § 102.

65 *See* 35 U.S.C. § 103. A person of ordinary skill in the art (POSA) (also known as a person having ordinary skill in the art (PHOSITA) or a skilled artisan) refers to a fictitious person with normal skills and knowledge in the field of technology in question. *See* Jonathan J. Darrow, *The Neglected Dimension of Patent Law's PHOSITA Standard*, 23 HARV. J.L. & TECH. 227, 233–35 (2009).

66 Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (codified as amended in scattered sections of 35 U.S.C. (2011)).

67 *See* discussion, *supra* notes 62–63.

requirement, under which all elements of a claimed invention must be found within the four corners of a single prior art reference, the obviousness requirement is typically, but not always, evaluated based on a combination of prior art references.[68] For example, one feature of the claimed invention might be present in one prior patent, and another feature might be present in another, leaving a patent examiner to determine whether it would have been obvious to reach the claimed invention from the two separate references.[69]

In *KSR International Co. v. Teleflex Inc.*, the Supreme Court found that obviousness is a question of law based on underlying factual inquiries.[70] These factual inquiries concern (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; and (3) the level of ordinary skill in the pertinent art.[71] Stated another way, the Supreme Court in this case stated that non-obviousness of a claimed invention depends on what material relating to the invention is publicly available, what such material teach, how such material is different from the claimed invention, and how creative a fictious person with ordinary skills in the relevant technology needs to be to derive what is claimed from the publicly available material.[72]

A quick study of these factual inquiries reveals the extent of the problem in the context of marijuana-related patent applications. Absent an accessible substantial library of patents, patent applications, and well-established channels

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[68] *In re* Spooner, 918 F.2d 186 (Fed. Cir. 1990) ("While no single reference discloses all three elements, it must be remembered that the rejection is based on § 103 for obviousness and not on § 102 for anticipation . . . Accordingly, all elements of the applicant's invention need not be disclosed in a single prior art reference to warrant a rejection of the claims."); Advanced Display Sys. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000) ("[I]nvalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation.").

[69] Arendi S.A.R.L. v. Apple Inc., 832 F.3d 1355, 1361 (Fed. Cir. 2016) ("Though less common, in appropriate circumstances, a patent can be obvious in light of a single prior art reference if it would have been obvious to modify that reference to arrive at the patented invention.").

[70] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 415 (2007) (reaffirming the objective analysis of obviousness framework set forth in Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966)).

[71] *Id.* at 399.

[72] *Id.*

of commerce, it is likely difficult for the USPTO to learn about the relevant prior art and evaluate their scope and attempt to ascertain the differences between the prior art and the claimed invention.[73] This could result in granting bad patents. A limited and hard to find universe of prior art makes it difficult for the examiners to adequately evaluate the novelty and non-obviousness of a claimed invention.[74] Without adequate evaluation, a patent applicant may claim, recapture, and monopolize something that is already public information. This defeats the purpose of patents. Patents simply grant a limited monopoly to patent owners in exchange for disclosing their invention to the public.[75] Patents do not permit recapture and re-monopolization of what was already devoted to the public.[76] Conversely, a limited and hard to find universe of prior art may lend itself to wastefulness. For example, an inventor could spend precious resources reinventing what is already in public—albeit hard to find—seek and receive a patent from the Patent Office which may face the same issue, only to have the patent invalidated down the road when the publicly available information comes to light.

Lack of substantial accessible prior art and well-established practices may also affect the ability of the person of ordinary skill in the art to determine if the claimed invention is obvious in view of common—yet secret—practices.[77] This

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[73] In patent law while the specification (*i.e.*, the patent application) could provide a background for the invention and elaborates on its subject matter, it is the scope of the claims that illustrate the boundaries (otherwise referred to as metes and bounds) of an invention. In other words, patent claims set the legal boundaries of what the patentee can exclude others from making, using, selling, offering to sell, importing to the U.S. *See* MANUAL OF PATENT EXAMINING PROCEDURE § 2173 (9th ed. Rev. 10.2019, June 2020) [hereinafter MPEP].

[74] *See* David S. Abrams & Bhaven N. Sampat, *What's the Value of Patent Citations? Evidence from Pharmaceuticals* 5 (June 9, 2017) (unpublished manuscript), https://wwws.law.northwestern.edu/research-faculty/clbe/events/innovation/documents/abramssampatdrugcites060917.pdf [https://perma.cc/9ZSD-VHNX]).

[75] *See* United States v. Dubilier Condenser Corp., 289 U.S. 178, 186 (1933).

[76] *See* Eldred v. Ashcroft, 537 U.S. 186, 240 (2003); Thomas & Betts Corp. v. Panduit Corp., 65 F.3d 654, 658 (7th Cir. 1995).

[77] *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 415, 421 (2007) ("A person of ordinary skill is also a person of ordinary creativity, not an automaton."); *In re* Heck, 699 F.2d 1331, 1333 (Fed. Cir. 1983) (stating that persons of ordinary skill in the art are presumed to be familiar with the art); Malsbary Mfg. Co. v. ALD, Inc., 447 F.2d 809, 811 (7th Cir. 1971) (explaining that those with ordinary skill are those thoroughly familiar with the particular art).

could severely impact the ability of a person of ordinary skill in the art to use common sense, logic, and judgment to determine whether the claimed invention is obvious in view of limited universe of prior art.[78] Indeed, how can ordinary skills and experience in a field be defined when at least some of the science, technique, or knowhow is kept secret or hard to find?

Apart from the three *KSR* factors mentioned above,[79] courts often use secondary factors such as unexpected results, commercial success, long-felt but unsolved need, copying, failure of others, and teaching away to "give light to the circumstances surrounding the origin of the subject matter sought to be patented."[80] Since these secondary factors are also factual in nature,[81] they, too, could be affected by lack of substantial accessible prior art and well-established practices. For example, without substantial and accessible prior art, how can the U.S. Patent and Trademark Office determine whether the claimed subject matter is thought away by prior art? The Open Cannabis Project ("OCP"), an Oregon non-profit corporation, was an effort, in part, to establish a library of prior art for marijuana to forestall patent trolls,[82] and more broadly, to inhibit the granting of marijuana patents so as to encourage the economic diversity of the cannabis industry as well as to protect the genetic diversity of the cannabis plant. The OCP collected genetic and chemotypic[83] data as to cannabis strains, which it stored in

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78 Perfect Web Techs. Inc. v. InfoUSA, Inc., 587 F.3d 1324, 1329 (Fed. Cir. 2009) (stating that the analysis of obviousness "may include recourse to logic, judgment, and common sense available to the person of ordinary skill").

79 *See supra* text accompanying note 71.

80 Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17–18 (1966).

81 *See* Specialty Composites v. Cabot Corp., 845 F.2d 981, 991 (Fed. Cir. 1988).

82 *Open Cannabis Project: The Fight to Get Marijuana Patent Rights*, CANNA L. BLOG (Feb. 23, 2018), https://harrisbricken.com/cannalawblog/open-cannabis-project-and-the/ [https://perma.cc/GLV5-JV8R]; *infra* Section IV.D.

83 Kimberly Ross, *Leveraging Chemotyping Techniques for Data-Driven Classification of Cannabis*, ANALYTICAL CANNABIS (May 31, 2019), https://www.analyticalcannabis.com/articles/leveraging-chemotyping-techniques-for-data-driven-classification-of-cannabis-311719#:~:text=The%20term%20chemotype%20refers%20to,in%20cannabis%20and%20other%20plants.&text=Chemotypic%20profiling%20of%20medicinal%20and,%2C%20sage%2C%20and%20many%20others [https://perma.cc/M3VA-57N9] ("Chemotype is formally defined as 'subspecies of a plant that have the same morphological characteristics (relating to form and structure) but produce different quantities of chemical components in their essential oils.'").

an open-source repository at the National Center for Biotechnology Information.[84] Motivated in part by a progressive perspective on economic issues, the hope was that by making this prior art available to the Patent Office, large and well-resourced corporations ("Big Weed") would be unable to monopolize the industry by securing overbroad patents of cannabis strains, and that small, independent, and individual farmers and producers would be able to search the repository for information on strains that were economical for them to produce.[85] Because the OCP would show cannabis strains that were naturally occurring or that were previously in use, these strains could not be patented.[86] Unfortunately, despite enthusiasm in the cannabis community, and several laboratories depositing their data in the OCP, it was dissolved on May 6, 2019, out of fear that its data would be used by large companies to create new cannabis strains.[87]

Despite the problems that arise because of lack of accessible, relevant, and cataloged prior art, obviousness does not present a particularly unique problem for marijuana patenting.

C. UTILITY

Satisfying the utility requirement in this context could be more difficult than establishing novelty or obviousness. The statutory requirement of utility is found in § 101 and hinted at in § 112 of the Patent Act.[88] Section 101 states that "whoever invents or discovers any new and *useful* process, machine, manufacture, or composition of matter, or any new and *useful* improvement thereof," is entitled to a patent.[89] Section 112 states that "the specification shall contain a written description of the invention, and of the manner and process of making and *using*

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84 *Open Cannabis Project*, *supra* note 82.

85 *Id.*

86 *See* 35 U.S.C. § 102; Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 589 (2013).

87 Katie Shepherd, *Open Cannabis Project Dissolves in Response to Controversy Over Ag-Science Company Phylos Bioscience's Breeding Program*, WILLAMETTE WEEK (May 6, 2019, 12:48 PM), https://www.wweek.com/news/business/2019/05/06/open-cannabis-project-dissolves-in-response-to-controversy-over-ag-science-company-phylos-biosciences-breeding-program/ [https://perma.cc/N7CA-MP83].

88 35 U.S.C. §§ 101, 112.

89 35 U.S.C. § 101 (emphasis added).

it."[90] Accordingly, there is an overlap between the utility requirement of § 101 and the "how to use" requirement of § 112.[91] This statutory requirement comes from the language in the Constitution allowing Congress to provide patent protection for "useful arts."[92]

To meet the utility requirement, an invention needs to be operable, beneficial, and substantial.[93] As to operability, an applicant must show the utility of the claimed invention with credible evidence of operability. An unbelievable, or "incredible" claim,[94] fails on both § 101 and § 112 grounds.[95] Section 101 failure indicates that the invention is not useful, while § 112 failure implies that the manner and process of using the invention is not sufficiently conveyed.[96] Because

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[90] 35 U.S.C. § 112 (emphasis added).

[91] Chisum, *supra* note 63, at § 4.04.

[92] U.S. CONST. art. I, § 8, cl. 8 ("The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.").

[93] *See* Newman v. Quigg, 877 F.2d 1575, 1581 (Fed. Cir. 1989) (stating "it is apparent that lack of utility because of inoperativeness, and absence of enablement, are closely related grounds of unpatentability"); Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (stating "[t]he word 'useful,' therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention"); *In re* Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005) ("[T]o satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.").

[94] *In re* Citron, 325 F.2d 248 (C.C.P.A. 1963) (stating that an incredible claim is claim that is unbelievable "in the light of the knowledge of the art, or [is] factually misleading").

[95] *See id.*; *In re* Ziegler, 992 F.2d 1197, 1200–01 (Fed. Cir. 1993) ("The how to use prong of section 112 incorporates as matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention."); *see also In re* Fouche, 439 F.2d 1237, 1243 (CCPA 1971) (stating that if "compositions are in fact useless, [a] specification cannot have taught how to use them").

[96] *See* 35 U.S.C. §§ 101, 112.

situations in which claims are found "inoperable" are rare,[97] similar to § 102 and § 103 above, an applicant seeking a marijuana-related patent can presumably satisfy the operability aspect of the utility requirement with credible evidence by demonstrating that the invention actually works and is not a mere wonderful allegation.[98] For example, an applicant could claim a process of growing cannabis that yields a substantially higher CBD content.[99]

Establishing that an invention is beneficial may be more arduous. In the early nineteenth century, the court in *Lowell v. Lewis* held in an opinion by Justice Story that the utility requirement is satisfied as long as the invention has some beneficial use and is not "frivolous or injurious to the well-being, good policy, or sound morals of society."[100] Marijuana-related inventions may not satisfy that requirement. As determined by the DEA, Schedule I drugs are "drugs with no currently accepted medical use and a high potential for abuse."[101] Because

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97 MPEP, *supra* note 73, § 2107 II.

98 The Patent Office, for example, routinely rejects patent applications directed to perpetual motion machines because they claim to produce more energy than they consume which runs afoul of the law of conservation of energy and by extension the first law of thermodynamics. *See, e.g.*, *Newman*, 877 F.2d at 1577.

99 The Cannabis plant contains over 400 chemicals, including more than 60 cannabinoids. Zerrin Atakan, *Cannabis, a Complex Plant: Different Compounds and Different Effects on Individuals*, 2 THERAPEUTIC ADVANCES PSYCHOPHARMACOLOGY 241, 241. Cannabinoids refer to a class of compounds that act on cannabinoid receptors. *Id.* at 242. Generally, cannabinoids that originate in plants such as cannabis are called phytocannabinoids and include sativa hemp cannabidiol (CBD) and tetrahydrocannabinol (THC). *Id.* at 245. CBD and THC are the most common cannabinoids. *Id.* Cannabidiol or CBD is the second most prevalent active component of sativa plant (marijuana) that does not cause intoxication or euphoria. Peter Grinspoon, *Cannabidiol (CBD) — What We Know and What We Don't*, HARVARD HEALTH PUBL'G (Sept. 24, 2021), https://www.health.harvard.edu/blog/cannabidiol-cbd-what-we-know-and-what-we-dont-2018082414476 [https://perma.cc/X39Z-3P26].

100 Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817).

101 *Drug Scheduling*, U.S. DRUG ENF'T ADMIN. (July 10, 2018), https://www.dea.gov/drug-information/drug-scheduling [https://perma.cc/373H-Y66S] (stating "[t]he abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs have a high potential for abuse and the potential to create severe psychological and/or physical dependence").

marijuana is a Schedule I drug, at least some sectors of the U.S. government, therefore likely consider marijuana to be injurious to the well-being, good policy, or sound morals of society.[102]

Fortunately for marijuana-related patent applicants, the Supreme Court's mid-twentieth century decision in *Brenner v. Manson*[103] appeared to reject Justice Story's view of utility, stating that this definition "sheds little light on our subject."[104] Instead, the Supreme Court stated that

> [t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with *substantial* utility. Unless and until a process is refined and developed to this point—where *specific* benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.[105]

This holding gave birth to the new utility requirements of specificity and substantiality. The Supreme Court, however, defined neither "specific" nor

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[102] Jason Blevins, *Pot Growers Cultivating in the Shadows Seek U.S. Patent Protection*, DENVER POST (Dec. 19, 2014, 12:57 PM), https://www.denverpost.com/2014/12/19/pot-growers-cultivating-in-the-shadows-seek-u-s-patent-protection/ [https://perma.cc/8DVN-E785]("The U.S. Patent and Trademark Office has rejected cannabis-related patents consistently, arguing that the invention is "immoral and scandalous" because marijuana is illegal or that the invention has no useful purpose because its use violates federal drug law."). In contrast, neither an FDA, nor a DEA approval, however, is necessary for finding a compound useful within the meaning of the patent laws. *See* Scott v. Finney, 34 F.3d 1058, 1063 (Fed. Cir. 1994) (holding that testing necessary to show adequate utility for invention to be patentable is much less stringent than testing necessary to demonstrate full safety and effectiveness of the invention to FDA). This is evident from the fact that marijuana-related patents were issued long before the FDA's endorsement of the benefits of marijuana in treating Lennox-Gastaut syndrome and Dravet syndrome, or de-scheduling of the CBD from the CSA, or the legalization of industrial hemp. *See* '669 Patent.

[103] Brenner v. Manson, 383 U.S. 519, 532–33 (1966).

[104] *Id.*; *see also* MPEP, *supra* note 73, § 2107 II (providing guidelines for examination of applications for compliance with the utility requirement no longer references *Lowell*).

[105] *Brenner*, 383 U.S. at 534–35 (emphasis added).

"substantial."[106] Indeed, the Patent Office's Manual of Patent Examining Procedure ("MPEP") providing guidelines for examination of applications for compliance with the utility requirement does not reference *Lowell* at all.[107] Instead, it instruct the examiners that

> [d]eficiencies under the 'useful invention' requirement of 35 U.S.C. § 101 will arise in one of two forms. The first is where it is not apparent why the invention is 'useful.' This can occur when an applicant fails to identify any specific and substantial utility for the invention or fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. . . . The second type of deficiency arises in the rare instance where an assertion of specific and substantial utility for the invention made by an applicant is not credible.[108]

Nearly four decades later, the Federal Circuit elaborated on the specificity requirement, stating that to satisfy specificity, "an application must disclose a use which is not so vague as to be meaningless."[109] Furthermore, the Court reaffirmed the holding below of the Court of Customs and Patent Appeals that "to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public."[110] Accordingly, not only must an applicant show that their marijuana-related application is directed toward a meaningful end use, but they must also demonstrate that their claimed invention has a presently available benefit to the public.[111]

Unfortunately for such applicants, and despite the efforts of the pro-marijuana community in establishing the benefits of marijuana use for pain

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106 *See id.*

107 MPEP, *supra* note 73, § 2107.

108 *Id.* § 2107.01 (citations omitted).

109 *In re* Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

110 *Id.* at 1371 (citing Nelson v. Bowler, 626 F.2d 853, 856 (C.C.P.A. 1980)).

111 Dawson Hahn, *That is Northern Lights Cannabis Indica . . . No, It's Marijuana: Navigating Through the Haze of Cannabis and Patents*, 4 CONCORDIA L. REV. 254, 259 (2019) ("The utility bar of Section 101 is not hard to meet—to be considered useful, an invention or process must be capable of providing some identifiable benefit.").

management, for treatment of epilepsy and multiple sclerosis, and for relief from anxiety, stress, and depression, the federal government for the most part remains unpersuaded, at least as far as the DEA is concerned.[112] Yet, on June 25, 2018, the FDA approved Epidiolex, the first approved drug comprising an active ingredient derived from marijuana to treat rare and severe forms of epilepsy—Lennox-Gastaut syndrome and Dravet syndrome—and for tuberous sclerosis complex.[113] On September 28, 2018, the DEA classified Epidiolex in Schedule V, the first extract of the cannabis plant to be placed in a less stringent schedule than Schedule I.[114] Nearly two years later, on April 6, 2020, GW Pharmaceuticals revealed that the company had received notice from the DEA stating that the Epidiolex was no longer subject to the requirement of the CSA.[115]

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[112] Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53688, 53689 (Aug. 12, 2016) (stating that the DEA and HHS concluded that "[m]arijuana meets the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(1)" as it "has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision"); Salomeh Keyhani et al., *Risks and Benefits of Marijuana Use: A National Survey of U.S. Adults*, 169 ANNALS INTERNAL MED. 282, 284–88 (2018) (illustrating the benefits of marijuana use for management of pain and treatment of disorders or conditions).

[113] *FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy*, U.S. FOOD & DRUG ADMIN. (June 25, 2018), https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms#:~:text=The%20U.S.%20Food%20and%20Drug,years%20of%20age%20and%20older [https://perma.cc/3H4K-SHLF]. Synthetic forms of marijuana have been approved by the FDA over the last 35 years. See *FDA and Cannabis: Research and Drug Approval Process*, *supra* note 30. Dronabinol, marketed under the brands Marinol and Syndros, was approved in 1985 and is currently classified in Schedule III. *Id.* The oral synthetic cannabinoid Nabilone was approved as a Schedule II drug in 1987 and is marketed under the name Casamet. *Id.*; *see also* '669 Patent.

[114] Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol, 83 Fed. Reg. 48950 (Sept. 28, 2018) (to be codified at 21 C.F.R. pt. 1308, 1312).

[115] Alexis Barnes, *DEA Removes CBD from Controlled Substances Act*, JD SUPRA (Apr. 16, 2020), https://www.jdsupra.com/legalnews/dea-removes-cbd-from-controlled-71065/ [https://perma.cc/VG8D-C9RY].

On December 20, 2018, President Trump signed into law the 2018 Farm Bill, which legalized industrial hemp.[116] This act essentially modifies the definition of marijuana presented in Section 802 of the CSA to allow for production of non-intoxicating strains of marijuana.[117] As a result, the FDA released a Draft Guidance for Industry outlining FDA's current thinking on cannabis and cannabis-related compounds.[118] This guidance generally clarifies that cannabis below 0.3 percent THC does not need to be sourced from the federal government and provides a list of sources that should be consulted.[119] These advances appear to be contrary to the DEA's view that marijuana has no currently accepted medical use. Thus, at least from the perspective of these sectors of the U.S. government, marijuana inventions could meet the substantiality requirement and satisfy the utility requirement. Accordingly, a dichotomy appears to exist between different sectors of the U.S.

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116 *See* Agriculture Improvement Act of 2018, Pub. L. No. 115-334, § 10113, 132 Stat. 4490. *See also* Agriculture Improvement Act § 297A(1) (defining hemp as, "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis").

117 21 U.S.C. § 802 states:

> the term 'marihuana' means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin . . . . The term 'marihuana' does not include . . . the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

118 *See Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research*, U.S. FOOD & DRUG ADMIN. (July 21, 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cannabis-and-cannabis-derived-compounds-quality-considerations-clinical-research-guidance-industry [https://perma.cc/GPH8-BBU6] ("outlin[ing the] FDA's current thinking on several topics relevant to the development of cannabis and cannabis-derived products").

119 *Id.* at 3–4.

government. From the perspective of some, marijuana-inventions could meet the utility requirement while from the perspective of others they could not.

Looking inside the Patent Office fares no better. In the Patent Office, examiners are directed to "not impose a rejection based on lack of utility" if "the claimed invention has a well-established utility."[120] Furthermore, the patent application examination guidelines, which are used by the patent examiners to evaluate patentability of an invention, state that

> [a]n invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.[121]

These instructions are largely circular in shedding a light on how applicants establish substantiality as substantiality, itself, is a part of the definition used in showing that the invention has a well-established utility.[122] Thus, it is unclear whose perspective matters. Does marijuana have a presently available benefit to the public?

Applicants have, at least presumably, demonstrated the substantiality of their invention since the Patent Office has granted marijuana-related patents.[123] So how do the applicants establish the utility of their marijuana-related invention? There are two possible explanations. First, since the USPTO has the initial burden of challenging utility a patent applicant can avoid having to establish utility unless a patent examiner rejects the claims for lack of utility as the USPTO has the initial

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120 MPEP, *supra* note 73, § 2107.

121 *Id.*

122 *See id.* (discussing recursively that "specific and substantial utility" is not "insubstantial," or "nonspecific").

123 Smoking Device for Smoking Through a Liquid, U.S. Patent No. 8,905,038 (issued Dec. 9, 2014) ("The invention provides a portable hookah for smoking a smokable substance such as tobacco or medical marijuana."); Methods for Preparing Cannabis and Related Products, U.S. Patent No. 8,753,696 (issued June 17, 2014) ("A method for preparing a medical marijuana mixture includes combining prepared medical marijuana and an alkaline substance in a pulverizing device."). Notably, neither of these patents were objected to on the ground of lack of utility.

burden of challenging utility.[124] Second, marijuana's placebo effect associated with consumption may be sufficient to satisfy utility. [125]

First, in a relatively recent case, *In re* Brana, the Federal Circuit held that the Patent Office has the initial burden of challenging a presumptively correct assertion of utility by alleging that a person of ordinary skill in the art would reasonably doubt the asserted utility.[126] If the Patent Office meets this requirement, then the burden shifts back to the applicant to prove utility.[127]

Placing the initial burden on the Patent Office, instead of the applicant is perhaps the reason why applicants are able to prove—or rather avoid proving utility. After all, a significant body of literature, and a fair amount of media coverage, exists that conclude through medical evidence that marijuana is effective for treatment of chronic pain or treatment of nausea associated with chemotherapy.[128] But, notably, in comparison with the pharmaceutical industry, clinical data derived from studies of cannabinoid therapies are scarce. This scarcity is potentially the result of difficulties associated with obtaining the necessary

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124 *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

125 *See* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999) ("Until such time as Congress [declares deceptive inventions unpatentable], we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public."). *See generally* Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1 (1995) (providing a comprehensive analysis of the PTO and Courts' interpretation of pharmaceutical patents' utility).

126 *In re Brana*, 51 F.3d at 1566.

127 *Id.* ("[O]nly after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

128 Donald I. Abrams, *The Therapeutic Effects of Cannabis and Cannabinoids: An Update from the National Academies of Sciences, Engineering and Medicine Report*, 49 EUR. J. INTERNAL MED. 7, 7–9 (2018) (referring to the National Academies of Sciences, Engineering and Medicine comprehensive review of medical literature on the health effects of cannabis and cannabinoids and concluding that "there was conclusive and substantial evidence that *Cannabis* or cannabinoids are effective for the treatment of pain in adults; chemotherapy-induced nausea and vomiting and spasticity associated with multiple sclerosis").

permission.[129] Nevertheless, an examiner, reviewing the patent application through the lens of a person of ordinary skill in the art and adopting the examination guidelines discussed above, could be sufficiently convinced that the invention under review is useful and never shift the burden back to the applicant.[130] This process may make the patent examination process pertaining to marijuana-related inventions more subjective than other inventions. In other words, it would be up to each examiner to accept or reject an applicant's assertion that a claimed invention has utility.[131]

Alternatively, another explanation for historical grant of marijuana-related patents may be from the notion that even placebo effects associated with marijuana consumption may satisfy both the specificity and the substantiality requirements regardless of actual effects.[132] This theory is based on the Federal Circuit's decision in *Juicy Whip v. Orange Bang, Inc.*, holding that "[t]he fact that one product can be altered to make it look like another is in itself a specific benefit sufficient to satisfy the statutory requirement of utility," for the purpose of patentability.[133] Hence, it follows that, even absent actual medical benefits, the placebo effect of marijuana consumption could satisfy the utility requirement if the consuming public believe its implicit or explicit intended purpose.

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129 *See* 21 C.F.R. § 1301.18 (2021) (detailing the requirements for research protocols for Schedule I drugs).

130 *See* NAT'L ACADEMIES OF SCI., ENG'G, AND MEDICINE, *supra* note 28, at 1–9, 25–28 (summarizing and describing the background of the National Academy's research data, recommendations, and methodology, and noting the potential breadth of health benefits and hazards of medicinal cannabis use).

131 In fact, the patent examination guidelines state:

> practical considerations require the Office to rely on the inventor's understanding of the invention in determining whether and in what regard an invention is believed to be 'useful.' Because of this, Office personnel should focus on and be receptive to assertions made by the applicant that an invention is 'useful' for a particular reason.

MPEP, *supra* note 73, § 2107.

132 *See* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999) ("Until such time as Congress [declares deceptive inventions unpatentable], we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public.").

133 *Id.* at 1367.

Another avenue for acquiring patent protection is a plant patent granted under the Plant Patent Act of 1930.[134] The Plant Patent Act allows asexually propagated species of plants that are clearly distinguishable from other varieties to receive patent protection.[135] This federal legislation could inform applicants' approach to securing marijuana-related patents by characterizing and claiming asexually reproduced plants.[136] In fact, it appears that until recently, growers seemingly used plant patents more frequently than utility patents.[137] Even though plant patents offer similar protection to patentees as utility patents, i.e., preventing others from making (reproducing), using, offering to sell, or selling asexually reproduced plants for a period of twenty years, plant patents are limited to a single claim.[138] Since claims are the part of patents that define the boundaries of an invention, having a single claim is potentially narrower than having multiple claims. Additionally, and more importantly, to prove infringement, a patentee must prove that the alleged infringer asexually reproduced the plant, which may be very difficult.[139] Since plant patents provide the applicants with a very narrow protection, this Article focuses on utility patents, which allow applicants to gain broader protection.[140]

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134 35 U.S.C. §§ 161–164.

135 *Id.* ("Asexually propagated plants are those that are reproduced by means other than from seeds, such as by the rooting of cuttings, by layering, budding, grafting, inarching, etc."); MPEP, *supra* note 73, § 1601.

136 *See* Imazio Nursery, Inc. v. Dania Greenhouse, 69 F.3d 1560, 1563–64 (Fed. Cir. 1995) (describing the requirements of an asexually propagated plant patent claim).

137 *See* Brett Schuman et al., *Emerging Patent Issues in The Cannabis Industry*, LAW360 (Feb. 20, 2018), https://www.law360.com/articles/1013575/emerging-patent-issues-in-the-cannabis-industry [https://perma.cc/L77W-DKKR] (noting that the first cannabis utility patent was only issued in 2015); Natali De Corso, *Obtaining Marijuana Patents*, B.C. INTELL. PROP. & TECH. F. 6 (Jan. 16, 2018).

138 Schuman et al., *supra* note 137. *See, e.g.*, Cannabis Plant Named 'Ecuadorian Sativa', U.S. Patent No. PP27475 (filed Mar.13, 2010) (issued Dec. 20, 2016) (claiming "[a] new and distinct cultivar of 'Cannabis' Plant as shown and described"); Blevins, *supra* note 102.

139 *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 133 (2001) ("Plant patents under the PPA . . . have very limited coverage and less stringent requirements than § 101 utility patents.").

140 *See id.*; Ann K. Wooster, Annotation, *Construction and Application of Plant Patent Act, 35 U.S.C.A. §§ 161 et seq.*, 135 A.L.R. Fed. 273 (1996). Similarly,

The reason for this delayed paradigm shift in applicants' approach, i.e., using utility patents instead of plant patents, could be directly attributed to patentable subject matter analysis below, and is perhaps the result of the Supreme Court's decision in *Diamond v. Chakrabarty* holding that genetically modified live organisms are patent-eligible as "manufactures" thereby expressly opening the gates for applicants to seek utility patents instead of plant patents.[141]

In summary, lack of uniformity between government sectors makes its unclear whose perspective matters when it comes to the usefulness of marijuana. While operability and substantial utility do not appear to pose any particular problems for marijuana-related inventions, there are interesting and unanswered questions regarding the beneficial aspect of the utility requirement for applicants seeking to protect marijuana-related inventions.[142]

D. PATENTABLE SUBJECT MATTER

Contrary to the often-recited phrase that patentable subject matter may include "anything under the sun that is made by man,"[143] to be patent-eligible an invention must be directed to one of the four statutory categories: "process, machine, manufacture, or composition of matter."[144] While seemingly straightforward on its face, patent eligibility is often a topic of ongoing controversy because of judicial exceptions to patentability.[145] Simply put, these judicial

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because protection for plants patented under the Plant Variety Protection Act comes from the Department of Agriculture instead of the USPTO this article does not address such patents. *See also* Joseph Dylan Summer, *Patenting Marijuana Strains: Baking up Patent Protection for Growers in the Legal Fog of This Budding Industry*, 23 J. INTELL. PROP. L. 169, 187, 189–90, 192–94, 203, 208 (2015) (elaborating on three different paths to gaining patent or patent-like protections using utility patents, PPA patents, or PVPA protections).

141 Diamond v. Chakrabarty, 447 U.S. 303, 309–10 (1980).

142 Manuela Cabal Carmona, *Dude, Where's My Patent: Illegality, Morality, and the Patentability of Marijuana*, 51 VAL. U.L. REV. 651, 673–84 (2017) (discussing the relationship between marijuana's illegality and its patentability).

143 *Patent Law Codification and Revision*: *Hearing on H.R. 3760 Before the Subcomm. No. 3 of the H. Comm. on the Judiciary*, 82d Cong. 37 (1951).

144 35 U.S.C. § 101. For a general discussion of this topic, see Alan J. Gocha, *Avoiding the Rabbit Hole: An Ontological Model For Determining Section 101 Patent-Eligibility Under* Alice, 17 J. MARSHALL REV. INTELL. PROP. L. 192 (2017).

145 *See* Dani Kass, *Fed. Circ. Judge Rebukes Panel for Alice Ax of Camera Patent*, LAW360 (June 11, 2021, 4:37 PM), https://www.law360.com/articles/

exceptions posit that an invention cannot be directed to laws of nature, natural phenomena, and abstract idea unless it includes some other inventive concept that amounts to significantly more than the judicial exception.[146] Stated in another way, an applicant is not entitled to a monopoly if the claimed invention is no more than recitation of a law of nature, natural phenomena, or an abstract idea—some other inventive concept is needed to bring the invention as a whole under the umbrella of patentable subject matter.

Some subject matter, for example inventions related to atomic energy or nuclear material, is precluded from patentability by statute.[147] But nowhere does the patentable subject matter provision of the Patent Act adopt a categorical ban

1393248/fed-circ-judge-rebukes-panel-for-alice-ax-of-camera-patent [https://perma.cc/3PQS-DBR6] (discussing a recent Federal Circuit decision where the panel was split on the interpretation of § 101, with the majority finding the claim at issue was abstract and the dissent claiming the majority was "conflating patent eligibility and novelty"). Press Release, Thom Tillis, U.S. Sen. for North Carolina, Tillis Introduces Landmark Legislation to Restore American Innovation (Aug. 3, 2022), https://www.tillis.senate.gov/2022/8/tillis-introduces-landmark-legislation-to-restore-american-innovation [https://perma.cc/P783-BELE]) (explaining that an Act has recently been proposed to address at least some of the ongoing controversy around patent eligibility).

146 *See, e.g.*, Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 216, 218–21 (2014) (applying the *Mayo* two-step framework to abstract ideas, finding the concept of intermediated settlement was an abstract idea); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 589, 591, 594–95 (2013) (finding the discovery and isolation of naturally occurring DNA was not patent eligible because even "[g]roundbreaking, innovative, or brilliant discovery does not by itself satisfy the § 101 inquiry," while cDNA was patent eligible because it is not naturally occurring); Mayo Collaborative Servs. v. Prometheus Lab'y, Inc., 566 U.S. 66, 70 73, 78–79 (2012) (holding a patent embodying a law of nature is unpatentable unless there is an additional feature, an inventive step, that is not well-understood, routine, and conventional to ensure the patent does not merely recite laws of nature); Bilski v. Kappos, 561 U.S. 593, 601 611 (2010) (explaining method claims for the concept of hedging risk in the energy markets was an abstract idea because it was a basic economic principle simply reduced to a mathematical formula).

147 *See* 42 U.S.C. § 2181 (under the Atomic Energy Act of 1954, no patent shall be "granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon").

on illegal substances. Any such concern has historically been addressed through the utility requirement of the Patent Act as discussed above.[148] For example, in 1889, an Illinois court in *National Automatic Device Co. v. Lloyd*, held that a patent on a Toy Automatic Race-Course commonly used in bars for gambling was unpatentable because "it [was] not a useful device, within the meaning of the patent law, as its use so far has been only pernicious and hurtful."[149] Similarly, in 1897, a California court in *Schultze v. Holtz*, held that a patent for a coin-operated device applied for gambling purposes was invalid where the inventor's claimed utility was "the telling of a fortune, which may be effected by means of a prepared list of statements corresponding to the various positions of the indicating disk."[150]

Nor does the MPEP, which provides patent examiners and patent attorneys with guidance regarding the Patent Office's practice and procedure, take a position on whether illegal innovations are patentable.[151] This stance is contrary to the European Union Guidelines for Patent Examination, which provide that "[a]ny invention the commercial exploitation of which would be contrary to '*ordre public*' or morality is specifically excluded from patentability."[152] Yet Subsection (1) of the European Union guidelines provides that "[e]xploitation is not to be deemed to be contrary to '*ordre public*' or morality merely because it is prohibited by law or regulation in some or all of the contracting states."[153] This provision continues to state that "[o]ne reason for this is that a product could still be manufactured under a European patent for export to states in which its use is not prohibited."[154] Accordingly, the United States' justification for not prohibiting the patenting of illegal substances altogether could be similar to its European counterpart allowing patentability of illegal substances for use in countries in which the

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148 *See supra* Section II.C (explaining the utility requirement and potential hurdles applicants face when demonstrating the usefulness of marijuana-related inventions).

