

## NOTES

### PATENTABILITY CHALLENGES IN PERSONALIZED MEDICINE: A FORK IN THE ROAD

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#### INTRODUCTION

Personalized medicine or personalized treatment, which is increasingly based on big data medicine, has been advocated as a potential treatment strategy for various indications, including but not limited to cystic fibrosis, hematological diseases, and cancer.<sup>1</sup> With an increase in the availability of large information databases, and with advances in knowledge for utilizing such databases for medical care, personalized treatment is becoming increasingly vital for healthcare. Big data medicine has evolved since its emphasis on research endeavors expanded almost a decade ago.<sup>2</sup> Its influence on the healthcare sector was brought to the forefront during the recent COVID-19 pandemic.<sup>3</sup> Trends in symptoms and responses to treatments were used to better understand COVID-19 and its impact.<sup>4</sup>

Advances in neural networks, omics data integration, and the assimilation of such information with electronic health record data continue to drive progress in personalized medicine.<sup>5</sup> Omics data integration refers to the use and exploitation

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1. *Personalized Medicine: A Biological Approach to Patient Treatment*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/news-events-human-drugs/personalized-medicine-biological-approach-patient-treatment> [<https://perma.cc/FL2E-AJFF>] (last visited Oct. 20, 2022) [hereinafter *Personalized Medicine*].

2. Tom Kalil, *Big Data Is a Big Deal*, WHITE HOUSE BLOG (Mar. 29, 2012, 9:23 AM), <https://obamawhitehouse.archives.gov/blog/2012/03/29/big-data-big-deal> [<https://perma.cc/5J2G-FM2E>].

3. *Big Data and Long COVID*, LANCET DIGIT. HEALTH (July 1, 2022), <https://www.thelancet.com/action/showPdf?pii=S2589-7500%2822%2900113-3> [<https://perma.cc/H2RX-XVA9>].

4. *Id.*

5. Daryl E. Pritchard et al., *Strategies for Integrating Personalized Medicine Into Healthcare*

of patient-specific factors such as proteomics, genomics, metabolomics, or other similar factors in predicting disease symptoms, treating diseases, or assessing patient responses to different treatment options.<sup>6</sup> Personalized medicine typically comprises a diagnostic test and a therapeutic intervention, and it is customarily a result of substantial scientific and clinical research.<sup>7</sup> Furthermore, there is also a growing number of applications where artificial intelligence is being used to analyze the large patient-specific databases that are being developed by processing omics-based information.<sup>8</sup>

Considering innovation is driven by intellectual property rights, it is important to understand the available intellectual property rights as they relate to matters concerning personalized medicine.<sup>9</sup> Additionally, the consequences of using the available intellectual property protection strategies may differentially impact various stakeholders, including but not limited to inventors, small companies, large companies, and society in general.<sup>10</sup> Patents in the field of personalized medicine may be directed towards processes implemented to analyze such databases, methods to discern individual variability in population-based trends, or tools utilized to design individualized treatments based on those assessments.<sup>11</sup> While patents provide the strongest protection for intellectual property, getting patent rights directed toward systems or methods used in personalized medicine has been challenging.<sup>12</sup> This observation is especially valid with respect to inventions concerning diagnostics.<sup>13</sup> In light of the role that diagnostics in personalized medicine play in the well-being of our society,<sup>14</sup> there is an imminent need to review the current patent laws.

This Note examines the importance of personalized medicine in our society and evaluates how patents, trade secrets, and open-source methods can be employed to protect intellectual property advances in that field. This Note highlights the importance of improving the present patent laws, explores different options to make the patent laws more predictable, and concludes that the creation

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*Practice*, 14 PERSONALIZED MED., 141, 142 (2017); *Personalized Medicine*, *supra* note 1.

6. Pritchard et al., *supra* note 5, at 142.

7. *Id.* at 141.

8. See generally Nicholas J. Schork, *Artificial Intelligence and Personalized Medicine*, in PRECISION MEDICINE IN CANCER THERAPY (CANCER TREATMENT AND RESEARCH #178) 265-83 (Daniel D. Von Hoff & Haiyong Han, eds. 2019).

9. 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 (2019).

10. KATHERINE K. VIDAL, U.S. PAT. & TRADEMARK OFF., PATENT ELIGIBLE SUBJECT MATTER: PUBLIC VIEWS ON THE CURRENT JURISPRUDENCE IN THE UNITED STATES 2-3 (2022).

11. Mohammed Uddin et al., *Artificial Intelligence for Precision Medicine in Neurodevelopmental Disorders*, 2 NPJ DIGIT. MED. 112 (2019).

12. Laura H. Goetz, M.D. & Nicholas J. Schork, Ph.D., *Personalized Medicine: Motivation, Challenges and Progress*, 109 FERTILITY & STERILITY 952 (2018).

13. See Roger D. Klein, MD, JD, *Gene Patents and Personalized Medicine*, 32 AM. SOC'Y CLINICAL ONCOLOGY EDUC. BOOK 81 (2012).

14. *See id.*

of a new patent type directed towards diagnostics will be beneficial to society. This Note proceeds in four parts. Part I provides an overview of personalized medicine and a brief introduction to important elements in the field of personalized medicine. Part II describes the intellectual property strategies available for inventions in personalized medicine. Part II also discusses the advantages and disadvantages of the different options, as well as the challenges in obtaining patents in this field. Part III proposes different solutions to resolve the uncertainty and predictability associated with getting allowable patents. Finally, Part IV argues for a legislative action directed towards creating a new patent type that is more amenable to diagnostic inventions.

## I. OVERVIEW OF BIG DATA AND ITS APPLICATION IN PERSONALIZED MEDICINE

### *A. Importance of Personalized Medicine*

Human beings are not all the same. They have varied genetic, biochemical, and physiological compositions, and they may exhibit varied responses and behaviors when exposed to different environmental variables.<sup>15</sup> Personalized medicine drives at this human characteristic by using continuous advances in technology to discern such individual responses and providing appropriately designed individualized treatments to patients.<sup>16</sup> Thus, the diversity in human composition and responses “suggests . . . a need to tailor, or ‘personalize,’ medicines.”<sup>17</sup> Personalized medicine relies on a patient’s unique biological markers to determine the most appropriate medical treatments and procedures.<sup>18</sup> Every individual may respond differently to different treatment options based on their genetic make-up.<sup>19</sup> Caregivers can identify the best medical care by using such patient information in addition to patient medical records when prescribing treatments.<sup>20</sup> Personalized medicine can be defined as “an approach to provide the right treatments to the right patients at the right time.”<sup>21</sup> However, in almost all instances, personalized diagnosis is required to allow such personalized treatment.<sup>22</sup> Consequently, personalized medicine targeted toward any disease usually includes a diagnostic component and a therapeutic component.<sup>23</sup>

The ability to diagnose a specific biological marker in a patient has driven the

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15. Schork, *supra* note 8, at 265.

16. *See id.*

17. *Id.*

18. Pritchard et al., *supra* note 5, at 141.

19. *Id.*

20. *Id.*

21. Tim Hulsen et al., *From Big Data to Precision Medicine*, 6 FRONTIERS MED 1, 2 (Mar. 1, 2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6405506/pdf/fmed-06-00034.pdf> [<https://perma.cc/73DH-E9Y4>].

