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Praxair and the PTAB's Shadow Over Biotechnology Patents

Nora J. McGuffey

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ABSTRACT

The biotechnology industry is one of the fastest growing fields in research and development. This may be attributed to the decision in Diamond v. Chakrabarty*, where the Supreme Court held that a biotechnology invention was patent-eligible subject matter under 35 U.S.C. § 101. However, recent Supreme Court rulings have left the boundaries of § 101 uncertain, unworkable, and difficult for biotechnology industries to gain patent protections for their inventions. Before Congress enacted the AIA in 2011, the courts were the biggest influence on shaping the doctrine of patent eligible subject matter under § 101. But now with the new AIA post-grant proceedings, the PTAB plays an influential role in determining subject-matter eligibility.*

Through the new AIA post-grant proceedings, the PTAB has the ability to hear petitions that challenge the validity of a patent under §§ 101, 102, 103, or 112. But after the recent decision in Praxair Distribution., Inc. v. Mallinckrodt Hospital Products IP Ltd.*, the PTAB may now begin exerting too much influence over the doctrine of § 101. This decision, a case heard in* inter partes *review, threatens to stretch the PTAB's power dangerously thin. Under the AIA, cases reviewed in* inter partes *review may not present challenges on patentable subject matter under § 101. However, in* Praxair*, the PTAB used parts of a § 101 analysis to determine that the claims were ineligible subject matter. The Federal Circuit affirmed the PTAB's reasoning, suggesting that PTAB may be able to expand the reach of § 101 and allow petitioners to bring eligibility claims in* inter partes *review—where it is statutorily not allowed. Overall, the PTAB's power over eligible subject matter makes it easier for applications and patents to be invalidated under § 101. This could particularly harm biotechnology and bioscience industries where patent protection is at a disadvantage.*

This Note will discuss how the Supreme Court and PTAB have affected the subject-matter eligibility under § 101 and how this impacts patent rights for biotechnology innovation. Specifically, this Note will discuss how the PTAB's

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decision in Praxair *has expanded the scope of* inter partes *review and further added to the uncertainty of patentable subject matter.*

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INTRODUCTION

Biotechnology is one of the fastest growing fields of research. The study of biotechnology encompasses many different fields of research and development, including biology, genetics, medicine, and software and technology. Advancements in biotechnology combine biological mechanisms and technology to invent new products such as drugs, diagnostic tests, and other pharmaceutical related inventions.[1] The biotechnology industry has produced drugs and vaccines for cancer, Alzheimer's disease, Parkinson's disease, diabetes, AIDS, and others.[2] Additionally, biotechnology produces hundreds of diagnostic tests based on the identification of genetic mutations in human DNA.[3] Molecular diagnostics play a key part in medical research and development because it can identify genetic mutations in human DNA to show an individual's predisposition to certain diseases and conditions.[4] Some of the most prominent diagnostic tools identify an individual's genetic susceptibility to breast or ovarian cancer and detect pathogens

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[1] CLAUDE BARFIELD & JOHN E. CALFEE, BIOTECHNOLOGY AND THE PATENT SYSTEM: BALANCING INNOVATION AND PROPERTY RIGHTS 3–4 (2007).

[2] *Id.* at 4 (discussing the advancement of different biotechnology drugs and vaccines).

[3] *Id.*

[4] *Id.*; *see also* Jeffrey A. Lefstin, Peter S. Menell, & David O. Taylor, *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Changes*, 33 BERKELEY TECH. L.J. 551, 582 (2018).

in the blood supply like streptococcus and HIV.[5] Research and development within the biotechnology industry are important to improve medical treatments, pharmaceutical products, healthcare costs, and advance other areas of research.[6] And the main incentive for biotechnology research and development are intellectual property rights.[7] As such, intellectual property rights are crucial to ensure that the biotechnology industry continues to make advancements in innovation.

Biotechnology patents[8] encompass a wide range of inventions such as medical diagnostic test and purified substances like enzymes and proteins.[9] One of the first biotechnology patents recognized was in *Diamond v. Chakrabarty*. In *Chakrabarty*, the Supreme Court held that a patent for genetically modified bacterium was patentable under 35 U.S.C. § 101.[10] Many acknowledge the Supreme Court's decision in *Chakrabarty* as the key factor in sparking interest in biotechnology innovation.[11] The Court paved the way for dramatic advances in life science and medical research by recognizing that biotechnology inventions involving genetically modified living organisms are patentable subject matter.[12] As a result, the United States became one of the first countries to secure property rights in advanced biotechnology inventions.[13] The *Chakrabarty* decision encouraged large private firms to strengthen their investment in biotechnology research, and caused the formation of thousands of small firms that would license patented biotechnology research.[14] This made the United States the birthplace of the biotechnology revolution.[15]

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5 BARFIELD & CALFEE, *supra* note 1, at 4.

6 *Id.* at 3–10 (discussing the impacts that advancement in biotechnology has had over different industries and fields).

7 *See id.* at 26 (noting that "patents can motivate new inventions, and/or the commercialization of inventions that might have been created (but not commercialized) without patent protection, and/or motivate the efficient coordination of follow-up research").

8 The United States Patent and Trademark Office classifies biotechnology and organic patent applications in Technology Center 1600. *See Patent Technology Centers Management*, U.S. PATENT & TRADEMARK OFFICE, https://www.uspto.gov/patent/contact-patents/patent-technology-centers-management (last visited Feb. 27, 2019).

9 Lefstin et al., *supra* note 4, at 583.

10 Diamond v. Chakrabarty, 447 U.S. 303 (1980); 35 U.S.C. § 101 (2012).

11 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, 943 (2017); John Edward Schneider, *Microorganisms and the Patent Office: To Deposit or Not to Deposit, That is the Question*, 52 FORDHAM L. REV. 592, 594 (1984) (noting that Chakrabarty "spurred the increased commercial interest in biotechnology," and the biotechnology revolution is one of the most important developments affecting industries in the twentieth century).

12 Madigan & Mossoff, *supra* note 11, at 943.

13 *Id.*

14 BARFIELD & CALFEE, *supra* note 1, at 48.

15 *See id*. at 24–29 (discussing the important role that patent protection has on biotechnology innovation); Madigan & Mossoff, *supra* note 11, at 944.

But under current jurisprudence, patent protection for biotechnology inventions has been on the decline.[16] This is largely because the doctrine of patent-eligible subject matter under 35 U.S.C. § 101 is a real mess.[17] After the modern § 101 cases—*Bilski v. Kappos*,[18] *Mayo Collaborative Services. v. Prometheus Laborites, Inc.*,[19] *Ass'n for Molecular Pathology v. Myriad Genetics*,[20] and *Alice Corp. Pty. v. CLS Bank International*[21]—the Supreme Court left the boundaries of subject-matter eligibility uncertain and unworkable. These cases, especially *Mayo* and *Myriad*, considerably eroded patent protection for biotechnology innovation.[22]

Although the United States Patent and Trademark Office ("USPTO") continues to issue patents, the rulings in *Mayo* and *Myriad* make it difficult for inventions in the biotechnology field to gain patent protection.[23] This is likely because the bulk of modern biotechnology inventions stem from varying degrees the ineligible subject matter, such as laws of nature, natural phenomena, or abstract ideas.[24] Moreover, the *Alice-Mayo* test contributes to this issue because the test fails to set clear guidelines between inventions that are eligible subject matter and inventions that are not.[25]

After the signing of the American Invents Act ("AIA") of 2011, the judicial system is not the only one to blame for § 101's current state.[26] The AIA gives a

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16 Lefstin et al., *supra* note 4, at 561 (noting that "[S]ince *Mayo*, the number of § 101 invalidity rulings has skyrocketed, with more than one hundred invalidity determinations per year during the past two years").

17 Kristen Osenga, *The Problem with PTAB's Power Over Section 101*, 17 CHI.-KENT J. OF INTELL. PROP. 401, 405 (2018).

18 Bilski v. Kappos, 561 U.S. 593 (2010).

19 Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012).