149 Nat'l Automatic Device Co. v. Lloyd, 40 F. 89, 90 (C.C.N.D. Ill. 1889).

150 Schultze v. Holtz, 82 F. 448, 449 (C.C.N.D. Cal. 1897).

151 *See* MPEP, *supra* note 73, §§ 2106–2107 (providing guidance on patent eligibility and utility without reference to the patent eligibility or utility of either marijuana or illegal substances).

152 EUR. PAT. OFF., GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE, pt. G, ch. II, art. 4.1 (2022).

153 *Id.* art. 4.1.1.

154 *Id.*

use is not prohibited. Yet, unlike the European Union, U.S. patent law is federal law and covers all places in which the patent is valid.[155]

Regardless, the patentable subject matter requirement does not appear to pose any unique problems for patenting marijuana-related inventions.

III. ILLEGALITY AS AN IMPEDIMENT TO PATENTABILITY

There are several reasons why illegality may not be an impediment to patentability. These reasons apply especially in the case of marijuana.

First, as explained earlier, marijuana has been legalized for at least medical purposes in the majority of states in the nation.[156] Thus, it is difficult to maintain that marijuana is uniformly illegal in the United States. Theoretically, the federal prohibition is not in practical effect, except in certain areas, such as large scale, surreptitious growing and trafficking of marijuana.[157] Law enforcement in the United States is primarily an affair of the states.[158] It is estimated that of every 100 arrests that are made for marijuana crimes, ninety-nine are made by state officials and one by federal officials.[159]

Second, even the federal prohibition has itself become unstable to a large extent. Although marijuana's status on Schedule I is largely unchanged, federal action has substantially weakened the prohibition. In a series of memoranda promulgated from 2009 to 2014, the Department of Justice ("DOJ") announced that DOJ has certain enforcement priorities, and that outside of those priorities the federal government usually relies on local law enforcement to enforce their own local marijuana laws. it would not enforce the CSA's prohibition against marijuana if certain conditions are met.[160] Although Attorney General Jeff Sessions rescinded

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155 *See id.* General Part 4 ("These Guidelines provide guidance in respect of the practice in proceedings before the [European Patent Office] in accordance with the European Patent Convention and its Implementing Regulations.").

156 *See* Leins et al., *supra* note 5.

157 *See* LISA N. SACCO, CONG. RSCH. SERV., R43749, DRUG ENFORCEMENT IN THE UNITED STATES: HISTORY, POLICY, AND TRENDS 14–15 (2014).

158 *Id.* at 21 ("Most drug arrests are made by state and local law enforcement . . . .").

159 *See* MICH. COMP. LAWS § 333.26424 (2008) (referring to data from the Federal Bureau of Investigation Uniform Crime Reports and the Compendium of Federal Justice Statistics).

160 *See* OSBECK & BROMBERG, *supra* note 10, at 152–58. In a 2013 memorandum, the Justice Department announced that it would not enforce the prohibition against marijuana in states that decriminalized its use so as long as the states

these memoranda on January 4, 2018, this rescission seems to have made no practical difference.[161] In fact, William Barr, who succeeded Sessions as U.S. Attorney General from 2019 to 2020, pledged in writing to the Senate that he "[did] not intend to go after parties who have complied with state law in reliance on the [prior DOJ] Memorandum."[162] In the years since, the DOJ seems to be operating under the guidelines set out in the Obama Administration memoranda, which basically recognizes the legality of marijuana according to state law.[163] Under the Amendment, the DOJ is prohibited from using any of its funding to interfere with state laws authorizing the use, distribution, possession, or cultivation of medical marijuana.[164]

Third, it does not seem correct to describe marijuana use as illegal *per se*, in the same sense as acts such as arson or larceny. The CSA is essentially a public health measure, creating a comprehensive, closed system for regulating, distributing, and monitoring drugs.[165] The strictness of the controls is determined

do not allow marijuana use that violates federal priorities. The memorandum lists eight federal enforcement priorities to guide the states: (1) preventing distribution of marijuana to minors, (2) preventing revenue from sale of marijuana going to criminal enterprises, (3) preventing diversion of marijuana from states where it is legal to other states, (4) preventing marijuana activity from being used as a cover for trafficking of illegal drugs, (5) preventing violence and the use of firearms in marijuana activity, (6) preventing marijuana driving and other adverse public health consequences, (7) preventing growing of marijuana on public lands, and (8) preventing marijuana possession and use on federal property. So long as states have adequate measures to prevent those eight outcomes, the Justice Department indicates that it will not interfere with state legalization of marijuana. Memorandum from James M. Cole, Deputy Att'y Gen., U.S. Dept. of Just., for All U.S. Att'ys (Aug. 29, 2013), http://www.justice.gov/iso/opa/resources/305201382913275685746 7.pdf [https://perma.cc/RLG5-GXPG].

161 *See* Memorandum from Jefferson B. Sessions, III, Att'y Gen., U.S. Dept. of Just., for All U.S. Att'ys (Jan. 4, 2018), https://www.justice.gov/opa/pr/justice-department-issues-memo-marijuana-enforcement [https://perma.cc/2W35-CQ4A]; OSBECK & BROMBERG, *supra* note 10, at 170.

162 *See* Responses to Questions for the Record from William P. Barr, Nominee to Be U.S. Att'y Gen., to Sen. Cory Booker 217 (Jan. 27, 2019), https://www.judiciary.senate.gov/download/01/28/2019/barr-responses-to-booker-questions-for-the-record [https://perma.cc/3DHS-2EFZ].

163 *See* Memorandum from James M. Cole, *supra* note 160, at 1–2.

164 *See* 161 CONG. REC. H3745 (daily ed. June 2, 2015).

165 *See* OSBECK & BROMBERG, *supra* note 10, at 74.

by a drug's classification on the CSA's five schedules.[166] Likewise, the DEA combines administrative and enforcement functions, in that its duties are related both to public health, in determining the scheduling of drugs, and in law enforcement, in monitoring drug distribution and violations thereof.[167] Public health concerns have always created exceptions to the marijuana classification on Schedule I.[168] Certainly, researchers have been able to make use of marijuana in controlled clinical trials, however difficult DEA registration has been to obtain.[169] In addition, since 1978, under the NIDA's single patient compassionate use Investigational New Drug Applications ("IND") program, the federal government has supplied marijuana to a limited number of patients to treat medical conditions.[170] This is not to deny that use of marijuana is generally a crime under federal law, punishable by severe penalties, but it does suggest that under the modern marijuana regime in the various jurisdictions of the United States, a strict application of the illegality doctrine, even if applicable in general patent law, would be unsuited for marijuana patents.

Even if marijuana were to be considered as strictly illegal, it should be noted that the absence of limitations on the patentability of immoral or illegal subjects in the United States is not unusual. In fact, the United States has adopted a similar approach in both copyright law and trademark law. For example, buying and selling sex is illegal in most states, yet when sex-for-hire is fixed in a tangible medium of expression, it is protected by copyright law.[171]

Trademarks are also similar. Section 2(a) of the Lanham Act states in part that no trademark shall be refused registration on the principle register unless it "consists of or comprises immoral, deceptive, or scandalous matter; or matter which may disparage or falsely suggest a connection with persons, living or dead, institutions, beliefs, or national symbols, or bring them into contempt, or disrepute."[172] Yet, the Supreme Court in *Matal v. Tam* held that the prohibition on

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166 *See id.* at 79.

167 *See id.* at 74, 88, 90.

168 *See id.* at 89, 140–50.

169 *See id.* at 88, 109, 111.

170 *See FDA and Cannabis: Research and Drug Approval Process*, *supra* note 30. BLANCHARD RANDALL IV, CONG. RSCH. SERV., RL30274, MEDICAL USE OF MARIJUANA: POLICY AND REGULATORY ISSUES 22–23 (2002).

171 *See* Ann Bartow, *Copyright Law and Pornography*, 91 OR. L. REV. 1, 3 (2012).

172 *See* 15 U.S.C. § 1052.

registering trademarks that may "disparage" violates the First Amendment.[173] Following in the footsteps of *Matal*,[174] the Supreme Court in *Iancu v. Brunetti* held that the neighboring "immoral or scandalous" provision of Section 2(a) similarly violates the First Amendment.[175] Specifically, the Court stated that the discrimination of this provision—disfavoring certain ideas—violates the First Amendment.[176] Notably, trademark owners for cannabis and cannabis-related products faced a different problem than immorality for registering their marks. Specifically, they failed to establish use of the mark in commerce because any use of the mark in commerce must be lawful under the federal law to be the basis for federal registration.[177] Inability to legally use a mark in commerce disqualifies an applicant from securing the protection of the Lanham Act.[178]

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173 *See* Matal v. Tam, 137 S. Ct. 1744, 1748 (2017).

174 *Brunetti* was pending in front of the Federal Circuit when the decision for *Matal* was entered. *Id.* The case concerned USPTO's refusal to register "FUCT" because it deemed it immoral or consisting of scandalous matter. *See In re* Brunetti, Serial No. 85310960 at *5 (T.T.A.B. 2014) (holding that "from the dictionary definitions of record," the various meanings of the proposed mark were "vulgar terms" whether "in the context of extreme misogyny, nihilism or violence," and thus "extremely offensive terms" not capable of registration).

175 Iancu v. Brunetti, 139 S. Ct. 2294, 2302 (2019).

176 *See id.* at 2302.

177 Viva R. Moffat et al., *Cannabis, Consumers, and the Trademark Laundering Trap*, 63 WM. & MARY L. REV. 1939, 1966 (2022). In 2010, USPTO created a new trademark category for "processed plant material for medicinal purposes, namely medical marijuana." Within three months however USPTO abrogated this category, instead instructing its attorneys reviewing patent applications to ask applicants whether the goods or services at issue in the application violated the Controlled Substances Act ("CSA"). *See* De Corso, *supra* note 137, at 4; *see In re* Stanley Bros. Soc. Enter., LLC, Serial No. 86568478 at *9 (T.T.A.B. 2020) (refusing to register a mark for a cannabis-derived dietary supplement).

178 *See* TRADEMARK MANUAL OF EXAMINING PROCEDURE § 907 (July 2021). The 2018 Farm Bill and legalization of hemp eliminated this problem for application filed on or after December 20, 2018, that identify goods encompassing cannabis or CBD, "but *only* if the goods are derived from 'hemp'." *See* USPTO, EXAMINATION GUIDE 1-19 EXAMINATION OF MARKS FOR CANNABIS AND CANNABIS-RELATED GOODS AND SERVICES AFTER ENACTMENT OF THE 2018 FARM BILL 1 (May 2, 2019),

Additionally, the United States is a signatory to the Agreement on Trade Related Aspects of Intellectual Property ("TRIPS"), which requires patent protection to be equally available for all inventions without regard to subject matter.[179] Yet, Article 27 of TRIPS, like the European Patent Examination Guidelines, provides for an exception of patentability if commercial exploitation of such patents would violate "*ordre public*" or morality.[180] Thus, the United States' refusal to adopt a law expressly limiting patentability based on legality, despite the existence of the framework in the TRIPS Agreement, bolsters the conclusion that the illegality of marijuana does not generally limit applicants' ability to pursue marijuana-related patents.

This argument could be further evidenced by the legislative intent in the enactment of patent law. Simply put, if Congress desired to prevent patenting of what is illegal, it would have done so expressly. The Lanham Act, which is nearly a decade older than the modern Patent Act,[181] expressly states Congress's intent to regulate what constitutes immoral (i.e., disparaging, immoral, and scandalous).[182] Thus, had Congress had the intention to regulate morality via the patent system,

https://www.uspto.gov/sites/default/files/documents/Exam%20Guide%201-19.pdf [https://perma.cc/YC4X-PZGQ].

179 *See* Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 1867 U.N.T.S. 14, 33 I.L.M. 1143 (1994) [hereinafter Final Act]; Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 331 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

180 *See* TRIPS Agreement, *supra* note 179 (allowing an exception to patentability when commercial exploitation of patents violate the member country's *ordre public* or morality); *see also* Schuman et al., *supra* note 137 (explaining that unlike the E.U. patent law, there is no morality or legality requirement for patent eligibility in U.S. patent law).

181 U.S. Patent Act of 1952, Pub. L. 93-596, 66 Stat. 792 (1952) (codified at 35 U.S.C. §§ 1–42) (Lanham Act was enacted in 1946 while the Patent Act was in 1952).

182 *See* Lanham Act, Pub. L. No. 87-772, 60 Stat. 427 (1946) (codified at 15 U.S.C. §§ 1051–1141); 15 U.S.C. § 1052(a) (stating that immoral, deceptive, or scandalous marks are not eligible for federal registration); *see supra* notes 151–152 (listing statutory and judicial exceptions to patentable subject matter).

it would have expressly said so.[183] This argument, however, is not dispositive of congressional intent.[184] In fact, at the time of the Patent Act's passage, Justice Story's construction of the utility requirement—uninjurious to the well-being, good policy, or sound morals of society—was controlling law, and had not yet sunk into contempt and disregard by Justice Fortas' opinion in *Brenner*.[185] Therefore, Congress did not necessarily need to expressly state its intentions.

Congress's intent concerning the patentability of illegal substances is perhaps better examined from a parallel situation—the Prohibition era.[186] Pursuant to the Eighteenth Amendment, the National Prohibition Act banned the manufacture, sale, and transport of alcoholic beverages in the United States from 1920 to 1933.[187] There is evidence to show, however, that patents pertaining to alcoholic beverages were granted during this period. For example, Patent No. 1,551,979 was granted on September 1, 1925, to Henry E. Deckebach, for a "Process and Apparatus for Making Beer of Low Alcoholic Content."[188] Even though this application was "filed in 1919 between the ratifying of the National Prohibition Act in 1919 and Prohibition going into effect in 1920[,]"[189] it was still

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183 *See* Carmona, *supra* note 142, at 693 ("If Congress intended to limit the patentability of illegal or immoral subject matter, . . . it would have included a morality or legality clause in the Patent Act.").

184 *Cf. id.* (indicating that the "Patent Act is silent on morality").

185 *See* Brenner v. Manson, 383 U.S. 519, 533–34 (1966); Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817).

186 *See generally Prohibition*, BRITANNICA, https://www.britannica.com/event/Prohibition-United-States-history-1920-1933 [https://perma.cc/ZGY4-9G5G] (explaining that the manufacture, sale, and transportation of alcoholic beverages were legally prevented by the National Prohibition Act pursuant to the Eighteenth Amendment during the prohibition).

187 *See* U.S. CONST. amend. XVIII, *repealed by* U.S. CONST. amend. XXI (prohibiting the manufacture, sale, transportation, importation, or exportation of alcoholic beverages).

188 *See* Process and Apparatus for Making Beer of Low Alcoholic Content, U.S. Patent No. 1,551,979 (filed Sep. 20, 1919) (issued Sep. 1, 1925) (showing that the patent was issued for a process and apparatus for making alcoholic beverages in 1925).

189 John Horneber, *A Brief History of Beer and Patents*, SUITER SWANTS (Aug. 27, 2018), https://www.suiter.com/a-brief-history-of-beer-and-patents/ [https://perma.cc/9DBV-TMER]

granted during the prohibition era.[190] Given that Congress's power "to legislate upon the subject of patents is plenary by the terms of the Constitution," if it had the desire to limit patentability based on legality, following the Prohibition era, it could have done so.[191]

Even the U.S. District Court for the Northern District of Texas, in *Whistler v. Autotronics, Inc.*, adjudicating a patent infringement case in 1988 about a radar detector noted the "incongruity of asking a court of law to protect a device used to circumvent the law," and upheld the patent as valid.[192] In doing so, this court observed "the matter is one for the legislatures of the states, or for the Congress, to decide."[193] Yet, at the time of *Whistler*, only two states had prohibited the use of such a device, leading the court to assert that "[u]nless and until detectors are banned outright, or Congress acts to withdraw patent protection for them, radar detector patentees are entitled to the protection of the patent laws."[194] With marijuana, however, Congress's ban is outright.[195] It is plausible that the court would not have deemed the patent valid had the radar detection device been illegal in every state or banned by Congress.

Although schools of statutory interpretation differ, three principal philosophies are commonly used by courts. These are textualism, intentionalism, and purposivism.[196] Although this Article cannot address the intricacies of these principal philosophies, it suffices to say that under any of these, as mentioned

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190 *See also* Process of Producing Nearly Nonalcoholic Liquors, U.S. Patent No. 1,537,252 (filed May 10, 1924) (issued May 12, 1925) (showing that another patent pertaining to production of alcoholic beverages was granted in 1925).

191 *See* McClurg v. Kingsland, 42 U.S. 202, 206 (1843) (stating that Congress has full authority to legislate upon the subject matter of patentability and "there are no restraints on its exercise"); *see also* Boyden v. Comm'r of Pat., 441 F.2d 1041, 1043 (D.C. Cir. 1971) ("Certainly the powers of Congress in the patent law field are plenary for they stem directly from the Constitution.").

192 *See* Whistler Corp. v. Autotronics, Inc., No. CA3-85-2573-D, 1988 WL 212501 at *1 (N.D. Tex. July 28, 1988) (deciding that radar detectors are protected by the patent law even if their purpose is to circumvent the law).

193 *See id.*

194 *See id.*

195 Robert A. Mikos, *On the Limits of Supremacy: Medical Marijuana and the States' Overlooked Power to Legalize Federal Crime*, 62 VAND. L. REV. 1421, 1422 (2009).

196 *See* Jonathan R. Siegel, *The Inexorable Radicalization of Textualism*, 158 U. PA. L. REV. 117, 118–119, 123–124 (2009) (introducing textualism, intentionalism and purposivism as main three approaches to statutory interpretation).

above, the Patent Act, on its face or through its underlying purpose, does not appear to conflict with the CSA despite the striking obstacles that marijuana-related patent applicants face in view of the illegality of marijuana.

Ironically, the U.S. Department of Health and Human Services ("HHS") has a patent on non-psychoactive cannabinoids titled "Cannabinoids as Antioxidants and Neuroprotectants[.]"[197] This patent, issued in 2003, expressly states that the antioxidant properties of cannabinoids make them "useful in the treatment and prophylaxis of wide variety of oxidation associated diseases, such as ischemic, age-related, inflammatory and autoimmune diseases."[198] This adds to the ambiguity surrounding whether or not the United States recognizes medical benefits of cannabis.

IV. ENFORCING MARIJUANA-RELATED PATENTS IN FEDERAL COURT

Despite the issues outlined above, it appears that the USPTO is truly non-judgmental and evaluates all patent applications the same way, whether mundane or controversial as evident through the grant of marijuana-related patents.[199] Yet, the interactions between the Patent Act and the CSA raise even more interesting questions when it comes to the enforcement of such patents. Since the Constitution gives Congress the power to regulate the patent system, only federal courts have subject matter jurisdiction to adjudicate patent infringement cases.[200] Thus, a patent infringement case can only be brought in one of the ninety-four federal

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197 *See* Cannabinoids as Antioxidants and Neuroprotectants, U.S. Patent No. 6,630,507 (filed Apr. 21, 1999) (issued Oct. 7, 2003) (showing the HHS as an owner of the patent).

198 *See id.*

199 *See* Craig Nard, *Companies Are Quietly Patenting Marijuana, and It Could Lead to a Messy Legal Future*, BUSINESS INSIDER (July 8, 2017), https://www.businessinsider.com/companies-are-patenting-pot-and-it-could-lead-to-a-messy-legal-future-2017-7 [https://perma.cc/TT8L-PV2M] (explaining that the USPTO has been evaluating and issuing cannabis-related patents based on the requirement of "amoral and nonjudgmental" from the U.S. patent law).

200 *See* U.S. CONST. art. I, § 8, cl. 8; *see also* 28 U.S.C. § 1338(a) (2018) ("No State court shall have jurisdiction over any claim . . . arising under any Act of Congress relating to patents.").

district courts that are bound to interpret and administer all federal laws—including the CSA.[201]

Federal courts have a duty to enforce all federal laws.[202] When it comes to enforcing marijuana patents, on the one hand, patent law demands that the court make the patentee whole at the expense of the wrongdoer, but on the other hand, the CSA criminalizes the very act for which the court is granting a remedy.[203] Thus, before addressing the challenges associated with litigating marijuana-related patents, the courts' willingness to address such issues should be considered. After all, there are a series of realistic policy-oriented objections associated with enforcement of marijuana-related patents.

One example of these objections is the doctrine of *ex turpi causa non oritur actio* ("No action arises from a wrongful contract"), meaning that a claimant cannot pursue a legal remedy if the claimant's cause of action arises from an illegal act.[204] This doctrine is deeply rooted in the fabric of common law, with its application recorded as early as 1725, and is alive and well to this day.[205] Application of this doctrine to marijuana would square with what federal courts have held time after time: "courts will not lend their aid to a criminal enterprise by adjudicating disputes over entitlement to the fruits of a criminal enterprise."[206] Therefore, in

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201 *See* Admin. Off. of the U.S. Courts, *Court Role and Structure*, UNITED STATES COURTS, https://www.uscourts.gov/about-federal-courts/court-role-and-structure [https://perma.cc/U3QE-5X97].

202 *See id.*

203 *See* 35 U.S.C. § 284 ("Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court."); s*ee also* 35 U.S.C. § 27 ("Except as otherwise provided in this title, whoever 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."); 21 U.S.C. §§ 811–812.

204 *See Ex Turpi Causa*, BLACK'S LAW DICTIONARY (11th ed. 2019); *see also* William J. McNichol, Jr., *The New Highwayman: Enforcement of U.S. Patents on Cannabis Products*, 101 J. PAT. & TRADEMARK OFF. SOC'Y 24, 40 (2019) (providing an example of a potential objection to a marijuana patent infringement case).

205 *See* McNichol, *supra* note 204, at 40 (citing to the English case of *Everett v. Williams* known as the *Highwayman's Case* dated 1725 and the Federal Circuit case of *Formby-Denson v. Dep. of the Army* dated 2001).

206 *See id.* at 49 (explaining that enforcement of a marijuana-related patent in a federal court cannot realistically be distinguished from *stare decisis* even

addition to the issues concerning securing a marijuana-related patent and the difficulties associated with enforcing the same, a court's willingness to make a patentee whole at the expense of the wrong doer poses yet another concern when the underlying action pertains to a "criminal enterprise."

Some of the challenges associated with enforcement of marijuana-related patents are outlined below.[207] In particular, this section begins by discussing that even securing legal counsel could pose a problem.[208] Subsequently, this section examines issues that arise in the pleading stage and considers the shortcomings of the discovery stage in this context.[209] Next, this section assesses the judicial limitations on granting remedies.[210] The last part of this Article suggests that our current approach to patenting illegal substances is bound to raise new patent troll problems.[211]

A. SECURING LEGAL REPRESENTATION

Rule 1.2(d) of the Model Rules of Professional Conduct states in part that "[a] lawyer shall not counsel a client to engage, or assist a client, in conduct that the lawyer knows is criminal or fraudulent."[212] Therefore, because of the illegality of marijuana, securing an attorney for the purposes of patent litigation can be challenging, especially as federal courts have exclusive jurisdiction over cases arising under any act of Congress related to patents.[213] This is true despite the fact that many states have modified their version of Rule 1.2(d) to the effect that

though the majority of cases dealing with the doctrine of *ex turpi causa* concern contracts).

207 *See infra* Sections IV.A-D.

208 *See infra* Section IV.A.

209 *See infra* Section IV.B.

210 *See infra* Section IV.C.

211 *See infra* Section IV.D.

212 *See* MODEL RULES OF PRO. CONDUCT r. 1.2(d) (AM. BAR ASS'N 2002).

213 *See* 28 U.S.C. § 1338(a) (2018) ("No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights . . . [t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks.").

lawyers do not commit an ethical violation if they represent marijuana clients, according to state parameters.[214]

The representation issue, however, does not end with the federal court. Securing an attorney to practice before the USPTO to secure patent rights or engage in post-grant proceedings may also be problematic. In fact, the USPTO replaced the USPTO Code of Professional Responsibility with the USPTO Rules of Professional Conduct to conform to the Model Rules of Professional Conduct promulgated by the American Bar Association.[215] The language of Rule 1.2(d) mentioned above is adopted almost verbatim by the USPTO.[216] Therefore,

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[214] *See Advising Clients on Marijuana Use, Sale*, AM. BAR ASS'N (Nov. 2017), https://www.americanbar.org/news/abanews/publications/youraba/2017/november-2017/the-ethical-landmines-surrounding-advising-clients-about-marijua/ [https://perma.cc/9GEB-LNZN] (stating that as of July of 2017 "16 states' lawyer disciplinary offices . . . have modified the rule, adding official commentary and issuing binding ethics opinions, or announced a policy to permit counseling and assistance of a client with conduct permitted by state marijuana laws"). As of May, 2019, 25 states have so modified their rules. *See Has Your State Weighed in on Providing Advice to Cannabis Industry Clients?*, INT'L CANNABIS BAR ASS'N, https://canbar.org/ethics-overview/ [https://perma.cc/NDF6-W75B]. On February 17, 2020, the ABA itself passed House of Delegates Resolution 103 urging "Congress to enact legislation to clarify and explicitly ensure that it does not constitute a violation of federal law for lawyers, acting in accord with state, territorial, and tribal ethical rules on lawyers' professional conduct, to provide legal advice and services to clients regarding matters involving marijuana-related activities that are in compliance with state, territorial, and tribal law." *See* Kyle Jaeger, *American Bar Association Wants Protections for Marijuana Banking and Lawyers Working with Cannabis Clients*, MARIJUANA MOMENT (Feb. 17, 2020), https://www.marijuanamoment.net/american-bar-association-wants-protections-for-marijuana-banking-and-lawyers-working-with-cannabis-clients/ [https://perma.cc/MUM3-LU3W].

[215] *See Ethics Rules of Professional Conduct*, USPTO (2013), https://www.uspto.gov/learning-and-resources/patent-and-trademark-practitioners/current-patent-practitioner/ethics-rules [https://perma.cc/W494-P76X] (stating that the USPTO has replaced the USPTO Code of Professional Responsibility with the Model Rules of Professional Conduct of the ABA).

[216] *See* 37 C.F.R. § 11.102 (2018) ("A practitioner shall not counsel a client to engage, or assist a client, in conduct that the practitioner knows is criminal or fraudulent, but a practitioner may discuss the legal consequences of any proposed course of conduct with a client and may counsel or assist a client

representing a marijuana business "in conducting its business affairs, including applying for a patent, could under some circumstances be deemed both a violation of the CSA and an instance of professional misconduct."[217]

Fortunately, marijuana-related patent applications, unlike an application for a trademark, do not require a declaration that the invention is being used or will be used in interstate commerce in connection with the sale of goods and services.[218] An application to register a trademark requires a declaration by the applicant that either the trademark is "in use in commerce" or only "not in use in commerce due to special circumstances."[219] This is because "[t]rademark ownership in the U.S. is founded on the principal that the first to *use* a name (i.e. a trademark, or mark) 'in commerce' is the owner of that mark, with the right to exclude others from using a mark that is identical or confusingly similar to theirs."[220] Therefore, an application for trademark could in and of itself demonstrate an intent to violate the CSA.[221]

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to make a good-faith effort to determine the validity, scope, meaning or application of the law.").

217 *See* Kamin & Moffat, *supra* note 37, at 265. Several bar associations in states that have legalized marijuana have revised their version of rule 1.2(d). By and large they have ruled that lawyers may counsel and assist clients in their marijuana businesses so long as they advise the clients as to the federal prohibition. *See, e.g.*, COLO. RULES OF PRO. CONDUCT 1.2 (COLO. SUP. CT. 2020); N.Y. State Bar Ass'n Comm. on Pro. Ethics, Op. 1024 (2014); Md. State Bar Ass'n Comm. on Ethics, Ethics Docket No. 2016-10 (2016); Ill. State Bar Ass'n, Pro. Conduct Advisory Op. 14-07 (2014); Me. Bd. of Overseers of the Bar, Pro. Ethics Comm'n, Vacating Op. 215 (2017); R.I Sup. Ct. Ethics Advisory Panel, Op. 2017-01 (2017); State Bar of Ariz. Ethics Comm., Op. 11-01 (2011).

218 *See* Kamin & Moffat, *supra* note 37, at 264.

219 *See* USPTO, DEFINITIONS FOR MAINTAINING A TRADEMARK REGISTRATION (Dec. 20, 2018), https://www.uspto.gov/trademarks-maintaining-trademark-registration/forms-file/definitions-maintaining-trademark [https://perma.cc/4REH-ZM87].

220 *See* Bennett Collen, *Trademarks: Everything You Need to Know – Part I*, SCORE (Jul. 14, 2016), https://www.score.org/blog/trademarks-everything-you-need-know-part-i [https://perma.cc/6FM2-YGNP].

221 Illegality of marijuana has forced the trademark owners in this industry to seek state-level IP and IP-like rights "to achieve what it cannot under federal law[.]" *See* Kamin & Moffat, *supra* note 37, at 244; *see also* Mikos, *Unauthorized and Unwise*, *supra* note 37, at 163 for a scathing critique of PTO's requirement of trademark owners to comply with sundry nontrademark

In the patent context, however, neither filing an application for a patent nor an actual grant of a patent violates the CSA.[222] A patent is a negative right, meaning that a patent owner has the right to exclude others from making, using, offering to sell, selling, or importing into the United States its patented process, machine, manufacture, or composition of matter—but does not have to itself practice the invention.[223] In a sense, patents are like many other property rights. Owning a patent is like owning a car. The ownership does not give the owner the right to drive the car, but it does give the owner the right to exclude others from the driving the car.[224] In some ways, however, patents are different. For example, even after securing a patent, a patentee may not be able to practice his invention if practicing it would necessarily require infringing another patent.[225]

Accordingly, while application for or ownership of a marijuana-related patent does not necessarily violate any laws, an attempt to enforce such a patent against an alleged infringer may prove challenging for two reasons. First, admitting to practicing the patented invention would be in violation of federal law.[226] Second, any allegations made could incriminate the defendant.[227]

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law. Unfortunately, for patent owners, however, there are no state-level patent-like IP protection. *See* Bonito Boats v. Thunder Craft Boats, 489 U.S. 166, 164–65 (holding that that federal law preempts any and all patent-like state level protections, stating "[t]he states are simply not free in this regard to offer equivalent protections to ideas which Congress has determined should belong to all").

222 There is, however, the problem that a patent holder answering questions in litigation to defend their patent, could expose themselves to the crime of violating the CSA. *See* Emily Pyclik, *Obstacles to Obtaining and Enforcing Intellectual Property Rights in the Marijuana Industry*, 9 AM. U. INTELL. PROP. BRIEF 26, 43 (2018); *see also* Mikos, *Unauthorized and Unwise*, *supra* note 37, at 206.

223 *See* 35 U.S.C. §§ 271(a), 101.

224 *See* Richard H. Shear & Thomas E. Kelley, *A Researcher's Guide to Patents*, 132 PLANT PHYSIOLOGY 1127, 1127 (2003).

225 *See* Acorda Therapeutics, Inc. v. Roxane Labs., Inc., 903 F.3d 1310, 1337 (Fed. Cir. 2018) (discussing how "[a] patent has been called a 'blocking patent' where practice of a later invention would infringe the earlier patent").

226 *See* 21 U.S.C. §§ 841, 844 (2018) (discussing that it is illegal under federal law to possess and distribute marijuana).

227 *See* 35 U.S.C. § 271 (stating that "whoever without authority makes, uses, offers to sell, or sells any patented invention . . . during the term of the patent therefor, infringes the patent").

Specifically, to bring a patent infringement suit, the plaintiff must allege that the defendant has made, used, offered to sell, sold, or imported into the United States its patented marijuana-related process, machine, manufacture, or composition.[228] When it comes to marijuana, the aforementioned conduct could constitute a federal crime.[229]

To make matters worse, as mentioned above, all patent infringement actions must be brought in one of the ninety-four federal district courts because federal courts have exclusive subject matter jurisdiction over patents.[230] At the federal level, the Freedom of Information Act, signed into law in 1966, provides the public—including the prosecutors' office—with access to federal agency records.[231] Therefore, a simple allegation of patent infringement could provide prosecutors with the necessary information to investigate or to bring a criminal action against the defendant. As far as the CSA is concerned, it is irrelevant whether or not the state in which the patent infringement action has legalized medical marijuana or recreational marijuana.[232]

B. PLEADING MARIJUANA-RELATED PATENT INFRINGEMENT

Apart from problems associated with securing representation and the potential for self-incrimination, litigating a marijuana-related patent can raise many other challenges.[233] Even identifying the defendants can prove difficult

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228 *See* 35 U.S.C. § 101 (stating that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent"); 35 U.S.C. § 271.

229 *See* Controlled Substances Act § 401 (listing marijuana as a Schedule I controlled substance and making it unlawful for one to "to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance").

230 *See Court Role and Structure*, *supra* note 201.

231 *See* 5 U.S.C. § 552 (stating in part "each agency, upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person").

232 *See* United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483, 489–90 (2001) (holding that there is no medical necessity exception to the federal Controlled Substance Act).

233 *See* Pyclik, *supra* note 222, at 37.

because many marijuana growers cultivate marijuana in secret.[234] Operating under the radar can make it difficult to determine if such growers are infringing a patent.[235] Indirect infringement cases can make identifying the defendants even more challenging—if not impossible. In an inducement patent infringement action, for example, the patent owner must determine if the actions of one party could be construed as asking or inducing another to infringe on its patent.[236] Identifying the infringing parties could be difficult because the first party, the second party, or both, could be operating in secret.

Closely tied to this issue is the problem associated with identifying prior art. As discussed, because of the illegality of marijuana, patent examiners face a unique challenge in uncovering relevant art.[237] But the problems associated with prior art identification are not limited to patent procurement. It is a common practice for defendants to raise a patent invalidity defense asserting that a "patent holder did not satisfy the basic requirements to obtain a patent."[238] The majority of such defenses challenge the novelty or the non-obviousness of the patented invention.[239] Even absent a patent infringement action, an entity fearing future

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234 *See* William J. Meadows, *Cannabis Legalization: Dealing with the Black Market*, 13 OHIO STATE U. DRUG ENF'T & POL'Y CTR., Oct. 2019, at 19 (discussing that "illegal growers are producing five times more marijuana than licensed dealers in California").

235 Legalization of marijuana in many states as well as the grant of licenses of pot shops generally functioning under the umbrella of a corporate entity has to some extent alleviated this problem. Yet, the illegal market remains stubbornly robust. *See* Naomi Martin, *Why Most Mass. Marijuana Sales are on the Black Market, Two Years After Legalization*, BOSTON GLOBE (Feb. 2, 2019), https://www.bostonglobe.com/news/marijuana/2019/02/02/illicit-pot-market-remains-stubbornly-robust/Fqq5baxLvgkrTB1ABJRbEL/story.html [https://perma.cc/9ETC-LPJK] (discussing "[a]s more states legalize marijuana, they're finding mixed success shrinking the criminal trade").