22. *See id.*

23. *Personalized Medicine, supra* note 1.

development of targeted therapies. A review of the field of medicine reflects the increasing impact of personalized treatment over the last several decades.<sup>24</sup> Treatment based on a patient's lack of a particular enzyme, a patient's ability to metabolize a particular enzyme, or the presence of a specific gene in a patient has impacted diseases such as malaria, cancer, Alzheimer's disease, Parkinson's disease, and cardiovascular disease.<sup>25</sup> However, despite the progress in the field, the lack of tools and devices necessary for countering the recent COVID-19 pandemic, which manifested in the form of a very patient-specific disease and treatment response, was blatantly obvious.<sup>26</sup>

Furthermore, while beneficial to society, the adoption of personalized medicine is not without its challenges. In addition to challenges in patient care and impediments in infrastructure, recognizing the value inherent in personalized medicine has been a demanding prospect.<sup>27</sup> Though "payers and providers are often reluctant to change policies and practices without convincing evidence of clinical and economic value," many "organizations are actively engaged in implementing personalized medicine programs."<sup>28</sup> Thus, personalized medicine is slated to become an integral component of medical care in the near future.

### *B. Big Data and Its Application*

While big data has been typically used to describe "the rapid increase in volume, variety and velocity of information available," it is also used to describe "our increasing ability to analyze and interpret those [large volumes of] data."<sup>29</sup> Large volumes of data can be studied to discern "trends or associations that are not otherwise evident."<sup>30</sup> The development of new tools and methods to clean, exploit, analyze, mine, store, process, or interpret such large volumes of data presents unique challenges.<sup>31</sup> Personalized medicine is based on effectively using this massive data resource to identify the correct treatment for a particular patient and ascertaining the appropriate timeframe for administering the identified treatment.<sup>32</sup> Progress in the field of personalized medicine depends on the ability to collect, process, and infer critical information from the data. Thus, it can be hypothesized that big data contributes to the development of both the diagnostic component and the therapeutic component of personalized medicine.

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24. See generally Sophie Visvikis-Siest et al., *Milestones in Personalized Medicine: From the Ancient Time to Nowadays—the Provocation of COVID-19*, 11 FRONTIERS GENETICS 1 (Nov. 30, 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7794000/pdf/fgene-11-569175.pdf> [<https://perma.cc/3ZH6-A3UK>].

25. *Id.* at 4.

26. *Id.*

27. Pritchard et al, *supra* note 5, at 143.

28. *Id.* at 147, 150.

29. Hulsén et al., *supra* note 21, at 1.

30. *Id.* at 2.

31. See *id.* at 5.

32. *Id.* at 3.

The ability to process “hundreds, thousands or even millions of measurements being made concurrently, often combining technologies to give simultaneous measures of DNA, RNA, [and] protein, function alongside clinical features including measures of disease activity, progression and related metadata” is critical for personalized medicine.<sup>33</sup> Artificial intelligence, which can include quantum computing, neural networks, deep learning, and machine learning techniques, is being used to process large volumes of data to discern information in a timely manner.<sup>34</sup>

Since an important factor for success in the deployment of big data analysis is the determination of “robust and reproducible input data,” methods to standardize data collection and data processing are critical tools.<sup>35</sup> Therefore, advances in artificial intelligence-based high-throughput and data-intensive technologies can be deemed imperative for progress in the field of personalized medicine. Though there has been considerable progress in big data analysis and research directed towards personalized medicine, widespread clinical translation of such principles is dependent on the generation of new intellectual property.<sup>36</sup> Thus, the success and application of these new data processing technologies, and in turn, the progress in personalized medicine, is reliant on the ability to protect the intellectual property rights associated with these tools.

## II. CURRENT OPTIONS FOR INTELLECTUAL PROPERTY

### *A. Overview*

While recent trends in collecting and processing data and related information have expanded the possibilities for disease treatment and patient care, the current options in intellectual property law may not be able to fully support the pace of growth in this field.<sup>37</sup> This is especially true for the diagnostic component of personalized medicine, and in some instances, this reasoning may also hold true for the therapeutic component. Most frequently, inventors choose to file patents or pursue trade secrecy.<sup>38</sup> Additionally, or alternatively, inventors may explore open-source options, where information (e.g., computational code, amino acid sequence, gene sequence) is made freely available to the public.

### *B. Patents*

*1. Requirements for Obtaining a Patent.*—Patents provide protection for innovation in several fields, including those fields that are critical for public

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33. *Id.* at 2.

34. *Id.* at 5; *see also* Schork, *supra* note 8, at 265.

35. Hulsen et al., *supra* note 21, at 9.

36. *Id.* at 5.

37. W. Nicholson Price II, *Big Data, Patents, and the Future of Medicine*, 37 *CARDOZO L. REV.* 1401, 1406 (2016).

38. *See id.*

health, national security, and consumer use.<sup>39</sup> Patents are granted to inventors as a reward for their inventions in return for a complete public disclosure of the same inventions.<sup>40</sup> Entities other than the inventor are precluded from using, creating, or selling the claimed invention unless they are assigned the invention or have licensed the invention from the assignee.<sup>41</sup> The right to patents has existed since the inception of the United States Constitution.<sup>42</sup> It has long been heralded as a driving force of American innovation.<sup>43</sup> Abraham Lincoln viewed the creation of patent laws as one of the greatest innovations of mankind.<sup>44</sup> On February 11, 1859, at Illinois College at Jacksonville, Lincoln said,

Next came the Patent laws. These began in England in 1624; and, in this country, with the adoption of our constitution. Before then any man might instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; *secured to the inventor, for a limited time, the exclusive use of his invention*; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.<sup>45</sup>

However, as this Note will discuss, the current state of patent law is in disarray because of inconsistent case law.<sup>46</sup>

In order for a patent to be granted, an invention has to be useful under section 101,<sup>47</sup> enabled under section 112,<sup>48</sup> enabled and sufficiently described in the written description under section 112,<sup>49</sup> novel under section 102,<sup>50</sup> and non-obvious over existing prior art under section 103.<sup>51</sup> Furthermore, the subject

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39. VIDAL, *supra* note 10, at 29-31.

40. 35 U.S.C. § 112.

41. *Id.* § 271.

42. U.S. CONST. art. 1, § 8, cl. 8 (“To promote the [p]rogress of [s]cience and useful [a]rts, by securing for limited [t]imes to [a]uthors and [i]nventors the exclusive [r]ight to their respective [w]ritings and [d]iscoveries”).

43. See Gene Sperling, *Taking on Patent Trolls to Protection American Innovation*, THE WHITE HOUSE (June 4, 2013, 1:55 PM), <https://obamawhitehouse.archives.gov/blog/2013/06/04/taking-patent-trolls-protect-american-innovation> [<https://perma.cc/A2EL-6M3G>].

44. Gene Quinn, *Celebrating Presidents Who Advocated for the U.S. Patent System*, IPWATCHDOG (Feb. 18, 2013, 9:55 AM), <https://ipwatchdog.com/2013/02/18/celebrating-presidents-who-advocated-for-the-u-s-patent-system/id=34896/> [<https://perma.cc/8RDP-R8VK>].

45. *Id.* (emphasis added).

46. Paul Michel et al., *Presenting the Evidence for Patent Eligibility Reform: Part I—Consensus from Patent Law Experts*, IPWATCHDOG (Oct. 6, 2022, 3:15 PM), <https://www.ipwatchdog.com/2022/10/06/presenting-evidence-patent-eligibility-reform-part-consensus-patent-law-experts/id=151886/> [<https://perma.cc/TY9P-SESN>].

47. 35 U.S.C. § 101.

48. *Id.* § 112.

49. *Id.*

50. *Id.* § 102.