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

21 Alice Corp. Pty. v. CLS Bank, Int'l*,* 573 U.S. 208 (2014).

22 *See* Lefstin et al., *supra* note 4, at 583 (stating that "patent protection for diagnostics has significantly eroded over the past decade due to judicial decisions.").

23 *Id.* The USPTO continues to issue patents related to biotechnology inventions despite the Supreme Court's ruling. Kate Gaudry et al., *Trends in Subject Matter Eligibility For Biotechnology Inventions*, IPWATCHDOG (July 12, 2015), http://www.ipwatchdog.com/2015/07/12/trends-in-subject-matter-eligibility-for-biotechnology-inventions/id=59738/.

24 *See* Shen Lin, *The Limits of Biotechnology Inventions in Patent Eligibility*, MEDIUM (Oct. 26, 2018), https://medium.com/@shenlin2/the-limits-of-biotechnology-inventions-in-patent-eligibility-3fba5450955 (discussing biotechnology and pharmaceutical inventions are likely to fall into a judicial exception because law surrounding § 101 is vague); Gene Quinn, *The Looming Patent Nightmare Facing the Pharmaceutical Industry*, IPWATCHDOG (July 8, 2015), http://www.ipwatchdog.com/2015/07/08/the-looming-patent-nightmare-facing-the-pharmaceutical-industry/id=51428/ [hereinafter *Looming Patent*] (noting that the pharmaceutical industry relies heavily on computer-aided drug design, which makes those inventions susceptible to being rejected as ineligible subject matter for relating to an abstract idea).

25 *See* Lefstin et al., *supra* note 4, at 593 (noting that application of the *Alice-Mayo* test's inventive concept step for natural law or phenomenon does not provide objective guidance to examiners, jurists, practitioners, or inventors).

26 Osenga, *supra* note 17, at 408.

great deal of power to the USPTO and, in turn, the Patent Trial and Appeal Board ("PTAB") and its post-grant proceedings.[27] Through the AIA's post-grant proceedings, covered business method review ("CBMR"), post-grant review ("PGR"), and *inter partes* review ("IPR"), the PTAB has more power and discretion to shape § 101 doctrine and what it considers patentable subject matter. Because of modern § 101 Supreme Court cases, the PTAB has been able to significantly influence the development of subject-matter eligibility.[28] As a result, the PTAB's ability to determine what constitutes patentable subject matter increases the power of the USPTO.[29]

The following discussion describes how the Supreme Court's jurisprudence on patentable subject matter under 35 U.S.C. § 101 has shaped PTAB decision making and, in turn, what this effect means for patent rights in biotechnology innovation. Part II of this Note will discuss how the Supreme Court's modern § 101 cases—*Bilski*, *Mayo*, *Myriad*, and *Alice*—developed subject-matter eligibility and influenced patent protection for biotechnology inventions and industries. Part III will give a brief overview of the PTAB and the basics of each post-grant proceeding. Part IV will discuss how each post-grant proceeding interacts with § 101 invalidity challenges by analyzing specific biotechnology patent cases. Part V will discuss *Praxair Distribution., Inc. v. Mallinckrodt Hospital Products IP Ltd.'s* future impact and implications on subject-matter eligibility under § 101 and future patent protection for the biotechnology industry.

I. THE SUPREME COURT'S DEVELOPMENT OF § 101 SUBJECT-MATTER ELIGIBILITY

The Supreme Court acknowledged that it is the role of Congress, not the courts, to define the limits of patentability; but once Congress has spoken, it is "the province and duty of the judicial department to say what the law is."[30] In relation to patentable subject matter, Congress fulfilled its role by enacting 35 U.S.C. § 101 which states, "[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 therefor, subject to the conditions and requirements of this title."[31] It follows that courts must uphold their constitutional duty to further determine the limits of patentable subject matter under § 101.[32]

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[27] *Id.* at 405.

[28] *Id.* at 406.

[29] Conor T. Flynn, *Here Today, Gone Tomorrow? Post-Grant Review and PTAB Interpretation of Sec. 101 Subject Matter after Myriad*, 11 BUFF. INTELL. PROP. L.J. 1, 26 (2015).

[30] Diamond v. Chakrabarty, 447 U.S. 303, 315 (1980) (quoting Marbury v. Madison, 1 Cranch 137, 177 (1803)).

[31] 35 U.S.C. § 101 (2012) (emphasis added).

[32] *See Diamond*, 447 U.S. at 315.

This section will discuss (1) the modern Supreme Court cases and their subsequent development of the governing analytical framework for determining subject-matter eligibility under § 101, and (2) the impact of current jurisprudence on biotechnology patent protection and innovation.

A. The Supreme Court's Development of the Judicial Exceptions and § 101 Framework

Pursuant to § 101, patent-eligible subject matter is "any new and useful process, machine, manufacture, or composition of matter."[33] Historically, courts have given § 101 a broad interpretation to include "anything under the sun that is made by man."[34] But that does not mean § 101 is limitless.[35] The Supreme Court has "long held that [§ 101] contains an important implicit exception: laws of nature, natural phenomena and abstracts ideas are not patentable."[36] The Court created judicial limitations to § 101 reasoning that granting a patent over subject matter relating to the laws of nature, natural phenomena, or abstract ideas would obstruct the primary goal of patent law.[37]

Until 2010, the Supreme Court has taken an expansive interpretation of what constitutes patentable subject matter under § 101.[38] Following this lower courts essentially reduced the limitations of subject-matter eligibility to whether the invention related to a useful, concrete and tangible result.[39] However, after four landmark Supreme Court cases, the analysis for subject-matter eligibility requires a much more stringent approach.

In *Bilski v. Kappos*, the Court decided the fundamental question for determining a process claim's subject-matter eligibility was to ascertain whether the claim related to "three specific exceptions to § 101's broad patent-eligibility principles: laws of nature, physical phenomena, and abstract ideas."[40] The Court declined to adopt the machine-or-transformation test for determining a process claim's subject-matter eligibility.[41] The Court held the patent's claims were

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33 35 U.S.C. § 101 (2012).

34 *See Diamond*, 447 U.S. at 309.

35 *Id.*

36 Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 70 (2012); *see also Diamond*, 447 U.S. at 309; Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63, 67 (1972); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

37 Alice Corp. Pty. Ltd. v. CLS Bank, Int'l*,* 573 U.S. 208, 216 (2014) ("Monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it, thereby thwarting the primary object of the patent laws.").

38 John M. Golden, *Flook Says One Thing, Diehr Says Another: A Need for Housecleaning in the Law of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1765, 1767 (2014).

39 *Id.* at 1768.

40 Bilski v. Kappos, 561 U.S. 593, 601 (2010).

41 *Id.* at 3226–27. The machine-or-transformation is one way to show that process claim relating to an abstract idea or law of nature is patentable subject matter if the process is linked to a machine or

ineligible subject matter and, therefore, unpatentable because the claims described the basic concept of hedging, or protecting against risk which was nothing more than an abstract idea.[42] The Court went further in *Mayo Collaborative Services v. Prometheus Laboratories, Inc*., when it held patent claims directed to the personalized process for administering drug doses were unpatentable under § 101 because they claimed the underlying laws of nature.[43] The Court reasoned that if a law of nature was not patent eligible, then neither was a process that recited the law of nature, unless the process had an additional feature which made the process *significantly more* than the natural law alone.[44] Additionally, in *Ass'n for Molecular Pathology v. Myriad Genetics*, the patent claimed the isolated DNA coding for both BRCA1 and BRCA2 and their synthetic sequence.[45] The Court held naturally occurring DNA was a product of nature and not patent eligible under § 101 simply because it was isolated.[46] But the Court held that synthetically created DNA ("cDNA") was not naturally occurring and thus, eligible subject matter.[47] Furthermore, the Court noted "ground breaking, innovative, or even brilliant discoveries does not by itself satisfy the § 101 inquiry."[48]

Lastly, in *Alice Corp. Pty. v. CLS Bank International*, the Court concluded that specific claims for a computer-implemented scheme for mitigating settlement risk were unpatentable because they "added nothing of substance to the underlying abstract idea."[49] However, the Court acknowledged that "[a]t some level all inventions . . . embody, use, reflect, upon, or apply laws of nature, natural phenomena, or abstract ideas."[50] An invention is not always patent ineligible merely because it includes one of the judicial exception.[51] Thus, when an invention includes one of the judicial exceptions, courts must distinguish between patents that claim an ineligible concept and patents that integrate the ineligible concept into something more, thereby becoming patent eligible.[52] From these four cases, the Court developed a systematic approach—now known as the *Alice-Mayo* two-step test—to determine subject-matter eligibility under § 101:

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transforms the object. *Id.* If the machine-or-transformation was the sole test for determining subject-matter eligibility, it would make patent protection for diagnostic medicine techniques uncertain. *Id.*

42 *Id.* at 611.