236 *See* 35 U.S.C. § 271(b) (2018) (stating that "[w]hoever actively induces infringement of a patent shall be liable as an infringer").

237 *See* Wyse & Luria, *supra* note 54, at 12–13 (defining "prior art" as "publicly available literature published before the date of the patent application").

238 *See* Roger Allan Ford, *Patent Invalidity Versus Noninfringement*, 99 CORNELL L. REV. 71, 73 (2013); *see also* 35 U.S.C. § 282(b) (stating in part that invalidity of the patent or any claim in suit on any ground as condition of patentability is a defense in a patent infringement action).

239 *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. J. 185, 208 (1998) (citing data to corroborate

infringement actions can seek declaratory judgment of invalidity under the Declaratory Judgment Act of 1934.[240] Under such circumstances, assuming that the invalidity grounds are novelty or obviousness, it is the court's responsibility to examine the prior art asserted by the patent challenger to determine the validity of the patent-in-suit.[241] Without access to a substantial body of prior art, an accused infringer's chance of securing an invalidity judgment is severely abridged.

As a result, marijuana-related patent litigation cases disfavor defendants for two reasons. First, the consequences of such an action could go beyond civil liability and incriminate the defendant.[242] Second, the defendant may not have access to a substantial body of relevant art to mount an invalidity challenge sufficient to overcome a patent's assumption of validity.[243]

On the other hand, plaintiffs are generally dealt a better hand. First, the absence of substantial literature on marijuana-related compositions, processes, or products may make it easier to have a patent granted by the USPTO.[244] Second, a granted patent comes with a presumption of validity that is difficult to rebut by the defendant for the reasons stated above.[245] Third, a plaintiff may be able to strong-arm a defendant to settle because of the incrimination risk associated with discovery and litigation.[246]

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that a majority of patent invalidity determinations are based on the patent in question being identified as prior art or obvious).

240 *See* 28 U.S.C. § 2202.

241 *See* Deep Welding, Inc. v. Sciaky Bros., 417 F.2d 1227, 1233 (7th Cir. 1969) (stating that the court "must examine the nature, content and scope of the prior art to see what it fairly taught one having ordinary skill in the art as the art existed on the date of invention. If the state of the art anticipated or made obvious the invention sought to be patented, 35 U.S.C. § 103 (as well as §§ 102(a), (b), (e) or (g)) requires a holding of invalidity").

242 *See* 21 U.S.C. § 841.

243 *See* 35 U.S.C. § 282(a) (stating that "[a] patent shall be presumed val*id.* Each claim of a patent . . . shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity").

244 *See* 35 U.S.C. §§ 102–103 (less literature available for patent examiners would make it easier for applicants to meet the novelty requirement under § 102).

245 *See* 35 U.S.C. § 282(a).

246 *See* 35 U.S.C. § 271.

Yet another advantage for the plaintiff in marijuana-related patent infringement actions is that a patent provides the owner with a negative right and not a positive privilege.[247] Because of this, a patent owner does not need to practice the patent; instead, the patent owner can simply exclude others from making, using, selling, or offering for sale its patented invention.[248] Therefore, a patent infringement action is not *per se* incriminating to the owner. The same, however, cannot be said about the defendants. Every action that can result in infringement of a marijuana-related patent constitutes a violation of the criminal law.[249] Accordingly, the negative right aspect of patents provides the plaintiffs with significant leverage over the defendants.

While a plaintiff may have leverage over a defendant because they can bring a patent infringement action without having to practice the patent, that does not necessarily mean they will not incriminate themselves. In fact, a patent holder may have an incentive to demonstrate that it is practicing the invention for two reasons. First, practicing entities have a much better chance of succeeding in trial, as opposed to non-practicing entities.[250] Second, establishing that the patent owner is a practicing entity qualifies the plaintiff to seek higher damages: lost profits, instead of reasonable royalties.[251]

Even if the plaintiffs do not disclose this themselves, the fact that the plaintiff is practicing the patent-in-suit or a variation thereof could become evident during the discovery stage. It is commonplace for the defendant in a patent infringement action to seek the plaintiff's financial documents including any license agreements on the patent(s)-in-suit.[252] Defendants generally use this

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247 *See id.*

248 *See id.*

249 *See* Controlled Substances Act § 401(a).

250 *See 2018 Patent Litigation Study*, PWC, May 2018, at 8 (finding that "[t]here is a pronounced difference in trial success rates for [non-practicing entities versus practicing entities] depending on the trier of fact").

251 *See* 35 U.S.C. § 284 ("Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court."); *see also* Wechsler v. Macke Int'l Trade, Inc., 486 F.3d 1286, 1293 (Fed. Cir. 2007) (stating that to recover lost profits, the patent owner must "show 'causation in fact,' establishing that 'but for' the infringement, he would have made additional profits").

252 *See* FED. TRADE COMM'N, PATENT ASSERTION ENTITY ACTIVITY 9 (Oct. 2016).

information to approximate damages and weigh their odds of winning against their potential liability.[253] Generally, a plaintiff's financial statements can reveal if it is engaged in production and sale of the patented invention or a variation thereof.[254]

Likewise, interrogatories and depositions could shed light on a plaintiff's own conduct.[255] Additionally, "[i]n almost every setting where important decisions turn on questions of fact, due process requires an opportunity to confront and cross-examine adverse witnesses."[256] Therefore, despite the fact that patents are negative rights, if the plaintiff is a practicing entity, it may still have to admit to the court that it has engaged in the practice of the claimed invention. This may prompt patentees to sell their patents to non-practicing entities as straw buyers or otherwise to avoid this issue.

Thus far, there have been very few marijuana patent infringement cases.[257] While none have reached to stages of litigation that could answer some of the questions raised here, one has a relatively developed docket. United Cannabis

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253 *See* Kevin Neels et al., *A Quick Guide to Patent Damages Discovery*, LAW360 (Aug. 12, 2016), https://www.law360.com/articles/826184/a-quick-guide-to-patent-damages-discovery [https://perma.cc/K7ZS-TABP].

254 *See id.*

255 *See* FED. R. CIV. P. 33 ("A party may serve on any other party no more than 25 written interrogatories, including all discrete subparts . . . [and] [a]n interrogatory may relate to any matter that may be inquired into under Rule 26(b)."); *see also* FED. R. CIV. P. 30 ("A party may, by oral questions, depose any person, including a party, without leave of court except as provided in Rule 30(a)(2). The deponent's attendance may be compelled by subpoena under Rule 45.").

256 *See* Goldberg v. Kelly, 397 U.S. 254, 269 (1970); *see also In re* Alamance Cnty. Ct. Facilities, 405 S.E.2d 125, 137 (N.C. 1991) (indicating that even in civil proceedings substantive right to confront and cross-examine applies) (citations omitted).

257 Canopy Growth Corp. v. GW Pharms. PLC, No. 6-20-CV-01180, 2021 WL 801584 (W.D. Tex. Nov. 27, 2021), *appeal filed*, No. 22-1603 (Fed. Cir. Apr. 7, 2022); Original Resinator, LLC v. TTT Innovations LLC, No. 5:21-cv-02002 (C.D. Cal. filed Nov. 29, 2021). In 2019, the PTAB adjudicated its first ever marijuana-related patent in an *inter partes review*. The Board found claims 1 and 2 of the patent-in-suit invalid in view of prior art generally teaching administration of CBD to treat epilepsy. The Board, however, found claims 3–13 to be patentable. This example further illustrates the importance of the existence of prior art. *See* Insys Dev. Co. v. GW Pharma Ltd., No. IPR2017-00503, 35 (P.T.A.B. Jan. 3, 2019).

Corporation ("UCANN") sued Pure Hemp Collective Incorporation for infringement of UCANN's patent entitled "Cannabis Extracts and Methods of Preparing and Using Same" (U.S. Patent No. 9,730,911, the "'911 patent") in federal court.[258] This patent is generally directed to liquid cannabinol formulations comprising tetrahydrocannabinol ("THC"), cannabidiol ("CBD"), and numerous other terpenes.[259] An examination of this case can highlight some of the issues, discussed above, associated with enforcing a marijuana-related patent in federal court.

In its complaint, UCANN stated that it had "been involved with medical cannabis for almost two decades."[260] Further, it expressly stated that following the issuance of the '911 patent, it had developed its Prana Bio Nutrient Medicinals line, which consists of a variety of products divided into five categories with specific cannabinoid ratios and terpene profiles.[261] Additionally, UCANN alleged that, "Pure Hemp makes, uses, offers to sell, and sells a range of wellness products containing cannabis extracts, including tinctures, gel capsules, vape pens, salves, and topical ointments."[262] Interestingly, UCANN acknowledged that it had purchased "Pure Hemp's Vina Bell 5000mg product and ran chemical composition tests on it to determine whether the cannabinoid formulations within the product are covered by the '911 Patent."[263]

In its Answer, Pure Hemp raised a prior art argument similar to what was anticipated above. Specifically, after listing a few product brands that were around before the filing of the '911 patent[264] that allegedly practiced the claimed invention,

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258 *See* Cannabis Extracts and Methods of Preparing and Using Same, U.S. Patent No. 9,730,911 (filed Oct. 21, 2015) (issued Aug. 15, 2017).

259 *See id.* Cannabis plant includes a number of terpenes such as myrcene, linalool, and limonene which provide cannabis with its characteristic scents. *See* Grinspoon, *supra* note 99.

260 *See* Complaint for Patent Infringement & Demand for Jury Trial at 3, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922 (D. Colo. July 30, 2018).

261 *See id.* at 4 (stating that [t]he product line has enjoyed great medical success with observational data from more than 15,000 patients to date showing the products are safe and effective").

262 *See id.* at 5.

263 *See id.* at 5–6.

264 In essence, Pure Hemp argues that because products practicing the invention of the '911 Patent were already on sale at the time of the application for this patent, the patent should not have been granted. *See* 35 U.S.C. § 102 ("A person shall be entitled to a patent unless the claimed

Pure Hemp argued that the inventions encompassed by the '911 patent are "ubiquitous" and "were not invented in this millennium . . . ."[265] While Pure Hemp named several products that allegedly practice the '911 patent, supporting these allegations are a different story.[266] In patent litigation cases, defendants usually produce years, sometimes decades worth, of "scientific articles and other writings to demonstrate a given industry's preexisting research and knowledge."[267] But this wealth of evidence likely does not exist for Pure Hemp given the general illegality of marijuana to date.[268]

Pure Hemp raised another interesting challenge in its Answer: patentable subject matter.[269] In particular, it referred to the Supreme Court's framework concerning patentable subject matter and alleged that the claim asserted by UCANN is directed to a naturally occurring compound.[270] Because naturally

invention was . . . on sale . . . before the effective filing date of the claimed invention.").

265 *See* Defendant's Answer, Defenses, and Counterclaims at 7–8, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922 (D. Colo. Oct. 29, 2018).

266 In its amended Response, Pure Hemp identifies U.S. Patent No. 2,304,669, titled Isolation of Cannabidiol as a potential prior art against the invention of the '911 Patent. *See* Defendant's First Amended Answer, Defenses, and Counterclaims at paras. 39–46, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922 (D. Colo. Nov. 5, 2018); *see* '669 Patent, *supra*; *see also* Defendant's First Amended Answer, Defenses, and Counterclaims at para. 71, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922 (D. Colo. Nov. 5, 2018) (alleging that publicity surrounding the lawsuit resulted in damage to the relationship between defendants and their suppliers, retailers, and affiliates).

267 *See* Jihee Ahn, *Cannabis Patent Litigation Update: Is Extraction and Preparation Prior Art?*, HARRIS BRICKEN: CANNA L. BLOG (Mar. 4, 2019), https://www.cannalawblog.com/cannabis-patent-litigation-update-is-extraction-and-preparation-prior-art/ [https://perma.cc/E36N-TDDP].

268 *See id.* (stating that the illegality of marijuana to date makes it challenging for Pure Hemp to produce prior art supporting their argument).

269 *See* Defendant's Answer, Defenses, and Counterclaims, *supra* note 265, at 9.

270 *See id.*

occurring compounds are not patent eligible,[271] Pure Hemp argued that the asserted claims were invalid.[272]

Subsequently, Pure Hemp moved for partial summary judgment on the grounds that the claims in dispute are directed to patent-ineligible natural phenomena: cannabinoids and terpenes found naturally in the cannabis plant.[273] This motion invited the court to examine patent eligibility through the two-step framework most recently set forth by the Supreme Court in *Alice Corporation v. CLS Bank International* in 2014.[274] First, a court must determine whether the claims at issue are "directed to" one of the three patent-ineligible concepts: laws of nature, natural phenomena, and abstract ideas.[275] If the answer is "yes," then the court must ask whether the claims at issue nonetheless offer an "inventive concept."[276]

In opposition to this motion, UCANN argued that "the claims are not directed to laws of nature or natural phenomena because they claim human-modified liquid formulations that require converting solid cannabinoids into a different state with markedly different physiological characteristics."[277] The court agreed.[278] In doing so, the court did not reach the second part of UCANN's assertion concerning physiological characteristics of the liquid formulation.[279]

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271 *See* Mayo Collaborative Servs. v. Prometheus Lab'y, Inc., 566 U.S. 66, 70 (2012).

272 *See* Defendant's Answer, Defenses, and Counterclaims, *supra* note 265, at 9 (stating that "UCANN is intentionally asserting patent claims that are clearly invalid, which is an unreasonable and bad faith restraint on trade").

273 *See* Defendant's Early Motion for Partial Summary Judgment at 1, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922 (D. Colo. Nov. 29, 2018).

274 *See* Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 217 (2014) (laying out the two-step framework for distinguishing patents that claim ineligible subject matter from those that claim patent-eligible applications of said ineligible subject matter).

275 *See id.* at 218.

276 *See id.* at 221.

277 *See* United Cannabis' Opposition Brief to Pure Hemp Collective's Early Motion for Partial Summary Judgment at 7, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922 (D. Colo. Dec. 31, 2018).

278 *See* Order Denying Defendant's Early Motion for Partial Summary Judgment at 13, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922 (D. Colo. Apr. 17, 2019).

279 *See id.*

Specifically, the court stated that, "Pure Hemp has failed to establish beyond genuine dispute that a liquefied version of cannabinoids and related chemicals at the concentrations specified in the '911 Patent is anything like a natural phenomenon."[280]

Finding that the claims at issue were directed to "a non-naturally occurring delivery method of naturally occurring chemicals in . . . non-naturally occurring proportions and concentrations," the court did not reach the second *Alice* inquiry.[281] Following the court's denial of its motion for partial summary judgment, Pure Hemp sought to expand the scope of the claim construction briefing, challenging the validity of a certificate of correction.[282] UCANN acquired a certificate of correction for a claim in the '911 patent with an alleged typo, which Pure Hemp argued improperly broadened the scope of the asserted claims.[283] On May 22, the Court denied Pure Hemp's attempt to explain invalidity and found that "it is more appropriate for Defendant to raise, and the Parties to brief, the issue of the validity of the certificate of correction in the context of a motion for

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280 *See id.*

281 *See id.*

282 *See* Motion for Leave to Brief the Invalidity of Certificate of Correction for U.S. Patent No. 9730911 in Conjunction with Claim Construction filled by Pure Hemp Collective Inc., United Cannabis Corp. v. Pure Hemp Collective Inc., No. 1:18-cv-01922, at 1 (Apr. 29, 2019). A claim construction brief, otherwise known as a *Markman* brief, is generally used to clarify the scope of a patent claim, i.e., the scope of the invention, through defining some of its terms. For guidance on submitting a certificate of correction, see 35 U.S.C. § 255, which states:

> Whenever a mistake of a clerical or typographical nature, or of minor character, which was not the fault of the Patent and Trademark Office, appears in a patent and a showing has been made that such mistake occurred in good faith, the Director may, upon payment of the required fee, issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination. Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.

283 *See* Motion for Leave to Brief, *supra* note 282, at 1.

summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure."[284] Accordingly, this case was set to proceed to trial.[285] This was so until April 20, 2020, when UCANN filed a Chapter 11 bankruptcy petition in Colorado.[286] Judge William J. Martinez administratively closed the infringement case against Pure Hemp, while Pure Hemp's counterclaims were automatically stayed.[287] Since this case was the first marijuana-related patent infringement case, it had major ramifications for the industry and had the potential to shape how federal courts treat such patents for years to come.[288]

Unfortunately, unable to reorganize its finances under the federal bankruptcy law, UCANN had to drop its case against Pure Hemp, leaving a host of questions unanswered.[289]

For example, had this action been reopened, Pure Hemp could still challenge the validity of the '911 patent on several grounds. While invalidity challenges based on novelty and obviousness were likely to face the same prior art issues stated above, the '911 patent was still vulnerable to enablement and definiteness challenges.[290] The broadness of the '911 patent claims made them particularly prone to definiteness challenges.[291] In fact, many intellectual property

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284 Order Denying Defendant's Opposed Motion for Leave, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922, at 6 (May 22, 2019).

285 *See* Ahn, *supra* note 267.

286 *See* Chapter 11 Voluntary Petition for Non-Individual at 1, *In re* United Cannabis Corp., No. 1:20-bk-12692 (Bankr. D. Colo. Apr. 20, 2020).

287 *See* Order Administratively Closing the Infringement Action, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922 (Apr. 21, 2020).

288 *See* Cheryl Miller, *Why Patent Lawyers Are Watching This Colorado Cannabis Case*, THE RECORDER (Aug 8, 2018), https://www.law.com/therecorder/2018/08/08/why-patent-lawyers-are-watching-this-colorado-cannabis-case/?slreturn=20190414181648 [https://perma.cc/57XR-8K2U].

289 *See* Stipulation of Dismissal by Plaintiff at 1, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 1:18-cv-01922 (D. Colo. March 31, 2021).

290 *See* 35 U.S.C. § 112.

291 *See* '911 Patent (Independent claim 1 is an example of the broadness of the '911 Patent claims which reads in its entirety: "A liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids is tetrahydrocannabinolic acid (THCa)").

scholars had strong opinions on the validity of the '911 patent claims arguing that the patent may not withstand definiteness challenges.[292]

UCANN's Chapter 11 bankruptcy petition itself brought about another test case for the industry.[293] In particular, because UCANN's patent involved THC, suggesting that its business debts were "incurred to further criminal conduct," United States Bankruptcy Trustee for Region 19 argued that UCANN's bankruptcy filing should be dismissed.[294] An argument that likely was found persuasive because on January 12, 2021 Judge Joseph Rosania dismissed the case.[295] This Order did not set forth Judge Rosania's reasons for dismissing the case but based on his Order to Show Cause he dismissed the case at least in part because "[d]espite being legal under state law, activities associated with the marijuana industry are illegal under federal law and cannot be condoned by the bankruptcy courts."[296]

This dismissal highlights the far-reaching consequence of disharmony between federal and state law in this context.

C. REMEDIES FOR INFRINGEMENT OF A MARIJUANA-RELATED PATENT

UCANN v. Pure Hemp provided many issues of first impression and was closely watched by major players, such as Coca-Cola and Molson Coors, who may

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[292] Amanda C. Maxfield, *Intellectual Property Survey: Cannabis Plant Types, Methods of Extraction, IP Protection, and One Patent That Could Ruin It All*, 3 OHIO STATE U. DRUG ENF'T & POL'Y CTR., May 2019, at 8.

[293] *See Biggest Risks Facing Cannabis Businesses*, *supra* note 20; *see also* Diana Novak Jones, *United Cannabis Corp. Files for Ch. 11 In Colo.*, LAW360 (Apr. 21, 2020), https://www.law360.com/articles/1265959/united-cannabis-corp-files-for-ch-11-in-colo- [https://perma.cc/ML23-GNW2].

[294] *See* Jesse Mondry, *Cannabis Litigation: U.S. Trustee in UCANN Bankruptcy Requests Marijuana Patent Infringement Case Dismissal*, HARRIS BRICKEN: CANNA L. BLOG (June 23, 2020), https://harrisbricken.com/cannalawblog/cannabis-litigation-u-s-trustee-in-ucann-bankruptcy-requests-marijuana-patent-infringement-case-dismissal/ [https://perma.cc/D53M-MXWY].

[295] *See* Order Granting the United States Trustee's Motion to Dismiss Chapter 11 Cases, *In re* United Cannabis Corp., No. 1:20-bk-12692 (Bankr. D. Colo. Jan. 12, 2021).

[296] *See* Order to Show Cause, *In re* United Cannabis Corp., No. 1:20-bk-12692 (Bankr. D. Colo. Apr. 22, 2020).

want to enter the market for formulations containing CBD or THC.[297] Perhaps the most interesting question of all, in view of the following bankruptcy courts' dismissal, was how a federal judge would determine a remedy for a practice that could constitute a violation of federal law. Under Sections 283 and 284 of the Patent Act, upon a finding of infringement, a court may grant an injunction or grant the patent owner compensatory damages in the form of either lost profits or reasonable royalty.[298]

To recover lost profits, the patent owner must show that, but for the alleged infringement, it would have earned the additional profits associated with practicing the patent.[299] This inquiry alone is problematic because it implies not only that the patent owner has broken the law by practicing the patent-in-suit, but also that it would have done so even more. In a sense, a grant of lost profit damages by the federal court amounts to endorsing such conduct. This is contradictory to the federal courts' responsibility of assuring compliance with the United States' laws and punishing those in violation even if courts do not have a duty to go out of their way to punish outside the criminal context.[300]

A remedy based on a reasonable royalty raises similar concerns. Although a grant of a reasonable royalty does not presume that the patent owner would have captured the market share associated with the practice of the patent, it implies that the patent owner is entitled to a market-dictated rate.[301] To determine the value of

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297 *See* Jen Skerritt & Craig Giammona, *Coca-Cola is Eyeing the Cannabis Market*, BLOOMBERG (Sep. 17, 2018), https://www.bloomberg.com/news/articles/2018-09-17/coca-cola-eyes-cannabis-market-in-push-beyond-sluggish-sodas#:~:text=Open ,Aurora%20Cannabis%20Inc.,products%20as%20traditional%20sales%20slow [https://perma.cc/W4YG-ACDL] (stating that Coca-Cola is monitoring the case and has an interest in drinks infused with CBD).

298 *See* 35 U.S.C. §§ 283–284 (2018); Lucent Tech., Inc. v. Gateway, Inc., 580 F.3d 1301, 1304 (Fed. Cir. 2009).

299 *See* Zelin Yang, *Damaging Royalties: An Overview of Reasonable Royalty Damages*, 29 BERKELEY TECH. L.J. 647, 647 (Aug. 1, 2014).

300 *See* U.S. CONST. art. III, § 2 ("The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority.").

301 *See* Mark A. Lemley, *Distinguishing Lost Profits from Reasonable Royalties*, 51 WM. & MARY L. REV. 655, 661 (2009) (explaining that reasonable royalty case law inquires into what the market would actually pay to license rights and that these remedies are very different from a patentee seeking lost profits from maintaining a monopoly).

reasonable royalty damages, courts generally use the fifteen factors set forth in *Georgia-Pacific v. United States Plywood Corp.* by the District Court for the Southern District of New York.[302]

A majority of these factors are factual and concern a patent owner's conduct. For example, these factors ask about patent owners' licensing practice not only for the patent at issue but for comparable patents also. Similarly, the utility of the patent and profitability of commercial products embodying the patents are considered.[303] Inquiring into each factor and awarding a reasonable royalty based on such inquiry, presents interesting questions concerning federal courts' willingness to turn a blind eye to the illegality of marijuana.

D. MARIJUANA-RELATED PATENTS AND PATENT ASSERTION ENTITIES

Apart from the absence of prior art during both prosecution and litigation of marijuana-related patents, pleading shortcomings, and the issues associated with the grant of relief, marijuana-related patents pose additional policy concerns. In particular, marijuana-related patents may have the potential to lend themselves to frivolous lawsuits. Some scholars believe that Patent Assertion Entities ("PAE") have been posing a problem for United States' businesses for decades.[304] A PAE, alternatively, a "non-practicing entity" or a "patent troll," is generally a non-inventor entity that secures patent portfolios for the sole purpose of extorting revenue through litigation rather than for creating products or protecting its intellectual property.[305] PAEs use their unduly broad patents to bring patent

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302 *See* Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) (stating that the court set out 15 factors to determine the value of reasonable damages).

303 *See id.* at 1120 (considering the utility and profitability of the patent in factor 8 and 9).

304 *See* Prachi Agarwal, *Patent Troll: The Brewing Storm of Patent Reform in the United States of America*, 15 J. MARSHALL REV. INTELL. PROP. L. 63, 66 (2015) (stating that PAEs take advantage of the fact that legal defense costs are much higher than settlement demands and that PAEs use this to their advantage to extort large sums of money from honest businesses).

305 *See* FED. TRADE COMM'N, *supra* note 252, at 15 (Oct. 2016) (stating that PAEs are entities who acquire patents solely to institute lawsuits against infringers).

infringement actions against businesses with products or innovations that are similar to the patents owned by the PAE.[306]

PAEs generally seek a "licensing fee" from small- and mid-size businesses that do not have the resources to face them in court.[307] This problem is particularly prevalent in the software and technology space because of the potential breadth of these patents in comparison with mechanical patents.[308] A recent study found that patent infringement lawsuits have increased by a factor of ten and that PAEs are responsible for nearly two-thirds of that increase.[309] The same study demonstrates that PAEs can influence unemployment and play a significant role in securing venture capital funding.[310]

Yet there is disagreement among scholars about the impact of PAEs on innovation:

Some claim that PAEs are antithetical to the Constitution's mandate that the patent laws encourage innovation. They argue that PAEs hinder rather than encourage innovation, especially in the software field. Others claim that PAEs provide small inventors and companies an opportunity otherwise missing to receive rewards for their inventions.[311]

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306 *See id.* at 14, 57–58 (suggesting that PAEs tend to pick lawsuit target companies whose products are similar to the patents they own, and some patents are overly broad).

307 *See* Jay Walker, *Our System is so Broken, Almost No Patented Discoveries Ever Get Used*, WIRED (Jan. 5, 2015), https://www.wired.com/2015/01/fixing-broken-patent-system/ [https://perma.cc/MW68-REZD] (stating that PAEs pick on small businesses who can't afford litigation).

308 *See* James Bessen, *The Patent Troll Crisis is Really a Software Patent Crisis*, WASH. POST (Sept. 3, 2013), https://www.washingtonpost.com/news/the-switch/wp/2013/09/03/the-patent-troll-crisis-is-really-a-software-patent-crisis/ [https://perma.cc/BA8D-BMBU] (explaining that the patent troll problem is prevalent in the software industry because software patents are overly broad).

309 *See* Ian Appel et al., *Patent Trolls and Startup Employment*, 133 J. FIN. ECON. 708, 708–11 (2019) (stating that patent litigation has increased tenfold since 2005 and that NPEs constitute 69% of it).

310 *See id.* at 724 ("[F]ollowing the adoption of anti-troll legislation, employment at high-tech startups in a state increases by 4.4%—an increase that is driven by firms in the IT sector, where NPEs are most active.").

311 *See* David L. Schwartz & Jay P. Kesan, *Analyzing the Role of Non-Practicing Entities in the Patent System*, 99 CORNELL L. REV. 425, 427 (2014).

Surely, in some circumstances, patent infringement suits by PAEs provide patent owners with the opportunity to reap the fruits of their labor by suing infringers for the fair value of their innovation. For example, a patent infringement action provides a university's tech transfer office with the means to secure the fair value of its patented innovation even though it is technically a PAE.[312] In other cases, however, infringement action by PAEs can negatively impact small- and mid-size businesses.[313] Such lawsuits, for example, can take away "valuable time and money from the business to evaluate the claims and engage legal counsel to address the assertions."[314]

PAEs can pose a real problem in the context of marijuana-related patents for two reasons. First, in addition to the risk of losing when fighting a frivolous patent infringement action, PAEs could force businesses into settlement because of the risk of incrimination. PAEs, by definition, do not practice their patented innovation and thereby are not in violation of the federal drug laws.[315] This provides them with an advantage against the opposing party who is likely engaged in the sale, cultivation, or processing of marijuana in violation of federal laws. PAEs could use this moral high ground to their advantage and strong-arm businesses for "licensing fees" even though they would not be entitled to relief had the case gone to trial.

Second, PAEs can take advantage of the difficulties associated with invalidating a marijuana-related patent. As stated above, a common strategy for defendants in patent infringement actions is to attempt to invalidate the patent.[316] Particularly, defendants often attempt to invalidate patents based on lack of

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312 *See* Mark A. Lemley, *Are Universities Patent Trolls?*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611, 612 (2008) (arguing that universities should not be deemed trolls).

313 *See* Minda Zetlin, *Patent Trolls Target Small Businesses with Lawsuit Threats. Here's How One Startup Fought Back*, INC. (Feb. 22, 2018), https://www.inc.com/minda-zetlin/patent-trolls-target-small-businesses-with-lawsuit-threats-heres-how-one-startup-fought-back.html [https://perma.cc/NQ5T-ZJQG] (suggesting that patent infringement suits may be a huge cost for small businesses).

314 *See id.*

315 Since patent trolls do not practice their patented innovation, they are not entitled to lost profit damages. As such, if their patent is found valid and infringed, the granted relief is usually reasonable royalty. *See* 35 U.S.C. § 284 (stating that the damage award for infringement is reasonable royalty).

316 *See* Ford, *supra* note 238, at 73.

novelty or obviousness.[317] Because of the lack of substantial prior art, however, defendants in this area may find it difficult to invalidate patents.[318] If defendants fail to invalidate patents, their chance of losing the case is substantially higher. Therefore, they may resort to settling more frequently than they otherwise would have.

V. CONCLUSION

The interface between the Patent Act and the CSA raises many interesting questions. Given some of the discrepancies between federal agencies' treatment of marijuana and its medical benefits, it is challenging to accept that the Patent Act and the current American marijuana regime, as represented by the CSA and discordant state marijuana laws, harmonize. Yet the status quo suggests that, as far as the USPTO is concerned, marijuana products and processes are patentable if they satisfy the statutory patentability requirements. Enforcement of such patents is a different question and raises even more interesting issues of first impression. Assuming that marijuana-related patents are duly granted and that the plaintiffs and the defendants have both secured competent legal counsel, a federal court's grant of a relief in a marijuana-related patent infringement action, could signal, by proxy, its endorsement of such conduct. Conversely, given that patents only vest in the owners a right to exclude, a federal court's grant of relief in a marijuana-related patent infringement action could be considered just that—relief anchored in property rights.

The debate regarding whether PAEs hinder innovation or provide inventors and small companies with a fighting chance against large corporations is not directly mirrored in the marijuana patent context. While a marijuana-related patent infringement action by a PAE, does provide the patentee with an opportunity to reap the benefit of its labor, it may also incentivize frivolous lawsuits directed at extracting settlements because of the incrimination risk. Absent statutory, judicial, or regulatory guidelines the problem associated with the PAEs may intensify as more states legalize marijuana and big corporations enter the market.

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317 *See generally* 35 U.S.C. §§ 102–103 (stating that a patent cannot be obtained if it is obvious or lacks novelty, but without substantial prior art it may be difficult to prove in an infringement suit that an issued patent is nonobvious or is not novel).

318 *See* Abrams & Sampat, *supra* note 74, at 5.

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NOTE

TRAGEDY OF THE COMMONS: WHY THE SUPREME COURT'S LITERAL APPLICATION OF "PRODUCT OF NATURE" RULE IN *AMP V. MYRIAD GENETICS* NECESSITATES A LEGISLATIVE CHANGE TO 35 U.S.C. § 101

*Henry Loznev**

 I want to thank my family and my dog "Nika" for their immense support and encouragement in the writing process.

I. INTRODUCTION

> *The end of law is not to abolish or restrain, but to preserve and enlarge freedom. For in all the states of created beings capable of law, where there is no law, there is no freedom.*
>
> - *John Locke*

In the famous article "The Tragedy of Commons," Garrett Hardin, an ecologist, addressed the issue of over-exploitation of shared resources by both humans and animals acting in rational self-interest.[1] Hardin advocated for a fundamental extension to morality by establishing clear boundaries for resources that private individuals may use to preserve the entire society's optimal consumption for years to come.[2] Patent systems throughout the world were established, in part, to address this issue by reserving a "plot" for inventors who first discover a new finding.[3] This "plot" incentivizes further investment into new research and prevents the benefits of recent inventions from spreading throughout the society without rewarding the inventors.[4]

While the most popular theory supporting the U.S. patent system stems from the utilitarian perspective,[5] this Note argues for the application of John Locke's labor theory to avoid "the tragedy of commons" with respect to specific fields of science and to conform with the foundational principles of the U.S. property system by providing the U.S. Patent and Trademark Office ("USPTO") with a power to establish different requirements for patent applications from various fields of science. While some parts of this Note may seem to argue for a complete abolishment of non-statutory exceptions to § 101, this Note only analyzes

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1 *See* Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243, 1243 (1968) (discussing the downfall of societies from uncontrolled use of natural resources).

2 *See id.*

3 *See* Michael Reda, *The Tragedy of the Commons*, GOV.UK: INTELL. PROP. OFF. BLOG (Jan. 10, 2014), https://ipo.blog.gov.uk/2014/01/10/the-tragedy-of-the-commons/ [https://perma.cc/8MDZ-EYBV] (addressing the necessity of government incentives for patents as a tool to avoid tragedy of commons).

4 *See id.*

5 *See* William Fisher, *Theories of Intellectual Property*, *in* NEW ESSAYS IN THE LEGAL AND POL. THEORY OF PROP. 168, 169 (Stephen R. Munzer ed., Cambridge Univ. Press 2001).

the negative implications of the "natural product" exception used in *Association for Molecular Pathology v. Myriad Genetics*.[6]

II. BACKGROUND

Since their inception, the United States government and the Constitution that guides our day-to-day lives are entrusted with preserving the traditions of liberty and equality for us, and our posterity, ever-changing as our understanding of morals and freedoms evolve.[7] These somewhat amorphous ideals arose long before the United States was established.[8] They have been analyzed in-depth by John Locke, whose works have been highly influential in guiding our founding fathers' perception of a just government.[9] His ideals on how governments can adapt the concepts of liberty and private property to improve their citizens' livelihood became the core of our Constitution.[10] Legal scholar Louis Hartz states that the American democracy is a "society which begins with Locke, and thus transforms him, stays with Locke, by virtue of an absolute and irrational attachment it develops for him . . . ."[11] To this day, many scholars consider the United States as a "Lockean nation."[12]

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[6] *See infra* Part III; Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

[7] *See* Wilson Huhn, *Mill's Theory of Liberty in Constitutional Interpretation*, 22 AKRON L. REV. 133, 146–47 (1989) (discussing the ultimate role of the Constitution as a conduit to society's ever-changing understanding of morals and freedoms and reiterating its importance in preservation of said freedoms).

[8] *See Individual Freedom and Rights*, UKESSAYS (Nov. 2018), https://www.ukessays.com/essays/philosophy/individual-freedom-and-rights-philosophy-essay.php [https://perma.cc/789F-HCQV] (analyzing various historical interpretations of individual freedom and rights).

[9] *See* Gianna Englert, *Liberty and Industry: John Locke, John Stuart Mill, and the Economic Foundations of Political Membership*, 48 POLITY 551, 551 (2016) (expanding on the role of John Locke in influencing founding fathers' aspiration to create a "free and just" nation and how his theories were incorporated into the U.S. Constitution).