51. *Id.* § 103.

matter of the invention has to be patentable under section 101.<sup>52</sup> The scope of these requirements, especially concerning patent eligibility under section 101, has been highly litigated and illustrated by case law.<sup>53</sup>

The enablement and written description requirements under section 112 present unique challenges to inventions applicable to personalized medicine. Historically, the written description requirement is a “test for sufficiency” and a test for ensuring “the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.”<sup>54</sup> However, describing data mining and data processing algorithms that employ complex artificial intelligence tools for diagnosing trends and uncovering unique human responses from large databases in a patent application is not always possible.<sup>55</sup> Furthermore, since data can include relationships between genes, transcripts, proteins, metabolites, functional traits, and structural traits,<sup>56</sup> an accurate and complete description of the data being processed may be challenging.

Recently, the Supreme Court held that a claim that included an entire genus of antibodies that perform specific functions was not enabled by the identification of 26 exemplary antibodies that perform the functions.<sup>57</sup> According to the Court,

If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent’s specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable.<sup>58</sup>

Though the Court acknowledged that “a specification may call for a reasonable amount of experimentation to make and use a patented invention,” it also cautioned that “[w]hat is reasonable in any case will depend on the nature of the invention and the underlying art.”<sup>59</sup>

Nevertheless, even though section 112 might limit certain broad patents from being issued, it is usually not as effective as section 101 in limiting claims.<sup>60</sup> The enablement requirement is not the primary deterrent for patents filed in the field of personalized medicine.

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52. *Id.* § 101.

53. *See Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66 (2012); *Alice v. CLS Bank Int’l*, 573 U.S. 208, 218 (2014); *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

54. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010).

55. *Price II*, *supra* note 37, at 1421.

56. *Hulsen et al.*, *supra* note 21, at 6.

57. *Amgen Inc. v. Sanofi*, 143 S. Ct. 1243 (2023).

58. *Id.* at 1254.

59. *Id.* at 1255.

60. *Samantak Ghosh, Prometheus and the Natural Phenomenon Doctrine: Let’s not Lose Sight of the Forest for the Trees*, 94 J. PAT. & TRADEMARK OFF. SOC’Y 330 (2012).

2. *Evolution of the Patent Eligibility Requirement.*—Section 101 of the patent law requires that the subject matter of a patent filed is eligible for a patent.<sup>61</sup> Lincoln’s remarks, like the current patent law, are directed towards a “discovery” or at “one who discovers.”<sup>62</sup> In his speech, Lincoln probably did not foresee categorizing certain inventions and discoveries worthy of patent, and designating others as not.<sup>63</sup> Nevertheless, based on case law, the United States Patent and Trademark Office (USPTO) has identified several classes of inventions that are not patent-eligible, including, but not limited to, laws of nature, natural phenomena, and abstract ideas.<sup>64</sup> A proper understanding of how this requirement translates for patent eligibility is especially critical for personalized medicine. This is because disease indications and subsequent treatments invariably involve the identification of naturally occurring biomarkers or the determination of naturally occurring phenomena in a patient.<sup>65</sup> Since personalized medicine includes a diagnostic component and may include complex algorithms to process large databases, claims directed to applications in this field have to be constructed in view of the unpredictable case law discussed below.

The Supreme Court invalidated a patent for a method of optimizing a drug-based treatment by measuring serum drug metabolite level in a patient in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*<sup>66</sup> The Court based its holding on the “laws of nature” exclusion under section 101.<sup>67</sup> The Supreme Court invalidated a patent on a computer-implemented method for risk mitigation in *Alice Corp. Proprietary v. CLS Bank International*.<sup>68</sup> The Court based its holding on the “abstract ideas exclusion” under section 101.<sup>69</sup> The holdings in these two cases led to the establishment of the *Alice/Mayo* test, which is a two-step test. First, it required the determination of, “whether the claims at issue are directed to a patent-ineligible concept.”<sup>70</sup> If satisfied, the second step asks whether the claimed invention contains an “‘inventive concept’ sufficient to ‘transform’ the claimed abstract idea into a patent-eligible application.”<sup>71</sup> The court also reiterated that “the basic tools of scientific and technological work,” i.e., laws of nature, natural phenomena, and abstract ideas, are not patentable.<sup>72</sup> Furthermore, according to the *Alice/Mayo* test, simply adding “computer

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61. 35 U.S.C. § 101.

62. Quinn, *supra* note 44.

63. *Id.*

64. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019) [hereinafter Revised Patent Subject Matter].

65. See generally *Personalized Medicine*, *supra* note 1.

66. 566 U.S. 66 (2012).

67. *Id.* at 79.

68. 573 U.S. 208 (2014).

69. See generally *id.*

70. *Id.* at 218 (discussing *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66 (2012)).

71. *Id.* at 221.

72. *Id.* at 216.



implementation” to the claims did not negate the abstract idea to make the claim patentable.<sup>73</sup>

In *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*,<sup>74</sup> the invention was based on the discovery that certain genetic differences could indicate if a patient was an effective metabolizer of iloperidone, a drug used to treat schizophrenia.<sup>75</sup> It has been claimed that the court may have misapplied the original *Alice/Mayo* test to *Vanda* in an “effort to loosen the constraints on patentable natural phenomena.”<sup>76</sup> Even though the claims were directed toward methods, the court found that a patent directed to this invention was eligible based on the fact that the discovery was related to a treatment.<sup>77</sup> The court distinguished *Vanda* from *Mayo* by stating that in *Mayo*, the claim was broad and as a whole was not directed to an inventive application.<sup>78</sup> The court reasoned that the main difference between *Mayo* and *Vanda* was that the claim in *Mayo* was not directed to a particular disease treatment.<sup>79</sup>

In 2018, the USPTO provided a memorandum to clarify the *Vanda* holding.<sup>80</sup> In the memorandum, the USPTO stated that mere determination of when treatment is required may not be enough to obtain patent rights.<sup>81</sup> The memorandum further stated that the application of that determination followed by an administration of a treatment may be required for a claim to be patent eligible.<sup>82</sup> However, based on *Vanda*, if a diagnostic method is not directly tied to a method of treatment (i.e., a therapeutic component), patentability will be challenging.<sup>83</sup> The treatment step must apply the natural relationship being claimed in a manner that integrates the natural relationship into a practical application.<sup>84</sup> Nevertheless, how much integration was required for patentability was left to interpretation.

In *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*,<sup>85</sup> the

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73. *Id.* at 222.

74. 887 F.3d 1117 (Fed. Cir. 2018).

75. *See generally id.*

76. Kevin A. Sfroza, *Vanda v. West-Ward: Swinging Back the Pendulum for Patenting Natural Phenomena*, 101 J. PAT. & TRADEMARK OFF. SOC’Y 252, 256 (2019).

77. *Vanda*, 887 F.3d at 1135.

78. *Id.* at 1281.

79. *Id.*

80. Robert W. Barr, *Recent Subject Matter Eligibility Decision: Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, U.S. PAT. & TRADEMARK OFF. (June 7, 2018), <https://www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.PDF> [<https://perma.cc/7RUC-6AMC>].

81. *Id.*

82. *Id.*

83. *See generally Vanda*, 887 F.3d at 1135.

84. *2106 Patent Subject Matter Eligibility [R-10.2019]*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/web/offices/pac/mpep/s2106.html> [<https://perma.cc/8WE9-DHLX>] (last visited Oct. 20, 2022) [hereinafter *2106 Patent Subject Matter Eligibility*].

85. 919 F.3d 1347 (Fed. Cir. 2019).