43 *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71–73 (2012).

44 *Id.* at 71–72.

45 Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 583–84 (2013). Mutations in BRCA genes are commonly linked to breast cancer. *Id.* at 582–83.

46 *Id.* at 580.

47 *Id.*

48 *Id.* at 591.

49 Alice Corp. Pty. Ltd. v. CLS Bank, Int'l, 573 U.S. 208, 212 (2014).

50 *Id.* at 217 (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71 (2012)) (internal quotations omitted).

51 *Id.*

52 *Id.*

> First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, what else is there in the claims before us? To answer that question, we consider the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application. We have described step two of this analysis as a search for an inventive concept—i.e., an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.[53]

From this, the *Alice-Mayo* two-step test can be summarized in the following two questions:

> (1) Does the patent claim relate to an abstract idea, law of nature, or natural phenomena?
> (2) If so, does the patent claim an element or combination that is significantly more than an ineligible concept (i.e., an inventive concept)?[54]

In *Alice*, the Court was clear that this framework should apply to all judicial exceptions and all types of claims.[55] But this judicial framework has not been kind to biotechnology industries.[56]

B. The Repercussions of the Alice-Mayo *Two-Step Test*

The USPTO developed guidelines based on the Supreme Court holdings in *Bilski*, *Mayo*, *Myriad*, and *Alice*.[57] The USPTO synthesized the *Alice-Mayo* two-step into a flow chart and added it into the Manual of Patent Examining Procedure to help practitioners and examiners.[58] However, many criticize the *Alice-Mayo* two-step test for being difficult to apply consistently and varying substantially

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[53] *Id.* at 217–18 (internal citations omitted).

[54] *See* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE, 2100-16 (U.S. Pat. and Trademark Off. (2018)) [hereinafter MPEP].

[55] *Id.*

[56] *See* Naira R. Simmons, *Why the Supreme Court Should Use* Ariosa v. Sequenom *to Provide Further Guidance on 35 U.S.C. § 101 Patent Eligibility*, 16 CHI.-KENT J. INTELL. PROP. 112, 130 (2016).

[57] Following any important or groundbreaking case that adds or clarifies the *Alice-Mayo* two-step the USPTO will post additional guidelines on their website for examiners and practitioners to use. *See* U.S. PATENT & TRADEMARK OFFICE, SUBJECT MATTER ELIGIBILITY: EXAMINATION GUIDANCE (Jan. 10, 2019, 10:59 AM), https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility.

[58] MPEP, *supra* note 54.

between examiners and administrative judges.[59] This variation affects patent prosecution because examiners and administrative judges could reach completely different outcomes under § 101—eligible and not eligible—for the same set of claims.[60]

These Supreme Court rulings—particularly *Mayo*—significantly impacted patent protection for biotechnology inventions.[61] One report shows that before *Mayo,* the USPTO and courts rarely rejected patent applications for ineligible subject matter; but after *Mayo*, the number of subject-matter rejections skyrocketed.[62] For example, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the Federal Circuit—relying on *Mayo*—held that a diagnostic test that created an alternative for prenatal diagnosis of fetal DNA was not patentable subject matter under § 101.[63]

The invention in *Ariosa* revolved around the discovery of cell-free fetal DNA ("cffDNA") in maternal plasma and serum.[64] cffDNA is the fetal DNA that circulates freely in the bloodstream of a pregnant woman.[65] The patent did not claim the cffDNA, but claimed the method of using it.[66] The method involved detecting small amounts of paternally inherited cffDNA in maternal plasma or serum to determine certain fetal characteristics, like gender.[67] Following the *Alice-Mayo* two-step framework, the Court found that the method claims related to the naturally occurring phenomena, the cffDNA.[68] But the method claims failed the *Mayo's* second step because they "[did] not result in an inventive concept that transform[ed] the natural phenomenon of cffDNA into a patentable invention."[69] Thus, the Court held the invention unpatentable under § 101 for ineligible subject matter.[70]

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59 Lefstin et al., *supra* note 4, at 589.

60 *Id.*

61 *See* Simmons, *supra* note 56, at 130 ("Ariosa v. Sequenom is a case that clearly illustrate why the newly created judicial framework fails to protect many inventions in biotechnology."); Lefstin et al., *supra* note 4, at 588 (discussing that patent invalidity rates for § 101 have been the most dramatic for covered business method and gaming patents, but § 101 invalidity rates are high among biotechnology and agriculture); Madigan & Mossoff, *supra* note 11, at 948–49 (noting that the pharmaceutical innovation struggles to gain patent protection because of their high invalidation rates).

62 Lefstin et al., *supra* note 4, at 561, 576.

63 Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371,1378 (Fed. Cir. 2015).

64 *Id.* at 1373.

65 *Id.*; *see also* Robert Bock & Meredith Daly, *Fetal DNA Sequencing Potentially Could Reduce Need For Invasive Prenatal Diagnostic Procedures*, NAT'L INST. HEALTH (Aug. 1, 2018), https://www.nih.gov/news-events/news-releases/fetal-dna-sequencing-potentially-could-reduce-need-invasive-prenatal-diagnostic-procedures.

66 *Ariosa Diagnostics, Inc.*, 788 F.3d at 1373.

67 *Id.*

68 *Id.* at 1376.

69 *Id.*

70 *Id.* at 1380.

The Federal Circuit later denied the petition for a rehearing en banc.[71] Circuit Judge Lourie reasoned the petitions denial was based on the precedent of *Mayo* because there was no principled basis to distinguish the two cases.[72] However, Judge Lourie noted that because of the Supreme Court's ruling in *Bilski*, *Mayo*, *Myriad*, and *Alice*, medical inventions (i.e., diagnostic inventions) could be at risk of losing patent protection.[73] Judge Lourie cautioned that "a crisis of patent law and medical innovation may be upon us."[74] Other circuit justices, like Circuit Judge Dyk, shared similar concerns:

> I share the concerns of some of my colleagues that a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in *Mayo*) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena.[75]

Unfortunately, the Supreme Court implicitly affirmed the *Mayo* ruling when it denied the petition for a writ of certiorari in *Sequenom Inc. v. Ariosa Diagnostics, Inc.*[76]—a case that many hoped would clarify what the Supreme Court regarded as patentable subject matter.[77] But *Ariosa* clearly demonstrates that the current § 101 test severely impacts future patent protection for biotechnology and medical innovation.

Some commentators noted that the *Alice-Mayo* two-step test may prevent potentially lifesaving treatments and antibiotics from patent protection because they do not conform to the Supreme Court's definition of eligible subject matter[78] (i.e., the inventions relate to a law of nature, natural phenomena, or abstract idea). If these advancements fail to gain patent protection, an alternative is to seek

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71 Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1284 (Fed. Cir. 2015) (denying hearing en banc).

72 *Id.* at 1284 (Lourie, J., concurring).

73 *Id.* at 1285 (Lourie, J., concurring).

74 *Id.*

75 *Id.* at 1287 (Dyk, J., concurring).

76 Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

77 Lefstin et al., *supra* note 4, at 557. Notably, the Court's denial signals that it is inclined to address the serious challenges created by recent § 101 jurisprudence, thereby leaving patent law with the *Alice-Mayo* two-step test. *Id.* at 562.