[10] *See id.* at 556.

[11] LOUIS HARTZ, THE LIBERAL TRADITION IN AMERICA 6 (1955) (discussing the importance of Locke's liberal traditions for American democracy).

[12] *See* GEORGE MACE, LOCKE, HOBBES AND THE FEDERALIST PAPERS: AN ESSAY ON THE GENESIS OF THE AMERICAN POLITICAL HERITAGE 9 (1979) (emphasizing the importance of John Locke as a prominent philosopher in America and

Most prominently (for the purposes of this Note), John Locke's labor theory formed the foundation of the American property system.[13] His theory was even used as a justification for settlers to take the land from Native Americans.[14] As long as the settlers were adding a substantial value to a plot of land, they were given the title to it.[15] Despite being interpreted to justify this inhumane practice, Locke's philosophy forbade claiming undeveloped land.[16] Over the years, Locke's writings on "labor theory" remained a prominent part of our current understanding of private property and, by extension, intellectual property in the United States.[17] For example, Locke's spoilage proviso of the labor theory warns against "appropriating more than one can make use of" and it has been applied to this day to abandoned buildings and their potential use by people other than the legal owner.[18] This theory is adhered to in many states by providing such "squatters" with an ability to convert the title to property through adverse possession if they lived and operated these properties long enough to be their constructive owners.[19]

Before we address the analysis of the Supreme Court's expansion of the "natural product" exception to 35 U.S.C. § 101 in *Association for Molecular Pathology*

England); *see also* George Thomas, *John Locke's America*, 50 SOCIETY 464 (2013) (addressing the influence John Locke's philosophy has on Americans to this day).

13 *See* BARBARA ARNEIL, JOHN LOCKE AND AMERICA: THE DEFENCE OF ENGLISH COLONIALISM 132 (Oxford Scholarship Online 2011) (discussing the justification of English and early American colonialism from the perspective of Locke's philosophies).

14 *See id.* at 135.

15 *See id.* at 138, 141.

16 *See* John Kane, *Man the Maker Versus Man the Taker: Locke's Theory of Property as a Theory of Just Settlement*, 3 EIGHTEENTH CENTURY THOUGHT 235 (2007) (discussing the peculiar adaptation of Locke's theories used to justify taking Indian Land).

17 *See* JAMES V. DELONG, PROPERTY MATTERS: HOW PROPERTY RIGHTS ARE UNDER ASSAULT – AND WHY YOU SHOULD CARE 31 (1997) (describing the origins of property law in Locke's writings).

18 *See* Eloise Harding, *Spoilage and Squatting: A Lockean Argument*, 26 RES PUBLICA 299, 299 (2020) (addressing the philosophical underpinnings of John Locke's labor theory as a justification to giving property titles to squatters).

19 *See* D. MacIntyre, *Adverse Possession of Land*, 34 CAMBRIDGE L.J. 32 (1975) (explaining the concept of adverse possession).

v. Myriad Genetics, we should note the historical background that led the Supreme Court to their decision.[20] Throughout the remainder of the background section, this Note will briefly address: (a) John Locke's background and his philosophy of labor theory;[21] (b) John Locke's influence on the founding fathers when they wrote the U.S. Constitution;[22] (c) the origins of 35 U.S.C. § 101;[23] (d) the development of judicial exceptions to 35 U.S.C. § 101;[24] and (e) the factual background of *AMP v. Myriad Genetics*.[25]

A. JOHN LOCKE AND LABOR THEORY

John Locke was a British philosopher born on August 29, 1632, in Wrington, England, and who died on October 28, 1704, long before the Thirteen Colonies established the United States of America and rebelled against British rule.[26] Yet, there was a fair share of abuse of monarchy powers witnessed by Locke during his upbringing.[27]

When Locke was just ten years old, his father joined the parliamentarians led by Oliver Cromwell to prevent British King Charles I from governing without the elected parliament's influence.[28] At the time, the Puritans, who later settled in North America, predominantly supported Cromwell in his endeavor.[29] One can

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20 For more information, *see* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

21 *See infra* Section II.B.

22 *See id.*

23 *See infra* Section II.C.

24 *See infra* Section II.D.

25 *See infra* Section II.E.

26 *See* Graham A.J. Rogers, *John Locke*, BRITANNICA (July 20, 1998), https://www.britannica.com/biography/John-Locke [https://perma.cc/X3YB-QWTF] (describing John Locke's biography and, particularly, focusing on his conflict with the ideas of absolutism and monarchy that were prominent in England at the time).

27 *See id.*

28 *See id.*; *English Civil Wars*, HISTORY (Sept. 20, 2021), https://www.history.com/topics/british-history/english-civil-wars [https://perma.cc/XW8X-V2BN] (discussing the history of Oliver Cromwell's uprising).

29 *See* Carla Pestana, *The English Civil Wars and Virginia*, ENCYCLOPEDIA VIRGINIA (Dec. 7, 2020), https://encyclopediavirginia.org/entries/english-civil-wars-

argue that their distaste for monarchy started developing during that revolution.[30] Likewise, according to Professor Rogers of Keele University, "one may thus assume, Locke rejected any claim by the king to have a divine right to rule."[31]

Locke's early writings established his perspective on the law of nature, "a natural moral law that underpins the rightness or wrongness of all human conduct, and, . . . his subscription to the empiricist principle that all knowledge, including moral knowledge, is derived through experience and not innate."[32] Later in life, Locke further developed a comprehensive theory of private property called "Labor theory."[33] He theorized that goods exist in nature through the act of God, and the only way for people to truly achieve ownership over these goods is through labor necessary for their extraction.[34] Locke believed that only through the exertion of labor, individuals could appropriate goods and, by definition, labor would be a limiting factor, ensuring that the natural state of the environment, gifted to us by God, remains in common ownership, all while the fruits of labor are awarded to those that deserve such.[35]

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and-virginia-the/ [https://perma.cc/7J7Q-34L7] (addressing the potential influence English civil war had on the American revolutionaries).; Maurice Ashley, *Oliver Cromwell*, BRITANNICA (July 28, 1999), https://www.britannica.com/biography/Oliver-Cromwell/additional-info#history [https://perma.cc/TD29-KSVA] (describing the establishment of a Puritan Church as one of Oliver Cromwell's primary goals); Emory Elliott, *Divining America: The Legacy of Puritanism*, NAT'L HUMANS.CTR.: TEACHERSERVE, http://nationalhumanitiescenter.org/tserve/eighteen/ekeyinfo/legacy.htm [https://perma.cc/6P94-RKQ3] (discussing Puritan settlement of colonial America and describing their influence on United States as integral to the "American identity").

30 *See* Steven Kreis, *Lecture 7: The English Civil War*, HISTORY GUIDE (2002), http://www.historyguide.org/earlymod/lecture7c.html [https://perma.cc/R75Q-L8AF].

31 Rogers, *supra* note 26.

32 *Id.*

33 *See* John Locke, *Essay Two: Concerning the True Original Extent and End of Civil Government*, *in* TWO TREATISES OF GOVERNMENT 105, 116 (P. Laslett rev. ed. 1963 3d ed. 1698).

34 *See id.*

35 *See id.* at 119.

B. JOHN LOCKE'S INFLUENCE ON FOUNDING FATHERS AND THE PROPERTY THEORY

The founding fathers of the United States have taken Locke's philosophies close to their hearts.[36] At the time, Locke and his writings were contrary to the very essence of monarchy and absolutism; the drafters of our Constitution were deeply influenced by his ideals as they themselves succeeded in overthrowing the reign of the British crown.[37] To this day, Locke's writings serve as one of the primary sources for philosophical justifications behind the protections from unjust government actions afforded to citizens.[38] Thomas Jefferson, for example, viewed Locke as one of "the three greatest men the world had ever produced."[39] Therefore, it is not surprising that these ideals of private property and liberty for individuals to "claim the fruits of their labor" were further codified in our Constitution.[40]

Despite the ever-more secular nature of our country, Locke's ideas regarding private property still carry a lot of weight even in modern property legislation.[41] This is the most evident in the drafting of the Takings Clause from the Fifth Amendment.[42]

The Takings Clause establishes that "private property [shall not] be taken for public use, without just compensation."[43] James Madison, the founding father responsible for writing the Takings Clause, was deeply influenced by Locke's ideas during the process.[44] Mainly, Madison believed that Locke's views of the

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36 *See* Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287, 296–300 (1988) (discussing the importance of Locke's writings for the development of the U.S. property theory).

37 *See id.*

38 *See* Jeffrey Koehlinger, *Substantive Due Process Analysis and the Lockean Liberal Tradition: Rethinking the Modern Privacy Cases*, 8 IND. L.J. 723, 724 (1990) (discussing the Lockean origins of Due Process).

39 *See* Robert Wernick, *At Monticello, a Big Birthday for the Former Owner*, 24 SMITHSONIAN, MAY 1993, at 2.

40 *See id.*

41 *See* Jeffrey M. Gaba, *John Locke and the Meaning of the Takings Clause*, 72 MO. L. REV. 525, 526–28 (2007).

42 *See id.*

43 U.S. CONST. amend. V.

44 *See* William Michael Treanor, *The Origins and Original Significance of the Just Compensation Clause of the Fifth Amendment*, 94 YALE L.J. 694, 708–12 (1985)

property system developed from the "diversity in the faculties of men" and that "protection of these faculties is the first object of government."[45] These beliefs were the primary reason Madison included the Takings Clause in the Constitution, substantially limiting the government's control over private property.[46] For this reason, the discussion of private property rights within the U.S. Constitution cannot proceed without an acknowledgment of the rights afforded by the Takings Clause to people located within the United States and its territories.[47]

In light of this, the Supreme Court has consistently recognized that patents are property rights protected by the Takings Clause of the Constitution.[48] Although intellectual property is intangible, it is a subcategory of real property and abides by the vast majority of real property statutes and philosophies.[49] Since the creation of the first patent statutes, they act as a tool to recognize intangible property rights earned by inventors who invested their labor in discovering new and useful products.[50]

Locke's philosophies behind the protection of property rights of individuals who have invested time and labor into their projects can be traced in Congress' grant of power to the government to issue patents in order "[t]o promote the Progress of Science and useful Arts."[51] All branches of the

(discussing the history of the adoption of the Takings Clause and outlining Madison's views on John Locke and his philosophies).

45 THE FEDERALIST NO. 10 (James Madison).

46 *See id.*; *see also* William Michael Treanor, *The Original Understanding of the Takings Clause*, GEO. ENV'T L. & POL'Y INST. PAPERS & REPS. (1998) (elaborating on the proposition that James Madison unilaterally included the Takings Clause in the amendments, likely due to his concern regarding the physical seizure of property).

47 *See* Dennis Crouch, *Cancelling Pre-AIA patents and the Takings Clause*, PATENTLY-O (Apr. 23, 2020), https://patentlyo.com/patent/2020/04/cancelling-patents-takings.html [https://perma.cc/4SSQ-476].

48 *See id.*

49 *See* Sudhir Ravindran, *Real Property vs Intellectual Property*, ALTACIT GLOBAL, https://www.altacit.com/ip-management/real-property-vs-intellectual-property/ [https://perma.cc/GR5D-LZVD].

50 *See* Fisher, *supra* note 5, at 168.

51 U.S. CONST. art. I, § 8, cl. 8; *see* 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

government had consistently recognized the importance of this power; President Lincoln, for example, noted that: "[T]he inventor had no special advantage from his own invention. The patent system changed this . . . and thereby added the fuel of *interest* to the *fire* of genius, in the discovery and production of new and useful things."[52]

Throughout our judicial history, the Supreme Court has often cited this incentive for inventors to produce discoveries as the primary purpose of patent law.[53] Unfortunately, our judicial system has recently neglected the original goal of promoting useful inventions.[54] The wording of the current version of 35 U.S.C. § 101 forced the court to recognize exceptions to potentially patentable inventions that were likely not foreseen by the original drafters of the Constitution.[55]

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effort by personal gain is the best way to advance public welfare through the talents of authors and inventors.")

[52] ABRAHAM LINCOLN, *Second Lecture on Discoveries and Inventions*, *in* 3 COLLECTED WORKS OF ABRAHAM LINCOLN 356, 363 (Roy P. Basler et al. eds., 1953) [hereinafter COLLECTED WORKS] (discussing patent law and its importance in promoting scientific innovations amongst American inventors); *see also* Goldstein v. California, 412 U.S. 546, 555 (1973) ("[T]o encourage people to devote themselves to intellectual and artistic creation, Congress may guarantee to authors and inventors a reward"); USPTO, REPORT TO CONGRESS PURSUANT TO P.L. 115-273, THE SUCCESS ACT 14–15 (2019), https://www.uspto.gov/sites/default/files/documents/USPTOSuccessAct.pdf [https://perma.cc/9DYY-5MWT] (describing the benefits that patents afford to inventors).

[53] *See, e.g.*, Zacchini v. Scripps-Howard Broad. Co., 433 U.S. 562, 576 (1977) ("The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of dividual effort . . . ."); *see also Goldstein*, 412 U.S. at 555.

576; United States v. Paramount Pictures, Inc., 334 U.S. 131, 158 (1948) ("reward to the author or artist serves to induce release to the public of the products of his creative genius").

[54] *See* Lisa Larrimore Ouellette, *Patentable Subject Matter and Nonpatent Innovation Incentives*, 5 U.C. IRVINE L. REV. 1115, 1116-18 (2015) (discussing how the recent judicial decisions discourage the confidence of researchers and investors).

[55] *See infra* Section II.D; Paul Morinville, *If Exceptions to 101 are Codified, Patent Eligibility Chaos Will Be Worse*, IP WATCHDOG (Apr. 23, 2019, 2:15 PM), https://www.ipwatchdog.com/2019/04/23/if-exceptions-to-101-are-codified-patent-eligibility-chaos-will-be-worse/id=108516/ [https://perma.cc/4RPW-UE2S] (discussing the potential dangers of codifying the judicial exceptions

C. ORIGINS OF 35 U.S.C. § 101

In their unanimous opinion for *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court stated that: "Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."[56] This is a clear departure from the literal wording of 35 U.S.C. § 101, which states that: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[57] To fully understand the reasons behind this seeming departure by the Supreme Court from the literal wording of the statute, it is worth looking into the statute's extensive legislative history and the common law precedents of its interpretation.

The Patent Act of 1790 serves as the foundation for the legislative history of the statute.[58] Then, Congress used its constitutional powers to establish what patents are and the qualifications for the government to award them.[59] At the time of its creation, the Patent Act stated that: "he, she, or they, hath or have invented or discovered any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used [is entitled to a patent]."[60] The Act mandated that inventions or discoveries were useful and novel for the government to enforce patents associated with them.[61] In accordance with John Locke's labor theory, the Act rewarded individuals who took possession of a new and useful invention or discovery with federally enforced patents.[62]

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to 35 U.S.C. § 101 as they are likely to severely limit the patentable matters and incentivize U.S. firms to relocate into foreign markets).

56 *Myriad*, 569 U.S. at 591.

57 35 U.S.C. § 101.

58 *See* Patent Act of 1790, ch. 7, 1 Stat. 109 (current version at 35 U.S.C. § 101 (2012)).

59 *See id.*; Jessie Kratz, *Inventing in Congress: Patent Law Since 1790*, NAT'L ARCHIVES: PIECES OF HIST. (Mar. 11, 2015), https://prologue.blogs.archives.gov/2015/03/11/inventing-in-congress-patent-law-since-1790/ [https://perma.cc/PEB9-U7SA].

60 Patent Act of 1790 § 1.

61 *See* Sherry Knowles & Anthony Prosser, *Unconstitutional Application of 35 U.S.C. § 101 by the U.S. Supreme Court*, 18 J. MARSHALL REV. INTELL. PROP. L. 143, 148 (2018) ("The Act required that inventions had to be useful and could only be enforced if they were novel.").

62 *See id.* at 147.

The Patent Act of 1793 amended the earlier statute by removing the word "discovered" from its language.[63] Nevertheless, Dr. Anthony Prosser and Sherry Knowles, authors of a law review note from John Marshall Law School, believe that this omission may have been a mere oversight by the drafters.[64] Authors reason that "discovery," "discovered," and "discoverer" are used in the remainder of the statute without any substantial alteration.[65]

For the next forty years, the statute's language and the requirements and limitations on issuing patents remained largely the same.[66] However, the Patent Act of 1836 repealed all of the prior Patent Acts and reintroduced "discovered" into the beginning of the statute.[67] At the time, the 1836 Act stated that "any person or persons having discovered or invented any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement of any art, machine, manufacture or composition of matter" is entitled to a patent.[68]

According to Knowles and Prosser, restoring the "discoveries" language clarified that discoveries should indeed be eligible for patent protection.[69] The purpose of maintaining "discovery" to grant patents is further proven in the 1952 Patent Act hearings before the Subcommittee of the Committee on the Judiciary of the House of Representatives.[70] This leaves no question as to Congress's intent to maintain a stance that useful discoveries are entitled to patent protection.[71]

At the time, the disparity between the Supreme Court's interpretation of the statute and the congressional intent became evident in the Department of Justice's request to remove the "discovery" portion from the statute in consideration of the Supreme Court's interpretation.[72] Nevertheless, Congress decided to keep "discoveries" within the statute, considering its original

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63 Patent Act of 1793, ch. 11, 1 Stat. 318, § 1.

64 *See* Knowles & Prosser, *supra* note 61, at 148.

65 *Id.; see* Patent Act of 1793, §§ 1–10.

66 *See* Knowles & Prosser, *supra* note 61, at 148.

67 *See id.* at 149.

68 Patent Act of 1836, ch. 357, 5 Stat. 117, § 6.

69 Knowles & Prosser, *supra* note 61, at 149.

70 *See id.* at 151.

71 *See id.* at 151–52.

72 *See id.* at 151.

purpose.[73] Legislature doubled down on this idea by including "discovery" in the definition of invention in § 100 before § 101.[74]

Throughout its legislative history, § 101 adhered to Lockean ideals by maintaining that useful discoveries should be incentivized by providing researchers with patent protections.[75] Nevertheless, throughout its extensive patent litigation precedents, the Supreme Court established several exceptions that it considered not covered by the statute.[76]

D. DEVELOPMENT OF JUDICIAL EXEMPTIONS

One of the earliest U.S. Supreme Court opinions on patent eligibility in *Le Roy v. Tatham* held that patent statutes of the time, which have not changed substantially for this discussion, allowed patenting a practical application of a property discovered in nature.[77] This opinion was later supported in *O'Reilly v. Morse*, claiming that a process for making lead pipes that used a natural principle was patentable.[78] This precedent faithfully adhered to the literal wording of the statute at the time; however, the Supreme Court began reversing and expanding its interpretation of the statute by the middle of the twentieth century.[79]

In 1948, the Supreme Court issued a highly controversial opinion in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, in which it deemed newly discovered laws of nature to be ineligible for patents.[80]

> Even though [the discovery] may have been the product of skill, it certainly was not the product of invention. There is no way in which we would call it such unless we borrowed invention from the discovery of the natural principle itself . . . but we cannot so

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73 *See id.*

74 35 U.S.C. § 100; *see id.* at 153.

75 *See* Knowles & Prosser, *supra* note 61, at 147–53 (discussing the legislative history of § 101).

76 *See* Wesley D. Markham, *How to Explain the "Implicit Exceptions" to Patent-Eligible Subject Matter*, 16 VAND. J. ENT. & TECH. L. 353, 356–59 (2014) (describing the implicit exceptions to 35 U.S.C. § 101 established by the Supreme Court).

77 *See* Le Roy v. Tatham, 55 U.S. 156, 175 (1853).

78 *See* O'Reilly v. Morse, 56 U.S. 62, 117–18 (1854).

79 *See* Knowles & Prosser, *supra* note 61, at 155.

80 *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 132 (1948).

> hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed.[81]

This was the first time the Supreme Court departed from the "invention or discovery" principle outlined by the statute and determined that laws of nature cannot be patentable even if they were unknown before the discovery.[82]

In the opinion outlined by Prosser in his co-authored article: "[P]atents are used to protect commercial endeavors that have an element made by man, and thus they attempt to cover products, processes, and manufactures with commercial uses, which are almost always based on how nature works because that is the world we live in."[83] Prosser contemplated the potential difficulties the patent system may endure if the statutory exceptions continue to expand, leaving more and more inventions outside of the scope of patent incentives.[84]

The exceptions were developed even further during the *Gottschalk v. Benson* litigation.[85] Here, the Supreme Court determined that mathematical formulas, regardless of their usefulness and application, are not patent eligible simply because it is "an idea."[86] The opinion written by Justice Douglas does not address any issues of statutory construction or legislative intent analysis, but it heavily relies on the earlier precedent of *Funk Brothers*.[87] Later the Supreme Court admitted that its decision in *Gottschalk* was inconsistent with a literal reading of 35 U.S.C. § 101.[88]

Finally, in *Diamond v. Chakrabarty*, the Supreme Court outlined the three exceptions to patent eligibility that are known today: laws of nature, abstract ideas, and natural products.[89] Interestingly enough, however, the Supreme Court determined that genetically altered bacteria (despite being composed of naturally occurring DNA patterns) were still patent eligible.[90] The exceptions established by

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81 *Id.* at 132.

82 *See* Knowles & Prosser, *supra* note 61, at 156.

83 *Id.*

84 *See id.*

85 *See id.* at 157; Gottschalk v. Benson, 409 U.S. 64 (1972).

86 *See Gottschalk*, 409 U.S. at 71.

87 *See id.* at 67–68; Knowles & Prosser, *supra* note 61, at 157.

88 *See* Parker v. Flook, 437 U.S. 584, 587 (1978).

89 *See* Diamond v. Chakrabarty, 447 U.S. 303, 303–04 (1980).

90 *See id.*

this decision were not based on statutory interpretations but rather on prior precedents and the concerns with potential patent eligibility of laws of nature.[91]

These exceptions, however, created considerable confusion throughout the patent system as they did not establish a clear line between what is considered a patent ineligible law of nature and what would be a patent eligible novel application of a law of nature.[92] Since the Supreme Court's ruling in *Association for Molecular Pathology v. Myriad Genetics*, the line between the two has been blurred.[93] At this time, it is questionable if the current judicial interpretation of the statute remains true to the foundational philosophies of property and the commitment to reward inventors for new and useful applications of their discoveries or inventions.[94]

E. ASSOCIATION FOR MOLECULAR PATHOLOGY V. MYRIAD GENETICS

As innovation is driven forward by scientists and inventors, the line between what constitutes a natural product and what is a useful application of such is becoming "ever more blurry".[95] This observation is evident when considering the pharmaceutical industry.[96] With the recent advancements in the field of genetics, scientists have discovered that many of the diseases that patients encounter throughout their lives can be readily diagnosed and treated before their manifestation through detection of mutations in the human genome and subsequent use of such mutations to identify and correct issues throughout the human body.[97]

Most of these detection and treatment techniques rely on a successful extraction of patients' DNA and subsequent use of found mutations to detect

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91 *See id.*

92 *See* Markham, *supra* note 76, at 356–59.

93 *See* Knowles & Prosser, *supra* note 61, at 166.

94 *See* Yun-Han Huang, *Gene Patents: A Broken Incentives System*, 52 J. RELIGION & HEALTH 1079, 1079 (2013).

95 *See Blurring the Line Between Natural and Artificial*, EVOLUTION NEWS (Mar. 13, 2020, 5:11 AM), https://evolutionnews.org/2020/03/blurring-the-line-between-natural-and-artificial/ [https://perma.cc/H7J2-Y9KM].

96 *See* Evan H. Tallmadge, *Patenting Natural Products After* Myriad, 30 HARV. J.L. & TECH. 569, 573–74 (2017).

97 *See What Is Gene Therapy? How Does It Work?*, U.S. FOOD & DRUG ADMIN. (Dec. 22, 2017), https://www.fda.gov/consumers/consumer-updates/what-gene-therapy-how-does-it-work [https://perma.cc/ST93-BW63].

similar issues in patients that appear healthy yet may develop similar symptoms later in their lives.[98] While these techniques' usefulness cannot be overstated, the Supreme Court challenged their patent eligibility in *Association for Molecular Pathology v. Myriad Genetics*.[99]

The Court considered the technique of using patients' DNA for such treatment options.[100] Myriad Genetics attempted to patent a human gene that they found to be a reliable predictor of ovarian and breast cancer to secure their monopoly on using the said gene for twenty years.[101] The Supreme Court performed an extensive analysis of the origins of BRCA1 and BRCA2 genes that Myriad attempted to patent during the trial.[102] The Court's analysis focused on the fact that these genes originate within the human genome.[103] For this decision, the Supreme Court applied the practice of excepting "natural products" from patents due to their original, unaltered existence in nature.[104] Under the current interpretation of 35 U.S.C. § 101, the Supreme Court has appropriately invalidated the patent after consulting with abundant precedents that established the century-old tradition of invalidating patents on naturally occurring products.[105]

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98 *See id.*

99 *See* Huang, *supra* note 94, at 1080; Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013); Leo O'Connor, *Experts Debate MDx Industry Impact of* AMP v. Myriad *Three Years After Court's Decision*, GENOMEWEB (Nov. 15, 2016), https://www.genomeweb.com/business-news/experts-debate-mdx-industry-impact-amp-v-myriad-three-years-after-courts-decision#.Yl4QAujMIuU [https://perma.cc/JX68-5R7P]; Peter Edwards, AMP v. Myriad*: The Future of Medicine and Patent Law*, 12 MINN. J.L. SCI. & TECH. 811, 812.

100 *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 576.

101 *See id.* at 579–82.

102 *See id.* at 58285.

103 *See id.*

104 *See id.*

105 *See* Diamond v. Chakrabarty, 447 U.S. 303, 303–04 (1980).

III. ANALYSIS

Many intellectual property scholars criticized the decision in *Myriad*.[106] While the Supreme Court appropriately applied the "product of nature" exception established through the judicial history of 35 U.S.C. § 101 subject-matter requirements, as a result of this case, the U.S. government had, in effect, deemed all patents on naturally occurring DNA segments to be invalid due to the "natural product" rule.[107] The decision resulted in the invalidation of many previously valid patents on these grounds.[108]

Even though the "natural product" exception was a long-standing part of the U.S. patent system,[109] only recently did the courts start invalidating genome patenting on this basis.[110] It used to be that such patents were widely available throughout the United States.[111] For example, the landmark case of *Diamond v. Chakrabarty* concerned a patent of a genetically altered bacterium.[112] The inventor in this case used genetic splicing to imbed naturally occurring DNA sequences of one organism into a bacterium to give it the capability of breaking down multiple components of crude oil.[113] In *Chakrabarty*, the Supreme Court determined that creating a new bacterium that possesses a unique and useful ability is sufficient to overcome the "natural product" limitation of § 101.[114]

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106 *See* Anne Paxton, AMP v. Myriad*: Driving or Disrupting Innovation?*, CAP TODAY (Feb. 2017), https://www.captodayonline.com/amp-v-myriad-driving-disrupting-innovation/ [https://perma.cc/3UWZ-8SJC].

107 *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 591–604 (2013).

108 *See In re* BRCA1– & BRCA2–Based Hereditary Cancer Test, 774 F.3d 755, 760–62 (Fed. Cir. 2014) (ruling previously held cDNA patents to be patent ineligible due to the violation of the natural product exception).

109 *See* Diamond v. Diehr, 450 U.S. 173, 185 (1981) (discussing the 3 exceptions to 35 U.S.C. § 101 that deem objects unpatentable).

110 *See* E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS IN MED. S39, S45 (Supp. 2010) (discussing prior situation of human genome patenting in U.S.).

111 Robert Cook-Deegan & Christopher Heaney, *Patents in Genomics and Human Genetics*, 11 ANN. REV. OF GENOMICS AND HUM. GENETICS 383, 391–93 (2010) (addressing the wide use of patents on nucleic acids prior to *Charkrabarty*).

112 *See* Diamond v. Chakrabarty, 447 U.S. 303, 303–04 (1980).

113 *See id.* at 303–04.

114 *See id.* at 317.

In *Myriad*, however, the Supreme Court applied a different kind of analysis to the statute.[115] It determined, regardless of the importance of the scientific discovery, naturally occurring genes were not patentable due to their existence in the human genome.[116] While patents in *Chakrabarty* involved a gene spliced and embedded into a new organism's DNA, patents in *Myriad* differed primarily in that they were used in the procedure to detect faulty DNA that leads to early onset of cancer in the human population.[117] *Myriad's* expansion of the "natural product" exception does not sufficiently address public policy issues related to gene patenting, and it also gives rise to rampant abuse of trade secrets by the pharmaceutical companies.

The following subsections of this Note will focus on: (a) inefficient resolution of public policy issues raised before *Myriad*;[118] (b) disincentives for investors to fund research in genetics as a result of *Myriad*;[119] and (c) rampant abuse of trade secrets by pharmaceuticals after *Myriad*.[120] This Note will also propose an amendment to 35 U.S.C. § 101 that attempts to address the issues raised in subsections a, b, and c.[121]

A. PUBLIC POLICY CONCERNS RAISED BY *MYRIAD*

While the Court in *Myriad* did not discuss public policy issues in detail, it is hard to imagine that the judges did not give any weight to the considerable public outcry against gene patenting.[122] The idea of human genome patenting was considered an abuse of the patent system and unethical by many prominent public figures.[123] One of the primary arguments used at the time was that allowing human genome patenting would decrease access to patient care by raising the prices on

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115 *See* Ass'n for Molecular Pathology v. Myriad, Genetics, Inc., 569 U.S. 576, 591–94. (2013).

116 *See id.*

117 *Compare Myriad*, 569 U.S. at 591–94, *with Chakrabarty*, 447 U.S. at 303–04.

118 *See infra* Section III.A.

119 *See infra* Section III.B.

120 *See infra* Section III.C.

121 *See infra* Section III.D.

122 Jean Marbella, *Ban on Patenting DNA Cheers Researchers*, BALTIMORE SUN (Jun. 13, 2013, 9:31 PM), https://www.baltimoresun.com/health/bs-md-scotus-gene-patent-react-20130613-story.html [https://perma.cc/Z5C9-LFJ5].

123 *See id.*

patented procedures.[124] A hopeful outlook on the implications of the Supreme Court's decision in *Myriad* may lead to a conclusion that it would allow more pharmaceutical companies to offer genetic testing and treatments to patients at lower costs, increasing patient access to healthcare in the process.[125] The decision invalidated the patents on all the information regarding the discoveries of BRCA1 and BRCA2 genes and their functions, which became public knowledge afterward.[126] This created a reasonable expectation that these tests would become widely available and less expensive.[127] However, that expectation was unfortunately proven to be false.[128]

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124 *See id.*

125 *See* Lara Smith, *Patenting Genes: What Does* Association for Molecular Pathology v. Myriad Genetics *Mean for Genetic Testing and Research?*, 129 PUB. HEALTH REP. 289, 290–91 (2014).

126 *See id.*; Ass'n for Molecular Pathology v. Myriad, Genetics, Inc., 569 U.S. 576, 595–96.

127 *See Myriad*, 569 U.S. at 595–96.

128 *See* Kolor et al., *BRCA Genetic Testing and Receipt of Preventing Interventions Among Women Aged 18-64 Years with Employer-Sponsored Health Insurance in Nonmetropolitan and Metropolitan Areas – United States, 2009-2014*, 66 MORBIDITY AND MORTALITY WKLY. REP., Sept. 8, 2017, at 1, 5–6 (analyzing the prevalence of BRCA test use throughout the United States).

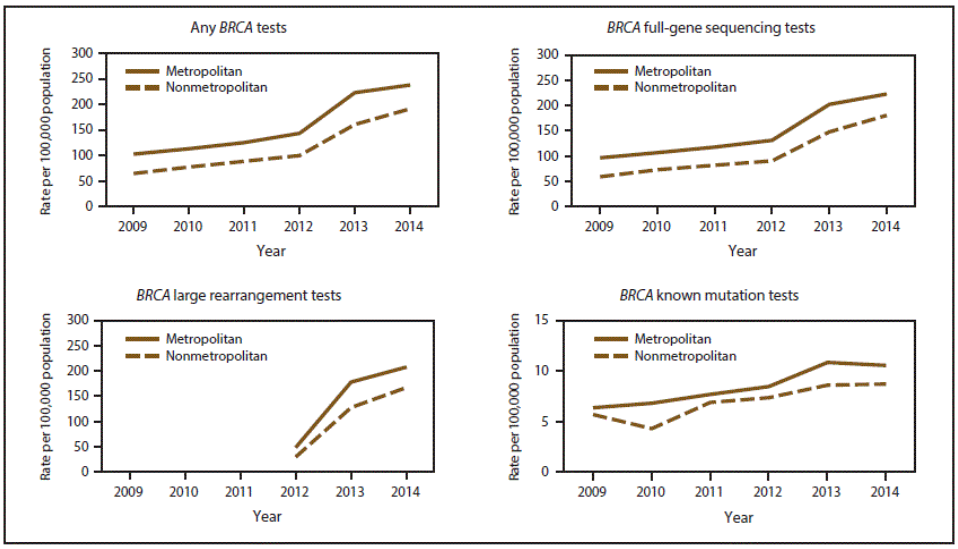

Figure 1. BRCA Testing Rates per 100,000 Population[129]

Figure 1 illustrates the prevalence of BRCA testing in public between 2009 and 2014.[130] Although there was a significant spike in BRCA test use when the *Myriad* case gathered substantial public attention during the litigation, the rate of increase in the use of these tests remained the same as before the Supreme Court invalidated Myriad's patents.[131]

The likely reason for this is simple—the Supreme Court's decision did not invalidate all of Myriad's DNA patents.[132] Instead, it invalidated only the isolated human DNA.[133] At the same time, the artificial complementary strands of that DNA, called cDNA, and some of the techniques associated with the procedure were still patentable since they were not originating in nature and were human-made.[134] Justice Thomas outlined: "The lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result,

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129 *See id.* at 6.

130 *Id.*

131 *See id.*

132 *See* Ass'n for Molecular Pathology v. Myriad, Genetics, Inc., 569 U.S. at 587–89.

133 *See Myriad*, 569 U.S. 576, 587–89.

134 *See id.*

cDNA is not a "product of nature" and is patent eligible under § 101."[135] Myriad could still sue for patent infringement by the genetic testing providers that used cDNA of BRCA1/BRCA2 or similar testing techniques in their procedures.[136] The decision did not achieve the effect desired by its proponents. Myriad Genetics still retained some of the patents vital for the procedure, and the evidence suggests that the patient access remained the same even after the court deemed BRCA1/BRCA2 patents invalid.[137] However, *Myriad* created significant impediments to incentivizing continued research in this field.

B. NEED FOR INCENTIVES IN GENETIC RESEARCH

In addition to not increasing patient access to the procedure, the decision led to a potentially substantial decrease in research funding in this field of biopharmaceutics.[138] The Supreme Court did not address the potential utility of DNA-related therapies and the need for incentives to support the research in this field.[139] The process itself is exceptionally involved and requires enormous investments on the part of the research institutions determined to find new treatments.[140] Biopharmaceutical research, in general, has a meager success rate, with only fourteen percent of treatments getting through Phase 1 of clinical trials.[141] *Myriad* ignored the substantial implications of refusing patent protections

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135 *See id.* at 587.