Federal Circuit Court reversed a lower court holding that a method claim that relied on a law of nature was patent ineligible.<sup>86</sup> The claims in *Endo* were based on the discovery that a lower dosage of oxymorphone may be given to patients with impaired kidney function to achieve the same pain relief.<sup>87</sup> The court stated that “the specification predominantly describes the invention as a method that treats renally impaired pain patients with less oxymorphone while still treating their pain.”<sup>88</sup> Thus, the court based its holding on the fact that the claimed invention was directed toward a method of treatment.<sup>89</sup> Nevertheless, the ensuing uncertainty concerning method claims following *Vanda* and *Endo* led to further revision of the *Alice/Mayo* test.

3. *Current State of Patent Eligibility Requirement.*—A revised *Alice/Mayo* test<sup>90</sup> was put forth to provide clarity and consistency in the interpretation of section 101 and was essentially still based on the two Supreme Court holdings.<sup>91</sup> This test is comprised of two prongs.<sup>92</sup> Prong one of the revised step 2A analysis includes the determination of whether or not the identified limitation(s) fall within the subject matter grouping of judicial exceptions.<sup>93</sup> Prong two of the revised step 2A analysis requires the determination of whether the claim recites additional elements that integrate the judicial exception into a practical application of the exception.<sup>94</sup> Furthermore, under step 2B, if the claims do not recite any additional elements or evidence that amount to significantly more than the judicial exception, it is necessary to analyze if the claims add “significantly more than a patent upon [an] ineligible concept itself.”<sup>95</sup>

In *Athena Diagnostics, Inc. v. Mayo Collaborative Services*,<sup>96</sup> the Federal Circuit Court arguably constrained the *Alice/Mayo* test instead of following the Supreme Court’s instruction to apply the exclusions under section 101 judiciously and denied claims directed towards a new method of diagnosing a neuromuscular disease.<sup>97</sup> The court considered “step one ‘directed to’ inquiry focuses on the claim as a whole,” when determining that the claims were not eligible under the exception for natural laws.<sup>98</sup> The revised *Alice/Mayo* test requires the

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86. *See id.* at 1348.

87. *Id.*

88. *Id.* at 1353.

89. *Id.*

90. Revised Patent Subject Matter, *supra* note 64, at 50-51.

91. *Alice Corp. Proprietary v. CLS Bank Int’l*, 573 U.S. 208 (2014); *Mayo Collaborative Servs. V. Prometheus Lab’ys, Inc.*, 566 U.S. 66 (2012).

92. Revised Patent Subject Matter, *supra* note 64, at 50-51.

93. *Id.*

94. *Id.*

95. *Id.*; *see also* *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1312 (Fed. Cir. 2016); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, 915 F.3d 743 (Fed. Cir. 2019).

96. 915 F.3d 743 (Fed. Cir. 2019).

97. *Id.*; A. Saha Hoyt, *The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies*, 79 WASH. & LEE L. REV. 397, 428 (2022).

98. *Athena*, 915 F.3d at 750.

consideration of other factors that may add more to the method.<sup>99</sup> In *Athena*, the majority “does not distinguish between the question of whether the claimed method as a whole is eligible, and the question of whether the separate steps use conventional procedures.”<sup>100</sup>

Furthermore, while denying rehearing, the twelve active judges of the Federal Circuit Court unanimously agreed there is widespread uncertainty about the application of patent eligibility criteria.<sup>101</sup> There were eight separate opinions for the first time in the history of the Federal Circuit Court, suggesting the judges do not share a common understanding of Section 101.<sup>102</sup> Nevertheless, the Supreme Court denied certiorari in 2020.<sup>103</sup>

The uncertainty and unpredictability in the current jurisprudence can negatively impact innovation by leading to a decrease in investment in new start-ups or by driving industries to pursue intellectual property strategies that do not require them to share their inventions with society.<sup>104</sup> Start-ups with early patent filings tend to attract more venture capital funding than those without patent activity.<sup>105</sup> Nevertheless, if an entity is faced with the prospect of uncertainty at the patent office, it may choose not to risk filing for a patent and disclosing its findings. Instead, it may choose to keep its findings as a trade secret. Additionally, based on these holdings and current patent eligibility tests, purely diagnostic methods that may contribute to personalized medicine cannot be patented without an accompanying treatment component.<sup>106</sup> The fact that a method of treatment is required for a claim to be patentable may cause small start-ups and research labs that are focused on the diagnostic component to be unfairly compensated.<sup>107</sup> Such diagnostic start-ups may not be able to survive the competitive landscape without patent-based funding from venture capitalists.<sup>108</sup>

However, it may be argued that the limitations in the ability to get patents have not affected pure scientific research in the field of personalized medicine. An increase in corporate and academic research funding and an increase in the identification of personalized treatments are testaments to the growing trajectory of the field.<sup>109</sup> However, an increase in research focus and funding should not be confused with an increase in translation from bench to bedside applications. This

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99. Revised Patent Subject Matter, *supra* note 64, at 50-51.

100. *Athena*, 915 F.3d at 761 (Newman, J., dissenting).

101. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1357 (Fed. Cir. 2019).

102. Michel et al., *supra* note 46.

103. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 140 S. Ct. 855 (2020) (mem.), *denying cert.* 915 F.3d 743 (Fed. Cir. 2019).

104. Hoyt, *supra* note 97, at 436.

105. *Id.*

106. *See generally* *Vanda Pharms. Inc. v. West-Ward Pharms.*, 887 F.3d 1117 (Fed. Cir. 2018).

107. *See generally* *2106 Patent Subject Matter Eligibility*, *supra* note 84.

108. *Id.*

109. Visvikis-Siest et al., *supra* note 24.

bench-to-bedside translation requires substantial financial investments.<sup>110</sup> Unlike the federal government, which may be motivated by societal impact, private investment by venture capitalists is primarily driven by economic gain and potential exit strategies.<sup>111</sup> Start-ups tend to receive more venture capital investment if they have strong patent portfolios.<sup>112</sup> The diagnostic industry lost an estimated 9.3 billion dollars due to the *Mayo* decision.<sup>113</sup> It could be argued that the lost revenue translated to lost diagnostics and associated treatment strategies for patients. Similarly, a mere increase in translation of treatments should not be taken to imply optimal or acceptable growth in the field. While progress in personalized medicine is obvious to the layperson, this progress can probably be amplified with better access to patent rights.

### C. Trade Secrets

Trade secrets are information that has actual or potential economic value because it is not generally known and cannot be otherwise obtained.<sup>114</sup> An inventor is entitled to trade secret protection so long as they make a reasonable effort to maintain its secrecy.<sup>115</sup> An inventor may choose to pursue trade secrecy because a patent may be less useful or because a patent may not be essential for protecting a specific invention's rights. In those instances, the current provisions in trade secret law are sufficient for the inventor's needs.

In order to be eligible for trade secret protection, the invention must comply with state trade secret law. Trade secret laws in most states align with the Uniform Trade Secrets Act.<sup>116</sup> The inventor must show that sufficient efforts have been made to keep the findings a secret.<sup>117</sup> In some instances, this may be hard to prove. Another important distinction when choosing trade secret protection is that trade secret violation can occur only if improper means have been employed by the supposed violator.<sup>118</sup> Thus, the invention can be legitimately invented by a second entity without any repercussions.<sup>119</sup> Unlike patent protection, an inventor who pursues a trade secret does not have the right to prevent anyone else from

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110. Bench to bedside describes the process of taking inventions from the laboratory to the clinic so that a patient can benefit from the inventions. DocWire News Editors, *Bench to Bedside: Translating Science From the Lab to the Clinic* (May 2, 2019), <https://docwirenews.com/post/bench-to-bedside-translating-science-from-the-lab-to-the-clinic> [<https://perma.cc/WF7V-BSSE>].

111. Hoyt, *supra* note 97, at 435.

112. *Id.*

113. *Id.* at 398.