78 *See* Simmons, *supra* note 56, at 131 (noting that inventions that relate to a judicial exception "may well be deserving of patent protection," like prenatal tests that diagnosis possible birth defects without intrusive means); Lin, *supra* note 24 (discussing that a bulk of biotechnology and pharmaceutical innovation are extremely useful and have potentially lifesaving qualities but get rejected because they related to one or more judicial exceptions); Gaudry et al., *supra* note 23 (showing an increase in § 101 rejections from 2012 pre-*Mayo* to February 2015).

property protection under trade secrets.[79] However, trade secret protection for biotechnology can be hard to maintain because these technologies and diagnostic tools need to be fully disclosed to the public during the regulatory approval process.[80] For example, biotechnology companies that develop medical diagnostic tools must publish most of their research in journals to become eligible for financial reimbursement.[81]

Others noted that post-*Myriad* and *Mayo*, biotechnology industries have experienced a decrease in patent protection.[82] This lowers the possibilities for biotechnology research to attract investors and possible funding to biotechnology industries.[83] Investors are not interested in investing in Industries where it is difficult to gain patent protection are unattractive to investors. Patents help investors remain competitive in the market.[84] Patent protection also allows investors to enforce their property right against potential infringers. Moreover, biotechnology companies rely on investment funding to survive, and in turn, rely on strong patent protection.[85] Consequently, biotechnology industries with weak or no patent protection will receive less funding for research and development. The lack of investment in biotechnology research and development will limit future advances in the field,[86] which would not only affect companies but prevent people from receiving the benefits of biotechnology innovation. Examples of scientific research that are experiencing funding difficulties as a result of § 101 standards are: "cytotoxins derived from sea organisms (purified natural products) that could be used in treating tissue sarcoma; genes relating to particular genetic mutations; and snake toxins used for treating multiple sclerosis."[87] Because of the Supreme Court's uncertain and unworkable guidance in *Bilski*, *Mayo*, *Myriad*, and *Alice*, patent rights for biotechnology industries have been negatively impacted.[88] Overall, this could affect future research and development within the medical, pharmaceutical, and other biotechnology industries.

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79 Simmons, *supra* note 56, at 126.

80 *Id.*

81 Lefstin et al., *supra* note 4, at 583.

82 *Id.*

83 *Id.* at 583–84; Gene Quinn, *Did the Supreme Court Intentionally Destroy the U.S. Patent System?*, IPWATCHDOG (May 22, 2018), http://www.ipwatchdog.com/2018/05/22/did-the-supreme-court-intentionally-destroy-the-u-s-patent-system/id=97514/ [hereinafter *Supreme Court*].

84 *See Supreme Court*, *supra* note 83; *Should You Invest in Patent Protection?*, COOLEYGO, https://www.cooleygo.com/should-you-invest-in-patent-protection/ (last visited Nov. 4, 2019).

85 *See* BARFIELD & CALFEE, *supra* note 1, at 30.

86 Lefstin et al., *supra* note 4, at 583–84.

87 *Id.*

88 *See id.* at 582–584; Osenga, *supra* note 17, at 410.

II. THE PATENT TRIALS AND APPEALS BOARD

Under the AIA, [89] Congress conferred a significant amount of power to the USPTO by creating the PTAB, which replaced the former Patent Board of Interferences. This section will briefly discuss (1) the structure of the PTAB, and (2) the general mechanics of the post-grant proceeding.

Because the U.S. patent system had become complex, Congress created the AIA to "establish a more efficient and streamlined patent system that [would] improve patent quality and limit unnecessary and counterproductive litigation costs."[90] The PTAB has a panel of three judges who are selected based on their area of expertise needed in the science or technology field.[91] The AIA requires PTAB judges to be "persons of competent legal knowledge and scientific ability,"[92] which helps them understand the complexities of patents and its subject matter. Additionally, knowledgeable judges can answer legal questions from the perspective of a 'person of ordinary skill in the art.'[93]

The AIA granted the PTAB the power to hear three new post-grant proceedings: IPR,[94] CMBR,[95] and PGR.[96] These new proceedings provide a cost-effective alternative to litigation for patent validity challenges.[97] These post-grant proceedings have "significantly strengthened the U.S. system for administrative review of patent validity,"[98] and give the USPTO a better forum to correct the errors in "bad patents" from the initial examination process. Before the AIA, it was common for a defendant to assert an invalidity claim as a defense to infringement, but these post-grant proceedings allow potential defendants to preemptively invalidate a patent.[99]

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

[90] Flynn, *supra* note 29, at 7 (quoting Mark Consilvio & Jonathan R.K. Stroud, *Unraveling the U.S.P.T.O.'s Tangled Web: An Empirical Analysis of the Complex World of Post-Issuance Patent Proceedings*, 21 J. INTELL. PROP. L. 33, 43–45 (2013)).

[91] Stuart Minor Benjamin & Arti K. Rai, *Administrative Power in the Era of Patent Stare Decisis*, 65 DUKE L.J. 1563, 1569 (2016).

[92] AIA § 7(a); 35 U.S.C. § 6(a) (2012).

[93] A person of ordinary skill in the art ("PHOSITA") is similar to a "reasonable person" in torts law. However, because of the complex and technical nature of patent law, a PHOSITA is specific to that inventions technical field of study. *See* Nainia & Jasmeet Gulati, *Knowledge/Skill Standards of "Person Skilled in Art": A Concern Less Visited*, 17 J.MARSHALL REV. INTELL. PROP. L. 588, 601-602 (2018).

[94] AIA § 6(a); 35 U.S.C. § 311(a).

[95] AIA § 18; 35 U.S.C. § 321 (note).

[96] AIA § 6(d); 35 U.S.C. § 321.

[97] Flynn, *supra* note 29, at 8.

[98] Saurabh Vishnubhakat et al., *Strategic Decision Making in Dual PTAB and District Court Proceedings*, 31 BERKELEY TECH. L.J. 45, 58 (2016).

[99] *Id.* at 48.

Generally, each post-grant proceeding follows the same process. First, a person—not the patent holder—submits a petition to the USPTO to institute a post-grant proceeding.[100] The petition must challenge the patent's validity under either §§ 101, 102, 103, or 112. However, the AIA limits what each post-grant proceeding may hear. IPR allows challenges based on § 102 novelty or § 103 obviousness,[101] CMBR allows challenges on any ground of invalidity, but only for certain types of business method patents,[102] and PGR allows challenges on any ground of invalidity for patents filed on or after March 16, 2013.[103] Second, the panel of judges sitting on the PTAB decides whether the petition satisfies the statutory threshold to institute the proceeding. To initiate an IPR, the petition must show there is a "reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."[104] For CBMR and PGR, a petition must show that it is "more likely than not that at least 1 of the claims challenged in the petition is unpatentable."[105] If the panel decides that the petition satisfies the required standard, it will initiate a review of the patent.[106] The PTAB's decision to institute a proceeding is final and not appealable.[107] Once initiated, the PTAB tends to make its final decision within a year.[108] Although the goal of the PTAB and post-grant proceedings was to improve the patent system, these new AIA additions have created more confusion and complications for subject-matter eligibility.

III. CHALLENGING § 101 SUBJECT-MATTER ELIGIBILITY IN POST-GRANT PROCEEDINGS

Before the AIA, courts were one of the biggest influences on shaping the doctrine of patent eligible subject matter under 35 U.S.C. § 101. Through the scope of the post-grant proceedings, Congress gave the PTAB, and inherently the USPTO, the power to answer pivotal questions of law. Explicitly through CBMR and PGR, the PTAB has significant power and discretion to determine patentable subject matter under § 101,[109] an area of patent law that has previously been left for the courts to interpret. Many scholars attribute § 101 uncertainty to the Supreme Court's decisions in *Bilski*, *Mayo*, *Myriad*, and *Alice*; however, now the Supreme

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100 *See* 35 U.S.C. § 311 (providing for IPR); *id.* § 321(a) (providing for PGR); *id.* § 321(note) (providing for CMBR).

101 *Id.* § 311(b).

102 *Id.* § 321(a)(1) (note).

103 *Id.* § 321(b).