136 *See Owning the Code: The U.S. Supreme Court's Decision in* Myriad Genetics *Distinguishes Between DNA and cDNA*, GLASER WEIL (Dec. 18, 2013), https://www.glaserweil.com/news-resources/owning-the-code-the-u.s.-supreme-courts-decision-in-myriad-genetics-disting [https://perma.cc/VQ3W-R6NM].

137 *See* Kolor et al., *supra* note 128, at 6 (analyzing the prevalence of BRCA test use throughout the United States).

138 *See* Michele Wales & Eddie Cartier, *The Impact of* Myriad *on the Future Development and Commercialization of DNA-Based Therapies and Diagnostics*, 5 COLD SPRING HARBOR PERSPS. IN MED., Dec. 2015, at 1, 2–3.

139 *See* Ass'n for Molecular Pathology v. Myriad, Genetics, Inc., 569 U.S. 576, 580–96.

140 Chris Bailey, *Gene Therapies Offer Breakthrough Results but Extraordinary Costs*, MASS. MUN. ASS'N. (Mar. 18, 2020), https://www.mma.org/gene-therapies-offer-breakthrough-results-but-extraordinary-costs/ [https://perma.cc/JU4V-TP45] (discussing the exceptionally high costs of gene therapies).

141 Jonathan Gardner, *New Estimate Puts Cost to Develop a New Drug at $1B, Adding to Long-Running Debate*, BIOPHARMA DIVE (Mar. 3, 2020),

on research that has such a low success rate and costs billions of dollars per new treatment.[142] As it stands now, due to the "natural product" exception first articulated by the Supreme Court about seventy years ago and expanded on by *Myriad*, many of the inventors and researchers who work on the precipice of human discovery face a risk of litigation and potential invalidity of their patents.[143]

The importance of patentability for bringing investors to support further research cannot be underestimated: "[T]he filing of at least one patent application has been shown to increase the chance of obtaining venture capital funding by 97% and reduce the time for first investment by 76%."[144] *Myriad* raised a concern that, absent patent incentives to promote further developments in this field, practitioners would redirect their research or move to intellectual property practices that are potentially more harmful to consumers, mainly trade secrets.[145] For example, Mr. Rohbraugh, a director of NIH's Office of Technology, stated that: "without genomic DNA being patentable, it may throw into question protection for important technology that is critical to improving public health. The decision may even backfire on its proponents, leading to increased secrecy in research and reduced collaboration."[146]

Indeed, even prior to the Court's decision, *Myriad* began the practice of diversifying their investment by further relying on their proprietary databases of genetic "variants of unknown significance" in addition to patents.[147] The decision

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https://www.biopharmadive.com/news/new-drug-cost-research-development-market-jama-study/573381/ [https://perma.cc/Z3UT-ZCZL].

142 *See id.*; Wales & Cartier, *supra* note 138, at 1; *see also* Shingo Yamaguchi et al., *Approval Success Rates of Drug Candidates Based on Target, Action, Modality, Application, and Their Combinations*, 14 CLINICAL & TRANSLATIONAL SCI. 1113, 1114 (2021) (stating that the success rate of the development of a compound from clinical trial to market approval).

143 *See generally* Diamond v. Chakrabarty, 447 U.S. 303 (1980); Ass'n for Molecular Pathology v. Myriad, Genetics, Inc., 569 U.S. 576 (2013).

144 *See* Wales & Cartier, *supra* note 138, at 2.

145 Chris Palmer, *The* Myriad *Decision: A Move Toward Trade Secrets?*, 22 NIH CATALYST, Mar.–Apr. 2014, at 3 (2014) (outlining the concerns raised by Mark Rohbraugh, a director of NIH's Office of Technology Transfer, and Eleonore Pauwels, a public policy scholar at Woodrow Wilson International Center).

146 *Id.*

147 Derek So & Yann Joly, *Commercial Opportunities and Ethical Pitfalls in Personalized Medicine: A Myriad of Reasons to Revisit the Myriad Genetics Saga*, 11 CURRENT PHARMACOGENOMICS AND PERSONALIZED MED. 98, 103–04 (2013).

only furthered these kinds of practices because, absent the prospect of patents, biotech innovators have to find ways to "claim around" the limitations or resort to alternative ways of intellectual property protections.[148] This behavior of pharmaceutical enterprises is not merely a concern but a reality that has manifested itself in preparation for the fallout after the decision.[149] This leads to a substantial hindrance of the potential new discoveries in such treatments, limiting patient access to potentially life-saving treatments in the long-run.[150]

While the original Lockean incentives of § 101 made research in this field attractive for inventors and investor funding, *Myriad's* application of the "natural product" exception defeats the original purpose of the statute, forcing private research institutions to invest in research that has the potential to provide them with enforceable patents or resort to other means, such as trade secret use.

C. DANGEROUS RISE IN TRADE SECRET USE

Trade secrets are uniquely distinct from patents.[151] They do not require an affirmative decision on the USPTO's part to ensure legal protections for an invention.[152] Under the guidance of the USPTO, a trade secret:

- is information that has either actual or potential independent economic value by virtue of not being generally known,
- has value to others who cannot legitimately obtain the information, and
- is subject to reasonable efforts to maintain its secrecy.[153]

The very nature of trade secrets is in their name; they have to remain "secret."[154] They allow for savvy inventors to enjoy the fruits of their labor without

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148 *Id.* at 104; *see also* Wales & Cartier, *supra* note 138, at 2.

149 *Id* at 107.

150 *See* Palmer, *supra* note 145, at 9.

151 *What Is a Trade Secret, and How Is It Different From a Patent or Copyright?*, HOWSTUFFWORKS, https://money.howstuffworks.com/patent.htm [https://perma.cc/4HWA-N6WH].

152 *See Trade Secrets/Regulatory Data Protection* , USPTO, https://www.uspto.gov/ip-policy/trade-secret-policy [https://perma.cc/9XCW-L7HY].

153 *Id.*

154 *Trade Secrets Protection: A Primer and Desk Reference for Managers and In House Counsel*, FENWICK & WEST LLP, 2 (2001), https://assets.fenwick.com/legacy/

the necessity of compliance with the rigid structure of 35 U.S.C § 101.[155] Furthermore, unlike patents, trade secrets do not have a time limit associated with them.[156] As long as a trade secret remains secret, its holder can derive all the legal protections afforded by law, regardless of the time passed since the invention.[157] These unique kinds of protections often leave inventors with an enormous potential to maintain a monopoly on the market and avoid sharing discoveries with their competitors.[158]

While trade secrets do provide an option for independent reverse engineering, some fields of science are extremely difficult to reverse engineer inventions in.[159] For example, first derived in 1942, Premarin was the only hormone replacement therapy drug derived from a natural source for many decades.[160] No other firm could reverse engineer the process of its creation, and the company that owned Premarin enjoyed full protection of the trade secret status.[161] For obvious reasons, these kinds of protections awarded through trade secrets often lead innovators to strategically combine trade secrets and patents to enjoy the most comprehensive conservation of their intellectual property.[162]

FenwickDocuments/Trade_Secrets_Protection.pdf [https://perma.cc/A4CU-9KSE].

155 *Id.* at 4–8.

156 *See Trade Secrets/Regulatory Data Protection*, *supra* note 152.

157 *Id.*

158 Orly Lobel, *Filing for a Patent Versus Keeping Your Invention a Trade Secret*, HARV. BUS. REV. (Nov. 21, 2013), https://hbr.org/2013/11/filing-for-a-patent-versus-keeping-your-invention-a-trade-secret [https://perma.cc/L62A-CL5A].

159 Neil Wilkof, *The Process May (Or May Not) Be the Product: Trade Secrets and COVID Research*, IPKAT (Aug. 3, 2020), https://ipkitten.blogspot.com/2020/08/the-process-may-or-may-not-be-product.html [https://perma.cc/5GCE-KTXM]; *see also* Allison Durkin et al., *Addressing the Risks That Trade Secret Protection Pose for Health and Rights*, 23 HEALTH & HUM. RTS. J. 129, 134 (2021).

160 *See* Lobel, *supra* note 158; Leila Abboud, *How Drug Giant Keeps a Monopoly on 60-Year-Old Pill*, WALL ST. J. (Sept. 9, 2004, 12:01 AM), https://www.wsj.com/articles/SB109467466893212658 [https://perma.cc/GHA3-X4BU].

161 *Id.*

162 *Id.*

After the Supreme Court decided *Myriad*, the public was ecstatic from what they perceived to be a huge victory and preservation of the right to access life-saving diagnostic testing.[163] Yet, at the same time, many legal scholars heavily criticized the decision, citing broad and highly concerning negative consequences regarding trade secret abuse as a likely result of the decision.[164] Unfortunately, these concerns proved to be true. Before this decision, the patents on the human genome were granted for only twenty years, and treatments were available for all providers and pharmaceutical companies after the patent expiration.[165] The court's decision has since incentivized Myriad and other pharmaceutical companies to keep their discoveries as trade secrets.[166]

Although the vast majority of trade secret litigation is conducted in state courts, as the federal government only recently codified trade secrets into federal law, the vast majority of state laws conform to the Uniform Trade Secrets Act.[167] It is considered to be such a foundational piece of trade secret litigation that even the federal Defend Trade Secrets Act kept all of the definitions essentially the same, only altering the potential damages and awards afforded to the plaintiffs who win federal litigation.[168]

According to the Uniform Trade Secrets Act, "trade secrets" are defined as:

> (1) information, including a formula, pattern, compilation, program, device, method, technique, or process that (2) derives independent economic value, actual or potential, (3) from not

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163 *See generally* Gold & Carbone, *supra* note 110; *see also* Donald Zuhn, *Reaction to Supreme Court's Decision in* AMP v. Myriad, JD SUPRA (July 2, 2013), https://www.jdsupra.com/legalnews/reaction-to-supreme-courts-decision-in-62799/ [https://perma.cc/56CF-85RH].

164 *See* Wales & Cartier, *supra* note 138, at 2.

165 *See Duration of Patent Protection*, JUSTIA, https://www.justia.com/intellectual-property/patents/duration-of-patent-protection/ [https://perma.cc/M3C7-W7PV] (Oct. 2021).

166 *See* So & Joly, *supra* note 147, at 102–03.

167 Sid Leach, *Anything but Uniform: A State-By-State Comparison of the Key Differences of the Uniform Trade Secrets Act*, SNELL & WILMER LLP, https://www.swlaw.com/assets/pdf/news/2015/11/06/How%20Uniform%20Is%20the%20Uniform%20Trade%20Secrets%20Act%20-%20by%20Sid%20Leach.pdf [https://perma.cc/FZK8-WBJN].

168 *Compare* UNIF. TRADE SECRETS ACT § 1 (UNIF. L. COMM'N 1979) (amended 1985), *with* 18 U.S.C. § 1836.

> being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and (4) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.[169]

Generally, regardless of the state and its application of the Uniform Trade Secrets Act, any information that is not known to the public and affords businesses with a competitive advantage on the market can be classified as a trade secret, as long as it, indeed, remains secret through the efforts of these businesses.[170] Furthermore, there are no time limits nor requirements to disclose that run together with trade secret protections.[171] This means that as long as a company keeps the information that benefits their operations in secrecy, there is no statutory mechanism to make this information public.[172]

Such broad protections are exceptionally appealing to the pharmaceutical industry.[173] The Supreme Court's decision in *Myriad* reinforced these practices because the pharmaceutical industry lost the option to patent many of its products involving the human genome.[174] Consequently, there is a substantial increase in both trade secret litigation and patent enforcement in the industry.[175] From 2015 to 2019, the cost of pharmaceutical patents rose by sixty-seven percent.[176]

There is no reliable information on evaluating the increase of trade secret use in the healthcare industry, though some academics have pointed out the

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169 UNIFORM TRADE SECRETS ACT § 1 (1985).

170 *See id.*

171 *See id.*; *Trade Secrets/Regulatory Data Protection*, *supra* note 152.

172 UNIFORM TRADE SECRETS ACT § 1.

173 *See* So & Joly, *supra* note 147, at 104 (discussing the keeping of genetic data as trade secretes getting increasing attention from biotechnology companies).

174 *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 595–96 (2013).

175 *See* Malathi Nayak, *Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds*, BL (Sept. 10, 2019, 8:01 AM), https://news.bloomberglaw.com/ip-law/costs-soar-for-trade-secrets-pharma-patent-suits-survey-finds [https://perma.cc/9GES-ABN9].

176 *Id.*

absence of any other "way to earn a return on . . . investments."[177] The rise in use of trade secrets is significant enough to be traced to an increase in healthcare trade secrets litigation throughout the country.[178] This is understandable, given that even the experts in intellectual property litigation came out stating that, "[t]hose in biotech, medical diagnostics and pharmaceutical industries have just been taken out behind the woodshed and summarily executed by the Supreme Court this morning. An enormous number of patents will now have no enforceable claims. Hundreds of billions of dollars in corporate value has been erased."[179] Because of this, the popularity of trade secrets in the pharmaceutical industry has skyrocketed after the *Myriad* decision.[180] Understandably, pharmaceutical firms prefer to keep their findings secret and ensure that their, sometimes billion-dollar, investments remain profitable.[181]

Given the nature of trade secrets, it is not a reach to assume that the Supreme Court's decision in *Myriad* will result in a substantial slowdown of scientific progress as, without patents, pharmaceutical companies do not have any incentive to share their research with others.[182] Several researchers and health

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177 *See* Barbara J. Evans, *Mining the Human Genome After* Association for Molecular Pathology v. Myraid Genetics, 16 GENETICS IN MED. 504, 508 (discussing the inevitability of an increase in trade secret use).

178 *See* Rachel Harris, *Healthcare Industry Increasingly Using Trade Secret Litigation to Protect Intellectual Property Rights*, SQUIRE PATTON BOGGS: TRIAGE HEALTH L. BLOG (Aug. 13, 2018), https://www.triagehealthlawblog.com/life-sciences/healthcare-industry-increasingly-using-trade-secret-litigation-to-protect-intellectual-property-rights/ [https://perma.cc/32CN-6E2T] (discussing healthcare companies being at the forefront of the movement of increasing trade secret litigation).

179 *See* Gene Quinn, Killing Industry*: The Supreme Court Blows* Mayo v. Prometheus, IPWATCHDOG (Mar. 20, 2012, 1:44 PM), https://www.ipwatchdog.com/2012/03/20/supreme-court-mayo-v-prometheus/id=22920/# [https://perma.cc/T9F7-44B3]

180 *See* Harris, *supra* note 178.

181 *See* Evans, *supra* note 177, at 508.

182 *See* Alexis K. Juergens & Leslie P. Francis, *Protecting Essential Information About Genetic Variants as Trade Secrets: A Problem for Public Policy?*, 5 J.L. & BIOSCIENCES 682, 700–01 (2019) (discussing the consequences of pharmaceutical companies pursuing trade secret protection as opposed to patent protection).

providers have recognized the issues with the growing secrecy of data.[183] Some of them proposed to curb the negative implications for research by organizing voluntary databases to share data on inventions, but few of the firms have decided to join the effort.[184] Without the necessary flow of information between the research institutions, scientific discoveries often need to be repeated in separate institutions without any knowledge that such has already been performed successfully earlier.[185]

One of the best examples of this kind of market behavior can be seen in the very firm that participated in this case, Myriad Genetics.[186] During the ongoing litigation, Myriad Genetics quickly expanded its BRCA testing network within the United States and overseas, relying on trade secrets as a tool to ensure its near-monopoly over the market.[187] Unfortunately, they have succeeded in this, proving to other pharmaceutical enterprises that trade secrets are much more lucrative of an opportunity than attempting to patent an invention and holding the monopoly of its use for mere twenty years, having to share all the discoveries with the competitors in the meantime.[188] Myriad Genetics' success in the abuse of trade secrets in foreign and domestic markets has achieved such notoriety that the European Society of Human Genetics ("ESHG") had to issue a statement criticizing Myriad's new strategy on the European market.[189] The ESHG stated that

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183 *Id.*; Robert Cook-Deegan & Amy L. McGuire, *Moving Beyond Bermuda: Sharing Data to Build a Medical Information Commons*, 27 GENOME RSCH. 897, 897 (2017) (discussing the initiative for pharmaceutical companies to share their data to combat trade secret use); Evans, *supra* note 177, at 508.

184 *See* Cook-Deegan & McGuire, *supra* note 183, at 898 (proposing a medical information commons based on the Bermuda Principles).

185 *Id.* at 900.

186 *See* Steve Connor, *Genetic Profiteering: Scandal of Firm 'Hiding Vital Breast Cancer Data'*, INDEPENDENT (Nov. 1, 2012), https://www.independent.co.uk/news/science/genetic-profiteering-scandal-of-firm-hiding-vital-breast-cancer-data-8270020.html [https://perma.cc/RWS8-Y9CU] (discussing Myriad Genetics abusing trade secrets to ensure their firm control over the market).

187 *See* W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419, 447 (2015) (discussing policy concerns with the potential abuse of trade secrets in pharmaceutics and how they were illustrated by Myriad's practices).

188 *Id.* at 444–88.

189 *Id.* at 447–48 n.132; Press Release, European Soc'y of Hum. Genetics, Privately Owned Genetic Databases May Hinder Diagnosis and Bar the Way to the Arrival Of Personalised Medicine: ESHG Reacts to the Report In the

Myriad Genetics was given an unfair advantage against European academic institutions and severely hindered the progress of personalized medicine.[190]

D. PROPOSED SOLUTION

In the set of their decisions establishing the exceptions to 35 U.S.C. § 101, the Supreme Court ensured that discoveries that are not eligible for patenting due to the shared logical assumptions of the time are not given patent protections.[191] This strategy of the Supreme Court has culminated with their most recent decision in *Myriad*.[192]

Despite the now apparent departure from the original principles embedded in the U.S. patent system, the Supreme Court was correct in deciding the case in the way it did. *Stare decisis* requires the Supreme Court to avoid differential treatment of similar cases based on judges' personal opinions.[193] Nevertheless, the Supreme Court's decision ignored the substantial changes in the scientific development of genetics, where the "natural product" exception fails to maintain the incentives for new and useful discoveries.[194]

For the reasons described prior in the analysis, the decision in *Myriad* did not result in improved access to patient care, yet it has the potential to divert funding from scientific research and incentivizes the use of trade secrets, which has the potential to harm scientific development for years to come.[195] This necessitates a response from Congress that would supplement 35 U.S.C. § 101 in

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European Journal Of Human Genetics (Oct. 30, 2012), https://www.eshg.org/13.0.html [https://perma.cc/B4Y3-W8HE].

190 Price, *supra* note 187.

191 *See* Mayo Collaborative Servs. v. Prometheus Lab'ys., Inc., 566 U.S. 66 (2012); *see also* Diamond v. Chakrabarty, 447 U.S. 303 (1980); Gottschalk v. Benson, 409 U.S. 64 (1972); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

192 *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 576 (2013).

193 *See* Jeremy Waldron, *Stare Decisis and the Rule of Law: A Layered Approach*, 111 MICH. L. REV. 1, 1 (2012) (exploring a layered approach to stare decisis and its relationship to the rule of law).

194 Huang, *supra* note 94, at 1080–81.

195 *See* Kolor et al., *supra* note 128; Wales & Cartier, *supra* note 138, at 2; So & Joly, *supra* note 147, at 1.

order to bring back the incentives for inventors in genetic research, as well as other fields of science, and comport with the founding philosophies of property law.[196]

Some legal scholars argue for providing non-patent innovation incentives.[197] Furthermore, there is already a proposed bill to eliminate the subject-matter exceptions to the statute altogether.[198] This Note, however, argues for a milder resolution. Considering the extensive judicial history of 35 U.S.C. § 101, concerns about the patent system's abuse support the court's decisions in developing the exceptions.[199] Notably, the "natural product" rule was sensible, given the likelihood of a naturally occurring compound or product patented by an inventor who merely stumbled on it and did not put substantial labor or monetary investments into the discovery.[200]

Instead of entirely abolishing the exceptions or inventing new incentives for non-patentable inventions, intellectual property scholars and Congress should consider looking into the structure and the powers of the Securities and Exchange Commission ("SEC").[201] While the USPTO and SEC are vastly different organizations, one can argue that they have similar goals.[202] Congress could use the lessons learned from giving broad rulemaking authority to the SEC and continue promoting incentives for researchers and inventors by supplementing USPTO with a similar kind of rulemaking authority as to the patentability of certain subject-matter in specific fields of science.[203]

The SEC's primary objective is to ensure that investors and shareholders on the market have all the necessary information to make informed decisions

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196 *See* Ouellette, *supra* note 54, 1142.

197 *Id.* at 1142–43.

198 Denise Main, *Draft Bill Released to Reform Section 101 of the Patent Act*, FINNEGAN (May 28, 2019) https://www.finnegan.com/en/insights/blogs/prosecution-first/draft-bill-released-to-reform-section-101-of-the-patent-act.html [https://perma.cc/TRA3-GGU8].

199 *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

200 *Id.*

201 *See* J. Robert Brown Jr., *Corporate Governance, the Securities and Exchange Commission, and the Limits of Disclosure*, 57 CATH. U.L. REV. 45, 49 (2007) (brief discussion of the powers of the SEC).

202 *Compare id.*, *with History and Background*, USPTO (Dec. 8, 2017), https://www.uspto.gov/learning-and-resources/support-centers/patent-and-trademark-resource-centers-ptrc/history-and-0 [https://perma.cc/B6KC-6TPY] (discussing the incentives motivating the patent system).

203 *See* Brown, *supra* note 204, at 49.

regarding their purchase of securities and incentivize trade on the financial market.[204] Congress has long recognized that different types of securities require different levels of disclosure provided to investors to ensure the appropriate balance between putting too high of a burden of disclosure on the traded companies (thereby disincentivizing them from publicly trading their stocks) and putting too little of a burden on them, incentivizing fraudulent activities on the market.[205] Therefore, Congress provided the SEC with ample powers to issue rules on various securities types and to differentiate between investors.[206] This way, the SEC can quickly respond to the ever-changing financial market and tailor the rules for disclosure based on various types of stocks, without the necessary costs and burdens of changing the rules for the entire market as the issues arise.[207]

The USPTO is largely similar to the SEC in one way. Its primary goal is to provide the public with knowledge of new patented inventions and financially incentivize the inventors by providing them with monopoly powers for a twenty-year period.[208] USPTO has the rulemaking authority to issue regulations requiring "reporting, or updating, of assignment information at three different stages during application."[209] Unlike the SEC, however, the USPTO lacks the power to regulate subject-matter requirements of 35 U.S.C. § 101.[210] This gives rise to an issue that some discoveries in particular fields of science may not fit into the subject-matter requirements of the statute. However, providing patent protections and rewarding inventors with property rights for their labor is still necessary to

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204 *See id.* at 86.

205 15 U.S.C. § 77g(c)(1).

206 15 U.S.C. § 77s(a) (noting the commission's broad rulemaking power).

207 *Id.* (noting the commission's ability to issue "necessary" regulations); *Investor Bulletin: An Introduction to The U.S. Securities and Exchange Commission – Rulemaking and Laws*, U.S. SEC. & EXCH. COMM'N (Aug. 20, 2015), https://www.sec.gov/oiea/investor-alerts-and-bulletins/ib_rulemaking [https://perma.cc/Z87Z-2XGT (describing the various Acts that give SEC broad rule-making authority over the different aspects of securities exchange).

208 *History and Background*, USPTO, *supra* note 202.

209 Arti K. Rai, Comment Letter in Response to Request for Comments on Eliciting More Complete Patent Assignment Information, https://www.uspto.gov/sites/default/files/patents/law/comments/f_rai_120130.pdf [https://perma.cc/CZW8-R8KE].

210 *See id.* (noting that the agency's rulemaking power is limited to three different stages in the patent application).

maintain the original spirit of our Constitution first articulated by John Locke in his writings on "Labor Theory."[211]

Under this proposal, USPTO would be finally given a rulemaking authority to determine subject-matter requirements for patents based on the scientific field to which they belong. It would avoid the complications of reviewing all patent applications without the necessary regard to the amount of effort and finance that is necessary to obtain these discoveries.

Instead of abolishing all the subject-matter exceptions, as suggested by the current bill in Congress, this solution would recognize that these exceptions are necessary for some fields of science, yet detrimental for incentivizing research in others.[212] Furthermore, unlike providing incentives for non-patentable inventions, this proposal would avoid the unnecessary complication of establishing new statutes and regulations. Instead, it would simply provide the USPTO with the additional rulemaking power, without the necessity of using substantial resources to develop new commissions or write new statutes. Finally, it would provide the USPTO with the ability to quickly respond to new developments in scientific research and issue new up-to-date regulations specific to the problems that arise, without the necessity of constant change in judicial interpretation and new bills from the legislature.

Certainly, there are negative consequences to any change within the statutory structure of almost any law or organization. Regarding patents, there are realistic concerns that patents would be awarded for any new observation within the natural world. These could result in potential shortfalls of a monopoly being awarded on a subject matter that is too broad or ethically questionable.[213] Furthermore, there are concerns that a twenty-year monopoly on a pharmaceutical treatment could result in a higher-than-necessary price for such services.[214]

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211 *See supra* Section II.B.

212 *Compare* Denise Main, *Draft Bill Released to Reform Section 101 of the Patent Act*, FINNEGAN (May 28, 2019) https://www.finnegan.com/en/insights/blogs/prosecution-first/draft-bill-released-to-reform-section-101-of-the-patent-act.html [https://perma.cc/TRA3-GGU8], *with* 35 U.S.C. § 101.

213 *See* Marbella, *supra* note 122 (noting that bioethicists and human rights organizations were pleased when the Supreme Court held that claims to human genes were invalid as this holding will "[increase] access to genetic testing").

214 *See* Tahir Amin, *Patent Abuse is Driving up Drug Prices. Just Look at Lantus*, STAT, (Dec. 7, 2018), https://www.statnews.com/2018/12/07/patent-abuse-rising-drug-prices-lantus/ [https://perma.cc/DN35-4A56] (arguing that

However, even if a twenty-year patent monopoly on new discoveries and treatments is likely to result in higher prices for patients, it would avoid a much more lucrative option for pharmaceutical companies to pursue trade secrets with an ability to keep the monopoly for generations, as some companies have done already.[215] Furthermore, it is vitally important to recognize that providing the USPTO with broader rulemaking authority would allow the USPTO to ensure the balance between incentivizing discovery and patent abuse, by giving it broad powers to address these issues as they arise.

IV. CONCLUSION

Since its inception, intellectual property was primarily seen by the legislature as an intangible type of property that abided by the same philosophies and standards as any other property in the country.[216] Insistence on retaining the word "discovery" in 35 U.S.C. § 101 by Congress and the analysis of "Takings Clause" in courts only furthers this idea. Following the ideas developed by John Locke and further incorporated into our constitution by our founding fathers, scientists and inventors deserve to receive the fruits of their labor and be incentivized to further the progress of science, without the fear of losing the title to their discoveries and disseminating it freely to the public. Throughout the latter portion of the twentieth century, the courts have addressed some concerns about the patent system's abuse by establishing a set of subject-matter exceptions that make certain innovations and discoveries patent ineligible.[217] This approach, however, begins to struggle as some fields of science require substantial funding even for the kinds of discoveries that are not patent eligible, creating an ages-old tragedy of commons problem.[218]

The Supreme Court's decision in *Myriad* exemplifies this issue. By expanding the "natural product" rule, the Court effectively removed boundaries of the genetics field and incentivized the use of trade secrets, hampering research

twenty years of monopoly may be too much for drugs that are developed in less than twenty years).

215 *See* Lobel, *supra* note 158 (noting that a menopause drug forwent patent protection for trade secret protection because it does not expire like a patent does).

216 *See supra* Section II.B.

217 *See supra* Sections II.C, D.

218 *See supra* Section III.B.

progress for years to come.[219] Furthermore, the decision disincentivized further funding into genetics and did not improve patient care access, as was expected by many advocates of the ruling.[220] By allowing the USPTO to regulate subject-matter requirements for patents, akin to SEC, these issues can be easily addressed and individualized for every potential field of science, reflecting the current reality of fast scientific development.

The USPTO would have an opportunity to adhere to the original principles outlined by John Locke and codified by the founding fathers through the first Patent Act in 1790 and could ensure that a discovery or an invention that provides value to society, especially if it required an extensive labor input, was granted a patent. This was the original way to ensure that researchers are encouraged to perform their experiments and that their pursuit of knowledge is not hindered by the potential concerns that their inventions would be taken away from them.[221] At the same time, however, granting broad authority to regulate subject-matter eligibility requirements to the USPTO will allow for the developed exceptions to the statute to remain in areas where they are necessary to maintain an appropriate balance between proper incentives and abuse of the patent system.

[219] *See supra* Section III.C.

[220] *See supra* Section III.B.

[221] *See supra* Section II.C.

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NOTE

NOT SO NATURAL PHENOMENA:
A LOOK AT § 101'S IMPACT ON BIOTECH PATENTS

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I. INTRODUCTION

The uncertainty of patent eligibility under § 101 limits biotechnology companies from obtaining patents on compounds that may imitate "natural phenomena" such as human DNA.[1] Recent biotechnology research has led to the development of "artificial organelles" that aid in cell-free protein synthesis, which helps manipulate enzyme and protein levels without the negative side effects of previous protein-synthesis technologies.[2]

While many companies have been able to obtain method patents on these technologies, they are unable to obtain patents on the actual DNA sequences utilized in the protein synthesis.[3] Recent Federal Circuit decisions continue to re-assert Supreme Court doctrine that even imitations of human DNA are patent ineligible, even when it is man-made.[4] This is a problem because it can take longer to develop a patent-eligible method for utilization of the discovered protein sequences,[5] and as a result, the public is harmed by the deterrence from disclosure and innovation.

Lack of Supreme Court action on § 101 issues leaves Congress responsible for taking action. This Note discusses why Congress should adopt a revised

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1 *See* Jonathon Liddicoat et al., *The Effects of* Myriad *and* Mayo *on Molecular-Test Development in the United States and Europe: Interview from the Frontline*, 22 VAND. J. ENT. & TECH. L. 785, 829 (2020).

2 *See* Ken Kingery, *Artificial Organelles Created to Control Cellular Behavior: New Form of Synthetic Biology for Controlling Cellular Behavior Uses Intrinsically Disordered Proteins*, SCIENCEDAILY (Aug. 4, 2020), https://www.sciencedaily.com/releases/2020/08/200804122214.htm [https://perma.cc/5D6M-9L8J]; Celia Henry Arnaud, *Artificial Organelles are Designed for Protein Engineering*, CHEM. & ENG'G NEWS (Mar. 20, 2019) [hereinafter *Artificial Organelles are Designed for Protein Engineering*], https://cen.acs.org/biological-chemistry/synthetic-biology/Artificial-organelles-designed-protein-engineering/97/i13 [https://perma.cc/E5D9-X3ZM].

3 *See* Illumina, Inc. v. Ariosa Diagnostics, Inc., 967 F.3d 1319, 1329 (Fed. Cir. 2020).

4 *See* Roche Molecular Sys., Inc. v. Cepheid, 905 F.3d 1363, 1369, 1371, 1374 (Fed. Cir. 2018) (holding that Roche's primer and method claims were directed toward patent-ineligible natural phenomenon).

5 *Compare Illumina*, 967 F.3d at 1329, *with* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 596 (2013) (noting that the patent-eligible method in *Illumina* is a "product of further research" from the patent-ineligible detection method in *Myriad*).

version of stalled legislation that incorporates the European Union's approach to allowing patents for natural phenomena that are "isolated" from their natural environment.

II. BACKGROUND

This Part provides a background of patent eligibility case law, as well as a discussion of key biopharmaceutical technologies that may not be patent eligible under the current system.

A. LEGAL BACKGROUND

Patent eligibility law describes the subject matter worthy of patent protection.[6] Rooted in statute, § 101 defines "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" as eligible for patent protection.[7] The Supreme Court first extended patent eligibility to living organisms in *Diamond v. Chakrabarty*, where they held that a lab-generated genetically modified bacterium was eligible for patent protection.[8] The Court also reiterated the longstanding statutory exceptions to eligibility: (1) laws of nature, (2) natural phenomena, and (3) abstract ideas.[9] Defining the boundaries of where these exceptions end and patent-eligible subject matter begins is still wreaking havoc on modern U.S. patent law in the Federal Circuit and Supreme Court.[10]

One of the defining pillars of patent eligibility exceptions for biotechnology is that DNA-derivative patents are often found to be ineligible natural phenomena because they do not add a sufficient "inventive step" beyond

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6 *See* 35 U.S.C § 101 (defining patent subject matter eligibility).

7 *See id.*

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

9 *See* Mayo Collaborative Servs. v. Prometheus Lab'y, 566 U.S. 66, 70 (2012) (citing Diamond v. Diehr, 450 U.S. 175, 185 (1981)).

10 *See The State of Patent Eligibility in America Part I*: *Hearing Before the Subcomm. on Intell. Prop. of the S. Comm. on the Judiciary*, 116th Cong. 6–7 (testimony of Retired J. Paul R. Michel, Fed. Cir.) (testifying to the subcommittee that "[t]he current state of eligibility must be characterized as chaotic. Massive uncertainty pervades all determinations, whether by 8,300 patent examiners, 1,000 federal trial judges, or 18 Federal Circuit judges").

merely detecting or creating something that exists in nature.[11] In *Mayo Collaborative Services v. Prometheus Laboratories*, the Supreme Court found that a method for detecting thiopurine concentration levels did not sufficiently advance the "natural phenomena" of how the body metabolizes thiopurine drugs.[12] In modern patent law, this case had the most significant impact on biotechnology patent practice and how research entities and pharmaceutical companies approach their patent portfolios.[13] For example, many companies shifted their investments away from the United States and towards places like the European Union, where DNA and DNA-derivatives are patent eligible.[14]

The next key decision grappling with the natural phenomena exception was *Association for Molecular Pathology v. Myriad Genetics, Inc*.[15] Myriad Genetics had discovered the location and sequence of the gene whose mutation increases the chance for women to develop breast cancer.[16] Myriad Genetics argued that the method for isolating the gene was similar to the protection offered to the living genetically modified organisms in *Chakrabarty*.[17] The Supreme Court, however, determined that because the isolated DNA was merely "naturally occurring" DNA in the human body, the discovery did not rise above the natural phenomena exception to warrant patent eligibility.[18]

Recognizing that *Mayo* and *Myriad* created a vague borderland between naturally occurring phenomena and an actual patent-eligible invention, the

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11 *See Mayo*, 566 U.S. at 71 (stating that natural phenomena are patent ineligible unless they add an application to a process).

12 *See id.* at 66 (noting that the thiopurine processes were not themselves natural laws and they are also not sufficient to transform the nature of the claims).

13 *See* Liddicoat et al., *supra* note 1, at 832, 837 (discussing the impact that *Mayo* had on companies manage their patent portfolios).

14 *See* Kevin Madigan & Adam Mossoff, *Turning Gold into Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939, 958–59 (2017) (finding that "the manufacturing, licensing and other key economic activities predicated on [patent eligibility] will not occur in [European and Chinese] jurisdictions, and not in the U.S.").

15 *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 596 (2013) (discussing the natural phenomena exception).

16 *See id.* at 576.

17 *See id.* at 589–91 (acknowledging *Myriad's* reliance on *Chakrabarty*).

18 *See id.* at 589 (noting that *Myriad's* discovery of genes was not patent eligible because it did not render a new composition of matter).