114. *Trade Secrets/Regulatory Data Protection*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/ip-policy/trade-secret-policy> [<https://perma.cc/442P-G3BH>] (last visited Oct. 20, 2022).

115. *Id.*

116. UNIFORM TRADE SECRETS ACT §§ 1-12 (amended 1985), 14 U.L.A. 437 (1990).

117. *Id.*

118. *Id.*

119. *Id.*

using, distributing, or selling the invention.<sup>120</sup>

However, an inventor may choose to file a trade secret simply because of the uphill struggle for patentability. It is especially challenging for purely diagnostic inventions or artificial intelligence-based inventions to satisfy patent law requirements.<sup>121</sup> Thus, even if the inventor would benefit from patents, he/she may not be able to pursue that avenue. Additionally, or alternatively, in some instances, the financial commitment for prolonged litigation may simply not be worth the possibility of patent rights.

Nevertheless, the impact on innovation, investment, and competition due to the utilization of trade secrecy as the intellectual property strategy of choice in personalized medicine may be substantial and may result in a tremendous cost to society. Attempts to keep research findings secret may negatively affect research collaboration, research funding, or research publications. This is especially true in academic settings where faculty tenure is dependent on publication and research funding, both of which in turn depend on collaboration and public disclosure of findings.<sup>122</sup> If an inventor or an entity decides that keeping an incremental innovation in-house is more beneficial to itself, society as a whole is deprived of that knowledge. Fewer scientists and researchers are aware of the progress, and by consequence, fewer individuals can contribute to future inventions in that particular field. Fewer individuals will be able to benefit from scientific progress if the findings are not translated into usable treatments with appropriate intellectual property protection.

#### *D. Open-Source Use*

Many in the software and technology industry have adopted the concept of open-source access, including making patents widely available for use.<sup>123</sup> Whereas a patent excludes others from making, using, or selling a claimed invention, and a trade secret prevents anyone from being aware of a given invention, open-source software invites others to use, change, and adapt a source code.<sup>124</sup>

Open-source software has made its mark even in the field of big data medicine.<sup>125</sup> Organizations including the Open Bioinformatics Foundation and the International Society for Computational Biology have “had a huge impact on the

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120. *Id.*

121. W. Nicholson Price II, Rachel E. Sachs, & Rebecca S. Eisenberg, *New Innovation Models in Medical AI*, 99 WASH. U. L. REV. 1121, 1156-57 (2022).

122. See Meredith T. Niles, *Why We Publish Where We Do: Faculty Publishing Values and their Relationship to Review, Promotion, and Tenure Expectations*, 15 PLoS ONE 1 (2020).

123. *E.g.*, Elon Musk, *All Our Patent Are Belong to You*, TESLA (June 12, 2014), <https://www.tesla.com/blog/all-our-patent-are-belong-you> [<https://perma.cc/EB3M-TN3N>].

124. *Patents v. Opensource*, MILLER IP L., <https://milleripl.com/blogs/patents/patents-v-opensource> [<https://perma.cc/J2K4-AR3M>] (last visited Oct. 20, 2022).

125. Hulsén et al., *supra* note 21, at 8.

rate of progress and [the] ability to harness the potential of [b]ig data.”<sup>126</sup> However, open-source software does not prevent an inventor from applying for a patent. In some instances, utilizing open-source publications may be an avenue an inventor uses to exploit his/her patent rights.<sup>127</sup> This option, however, may not be the best choice for every inventor, and an inventor may be “forced” to pursue this route if eligibility requirements or written description requirements for obtaining a patent pose increasing challenges.

The impact of open-source access on innovation and research is debatable. While one school of thought claims that increased access to freely available information increases innovation, another claims that competition in the absence of easy access drives the creation of the next generation of products.<sup>128</sup> Nevertheless, increasing the certainty in patent eligibility or increasing the ability to get patents will not negatively impact the decision of an inventor to pursue open-source listing, as they are not mutually exclusive.<sup>129</sup> Thus, despite alternative intellectual property protection options, encouraging patent filing and alleviating the challenges in getting patents is beneficial for society and innovation.

### III. PROPOSED SOLUTIONS TO ENCOURAGE PATENT FILING

#### A. Judicial Clarity

1. *Scope of Judicial Clarity.*—Despite the establishment of the revised *Alice/Mayo* test,<sup>130</sup> further judicial clarity is required to overcome the uncertainty and unpredictability about the patent eligibility of inventions directed toward diagnostics in personalized medicine. The field of personalized medicine was not the robust field it is today when the patent statutes were last amended in 2011.<sup>131</sup> Thus, the Supreme Court may elect to provide further judicial clarity about interpreting the statutes in view of the progress in personalized medicine and in view of the unclear holdings. While it may be argued that judicial review is better than a legislative overhaul,<sup>132</sup> all judicial holdings explaining patent requirements will be framed within the confines of the current legislative statutes. Furthermore, establishing the breadth of the judicial holdings within the current framework will remain a challenge, as has been illustrated by recent holdings.<sup>133</sup> Interpretations

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126. *Id.*

127. *Patents v. Opensource*, *supra* note 124.

128. *Id.*

129. An individual can obtain one or more patents directed to one or more parts of their invention while allowing open-source access to different parts.

130. Revised Patent Subject Matter, *supra* note 64, at 50-51.

131. Leahy-Smith American Invents Act of 2011, Pub. L. No. 112-29, 125 Stat. 284 (codified in scattered sections of 28 U.S.C. and 35 U.S.C.).

132. Elaine H. Nguyen, *Scalpels Over Sledgehammers: Saving Diagnostic Patents Through Judicial Intervention Rather than Legislative Override*, 70 DUKE L.J. 1631 (2021).

133. *See, e.g., 2106 Patent Subject Matter Eligibility*, *supra* note 84.

will continue to be disputed. Though all technological advances may not necessitate legislative changes, certain advances compel them. The revolution in personalized medicine is one such technology.

2. *Guidance Provided by the USPTO.*—Section 101 is very concise and states, “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.”<sup>134</sup> Thus, an inventor who discovers a gene, a protein, a metabolite, or any biomarker that can be used as a diagnostic may be eligible to obtain a patent because he “discovers [a] new and useful process” for diagnosing a disease or for better treating a disease.<sup>135</sup> Read literally, it may be argued that section 101 does not bar diagnostics from being issued as patents. However, the Supreme Court has interpreted the limitations described previously into this section and has subsequently limited the patent scope of several inventions.<sup>136</sup>

The USPTO may provide guidance to inventors about the various aspects of the present patent laws, regulations, processes, and procedures. The USPTO publishes the Manual of Patent Examining Procedure (MPEP), publishes regular updates and memorandums, and provides a forum for online discussion.<sup>137</sup> The USPTO has provided guidance to inventors about the scope of Section 101.<sup>138</sup> For example, according to the USPTO, *Vanda* requires the diagnostic method recited in a claim to be directly tied to the method of treatment.<sup>139</sup> *Vanda* emphasizes that the treatment may not be ancillary to the invention being claimed.<sup>140</sup> The question arises: How much of a direct connection suffices?

According to the USPTO, one way to determine if a claim integrates an exception into a practical application is to “apply or use the recited judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition.”<sup>141</sup> The Supreme Court held that the administration of a drug occurred prior to any data gathering will not enhance the patentability of a claim.<sup>142</sup> However, the USPTO has interpreted the holding to determine that treatment has to be “particular” and have more than a “nominal or insignificant relationship to

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134. 35 U.S.C. § 101

135. *Id.*

136. *See generally* Alice Corp. Proprietary v. CLS Bank Int’l, 573 U.S. 208 (2014); Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc., 566 U.S. 66 (2012); Revised Patent Subject Matter, *supra* note 64, at 50-51.

137. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINATION PROCEDURE (9th ed.) (last revised July 2022), <https://www.uspto.gov/web/offices/pac/mpep/index.html> [<https://perma.cc/SDX3-LEYL>].

138. *Id.*

139. *Id.*

140. *Id.*

141. *2106 Patent Subject Matter Eligibility*, *supra* note 84.

142. Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc., 566 U.S. 66, 101 (2012).

the exception,” (e.g., natural law or natural phenomenon).<sup>143</sup>

Nevertheless, the evolution of personalized medicine in recent years may be a reason to give pause and reexamine the several holdings of the Supreme Court. The phrase “any new and useful improvement” surely encompasses the diagnostic inventions in personalized medicine.<sup>144</sup> Furthermore, the underlying theory behind the Supreme Court’s holding to prevent patents directed towards natural laws and natural phenomena was to ensure that lack of access to laws does not harm innovation.<sup>145</sup> The driving force behind this exception is that “‘manifestations of laws of nature’ are ‘part of the storehouse of knowledge,’ ‘free to all men and reserved exclusively to none.’”<sup>146</sup> This exception was surely not articulated to propel innovation at the cost of not rewarding inventors in a burgeoning scientific field.

The USPTO should interpret the Federal Circuit Court and Supreme Court holdings in view of the challenges being faced by entities inventing in the field of personalized medicine and provide newer guidance. For example, the USPTO can provide additional clarification about how much a relationship between the treatment and the diagnostic may suffice for patentability purposes. It can provide guidance to elaborate what constitutes treatment. It can be argued that a treatment can be construed to be any information that users could potentially use to benefit their health. Furthermore, a treatment can include guidance concerning a user’s nutritional intake or a user’s action involving exercise or physical therapy. Thus, a treatment may not be limited to the consumption of a specific drug, but it may be leveled at a class of drugs that would instigate a directed response. And if so, it follows that most diagnostics will be inherently linked to therapeutics.

Such guidance by the USPTO may be useful and may be more time efficient compared to some other solutions discussed below. Nevertheless, USPTO guidance is not binding on the courts, and patents granted under that guidance are open to challenge and invalidation in the federal courts.<sup>147</sup> Even the USPTO examiners may apply the USPTO guidance differently, resulting in uncertainty in the fate of any patent application that may have been filed based on the inventor’s interpretation of the guidance.<sup>148</sup> Furthermore, in some instances, the guidance may exceed the reach of the previous Supreme Court holdings, and may need further judicial clarity.<sup>149</sup> For example, it may be argued that claims considered ineligible under Supreme Court holdings (e.g., *Alice*) may be improperly granted, and thus, subject to post-grant review.<sup>150</sup>

2. *Holdings by the Supreme Court.*—In recent years, the Supreme Court has

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143. *2106 Patent Subject Matter Eligibility*, *supra* note 84.

144. 35 U.S.C. § 101.

145. *2106 Patent Subject Matter Eligibility*, *supra* note 84.

146. *Id.*

147. VIDAL, *supra* note 10, at 19.

148. *Id.* at 20.

149. *Id.*

150. *Id.*; *see also* *Alice Corp. Proprietary v. CLS Bank Int’l*, 573 U.S. 208, 218 (2014) (discussing *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66 (2012)).



been reluctant to grant petitions for certiorari in more than fifty patent-related cases.<sup>151</sup> As recently as 2022, the Supreme Court has refused to take the opportunity to provide further judicial clarity on the issue of patent eligibility.<sup>152</sup> Though the Court agreed to determine what an applicant must describe to ensure that a “skilled artisan” can make the invention, it has refused to review cases concerning patent eligibility.<sup>153</sup> The Supreme Court’s recent refusal to hear *American Axle v. Neapco Holdings LLC*<sup>154</sup> without comment, despite the recommendation by the U.S. Solicitor General, indicates judicial clarity may not be forthcoming.<sup>155</sup> While *American Axle* is not directed towards personalized medicine, the claim at issue was not allowed because it was supposedly directed towards a natural law.<sup>156</sup> Since most diagnostics in personalized medicine do not meet the patent eligibility requirements because they are directed towards naturally occurring phenomena, any additional clarity provided in *American Axle* would have been relevant. However, even if the Supreme Court grants certiorari in another case on point, it might not provide further clarity and may refuse to reverse any of its decisions because of *stare decisis*.<sup>157</sup> Though the Supreme Court has not hesitated to change existing laws affecting patent statutes, it has not shied away from using the doctrine of *stare decisis* previously in a patent case.<sup>158</sup>

The challenge with patent cases is that most cases involve substantially unique and difficult subject matters that require expertise not regularly found on the bench.<sup>159</sup> “[T]he Court has revealed that . . . it believes that patent law is comprehensible by a generalist judiciary, [but] the Court recognizes that the facts in patent cases are another issue entirely.”<sup>160</sup> Expecting such jurists to deliberate the nuances in patent cases while deciphering the inventions and identifying aspects that distinguish them or align them with other cases may not always be

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151. Gene Quinn, *Senator Thom Tillis: If IP Stakeholders Can’t Find Consensus, Congress Can’t Help*, IPWATCHDOG (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/G5EG-PRXZ>].

152. Eileen McDermott, *SCOTUS Kicks Patent Eligibility Cases to the Curb in Last Move of the Term*, IPWATCHDOG (June 30 2022), <https://www.ipwatchdog.com/2022/06/30/scotus-kicks-patent-eligibility-cases-curb-last-move-term/id=149928/> [<https://perma.cc/PD6N-7WYM>].

153. Amy Howe, *Justices Grant Review in Cases on Patents, Trademarks, and Water Rights for Native Americans*, SCOTUSBLOG (Nov. 4, 2022, 4:02 AM), <https://www.scotusblog.com/2022/11/justices-grant-review-in-cases-on-patents-trademarks-and-water-rights-for-native-americans/> [<https://perma.cc/X3H3-9NZ8>].

154. 967 F.3d 1285 (Fed. Cir. 2019).

155. McDermott, *supra* note 152.

156. *Id.*

157. David O. Taylor, *Amending Patent Eligibility*, 50 U.C. DAVIS L. REV. 2149, 2159 (2017).

158. See *Kimble v. Marvel Ent., LLC*, 576 U.S. 446 (2015).

159. Michael Goodman, *What’s So Special About Patent Law?*, 26 FORDHAM INTELL. PROP., MEDIA ENT. L.J. 797, 800 (2016).

160. *Id.* at 830 (emphasis in original).

the best option. The Court may not understand the subtleties of personalized medicine to be able to tease apart when a method comprises a treatment step that integrates the natural relationship into a practical application and when the method does not. This leads to unpredictable and inconsistent decisions. As has been eloquently stated by Learned Hand, “[h]ow long we shall continue to blunder along without the aid of unpartisan and authoritative scientific assistance in the administration of justice, no one knows; but all fair persons not conventionalized by provincial legal habits of mind ought, I should think, unite to effect some such advance.”<sup>161</sup>

### *B. Legislative Changes to Existing Statutes*

In 2019, there was a legislative effort to reform section 101 of the patent law.<sup>162</sup> However, the stakeholders refused to compromise and allowed the process to stall by letting “the great and the perfect get in the way of the good.”<sup>163</sup> In August 2022, there was another attempt to reform section 101. The Patent Eligibility Restoration Act of 2022 attempts to eliminate judicial exceptions to patentability by amending section 101 to include discoveries as being patent-eligible.<sup>164</sup> The bill states “an invention or discovery may be patentable ‘subject only to the exclusions in subsection (b).’”<sup>165</sup> Thus, anything not included in subsection (b) would be patent eligible. Furthermore, the proposed bill states that any “human gene or natural material that is . . . altered by human activity, or . . . employed in a useful invention or discovery” would be patent eligible.<sup>166</sup> Thus, the proposed bill may be construed as aligning with *Diamond v. Chakrabarty*,<sup>167</sup> where human activity was critical to patentability, and the bill may overrule the longstanding holding in *Mayo*.<sup>168</sup> This bill was re-introduced in June 2023 as the Patent Eligibility Restoration Act of 2023.<sup>169</sup>

Though the goal of revising and clarifying section 101 may be achieved by

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161. *Id.* at 831 (quoting *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 115 (S.D.N.Y. 1911)).