104 *Id.* § 314(a).

105 *Id.* § 324(a).

106 *Id.* §§ 314(a), 324(a).

107 *Id.* §§ 314(e), 324(d); *see also* Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131 (2016).

108 35 U.S.C. §§ 316(a), 326(a)(11).

109 Flynn, *supra* note 29, at 3.

Court may not be the only one to blame.[110] The PTAB's broad power over § 101 allows the USPTO to expand or shrink the scope of patentable subject matter.[111] This is not the only way the PTAB has affected § 101.

This section will examine how each post-grant proceeding has interacted with § 101 invalidity challenges relating to a biotechnology patent. Each section will briefly discuss how each decision affects subject-matter eligibility under § 101 and any future implications the decision may have on patent protection for biotechnology innovation.

A. Covered Business Method Review

Within the CBMR, the PTAB has been known to be very "aggressive, particularly with respect to its interpretation of section 101."[112] This is likely because the USPTO has a large amount of discretion in determining what patents are subject-matter eligible for a CBMR.[113] Unlike IPR or PGR, "a person may not file a petition for a [CBMR] . . . unless the person or the person's real party in interest or privy has been sued for infringement of the patent or has been charged with infringement under that patent."[114] Another key distinction is that CBMRs only apply to covered business method patents,[115] which the AIA defines in § 18(d)(1):

> The term 'covered business method patent' means a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions.[116]

In addition to this broad definition, the AIA directs the USPTO to further define "technological invention."[117] The USPTO decides "whether the claimed subject matter as a whole recites a technological feature that is novel and unobvious over the prior art; and solves a technical problem using a technical solution."[118] This broad definition of "technological invention" gives the USPTO a fair amount of discretion in determining the subject matter that is eligible for instituting a

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110 Osenga, *supra* note 17, at 405–06 (discussing that the PTAB should share the blame for the confusion of § 101).

111 *Id.* at 407.

112 Benjamin & Rai, *supra* note 91, at 1577.

113 *Id.* at 1573.

114 AIA § 18(a)(1)(B) (2011).

115 *Id.* (stating that the "Director shall issue regulations establishing and implementing a transitional post-grant review proceeding for review of the validity of covered business method patents").

116 *Id.* § 18(d)(1).

117 Benjamin & Rai, *supra* note 91, at 1573.

118 *Id.* at 1576 (quoting 37 C.F.R. § 42.301(b)).

CMBR.[119] Typically, CBM reviews are limited to patents that are "financial in nature," "incidental to financial activity," or "complementary to financial activity."[120] In the past, a majority of the CBMR petitions challenged claims on subject-matter eligibility.[121]

Although most biotechnology uses software in research and development, the PTAB generally does not institute CBMR petitions challenging biotechnology or medical patents[122] because they are not a "financial product or service."[123] For example, in *Amneal Pharmaceuticals, LLC v. Jazz Pharmaceuticals, Inc.* and *Roxane Laboratories, Inc. v. Jazz Pharmaceuticals, Inc.*, the PTAB declined to institute a CBMR because the petitioner failed to show that the claim language recited a method involving the movement of money or credit in exchange for a product or service.[124] In *Amneal Pharmaceuticals*, the patent related to a "method for controlling access to a sensitive prescription drug prone to potential abuse or diversion, by utilizing a central pharmacy and database to track all prescriptions for the sensitive drug."[125] In *Roxane Laboratories*, the patent related to a "method for treating a patient with a sensitive prescription drug and controlling access to the sensitive prescription drug, which is prone to potential abuse, misuse, or diversion, by utilizing a central pharmacy and database to track all prescriptions for the sensitive drug."[126] Because the PTAB held that the patents were not subject-matter eligible for a CBMR, it could not institute the proceeding to determine the patents' validity.

The PTAB has a fair amount of discretion on the subject-matter eligibility for covered business method patents. However, *Amneal Pharmaceuticals* and *Roxane Laboratories* suggest that the PTAB has not found a way to expand the definition of a "technological invention" to encompass biotechnology subject matter. Thus, within the scope of CBMR, it is unlikely that the PTAB will have a significant impact on patent protection for biotechnology innovation.

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119 *Id.*

120 Marshall Gerstein*, For CBM Standing, Is "Incidental To" a Financial Produce Service Enough?*, PTABWATCH (July 7, 2016), https://www.ptabwatch.com/2016/07/for-cbm-standing-is-incidental-to-a-financial-product-or-service-enough/.

121 Vishnubhakat et al., *supra* note 98, at 67.

122 *Id.* at 92.

123 AIA § 18(d)(1) (2011).

124 *Denying Institution of Covered Business Method Review of CBM2014-00149, 150, 151, 153*, PTAB TRIAL BLOG (Jan. 26, 2015), http://ptabtrialblog.com/denying-institution-covered-business-method-review-cbm2014-00149-150-151-153/; *Denying Institution CMB2014-00161, 175*, PTAB TRIAL BLOG (April 15, 2015), http://ptabtrialblog.com/denying-institution-cbm2014-00161-175/.

125 Amneal Pharms., LLC v. Jazz Pharms., Inc., No. CBM2014-00149/150/151/153, slip op. at 4 (P.T.A.B. Jan. 13, 2015).

126 Roxane Labs., Inc. v. Jazz Pharms., Inc., No. CBM2014-00161/175, slip op. (P.T.A.B. Feb. 9, 2015), https://e-foia.uspto.gov/Foia/RetrievePdf?system=PRPS&flNm=CBM2014-00175_14.

B. Post-Grant Review

PGR may be the most powerful proceeding for invalidating patents.[127] PGR's scope is the broadest of any other post-grant proceeding[128] because a petitioner "may request to cancel as unpatentable one or more claims of a patent on *any ground*."[129] This includes novelty, obviousness, utility, indefiniteness, written description, enablement, and most importantly, for this Note's purpose, subject-matter eligibility. Unlike CBMR, PGR does not limit a petitioner to business method patents. But a major limitation for PGRs is petitioners may only challenge patents that issue under the AIA's first-to-file regime (i.e., have an effective filing date on or after March 16, 2013).[130]

Since the Supreme Court's ruling in *Bilski*, *Mayo*, *Myriad*, and *Alice*, petitioners have been challenging patents on the basis of subject-matter eligibility under § 101. In *American Simmental Ass'n v. Leachman Cattle of Colorado, LLC,* one of PGR's first final written decisions, the PTAB invalidated a patent under §§ 101 and 103. The patent "relate[d] generally to genetic quality and relative market value of livestock."[131] The patent specifically disclosed embodiments of the invention that facilitated "an owner or potential buyer of one or more sale groups of livestock to evaluate the relative market value of the sale groups based on predictions derived from genetic merit estimates of the herd."[132] With respect to § 101, the PTAB followed the *Alice-Mayo* two-step.[133] First, the PTAB found that the claims were directed to the fundamental concept of "'determining an animal's relative economic value based on its genetic and physical traits,' and that such a fundamental concept is a patent ineligible abstract idea."[134] After determining that the claims were directed to an abstract idea, the PTAB found that "all computer recitations in the challenged claims [were] recitations to generic computer hardware used in a conventional manner, which [were] insufficient to impart patentability under *Alice*." Following the *Alice-Mayo* framework, the PTAB held the claims were invalid because they were not patentable subject matter.[135]

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127 Flynn, *supra* note 29, at 8.

128 *Id.* at 9.

129 35 U.S.C. § 321(b) (2012) (emphasis added).

130 Flynn, *supra* note 29, at 10; *see also* U.S. PATENT & TRADEMARK OFFICE, MAJOR DIFFERENCES BETWEEN IPR, PGR, AND CBM, http://www.uspto.gov/sites/default/files/ip/boards/bpai/aia_trial_comparison_chart.pptx (last visited Sept. 15, 2018) [hereinafter MAJOR DIFFERENCES BETWEEN IPR, PGR, AND CBM].

131 Am. Simmental Ass'n v. Leachman Cattle of Colo., LLC, No. PGR2015-00005, 2016 WL326807 *2 (P.T.A.B. June 13, 2016).

132 *Id.* at 3.