Supreme Court continued to build on the *Mayo* test for patent eligibility in *Alice Corporation v. CLS Bank International*.[19] While *Alice* focused on a computer assisted method patent, the Court still needed to distinguish between an abstract idea or natural phenomena, and a useful art warranting patent protection. The court dictated a two-step test, which first asks "whether the claims at issue are directed to a patent-ineligible concept."[20] If the claims are directed to a patent-ineligible concept, then the analysis shifts to whether the "claim's elements . . . 'transform the nature of the claim' into a patent-eligible application."[21]

While this two-step test narrowed legal framework for distinguishing a phenomenon from patent-eligible subject matter, the test fails to address the demands of the biotech industry, ramifications of which are seen in the Federal Circuit cases that soon followed. For example, *In re* BRCAI- and BRCA2-Based Hereditary Cancer Test Patent Litigation looked to the patent eligibility of DNA primers.[22] DNA primers establish the starting point on a DNA strand to conduct replication, a naturally occurring process that takes place in human cells every second of every day.[23] Isolating these primers, however, allows scientists to manipulate cell replication through polymerase chain reaction, or PCR.[24] PCR is considered to be one of the "most important scientific advances in molecular biology" because it amplifies specific DNA sequences, making it possible to study, diagnose, and treat a variety of diseases and cell-based reactions in all organisms.[25]

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19 *See* Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 217–18, 221–22 (2014) (referring to the *Mayo* test multiple times throughout the opinion).

20 *Id.* at 218.

21 *See id.* at 208, 217–18.

22 *See In re* BRCAI- & BRCA2-Based Hereditary Cancer Test Pat. Litig., 774 F.3d 755, 758 (Fed. Cir. 2014) ("The four composition of matter claims now on appeal are directed to primers, which are 'short, synthetic, single-stranded DNA molecule[s] that bind[] specifically to . . . intended target nucleotide sequence[s].'").

23 *See id.* at 760–61 (explaining that DNA primers are involved in the first step in PCR).

24 *See id.* (stating that DNA fragments serve as a "starting material for a DNA polymerization process" when isolated as primers).

25 *See Polymerase Chain Reaction (PCR) Fact Sheet*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE, https://www.genome.gov/about-genomics/fact-sheets/Polymerase-Chain-Reaction-Fact-Sheet [https://perma.cc/FQG8-YRZ5] (Aug. 17, 2020) (explaining what PCR is and how it contributes to various laboratory and clinical techniques).

To jumpstart this process though, one needs the correct primer for the target strand, such as the specific primer for the *In re* BRCAI gene, before the lab can amplify the gene.[26] Having the ability to synthesize that gene through PCR gives scientists the ability to further understand how the all-too-often deadly BRCAI mutation, which leads to breast cancer, can occur.[27]

Nonetheless, following the natural phenomena exception, the Federal Circuit found that the primer fulfilled a "function similar to that found in nature" and therefore was not patent eligible.[28] The court relied heavily on *Myriad*, given the factual similarities.[29] Specifically, in *Myriad*, the patentee had isolated naturally occurring DNA, and here in *In re* BRCAI, the patentee had identified the primer that would naturally correspond to a DNA strand during replication in the human body.[30]

The Federal Circuit reiterated the patent ineligibility of DNA primers in *Roche Molecular Systems, Inc. v. CEPHEID*.[31] While Roche argued that these DNA primers take the second *Alice* "transformation step" because they are "directed to artificial, man-made primers that are different from naturally occurring DNA," the court did not find the argument compelling because of the identical sequences.[32] Relying heavily on *Myriad* and *In re* BRCAI, the court reiterated that "primers necessarily contain identical sequences of the nucleotide sequence directly opposite to the DNA strand to which they are designed to bind. They are structurally identical to the ends of DNA strands found in nature."[33]

Recently, the Federal Circuit has shied away from attempting to refine their § 101 case doctrine. In *Athena Diagnostics, Inc. v. Mayo Collaborative Services,*

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26 *See id.* (discussing the DNA denaturing and synthesizing process before amplifying the gene).

27 *See id.* (explaining valuable use of PCR in diagnosing genetic disorders).

28 *See In re* BRCAI- & BRCA2-Based Hereditary Cancer Test Pat. Litig., 774 F.3d 755, 761 (Fed. Cir. 2014) (holding that primers are not patent eligible as they have a "function similar to that found in nature" and do not have a unique structure).

29 *See id.* at 759–61 (discussing *Myriad* in depth by drawing factual similarities).

30 *See id.* (finding that primers in *BRCAI* are "not distinguishable from the isolated DNA found patent ineligible in *Myriad*").

31 Roche Molecular Sys., Inc. v. CEPHEID, 905 F.3d 1363 (Fed. Cir. 2018).

32 *See id.* at 1369 (rejecting Roche's argument for patent eligibility based on the identical nucleotide sequences to naturally occurring DNA).

33 *See id.* at 1369 (citing *In re* BRCAI- & BRCA2-Based Hereditary Cancer Test Pat. Litig., 774 F.3d 755, 760 (Fed. Cir. 2014)).

LLC, the Federal Circuit reiterated the Supreme Court's *Mayo* holding, finding that diagnostic patent claims that merely "detect" natural phenomena are ineligible.[34] This case in particular looked to a method for diagnosing an autoimmune disease by detecting the presence of MuSK antibodies in the blood.[35] The Federal Circuit panel held that patent holder's invention did "not point to any innovation other than its discovery of the natural law" and thus the patent was ineligible subject matter.[36] A key point of contention with *Athena* did not rest on the panel's opinion though, it came from the denial to rehear the case en banc.[37]

The *Athena* rehearing denial included eight concurring and dissenting opinions discussing a wide variety of doctrinal approaches to biotechnology patent eligibility,[38] reinforcing not only the Federal Circuit's dissatisfaction with its own approach, but the confusion they project to the biotechnology industry. A case with this much uncertainty and dispute should have been taken up by the Supreme Court, but the Supreme Court *also* denied to hear the case, indicating a nudge for Congress or the Federal Circuit to take action on clarifying these § 101 issues.[39]

In a parallel procedural posture surrounding § 101 issues, the Federal Circuit also denied a petition to rehear *Berkheimer v. HP Inc.* en banc.[40] While this case focused on the "abstract idea" exclusion from patent eligibility in the scope of computer-related technology, the Federal Circuit still made a similar plea to Congress and the Supreme Court as they did in the *Athena* en banc denial.[41] The

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[34] *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743, 749–50 (Fed. Cir. 2019).

[35] *See id.* at 747 (indicating that patent claims at issue concern "methods of diagnosing neurological disorders such as MG by detecting autoantibodies that bind to a MuSK epitope").

[36] *See id.* at 752.

[37] *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1335 (Fed. Cir. 2019) (denying rehearing en banc).

[38] *See id.*

[39] Athena Diagnostics, Inc. v. Mayo Collaborative Servs., 140 S. Ct. 855 (2020) (mem. denying cert.); *see* KEVIN T. RICHARDS, CONG. RSCH. SERV., LSB10344, JUDGES URGE CONGRESS TO REVISE WHAT CAN BE PATENTED 4 (2019).

[40] *See* Berkheimer v. HP Inc., 890 F.3d 1369, 1369 (Fed. Cir. 2018) (per curiam) (denying rehearing en banc).

[41] *See id.* at 1374 (Lourie, J. concurring in the denial of the petition for rehearing en banc) (pleading that "the law needs clarification by higher authority,

dissent iterates how complex the § 101 precedent has become, and how difficult it will be to continue to implement.[42]

For years, the Federal Circuit was consistent in how it approached the "naturally occurring" DNA-related patents, such as in *Myriad*, *In re* BRCAI, and *Roche*. A recent decision in *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, however, continued to build upon the confusion generated by the *Athena* denial.[43] While the patent at issue aligns more closely with the diagnostic patents discussed in *Mayo* and *Athena*, this case still helps provide some guidance on a patent eligibility of a biotech related natural phenomena.[44]

The *Illumina* patent involved a method for testing cell-free fetal DNA in maternal blood.[45] Under *Mayo*, this would have previously been considered a product of nature because it was not adding a sufficient "inventive step" beyond detecting a naturally occurring product and should have been found patent ineligible under *Roche* or *Myriad*. The Federal Circuit, however, found that because this patent included "physical process steps to selectively remove some maternal DNA in blood to produce a mixture enriched in fetal DNA" that it took the necessary transformative step under *Alice* to be patent eligible.[46]

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perhaps by Congress, to work its way out of what so many in the innovation field consider § 101 problems").

42 *See id.* at 1377, 1380 (Reyna, J. dissenting in the denial of the petition for rehearing en banc) (finding that "the court offers no meaningful guidance to the bar, the government, or the public on how to proceed on these new grounds" and "the consequences of this decision are staggering and wholly unmoored from our precedent").

43 *See* Illumina, Inc. v. Ariosa Diagnostics, Inc., 967 F.3d 1319 (Fed. Cir. 2020). Appellant, Roche Molecular Systems, filed a petition for certiorari with the Supreme Court, but both parties filed a joint stipulation of dismissal on May 21, 2021, leaving the Federal Circuit opinion as the final authority on this case. Docket No. 20-892, SUP. CT. OF THE U.S., https://www.supremecourt.gov/docket/docketfiles/html/public/20-892.html [https://perma.cc/N45E-RLUR]

44 *See id.* at 1329. According to the Federal Circuit, the technology in *Illumina* is "[n]ot a diagnostic," but a "method of preparation." *Id.* at 1325. The similarities, however, between the patent-eligible subject matter in *Illumina* and the patent-ineligible subject matter in *Athena* and *Mayo* attempt to provide some clarity on where the Federal Circuit draws the lines. *See infra* discussion below on p. 467.

45 *See id.* at 1326.

46 *See id.* at 1329.

While *Illumina* helps take a step in the right direction for providing much needed patent protection for novel biotechnology inventions, the vague and discretionary "physical process steps" that take this diagnostic tool from detecting a naturally occurring phenomena to a patent-eligible subject matter is still difficult to articulate, even for experts in the field.[47] This case is closely related to *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, which the Federal Circuit decided in 2015 because of the similar methods in "detecting" cell-free fetal DNA.[48]

In *Ariosa*, the patents claims "covered only the knowledge that [fetal DNA] exists and a method to see that it exists."[49] Whereas, in *Illumina*, the claims "do not merely cover a method for detecting" but a method that tangibly removes maternal DNA from the mother's blood to "prepare a fraction of cell-free DNA."[50] Although the patents are unrelated, this set of cases helps identify part of the gap in protection that novel innovations and discoveries receive in the current patent eligibility regime. The Federal Circuit themselves admitted in their *Illumina* decision that "inventors [in *Ariosa*] made a discovery" which had a "profound impact . . . on the field of prenatal medicine.[51] Yet, "no matter how significant it was to the medical field, was not itself patentable" under Supreme Court doctrine.[52]

Further, the Federal Circuit itself admits that it requires "further research" to get beyond the mere "discovery" of patent-ineligible detection of a natural phenomenon and to achieve the sufficient "inventive step" to achieve patent-eligible status.[53] What the court fails to acknowledge is the time, money, and investments that must be made between the discovery and the sufficient inventive step *without* guarantee of patent protection.

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47 *See* Warren D. Woessner & Robin A. Chadwick, *Section 101: What's Left to Patent in the Life Sciences after* Myriad, Mayo, *and* Alice, 101 J. PAT. & TRADEMARK OFF. SOC'Y 121, 125 (2019).

48 *See* Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1379–80 (Fed. Cir. 2015) (holding that the patent for detecting the presence of cell-free fetal DNA was directed to patent-ineligible natural phenomena).

49 Illumina, Inc. v. Ariosa Diagnostics, Inc., 952 F.3d 1367, 1373 (Fed. Cir. 2020), *petition for cert. filed* (Jan. 5, 2021) (providing a discussion on *Ariosa* in distinguishing the two patents).

50 *See id.*

51 *See id.* at 1374.

52 *See id* at 1375.

53 *See id.* (noting that discovery alone does not satisfy the § 101 inquiry).

B. SCIENTIFIC BACKGROUND

Naturally derived technologies are invaluable to the biotechnology industry.[54] Recently, scientists have discovered cutting edge technology that could change how the biotechnology industry approaches synthetic biologic treatments.[55] Within each cell in the human body are several organelles which carry out the varying functions of the cell, such as maintaining homeostasis and translating DNA for protein and enzyme creation.[56] Manipulating these cell functions (for instance, to increase or inhibit enzyme production) previously required manipulating all functions in the cell, which led to high risks of toxicity and upsetting the balance of the cell to maintain viability.[57] For example, someone suffering from cystic fibrosis has inherited a gene mutation in their CFTR gene, which results in the gene unable to properly express itself for translation into a protein the body needs to regulate salt levels in cells.[58] This lack of proper salt regulation in the cells causes a thick layer of mucus that results in severe respiratory problems.[59] Similarly, sickle cell anemia is caused by a gene mutation that results in the translation to abnormal hemoglobin, or the blood protein that

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54 *See* Liddicoat et al., *supra* note 1, at 805 (explaining that molecular test development is a risky proposition for companies from both a time and monetary perspective).

55 *See* Celia Henry Arnaud, *Artificial Organelles Are Designed for Protein Engineering*, CHEM. & ENG'G NEWS: SYNTHETIC BIOLOGY (Mar. 30, 2019), https://cen.acs.org/biological-chemistry/synthetic-biology/Artificial-organelles-designed-protein-engineering/97/i13 [https://perma.cc/GE4K-TQTT] (discussing how the development of "designer organelles might make it easier to produce engineered proteins in mammalian cells").

56 *See id.*; *Organelle*, NAT'L HUM. GENOME RSCH INST. (Aug. 9, 2022), https://www.genome.gov/genetics-glossary/Organelle [https://perma.cc/59TY-BA89].

57 *See* Kingery, *supra* note 2 (explaining new approach which manipulates intrinsically disordered proteins without having to disrupt all cell functions); Roy A.J.F. Oerlemans, et al., *Artificial Organelles: Towards Adding or Restoring Intracellular Activity*, 22 CHEMBIOCHEM 2051, 2074 (2021).

58 *See Cystic Fibrosis*, MAYO CLINIC (Nov. 23, 2021), https://www.mayoclinic.org/diseases-conditions/cystic-fibrosis/symptoms-causes/syc-20353700 [https://perma.cc/4Y9J-G8AZ].

59 *See id.*

carries oxygen throughout the body.[60] An inability to properly carry oxygen to the rest of the body can result in painful deoxygenation, fatigue, and other more serious symptoms.[61] In summary, these genetic mutations are uncontrollable and minute in theory, but they lead to irregular proteins which severely disrupt the body's homeostatic functioning.

Thus, finding technologies that provide a "personalized" approach to the specific gene expression or protein translation problem can make massive headway in mitigating the impacts of these deadly genetic diseases. Precision medicine, specifically, seeks to treat patients suffering from these genetic disorders by first identifying the gene mutation, and then designing targeted biological variations as a treatment to counteract the negative impact of the mutation.[62] For example, in non-small cell lung cancer, the EGFR gene is "frequently overexpressed" which results in metastasis of the cancer cells.[63] Therefore, generating a biologics-based treatment that includes genetic inhibitors to block gene expression results in lower expression, and subsequently slower cancer spread.[64]

Recent studies have identified "artificial organelles" as a novel alternative to protein creation.[65] These organelles can be manipulated to perform their traditional cell functions, but outside the cell to avoid the risk of toxicity and cell maintenance.[66] Specifically, these technologies could transform the approach to

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60 *See Sickle Cell Anemia*, MAYO CLINIC (Mar. 9, 2022), https://www.mayoclinic.org/diseases-conditions/sickle-cell-anemia/symptoms-causes/syc-20355876 [https://perma.cc/7V4L-M4WR].

61 *See id.* (noting other symptoms such as anemia, episodes of pain, swelling of hands and feet, frequent infections, delayed growth or puberty, and vision problems).

62 *See* Xiangdong Wang, *Gene Mutation-Based and Specific Therapies in Precision Medicine*, 20 J. CELLULAR & MOLECULAR MED. 577, 577 (2015) (discussing use of precision medicine to "fight the most difficult diseases" by targeting the abnormal gene directly).

63 *See id.* at 578.

64 *See id.* (discussing clinical study where an EGFR inhibitor showed effectiveness in patients).

65 *See* Kingery, *supra* note 2.

66 *See id.* (discussing use of the "floppy" regions of intrinsically disordered proteins to control various cellular functions).

targeted medication.[67] They are highly adaptable, "changing from a liquid to a gel, for example, or from a soluble to an insoluble state, and back again – in response to environment triggers, like changes in temperature."[68] Further, these cell-free organelles can eventually be modified to shift their response and reaction inside the body, making it vital to approaching personalized medicine.[69]

These cell-free technologies are not yet economical, and thus their development progress and approval has been slow.[70] Further, if these artificial organelles are derived from a non-modified DNA or RNA sequence, or too closely resemble a naturally occurring organelle, then it would be patent ineligible under *Roche*'s application of the *Alice* test.[71]

III. PROBLEM

The lack of doctrinal clarity on § 101 has left an uncertainty regarding biotechnology patent eligibility, which in turn, stifles development.[72] The Supreme Court has decided four cases in the past eight years in an attempt to refine its own interpretation of § 101, yet the doctrine still remains murky at best.[73] In fact, the Supreme Court had denied forty-two petitions for certiorari on patent eligibility concerns alone.[74] Subsequently, scholars have identified 1,694 patents that were

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67 *See id.* (explaining the use of "intrinsically disordered protein organelles to control the activity levels of bio-molecules important to disease states").

68 *See id.*

69 *See id.*

70 *See* David Burgenson et al., *Rapid Recombinant Protein Expression in Cell-Free Extracts from Human Blood*, SCIENTIFIC REPORTS 1 (June 22, 2018) (discussing difficulty of navigating safety regulatory requirements when developing cell-free technologies).

71 *See* Roche Molecular Sys., Inc. v. Cepheid, 905 F.3d 1363, 1369 (Fed. Cir. 2018).

72 *See* Liddicoat et al., *supra* note 1, at 837 (concluding that *Myriad* and *Mayo* have negatively affected the development of biotechnology tests).

73 *See* Shahrokh Falati, *To Promote Innovation, Congress Should Abolish the Supreme Court Created Exceptions to 35 U.S.C. § 101*, 28 TEX. INTELL. PROP. L.J. 1, 23 (2019) (stating that "[t]he Supreme Court has not heard four cases in the area of patent eligibility recently . . . [yet] has been unable to identify a coherent test").

74 *See The State of Patent Eligibility in America Part I*: *Hearing Before the Subcomm. on Intell. Prop. of the S. Comm. on the Judiciary*, 116th Cong. 4 (testimony of Q. Todd Dickinson, Former Under Sec'y of Com. and Dir. of the USPTO).

rejected in the United States as "patent ineligible subject matter" that were subsequently granted in the Europe, many of which "representing pioneering, life-saving inventions, such as treatments for cancer or diabetes."[75]

A. JUDICIAL UNCERTAINTY

Further, the Federal Circuit themselves are dissatisfied with both their own case law and that of decisions handed down by the Supreme Court. In the *Athena* en banc denial, Judge Lourie begrudgingly concurred in the denial to rehear the case, but only because of how restricting the case law was. Specifically, Judge Lourie articulated:

> If I could write on a clean slate . . . I would not exclude uses or detection of natural laws. The laws of anticipation, obviousness, indefiniteness, and written description provide other filters to determine what is patentable.
>
> But we do not write here on a clean slate; we are bound by Supreme Court precedent. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the claims at issue were held by the Court to be directed to the relationship between the concentration of metabolites in the blood and the likelihood that a drug dose will be ineffective, which it referred to as a law of nature.[76]

Judge Newman, however, felt that the court in *Athena* was inflating the *Mayo* holding in "substance and application."[77] Judge Newman wrote that the test does not bar diagnostic methods, but rather bars naturally occurring things.[78] She stressed that the claims in *Athena*, specifically the reaction between the specified antibodies and the protein discovered were "not previously known" and therefore

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[75] *See* Madigan & Mossoff, *supra* note 14, at 939. (finding the "cause of U.S. rejections is the Supreme Court's recent spate of decisions that upended patent eligibility doctrine, especially in . . . biotech innovation").

[76] *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1335 (Fed. Cir. 2019) (Lourie, J., concurring in the denial of rehearing en banc).

[77] *See id.* at 1364 (Newman, J., dissenting from denial of the petition for rehearing en banc).

[78] *See id.*

should have been found eligible under the second step in the *Alice/Mayo* test.[79] Judge Stoll, also dissenting, expressly called out the lack of consistency and doctrinal standards that exists in U.S. jurisprudence for § 101 issues, writing that "[a]t the very least, en banc review would help the court develop an articulable standard for its § 101 jurisprudence moving forward."[80]

While judicial disagreement is expected, this rapid evolution of a doctrine that cannot be articulated by the appellate court is problematic. The larger problem lies not within the United States' recent uncertainty in defining a natural phenomena, but in the larger patent law doctrine which may or may not allow patenting of DNA, or its naturally occurring derivatives such as artificial organelles, depending on what the judges decide is a sufficient transformation on a particular day.[81]

Apart from a mere "power play," keeping biopharmaceutical investments in the United States is important for maintaining drug manufacturing reliability via U.S. regulations, maintaining high paying jobs, and accessibility.[82] Patent eligibility is important for small businesses and start-ups to attract the necessary funding for the "riskier" investments.[83] To isolate, identify, and produce these DNA derivatives is a massive financial undertaking for a research institution or company, and patents remain a core motivation to companies developing their

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79 *See id.* at 1364 (Newman, J., dissenting from denial of the petition for rehearing en banc).

80 *See id.* at 1371 (Stoll, J., dissenting from denial of the petition for rehearing en banc).

81 *See supra* Section II.A and accompanying discussion on the *Alice/Mayo* test.

82 *See* PHARM. RSCH. & MFRS. OF AM., ECONOMIC IMPACT OF THE U.S. BIOPHARMACEUTICAL INDUSTRY: 2017 NATIONAL AND STATE ESTIMATES 4–7 (2019) (reiterating the high-quality jobs available in the biopharmaceutical industry).

83 *See* Press Release, Chris Coons, U.S. Sen. for Delaware, Sens. Coons and Cotton, Reps. Stivers and Foster Introduce Bipartisan, Bicameral Bill to Protect US Patent Holders, Inventors, Chris Coons (July 10, 2019), https://www.coons.senate.gov/news/press-releases/sens-coons-and-cotton-reps-stivers-and-foster-introduce-bipartisan-bicameral-bill-to-protect-us-patent-holders-inventors [https://perma.cc/M7TM-EJL9] (finding "if a startup receives a patent, its chance of securing venture capital increases over 50% and it is likely to have better growth in employment and sales").

research portfolio.[84] Patents provide "definable, exclusive, and transferable" rights for a company.[85]

The uncertainty of obtaining these rights in the United States incentivizes investors, who find the U.S. patent system "risky," to seek protection elsewhere, weakening not only the patent system but the U.S. economy as a whole.[86] In fact, it was considered the favorable ruling for biotechnology in *Chakrabarty* in the 80s that helped jumpstart the United States as a leader in the industry, a position that has only been weakened as the patent eligibility doctrine surrounding life sciences has strayed.[87]

The policy rationale behind finding DNA unpatentable stems from fear of excluding the "uses of a natural product" and thus "stifling innovation."[88] Those opposed to patenting natural derivatives of DNA often oppose for both ethical reasons and anticompetitive reasons.[89] First, the human genetic code is limited, so the potential for patenting DNA sequences and their "naturally occurring" mRNA

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[84] *See* Liddicoat et al., *supra* note 1, at 805 (finding that "costs could vary substantially from $1 million to $150 million for the full development of a [molecular biology] test in multiple countries").

[85] *See id.* at 808.

[86] *See* Testimony of Retired J. Michel, *supra* note 10 (testifying that "[patent] investments are vital to competing successfully with global rivals, particularly China, and creating good-paying jobs. Unless this problem is resolved, our nation's innovation economy will weaken and our world leadership in science and technology will decline."); *U.S. Patent Eligibility Muddle Sets It Apart from Other Countries*, BLOOMBERG L. (Nov. 12, 2021, 5:01 AM), https://news.bloomberglaw.com/ip-law/u-s-patent-eligibility-muddle-sets-it-apart-from-other-countries [https://perma.cc/A4Y2-VPTH] ("[M]any companies said the uncertainty around U.S. patent eligibility affects strategic decisions.").

[87] *See* Testimony of Q. Todd Dickinson, *supra* note 74 (testifying that "it is believed that it is easier to get software and life sciences patents in Europe and China, where previously the U.S. was the leader in expansive patent protection").

[88] *See* Woessner & Chadwick, *supra* note 47, at 158 (noting the rationale behind finding patent claims invalid for natural processes).

[89] *See* Stephen H. Schilling, *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents*, 61 DUKE L.J. 731, 732, 743 (2011) (acknowledging the ethical and anticompetitive objections to gene patents).

or protein derivatives is finite.[90] Further, some critics fear that this could lead to increased prices in life-saving diagnostic tests, or lack of accessibility to medical treatments.[91] These fears, however, are largely unfounded. Numerous life-saving drugs, treatments, and tests that are under exclusively-licensed patents are often similarly priced to those that are not.[92]

B. UPSTO IMPLEMENTATION GAPS

While the United States Patent and Trademark Office ("USPTO") attempts to provide administrative guidance for examiners and inventors on patent-eligibility restrictions, the rapid shift in case law coupled with a lack of Congressional action to update § 101 often leaves these suggestions outdated or inapplicable.[93] For example, the USPTO publishes a Manual of Patent Examining Procedure ("MPEP"), the most recent of which was revised and published in June of 2020.[94]

Regarding subject matter eligibility for DNA derivatives and other naturally occurring products, the MPEP first must define the "product of nature exception."[95] The MPEP attempts to reconcile competing doctrines, but even in articulating the doctrinal approach to the product of nature section, problems continue to come to light. For example, the MPEP even acknowledges that a "product of nature" does not necessarily have to be naturally derived.[96] Further,

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90 *See* Schilling, *supra* note 89, at 743 (noting that there is a limit in what is possible).

91 *See id.* at 744.

92 *See id.* (stating that exclusively licensed patents are often similarly priced to nonexclusively licensed patents).

93 *See* Falati, *supra* note 73, at 28 (noting the rapid shift in case law has resulted in inconsistencies). Further, despite the rapid changes in technology, Congress has not updated the patent eligibility statute since its adoption in 1952. *See* 35 U.S.C. § 101; *see also infra* Section IV.A–B (discussing calls to Congress, and failed attempts to update § 101).

94 *See* MANUAL OF PATENT EXAMINING PROCEDURE (9th ed. Rev. 10.2019, June 2020) [hereinafter MPEP].

95 *See id.* § 2106.04(c).

96 *See id.* (articulating that for subject matter eligibility "it makes no difference that the identified gene sequences are synthetically replicated . . . a synthetic, artificial, or non-naturally occurring product such as a cloned organism or a human-made hybrid plant is not automatically eligible because it was created by human ingenuity or intervention").

"[n]ature-based products, as used herein, include both eligible and ineligible products . . . ."[97] The MPEP attempts to reconcile the confusion by defining its own version of the *Alice*/*Mayo* test, calling it the "markedly different" test. A product is eligible for a patent from the USPTO if it satisfies the "markedly different characteristics analysis."[98]

While the markedly different characteristics analysis test incorporates the *Alice*/*Mayo* two-step analysis, it is no less complex. The first step requires identifying the "naturally occurring thing" that the nature-based product is derived from.[99] This includes (if the claimed product is a primer, such as in *Roche*[100]) the nucleotide sequence of DNA that the primer is derived from would be the naturally occurring product.[101] Or, for example, in *Myriad*,[102] comparing the corresponding naturally occurring BRCA1 gene to the purified and isolated BRCA1 gene and its cDNA counter parts.[103]

The second MPEP analysis step then requires identification of the "appropriate characteristics to compare" through the limiting of what exactly is claimed.[104] The second step, however, also demands consideration of "non-limiting characteristics" that are considered in patent eligibility. These include:

- Biological or pharmacological functions or activities;
- Chemical and physical properties;
- Phenotype, including functional and structural characteristics; and

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97 *See id.*

98 *See id.*

99 *See id.*

100 *See* Roche Molecular Sys., Inc. v. Cepheid, 905 F.3d 1363, 1366 (Fed. Cir. 2018).

101 *See* MPEP, *supra* note 94, § 2106.04(c) (listing the *Roche* case as an example).

102 *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 590 (2013).

103 *See* MPEP, *supra* note 94, § 2106.04(c) (listing the *Myriad* case as an example).

104 *See id.* (finding "appropriate characteristics can be expressed as the nature-based product's structure, function, and/or other properties, and are evaluated on a case-by-case basis.").

- Structure and form, whether chemical, genetic, or physical.[105]

Examples of biological or pharmacological functions or activities include, but are not limited to:

i) the protein-encoding information of a nucleic acid, *Myriad*, 569 U.S. at 590-91, 106 USPQ2d at 1979;

ii) the ability of complementary nucleotide sequences to bind to each other, *Ambry Genetics*, 774 F.3d at 760-61, 113 USPQ2d at 1244;

iii) the properties and functions of bacteria such as the ability to infect certain leguminous plants, *Funk Bros.*, 333 U.S. at 130-31, 76 USPQ2d at 281-82;

iv) the ability to degrade certain hydrocarbons, *Diamond v. Chakrabarty*, 447 U.S. at 310, 206 USPQ2d at 195; and

v) the ability of vitamin C to prevent and treat scurvy, *In re* King, 107 F.2d 618, 27 CCPA 754, 756-57, 43 USPQ 400, 401-402 (CCPA 1939).[106]

Thus, the patent examiner must consider far beyond just what is claimed. Finally, the third step requires the tangible "markedly different" characteristics analysis.[107] The MPEP suggests that in order to be markedly different the patentee applicant "applicant must have *caused* the claimed product to possess *at least one* characteristic that is different from that of the counterpart."[108] Further, the MPEP suggests if the invention does in fact possess at least one different characteristic, "then the change will generally be considered a markedly different characteristic such that the claimed product is not a product of nature exception."[109]

This guidance could be construed in a multitude of ways and clearly does not always align with the court's thinking, especially given the recent court cases

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105 *See id.* (listing examples but not restricting the set of possible cases).

106 *See id.* (listing examples but not restricting the set of possible cases).

107 *See id.*

108 *See id.*

109 *See* MPEP, *supra* note 94, § 2106.04(c).

that struck down patents because they were considered "products of nature."[110] For example, in *Roche*, the Federal Circuit held that a synthetic DNA primer that was identical to the naturally occurring primer in the human body was directed to patent-ineligible subject matter.[111] The MPEP requires consideration of non-limiting, "biological or pharmacological functions," which applicable, are enough to strike a patent from subject matter eligibility.[112]

An argument could be made that under the most current MPEP guidance, the *synthetic* production of the DNA primer (as opposed to the naturally occurring, and likely extended version of the primer found in the human body) could be the markedly different characteristic because it does not follow the most natural process of DNA replication.[113] For example, were all physiological features that typically trigger DNA replication, and therefore require the "laying down" of the DNA primer present in the synthetic development? Was the "cut" strand used in the *Roche* patent the exact same length as the naturally occurring product, or just an identical partial sequence? These questions may lead an examiner under MPEP, who is considering the "biological function" of DNA replication to grant the synthetic derivation of the DNA primer subject matter eligibility, when in fact the courts would see it differently.[114]

Further, MPEP guidance used in this hypothetical discussion of synthetic DNA primer production is the *most recent* set of parameters for examiners analyzing patent applications for subject matter eligibility and was developed post-*Roche*.[115] This guidance highlights the difficulties in tasking an administrative agency with not only keeping up with the rapidly shifting judicial doctrine coming down from the courts, but also implementing that doctrine into tangible and useful guidance for patent applicants and examiners.[116]

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110 *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743, 744 (Fed. Cir. 2019); *see also* Roche Molecular Sys., Inc. v. Cepheid, 905 F.3d 1363, 1368 (Fed. Cir. 2018).

111 *See Roche*, 905 F.3d at 1364.

112 *See* MPEP, *supra* note 94, § 2106.04(c).

113 *See id.*

114 *See generally id.*; *see also Roche*, 905 F.3d at 1364.

115 *See* MPEP, *supra* note 94, § 2106.04(c).

116 *Compare* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 744 (Fed. Cir. 2019), *with* MPEP, *supra* note 94, § 2106.04(c).

IV. SOLUTION

Congress must take action. That action, however, must be specific, targeted, and adopt a standard that does not upend the patent-eligibility system, while also allowing protection for DNA derivatives. Further, it is important that Congress address this issue purely in the scope of DNA-derivatives, and other life science biologics. § 101, and patent eligibility, are often discussed together.[117] Computer and artificial intelligence-related subject matter eligibility issues relate distinctly to a "law of nature" or "abstract idea" exception under the current doctrine, while DNA-derivatives must have a tailored approach which focuses exclusively on their role as "products of nature," i.e., deriving from a natural or living organism originally.[118]

A. JUDICIAL CALL FOR CONGRESSIONAL ACTION

Judge O'Malley, dissenting from the denial to rehear *Athena* en banc, expressly "encourage[d] Congress to amend the Patent Act once more to clarify" patent eligibility.[119] Judge Hughes, concurring in the denial to rehear the case en banc, even explicitly asked Congress to take action, citing their "distinctive role in making the factual and policy determinations relevant to setting the proper balance of innovation incentives under patent law."[120] Judge Moore urged § 101 parties to move their efforts for real doctrinal change away from the Federal Circuit.[121]

When the Supreme Court denied certiorari on the *Athena* and *Berkheimer* cases in the same term, the Court all but urged Congress or some other party to

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117 *See* Warren Woessner, *Supreme Court Denies Cert. in* Vanda, Berkheimer *and* Athena, 10 NAT'L L. REV. (Jan. 13, 2020).

118 *Compare* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1372 (Fed. Cir. 2019), *with* Berkheimer v. HP Inc., 890 F.3d 1369, 1374 (Fed. Cir. 2018).

119 *See Athena Diagnostics*, 927 F.3d at 1371 (O'Malley, J. dissenting from denial of the petition for rehearing the case en banc).

120 *See id.* at 1337 (Hughes, J. concurring in the denial of the petition for rehearing en banc).

121 *See id.* at 1363 (Moore, J. dissenting, stating that there is"[n]o need to waste resources with additional en banc requests. Your only hope lies with the Supreme Court or Congress. I hope that they recognize the importance of these technologies, the benefits to society, and the market incentives for American business").

take action on this issue.[122] Since 2012 in its *Mayo* decision, the Supreme Court even called on Congress to address the policy complexities surrounding the proper technologies and incentives for patent eligibility. [123] This "call to action" by the Supreme Court to Congress is not unprecedented; it is unlikely the Supreme Court will make any radical or substantial changes to patent eligibility doctrine, especially with the landscape shift to a more conservative court.[124] In fact, the Supreme Court, as recently as 2022, asked the Biden Administration for input on whether they should once more consider hearing a contentious patent eligibility case.[125] Despite urging from the Executive branch, the Court once more declined to hear a case on the issue.[126] All things considered, Congress must take action to resolve these ambiguities.