162. Quinn, *supra* note 151.

163. *Id.* (quoting Senator Thom Tillis).

164. S. 4734, 117th Cong. (2022).

165. Forest Gothia, *Calmer Waters Ahead? Senator Tillis’ Proposed 35 U.S.C. § 101 Legislation Brings Highly Requested Legislative Review to Patent Eligibility Storm*, HAYNES BOONE LLP (Aug. 22, 2022), <https://www.haynesboone.com/news/alerts/calmer-waters-ahead-senator-tillis-proposed-legislative-review-to-the-patent-eligibility-storm> [<https://perma.cc/MKD9-T5N5>] (emphasis in original) (quoting S. 4734, 117th Cong. (2022)).

166. S. 4734, 117th Cong. (2022).

167. *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980).

168. Gene Quinn, *Tillis’ Promised Patent Eligibility Bill Would Overrule Myriad, Mayo*, IPWATCHDOG (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/G5EG-PRXZ>]; *Diamond*, 447 U.S. at 309-10.

169. S. 2140, 118th Cong. (2023).

legislation, it does not appear promising as there remain competing interests at issue. While some stakeholders may claim that innovation calls for the grant of patents, others may argue that restricting access to natural laws and phenomena through granted patents for a substantial period of time may negatively affect the field.<sup>170</sup> It may be argued that new developments in the field increase costs and block biosimilar development, which may be negatively affected by patents.<sup>171</sup> Thus, similar to previous efforts, overhauling section 101 may prove to be a monumental task.

### *C. Development of a New Patent Type: Diagnostic Patent*

*1. Existence of Different Patent Types.*—Since one of the primary goals of patent protection is to reward inventors for their innovation while ensuring the inventions are available for use by society, it can be hypothesized that this balance may depend upon the specifics of the invention. Thus, different patent types may be applicable for different types of inventions.<sup>172</sup> The different patent types may have different criteria for allowance, or they may have different benefits when allowed.<sup>173</sup>

Separate types of patents already exist for different inventions. For example, whoever “invents or discovers and asexually reproduces any distinct and new variety of plant . . .” can receive a plant patent.<sup>174</sup> Similarly, a design patent is used to protect the visual appearance of an invention.<sup>175</sup> These patents are subject to different criteria when being evaluated by examiners at the USPTO, and in the case of design patents, the patent term is fifteen years from the day of granting the patent.<sup>176</sup>

Furthermore, utility model patents exist in other countries, such as China and Germany.<sup>177</sup> Though used as tools for flanking protection and usually employed to protect inventions that may not be worth the investment cost of a full patent,

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170. VIDAL, *supra* note 10, at 21.

171. *Id.*; see also Allison Inzerro, *Stakeholders Thinking About US Patent System Reform in 2019*, CTR. FOR BIOSIMILARS (Jan. 18, 2019), <https://www.centerforbiosimilars.com/view/stakeholders-thinking-about-us-patent-system-reform-in-2019> [<https://perma.cc/XTL8-WCQQ>].

172. See, e.g., 35 U.S.C. §§ 161, 171.

173. See, e.g., *id.*

174. *Id.* § 161.

175. *Id.* § 171.

176. *Id.* § 173.

177. *Comparison Table: Utility Models and Patents in Germany*, VENNERS SHIPLEY (Jan. 28, 2021), <https://www.vennershipley.co.uk/insights-events/comparison-table-utility-models-and-patents-in-germany/> [<https://perma.cc/792Y-VSHY>] [hereinafter Comparison Table]; Lunwei Huang, *A Glimpse into China's Utility Model System*, LEXOLOGY (Oct. 16, 2020), <https://www.lexology.com/library/detail.aspx?g=10593ff7-ebab-4bf7-9edf-283275098541> [<https://perma.cc/G4CB-HJA7>].

utility model patents provide protection from competitors.<sup>178</sup> Utility model patents have a ten-year patent term, compared to the twenty-year term for traditional invention patents.<sup>179</sup>

Additionally, altering patent terms to appropriately compensate the inventor has been previously discussed for other scientific endeavors.<sup>180</sup> For example, based on the fact that the antibiotic industry has not made significant advances in recent years, it was argued that extending patent terms may drive innovation and investment in the antibiotic industry.<sup>181</sup> Future legislation to create a new diagnostic patent having (a) a limited patent term, (b) a more aligned written description of requirements under section 112, and (c) clearer patent eligibility for diagnostics under section 101 may potentially solve the pressing need for appropriate intellectual property strategies in the field of personalized medicine.

2. *Creation of the Plant Patent.*—The Plant Patent Act of 1930 was created as an avenue for plant patents because the description and enablement requirements under section 112 created hurdles when describing new plant species.<sup>182</sup> The Plant Patent Act of 1930 amended the provision of utility patent provision to create a new category of patent eligible subject matter:

Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof, or who has invented or discovered and asexually reproduced any distinct and new variety of plant, other than a tuber-propagated plant, not known or used by others in this country, before his invention or discovery thereof, . . . may . . . obtain a patent therefor.<sup>183</sup>

However, the Plant Patent Act requirements were later removed from the code section that defined patent eligible subject matter. The Plant Patent Act requirements were separately categorized under Chapter 15 of Title 35 of the United States Code in sections 161-164.<sup>184</sup> It was only in 2001 that the Supreme Court interpreted plants to be patent eligible under section 101.<sup>185</sup> In *J.E.M. v. Pioneer*, the Supreme Court held claims towards newly developed plant breeds

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178. Comparison Table, *supra* note 177.

179. *Id.*

180. Daniel Gonzalez, *The Use of Ultra Long Patent Terms to Incentivize the Development of Novel Antibiotics*, 21 HOUS. J. HEALTH L. POL'Y 269, 310 (2022).

181. *Id.*

182. Ashley J. (Clever) Earle, *Planting Innovation: A Look into Plant Patent Protection and the Deficiencies of the Plant Protection Act and Plant Variety Protection Act*, U. CIN. L. REV. (May 26, 2015), <https://uclawreview.org/2015/05/26/planting-innovation-a-look-into-plant-patent-protection-and-the-deficiencies-of-the-plant-protection-act-and-plant-variety-protection-act/> [<https://perma.cc/W9ZV-RJRP>].

183. Townsend-Purnell Plant Patent Act, ch. 312, § 1, 46 Stat. 376 (1930) (codified as amended at 35 U.S.C. § 161 (2023)).

184. 5 U.S.C. §§ 161-164.

185. *See J.E.M. Agric. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001).

were within the scope of section 101.<sup>186</sup> The court further reasoned that the Plant Patent Act did not limit section 101, and plants were eligible for utility patents.<sup>187</sup> Thus, the creation of a strategy for patent protection of a subset of inventions, wherein the strategy is different from the mainstream patent law is not novel. Such a strategy has been previously successfully executed and can be adopted for diagnostics. The creation of a new patent type exclusively for diagnostics may or may not eventually result in its assimilation into the utility patent. Nevertheless, it provides an alternative channel for intellectual property protection in the interim.