133 *Id.* at 21.

134 *Id.* at 13.

135 *Id.* at 21 (holding that the PTAB was unpersuaded that the "problem, or its solution, involves or requires anything computer-related").

Deciding a petition that challenges subject-matter eligibility, the PTAB must apply the *Alice-Mayo* framework laid out by the Supreme Court. Because PGR is relatively new and can only hear patents that issued under the AIA, there are fewer petitions than other post-grant proceedings.[136] Because there are less filings, it will take time to see PGR's true effect on § 101, specifically in technology areas where issuing patents take longer.[137] Furthermore, because the PTAB may initiate a PGR petition if it "raises a novel or unsettled legal question that is important to other patents or patent applications,"[138] the PTAB has more discretion to either "shrink or expand" the scope of *what* is patentable subject matter under § 101.[139] This is true particularly in technology areas that are evolving at a fast rate—such as biotechnology and bioscience—because it is no secret that many in the patent community want to expand the scope of patentable subject matter.[140] As a result, the PTAB, through the venue of PGR, will soon become a crucial institution for shaping the doctrine of § 101. Currently, PGR has not allowed the PTAB to change what subject matter is patent eligible.

C. Inter Partes *Review*

IPR examines patents issued under either the pre-AIA's first-to-invent or AIA's first-to-file regime.[141] Petitions in IPR may challenge patents only under § 102 novelty and § 103 nonobviousness, and only on the basis of prior art consisting of patents or printed publications.[142] IPR proceedings do not have the authority to hear petitions that challenge patents under § 101 subject-matter eligibility.[143] However, in a recent case, the PTAB found a way to get around this limitation by using the printed matter doctrine.

The printed matter doctrine provides that: "[c]laim limitations directed to printed matter are not entitled to patentable weight unless the printed matter is functionally related to the substrate on which the printed matter is applied."[144] Simplified, the printed matter doctrine can form a two-part test:

(1) Is the claim limitation directed to printed matter?

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136 Benjamin & Rai, *supra* note 91, at 1569.
137 Flynn, *supra* note 29, at 10.
138 35 U.S.C. § 324(b) (2012).
139 Flynn, *supra* note 29, at 4.
140 *Id.* at 20.
141 *See* MAJOR DIFFERENCES BETWEEN IPR, PGR, AND CBM, *supra* note 130; Vishnubhakat et al., *supra* note 98, at 59.
142 35 U.S.C. § 311(b) (2012).
143 *Id.*
144 Praxair Distrib. v. Mallinckrodt Hosp. Prods. IP Ltd., 890 F.3d 1024, 1031 (Fed. Cir. 2018).

(2) If so, does the printed matter functionally relate to the substrate on which it is printed?[145]

Originally, courts applied the printed matter doctrine to encompass literal printed materials, but under current jurisprudence, printed matter can include any claims of content information.[146] If the printed matter functionally relates to its substrate, then the claim limitations are considered patentable weight and the patentability analysis will proceed. Printed matter functionally relates to its substrate when it *interrelates* with the rest of the claim so as to produce a new useful product.[147] But if the claim limitations lack a functional relationship, then they are not given patentable weight because they are not subject-matter eligible under 35 U.S.C. § 101.[148] Likewise, printed matter lacking a functional relationship to its substrate will not distinguish the invention from the prior art in terms of patentability.[149] While the underlying requirement of the printed matter doctrine is subject-matter eligibility, courts have traditionally applied this doctrine to the other patentability requirements—§ 102 novelty, § 103 non-obviousness, and § 112 written description.[150]

The IPR proceeding *Praxair Distribution, Inc. v. Mallinckrodt Hospital Products IP Ltd.* was the first time the PTAB applied the printed matter doctrine in the history of its establishment. The petitioner, Praxair Distribution, Inc. ("Praxair") challenged U.S. Patent 8,846,112 (the "'112 patent") owned by Mallinckrodt Hospitals Products IP Ltd. ("Mallinckrodt").[151] The '112 patent claimed a method for administering nitric oxide gas to patients with hypoxic respiratory failure (a condition where oxygen levels in blood are too low), and the information regarding the harmful side effects for this treatment:[152]

> [T]he '112 patent [ ] is directed to methods of distributing nitric oxide gas cylinders for pharmaceutical application . . . The claims of the '112 patent generally require supplying a medical provider

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145 *See* Paul E. Dietze & Elizabeth M. Crompton, *The Printed Matter Doctrine- Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd*., HAYNESBOONE (May 23, 2018), http://www.haynesboone.com/Alerts/the-printed-matter-doctrine (discussing the printed matter doctrine as a two-step process).

146 *Praxiar Distrib.*, 890 F.3d at 1032.

147 *Id.*; *see also In re* Gulack, 703 F.2d 1381, 1385 (Fed. Cir. 1883) (finding a functional relationship between the printed digits on circular band because "the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for educational and recreational mathematic purposes.").

148 *Praxiar Distrib.*, 890 F.3d at 1032.

149 *In re* Ngai, 367 F.3d 1336, 1339 (Fed. Cir. 2004).

150 *Praxair Distrib.,* 890 F.3d at 1032.

151 *See* Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd., No. IPR2015-00529, 2016 WL 3648375 at *1 (P.T.A.B. July 7, 2016).

152 *Praxair Distrib.,* 890 F.3d at 1028.

> with a cylinder of nitric oxide gas and providing the medical provider with certain prescribing information relating to the harmful side effects of nitric oxide for certain patients identified in the INOT22 study.[153]

The claim limitations at issue for the purpose of this Note are, as the Federal Circuit labeled them, the "providing information limitation" (from claim 1),[154] "evaluating limitation" (from claim 3),[155] "recommendation limitation" (from claim 7),[156] and "pharmaceutically acceptable" (from the preambles of claim 1 and 7).[157] Applying the printed matter doctrine, "the [PTAB] interpreted the providing information, evaluating, and recommendation limitations to be 'either printed matter or purely mental steps not entitled to patentable weight,'" because those limitations did not functionally relate to the other claim limitations (its substrate).[158] Overall, the PTAB invalidated the claims as obvious over the combination of prior art.[159] After the final decision, Praxair appealed and Mallinckrodt cross appealed.[160] Mallinckrodt challenged the PTAB's application of the printed matter doctrine on claims 1–8 and 10–11 of the '112 patent.[161]

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153 *Id.* (internal citations omitted).

154 The Federal Circuit used this label for referring to the last two "providing information" limitations of claim 1. *Id.* at 1029. Claim 1's providing information limitations read as: "providing to the medical provider (i) information that a recommended dose of inhaled nitric oxide gas for treatment of neonates with hypoxic respiratory failure is 20 ppm nitric oxide and (ii) information that, in patients with preexisting left ventricular dysfunction, inhaled nitric oxide may increase pulmonary capillary wedge pressure (PCWP), leading to pulmonary edema, the information of (ii) being sufficient to cause a medical provider considering inhaled nitric oxide treatment for a plurality of neonatal patients who (a) are suffering from a condition for which inhaled nitric oxide is indicated, and (b) have preexisting left ventricular dysfunction, to elect to avoid treating one or more of the plurality of patients with inhaled nitric oxide in order to avoid putting the one or more patients at risk of pulmonary edema." *Id.*

155 Claim 3 depends from claim 1 and "requires determining that a neonatal patient has preexisting LVD." *Id.* Claim 3's evaluating limitation reads as: "evaluating the potential benefit of treating the [neonatal patient] with 20 ppm inhaled nitric oxide vs. the potential risk that inhaled nitric oxide could cause an increase in PCWP leading to pulmonary edema." *Id.*

156 Claim 7's recommendation limitation reads as: "recommendation that, if pulmonary edema occurs in a patient who has pre-existing [LVD] and is treated with inhaled nitric oxide, the treatment with inhaled nitric oxide should be discontinued." *Id.*

157 Claim 1 and 7's preambles are "methods of providing pharmaceutically acceptable nitric oxide gas." *Id.* at 1030.

158 *Id.* (citing Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd., No. IPR2015-00529, 2016 WL 3648375 at *9–10 (P.T.A.B. July 7, 2016)).