B. PAST LEGISLATIVE FAILURES

Congress has attempted and failed to resolve § 101 issues.[127] In May of 2019, Senator Tillis, chairman of the Senate Subcommittee on Intellectual Property,

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122 *See* Woessner, *supra* note 117.

123 *See* Mayo Collaborative Servs. v. Prometheus Lab'y, 566 U.S. 66, 92 (2012) (finding that the Court, "must recognize the role of Congress in crafting more finely tailored rules where necessary . . . We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable").

124 *See* Jonathan S. Masur & Adam K. Mortara, *Patents, Property, and Prospectivity*, 71 STAN. L. REV. 963, 977 (2019) (finding "[e]ven during a period of rapid legal change, such as patent law has experienced over the past decade, courts may shy away from altering the law in ways that seem too sudden or consequential").

125 Blake Brittain, *U.S. Supreme Court Rejects American Axle Case on Patent Eligibility*, REUTERS (June 30, 2022, 7:45 PM), https://www.reuters.com/legal/litigation/us-supreme-court-rejects-american-axle-case-patent-eligibility-2022-06-30/#:~:text=WASHINGTON%2C%20June%2030%20(Reuters),which%20inventions%20warrant%20a%20patent [https://perma.cc/JP4U-2QXD].

126 *Id.*

127 On August 2, 2022, Senator Tillis introduced another bill in Congress seeking to address § 101 issues. However, for the purposes of this Note, the language of the 2019 draft bill provides the basis for analysis. Blake Brittain, *U.S. Senate Bill Would Reform Patent-Eligibility Standards*, REUTERS (Aug. 3, 2022, 11:32 AM), https://www.reuters.com/legal/government/us-senate-bill-

and Senator Coons, ranking member of the Senate Subcommittee on Intellectual Property, released a draft bill seeking to modify the definition of patent-eligible subject matter in 35 U.S.C. § 101.[128] The draft bill added new language as subsection (b) to § 101 and kept the original § 101 language as subsection (a). The draft text is as follows:

> (a) Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
>
> (b) Eligibility under this section shall be determined only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation.
>
> Additional Legislative Provision. No implicit or other judicially created exceptions to subject matter eligibility, including "abstract ideas," "laws of nature," or "natural phenomena," shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated.[129]

The draft outline of the Tillis-Coons bill also called for "exclusive categories of statutory subject matter which alone should not be eligible for patent protection" in an attempt to clear the muddy waters for both inventors and judges

would-reform-patent-eligibility-standards-2022-08-03/ [https://perma.cc/76NN-GLKS].

128 *See* Press Release, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act, Tom Tillis, U.S. Sen. for North Carolina (May 22, 2019), https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act [https://perma.cc/5ZHM-RH9T] (stating that the Senators want to reform the state of patent eligibility).

129 *See id.*

in the future.[130] This is a similar approach to the European Union's Patent Office, which provides a "non-exhaustive list" of subject matter categories.[131]

The Tillis-Coons bill was sent to committee and underwent multiple days of hearings a month before the *Athena* en banc denial called for congressional action.[132] Experts testifying spoke to the consequences of varied and uncertain judicial doctrine and the harms it has brought to the U.S. patent system.[133] The bill was subsequently sent back to committee for edits and stalled in committee.[134] In a politically charged statement, Senator Tillis accused the committee of refusing to compromise and letting "the great and perfect get in the way of the good."[135] No

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130 *See id.*; Press Release, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework, Tom Tillis, U.S. Sen. for North Carolina (Apr. 17, 2019) [hereinafter Tillis Press Release (Apr. 2019)], https://www.tillis.senate.gov/2019/4/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-section-101-patent-reform-framework [https://perma.cc/RXG8-28SJ].

131 *See* Evan H. Tallmadge, *Nationalizing TRIPS: An Examination Through Exceptions*, 18 J. MARSHALL REV. INTELL. PROP. L. 285, 295–96 (2019) (providing examples of patent-ineligible subject matter such as "(a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information").

132 *See* Press Release, Tillis and Coons: What We Learned at Patent Reform Hearings, Tom Tillis, U.S. Sen. for North Carolina (June 24, 2019), https://www.tillis.senate.gov/2019/6/tillis-and-coons-what-we-learned-at-patent-reform-hearings [https://perma.cc/XU2B-BBH5].

133 *See* Testimony of Retired J. Michel, *supra* note 10 (stating that stating that uncertainty, unpredictability, and inconsistency is harmful to the patent system).

134 *See* Jennifer Giordano-Coltart et al., *Patent Eligibility in Flux: Tracking the Tillis-Coons Bill*, KILPATRICK TOWNSEND (Aug. 9, 2019), https://kilpatricktownsend.com/Insights/Alert/2019/8/Patent-Eligibility-in-Flux [https://perma.cc/HAE2-V93U].

135 *See* Gene Quinn, *Senator Thom Tillis: If IP Stakeholders Can't Find Consensus, Congress Can't Help*, IP WATCHDOG (May 5, 2020), https://www.ipwatchdog.com/2020/05/05/senator-thom-tillis-ip-stakeholders-cant-find-consensus-congress-cant-help/id=121262/ [https://perma.cc/72MP-DPC2].

substantive congressional action has been taken since the subcommittee hearings in the summer of 2019.

Patent eligibility remains in the same state it was when the Federal Circuit judges desperately called for congressional and Supreme Court action in their *Athena* en banc denial in the summer of 2019. On his way out of the office in January 2021, former USPTO director Andrei Iancu called once more for patent eligibility reform that incentivizes all innovations.[136]

C. POTENTIAL COMPARATIVE APPROACH AND ASSESSING THE OPTIMAL SYSTEM

As the United States' approach to patent eligibility remains murky at best, other major patent issuing countries have found clear and assessable patent eligibility standards.[137] Looking to the European Union may reveal a potential guiding point for creating clear patent-eligibility doctrine for DNA-derivatives in the United States.

1. European Union

Described as a "biotech renaissance," Europe has recently seen an unprecedented growth in biopharmaceutical investments.[138] Coincidentally, as DNA-derivative products become an increasingly important component of biopharmaceuticals, the European Union continues to permit DNA and other biologically derived products to be eligible for patent protection. Foundational to their biotechnology patent-eligibility doctrine is the directive adopted by the European parliament in 1998, where section 21 reveals relevant language:

> Whereas such an element isolated from the human body or otherwise produced is not excluded from since it is, for example,

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136 *See* Muireann Bolger, *Iancu Resigns, Calls for End to 'State-Sponsored Theft'*, WORLD INTELL. PROP. REV. (Jan. 20, 2021), https://www.worldipreview.com/news/iancu-resigns-calls-for-end-to-state-sponsored-theft-20602 [https://perma.cc/H8D2-22DC] (stating that "[i]f the courts cannot do it, then will Congress step in with legislation and finally liberate our country from this quandary? We know that this issue is solvable").

137 *See* Testimony of Retired J. Michel, *supra* note 10 (suggesting that the US should learn from other countries' patent system); *U.S. Patent Eligibility Muddle Sets It Apart from Other Countries*, *supra* note 86.

138 *See* Melanie Senior, *Europe's Biotech Renaissance*, 38 NATURE BIOTECHNOLOGY 408, 408–09 (2020) (finding that Europe's "[g]lobal biotech venture funding in 2019, at $18.8 billion, was just up from the $17.0 billion raised in 2018").

> the result of a technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself;[139]

Further, the European Patent Council implemented these rules in accordance with the language of this directive, permitting "biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature" is patent eligible.[140] A direct comparison of the U.S. Patent Act with the European patent regime reveals the necessity of stronger legislative articulation of patent-eligible subject matter.[141] At a higher level, the European system for identifying patent-eligible subject matter is considered simpler, especially in the context of DNA-derivatives because the system expressly allows patenting DNA if some sort of inventive discovery or a technical process has been utilized in making use of the DNA.[142]

2. Proposed Solution

Congress should adopt a revised version of the Tillis-Coons bill,[143] where they abrogate previous judicial exceptions such as natural phenomena that have previously excluded vital technologies from patent protection, such as the isolation of the deadly BRCAI genetic mutation, or the identifying MuSK antibodies in the bloodstream.[144]

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139 *See* Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13, 15.

140 *See* Liddicoat et al., *supra* note 1, at 805.

141 See Ilija Ilijovski, *Perfecting U.S. Patentable Subject Matter – Merging the European Approach and the American Principles*, 19 CHI.-KENT J. INTELL. PROP. 182, 203 (2019) (finding that when comparing the U.S. and Europe patent regimes, "there is an insufficient amount of information about what is a patentable invention according to the U.S. Patent Act").

142 *See* Directive 98/44/EC, *supra* note 139, at 19 (indicating that derivatives of human genes can be patentable); *see also* Ilijovski, *supra* note 141, at 197 (stating that the EPO's approach for claiming patents is much simpler than the US).

143 Tillis Press Release (May 2019), *supra* note 128.

144 *See In re* BRCAI- & BRCA2-Based Hereditary Cancer Test Pat. Litig., 774 F.3d 755, 761 (Fed. Cir. 2014) (stating that the gene mutation in this case is a natural phenomenon and is not patentable); *see also* Athena Diagnostics, Inc.

Further, Congress should adopt a subsection (c) to § 101 of the draft Tillis-Coons bill that includes language targeting specific DNA sequences and derivative technologies, similar to the explicit language in the European Patent Directive.

Adopting target language for DNA derivatives specifically is critical due to the unique role that they play in precision medicine, and the massive financial undertaking that is required merely to isolate and identify the target gene strand before precision medicine can even begin to be effective.[145] Further, while explicit language does not make a statute immune to varying interpretations amongst the Federal Circuit and Supreme Court, it will ensure that DNA derivative technology is not subject to the *Alice*/*Mayo* "something more" than a natural phenomenon test. This solution will also clarify the competing regulations and examination methods in the USPTO MPEP manual.

v. Mayo Collaborative Servs., LLC, 915 F.3d 743, 750 (Fed. Cir. 2019) (stating that the antibody in this case is a natural law and is not patentable).

145 *See* Wang, *supra* note 62, at 578–79 (stating the importance of the language of DNA derivative and potential consequences of the massive financial burden).

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NOTE

TECHNOLOGICAL FAULT LINES: THE PROBLEMS WITH TAILORING PATENT ELIGIBILITY AT THE USPTO

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* © 2022 Joshua A. Lopez, J.D. Candidate, 2022, The George Washington University Law School; B.A., Physics, University of Pennsylvania. Thank you, Henry Loznev, for sharing your thoughtful and innovative arguments, and thank you to the editors of the *AIPLA Quarterly Journal*, for enabling me to present a response. Many thanks to my family, my friends, my classmates, and the inspiring faculty at GW Law for the invaluable support.

I. INTRODUCTION

In the wake of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, *Alice Corporation v. CLS Bank International*, and their progeny, the patent community has debated how to sort out the Supreme Court's exceptions to patent subject matter eligibility.[1] Starting in 2012 with *Mayo*, the Court reinvigorated a threshold patent inquiry, announcing that "laws of nature, natural phenomena, and abstract ideas" are inherent exceptions to patentable subject matter under § 101 of the Patent Act.[2] Patent claims now must be analyzed under the *Alice/Mayo* two-step inquiry: first, whether the claims are "directed to" one of the three judicial exceptions; and, if so, second, whether the claims add "something more" than conventional activity to achieve a patentable invention.[3] Many suggest that this judicially created § 101 standard is overly ambiguous and thus detrimental to innovators who will avoid the costs of research and development without more certain patent protection.[4] Lawmakers like Senator Thom Tillis and Senator Chris Coons would amend the patent statute to abrogate this line of cases altogether.[5] Some scholars suggest a deeper basis in the Constitution's Commerce Clause for an uprooting of the *Alice/Mayo* framework.[6] Critics call the *Alice/Mayo* test "broken" and argue the standard is "more appropriately an issue of patentability under 35 U.S.C. § 102

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1 Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208 (2014); Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66 (2012); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013); Henry Loznev, Note, *Tragedy of the Commons: Why the Supreme Court's Literal Application of "Product of Nature" Rule in* AMP v. Myriad Genetics *Necessitates a Legislative Change of 35 U.S.C. § 101*, 50 AIPLA Q.J. 427 (2022).

2 *Alice*, 573 U.S. at 2354; *Mayo*, 566 U.S. at 1290.

3 MANUAL OF PATENT EXAMINING PROCEDURE § 2106 (9th ed. Rev. 10.2019, June 2020) [hereinafter MPEP § 2106].

4 Jason D. Reinecke, *Is the Supreme Court's Patentable Subject Matter Test Overly Ambiguous? An Empirical Test*, 2019 UTAH L. REV. 581, 582 (2019).

5 Press Release, Sen. Thom Tillis, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act (May 22, 2019), https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act [https://perma.cc/C58P-5XFY].

6 Daniel Cole, *Why Removing 101 Won't Be Enough and What to Do Instead*, N.C. J.L. & TECH. 141, Mar. 2020, at 141 (discussing the need for significant alterations to the statutory text as abrogating the cases will not be enough).

and/or 35 U.S.C. § 103," the requirements for novelty and non-obviousness, respectively.[7]

Others recognize the merits of the *Alice*/*Mayo* patentability test.[8] During patent prosecution and litigation, the inquiry filters out mere acts of abstract contemplation or natural "discovery" from human-crafted, tangible, and patent-worthy innovations.[9] In his note, *Tragedy of the Commons: Why the Supreme Court's Literal Application of "Product of Nature" Rule in* AMP v. Myriad Genetics *Necessitates a Legislative Change of 35 U.S.C. §101*, Henry Loznev explores the Supreme Court's concern with overly broad patent protection and its endeavor to liberate the naturally occurring "building-block[s]" of scientific discovery.[10] Discussing the difficulties surrounding biotechnology patents and analyzing the judicial exceptions under John Locke's labor theory of property, Loznev arrives at a legislative solution to the subject matter eligibility debate.[11] Loznev generally agrees with the Supreme Court's reasoning in *Alice* and *Mayo* that the patent system should not restrain the fundamental tools of scientific research.[12] Yet, he acknowledges that overly burdensome, sweeping patent standards, like the *Alice*/*Mayo* test, should be revisited.[13] He explains that the judicially manufactured test could prevent scientific discovery and proliferation because this higher

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7 Eric W. Guttag, *The Broken Patent-Eligibility Test of Alice and Mayo: Why We Urgently Need to Return to Principles of* Diehr *and* Chakrabarty, IPWATCHDOG (Sep. 25, 2014, 8:00 AM), https://www.ipwatchdog.com/2014/09/25/broken-patent-eligibility-test-of-alice-and-mayo/id=51370/ [https://perma.cc/BD6K-9AXA] (discussing how the *Alice*/*Mayo* test provides no objective standard for judging patent eligibility).

8 *See* Erin E. Block & Eric Chadwick, *Subject Matter Eligibility Post* Alice*: A Boon Or A Bane For Tech Companies?*, HENNEPIN CNTY. BAR ASS'N: HENNEPIN LAWYER, https://www.mnbar.org/hennepin-county-bar-association/resources/hennepin-lawyer/articles/2020/02/04/subject-matter-eligibility-post-alice-a-boon-or-a-bane-for-tech-companies [https://perma.cc/3KJ4-KNFM] (discussing positive effect of "providing an avenue for tech companies to invalidate patents asserted against them by nonpracticing entities (NPEs)").

9 *See* Loznev, *supra* note 1, at 436–38.

10 Loznev, *supra* note 1; *Mayo*, 566 U.S. at 89.

11 *Id.* at 454–58.

12 *See id.*

13 *See id.* at 438–42.

burden for patent protection may foreclose investment or force innovators into trade secret protection and confidentiality.[14]

Loznev proposes legislation to imbue the United States Patent and Trademark Office ("USPTO") with "rulemaking authority as to the patentability of certain subject-matter in specific fields of science."[15] The U.S. Securities and Exchange Commission's ("SEC") authority to draft tailored rules and demand different levels of financial disclosure for different types of securities was inspiration for his proposed USPTO rulemaking authority.[16] Loznev suggests that flexible rulemaking is well-suited "to quickly respond to new developments in scientific research."[17] He seeks to balance the *Mayo* Court's goals of scientific liberation with the gripes of innovators who now possess uncertain patent protection under the current "rigid" judicial standard.[18] According to Loznev, the USPTO can most appropriately "tailor the [eligibility] rules" and strike the proper "balance between incentivizing discovery and patent abuse."[19] In *Rulemaking § 101*, Brendan Costello also discusses the USPTO's historical role as a "competent rulemaker," and he similarly advocates for legislation to equip the USPTO with "substantive rulemaking authority over subject-matter eligibility."[20]

This Note will explain, however, that allowing the USPTO to craft differential subject matter eligibility rules is not the appropriate solution. Such finetuned, discriminatory rules would threaten the United States' compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement" or "TRIPS"), frustrate international patent harmonization efforts, and expose the crucial patent field to regulatory capture and undemocratic law-making. Part II of this Note introduces the splintered nature of subject matter eligibility law and how its "fault lines" may motivate discriminatory rulemaking.[21] Part III provides the basis for the non-discrimination mandate of TRIPS Article 27 and how it is applied at the World Trade Organization ("WTO").[22] It concludes that legislation tailoring patent rules according to technology area likely disrupts

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14 *See id.* at 446–54.

15 *Id.* at 456.

16 *See id.* at 455–58.

17 Loznev, *supra* note 1, at 457.

18 *Id.* at 449 ("rigid"); *id.* at 458 ("balance").

19 *Id.* at 458, 499.

20 Brendan Costello, *Rulemaking § 101*, 129 YALE L.J. 2178, 2184 (2020).

21 *See infra* Part II.

22 *See infra* Part III.

international agreement on intellectual property rights.[23] Further, even if the United States defeats any potential WTO challenge to this proposed rulemaking legislation, the discriminatory practice will nonetheless undermine the United States' ability to maintain diplomatic positions against other instances of TRIPS noncompliance worldwide.[24] The proposed rulemaking authority would ultimately impede global patent harmonization efforts.

Part IV of this Note highlights the flaws of broad administrative control over patent law.[25] Generally, separation of powers alleviates the risk of regulatory capture of the patent system.[26] Different branches of government are separately responsible for drafting, interpreting, and applying patent law.[27] Centralizing this authority would undermine checks and balances, "the parent of the idea of the separation of powers."[28] A brief background of the evolving USPTO authority under the recently passed America Invents Act ("AIA") will demonstrate the agency's potential to exceed Congress's intentions when given rulemaking authority.[29] Loznev proposes "broad powers" for this specialized rulemaking body, which could expose the patent system to capture and abuse.[30] If subject matter eligibility rules are drafted unilaterally and tailored depending on technology, relevant technological interest groups could exercise greater influence in shaping patent law to suit their preferences.[31] Such undemocratic lawmaking at the USPTO could hamper patent protection in some of the most promising and

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23 *See infra* Section III.B.

24 *See infra* Section III.C.

25 *See* discussion *infra* Part IV.

26 *See* discussion *infra* Part IV; Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619, 1628 (2007) ("Capture theory posits that special interest groups may be able to influence and control a specialized institution (especially, though not necessarily, a centralized one) more easily than a generalized entity.").

27 *See* Justin Burnam, *Patents in the Political Branches*, 16 GEO. J L. & PUB. POL'Y 559, 561 (2018).

28 *See* Steven G. Calabresi et al., *The Rise and Fall of the Separation of Powers*, 106 NW. U. L. REV. 527, 531 (2012).

29 *See infra* Part IV.

30 Loznev, *supra* note 1, at 458; Nard, *supra* note 26, at 1628 ("Specialized governmental institutions present an interesting set of problems, including most prominently the threat of 'capture' by narrow interest groups.").

31 *See* Nard, *supra* note 26, at 1628–29 (discussing the problems of concentrating patent appellate jurisdiction in a single appellate institution).

important areas of technological advance, like biotechnology and genetic research.[32]

II. THE FRACTURED TRILOGY OF § 101 LAW

The recent "trilogy of cases" involving subject matter eligibility generally corresponds to three categories of technology: diagnostic tools, software, and genetic materials.[33] The Supreme Court broadly excludes "laws of nature, natural phenomena, and abstract ideas," but these exceptions are "particularly pronounced in the fields of computer technology and biomedical technology."[34] Many relevant Federal Circuit and district court cases align with these three factual categories of case law, and the USPTO has given examiners guidance with explicit examples corresponding to this patent categorization.[35] These segmented categories of law may suggest differentiated legal standards, or "fault lines," to separate different types of technology. Writers, such as Loznev and Costello, have embraced USPTO rulemaking along similar lines.[36] Loznev endorses the

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32 *See id.*

33 *See* Paul R. Michel, *The Supreme Court Saps Patent Certainty*, 82 GEO. WASH. L. REV. 1751, 1755 (2014). (discussing, prior to the *Alice* decision, *Bilski*, *Mayo*, and *Myriad* as a § 101 trilogy and referenced the previous "trilogy of cases: *Gottschalk v. Benson*, *Parker v. Flook*, and *Diamond v. Diehr*." *Alice* applies *Mayo*'s reasoning to *Bilski* in the software field, updating the trilogy as *Mayo*, *Myriad*, and *Alice*.). KEVIN J. HICKEY, CONG. RSCH. SERV., R45918, PATENT-ELIGIBLE SUBJECT MATTER REFORM IN THE 116TH CONGRESS I (2019) (The Court has held that "three main types of discoveries are categorically patent ineligible: laws of nature, natural phenomena, and abstract ideas," and "[t]he effects of this change have been particularly pronounced in the fields of computer technology and biomedical technology").

34 Hickey, *supra* note 33, at 2.

35 *See Chart of Post-*Alice Cases, GIBSON, DUNN & CRUTCHER LLP, 1 (Mar. 1, 2019), https://www.gibsondunn.com/wp-content/uploads/2019/03/Overview-of-Section-101-Patent-Cases-Decided-After-Alice-v-CLS-as-of-03-01-19.pdf [https://perma.cc/4N89-PJ7L] (noting the delineation between "Software/Tech" and "Biotechnology/Life Sciences"); USPTO 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618, 74,622 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1) (providing case law examples fitting into corresponding categories).

36 *See* Loznev, *supra* note 1, at 454–58; Costello, *supra* note 20, at 2211 (describing "buckets" of technology that are "purely a creation of the Patent Office").

adaptability of such delegated rulemaking.[37] Costello similarly advocates for the USPTO to "fulfill [its] clarity-enhancing role . . . with the traditional checks of the administrative state."[38] Section II.A will explore the current "fault lines" of patent eligibility law, and II.B will predict how this splintered landscape may support different patent standards for different technology.[39]

A. THE FAULT LINES OF SUBJECT MATTER ELIGIBILITY LAW

The Supreme Court established in 1853 that "principle[s] in natural philosophy or physical science" are not patentable.[40] The Court has since expanded this principle to three categories of exclusion, holding that "laws of nature, natural phenomena, and abstract ideas" are not eligible for patent protection because they are "implicitly excluded" at the threshold patentability inquiry of § 101.[41] The relevant statute is codified in 35 U.S.C. § 101, in which Congress provides that the USPTO can grant exclusive patent rights for "any new and useful process, machine, manufacture, or composition of matter, or any . . . improvement thereof."[42] Before *Mayo*, this threshold "was an exceptionally low hurdle."[43] The Court has since raised the hurdle significantly, propping up the barriers for eligibility using negative *judicial exceptions* to the rule rather than through positive inventive categories.[44] The Court's *Mayo*, *Myriad*, and *Alice* trilogy has explicitly targeted three corresponding categories of technology for exclusion. Diagnostic tools are excluded as "laws of nature," according to *Mayo*, biological matter is excluded as "natural phenomena," according to *Myriad*, and

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37 *See* Loznev, *supra* note 1, at 457 ("quickly respond to new developments").

38 Costello, *supra* note 20, at 2230.

39 *See* discussion *infra* Sections II.A, B.

40 O'Reilly v. Morse, 56 U.S. 62, 116 (1853) (invalidating broad patent claims for electromagnetic communication).

41 Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 70 (2012); Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 217 (2014).

42 35 U.S.C. § 101.

43 *See* Gene Quinn, *Congress is Trying to Fix 101: To Do So, They Must Overrule* Mayo, IPWATCHDOG (Mar. 7, 2019, 4:15 PM), https://www.ipwatchdog.com/2019/03/07/congress-trying-fix-101-must-overrule-mayo/id=107117/ [https://perma.cc/38WJ-JHYM].

44 *Mayo*, 566 U.S. at 92; *Alice*, 573 U.S. at 226–27.

conceptual software creations are excluded as "abstract ideas," according to *Alice*.[45]

The first targeted area emerged in 2012, when *Mayo* held that a medical diagnostic and treatment claim was unpatentable because of its unsatisfactory application of a natural law.[46] According to the Court, method claims for measuring the naturally occurring concentration of a metabolite in human blood should not preempt the entire use of that natural law.[47] Patent claims involving applications of a natural law are unpatentable if the inventive aspect merely involves steps that are "well-understood, routine, and conventional."[48] Inventors must "do more than simply state the law of nature while adding the words 'apply it'" to claim a patentable application.[49] In *Mayo*, the patentee did not overcome this newly heightened standard.[50] Now, district courts and the Federal Circuit apply *Mayo* often, finding various diagnostic tools and devices ineligible for patent protection and spawning "great uncertainty in the biotech industry."[51]

The second targeted area emerged in the 2013 *Myriad* case, which has heightened the § 101 standard for biotechnology innovation, especially in genetic

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45 *Mayo*, 566 U.S. at 92 (finding unpatentable a method for finetuning treatment according to natural state of metabolite level); *Alice*, 573 U.S. at 226–27 (finding unpatentable methods for the software implementation of an escrow arrangement for transactions); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 589 (2013) (finding unpatentable isolated naturally occurring segments of DNA).

46 *Mayo*, 566 U.S. at 72.

47 *Id.* at 72–73.

48 *Id.* at 79.

49 *Id.* at 72.

50 *Id.* at 72–73.

51 Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743 (Fed. Cir. 2019) (finding ineligible method for diagnosing neurological disorder); Roche Molecular Sys., Inc. v. Cepheid, 905 F.3d 1363 (Fed. Cir. 2018) (finding ineligible method for detecting bacterium); Cleveland Clinic Found. v. True Health Diagnostics LLC, 859 F.3d 1352 (Fed. Cir. 2017) (finding ineligible methods for detecting an enzyme and correlating the results to cardiovascular risk); *Athena Diagnostics Amici Warn of Harms to Biotech Revolution Under Current* Alice/Mayo *Framework*, IPWATCHDOG (Apr. 25, 2019, 6:15 pm), https://www.ipwatchdog.com/2019/04/25/athena-diagnostics-amici-warn-harms-biotech-revolution-current-alice-mayo-framework/id=108602/ [https://perma.cc/7WNL-S2GR].

research.[52] In *Myriad*, claims directed to isolated DNA segments were found patent ineligible because they were directed to a "product of nature."[53] Previously, the Court had found elements of a living organism patent eligible in *Diamond v. Chakrabarty* because the claims at issue involved a new variety of bacteria influenced by human innovation.[54] The *Myriad* Court distinguished the gene sequencing claims from the bacteria claims in *Chakrabarty* because the gene sequencing claims involved the mere isolation of naturally existing DNA segments using conventional techniques.[55] Although those DNA segments had never been isolated before and could now provide researchers new avenues for scientific exploration, they already existed in nature, unlike *Chakrabarty*'s bacteria.[56] Because the researchers merely carved out the claimed DNA using "well understood, widely used, and fairly uniform" techniques, their work was insufficient for patent protection.[57] Their "discover[y]," although groundbreaking, was thus unpatentable.[58] The *Myriad* Court did, however, provide patent owners a glimmer of hope.[59] It allowed patents on cDNA, or complimentary DNA, because this customized exon-only expression of DNA does not occur naturally.[60] Nonetheless, after *Myriad*, any biological inventions "directed to" naturally occurring phenomena may be found ineligible under § 101 analysis.[61] Loznev's note

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52 *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013) (finding isolated naturally occurring segment of DNA ineligible but finding synthetic cDNA eligible because not naturally occurring).

53 *Id.* at 580.

54 Diamond v. Chakrabarty, 447 U.S. 303, 305–10 (1980) (finding a "human-made, genetically engineered bacterium . . . capable of breaking down multiple components of crude oil" patent eligible).

55 *Myriad*, 569 U.S. at 590–91.

56 *Id.*

57 *Id.* at 595–96.

58 U.S. CONST. art. I, § 8; *see* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 595–96 (2013).

59 *Id.* at 595.

60 *Id.*

61 *Compare* 23andMe, Inc. v. Ancestry.com DNA, LLC, 356 F. Supp. 3d 889, 898 (N.D. Cal. 2018), *aff'd*, 778 F. App'x 966 (Fed. Cir. 2019) (finding patent claims concerning method for determining relative relationships of people based on DNA information lacked inventive concept and were patent ineligible) *with* Illumina, Inc. v Ariosa Diagnostics, Inc., 967 F.3d 1319, 1329 (Fed. Cir. 2020), *cert. dismissed*, 141 S. Ct. 2171 (2021) (finding the inclusion of

discusses *Myriad*'s implications for biotechnology innovation and how its "product of nature" test has stifled funding for gene technology research.[62]

Third, in 2014, *Alice* exposed the software industry to the *Mayo* framework, tightening the § 101 requirement such that the "building blocks of human ingenuity" must be integrated into "something more" to claim eligibility.[63] Under *Alice*, any "method of organizing human activity" applied to a generic computer (a.k.a. software) may be deemed an ineligible abstract idea.[64] Like *Mayo*, software claims must recite "something more" to achieve a patent-eligible invention—a profoundly ambiguous standard.[65] The *Alice* decision has made subject matter eligibility a common challenge to software patent enforcement and has manifested financial uncertainty for software innovators.[66]

These three categories of exclusion demarcate different § 101 standards for different areas of technology. The patent standards codified in 35 U.S.C. §§ 102, 103, and 112, in contrast, are more uniformly applied across technologies.[67] Of course, these other standards present different challenges and nuances depending on technology, but the legal standards are nonetheless generally consistent and

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physical process steps to change or treat fetal DNA makes the claims patent eligible by elevating them beyond patent-ineligible diagnostic claims).

62 Loznev, *supra* note 1, at 446–48; 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?)*, COLD SPRING HARBOR PERSP. MED., May 2015, at 10 (predicting stifling of research into lifesaving discoveries for diagnostics and treatments following *Mayo* and *Myriad*).

63 *Alice*, 573 U.S. at 216.

64 *Id.* at 220.

65 *Id.* at 217; Matthew Moldovanyi, Alice*: The Status Quo or Total Chaos?*, 7 CASE W. RES. J.L. TECH. & INTERNET 121, 152 (2016).

66 Daniel A. Taylor, *Down the Rabbit Hole: Who Will Stand Up for Software Patents After* Alice*?,* 68 ME. L. REV. 217, 247 (2016) (discussing the business implications of *Alice* on software companies and their portfolios); *The Effect of* Alice *and Its Progeny in 2020 on Software and 3D Printing Patents*, ORRICK, https://www.orrick.com/Articles/The-Effect-of-the-Alice-Decision-on-Software-and-3D-Printing-Patents [https://perma.cc/U5RQ-KAVD] (listing Federal Circuit decisions invalidating software patents under *Alice*).

67 35 U.S.C. §§ 102, 103, 112 (requiring a patentable invention to be new, non-obvious to a person of ordinary skill in the art, and sufficiently descriptive to enable a person of ordinary skill in the art to practice the invention, respectively).

interchangeable regardless of field. For example, litigators and courts will often cite novelty and non-obviousness case law involving very different technologies compared to the claims at issue.[68] To the contrary, the Supreme Court's judicial exceptions to 35 U.S.C. § 101 – laws of nature, natural phenomena, and abstract ideas – necessarily involve standards applied within silos of technological field because of their underlying fractured common law origins. *Alice* cites *Mayo*, but only for its general "natural law" exception and two-step framework.[69] The actual analysis and application of the "something more" standard tend to follow technology-specific lineages, as the *Alice* Court extended from the software applications in *Bilski v. Kappos*, *Gottschalk v. Benson*, and *Diamond v. Diehr*.[70] These technological categories sometimes overlap, and the lower courts may deem multiple lines of cases applicable to a single invention, but each targeted technological area nonetheless faces uniquely lopsided scrutiny.[71]

B. PERPETUATING § 101 FAULT LINES AT THE USPTO

The USPTO's patent examination guidance corresponds to the fractured judicial interpretations of § 101. Before *Mayo*, examiners applied *Bilski*'s general

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[68] *See, e.g.*, Sanofi-Aventis Deutschland GMBH v. Mylan Pharms. Inc., 791 F. App'x 916, 921 (Fed. Cir. 2019) (analyzing claims directed to insulin formulations under obviousness standard of *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727 (2007), concerning vehicle throttle control patents); *see, e.g.*, Schlumberger Tech. Corp. v. BICO Drilling Tools, Inc., No. H-17-3211, 2019 WL 2450948, *7 (S.D. Tex. June 12, 2019) (S.D. Tex. June 12, 2019) (analyzing invalidating sales of drill motors under novelty standard of *Helsinn Healthcare S.A. v. Teva Pharms.*, 139 S. Ct. 628 (2019), involving chemotherapy drug claims).

[69] Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 217 (2014) ("In *Mayo* . . . we set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.").

[70] *Id.*

[71] *See* 23andMe, Inc. v. Ancestry.com DNA, LLC, 356 F. Supp. 3d 889, 905 n.6 (N.D. Cal. 2018), *aff'd*, 778 F. App'x 966 (Fed. Cir. 2019) (discussing the additional contention that the claims at issue related to DNA comparison analyzed as laws of nature should also be analyzed as abstract ideas under *Alice*).

"machine-or-transformation" test.[72] Then, following the new categorical exceptions, former USPTO Director Michelle Lee's 2014 examination guidance instructed examiners to analogize inventions according to siloed technological category: "natural phenomena," "abstract ideas," and "nature-based products."[73] Director Lee gave examiners specialized guidance for testing subject matter eligibility within each inventive category.[74] The USPTO began to examine patent claims under § 101 by comparing them to case law examples found in specific categories and determining if they were factually similar and thus similarly eligible or ineligible.[75] Former Director Andrei Iancu's guidance also maintained "enumerated groupings," like mathematical concepts and mental processes for software patents.[76] Director Iancu even clarified that these guidelines "categorize the judicial exceptions and clearly instruct examiners on how to apply them."[77] Because these examination guidelines differentiate between technology, the Supreme Court's § 101 precedent has affected "different technology areas to different degrees."[78] Some patent drafters have responded by artfully drafting patents to avoid certain categories of invention and evade § 101 challenge altogether, but the judicial exceptions remain highly influential for the abovementioned technology areas.[79]

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[72] USPTO Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*, 75 Fed. Reg. 43,922, 43,924 (July 27, 2010).

[73] USPTO 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618, 74,621 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1) (providing case law examples fitting into corresponding categories).

[74] *See id.* at 74,623.

[75] *See id* at 74,628.

[76] USPTO 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 53 (Jan. 7, 2019).

[77] Andrei Iancu, Dir., USPTO, Remarks at the 10th Annual Patent Law and Policy Conference, (transcript available at https://www.uspto.gov/about-us/news-updates/remarks-director-iancu-10th-annual-patent-law-policy-conference [https://perma.cc/JHU4-G9AY]).