## V. EVALUATING THE CREATION OF A NEW PATENT TYPE

### *A. Advantages of a New Patent Type*

A new patent type directed towards diagnostic patents will be instrumental in meeting the needs of both inventors and society. First, since the affected stakeholders will be limited to the specific field of diagnostics, stakeholder reaction may be more measured. Conflicting stakeholder assessments of the current patent system make the attainment of any change in the patent laws a difficult prospect.<sup>188</sup> However, since the creation of a new patent type will be restricted to diagnostics and will provide a shorter patent term, there might be less opposition towards such legislation.

Second, the adoption of a limited patent term of less than twenty years can account for the competing interests described above. A shorter patent term will provide patent protection, and thus incentivize inventors and investors in the pure diagnostics field, while also ensuring new innovations are able to benefit from the patented material after the limited patent term. This option is better than encouraging an inventor to avail himself of trade secrets. The advantage is primarily because a patent provides exclusive rights to the inventor, albeit only for a shortened period of time, in exchange for a complete disclosure of the invention.<sup>189</sup> Society will benefit from such disclosure.

One primary objection to the legislative attempts at patent reform has been that the scarcity of allowed patents has helped patient care.<sup>190</sup> It is argued that an increase in the allowance of such patents will negatively impact healthcare.<sup>191</sup> Unlike the current utility patents, which have a patent term of twenty years, the limited patent term of the new diagnostic patent will allow access to and development of biosimilar diagnostics at a faster rate. While the exact patent term for the new diagnostic patent will need to be evaluated in view of different

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186. *Id.* at 145-46.

187. *Id.*

188. VIDAL, *supra* note 10, at 35.

189. 35 U.S.C. § 154.

190. VIDAL, *supra* note 10, at 32.

191. *Id.*

variables, a patent term of ten years may be a good option.<sup>192</sup>

Third, the patent eligibility standards in the United States will be more aligned with patent eligibility standards in other countries.<sup>193</sup> Europe, China, Korea, and Japan grant patents directed to diagnostics with varying requirements.<sup>194</sup> The discrepancy in patent eligibility was highlighted in 2019 during the congressional hearings on redrafting patent legislation.<sup>195</sup> A patent application from an academic lab directed toward a method to diagnose liver injuries or diseases was rejected in the United States.<sup>196</sup> However, the Chinese and the European Patent Office successfully patented the same invention.<sup>197</sup> Thus, currently, the United States has a disadvantage in the diagnostic industry.<sup>198</sup> The allowance of diagnostic claims under the new patent type will even the playing field, thereby sustaining and possibly even encouraging further innovation in both academic and corporate laboratories.

### *B. Challenges in the Creation and Adoption of a New Patent Type*

However, there may be a few challenges in the creation of a new type of patent. First, the adoption of a new patent type specifically for diagnostics may not be universal. For example, there was minimal litigation under the Semiconductor Chip Protection Act (SCPA), which was established specifically for the semiconductor industry.<sup>199</sup> The SCPA was created in an attempt to prevent rampant copying of semiconductor chips.<sup>200</sup> Though litigation under the SCPA may have been minimal because of the narrow protection provided by the SCPA, the act also became redundant because of technical advances in the semiconductor industry and the inability of smaller companies to replicate the chip designs of the large manufacturers.<sup>201</sup> While similar future advances may occur in personalized medicine, such technical progress is difficult to predict and should not be used as an excuse for legislative inaction.

Second, it may be contended that the legal investment to obtain a patent may not be validated by the limited patent term. However, while a shorter patent term may not be the perfect option for those inventors who would like to file utility

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192. A period of ten years would balance the incentives and rewards to an inventor with the public cause of ensuring that the invention is accessible to all in need.

193. *Id.*

194. *Id.*

195. *Biotech 'New Era' in Store if Patent Revamp Overcomes Opposition*, BLOOMBERGL. (Oct. 17, 2022, 5:41 AM), <https://news.bloomberglaw.com/health-law-and-business/biotech-new-era-in-store-if-patent-revamp-overcomes-opposition> [<https://perma.cc/A7DF-AALL>].

196. *Id.*

197. *Id.*

198. VIDAL, *supra* note 10, at 32.

199. Dan Callaway, *Patent Incentives in the Semiconductor Industry*, 4 HASTINGS BUS. L.J. 135, 139 (2008).

200. *Id.*

201. *Id.*

patents, it is better than the unpredictable and uncertain alternative, which is the current patent law. Furthermore, a new patent type will reduce the litigation costs associated with the current laws. The uncertainty embedded in the current laws increases post-litigation costs and the expenses associated with the development of legal strategies.<sup>202</sup>

Third, congressional action to create a new patent type may need to overcome substantial hurdles. Deliberations to determine the patent term or other eligibility criteria and to accrue the support of the relevant stakeholders will require a compromise similar to that needed to pass any legislation amending the current statute. However, since the new patent type will be directed toward a smaller group of stakeholders and be of limited scope, a consensus may be easier to obtain. The shorter patent term of less than twenty years will signify a balance of interest to all relevant stakeholders. In an effort to streamline patent prosecution, patent eligibility under the new patent type may be based on the criteria for diagnostic patents in other countries.<sup>203</sup>

The creation of a new patent type similar to the Plant Patent Act, which provided the first patent protection for plants, might lay the framework for patent protection for diagnostics. Plant patents were granted for more than half a century before the Supreme Court held that plants are eligible for patents under section 101.<sup>204</sup>

Thus, though clearer and more favorable interpretation by the USPTO may be a more time efficient solution to the patentability challenges faced by personalized medicine patent applications, the creation of a distinct patent type is the optimal solution. Furthermore, it may be the only option since the Supreme Court is hesitant to provide further clarity to existing case law and since legislative attempts to amend existing statutes have not been successful.

#### CONCLUSION

Tools available for the protection of intellectual property rights steer innovation and progress in society. This Note examined the different options available for protecting intellectual property rights in the field of personalized medicine, analyzed the issues most relevant to patentability, and evaluated different solutions to improve the process. Furthermore, this Note contended that there is widespread consensus that the current statutes concerning patent allowance are uncertain, unpredictable, and result in increased legal costs. These laws are especially problematic for any patents directed towards methods and processes in the field of personalized medicine. There exists a widespread understanding that the current state of patent laws needs to be revisited.

As illustrated above, in recent years, the Supreme Court has repeatedly refused to offer judicial clarity. It may be contemplated that since the subject

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202. VIDAL, *supra* note 10, at 32.

203. *Id.*

204. J.E.M. Agric. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001).

matter of many patent cases is challenging, the Court is attempting to let the USPTO or the legislature provide additional directives. Furthermore, while legislative attempts to revisit the existing patent codes have not been successful, congress is currently trying to amend the patent eligibility criteria and introduced a relevant bill in August 2022. Progress in the field of deciphering patent eligibility may be achieved through judicial clarity, the pursuit of further legislative refinement of the existing patent laws, or by reliance on the USPTO to provide additional insights.

This Note discussed these various solutions and argued that though viable, they present recurring challenges. This Note concludes that the creation of a new patent type directed towards diagnostics may prove to be the best solution. The creation of a patent type directed towards a particular type of invention has been successfully done in the past. The creation of a patent type directed towards diagnostics will balance conflicting stakeholders and serve to reward innovation, encourage investment, decrease legal costs, and improve patient care.