159 *Praxair Distrib.,* 2016 WL 3648375 at *22. The PTAB found claim 9 to be patentable, but the Federal Circuit later reversed the decision for claim 9. *See Praxair Distrib*., 890 F.3d 1024.

160 *Praxair Distrib*., 890 F.3d. at 1031.

161 *Id.*

In *Praxair*, the Federal Circuit agreed that the PTAB properly applied the printed matter doctrine during claim construction.[162] More importantly, the Federal Circuit agreed that printed matter lacking patentable weight can include claim limitations directed to mental steps or processes because they capture informational content.[163] The Court noted claims combining limitations into mental steps may be patentable if the limitations were functionally related to the substrate.[164] The Court reasoned claimed limitations directed to a mental step may capture information that would be printed matter lacking patentable weight in an obvious analysis.[165] For example, with respect to the evaluating limitation (claim 3), the Court found that it "[was] directed to a mental step that was also printed matter."[166] Claim 3's limitation required "a medical provider to think about the information claimed in the providing information limitation of claim 1."[167] But the Court noted that simply "adding an ineligible mental process to ineligible information" still left claim 3 directed to printed matter.[168] The Court concluded the evaluating limitation was invalid under the printed matter doctrine because the claim limitations were not functionally related to its substrate.[169]

Additionally, with respect to "pharmaceutically acceptable" claims, the Court agreed with the PTAB's construction the term did not create a functional relationship to its substrate.[170] The Court agreed the ordinary meaning of "pharmaceutically acceptable" referred to the physical condition of the nitric oxide gas, not the information that may come with it.[171] Moreover, the Court agreed and rejected Mallinckrodt's argument that construing "pharmaceutically acceptable" required considering information in the product's label because a functional relationship does not exist simply by adding an instruction sheet to the product.[172]

Therefore, because the claim limitations incorporated printed matter that did not functionally relate to their substrates, the claims were not eligible subject

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162 *Id.* at 1033 (noting that claim construction is a legal inquiry that the PTAB has the authority to make) (citing Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996)).

163 *Id.* (stating that "like the information claimed by printed matter, mental steps or processes are not patent eligible subject matter").

164 *Id.* at 1033.

165 *Id.*

166 *Id.*

167 *Id.*

168 *Id.* The Federal Circuit noted that to hold any other way would undermine the printed matter doctrine and render it moot. *Id.*

169 *Id.* at 1034.

170 *Id.* The PTAB construed "pharmaceutically acceptable nitric oxide gas as nitric oxide gas that [was] suitable for pharmaceutical use." *Id.*

171 *Id.*

172 *Id.*; *see also* AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1065 (Fed. Cir. 2010) (holding that FDA-required instructions did not create functional of a drug); *In re* Ngai, 367 F.3d 1336, 1339 (Fed. Cir. 2004) (finding no functional relationship between claimed instructions and a diagnostic kit).

matter under § 101 nor given any patentable weight in the § 103 analysis.[173] The Federal Circuit affirmed the PTAB's use of the printed matter doctrine in an IPR and decision holding claims 1–8 and 10 as obvious.[174] However, Judge Newman in the concurrence criticized and disagreed with the majority's application of the printed matter doctrine:

> The printed matter doctrine does not apply to unprinted matter… Mental steps are mental, not printed. The printed matter doctrine is directed to printed matter, not information and not mental steps. This 'doctrine' is not relevant to the claimed method of administering nitric oxide to infants with left ventricular dysfunction. The claimed method warrants analysis in accordance with the traditional grounds of sections 102, 103, and 112; not as a newly created category within section 101.[175]

Judge Newman correctly stated that that this could have been a straightforward § 103 analysis because the prior art references described the information claimed in the '112 patent.[176] Judge Newman disagreed with how both the PTAB and majority removed specific limitations within claims, decided such limitations were of "no patentable weight," and reviewed the remaining parts for patentability.[177] Specifically, Judge Newman called out the PTAB and majority for converting an obviousness-patentability analysis into eligibility analysis under § 101—noting that Praxair's IPR petition was on the ground of obviousness, not printed matter.[178]

The role of information in patentability should depend on novelty and non-obviousness as a whole.[179] A patent is not ineligible under § 101 simply because it includes information or a mental component for a step in a process.[180] As Judge Newman accurately noted, the majority did not add any clarity to patent law by adopting the meaning that both "information" and "mental steps" mean "printed matter."[181] Judge Newman firmly stated: "Printed matter is not a mental process, whatever the content."[182] Under the current jurisprudence, the PTAB and majority's new printed matter doctrine serves no purpose other than adding to the uncertainty of patent eligibility[183]—especially under § 101.

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173 *Praxair Distrib*., 890 F.3d. at 1035.
174 *Id.*
175 *Id.* at 1038 (Newman, J., concurring).
176 *Id.* at 1039 (Newman, J., concurring).
177 *Id.* at 1041 (Newman, J., concurring).
178 *Id.* at 1039–40 (Newman, J., concurring).
179 *Id.* at 1040 (Newman, J., concurring).
180 *See id.*
181 *Id.*
182 *Id.* at 1039 (Newman, J., concurring).
183 *Id.*

IV. THE EFFECTS OF *PRAXAIR* ON PATENT ELIGIBILITY UNDER § 101

While the printed matter doctrine's underlying rationale is subject-matter eligibility, courts traditionally applied this doctrine in § 102 novelty and § 103 nonobviousness analysis.[184] After the Federal Circuit's opinion in *Praxair*, the printed matter doctrine is intertwined with § 101 subject-matter eligibility analysis.[185] This case is another example showing the PTAB's significant influence over patent law—particularly § 101. *Praxair* allows the PTAB to impact subject-matter eligibility in three very important ways: (1) the potential scope and power of future IPR proceedings, (2) the analysis and application of the *Alice-Mayo* framework, and (3) the availability and extent of patent protection for biotechnology and other bioscience industries.

First, using the printed matter doctrine, the PTAB could expand the scope and power of IPRs to invalidate patents for ineligible subject matter under § 101. While the AIA supports an IPR petition can challenge claims under §§ 102 and 103,[186] the AIA does not explicitly state that those claims must be invalidated under §§ 102 and 103. In *Praxair*, the majority distorted a clear § 103 non-obviousness analysis into a *quasi*-§ 101 eligibility analysis.[187] If the patent clearly was obvious over the prior art, the majority should have left out the printed matter doctrine and followed the traditional non-obviousness analysis. The majority invalidated claims because they added ineligible subject matter (mental process or abstract idea) to ineligible information that was printed matter.[188] *Praxair* may have a substantial impact on IPR petitions because the Federal Circuit allowed claims challenged under § 103 to be invalidated under § 101 based on the printed matter doctrine. This suggests that the PTAB may be able to expand the reach of future IPRs to invalidate patents under § 101 or, even further, allow petitions that bring subject-matter eligibility claims. Allowing the printed matter doctrine in IPRs may give power to the PTAB that Congress did not intend when it created the AIA post-grant proceedings. Additionally, IPR has the capacity to hear more challenges than the other post-grant proceedings because it has a lower institutional threshold and can hear patent filed under both the first-to-invent and first-to-file regimes.[189] Combining those factors with *Praxair's* printed matter doctrine, future IPR proceedings will have more power and discretion to invalidate patents, thereby increasing the PTAB's influence over subject-matter eligibility under § 101.

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184 *Id.* at 1032 (majority opinion).

185 *See id.* at 1038 (Newman, J., concurring).

186 *See* 35 U.S.C. § 311 (b) (2010) ("A petition in an [IPR] may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 and 103").

187 *Praxair Distrib*., 890 F.3d at 1039 ("It is note-worthy that Praxair's petition for inter partes review was on the ground of obviousness, not printed matter.") (Newman, J., concurring).

188 *Id.* at 1033 (majority opinion).

189 *See* MAJOR DIFFERENCES BETWEEN IPR, PGR, AND CBM, *supra* note 130.