[78] Jay P. Kesan & Runhua Wang, *Eligible Subject Matter at the Patent Office: An Empirical Study of the Influence of* Alice *on Patent Examiners and Patent Applicants*, 105 MINN. L. REV. 527, 535 (2020).

[79] *See* Adam B. Jaffe & Josh Lerner, *Innovation and Its Discontents*, 6 NAT'L BUREAU OF ECON. 27, 60 (2006) (explaining that legislation to categorically exclude patentability of business methods incentivized creative patenting, where "applicants have been going out of their way to classify their patents

The academic world has also explored creative responses to the Supreme Court's fractured § 101 interpretation. As discussed above, writers like Loznev suggest that the Court's rules are too inflexible and that the USPTO should craft its own rules to "quickly respond to" groundbreaking and critical technology.[80] Loznev would provide the USPTO discretion to write subject matter eligibility rules tailored to different technology areas.[81] Like the SEC's authority to "tailor the rules for disclosure" depending on the type of regulated security, the USPTO could explicitly hold different types of inventions to different eligibility standards.[82] Further, Costello discusses how the USPTO's subject matter eligibility guidance has toed the line of unauthorized agency rulemaking.[83] According to him, the USPTO has arguably provided its own substantive § 101 rules, but without the necessary notice-and-comment procedure.[84] Instead, the USPTO has simply provided a warranty that its guidance is not agency rulemaking.[85]

If the USPTO is given explicit legislation to craft § 101 rules, the specialization of rules according to different technology areas would likely become even more pronounced. The USPTO would perhaps even add new technological categories for exclusion beyond the three discussed so far. The general § 101 standard, excluding patents for "principle[s] in natural philosophy or physical science," would be replaced with many splintered rules for different

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outside the class targeted for special (more rigorous) treatment"); Terri Shieh-Newton et al., *Examining Art Units to Avoid Subject Matter Eligibility Challenges for Bioinformatics and AI-related Patents*, MINTZ (Nov. 18, 2021), https://www.mintz.com/insights-center/viewpoints/2231/2021-11-18-examining-art-units-avoid-subject-matter-eligibility [https://perma.cc/YG5H-UK3Q] (recommending drafting patents to "target favorable art units" and avoid 101 rejections).

80 *See* Loznev, *supra* note 1, at 457.

81 *Id.*

82 *Id.*

83 *See* Costello, *supra* note 20, at 2178 (stating that without statutory authorization, "the USPTO's recent guidance threatens to push the boundaries of its current authority and run afoul of the Administrative Procedure Act").

84 *See id.* at 2205.

85 *See id.* (explaining that recent cases involving challenged USPTO conduct demonstrate how the Federal Circuit would nonetheless not likely find an APA violation.).

types of technology.[86] Loznev's proposal would allow the USPTO to explicitly discriminate and hold inventors to different standards depending on technological field.[87] Patent examiners in certain art units could employ entirely unique examining procedures depending on technology area, unlike previous guidance generalized for the entire agency.[88] This splintered, independent rulemaking could allow different examining units to dissociate from any general standard.[89] Ultimately, United States patent law would hold different technologies to different patent standards without any justification beyond "legislative convenience."[90]

III. TAILORING PATENT RULES DEPENDING ON TECHNOLOGICAL FIELD DEFIES INTERNATIONAL PATENT STANDARDS

Although the patent community continues to wrestle with the judicial exceptions to § 101, USPTO rulemaking is not the proper solution because it would defy international standards. This Section provides a background of the international standard for non-discrimination and analyzes whether USPTO rulemaking would comply. In sum, this Section concludes that crafting different patent rules for different technology areas likely violates international patenting standards and disrupts global patent harmonization efforts.

A. THE TRIPS PROHIBITION ON VARYING PATENT LAW DEPENDING ON TECHNOLOGICAL AREA

The TRIPS Agreement prohibits patent rules that discriminate according to technology.[91] First negotiated in the early 1990s and effective in 1995, the TRIPS Agreement binds WTO member nations to minimum standards of regulation,

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86 O'Reilly v. Morse, 56 U.S. 62, 116 (1853).

87 *See* Loznev, *supra* note 1, at 454–58.

88 *See* Costello, *supra* note 20, at 2230 (discussing general USPTO guidance with different sections only applying to different technologies).

89 *See id.*

90 Commodity Futures Trading Comm'n v. Schor, 478 U.S. 833, 863 (1986) (Brennan, J., dissenting) ("Article III's prophylactic protections were intended to prevent just this sort of abdication to claims of legislative convenience.").

91 *See* Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) (amended Jan. 23, 2017) [hereinafter TRIPS Agreement].

protection, and enforcement of intellectual property rights.[92] Article 27 of TRIPS requires that "patents shall be available and patent rights enjoyable *without discrimination* as to the place of invention, *the field of technology* and whether products are imported or locally produced."[93] This non-discrimination mandate is considered "the core provision, and the reason of being of the whole TRIPS Agreement."[94] The provision was intended to prevent member nations from favoring their own inventors or their preferred technological fields "for purely economic protectionist reasons."[95] To enforce TRIPS compliance and promote consistent patent protection, WTO member nations may challenge the rules and conduct of other nations by seeking dispute resolution at the WTO.[96]

In 2000, the WTO applied the non-discrimination mandate to Canada's Patent Act.[97] Following the European Communities' ("EC") 1997 request for consultation at the WTO regarding Canada's differential treatment of pharmaceutical patents, a WTO Panel reported on the requirements for violative technological discrimination.[98] The EC challenged Canada's law which allowed generic pharmaceutical companies to test, manufacture, and stockpile patented pharmaceutical products during a broad regulatory review period before expiration of the incumbent brand's patent.[99] The EC argued that Canada violated TRIPS Article 27 because such specialized treatment of pharmaceutical patents was specifically disadvantageous to pharmaceutical patent holders and thus

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92 *See* Kevin J. Nowak, *Staying Within the Negotiated Framework: Abiding by the Non-Discrimination Clause in Trips Article 27*, 26 MICH. J. INT'L L. 899, 900 (2005).

93 TRIPS Agreement, *supra* note 91.

94 NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS 245 (3d ed. 2010).

95 *See* Nowak, *supra* note 92, at 939 (exploring the negotiated framework and concluding that nondiscrimination under TRIPS Article 27.1 is "the foundation and guiding principle" of the TRIPS patents section).

96 *See* Panel Report, *Canada–Patent Protections of Pharmaceutical Products*, WTO Doc. WT/DS114/R, 13–14 (adopted Apr. 7, 2000) [hereinafter *Patent Protections Panel Report*].

97 *See Patent Protections Panel Report*, *supra* note 96, at 13.

98 *See* TRIPS Agreement, *supra* note 91 (requiring that "patents shall be available and patent rights enjoyable without discrimination as to the . . . field of technology"). *See* Patent Protections Panel Report, *supra* note 96, at 13.

99 *See Patent Protections Panel Report*, *supra* note 96, at 142–43.

discriminatory as to the field of technology.[100] The WTO panel ultimately found no violation.[101] It acknowledged that TRIPS Article 27 prohibits both *de jure* discrimination, which targets technologies explicitly by law, and *de facto* discrimination, or "ostensibly neutral" treatment in which the "actual effect is to impose differentially disadvantageous consequences on certain parties."[102] Yet, the panel rejected the EC's "strict interpretation of Article 27.1" that would prohibit any differential effect of patent law regardless of purpose.[103]

Ultimately, because the WTO panel "received no systematic information on the range of industries" that Canada's alleged discriminatory practice actually impacted, it "found that the evidence in record before it did not raise a plausible claim of discrimination under Article 27.1 of the TRIPS Agreement."[104] Although Canada's shortened effective patent term for certain process patents violated Article 28.1 and Article 33 of the TRIPS Agreement, the differential treatment of pharmaceutical patents did not violate Article 27's nondiscrimination mandate.[105]

1. WTO Prohibits de jure Discrimination, Which Requires a Legal Standard Explicitly Targeting a Technological Area.

The WTO panel explained that *de jure* discrimination in violation of TRIPS Article 27 "arise[s] from explicitly different treatment" under law.[106] According to the WTO, the normal requirement for *de jure* discrimination is when the challenged standard's "legal scope" is limited to a particular technology.[107] It exists "where unjustified differentiation is evident from the very nature of the law."[108] The panel concluded Canada's regulatory exception was not *de jure* discrimination because the exception was available "not just to pharmaceutical products but to 'any product' that requires regulatory approval for marketing (including agricultural

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100 *See id.* at 169.

101 *See id.* at 174.

102 *See id.* at 173.

103 *See* Maria Victoria Stout, *Crossing the TRIPS Nondiscrimination Line: How CAFTA Pharmaceutical Patent Provisions Violate TRIPS Article 27.1*, 14 B.U. J. SCI. & TECH. L. 177, 181 (2008).

104 *See Patent Protections Panel Report*, *supra* note 96, at 174.

105 *See* Stout, *supra* note 103, at 184–85.

106 *See Patent Protections Panel Report*, *supra* note 96, at 171.

107 *Id.* at 174.

108 Stout, *supra* note 103, at 182.

products, certain foods, cosmetics, automobiles, ships, and aircraft)."[109] Canada's regulatory scheme was therefore not *de jure* discrimination. In contrast to Canada's law, *de jure* discrimination would be found where the law explicitly impacts a *technological class* and not simply a *regulatory class* of products.[110]

De jure discrimination may also arise if certain technology areas are altogether excluded from patentability without a "bona fide reason" or TRIPS-enumerated exception.[111] For example, United States legislators introduced the Genomic Research and Accessibility Act to remove DNA statutorily from patentable subject matter.[112] Because it would be discriminatory to eliminate or hinder patent protection for certain technology, it would have likely violated TRIPS—it ultimately failed.[113] Conversely, the European Parliament introduced the Bio-Tech Directive to uphold patent rights for genes.[114] Because the Directive would *enhance* patent protection of certain technology, a European Parliament panel found that it would not likely violate TRIPS, unlike the Genomic Research and Accessibility Act.[115] Further discussed below, countries may also exclude certain technologies if explicitly allowed in the TRIPS Agreement, as justified for

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109 Stout, *supra* note 103, at 186.

110 *See id.* at 187 (noting if the treatment did not apply to "all products subject to regulatory approval, but only to pharmaceutical products, the Panel may have found de jure discrimination").

111 *Id.* at 188.

112 James DeGiulio, *The Genomic Research and Accessibility Act: More Science Fiction than Fact*, 8 NW. J. TECH. & INTELL. PROP. 292, 296 (2010).

113 *See id.*; John L. Ryan, *Unlikely Splicing: The* Myriad *Decision, the Genomic Research and Accessibility Act, Orphan Diseases, and the Future of Antisense Drugs*, 28 J. CONTEMP. HEALTH L. & POL'Y 144, 145 (2011) (criticizing the Genomic Research and Accessibility Act that was proposed to remove DNA from patentable subject matter).

114 *See* Council Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, arts. 3, 5, 1998 O.J. (L 213) 13 (stating that "[b]iological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature" and "[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element").

115 ECJ, Case C-377.98, [2001] ECR I-7079 (finding the Biotech-Directive did not violate TRIPS Article 27(3)).

ethical concerns around animal patents or to enable greater access to medical treatment.[116]

2. *The WTO Prohibits de facto Discrimination Unless the Nature of the Technology Requires Different Rules.*

De facto discrimination exists if a country's patent law is facially neutral but exhibits different effects for different areas of technology. In the EC's challenge to Canada's Patent Act, the WTO panel adopted a practical, flexible standard for measuring *de facto* discrimination rather than mandating a "one-size-fits-all" patent system.[117] *De facto* discrimination often requires (1) that the challenged treatment's effects are limited to a particular industry, and (2) a demonstrated intention to impose disadvantages on a particular industry.[118] The panel explained *de facto* discrimination exists if treatment exhibits different "legal effect" for different types of technology without justification, which is "the type of exploitation TRIPS was intended to protect."[119] Canada's differentiation of pharmaceutical patents resulted in a mere "commercial or economic effect" because stockpiling generic pharmaceutical products only created potential competitive advantages.[120] The panel allowed such differential "commercial or economic effect" as a byproduct of Canada's policy, which was "necessary for regulatory review" of pharmaceutical products during the patent term.[121]

For the second requirement of discrimination, because Canada had a "bona fide" reason to differentiate according to technology, in its case "to deal with problems that may exist only in certain product areas," its pharmaceutical differentiation did not violate TRIPS.[122] The differential timing of regulatory approval for pharmaceutical products in Canada was a permissible justification

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116 *See infra* Section III.A.III.3.

117 Stout, *supra* note 103, at 187.

118 *Id.*

119 Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *Diversifying Without Discriminating: Complying with the Mandates of the TRIPS Agreement*, 13 MICH. TELECOMM. & TECH. L. REV. 445 (2007).

120 *Id.* at 451; Stout, *supra* note 103, at 183 (explaining that stockpiling occurs when a patented invention is made, constructed, used, or sold "during a period set by regulation for the manufacture and storage of products intended for sale after the patent expires").

121 Dinwoodie & Dreyfuss, *supra* note 119, at 451.

122 *Id.* at 450.

because it was specific to the nature of the impacted technology.[123] Thus, effective differentiation based on an inherent aspect of the field of technology is often appropriate and allowable under TRIPS Article 27.[124] On the contrary, a member nation cannot discriminate based on technology without such specific justification.[125] In fact, the non-discrimination requirement was originally intended to prevent overly broad justifications, such as vague "public health concerns," for differential regulatory schemes that purposely disfavor certain patent owners.[126] TRIPS sought to harmonize pharmaceutical and medical patenting despite the variation of regulatory schemes for health-related products around the world.[127] Broad discriminatory treatment, such as "categorically preclud[ing] entire classes of inventions from patent protection, even if they are genuinely novel," is violative unless a practical or commercial justification exists and is inherent to the excluded technology.[128]

Illustratively, Wolrad Prinz zu Waldeck und Pyrmont has discussed patent schemes in Switzerland and Belgium that may constitute *de facto* discrimination.[129] Countries like Switzerland may require compulsory licenses for research patents to enable and spread the costs of biotechnology research, which

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123 Wolrad Prinz zu Waldeck und Pyrmont, *Special Legislation for Genetic Inventions – A Violation of Article 27(1) TRIPS?*, *in* PATENTS AND TECHNOLOGICAL PROGRESS IN A GLOBALIZED WORLD 289, 296, 302–04 (Wolrad Prinz zu Waldeck und Pyrmont, Martin J. Adelman, Robert Brauneis, Josef Drexl, & Ralph Nack, eds. 2009) [hereinafter *Special Legislation for Genetic Inventions*] ("A criterion for drawing a distinction must be an inherent characteristic of the technical field," such as regulatory approval in Canada's pharmaceutical scheme, rather than broad "public health concerns" because "the prohibition of such discrimination in the field of pharmaceutical inventions was one of the primary reasons for adoption of the non-discrimination requirement").

124 *Id.* at 300.

125 *Id.*

126 *Id.* at 297.

127 *See id.*

128 *See id.* at 299–302 (explaining the Canada panel also required some level of discriminatory intent, but it can be easily negated by positive objectives like "public health concerns, e.g., the desire to facilitate improved access to biomedical research tools"); Costello, *supra* note 20, at 2182; TRIPS Agreement, *supra* note 91, art. 27.3.

129 *See Special Legislation for Genetic Inventions*, *supra* note 123, at 302 (citing Swiss Patent Act and Belgium Patent Act).

is useful if patent standards lack international uniformity.[130] But requiring compulsory licenses for research tools would likely constitute *de facto* discrimination against the biotechnology field because of the high number of "dependent inventions" in biotechnology that require underlying research tools.[131] This discrimination likely could not be justified under TRIPS because forcing certain patent holders to license their research tools does not involve inherent features of the products at issue, unlike the necessary regulatory requirements found in Canada's law.[132] Switzerland's statutory licensing requirement tends to discriminate according to technology without justification inherent to the targeted technology; therefore, it is arguably an example of *de facto* discrimination.[133] Belgium similarly contemplated a broad experimental use exception to patent enforcement for research tools, which may also have the requisite "differentially disadvantageous treatment" to be *de facto* discrimination.[134] Belgium, therefore, changed its statute to comply with the TRIPS Agreement.[135]

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130 Molly Jamison, *Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate*, 15 CHI. J. INT'L L., 687, 691 (2015) (advocating for deployment of voluntary international licensing agreements to spread the costs of biotechnology R&D when patentability standards are incongruous); *Special Legislation for Genetic Inventions*, *supra* note 123, at 302.

131 *See Special Legislation for Genetic Inventions*, *supra* note 123, at 298 (citing Swiss Patent Act and Belgium Patent Act) (providing Switzerland's requirement of compulsory licensing for "instrument[s] or means in research" and Belgium's broad experimental use exception may be ostensibly neutral as to technology but have requisite "differentially disadvantageous treatment" of biotechnology inventions for de facto discrimination under Article 27).

132 *See id.* ("the mere fact of a high number of dependent inventions in the field of genomics – even if arguably higher than in other technical fields – cannot justify a different treatment") (citing Straus, Abhängigkeit bei Patenten auf genetische Information ein Sonderfall?, 1998 Gewerblicher Rechtsschutz und Urheberrecht, Internationaler Teil (GRUR Int.) 314, 319).

133 *See id.* at 302.

134 *Id.* at 303.

135 *See id.*

3. TRIPS Allows Limited Exceptions for Patent Eligibility.

Limited exceptions exist to the TRIPS non-discrimination mandate for certain medical methods, plants, and animals other than micro-organisms.[136] First, under TRIPS Article 27.3(a), methods of treatment may be excluded from patent protection to promote access to healthcare, but TRIPS does *not* allow the broad exclusion of all underlying product protection.[137] Therefore, gene treatments may be excluded properly under TRIPS, but the underlying research substances or equipment, such as the challenged genes in *Myriad*, cannot be broadly excluded.[138] Next, under TRIPS Article 27.3(b), member nations may exclude "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."[139] This exception reflects the different ethical standpoints recognized during TRIPS negotiations.[140] Additional interpretations of these exceptions suggest that TRIPS should reflect different philosophical and cultural understandings of genetic modification.[141] Relatedly, under TRIPS Article 27.2, member nations may exclude patenting if necessary to protect "*ordre public* or morality."[142] Some authors suggest that this exception can justify the exclusion of

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136 TRIPS Agreement, *supra* note 91, art. 27.3(a)-(b).

137 *See Special Legislation for Genetic Inventions*, *supra* note 123, at 301; TRIPS Agreement, *supra* note 91.

138 *See Special Legislation for Genetic Inventions*, *supra* note 123. It is likely that the *Mayo* line of cases and corresponding rules to exclude diagnostic methods are valid under TRIPS.

139 *See* TRIPS Agreement, *supra* note 91, art. 27.3(b).

140 *See* CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 284 (2d ed. 2020) (explaining that "Article 27.3(6) reflects the outstanding differences, among industrialized countries themselves and between them and developing countries, existing at the time of the TRIPS negotiations about the patenting of plants and animals").

141 *See* Evan H. Tallmadge, *Nationalizing TRIPS: An Examination Through Exceptions*, 18 J. MARSHALL REV. INTELL. PROP. L. 285, 323 (2019) (explaining that a "revision of TRIPS should reflect the new understanding of the usefulness of genetically modified higher life forms").

142 Lena A. Kuklińska, *A Short Introduction to Patenting of Animals and a Discussion on the Ethicality of Such*, INST. OF NEW EUROPE 4 (Oct. 4, 2021), https://ine.org.pl/en/a-short-introduction-to-patenting-of-animals-and-a-discussion-on-the-legal-morality-of-such-2/ [https://perma.cc/YH84-8LLC] (discussing the European *ordre public* policy, a policy with a moral focus that

genetic engineering and gene sequencing patents because of their ethical ambiguity.[143]

B. DIFFERENTIAL USPTO ELIGIBILITY RULES WOULD VIOLATE TRIPS ARTICLE 27 AND DISADVANTAGE CERTAIN PATENT HOLDERS

Pyrmont explains that legislation targeting gene patents or predominantly affecting gene patents without justification is *de facto* discrimination in violation of TRIPS Article 27.[144] Extending this argument to other classes of technology, USPTO authority to craft different patent eligibility standards for different technologies would likely violate the TRIPS Agreement. First, the rules would affect "different technology areas to different degrees," and second, the legislation would likely discriminate without proper justification inherent to the nature of the technology.[145] The current splintered rules of patent eligibility likely meet the first requirement for *de facto* discrimination, and the second requirement is met if the United States cannot present a "legitimate purpose" for its differentiation.[146]

The current categorized judicial exceptions to eligibility likely meet the first requirement for *de facto* discrimination because of their differential "legal effect."[147] Splintered case law demonstrates that epigenetic innovation and software are held to different standards under the eligibility law.[148] Even if the differential rules involve "ostensibly neutral" treatment of different technologies, lopsided requirements constitute requisite discrimination when they tend to impact patent rights in certain areas more than in others.[149] As Loznev explains, such discriminatory rulemaking threatens epigenetic innovation by uniquely

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would limit patentability of genetic engineering); TRIPS Agreement, *supra* note 91, art. 27.2.

143 *Id.*

144 *See Special Legislation for Genetic Inventions*, *supra* note 123, at 302.

145 *See* Kesan & Wang, *supra* note 78, at 535.

146 Dinwoodie & Dreyfuss, *supra* note 119, at 452.

147 *Id.* at 450.

148 *See* John R. Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 BERKELEY TECH. L.J. 727, 753–55 (2002) (discussing whether a proposed bill to limit software patents by holding them to higher standards at the USPTO conforms with TRIPS nondiscrimination).

149 *See Patent Protections Panel Report*, *supra* note 96, at 173.

diminishing the incentives for this research.[150] Other patent requirements, such as enablement or obviousness, could properly filter overly broad patents without isolating the entire fields of epigenetics and software.[151] Additionally, amicus briefs have indicated that the Supreme Court's differentiation of patent-eligible subject matter have discriminatory legal effect.[152] For example, Alnylam Pharmaceuticals has argued that the *Myriad* line of cases , which exclude isolated DNA from patent protection, undermines TRIPS compliance,[153] and the Chartered Institute of Patent Attorneys has urged the Supreme Court to revisit this area of law because patent exclusion for specific technological classes violates TRIPS.[154]

The second requirement for *de facto* discrimination is the lack of a "bona fide" reason to discriminate.[155] Countries can typically justify technological discrimination if necessary to handle unique characteristics of an industry, such as regulating pharmaceutical products or effectively enforcing patents in "complex

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150 *See* Loznev, *supra* note 1, at 446–48; *The State of Pat. Eligibility in Am.: Part I Before the Subcomm. on Intell. Prop. of the S. Comm. on the Judiciary*, 116th Cong. 20 (2019) (testimony of Q. Todd Dickinson, Senior Partner, Polsinelli PC) (discussing drawbacks of heightened subject matter eligibility standards, including "potential to reduce the incentive to discover and develop alternative or additional genetic diagnostic tests).

151 *See* Mike Sikora, Note, 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) (arguing that the obviousness requirement or Europe's "inventive step" requirement could adequately protect epigenetics-based inventions and bring certainty to investment in the field without violating TRIPS non-discrimination).

152 *See* Brief for Alnylam Pharmaceuticals, Inc., as Amicus Curiae Supporting Defendants-Appellants, Supporting Reversal at 17–20, Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off., 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406) (arguing judicial exclusion of isolated DNA from patent eligibility would undermine TRIPS compliance).

153 *See id.*

154 *See* Brief for The Chartered Institute of Patent Attorneys, as Amicus Curiae Supporting Petitioner, Sequenom, Inc. v. Ariosa Diagnostics, Inc., 136 S. Ct. 2511 (2016) (No. 15-1182) (arguing that the "technical process where substances are isolated and transformed by the hand of man" should be patentable, despite the Australian High Court decision in "Yvonne D'Arcy v Myriad Genetics, [2015] HCA 35 where the majority recognised that the decision to accord or refuse patentability to a particular class of claims could have implications for Australia's obligations under international law").

155 *See Special Legislation for Genetic Inventions*, *supra* note 123, at 303–04.

product industries," but the scope of differentiation cannot be "broader than necessary."[156] Currently, the Supreme Court's case-by-case judicial exceptions to patent eligibility are "sufficiently limited" to assessing whether a given patent claim is a "process, machine, manufacture, or composition of matter," as enumerated in 35 U.S.C. § 101.[157] Under TRIPS, legislation cannot expand the scope of this exclusion and allow the USPTO to hamper entire technology areas without a "legitimate purpose" specific to the impacted areas of technology.[158] Unlike Canada's justification for differentiating pharmaceutical products because of their health-related regulatory scheme, the USPTO's apparent justification for discriminating against swaths of technologies merely to be flexible and "respond to new developments in scientific research" would likely fail to meet the "bona fide" justification requirement—it would be "broader than necessary."[159] The current differential eligibility law likely meets the first factor of *de facto* discrimination, and broad, unjustified exclusions would likely meet the second requirement, violating TRIPS and harming innovation.[160]

Lastly, general authority to draft different rules for different types of technology is not allowed by the limited TRIPS exceptions to eligibility. The TRIPS exceptions do not broadly include all applications of biological material, only method patents related to diagnostics or treatment.[161] Although biomedical research should enable the use of discoverable tools, innovators in this space are protected from discriminatory treatment under TRIPS.[162] When gene sequencing patents involve isolating DNA to further explore the functional relationship

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156 *See* Dinwoodie & Dreyfuss, *supra* note 119, at 446–55 (illustrating that tailored rules for patent enforcement may be necessary to handle the complex nature of an industry, such as "a single electronic product [which] can require a multiplicity of patent licenses").

157 *See id.* at 449–55 (discussing Article 30's express requirement that exemptions for patent protection must be "limited"); 35 U.S.C. § 101.

158 *Id.* at 452.

159 *Id.* at 448; Loznev, *supra* note 1, at 457.

160 *See* USPTO, SIMON J. ELLIOT, PUBLIC COMMENT ON GUIDANCE FOR DETERMINING SUBJECT MATTER ELIGIBILITY OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE, NATURAL PHENOMENA, & NATURAL PRODUCTS 2 (July 30, 2014), available at https://www.uspto.gov/sites/default/files/patents/law/comments/mm-f-elliot20140730.pdf [https://perma.cc/CDU4-7L6K].

161 *See Special Legislation for Genetic Inventions*, *supra* note 123, at 301.

162 Michael Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 701 (1998).

between a gene and protein, incentives through patent protection should be granted even if the isolation method is not the inventor's primary contribution.[163]

C. USPTO ELIGIBILITY RULEMAKING WOULD DELEVERAGE U.S. POSITIONS AGAINST OTHER NATIONS' DISCRIMINATORY POLICIES

The United States should seek rigorous compliance with international treaties, like TRIPS, if it hopes to advance patent harmonization among the vastly different systems of national patent regulation.[164] A country cannot argue against problematic discriminatory practices unless it serves as an example of harmonization itself.[165] Patent systems throughout the world are crucial instruments to incentivize groundbreaking industries in biotechnology and life sciences, but countries have expressed reservations in providing relevant patent protection.[166] Certain African nations and Bolivia have expressed that the patent system should not "become an instrument of privatisation and commoditisation of life itself on a worrying scale and magnitude."[167]

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163 *See Special Legislation for Genetic Inventions*, *supra* note 123, at 299 ("Even though in most cases, the inventor's contribution will not be the isolation of a sequence, but the decoding of the functional relationship between gene and protein, limiting the protection of patents would not be appropriate in cases where the making available of the gene sequence was invention and diverge from ordinary patent practice") (citing Straus, An Updating Concerning the Protection of Biotechnological Inventions Including the Scope of Patents for Genes – An Academic Point of View, [2003] OJ EPO Special Issue 166).

164 Jackob Wested & Timo Minssen, *TRIPS and the Life Sciences: Perspectives on Limitations to Patentability*, U. COPENHAGEN, June 2017, at 1, 8 (discussing the tension between the "many different national regulations" of biotech patents and the TRIPS agreement's "ambitions of harmonization").

165 Stefania Fusco, *TRIPS Non-Discrimination Principle: Are* Alice *and* Bilski *Really the End of NPEs?*, 24 TEX. INTELL. PROP. L.J. 131, 158 (2016) (concluding that even if *Alice* and *Bilski* do not immediately "constitute a violation of the U.S. obligations under TRIPS," they "undermine its ability to promote TRIPS compliance" by lowering the bar for other countries' compliance).

166 *See* Dinwoodie & Dreyfuss, *supra* note 119, at 456 (supporting "industry-specific patent laws" to reflect "local technological capacity" and each "nation's ability to fully develop its own technological possibilities").

167 *See* Temitope O. Oloko, *An Examination of Article 27 of the TRIPS Agreement in Relation to the Provisions on Patentable Subject Matter Under the PDA in Nigeria*, 42 COMMONWEALTH L. BULL. 236, 252–53 (2016) (S. Afr.) (discussing reservations of African nations and Bolivia that the patent system should not

Proponents of this policy differentiation reference the flexibility intended in TRIPS negotiations.[168] U.S. cases like *Myriad* may align with this viewpoint by preventing naturally existing biological features from earning a patent, but the United States should nonetheless seek to comply with TRIPS Article 27. Despite calls to allow developing countries to tailor their patent rules for local needs, countries should be wary of drawing bright lines around areas of technology that remain unexplored.[169] These bright lines could disincentivize and ultimately forestall beneficial exploration, and the United States should instead seek to uphold uniformity and promote innovation.

IV. BROAD USPTO RULEMAKING AUTHORITY IS UNDEMOCRATIC AND WOULD MAKE THE PATENT SYSTEM VULNERABLE TO CAPTURE

Substantive rulemaking authority would heighten the USPTO's risk of private influence and agency capture because it is a "specialized institution," and the breadth of this agency rulemaking would threaten the efficacy of the Administrative Procedure Act ("APA") as a democratic safeguard.[170] The APA is considered "a tool for legitimating administrative rulemaking by holding agencies democratically accountable to the public."[171] Advocates for substantive USPTO rulemaking of patent eligibility consider the APA a backstop to "help protect against institutionally conditioned bias" arising from administrative

"become an instrument of privatisation and commoditisation of life itself on a worrying scale and magnitude").

168 *See* Chris R. Byrnes, Note, *Patenting Life: TRIPS Article 27 and Bolivia's Proposal to Ban the Patenting of all Life Forms*, 24 GEO. INT'L. ENV'T L. REV. 245, 265 (2012) (arguing that "Bolivia's policy objectives of living in harmony with nature and preserving biodiversity" may allow it to ban patenting of life forms).

169 *See* Peter K. Yu, *TRIPS and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 388 (2006) (advocating for a "pro-development" interpretation of TRIPS that takes local needs into account).

170 *See* Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619, 1628 (2007) (discussing heightened threat of "capture" by specialized interest groups if differential rulemaking for different areas of technology is left to a "specialized institution" rather than a more generalized entity, such as the federal court system).

171 *See* Emily S. Bremer, *The Undemocratic Roots of Agency Rulemaking*, 108 CORNELL L. REV. (forthcoming 2022) (manuscript at 5) (on file with author).

rulemaking.[172] But the APA exists in delicate tension between its "promise of democracy in rulemaking and administrative law's broader affirmation of agency authority."[173] An "underlying compromise" preserves the administrative apparatus, which requires procedural safeguards and judicial review without overly expansive legislative delegation.[174] As Bremer writes, if this underlying "compromise falls apart, the APA's procedures fall with it."[175]

Congress should not grant the USPTO broad authority to draft its own specialized rules in the boundless area of subject matter eligibility because the APA is not sufficient to contain such expansive authority—the compromise would fall apart.[176] Because patent "applicants tend to be from concentrated industries," a divided USPTO may be more prone to capture than a federal court with general jurisdiction because specialized interest groups can concentrate their lobbying influence to particular USPTO rule makers and leadership.[177] After the America Invents Act ("AIA") granted the USPTO significant rulemaking authority for creating the Patent Trial and Appeal Board ("PTAB"), the agency has demonstrated how it handles substantive rulemaking authority.[178] "After the AIA, administrative and patent law are more intertwined than ever," and literature suggests that the USPTO has overstepped its authority by unilaterally updating PTAB rules.[179] Additionally, the USPTO may have already engaged in

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172 *See* John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1104 (2011) (arguing for USPTO rulemaking authority in patent subject matter eligibility).

173 Bremer, *supra* note 171 (manuscript at 18).

174 *Id.* at 59.

175 *Id.*

176 Andrew Dietrick & Jonathan Stroud, *Rules to Bind You: Problems with the USPTO's PTAB Rulemaking Procedures*, 51 N.M L. REV. 430, 454 (2021).

177 Jonathan Masur et al., *Who Defines the Law? USPTO Rulemaking Authority*, 8 NW. J. TECH. & INTELL. PROP. 410, 421 (2010); *see also* Nard & Duffy, *supra* note 170, at 1628 ("Capture theory posits that special interest groups may be able to influence and control a specialized institution (especially, though not necessarily, a centralized one) more easily than a generalized entity.").

178 *See* Dietrick & Stroud, *supra* note 176, at 439–40.

179 William C. Neer, Note, *Discerning the Retroactive Policymaking Powers of the United States Patent and Trademark Office*, 71 AM. U. ADMIN. L. REV. 2, 433 (2019) (highlighting that "[a]fter the AIA, administrative and patent law are more intertwine than ever," and the PTO must "promulgate rules that maintain our nation's deeply rooted presumption against retroactivity"); *see also* Dietrick & Stroud, *supra* note 176, at 433 (arguing the USPTO fails to

unauthorized "substantive rulemaking" of patent subject matter eligibility by issuing independent guidance and "exerting power greater than intended by Congress, and more broadly, eschewing the APA's carefully designed rules and processes for holding agencies accountable to the public."[180] Although the USPTO may be capable of drafting rules quickly and flexibly to adapt to new areas of technology, Congress should not grant unilateral rulemaking authority in such a broad area of law merely for the "interest of legislative convenience."[181]

V. CONCLUSION

Congress should not grant the USPTO broad authority to legislate patent subject matter eligibility. The splintered nature of § 101 case law and the USPTO's practice of applying the law differently depending on technological category suggests that such rulemaking authority would perpetuate discriminatory patent standards for different technological fields. This would violate international agreement because TRIPS Article 27 prohibits such discrimination as to field of technology. Even if the patent rules remain facially neutral, variation in patentability across different fields of technology nonetheless constitutes *de facto* discrimination when it lacks justification, in violation of TRIPS. Further, even if other TRIPS members do not challenge the United States' conduct, such borderline discriminatory behavior would weaken the United States' ability to check other nations' discriminatory practices at the WTO. The United States should remain loyal to the TRIPS Agreement's goals of international patent harmonization and not pass hypocritical legislation for the sake of rulemaking convenience. Finally, heightened risks of divide-and-conquer regulatory capture arise if the USPTO can create rules tailored to specialized areas of industry. Instead, Congress should pass bicameral legislation to clarify the subject matter eligibility standard. In the meantime, USPTO guidance in the complicated area of patent eligibility law should remain "persuasive authority," subject to judicial interpretation and review.

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comply with the APA's public notice-and-comment requirement, including unilateral updates of the PTAB Trial Practice Guide without complying with procedural safeguards).

180 Costello, *supra* note 20, at 2218.

181 Burnam, *supra* note 27, at 568–69 ("[T]he Schor dissenters admonished the majority for violating the separation of powers in the interest of legislative convenience.").