Second, with the help of the Federal Circuit, the PTAB incorporated the printed matter doctrine into the *Alice-Mayo* two-step test. The PTAB addresses § 101 issues in different forums, like *ex parte* appeals.[190] This gives the PTAB many opportunities to develop the law surrounding subject-matter eligibility.[191] Since the Federal Circuit's opinion, the PTAB cited *Praxair* about fifteen times in different *ex parte* appeals.[192] From those cases, seven cases cite and discuss *Praxair's* use of the printed matter doctrine to determine whether the application is invalid under § 101.[193] In each case the PTAB affirmed examiners' § 101 rejections for patent applications because the claims were directed to printed matter that were not patent eligible subject matter.[194] As a result, these cases show that examiners and the PTAB have incorporated the printed matter doctrine into the *Alice-Mayo* framework. The PTAB's application of the printed matter doctrine in subject-matter eligibility analysis is significant to note because the PTAB's jurisprudence is often adopted or followed by courts.[195]

The Federal Circuit affirmed the PTAB's use of the printed matter doctrine in a § 101 analysis. In an appeal from the PTAB, the Federal Circuit, in *In re Marco Guldenaar Holding B.V.*, affirmed the rejection of a patent application for a method of playing a dice game under § 101:

> Because the only arguably unconventional aspect of the recited method of playing a dice game is printed matter, which falls outside the scope of § 101, the rejected claims do not recite an 'inventive

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[190] An *ex parte* appeal is when an applicant appeals an examiner's final rejection of her patent application to the PTAB in hopes of getting a patent granted. *Appeals*, U.S. PATENT & TRADEMARK OFFICE, https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/appeals (last visited Feb. 22, 2019).

[191] Osenga, *supra* note 17, at 407.

[192] For purposes of this Note, and as of January 2019, these fifteen cases are from a basic search on Westlaw and is not a definitive or conclusive list.

[193] *See generally Ex parte* Stone, No. 2017-010303, 2018 WL 6119991 (P.T.A.B. Oct. 30, 2018); *Ex parte* Dorr, No. 2017-006607, 2018 WL5294811 (P.T.A.B. Oct. 11, 2018); *Ex parte* Wallace, No. 2018-002391, 2018 WL 5043711 (P.T.A.B. Sept. 28, 2018); *Ex parte* Carrato, No. 2016-007538, 2018 WL 3756657 (P.T.A.B. July 23, 2018); *Ex parte* Hellem, No. 2016-004724, 2018 WL 3586188 (P.T.A.B. July 10, 2018); *Ex parte* Irby, No. 2016-008533, 2018 WL 3425429 (P.T.A.B. June 27, 2018); *Ex parte* Spooner, No. 2017-000514, 2018 WL 3425441 (P.T.A.B. June 27, 2018). Notably, two separate cases cited and rejected patent claims under Praxair's printed matter doctrine as obvious under § 103 because the printed matter was directed to ineligible subjected matter. *See Ex parte* Subha v. Raman, No. 2017-001873, 2018 WL 6338505 at *4 (P.T.A.B. Nov. 6, 2018); *Ex parte* Multer, No. 2017-002353, 2018 WL 5631437 at *8–9 (P.T.A.B. Oct. 15, 2018).

[194] *See Ex parte* Stone, 2018 WL 6119991 at *7–8; *Ex parte* Dorr, 2018 WL5294811 at*8–9; *Ex parte* Wallace, 2018 WL 5043711 at *6 n.3; *Ex parte* Carrato, 2018 WL 3756657 at *4; *Ex parte* Hellem, 2018 WL 3586188 at *7; *Ex parte* Irby, 2018 WL 3425429 at *5; *Ex parte* Spooner, 2018 WL 3425441 at *5.

[195] *See* Osenga, *supra* note 17, at 409 (noting that "the PTAB's jurisprudence is often adopted, or at least followed, by the courts").

> concept' sufficient to 'transform' the claimed subject matter into a patent-eligible application of the abstract idea.[196]

The Federal Circuit cited *Praxair* to invalidate the application's claims under the printed matter doctrine and § 101.[197] The ruling in *Marco* affirmed the PTAB's heightened influence over the law of subject-matter eligibility and expanded the scope of the *Alice-Mayo* two-step test to include the printed matter doctrine. Ultimately, this creates another basis on which the PTAB may invalidate applications and patents. Because of *Praxair*, USPTO examiners, the PTAB, and courts are free to use the printed matter doctrine in the § 101 *Alice-Mayo* analysis.

Finally, if the PTAB invalidates more patents—like in *Praxair*—additional biotechnology inventions could lose their patent rights. Some commentators refer to the PTAB as "death squads killing property rights."[198] While in the past the Federal Circuit acted as a "savior" by reversing the USPTO in certain circumstances, it has recently been less inclined to save claims.[199] The PTAB's power over § 101 could greatly affect biotechnology and bioscience industries by making patent protection even more uncertain and unlikely than when the courts had exclusive control.[200] For example, when the PTAB invalidates patents in post-grant proceedings, it signals to the company involved, as well as other companies in similar fields, that patent rights are uncertain or unlikely.[201] Uncertainty in patent rights will cause companies to change how they invest their research and development money.[202] A lack of investment in biotechnology research and development could limit future advances in the field.[203] Thus, while patent protection for biotechnology inventions was already declining after the *Mayo* and *Myriad* decisions, the PTAB's decision in *Praxair* may have a significant impact on patent rights and innovation in biotechnology industries.

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196 *In re* Marco Guldenaar Holding B.V., 911 F.3d 1157, 1162 (Fed. Cir. 2018).

197 *Id.* at 1161 ("Claim limitations directed to the content of information and lacking a requisite functional relationship are not entitled to patentable weight because such information is not patent eligible subject matter under 35 U.S.C. § 101.") (citing Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd., 890 F.3d 1024, 1032 (Fed. Cir. 2018)).

198 *See generally* Lefstin et al., *supra* note 4, at 589 (noting that with respect to the PTAB, "if a patent applicant or owner takes a patent eligibility case . . . it is 'not likely to end well.'"); Madigan & Mossoff, *supra* note 11, at 952 (discussing that the PTAB is one of the "bleakest" venues for patent owners); Rob Sterne & Gene Quinn, *PTAB Death Squads: Are All Commercially Viable Patents Invalid?,* IPWATCHDOG (March 24, 2014), http://www.ipwatchdog.com/2014/03/24/ptab-death-squads-are-all-commercially-viable-patents-invalid/id=48642 (discussing the unanticipated low success rate of patent owners in PTAB proceedings).

199 Lefstin et al., *supra* note 4, at 589.

200 *See id.* at 584.

201 *See* Osenga, *supra* note 17, at 409.

202 *See* Madigan & Mossoff, *supra* note 11, at 946–47 (discussing how the current state of § 101 has caused a lot of legal uncertainty in the U.S. patent system which undermines universities, venture capitalists, and companies making long-term investment decisions in research and development).

203 Lefstin et al., *supra* note 4, at 584.

CONCLUSION

Praxair is the perfect example of how much influence the PTAB has over § 101. As a result of *Praxair*, the PTAB (1) expanded IPR's scope and reach to possibly allow petitioners to bring § 101 challenges, and (2) added more uncertainty to subject-matter eligibility. Allowing the PTAB to invalidate patents under the printed matter doctrine only made § 101 more unworkable and uncertain. *Praxair* gives more power and discretion to the PTAB to determine patent subject-matter eligibility under § 101.

What does this mean for future biotechnology research and development? Property right protection, especially patent protection, drive biotechnology innovation. The recent § 101 Supreme Court cases create legal uncertainty for patent protection for future biotechnology inventions. Now adding the PTAB's impact on § 101, there is no telling what could happen to those patent rights. This uncertainty could force investors to stop funding research in these industries, which then could limit future advances in the field. Reports in the biotechnology fields for software and technology, show developments in the subject matter eligibility laws impact research and development.[204] Research and development within the biotechnology industries have been advancing with increasing speed. If the law surrounding § 101 remains stagnant, then advancement in future biotechnology innovation may be inhibited.

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[204] *Id.* at 582–85.